James J. Pisanelli, Esq., Bar No. 4027
JJP@pisanellibice.com
Todd L. Bice, Esq., Bar No. 4534
TLB@pisanellibice.com
Debra L. Spinelli, Esq., Bar No. 9695
DLS@pisanellibice.com
Emily A. Buchwald, Esq. Bar No. 13442
EAB@pisanellibice.com
PISANELLI BICE PLLC
400 South 7th Street, Suite 300
Las Vegas, Nevada 89101
Telephone: 702.214.2100

Electronically Filed
Aug 17 2018 08:59 a.m.
Elizabeth A. Brown
Clerk of Supreme Court

Kenneth G. Schuler, Esq.
(*pro hac vice* pending)
kenneth.schuler@lw.com
Michael J. Faris, Esq.
(*pro hac vice* pending)
michael.faris@lw.com
Alex Grabowski, Esq.
(*pro hac vice* pending)
alex.grabowski@lw.com
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611

Angela Walker, Esq.
(*pro hac vice* pending)
angela.walker@lw.com
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
Telephone: 202.637.3321

Attorneys for Alvogen, Inc.

E. Leif Reid, Esq., Bar No. 5750
EReid@lrrc.com
Daniel F. Polsenberg, Esq., Bar No. 2376
DPolsenberg@lrrc.com
Josh M. Reid, Esq., Bar No. 7497
JReid@lrrc.com
Kristen L. Martini, Esq., Bar No. 11272
KMartini@lrrc.com
LEWIS ROCA ROTHGERBER
CHRISTIE LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, Nevada 89169
Telephone: 702-949-8200

Attorneys for Hikma Pharmaceuticals USA, Inc.

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.

Case No. 76485

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

REAL PARTIES IN INTEREST'S SUPPLEMENTAL APPENDIX

(VOLUME III OF III)

Docket 76485 Document 2018-31876

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

Respondents,

ALVOGEN, INC., and HIKMA PHARMACEUTICALS USA, INC.,

Real Parties in Interest.

REAL PARTIES IN INTEREST'S SUPPLEMENTAL APPENDIX

DESCRIPTION	VOLUME	PAGE
Respondent's Supplemental Answering Brief filed in Case No. 60715, Coleman v. State of Nevada, dated October 23, 2013	I	0001 – 0021
In re Pulaski County Circuit Court, Fifth Division, Hon. Wendell Griffin Per Curiam Brief filed in Supreme Court of Arkansas Case No. 17-155, dated April 17, 2017	I	0022 – 0026
Formal Order filed in Supreme Court of Arkansas Case No. 17-317, dated April 30, 2018	I	0027 - 0030
Hikma Pharmaceuticals USA Inc.'s Motion to Intervene on Order Shortening Time, dated July 24, 2018	I	0031 – 0113
Defendants' Opposition to Hikma Pharmaceuticals USA Inc.'s Motion to Intervene on Order Shortening Time, dated July 27, 2018	I	0114 – 0187
Transcript of Hearing on Hikma Pharmaceuticals' Motion to Intervene, dated July 30, 2018	I	0188 – 0208
Hikma Pharmaceuticals USA Inc.'s Complaint in Intervention, dated July 30, 2018	II	0209 - 0268
Defendants' Motion to Stay Proceedings Pending Nevada Supreme Court Decision, dated August 1, 2018	II	0269 – 0353

DESCRIPTION	VOLUME	PAGE
Plaintiff Alvogen's Opposition to Defendants' Motion to Stay Proceedings Pending Nevada Supreme Court Decision on Order Shortening Time; Countermotion to Accelerate Discovery Responses and Set Preliminary Injunction Hearing, dated August 3, 2018	II	0354 - 0369
Notice of Entry of Order Granting Hikma Pharmaceuticals' Motion to Intervene, dated August 3, 2018	II	0370 - 0374
Letter from Todd L. Bice, Esq. to Jordan T. Smith, Esq., dated August 3, 2018	II	0375
Email from Jordan T. Smith, Esq. to Todd L. Bice, Esq., dated August 3, 2018	II	0376 - 0378
Transcript of Hearing on Defendants' Motion to Stay Proceedings, dated August 6, 2018	III	0379 - 0397
Hikma Pharmaceuticals' Joinder and Supplement to Alvogen, Inc.'s Motion for Preliminary Injunction, dated August 8, 2018	III	0398 - 0583

DATED this 16th day of August 2018.

PISANELLI BICE PLLC

By: _____

James J. Pisanelli, Esq., Bar No. 4027
Todd L. Bice, Esq., Bar No. 4534
Debra L. Spinelli, Esq., Bar No. 9695
Emily A. Buchwald, Esq., Bar No. 13442
400 South 7th Street, Suite 300
Las Vegas, Nevada 89101

Kenneth G. Schuler, Esq.
(*pro hac vice* pending)
Michael J. Faris, Esq.
(*pro hac vice* pending)
Alex Grabowski, Esq.
(*pro hac vice* pending)
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611

Angela Walker, Esq.
(*pro hac vice* pending)
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
Telephone: 202.637.3321

Attorneys for Real Party in Interest Alvogen

E. Leif Reid, Esq., Bar No. 5750
Daniel F. Polsenberg, Esq., Bar No. 2376
Josh M. Reid, Esq., Bar No. 7497
Kristen L. Martini, Esq., Bar No. 11272
LEWIS ROCA ROTHGERBER
CHRISTIE LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, Nevada 89169

Attorneys for Real Party in Interest
Hikma Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of PISANELLI BICE PLLC, and that on this 16th day of August 2018, I electronically filed and served by electronic mail and United States Mail a true and correct copy of the above and foregoing **REAL PARTIES IN INTEREST'S SUPPLEMENTAL APPENDIX (VOLUME III OF III)** properly addressed to the following:

Jordan T. Smith, Esq.
Assistant Solicitor General
555 East Washington Avenue, #3900
Las Vegas, Nevada 89101
JSmith@ag.nv.gov

Attorneys for Petitioners

E. Leif Reid, Esq.
Josh M. Reid, Esq.
Kristen L. Martini, Esq.
LEWIS ROCA ROTHGERBER CHRISTIE LLP
3993 Howard Hughes Parkway, Suite 600
Las Vegas, NV 89169-5996

Attorneys for Real Party in Interest
Hikma Pharmaceuticals USA, Inc.

SERVED VIA HAND-DELIVERY

The Honorable Elizabeth Gonzalez
Eighth Judicial District court, Dept. XI
Regional Justice Center
200 Lewis Avenue
Las Vegas, Nevada 89155

An employee of Pisanelli Bice PLLC

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Steven D. Grierson
CLERK OF THE COURT

TRAN

DISTRICT COURT
CLARK COUNTY, NEVADA
* * * * *

ALVOGEN INC.	.	
	.	
Plaintiff	.	CASE NO. A-18-777312-B
	.	
vs.	.	
	.	DEPT. NO. XI
STATE OF NEVADA, NEVADA DEPARTMENT OF CORRECTIONS, et al.	.	
	.	**Transcript of**
Defendants	.	**Proceedings**
. . . . .		

BEFORE THE HONORABLE ELIZABETH GONZALEZ, DISTRICT COURT JUDGE

HEARING ON DEFENDANTS' MOTION TO STAY PROCEEDINGS

MONDAY, AUGUST 6, 2018

COURT RECORDER:	TRANSCRIPTION BY:
JILL HAWKINS District Court	FLORENCE HOYT Las Vegas, Nevada 89146

Proceedings recorded by audio-visual recording, transcript produced by transcription service.

APPEARANCES:

FOR THE PLAINTIFF:	TODD L. BICE, ESQ. JAMES J. PISANELLI, ESQ. MICHAEL FARIS, ESQ.
FOR THE DEFENDANTS:	JORDAN T. SMITH, ESQ. RANDALL GILMER, ESQ.
FOR THE INTERVENOR:	JOSH M. REID, ESQ.
ALSO PRESENT:	COLBY WILLIAMS, ESQ. For Sandoz, Inc.

LAS VEGAS, NEVADA, MONDAY, AUGUST 6, 2018, 10:21 A.M.

(Court was called to order)

THE COURT: Before we start will you please identify yourselves for purposes of my record.

MR. BICE: Good morning, Your Honor. Todd Bice on behalf of Alvogen.

MR. PISANELLI: 'Morning, Your Honor. James Pisanelli on behalf of Alvogen.

MR. REID: Your Honor, Josh Reid representing Hikma Pharmaceuticals USA.

MR. WILLIAMS: 'Morning, Your Honor. Colby Williams on behalf of proposed intervenor Sandoz, which I'll bring up with the Court [inaudible].

THE COURT: I have your motion in a minute. We'll hit that as my stop.

MR. WILLIAMS: Perfect. Thank you.

MR. SMITH: Jordan Smith on behalf of defendants.

MR. GILMER: And Randall Gilmer on behalf of defendants, Your Honor.

THE COURT: All right. I have a media request and order for access to court proceedings from KSNB, which I have signed. I'm giving it back to Mr. Kutinac.

I have Sandoz's motion to intervene and order shortening time. Do you have a preference, Mr. Smith, as to when I set this?

MR. SMITH: A hearing Thursday would be great, Your Honor.

THE COURT: Is that okay?

MR. WILLIAMS: That's fine, Your Honor, if it works for the Court.

THE COURT: Thursday it is. Thursday's the 9th.

MR. SMITH: I'll get an opposition to you on Wednesday.

MR. WILLIAMS: At what time, Your Honor?

THE COURT: 9:00 a.m.

MR. WILLIAMS: Okay.

THE COURT: Mr. Williams, this is your pile.

MR. PISANELLI: Your Honor, I think our co-counsel is attempting to dial in.

THE COURT: Mr. Faris, are you on the phone?

MR. FARIS: Yes, Your Honor. This is Mike Faris on behalf of Alvogen.

THE COURT: Thank you.

All right. So now I'm to the point of the motion to stay from the State. I did receive an opposition, so --

MR. SMITH: Thank you, Your Honor. As you're aware, the State's petition before the Nevada Supreme Court really raises two straightforward purely legal issues, the first one being whether Your Honor's TRO impermissibly acts as a stay of an execution in violation of NRS 176.415; and, two, whether

Alvogen, now Hikma, and soon to be Sandoz, I imagine, whether the three of those companies have implied rights of actions under the statutes that they highlight. Those are the purely legal issues before the Nevada Supreme Court.

In their opposition Alvogen and the other plaintiffs don't dispute that the State has at least presented a substantial case on the merits of those serious legal questions, and they don't claim that they're going to suffer irreparable harm from a stay of proceedings pending the Nevada Supreme Court's decision. Nonetheless, Alvogen has countermoved to expedite discovery and to conveniently hold an evidentiary hearing at the end of September before the Supreme Court is expected to rule in October. And the reason they advance that schedule, Your Honor, is because they know there's a likelihood that the Supreme Court is likely going to dismiss their case, and they want to have a bunch of discovery and impose a bunch of burden on the State that they're not entitled to before the Nevada Supreme Court makes that decision. At minimum we should wait and see what the Nevada Supreme Court says with regard to whether they have any causes of action that entitle them to unlock the doors to discovery in the first place. If they don't have causes of action, there's no need for discovery and no need for an evidentiary hearing. It will likely be the end of this case. Nonetheless, Alvogen asserts that, well, the appellate record

would benefit from additional factual information. But the Nevada Supreme Court didn't say that --

THE COURT: That's why the appellate rules don't provide for an appeal after a TRO, because there's very little record. That's why it's typically done after a preliminary injunction. I understand your mechanism and your reasoning for doing it, but that's why, because we do not have a fulsome record before the District Courts at the time of a TRO hearing. We have a much more full record at the time of a preliminary injunction hearing.

MR. SMITH: A couple responses to that, Your Honor. And you're right. The first jurisdictional basis we have for our petition is under NRS 176.495 as an improperly granted stay of an execution. That's the first jurisdictional basis there, the second being a writ of mandamus or prohibition.

And I filed a protective notice of appeal just to cover myself, Your Honor.

THE COURT: I understand. I'm not criticizing you for making your decision. I'm just explaining that from a District Court judge's perspective the record at a TRO stage is very limited. The record at a preliminary injunction hearing is much more fulsome.

MR. SMITH: I understand that, Your Honor. But that's why it's important to highlight that the issues before the Nevada Supreme Court are purely legal issues. They're

essentially statutory interpretation. Does the TRO offend 176.415, and do they have implied causes of action under Chapter 41 and Chapter 453. Those are statutory interpretation questions, and there aren't any factual -- there's no factual development that has to do with that. I understand there might be factual development on things like irreparable harm. I understand that. But as far as the purely legal issues before the Nevada Supreme Court right now that are pending, there's no factual development that's needed.

They don't say in their motion -- they say, well, factual development is needed, but they don't say what facts are needed, they don't say what discovery and how that would impact the purely legal issues that are before the Nevada Supreme Court. And so instead they make insinuations throughout their opposition and countermotion that somehow the State misled Your Honor or misled the Nevada Supreme Court about the expiration dates for the drugs. They're trying to get discovery on any issue. There's no discovery to be had on the purely legal issues pending, and so they're trying to insinuate some other issue that needs and evidentiary hearing. But there's no basis for that whatsoever. It's just an attempt to get some additional discovery.

But if they want to -- if they're going to be worried about misrepresentations to the Court and sort of try

to manufacture one of those, they need to be more concerned about misrepresentation they actually did make to this Court.

You'll recall during the TRO hearing and TRO application they pounded the table about the McKesson-Arkansas case, they assured Your Honor two District Court judges had granted a TRO in that case and the Arkansas Supreme Court had affirmed it. I pointed out that that was flatly incorrect. That's not accurate. The Arkansas Supreme Court in fact summarily reversed both of those in short order. When Mr. Schuler in his rebuttal doubled down, and that's at page 70 of the transcript, and he said he was going to submit a supplement to the record explaining to Your Honor why he was right about the Arkansas case. Well, I've not seen that.

So before we start making wild accusations about misrepresentations and start going down that path they'd better make sure that their closet's clean. And it's not. So the prudent thing to do here is stay discovery, wait and see if the Nevada Supreme Court determines they even have causes of action that warrant discovery. It's short. The requested decision date is October 19th. The Supreme Court's given every indication they're going to meet that date. A lot of time, effort, and costs will be saved if we wait and see what the Nevada Supreme Court says. Thank you, Your Honor.

THE COURT: Okay. Thank you, Mr. Smith.

Mr. Bice.

MR. BICE: Yes, Your Honor.

Your Honor, the only reason that we didn't schedule a preliminary injunction hearing already in this action is because Mr. Smith told us all at the TRO hearing how he needed voluminous discovery. At no point -- and I would note at no point in time, Your Honor, did he represent to you that the State needed action, a preliminary injunction hearing or action to be taken by the end of November. And I don't think that was quite an accident, Your Honor.

I'm going to submit two things, I want them in the record, Your Honor, a letter that we sent to Mr. Smith on Friday and then an email where I confirmed the State's representations. And I don't know if these should be Court's exhibits, Your Honor. May I approach?

THE COURT: You may.

MR. BICE: Thank you. So I sent Mr. Smith a letter on Friday because we had concerns about --

THE COURT: Court's Exhibit 1, please, Dulce.

MR. BICE: -- the State's claims, Your Honor, that -- how it was going to run out of drugs and wouldn't be able to carry out Mr. Dozier's execution, of course, a disclosure that they never made to Your Honor, and then go to the Supreme Court and essentially accuse the Court and I guess me of duping the Court, I think is their terminology, into essentially extending out its TRO without disclosing to the

Nevada Supreme Court, of course, that they were the ones who asked the Court and told the Court that they needed all this voluminous discovery.

And so we sent out a letter to them, Your Honor, asking for an explanation for those representations, and what I got back was a phone call, which I confirmed in an email, and you'll notice that there's no denial of what's in the email, and that is the truth of the matter is that the State of Nevada has represented to the Nevada Supreme Court to get an emergency hearing on their writ and not await a preliminary injunction because they said that they won't be able to carry out this execution after November 30th.

That's not true. What the State is sort of playing games with is they say, well, an execution, Your Honor. Now, that's a coy play on words, because there is no one else on Nevada's Death Row that has exhausted all of their appeals, they have no other use for these drugs other than to carry out Mr. Dozier's execution, and they have volumes of it to carry out Mr. Dozier's execution well after November 30th of 2018. But we'll address that, Your Honor, with the Nevada Supreme Court.

The point that we're here on today is the State says, well, we're challenging your TRO as a stay of execution. Which is odd, because after your TRO, which only precluded them from using this drug, which you made crystal clear, our

particular version, they then moved for a stay of execution in front of Judge Togliatti. The State actually secured a stay of execution in front of Judge Togliatti. It's not this Court's order that imposed any stay of execution for Mr. Dozier. It's the State who sought a stay of execution and obtained it.

They next say, Your Honor, well, we're challenging one of the causes of action that they assert. Okay. Great. Where's your motion to dismiss which you have to file? Which I'm not even sure what the timing of their response is. I actually think it's probably past due at this juncture. Nevertheless, where is their motion to dismiss? And it doesn't even cover all the claims in the complaint, which -- and we will point out again, as we did at the time of the hearing, why they're wrong on that claim.

Nonetheless, Your Honor, we're here for one issue. They're saying the Nevada Supreme Court should review a TRO, and they, of course, did so by predicating it upon the fact that this Court won't hold a preliminary injunction hearing within a reasonable amount of time before November 30th. And so I'm saying, since they didn't tell the Nevada Supreme Court the truth about who it was that was delaying the preliminary injunction hearing, I ask you accelerate the discovery responses which we served timely, set that preliminary injunction hearing for the end of September so we'll have a

full and fair record. This motion for stay, Your Honor, is completely incompatible with their claims of need for speed. A stay will delay the process, it won't expedite the process. Let's hold the State to their word. They need quick action. Let's have quick action, Your Honor.

So I ask you to grant my countermotion.

THE COURT: Thank you.

Mr. Smith, anything else?

MR. SMITH: Just briefly, Your Honor.

Mr. Bice is right, I didn't mention the November 30th date to Your Honor on that day. I didn't know the November 30th --

THE COURT: Hold on a second. I missed Mr. Reid. He wanted to talk.

MR. SMITH: Oh.

MR. REID: Thank you, Your Honor. I'm easy to miss.

THE COURT: No, no. It's just --

MR. REID: I don't want to belabor things, Your Honor. We join in Alvogen's opposition to the motion to stay, and we're in agreement with any expedited process for the hearing. Like we promised last week, we served our discovery requests last week a couple days after we were able to intervene into the case.

And the only thing I wanted to add to Mr. Bice's comments is the reason why we're here is through an order for

court records made by a different court --

THE COURT: Judge Wilson.

MR. REID: -- yes, Judge Wilson -- there was a public records request, and those records weren't produced. And it took a judge's order, and the judge issued that order right after -- those records were produced right after the Fourth of July holiday, and this litigation ensued a week later.

And so I think as a matter of public policy, you know, when you talk about burden, the State talks about its burden, we're talking mainly about public records here that are supposed to be open to the public, and the State should not be able to claim that it's burdensome to produce public records which they're already by law required to produce. And I think it's just important if they're -- because it seems like the main point and main reason for the stay is to not produce public records. And I think that is a matter of public policy should be concerning to the State.

Also, to point out the TRO that was issued did not affect Hikma's rights, it did not apply. Yes, we chose not to file for a TRO because we knew there was a preliminary injunction hearing set, and I just wanted to point that out. But we don't have --

THE COURT: You're welcome to file a TRO application if you think it's appropriate. I've not precluded you from

doing so.

MR. REID: Yes. That's all I have to say, unless you have any other questions.

THE COURT: All right. Thanks.

Mr. Smith.

MR. SMITH: Thank you, Your Honor. As I was saying, you're right, I didn't mention the November 30th date to Your Honor on the morning of July 11th. I wasn't aware of the date given everything that was going on. By all accounts the execution was going to move forward. And so I didn't have that. But it doesn't change the State's need for discovery. I think it's completely consistent to ask the Nevada Supreme Court for expedited proceedings to determine whether there's even a cause of action that justifies discovery in the first place, that justifies and evidentiary hearing in the first place while simultaneously asking this Court to stay discovery pending that decision. It's completely consistent with that.

The State is now going to be facing two companies making claims of reputational harm, a third one is moving to intervene, making also broad claims of reputational harm. The State wants to take its time and thoroughly prepare itself. If there's causes of action here, the State wants to defend itself and have a chance to do that. So the two requests are completely consistent.

The State's brief moving to expedited in the Nevada

Supreme Court speaks for itself. The representations are accurate and correct. I've added a verification of that myself. So I stand by that. There's simply no there there, and it's attempt to just drum up another issue for discovery that should wait for the Nevada Supreme Court's decision.

THE COURT: So I'm going to deny your request to stay pending the completion of the preliminary injunction hearing.

I would be happy to move the preliminary injunction hearing up if you can find a way to get your discovery done more expeditiously, Mr. Smith. All of those people over on the other side are ready to go. They'll do whatever we say. You've told me you need longer.

MR. SMITH: And I understand the resources my colleagues on the other side have. But given the claims being made and what I'm able to do, the current schedule is -- the closest that it's going to work -- I would ask Your Honor for at least a five-day temporary stay so I can renew request to the Nevada Supreme Court.

THE COURT: No. But you can renew your request to the Supreme Court.

So let's go to the countermotion. And their countermotion is then to shorten discovery period so that the discovery that you need to do, that you've told me you need to do is done on a shorter time frame, because the periods are

shorter, not because of the volume of information is shorter. But instead of 30 days for written discovery, to shorten it to 15, to shorten deposition notices from 15 to something else. Do you want to talk to me about that issue?

MR. SMITH: Yes, Your Honor. I think there's no reason -- there's no reason to expedite it. The November 30th date is to determine whether there's even legal claims to even be going down that path to start with. If we're going to be getting into factual issues about reputational harm, et cetera, the State needs time to develop that. So I don't think the State can get that discovery done on a shortened time frame. The time frame that was set on the 11th is the time frame that should stay.

THE COURT: Okay. All right. Anything else on the countermotion?

MR. BICE: Yes, Your Honor, just briefly.

Let's remember this is simply a preliminary injunction hearing, not a trial on the merits. So discovery is regularly accelerated, and you don't have to prove the entirety of the case. And that's all we're asking, is since the State wants appellate review and they say that there's a need for speed on appellate review, let's have an actual fair appellate record with the discovery that we've asked for. If the State doesn't want to do expedited discovery for themselves, that's the State's decision. We ask you to

accelerate our discovery of them so that we can get this done and we are ready to hold a preliminary injunction hearing in September with more than ample time then for the State to seek review, appropriate review by way of an appeal at the Nevada Supreme Court with an actual and fair record.

THE COURT: Thank you.

I am going to grant the countermotion in part. I am going to shorten the time to respond to written discovery to 20 days, and I'm going to shorten time to notice depositions to 10 days.

I would still encourage the parties to work together on scheduling depositions so that we are not scheduling things when people are on vacation, at graduations, or weddings. But to the extent that we can complete the discovery earlier I would urge you to use your best efforts. I think it is critical that record for a preliminary injunction be developed prior to the appellate review, so I will do everything in my power to get the case -- the preliminary injunction resolved prior to that time.

MR. BICE: Thank you, Your Honor.

THE COURT: Anything else?

MR. SMITH: Your Honor, just to head off one issue that I see coming. With the 20 days' written discovery there was a discrepancy in timing when I received Alvogen's first round of discovery responses.

THE COURT: When do you think you got them, Mr. Smith?

MR. SMITH: I think I got them the day that I found out they had been served on that Tuesday.

THE COURT: Which was last week?

MR. SMITH: Yes.

MR. BICE: Your Honor, apparently we served them to the court system, but no one from the State is apparently registered, so they didn't know that they were there.

THE COURT: Well, you can't serve them if they're not registered. So have you served them now?

MR. BICE: We have.

THE COURT: Okay. So it will go 20 days from time you were actually served, not when they tried to serve you through an unregistered --

MR. SMITH: Understood. Thank you.

THE COURT: Okay. Anything else?

MR. BICE: No, Your Honor.

THE COURT: I will see you guys on Thursday.

MR. BICE: Thank you.

MR. SMITH: Thank you, Your Honor.

THE PROCEEDINGS CONCLUDED AT 10:40 A.M.

* * * * *

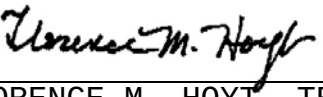
CERTIFICATION

I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE AUDIO-VISUAL RECORDING OF THE PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

AFFIRMATION

I AFFIRM THAT THIS TRANSCRIPT DOES NOT CONTAIN THE SOCIAL SECURITY OR TAX IDENTIFICATION NUMBER OF ANY PERSON OR ENTITY.

FLORENCE HOYT
Las Vegas, Nevada 89146



FLORENCE M. HOYT, TRANSCRIBER

8/8/18

DATE

JMOT
E. LEIF REID, ESQ., SBN 5750
JOSH M. REID, ESQ., SBN 7497
KRISTEN L. MARTINI, ESQ., SBN 11727
LEWIS ROCA ROTHGERBER CHRISTIE LLP
3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996
Tel: 702.949.8200
Fax: 702.949.8398
Email: lreid@lrrc.com
jreid@lrrc.com
kmartini@lrrc.com

Attorneys for Intervenor

DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC.,

Plaintiff,

vs.

STATE OF NEVADA;

NEVADA DEPARTMENT OF CORRECTION;

JAMES DZURENDA, Director of the Nevada Department of Correction, in his official capacity;

IHSAN AZZAM, Ph.D, M.D., Chief Medical Officer of the State of Nevada, in his official capacity;

And JOHN DOE, Attending Physician at Planned Execution of Scott Raymond Dozier, in his official capacity;

Defendants.

HIKMA PHARMACEUTICALS USA INC.,

Intervenor,

vs.

STATE OF NEVADA;

NEVADA DEPARTMENT OF CORRECTION;

JAMES DZURENDA, Director of the Nevada

Case No. A-18-777312-B

Dept. No. XI

HIKMA PHARMACEUTICALS' JOINDER IN AND SUPPLEMENT TO ALVOGEN, INC.'S, MOTION FOR PRELIMINARY INJUNCTION

Date of Hearing:

Time of Hearing:

Department of Correction, in his official capacity;

IHSAN AZZAM, Ph.D, M.D., Chief Medical Officer of the State of Nevada, in his official capacity;

And JOHN DOE, Attending Physician at Planned Execution of Scott Raymond Dozier, in his official capacity;

Defendants.

Hikma Pharmaceuticals USA Inc. ("Hikma"), through counsel of Lewis Roca Rothgerber Christie LLP, hereby joins in and supplements Alvogen, Inc.'s ("Alvogen"), Motion for Preliminary Injunction ("Alvogen's Motion").[1] Hikma seeks a preliminary injunction (1) enjoining Defendants from using Hikma's fentanyl product, Fentanyl Citrate Injection, USP C-11 ("Hikma's Fentanyl"), in any execution; and (2) requiring Defendants to return Hikma's Fentanyl that Defendants wrongfully obtained.

This Motion is made pursuant to NRCP 65 and EDCR 2.20, and based upon the following Memorandum of Points and Authorities, the attached Declaration and Exhibits, and the pleadings and papers on file herein.

DATED this 8th day of August, 2018.

LEWIS ROCA ROTHGERBER CHRISTIE LLP

By: /s/ *Josh M. Reid*
E. LEIF REID, ESQ., SBN 5750
JOSH M. REID, ESQ., SBN 7497
KRISTEN L. MARTINI, ESQ., SBN 11272
3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996

Attorneys for Intervenor

[1] *See* Pltf.'s *Ex Parte* App. for TRO & Mot. for Prelim. Inj.; *Ex Parte* Mot. for Order Shortening Time (July 10, 2018).

3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996
Lewis Roca ROTHGERBER CHRISTIE

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

While Hikma takes no position on the propriety of capital punishment or the death sentence imposed upon Scott Raymond Dozier, Hikma—a leading pharmaceutical company—is legally entitled to protect its proprietary interests in its products, its business reputation and goodwill, and its investor interests. Hikma, like Alvogen, possesses property interests in its products. Hikma, like Alvogen, has the right to determine to whom its products are sold, and restrict sales to those who intend to misuse the products, especially where such misuse will damage Hikma's reputation and goodwill.

Hikma has taken proactive action to prevent the sale and distribution of its products to Defendants, and Defendants' misuse of its products in the State's lethal injection protocol. Hikma published its policies regarding its refusal to sell to state departments of corrections for use in executions, and its vehement objection to the misuse of its products for such purpose. Hikma specifically notified Defendants in writing of Hikma's strenuous objection to Defendants' use of any of its products for lethal injunction as being contrary to the U.S. Food and Drug Administration's ("FDA") indication, Hikma's intention in manufacturing the products for the well-being of patients in need, and Hikma's values as an organization.

Nonetheless, Defendants refused to heed Hikma's warnings and, in knowing violation of Hikma's express policies and intentions, surreptitiously obtained Hikma's Fentanyl for use in the execution of Scott Raymond Dozier. Defendants' conduct constitutes violations of Nevada law, including the following:

(1) Unlawful Obtainment of a Controlled Substance, NRS 453.391(1): Defendants have unlawfully obtained Hikma's Fentanyl, a controlled substance, from a Hikma and an unsuspecting intermediary wholesaler.

(2) Administration of a Controlled Substance for an Illegitimate Purpose, NRS 453.381(1): Defendants' proposed use requires Defendants to administer Hikma's Fentanyl in a State-sponsored execution, which is not a legitimate medical purpose.

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(3) Unlawful Furnishing of a Controlled Substance, NRS 41.700(a), (b): Defendants' acquisition and proposed use and furnishing of Hikma's Fentanyl in Mr. Dozier's execution is unlawful, and Defendants are liable for all damages caused as a result of Defendant's actions, including injury to Hikma.

In addition to these statutory violations, Defendants' conduct violates Hikma's property rights, stemming Hikma's common law claims for replevin and conversion, and pursuant to Nevada's Uniform Commercial Code.

Defendants' unlawful obtainment and planned misuse of Hikma's Fentanyl is precisely the type of conduct that Hikma is legally entitled to prohibit. Accordingly, Hikma seeks an Order from this Court enjoining Defendants from using Hikma's Fentanyl in any executions, and further requiring Defendants to return Hikma's Fentanyl.

II. FACTUAL BACKGROUND

Since its inception, Hikma has become a leading manufacturer and provider of quality oral, liquid, inhalant, and injectable branded and non-branded generic medicines in the United States. **Ex. 1** at 2. Hikma aims to improve lives by providing patients access to high-quality, affordable medicines. *Id.* Hikma's medicines are used thousands of times a day around the world to treat illnesses and save lives. **Ex. 2**. It has built a global reputation for the same. Compl. in Intervention ¶ 14.

Hikma's Fentanyl is in the narcotic (opiate) analgesics class of medications. *Id.* ¶ 15. Fentanyl is a synthetic opioid that was originally developed in or about 1960 as a powerful, intravenous anesthetic for surgery. *See id.* ¶¶ 17-18; **Ex. 3** at 1216. It has been approved by the FDA since 1972 (but in combination since 1968) for use in as an analgesic (pain relief) and anesthetic. *See* **Ex. 3** at 1217-18. It is used to treat sudden breakthrough pain that occurs despite continuous treatment with pain medication, and in people who suffer from severe, long-term pain, primarily in cancer patients but also in other chronic, intense pain scenarios presenting with noncancerous maladies. *See generally* **Ex. 3**. It is also the most often used intraoperative analgesia. *See id.*

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Fentanyl has become extremely important in severe, chronic pain management in the practice of modern-day medicine due to its effectiveness, as well as its minimal or nonexistent effects to the cardiovascular system and plasma histamine (distinguishing it from other μ-opioid receptor agonists), its rapid onset of action and short duration of effects, and the ease and low cost in synthesizing and preparing for the marketplace. *See id.* Fentanyl is a Schedule II controlled substance. NAC 453.520(3).

To maintain Hikma's reputation for producing safe, high-quality products, Hikma has always been and is committed to going beyond mere compliance with the law and strives to uphold the highest ethical standards in everything it does. Compl. in Intervention ¶ 20. In an attempt to ensure that Hikma's Fentanyl, among its other products, is used responsibly, Hikma has placed controls on the purchase and use of its products. *See* **Ex. 2**. Such controls include internal policies and procedures with its customers to restrict the supply of Hikma products for the distribution and use in lethal injection protocols. *See id.* Hikma has refused the direct sale of its products to United States departments of corrections for use in capital punishment, and works directly with its distribution partners to add restrictions for unintended use to its distribution contracts. *See id.*

Hikma is not the only pharmaceutical company that has taken affirmative action to exercise their rights to not sell their products for use in lethal injection. *See* **Ex. 4**. More than 20 American and European pharmaceutical companies have taken similar action. *See id.*; *see also* Compl. for Emergency Injunctive Relief & Return of Illegally-Obtained Property (July 10, 2018) ("Alvogen Compl."). Similar to other pharmaceutical companies, Hikma has an important interest in protecting its business reputation and meeting its fiduciary duties to its investors. *See id.* Experts have commented that a pharmaceutical company's involvement with lethal injection may open the company to liability, including the loss of large institutional investors and litigation from their shareholders. *See* **Ex. 4**. As a subsidiary of an international pharmaceutical company publicly traded on the London Stock Exchange, Hikma has taken multiple proactive actions in order to protect its rights and values, and also to protect its investors. Compl. in Intervention ¶ 10.

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NDOC, like other death-penalty states, was well-aware of certain drug manufacturers' restrictions on the use of their drugs in executions. According to the Las Vegas Review-Journal, as reported on October 7, 2016, Defendant Nevada Department of Corrections ("NDOC") sent out 247 requests for proposals on September 2, 2016, to manufactures for the purchase of the drugs that it intended to use in legal injunctions after the stockpile of at least one of the drugs in its possession expired. **Ex. 5**. (Nevada's last execution occurred in 2006.) Not one response was received. *Id.* No vendor responded because not one of them could make the certification that the drugs the NDOC were seeking to obtain were authorized for use in executions. Because no pharmaceutical companies bid to supply the drugs for legal injections, Nevada prison officials were on the record as stating that "the state will have to explore its options to carry out executions." *Id.*

Upon learning that some states, including the State of Nevada, were considering new compounds to use in their lethal injection protocols, Hikma exercised its rights and took preemptive steps to prevent its products from being used for such purpose. *See* **Ex. 2**; **Ex. 6**. Such use is inconsistent with the FDA's indication, in addition to being contradictory to Hikma's intention in manufacturing its medicines, its values as an organization, the interests of its customers, and the financial interests of Hikma and its shareholders. *See* **Ex. 2**; **Ex. 6**.

In 2016, Hikma exercised its right to not sell its products to the State of Nevada for use in lethal injection, notifying the public and Defendants of its rights. As of October 2016, Hikma published on its website its policy on states' uses of its products in capital punishment regimes, voicing its strong objection to any department of corrections' acquisition and use of its products for such purpose. *See* Compl. in Intervention ¶ 23.

On December 20, 2016, Hikma went further to specifically notify Defendants that Hikma objected in the strongest possible terms to the use of any of its products for lethal injection. *See* **Ex. 6**. Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda, in which Hikma vehemently objected to any of its products being used for lethal injection ("2016 Letters"). *Id.* Hikma stated, "We object in the strongest possible terms to the use of any of our products for lethal injection," and again made clear that its objection

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3993 Howard Hughes Pkwy, Suite 600
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should be applied to all of its products, including Hikma's Fentanyl. *Id.* Hikma notified these recipients that such use was

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

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

Hikma further explained,

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

Id.

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

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

See **Ex. 2**. Hikma's website further publishes the various controls it has in place to "to prevent these products from being used for the purpose of capital punishment," including that Hikma "will not accept orders for these products directly from any Departments of Correction or correctional facilities in the United States, unless accompanied by an original, raised seal copy of an affidavit signed by the state attorney general (or governor), certifying under penalty of perjury that the product(s) will not be used for capital punishment," and that Hikma "will only sell these same drugs to pre-selected commercial customers who agree that they will not then sell them to

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Departments of Corrections/correctional facilities, or to secondary distributors or retail pharmacies." *Id.* Hikma also restricted particular drugs that have a heightened potential of misuse for lethal injection protocols and publishing them on Hikma's restricted list. *See id.*

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

Upon information and belief, shortly before the NDOC's execution manual was published, the drug manufacturer Pfizer claimed ownership of the fentanyl and diazepam products that NDOC originally intended to use to execute Scott Raymond Dozier. *See* **Ex. 7**. Pfizer, too, objected to NDOC's use of its products as lethal injections, and demanded return of the products. *See id.* NDOC spokeswoman Brooke Keast rejected any assertion that the State was obligated to return any product. *See id.*

Nonetheless, as another reminder to Defendants in light of the on-going controversy, in December 2017, Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda, in which Hikma again vehemently objected to any of its products being used for lethal injection ("2017 Letters"). **Ex. 8**. Hikma restated that such use of any Hikma products is "off-label" and contrary to the FDA indication, in addition to being contradictory to the intended use of the products and Hikma's organizational values. *Id.*

In spite of Hikma's written demands and warnings to not have its products sold and used in conjunction with lethal injection, Defendants sought to, and did, unlawfully acquire Hikma's products for use in the State's lethal injection protocol.

On or about July 10, 2018, Hikma learned through a public interest organization that the State had confirmed its intention to execute Scott Raymond Dozier on Wednesday, July 11, 2018, using fentanyl and midazolam in its three-drug cocktail. Compl. in Intervention ¶ 37. At that

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time, it was unclear whether Defendants were in possession of Hikma's Fentanyl or midazolam products. *Id*. On July 10, 2018, Hikma also learned of Alvogen's initiation of the instant lawsuit, and Alvogen's request for a temporary restraining order and preliminary injunction. *Id.* ¶ 38. Through these filings, Alvogen confirmed that Defendants were intending to use Alvogen's Midazolam Product in the execution, not Hikma's midazolam. *See generally* Alvogen Compl.

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

After the hearing on Alvogen's *ex parte* application, Hikma obtained copies of documents produced as a result of a court order in litigation initiated by the American Civil Liberties Union of Nevada ("ACLU action"). *See Am. Civil Liberties Union of Nev. Found. v. State*, Case No. 18 OC 00163 1B, Order Granting In-Part Emergency Pet. Issuing Writ of Mandamus (Nev. Dist. Ct. July 6, 2018). The court order issued in the ACLU action compelled NDOC to disclose the specific lethal injection procedures that it planned to implement in Scott Raymond Dozier's execution. *See id.* At least one Defendant to this case acknowledged in the ACLU action that they have taken efforts to maintain the secrecy of and/or conceal their acquisition and possession of these drugs to use in its lethal injection procedures 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." *See id.* at 4.

The documents disclosed by the State in the ACLU action included a list of the drugs to be included in the lethal injection cocktail, along with the invoices related to NDOC's purchase of those specific drugs. These invoices identified Defendants' purchase and receipt of Hikma's Fentanyl, identified as NDC/UPC 0061-6027-25. *See* **Ex. 9**. The invoices further showed that NDOC placed multiple small orders of the drugs over a number of months, with some orders following the last by only one day. Compl. in Intervention ¶ 40.

The invoice for Hikma's Fentanyl was from one of Hikma's wholesale distributors, Cardinal Health, placed on September 28, 2017, for shipment the next day, and addressed to be

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billed and shipped to the Nevada Department of Correction Center Pharmacy, located at the NDOC's administrative building in Las Vegas—not to the Ely State Prison, the execution site located over 200 miles away from its Las Vegas building. *See id.* Under the product description, Cardinal Health referenced message 121: "This product is required by the FDA to be dispensed with a medication guide." *Id.*

To purchase Hikma's Fentanyl, NDOC was required to provide Cardinal Health with proof of a medical license issued to NDOC's medical director. NDOC's purchase order to Cardinal Health for Hikma's Fentanyl used the Nevada Chief Medical Officer's license to unlawfully obtain Hikma's Fentanyl. *See* **Ex. 10**.

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

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

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

Id.

Hikma demanded that NDOC immediately return all of Hikma's Fentanyl, and other products, intended for use in executions, for such use would represent a serious misuse of life-saving medicines. *Id.* Hikma specifically requested that Defendant Dzurenda and other NDOC officials not circumvent Hikma's carefully-prepared controls or potentially undermine these

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specifically drafted legal provisions in its agreements. *Id.* Defendants have not responded to Hikma's letter.

III. ARGUMENT

Hikma joins in Alvogen's arguments in support of Alvogen's Motion as set forth in Section III of Alvogen's Motion, and incorporates those arguments as though fully set forth herein. *See* Alvogen Mot. 12-30. Hikma further supplements Alvogen's arguments with respect to Hikma's Fentanyl Product (and any other Hikma product), including the following supplemental arguments and authorities.

A. Standard for Injunctive Relief

Rule 65 of the Nevada Rules of Civil Procedure and NRS 33.010 authorize courts to grant injunctive relief when the commission of an act may produce great or irreparable injury to the plaintiff. NRS 33.010 provides:

> An injunction may be granted in the following cases:
>
> 1. When it shall appear by the complaint that the plaintiff is entitled to the relief demanded, and such relief or any part thereof consists, in restraining the commission or continuance of the act complained of, either for a limited period or perpetually.
>
> 2. When it shall appear by the complaint or affidavit that the commission or continuance of some act, during the litigation, would produce great or irreparable injury to the plaintiff.
>
> 3. When it shall appear, during the litigation, that the defendant is doing or threatens, or is about to do, or is procuring or suffering to be done, some act in violation of the plaintiff's rights respecting the subject of the action, and tending to render the judgment ineffectual.

Traditionally, to obtain a preliminary injunction, "the moving party must show that there is a likelihood of success on the merits and that the nonmoving party's conduct, should it continue, would cause irreparable harm for which there is no adequate remedy at law." *Dep't of Conservation & Natural Res., Div. of Water Res. v. Foley*, 121 Nev. 77, 80, 109 P.3d 760, 762 (2005); *accord Dangberg Holdings Nev., L.L.C. v. Douglas Cty.*, 115 Nev. 129, 142, 978 P.2d 311, 319 (1999). And, when considering preliminary injunctions, courts "also weigh the potential

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hardships to the relative parties and others, and the public interest." *Id.* The essence of the foregoing considerations is whether the rights of the parties will be best protected by the granting of the injunctive relief. *See Rhodes Mining Co. v. Belleville Placer Mining Co.*, 32 Nev. 230, 106 P. 561, 562 (1910). The decision to grant a preliminary injunction falls within the sound discretion of the district court. *Univ. & Cmty. Coll. Sys. of Nev. v. Nevadans for Sound Gov't*, 120 Nev. 712, 721, 100 P.3d 179, 187 (2004).

Applying these factors to this case reveals that each factor weighs in favor of a preliminary injunction enjoining Defendants from using Hikma's Fentanyl in any execution, and requiring Defendants to return Hikma's Fentanyl that Defendants wrongfully obtained. Each factor is discussed below, in turn.

B. Hikma is More than Reasonably Likely to Succeed on the Merits of Its Claims

In order to meet the first factor attendant to issuing a preliminary injunction, *i.e.*, a likelihood of success on the merits of the moving party's claims, the moving party is not required to prove that it will ultimately prevail on these claims in the lawsuit; rather, it is only required to establish "a reasonable probability of success on the merits." *See Clark Cnty. Sch. Dist. v. Buchanan*, 112 Nev. 1146, 1150, 924 P.2d 716, 719 (1996); *Dixon v. Thatcher*, 103 Nev. 414, 415, 742 P.2d 1029, 1031 (1987) (reversing a denial of an injunction after finding that the plaintiffs presented "sufficient indicia" to make a prima facie showing before a trier of fact). Though this Court need only find that Hikma has met this burden as it relates to any one of its claims supporting injunctive relief, as shown below, Hikma has met this burden with respect to each of its five claims for relief.

1. Unlawful Obtainment of a Controlled Substance

Hikma's First Claim for Relief is predicated on NRS 453.391(1), which provides that "a person shall not . . . unlawfully take, obtain or attempt to take or obtain a controlled substance from a manufacturer, wholesaler, pharmacist, physician, . . . or any other person authorized to administer, dispense or possess controlled substances." Defendants each qualify as a "person" for purposes of the foregoing. *See* NRS 453.113. Paralleling these statutes, the Nevada Administrative Code reads, in pertinent part, "A person who is licensed as a physician or

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physician assistant shall not . . . [a]cquire any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception or subterfuge." NAC 630.230.

Defendants' acquisition of Hikma's Fentanyl was unlawful for the reasons that Defendants' acquisition was: (1) in derogation and violation of Hikma's property rights, and (2) undertaken for purposes of administering it for a non-therapeutic use (an execution) as well as unlawfully furnishing it to non-physician administrators.

Concerning Defendants' acquisition of Hikma's Fentanyl in derogation of Hikma's property rights, and as more fully explained *infra* Section III.B.4, nearly 100 years ago, the United States Supreme Court recognized the "right of [a] trader or manufacturer engaged in an entirely private business freely to exercise his own independent discretion as to parties with whom he will deal, and, of course, [to] announce in advance the circumstances under which he will refuse to sell." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). Hikma has a property right in both its products and its right to deal—or refuse to deal—with particular prospective customers.

In accordance with its rights, Hikma specifically notified Defendants in 2016 that Defendants were not authorized to purchase or use any Hikma product, including Hikma's Fentanyl, for lethal injection purposes. *See* **Ex. 6**. Hikma also publicly published its policy on the use of its products in capital punishment, vehemently objecting to any state departments of corrections using any of its products in lethal injection protocols. *See* Compl. in Intervention ¶ 23. Despite Defendants knowledge that they were not authorized to purchase or use Hikma's Fentanyl (as being contrary to the FDA indication, Hikma's intention in manufacturing the product, and values as an organization), Defendants unlawfully circumvented Hikma's controls and express instructions by issuing purchase orders for Hikma's Fentanyl in September 2017. *See* **Ex. 9**.

Defendants had Hikma's Fentanyl shipped to the NDOC pharmacy in Las Vegas, rather than the execution site. *See id.* Hikma reasonably believes and contends that Defendants obtained Hikma's Fentanyl from an unsuspecting intermediary, without disclosing the contents of Hikma's 2016 Letters or Defendants' intention to use Hikma's Fentanyl for nontherapeutic purposes. Compl. in Intervention ¶¶ 62-63. Defendants have acknowledged that they took efforts to maintain the secrecy and/or conceal the fact that their acquisition of Hikma's Fentanyl because of

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a concern that the information as to "where a state obtains execution drugs" may be used "to persuade the manufacture and others to cease selling that drug for execution purposes." *See Am. Civil Liberties Union of Nev. Found. v. State*, Case No. 18 OC 00163 1B, Order Granting In-Part Emergency Pet. Issuing Writ of Mandamus, at 4 (Nev. Dist. Ct. July 6, 2018). Defendants would not have been able to obtain had they disclosed the contents of the letter or their intended use of Hikma's Fentanyl. Compl. in Intervention ¶¶ 62-63.

Regarding Defendants' acquisition of Hikma's Fentanyl for the purpose of administering it for a non-therapeutic use as well as for unlawfully furnishing it to non-physician administrators, further explained *infra* Section III.B.2-3, 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). Execution by lethal injection is not a "legitimate medical purpose." *See, e.g.*, American Medical Association, Code of Medical Ethics Opinion 9.7.3 (stating that "as a member of a profession dedicated to preserving life when there is hope in doing so, a physician must not participate in a legally authorized execution").

Hikma joins in and specifically incorporates as though fully set forth herein, Alvogen's analysis regarding the existence of a private right of action implied within NRS 453.391(1). *See* Alvogen Mot. 19 & n.6.

For these reasons, Hikma has satisfied its burden in showing its likelihood of succeeding on the merits of its First Claim for Relief.

2. Administration of a Controlled Substance for an Illegitimate Purpose

Pursuant to NRS 453.381(1), "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." A physician may not use a non-physician to evade that prohibition.

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. 12** § 110.02.

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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*, 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") (last accessed Aug. 8, 2018); Educational Commission for Foreign Medical Students, Health Care Team, 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") (last accessed Aug. 8, 2018).

Execution by lethal injection using Hikma's Fentanyl is not a "legitimate medical purpose" based on the uses for which Hikma's Fentanyl is approved. *See, e.g.*, American Medical Association, Code of Medical Ethics Opinion 9.7.3 (stating that "as a member of a profession dedicated to preserving life when there is hope in doing so, a physician must not participate in a legally authorized execution").

Defendants threaten to have Defendant John Doe I, a physician, administer and/or direct and supervise the administration of Hikma's Fentanyl for a purpose that is neither therapeutic nor in furtherance of the "healing arts" (as they are called under Nevada law), but rather to carry out a State-sponsored execution. The administration of Hikma's Fentanyl for lethal injection purposes constitutes the administration of a controlled substance for a purpose that does not qualify as a legitimate medical purpose. This is a violation of NRS 453.381(1).

Hikma joins in and specifically incorporates as though fully set forth herein, Alvogen's analysis regarding the existence of a private right of action implied within NRS43.381(1). *See* Alvogen Mot. 21 & n.7.

For the reasons stated herein, Hikma will likely succeed on the merits of its Second Claim for Relief.

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3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996

3. Unlawful Furnishing of a Controlled Substance

Pursuant to NRS 41.700, 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). Furthermore, a person who "knowingly 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 also liable for wrongdoing caused as a result of the use of the controlled substance. NRS 41.700(b).

Defendants' furnishing of Hikma's Fentanyl to non-physician administrators is unlawful for several reasons. Initially, Defendants have announced that they intend to furnish Hikma's Fentanyl to John Doe I and/or non-physician administrators for purposes of the scheduled execution. *See* **Ex. 13** ("As part of the execution protocol, an attending physician, who is a practicing physician in the State of Nevada, will attend the execution."); **Ex. 12** § 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]" for the reasons that: (1) Defendants' obtainment of Hikma's Fentanyl was in derogation and violation of Hikma's property rights, *see supra* Sections III.B.1, 4; and (2) Defendants' acquisition of Hikma's Fentanyl was undertaken for purposes of unlawfully administering it for a non-therapeutic use (an execution) as well as for unlawfully furnishing it to non-physician administrators. *See supra* Section III.B.2-3.

Hikma specifically joins in and incorporates as though fully set forth herein, Alvogen's argument pertaining to Defendants' violations of NRS 41.700(1)(b) but as applied to Hikma's Fentanyl. Alvogen Mot. 22.

This element has been satisfied as it pertains to Hikma's Third Claim for Relief.

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4. Replevin and Conversion

Defendants are wrongfully in possession of Hikma's property, Hikma's Fentanyl. Under Nevada law, the doctrines of replevin and conversion allow for Hikma's recovery of its own property. Replevin involves four elements: (1) the plaintiff's ownership of the property; (2) a right to immediate possession; (3) the defendant's wrongful taking of the property; and (4) a demand for its return. *Johnson v. Johnson*, 27 P.2d 532, 533 (1933). 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 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.

Hikma has a property right in not only it products, including Hikma's Fentanyl, but also its right to deal—or refuse to deal—with particular prospective customers with respect to its products. Particularly, Hikma benefits from "the long recognized right of [a] trader or manufacturer engaged in an entirely private business freely to exercise his own independent discretion as to parties with whom he will deal, and, of course, [to] announce in advance the circumstances under which he will refuse to sell." *See Colgate*, 250 U.S. at 307. Hikma has exercised those rights both generally in its statements to the public and specifically in communications with Defendants. *See* **Exs. 2**, **6**. To wit, Hikma specifically wrote to NDOC (through Defendant Dzurenda) and the Nevada Attorney General to expressly warn them that they were customers with whom Hikma refused to deal—both directly and indirectly—with regard to the acquisition of Hikma's Fentanyl. **Ex. 6**.

More particularly, Defendants sought to circumvent Hikma's controls and positions by issuing purchase orders for Hikma's Fentanyl for completion in September 2017 with an unsuspecting distributor, Cardinal Health. **Ex. 9**. Based on those purchase orders to be completed in September 2017, Cardinal Health shipped to Defendants a total of 25 2ml vials of 50mcg/ml Fentanyl. *See id.* Defendants knew or should have known that the distributor was not permitted, allowed, or authorized to sell Hikma's Fentanyl or other Hikma products to NDOC and the

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3993 Howard Hughes Pkwy, Suite 600
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remaining Defendants, let alone for the purpose of an execution. Indeed, Hikma had written to Defendants in December 2016—prior to their illicit acquisition of Hikma's Fentanyl—to warn them that Hikma "object[s] in the strongest possible terms to the use of any of [its] products for lethal injection," including Hikma's Fentanyl, and that certain controls were in place to prevent such usage. **Ex. 6**.

Hikma's website further published the various controls it has in place to "to prevent these products from being used for the purpose of capital punishment," including that Hikma "will not accept orders for these products directly from any Departments of Correction or correctional facilities in the United States, unless accompanied by an original, raised seal copy of an affidavit signed by the state attorney general (or governor), certifying under penalty of perjury that the product(s) will not be used for capital punishment," and that Hikma "will only sell these same drugs to pre-selected commercial customers who agree that they will not then sell them to Departments of Corrections/correctional facilities, or to secondary distributors or retail pharmacies." *See* **Ex. 2**.

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

Defendants received additional actual or constructive notice when Hikma again notified Defendants through Hikma's 2017 and 2018 Letters that none of Hikma's products could be used for lethal objection, and that it had controls in place to prevent departments of corrections from using Hikma products for capital punishment or sales to customers. *See* **Exs. 8**, **11**. Defendants were aware that their possession of Hikma's Fentanyl was unlawful.

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Upon learning that Defendants had unlawfully obtained Hikma's Fentanyl, Hikma specifically demanded that Defendants immediately return all product intended for use in executions in exchange for a full refund. *See* **Ex. 11**. Hikma also requested that Defendants not circumvent Hikma's controls, intentions, and legal provisions and agreements. *Id.* In spite of said demand, Defendants have refused to return Hikma's Fentanyl that they illicitly and improperly obtained.

Hikma meets the elements of replevin and conversion, and is therefore entitled to the return of its property. Hikma owns the property, and has a right to its immediate possession as a result of Defendants' unlawful obtainment and knowledge that they could not purchase, and Hikma's distributors, were not authorized to sell them, Hikma's Fentanyl. Defendants could not and did not in good faith acquire title to Hikma's Fentanyl. *See* NRS 104.2403(1, 104.2403(2); *Tempur-Pedic Int'l, Inc. v. Waste to Charity, Inc.*, No. 07-2015, 2007 WL 545041, at *1-2 (W.D. Ark., Feb. 16, 2007). Had Defendants disclosed the contents of Hikma's 2016 Letters to the intermediary, or disclosed their intended use for Hikma's Fentanyl to the intermediary, Defendants would not have been able to acquire the product. Defendants' actions are inconsistent with Hikma's property rights. For these reasons, Defendants' must return Hikma's Fentanyl: Hikma has demonstrated more than a reasonable probability of succeeding on the merits of its fourth and fifth claims for relief.

C. <u>Sovereign Immunity Does Not Shield the State's Conduct</u>

Hikma joins in and incorporates as though fully set forth herein Alvogen's argument as set forth in its Motion in Section III.C.

D. <u>Hikma Will Suffer Irreparable Harm if Defendants Are Not Enjoined From Using Hikma's Product in Their Lethal Injection Protocol</u>

1. Irreparable Harm is Presumed in this Case

Traditionally, where a plaintiff is likely to prevail on the merits, the burden to show irreparable harm is substantially reduced. *See Idaho Sporting Congress Inc. v. Alexander*, 222 F.3d 562, 565 (9th Cir. 2000) (noting that the likelihood of prevailing and irreparable harm are on a "sliding scale," such that the stronger the probability of success on the merits, the less burden is placed on the plaintiffs to demonstrate irreparable harm). However, "[w]here the action to be

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enjoined is unlawful, the unlawful act constitutes per se irreparable harm for the purposes of the preliminary injunction analysis." *E.g.*, *Union Tp. Sch. Corp. v. State ex rel. Joyce*, 706 N.E.2d 183, 192 (Ind. Ct. App. 1998) (alteration in original); *800 Iberville St. Ltd. P'ship v. V Rest. Grp., L.L.C.*, 171 So. 3d 1016, 1019 (La. Ct. App. 2015) ("[T]he violation of a statute precludes a showing of irreparable harm."); *Burton v. Celentano*, 658 P.2d 247, 249 (Ariz. Ct. App. 1982) ("It has been held ' . . . that when the acts sought to be enjoined have been declared unlawful or clearly are against the public interest, plaintiff need show neither irreparable injury nor a balance of hardship in his favor'") (ellipses in original).[2]

When the per se rule is invoked, the remaining prongs to the preliminary injunction analysis are mooted. *Burton*, 658 P.2d at 249; *accord Dep't of Fin. Institutions v. Mega Net Services*, 833 N.E.2d 477, 485-86 (Ind. Ct. App. 2005) & *infra* n.2. This is because "the defendant's actions have violated a statute and, thus, that the public interest is so great that the injunction should issue regardless of whether the plaintiff has actually incurred irreparable harm or whether the plaintiff will suffer greater injury than the defendant." *Dep't of Fin. Institutions*, 833 N.E.2d at 485-86. As a consequence, when it is clear that the statute has been violated, invocation of the per se rule is appropriate. *Id.* & *supra.*

As demonstrated above, *see supra* § III.B.1-3, Defendants have violated Nevada statutes. Defendants have unlawfully obtained a controlled substance, intends to administer a controlled substance for other than its intended purpose, and intends to unlawfully furnish a controlled

[2] *Accord Societe Des Produits Nestle v. Casa Helvetia, Inc*., 982 F.2d 633, 640 (1st Cir. 1992) (holding, "[I]rreparable harm flows from an unlawful trademark infringement as a matter of law."); *Commodity Futures Trading Comm'n v. Am. Bd. of Trade, Inc*., 803 F.2d 1242, 1250-51 (2d Cir. 1986) (stating, "An injunction prohibiting a party from engaging in conduct that violates the provisions of a statute is appropriate when there is a likelihood that, unless enjoined, the violations will continue"); *S.E.C. v. Holschuh*, 694 F.2d 130, 144 (7th Cir. 1982) (providing that "once a statutory violation has been demonstrated, the moving party need only show that there is a reasonable likelihood of future violations in order to obtain injunctive relief"); *CB Worldwide, Inc. v. Xena Express, Inc.*, No. 09CV02189, 2009 WL 3244735, *4 (C.D. Cal. Oct. 6, 2009) (holding that "Defendant's unlawful activities result in irreparable injury"); *Ouachita Parish Police Jury v. Am. Waste & Pollution Control*, 606 So.2d 1341, 1350 (La. Ct. App. 1992) (stating that "irreparable injury is a requisite only when the conduct sought to be enjoined is lawful" because "when the conduct is illegal, a showing of irreparable injury is not required"); *Dillon v. City of Erie*, 83 A.3d 467, 474 (Pa. Commw. Ct. 2014) ("When the Legislature declares certain conduct to be unlawful it is tantamount in law to calling it injurious to the public. For one to continue such unlawful conduct constitutes irreparable injury." (Quoting *Pa. Pub. Util. Comm'n v. Israel*, 52 A.2d 317, 321 (Pa. 1947))); *Piedmont Pub. Serv. Dist. v. Cowart*, 459 S.E.2d 876, 879 (S.C. Ct. App. 1995), *aff'd*, 478 S.E.2d 836 (S.C. 1996) (stating that "a violation of [state] statute must be considered irreparable injury for which no adequate remedy at law exists"); *Detroit Police Officers Ass'n v. City of Detroit*, 369 N.W.2d 480, 482 (Mich. Ct. App. 1985) (holding that no showing of irreparable harm is necessary to enjoin a violation of statute prohibiting changes in existing wages, hours, and other conditions of employment).

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3993 Howard Hughes Pkwy, Suite 600
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substance causing harm to Hikma. Defendants' obtainment, furnishing, and intended use of Hikma's Fentanyl violates NRS 453.391(1), 453.381(1), and 41.700(1)(a), (b). The injunction inquiry therefore stops here, and Defendants' violations of Nevada law should be enjoined.

2. Hikma Will Suffer Irreparable Harm if Defendants are Not Enjoined from Using Hikma's Fentanyl for Dozier's Execution

Even in the absence of applying the per se rule, Hikma will suffer irreparable harm if the injunction does not issue. "Evidence of loss of control over business reputation and damage to goodwill c[an] constitute irreparable harm." *Herb Reed Enterprises, LLC v. Fla. Entm't Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013). "These type of injuries are presumed to be irreparable because 'it is virtually impossible to ascertain the precise economic consequences of intangible harms, such as damage to reputation and loss of goodwill, caused by such violations.'" *Ty, Inc. v. Jones Grp., Inc.*, 237 F.3d 891, 902 (7th Cir. 2001) (quoting *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 16 (7th Cir. 1992)); *Swarovski Retail Ventures Ltd. v. JGB Vegas Retail Lessee, LLC*, No. 71618, 2018 WL 2041527, at *4, 416 P.3d 208 (Nev. April 27, 2018) ("'[A] damages remedy is inadequate if it would come too late to save the plaintiff's business, or if the nature of the plaintiff's loss makes damages very difficult to calculate.'") (quoting *Mass. Mut. Life Ins. Co. v. Associated Dry Goods Corp.*, 786 F. Supp. 1403, 1415 (N.D. Ind. 1992)); *Certified Restoration Dry Cleaning Network*, 511 F.3d 535, 550 (6th Cir. 2007) ("[A]n injury is not fully compensable by money damages if the nature of the plaintiff's loss would make the damages difficult to calculate.").

If Defendants are not enjoined from using Hikma's Fentanyl in their lethal injection protocol, Hikma will suffer damage to its reputation and goodwill. Since NDOC's declaration of its new and untested lethal injection protocol to be used in the execution of Scott Raymond Dozier, including the State's novel use of fentanyl in the execution, a media frenzy has transpired.

Hikma develops its products to save and improve patients' lives. *See* **Exs. 1**, **2**. Hikma's medicines are used thousands of times a day around the world to treat illnesses and save lives. *See id.* It has built a global reputation for the same. While Hikma works diligently to improve the safety of its life-saving products, including by actively controlling and monitoring the distribution

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of Hikma's Fentanyl, Defendants' intended actions will undo all of this work—instead painting Hikma as a manufacturer of "death cocktails." This assault on Hikma's reputation and goodwill will result in "economic consequences" that are "virtually impossible to ascertain." *See Abbott Labs.*, 971 F.2d at 16.

Defendants' actions have caused and will continue to cause, unless preliminarily and permanently enjoined, substantial and irreparable injury to Hikma, and its reputation and goodwill. Accordingly, a preliminary injunction preventing Defendants from using Hikma's Fentanyl in the execution of Scott Raymond Dozier, and returning Hikma's Fentanyl is warranted and necessary.

E. The Balance of Interests Supports Injunctive Relief

After consideration of the previous factors, courts will consider whether "the moving party's potential hardships outweigh any hardships to the nonmoving party caused by implementing the injunction." *Indep. Asphalt Consultants, Inc. v. Studebaker*, 126 Nev. 722, 367 P.3d 781 (2010) (unpublished but citing *Univ. & Cmty. Coll. Sys. of Nev. v. Nevadans for Sound Gov't*, 120 Nev. 712, 721, 100 P.3d 179, 187 (2004)); *accord Univ. & Cmty. Coll. Sys. of Nev.*, 120 Nev. at, 721, 100 P.3d at 187 (holding that "courts also weigh the potential hardships to the relative parties and others").

The balance of interests weighs heavily in favor of issuing the preliminary injunction in this case. The issuance of the requested injunction will not prejudice Defendants, for the injunction will preserve the status quo. Scott Raymond Dozier was sentenced to die on October 3, 2007, over 10 years ago. Thus, Defendants will suffer little, if any, prejudice if they are required to wait until the instant litigation is resolved. Issuing the injunction will simply maintain the status quo that has existed for over a decade. Moreover, the requested injunction will merely compel Defendants to act in compliance with Nevada law.

In the absence of an injunction, however, Hikma will suffer irreparable damage to its business reputation and goodwill. *See supra* § III.B. Unlike the absence of prejudice suffered by Defendants in preserving the status quo, disturbing the status quo and allowing Defendants to proceed with the execution using Hikma's Fentanyl will have the irreparable effect of painting Hikma as the manufacturer of "death cocktails." This stands in stark contrast to Hikma's mission

3993 Howard Hughes Pkwy, Suite 600
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of creating life-improving and life-saving drugs and negates—at least in the public perception—Hikma's diligent efforts to reduce the harmful and fatal effects caused by the misuse of its Fentanyl. In short, Hikma will suffer substantial hardship if the injunction is not issued.

Moreover, it is in the public interest to issue the injunction. The United States Supreme Court recognizes the sound public policy of protecting the property interests a private business has in the control and sale of its product. *Colgate*, 250 U.S. at 307. Thus, the balance of interests weighs strongly in favor of issuing the injunction.

IV. CONCLUSION

Hikma has a reasonable probability of prevailing on the merits of at least one, if not all, of its claims, and without an injunction preventing Defendants' threatened conduct, Hikma will suffer irreparable harm to its business reputation and goodwill. Moreover, delaying the execution, which has been pending for over a decade, will maintain the status quo, therefore causing defendants no additional hardship. A preliminary injunction (1) enjoining Defendants from using Hikma's Fentanyl in any executions, and (2) requiring Defendants to return to Hikma the Hikma Fentanyl that Defendants wrongfully obtained, is warranted.

DATED this 8th day of August, 2018.

LEWIS ROCA ROTHGERBER CHRISTIE LLP

By: /s/ *Josh M. Reid*
E. LEIF REID, ESQ., SBN 5750
JOSH M. REID, ESQ., SBN 7497
KRISTEN L. MARTINI, ESQ., SBN 11272
3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996

Attorneys for Intervenor

3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996
Lewis Roca ROTHGERBER CHRISTIE

CERTIFICATE OF SERVICE

Pursuant to Nevada Rule of Civil Procedure 5(b) and EDCR 8.05, I hereby certify that on the 8th day of August, 2018, I caused a true and correct copy of the foregoing **HIKMA PHARMACEUTICALS' JOINDER IN AND SUPPLEMENT TO ALVOGEN INC.'S MOTION FOR PRELIMINARY INJUNCTION** to be served via the Court's File & Serve Electronic Filing System, on the following parties in the above-referenced matter:

James J. Pisanelli
Todd L. Bice
Debra L. Spinelli
PISANELLI BICEP LLC
400 South 7th Street, Suite 300
Las Vegas, NV 89101
Attorneys for Plaintiff

Kenneth G. Schuler
Michael Faris
Alex Grabowski
LATHAM & WATKINS LLP
330 North Wabash Ave., Suite 2800
Chicago, IL 60611
Attorneys for Plaintiff

Angela Walker
LATHAN & WATKINS LLP
555 Eleventh Street NW, Suite 1000
Washington, DC 20004-1304
Attorneys for Plaintiff

Jordan T. Smith
Assistant Solicitor General
555 East Washington Ave., #3900
Las Vegas, NV 89101
Attorneys for Defendants

DATED this 8th day of August, 2018.

/s/ *Dawn M. Hayes*
AN EMPLOYEE OF LEWIS ROCA ROTHGERBER CHRISTIE LLP

3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996
Lewis Roca ROTHGERBER CHRISTIE

DECLARATION OF JOSH M. REID IN SUPPORT OF HIKMA PHARMACEUTICALS' JOINDER IN AND SUPPLEMENT TO ALVOGEN, INC.'S, MOTION FOR PRELIMINARY INJUNCTION

I, Josh M. Reid, make this Declaration based upon my personal knowledge, and information I believe to be true:

1. I am a resident of Nevada and over the age of 18.

2. I am a Nevada-licensed attorney with the law firm of Lewis Roca Rothgerber Christie LLP, and counsel of record for Intervenor Hikma Pharmaceuticals USA, Inc. ("Hikma"), in this action. I make this Declaration in support of Hikma's Joinder in and Supplement to Alvogen, Inc.'s Motion for Preliminary Injunction ("Joinder").

3. Attached as **Exhibit 1** to the Joinder is a true and accurate copy of a webpage from Hikma.com, entitled *Westward Pharmaceuticals now Hikma in the US as part of global rebranding* (June 26, 2018), and last accessed August 8, 2018.

4. Attached as **Exhibit 2** to the Joinder is a true and accurate copy of a webpage from Hikma.com, entitled *Use of products in capital punishment*, last accessed August 8, 2018.

5. Attached as **Exhibit 3** to the Joinder is a true and accurate copy of The Journal of Pain, Vol. 15, No. 12 (December), 2014, *The Fentanyl Story*.

6. Attached as **Exhibit 4** to the Joinder is a true and accurate copy of an article from The New York Times, entitled *Pfizer Blocks the Use of Its Drugs in Executions* (May 13, 2016).

7. Attached as **Exhibit 5** to the Joinder is a true and accurate copy of an article from Las Vegas Review-Journal, entitled *Nevada receives no bids from companies to supply lethal-injection drugs* (Oct. 7, 2016).

8. Attached as **Exhibit 6** to the Joinder is a true and accurate copy of Letters sent from Hikma to Nevada Attorney General Adam Laxalt, Governor Brian Sandoval, and Director Dzurenda of the Nevada Department of Corrections, dated December 20, 2016.

9. Attached as **Exhibit 7** to the Joinder is a true and accurate copy of an article from SFGate, entitled *Nevada rejects Pfizer's demand to return execution drugs* (Nov. 18, 2017).

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3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996

10. Attached as **Exhibit 8** to the Joinder is a true and accurate copy of Letters from Hikma to Nevada Attorney General Adam Laxalt, Governor Brian Sandoval, and Director Dzurenda of the Nevada Department of Corrections, dated December 12, 2017.

11. Attached as **Exhibit 9** to the Joinder is a true and accurate copy of Cardinal Health Invoice to Nevada Department of Correction Center Pharmacy, Invoice No. 3232190, dated September 29, 2017.

12. Attached as **Exhibit 10** to the Joinder is a true and accurate copy of the Controlled Substance Registration Certificate issued to the Nevada Department of Corrections.

13. Attached as **Exhibit 11** to the Joinder is a true and accurate copy of Letters from Kristen Martini, Esq., to Nevada Attorney General Adam Laxalt, Governor Brian Sandoval, and Director Dzurenda of the Nevada Department of Corrections, dated July 11, 2018, with enclosures.

14. Attached as **Exhibit 12** to the Joinder is a true and accurate copy of Nevada Department of Corrections, *Execution* Manual, effective June 11, 2018.

15. Attached as **Exhibit 13** to the Joinder is a true and accurate copy of Nevada Department of Corrections, *Update Regarding NDOC Process for Choosing Execution Drugs* (July 6, 2018).

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

Executed this 8th day of August, 2018.

/s/ Josh M. Reid
JOSH M. REID

Lewis Roca ROTHGERBER CHRISTIE
3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996

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EXHIBIT 1

26 June 2018

Eatontown, NJ, June 26, 2018 - Hikma Pharmaceuticals PLC (the Hikma Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY), the multinational generic pharmaceutical company, announced today that its wholly-owned US subsidiary, West-Ward Pharmaceuticals Corp., will now operate as Hikma Pharmaceuticals USA Inc. or simply "Hikma."

The Hikma Group acquired West-Ward Pharmaceuticals Corp. more than 20 years ago and since then it has become a leading provider of quality oral, liquid, inhalant, and injectable branded and non-branded generic medicines in the US.

The name change is part of the Hikma Group's global rebranding effort that is bringing all its subsidiary corporate brands under a refreshed Hikma Group brand, which includes a new positioning and visual identity. The new brand emphasizes the Hikma Group's role in improving the health of people around the world by making quality medicines and making them affordable and accessible. The unveiling marks the Hikma Group's 40th anniversary and the beginning of a new chapter in the company's history. Other US subsidiaries will also have similar name changes to align with the new Hikma brand.

"This is a really important turning point for our more than 2,000 US based employees," explained Brian Hoffmann, President of the US Generics Business. "In an increasingly global world, it is important that our employees, as well as our customers and partners, can benefit from the synergies

and efficiencies of Hikma operating all operations under one brand. While our US name is changing, our commitment to our state-of–the-art US manufacturing, robust R&D investments and the US market overall remains as strong as ever."

Dan Motto, Executive Vice President, Commercial Development Strategy for the US Injectables Business added, "For our US customers and partners the transition to Hikma will be seamless with no change to our strong portfolio of products or our ongoing commitment to deliver great customer service and our dedication to patients. Beginning today, most touchpoints in the US will now bear the new Hikma logo including our building signage, our company collateral, and our website. Our updated product packaging and labelling will be rolled out over the next 12 to18 months, with our priority being to maintain consistent supply and patient safety."

The Hikma Group's CEO, Siggi Olafsson added, "We believe that operating all our companies as Hikma in our markets will allow us to better serve customers, be

more efficient, and to build on the trusted Hikma name. We want to draw on the strengths we have around the world and unlock the power of a single, global brand."

The new logo is a wordmark with the name of the company in precisely drawn and spaced lettering, punctuated at the end with a full stop that conveys certainty and confidence, as well as a nod to the digital age. The coral color is connected to the legacy red of the original Hikma Group logo but re-interpreted in a contemporary hue. The simple style and lower-case letters make the brand friendly and approachable.

The US brand launch this week coincides with the European launch, and means that the new logo and new design system are now live across mobile, social and web properties in all of the Hikma Group's markets.

For more information about our US business, please visit www.hikma.com/us

Share this page 

EXHIBIT 2

Use of products in capital punishment

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

We object in the strongest possible terms to the use of any of our products for the purpose of capital punishment. Not

only is it contrary to the intended label use(s) for the products, but it is also inconsistent with our values and mission of improving lives by providing quality, affordable healthcare to patients.

While none of our products should ever be used for the purpose of capital punishment, in the table below, we have identified certain products that carry heightened risk of misuse for lethal injection protocols. Accordingly, to prevent these products from being used for the purpose of capital punishment, we will not accept orders for these products directly from any Departments of Correction or correctional facilities in the United States, unless accompanied by an original, raised seal copy of an affidavit signed by the state attorney general (or governor), certifying under penalty of perjury that the product(s) will not be used for capital punishment. Further, we will only sell these same drugs to pre-selected commercial customers who agree that they will not then sell them to Departments of Corrections/correctional facilities, or to secondary distributors or retail pharmacies.

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

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

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

MIDAZOLAM 2MG/2ML VIAL X 10
MIDAZOLAM 2MG/2ML VIAL X 25
MIDAZOLAM 50MG/10ML VIAL X 10
MIDAZOLAM 5MG/5ML VIAL X10
MIDAZOLAM 5MG/ML VIAL X 25
PHENOBARBITAL 130MG/ML VIAL X 25
PHENOBARBITAL 65MG/ML VIAL X 25
ETOMIDATE 20 MG/10 ML VIAL X 10
ETOMIDATE 40 MG/20 ML VIAL X 10
Fentanyl Citrate Injection, USP C-II (AMPULS) 100 mcg / 2 mL
Fentanyl Citrate Injection, USP C-II (AMPULS) 250 mcg / 5 mL
Fentanyl Citrate Injection, USP C-II (AMPULS) 1000 mcg / 20 mL
Fentanyl Citrate Injection, USP C-II (VIALS) 100 mcg / 2 mL
Fentanyl Citrate Injection, USP C-II (VIALS) 250 mcg / 5 mL
Fentanyl Citrate Injection, USP C-II (VIALS) 1000 mcg / 20 mL
Fentanyl Citrate Injection, USP C-II (VIALS) 2500 mcg / 50 mL

EXHIBIT 3

American Pain Society
RESEARCH
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The Fentanyl Story

Theodore H. Stanley
Department of Anesthesiology, School of Medicine, University of Utah, Salt Lake City, Utah.

Abstract: **Fentanyl, introduced more than 50 years ago, has become the most often used opioid for intraoperative analgesia. Since the early 1990s the fentanyl patch has been available for management of chronic pain of all forms of cancer as well as the persistent, intense pain from many noncancerous maladies. More than a half dozen rapid-onset transmucosal fentanyl preparations have been developed, approved, launched, and popularized for "breakthrough" pain syndromes in the past 20 years. The purpose of this article is to describe why this opioid has become so important in the treatment of pain in modern clinical practice. The data indicate that fentanyl's popularity has occurred because it has minimal cardiovascular effects, does not result in increases in plasma histamine, is relatively short in onset of action and duration of effect, is easy and inexpensive to synthesize and prepare for the marketplace, and is now familiar to clinicians working in pain and perioperative medicine throughout the world.**

Perspective: ***Fentanyl has become one of the most important opioids in the management of pain because it is available for administration intravenously, transdermally, and transmucosally. Its flexibility, potency, familiarity, and physical characteristics explain why it has become so valuable to clinicians managing pain throughout the world.***

Key words: *Fentanyl, rapid-acting opioids, sublingual, patch, nasal, oral transmucosal.*

Fentanyl (Fig 1), a potent synthetic μ receptor–stimulating opioid, was first synthesized by Dr. Paul Janssen and the Janssen Company of Beerse, Belgium, in December 1960.[45,46] The drug was first used as an intravenous analgesic clinically in Europe in 1963 and in the United States (as a component of Innovar) in 1968 and since then has become one of the world's most important and frequently used opioid analgesics. Today, fentanyl is the opioid most often used intravenously for intraoperative analgesia in the United States, the rest of North America, Central and South America, throughout Europe, the Middle East, and most of developed Asia and Africa. In some of the world, the fentanyl patch is often used for the chronic pain of all forms of cancer as well as the persistent, intense pain from many noncancerous maladies.[45,46] In the last 20 years, more than a half dozen rapid-onset transmucosal fentanyl preparations have been developed, approved, launched, and popularized for "breakthrough" pain syndromes.[46] Few physicians practicing anesthesia or managing all sorts of patients with chronic pain with the many fentanyl preparations now available appreciate how and why this compound has become so widely used in anesthesiology and is so valuable in the management of pain throughout much of the world.

The author received no financial support related to the creation and/or production of this manuscript. The author was the inventor and developer of oral transmucosal fentanyl citrate, including Actiq and Oralet, but has no relationship with TEVA or any of the generic companies that currently market these products. The author also has no relationship to any of the companies that are developing or have developed and/or market or sell any of the other rapid-acting fentanyl products or the fentanyl patches currently being sold today except he is a director of the Board of a public company Insys Therapeutics. Insys developed and currently markets and sells Subsys, a rapid-onset sublingual fentanyl spray that is approved for breakthrough cancer pain in opioid-tolerant patients.

Address reprint requests to Theodore H. Stanley, MD, Department of Anesthesiology, School of Medicine, University of Utah, 30 North 1900 East 3C444, Salt Lake City, UT 84132. E-mail: Theodore.stanley@hsc.utah.edu

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The Pre-Fentanyl Years (1953–1960)

One of the interests of Dr. Paul Janssen, who founded his company Janssen Pharmaceutica in 1953, was creating potent, effective, rapid-acting analgesics to treat the many pain problems of the time.[45] In 1953, both morphine and meperidine were known and available. Dr. Janssen and his colleagues in his company believed that the piperidine ring (Fig 2), present in both morphine and meperidine, was the most important chemical structure that produced analgesia in these molecules. They began working with meperidine, rather than morphine, as the parent molecule in the production

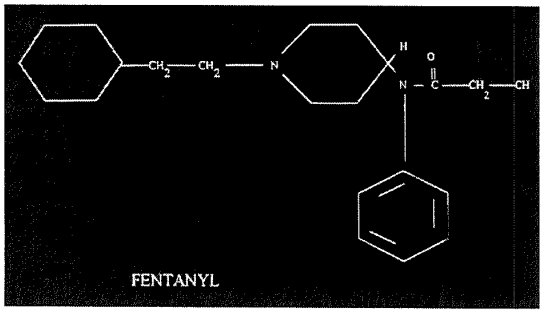


Figure 1. The chemical structure of fentanyl.

of newer and better compounds because it was much less complex a molecule and thus easier to manipulate. Their strategy was to find new molecules that were more powerful and specific analgesics than either morphine or meperidine. They hoped these newer molecules would have fewer unwanted side effects and have higher safety margins (therapeutic indices). The Janssen research team realized that both morphine and meperidine were poor and slow-onset analgesics because they could not easily penetrate into the central nervous system. Therefore, they concluded that they needed to synthesize more fat-soluble derivatives. In order to do this, they began adding to and/or replacing numerous chemical entities (N, benzene rings, methyl or ethyl groups, etc) to the meperidine molecule and thus created many new, more lipid-soluble drugs, most with greater potency and faster onset of analgesic action, presumably because of better penetration through the blood-brain barrier. The chemists knew that more than increased fat solubility was required for greater analgesic potency. The compounds would also have to bind with a receptor (at that time, the μ receptor had not yet been identified, but the concept of a pain receptor was well known). Thus, other chemical entities that they believed would enhance binding of the new compounds with the pain receptor were added, positioned properly, and the new compounds then tested.[45]

Between 1953 and 1957, dozens of new, more potent, lipid-soluble analgesics were created by the Janssen team until in August 1957 phenoperidine was synthesized (Fig 3).[45] Phenoperidine was 25 times more potent than morphine and more than 50 times more potent than meperidine in most animals in which it was tested. It was also, at the time it was first synthesized, the most potent opioid in the world. Phenoperidine was introduced into many European countries, but not the United States (because the Janssen Company did not have a U.S. organization at that time), as a potent, fast onset of action, short-lasting analgesic for anesthetic use. It is still available in many of the countries into which it was introduced.

The Janssen research team continued to create new molecules related to phenoperidine in the late 1950s and first synthesized fentanyl in 1960.[45] Fentanyl was more than 10 times more potent than phenoperidine and 100 to 200 times more potent than morphine in most animal models. It was also the most lipid-soluble (octanol/water partition coefficient = 813) and most potent opioid in the world when it was first created and had the fastest onset of action and highest therapeutic index (277 vs 4.7, 71, and 39.1 for meperidine, morphine, and phenoperidine respectively) ever measured in an opioid. The Janssen team only considered fentanyl useful as an intravenous analgesic when it was first synthesized because approximately 60 to 70% of

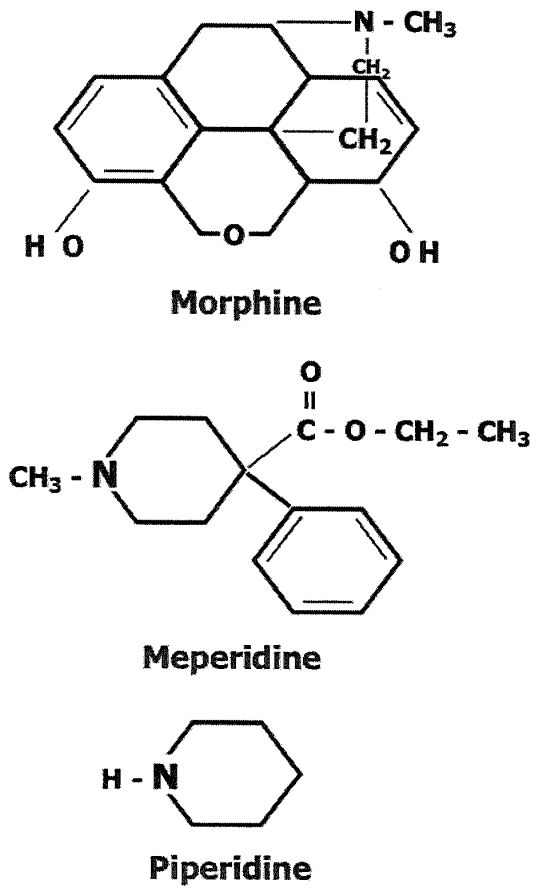


Figure 2. The chemical structures of morphine, meperidine, and piperidine.

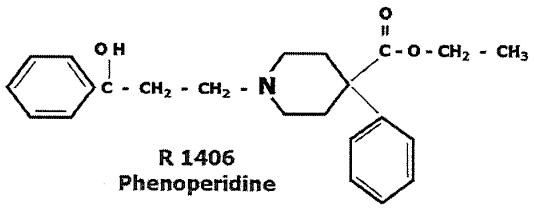


Figure 3. The chemical structure of phenoperidine, a precursor of fentanyl.

the compound was destroyed (only 30–40% bioavailable) after oral administration in their studies in the early 1960s (J. de Castro, 1961, unpublished data from Janssen Pharmaceutica).

Fentanyl Pharmacology

Fentanyl is a completely synthetic μ receptor–stimulating opioid.[7] It was the first of the fentanyl family of opioids that somewhat later included sufentanil, alfentanil, and remifentanil for human patients and carfentanil and thiofentanil approved for wild animals.[7,46] Fentanyl's onset of action and its peak plasma concentrations are dependent on the dosage used and the method of delivery.[4,8,35-38,40,41] Analgesia may occur as soon as 1 to 2 minutes after intravenous administration of fentanyl, whereas most buccal transmucosal delivery systems produce analgesia in 10 to 15 minutes.[4,8,35-38,40,41] In contrast, sublingual and intranasal sprays of fentanyl may produce analgesia in 5 to 10 minutes or sooner (see Fig 4).[35,38] Fentanyl plasma concentrations do not peak or plateau until 8 to 16 hours after application of a fentanyl transdermal patch.[2,7,11,17,32]

Significant analgesia may occur with fentanyl plasma concentrations as low as .2 to 1.2 ng/mL in opioid-naive patients and often at concentrations only slightly higher in some opioid-tolerant patients. However, plasma concentrations of fentanyl may need to be much higher in some other opioid tolerant patients. Fentanyl's duration of action usually lasts 2 to 4 hours after intravenous or transmucosal delivery, but fentanyl blood levels fall quite slowly after transdermal patch removal because absorption of drug deposited on the skin continues for some time. The half-life for the decline in fentanyl plasma levels after patch removal is high (17 ± 2.3 h).[7]

Fentanyl, like morphine, meperidine, oxycodone, and others, produces the usual μ opioid central nervous system actions such as fatigue, sedation, nausea, vomiting, dizziness, respiratory depression (leading to apnea in higher doses), bradycardia (secondary to a central vagal stimulating action), and unconsciousness/anesthesia in higher doses irrespective of the mode of administration.[7] Chest wall rigidity can be seen after intravenous administration and is related to the dose and speed of delivery and has occasionally been encountered with as little as 50 μg given intravenously.[7] The author is unaware of chest wall rigidity being reported after buccal, sublingual, intranasal, or transdermal fentanyl administration at any dose. Although constipation does occur after fentanyl irrespective of how the drug is given, it is reported to be less frequent than after morphine, as is pruritus.[31] Some have suggested that these advantages may be due to the fact that fentanyl does not cause increases in plasma histamine, in contrast to morphine, meperidine, and most of the nonfentanyl μ receptor–stimulating opioids.[7]

STORY OF FENTANYL: Rapid Onset Opioids (ROOs)

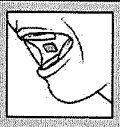
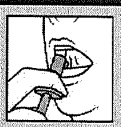
Formulation	FENTANYL CITRATE Compressed Powder	FENTANYL CITRATE Compressed Powder	FENTANYL CITRATE Compressed Powder	FENTANYL CITRATE Compressed Powder	FENTANYL CITRATE Nasal Solution	FREE FENTANYL Oral Solution
Route of Administration	 Buccal Lozenge	 Buccal Tablet	 Buccal Film	 Sublingual Tablet	 Intranasal Spray	 Sublingual Spray
Administration Time Requirements	Consumed over 15 min	Disintegration takes 14–25 min	Dissolves within 15–30 min	1–5 min	Seconds	Seconds
Bioavailability	50%	65%	71%	54%	Est 60%	76%
Onset of Action (mins)	10-15	15 minutes	15 minutes	10 minutes	10 minutes	5 minutes
Dosage Strengths (mcgs)	6 strengths	5 strengths	5 strengths	6 strengths	4 strengths	7 strengths

Figure 4. Some properties and characteristics of the rapid-onset opioid products currently available and being developed.

Fentanyl is metabolized mainly via the human cytochrome P450 (CYP3A4) isoenzyme system, and as a result, potential drug interactions may occur when fentanyl is given concurrently with other drugs that affect CPY3A4 activity.[19] When these interactions occur in patients in the operating room or intensive care unit, the potential increase in fentanyl plasma concentrations can rise or prolong the opioid's activity but are often not dangerous and usually are easily managed by clinicians in attendance. In contrast, concomitant use of transmucosal immediate-release fentanyl (TIRF) preparations (see section "Morbidity, Mortality, and Misuse of Fentanyl and the TIRF REMS Access Program") with CYP3A4 inhibitors (such as certain protease inhibitors, ketoconazole, fluconazole, diltiazem, erythromycin, and verapamil) may result in an increase in fentanyl plasma concentration sufficient to cause potentially fatal respiratory depression.[19,22,25] Thus, these patients need to be carefully monitored for signs of opioid overdose.

The Fentanyl Early Years (1960–1975)

After its introduction as an intravenous analgesic in 1963 in numerous Western European countries, fentanyl was often used in combination with a number of intravenous sedatives, hypnotics, and amnestics in a variety of mixtures in attempts to create a type of total intravenous anesthesia in the 1960s and 1970s.[12,34,45,46] Fentanyl was more potent than any other opioid analgesic available at that time, which meant that only small amounts of it was necessary in most of the mixtures evaluated. A combination that achieved a reasonable degree of popularity was fentanyl given with a new (at that time) butyrophenone called droperidol. The technique of giving the 2 drugs together was called neuroleptanalgesia, and when nitrous oxide was added to the mixture, it was labeled neuroleptanesthesia.[12,18,34,45,46] Neuroleptanalgesia and neuroleptanesthesia were described, studied, and used throughout Western and Eastern Europe for more than 25 years as an alternative to the potent inhaled anesthetics of the time. The technique is still sometimes used (where droperidol is still available) in some Eastern European countries, and a few South American countries.

In Belgium in the late 1960s and early 1970s, an anesthesiologist, Gorge de Castro, became interested in what he called "stress-free anesthesia."[14,15,46] Stress-free anesthesia was the use of a drug or combination of drugs that provided deep anesthesia with minimal or no alteration of cardiovascular dynamics and also blocked the increase in the stress-responding hormones that normally occurred with surgical stimulation. After some studies that de Castro was able to accomplish with the assistance of the Janssen team in animals and then later in patients, he announced that large doses of intravenous fentanyl could provide stress-free anesthesia. He called the technique analgesic-anesthesia and first reported on this experience at the World Congress of Anesthesia in 1976 in Mexico City.[15] Dr. de Castro gave analgesic-anesthesia using doses of fentanyl up to 50 μg/kg plus oxygen to patients having cholecystectomy, gastric resection, bowel surgery, and similar operations. He believed the technique was simple (it required no other drugs), was easy to master, blocked stress hormonal changes both during and after surgery, produced minimal cardiovascular changes, and resulted in minimal side effects. His patients did not report awareness but did often need to be ventilated for up to 3 hours after surgery before extubation could be accomplished. He was unable to publish his results in a major anesthesia journal but did publish them in a regional European journal.[14] Because his work remained unknown to most anesthesiologists, it had little impact on the world anesthesia community.

Though fentanyl, when used alone and also when used in combination with other intravenous drugs, including droperidol, was achieving success and enjoying popularity in Europe in the early and mid-1960s, the same did not occur at first in the United States.[45,46] Unfortunately, the Janssen Company had difficulty getting fentanyl through the Food and Drug Administration (FDA) approval process in the United States. One strong opponent to the approval of fentanyl was Dr. Robert Dripps, the distinguished professor of anesthesiology at the University of Pennsylvania, in Philadelphia. Dr. Dripps felt that fentanyl was too potent and caused rigidity. This, he thought, would result in many patients needing to be tracheally intubated and would lead to many abuse problems.[45] After a good deal of time, Dr. Janssen, the CEO of Janssen Pharmaceutical, managed to meet Dr. Dripps and begin a dialog and negotiation with him. Eventually, a compromise was reached that allowed Dr. Dripps to lessen his opposition to fentanyl's approval. The agreement was that fentanyl would only be approved in combination with droperidol. As a result, when fentanyl was approved by the FDA in 1968, clinicians could only get it in combination with droperidol in a ratio of 50:1 droperidol to fentanyl. The combination was called Innovar in the United States and Thalamonal in other countries.

The 50:1 ratio came about after Dr. Janssen consulted with his friend and advisor Dr. Gorge de Castro. Dr. de Castro often used fentanyl in combination with droperidol in patients in the neuroleptanalgesia technique he helped develop and make popular in Europe. Dr. de Castro calculated what his usual mixture of fentanyl to droperidol was in his clinical practice. It turned out to be approximately 50:1 droperidol to fentanyl. The ratio was suggested by Dr. Janssen to Dr. Dripps. Both of them knew that droperidol produced a "bad high" if taken as a recreational drug, and both believed that the mixture of droperidol and fentanyl would likely minimize its abuse potential. The FDA agreed, and Innovar was approved for use in the United States. Four years later, fentanyl became available alone, but for the next 6 years only as a 1-mL vial containing 50 μg.[45,46]

Neurolept-analgesia/anesthesia, but not fentanyl, began to lose its popularity in Europe in the late 1980s and early 1990s. Some historians believe that numerous variations in the technique used and unclear indications for and contradictions to its use were the most important

reasons for the lost interest. In the United States, neither neuroleptanalgesia nor neuroleptanesthesia achieved any popularity because of all of the above, plus a high incidence of associated dysphoria and the paucity of clinicians who were comfortable with droperidol, fentanyl, and some of the other intravenous agents that were often employed with the techniques.[46]

High-Dose Opioid Anesthesia

In the early to mid-1960s, cardiac surgery was still in its infancy, and patients with end-stage mitral and aortic valvular disease were a particular problem because the severity of their cardiopulmonary dysfunction made them huge anesthetic risks for the anesthetic techniques then available.[7,9,46] An induction of anesthesia, even carefully performed with thiopental and succinylcholine followed by N_2O, halothane, or any other inhaled agent and then curare, frequently resulted in severe hypotension and arrhythmias and often cardiac arrest. Death during or soon after surgery was common. However, in December 1969, the cardiac anesthesia group at the Massachusetts General Hospital published an important study in the *New England Journal of Medicine*.[29] The study demonstrated that large doses of morphine slowly administered intravenously could produce unconsciousness and extremely stable cardiovascular dynamics before, during, and after open heart surgical procedures in severely ill patients with valvular heart disease. As a result, large-dose morphine anesthesia became popular as an anesthetic technique in very sick patients having heart surgery within a year or so after the publication of the Massachusetts General Hospital paper.[9,24,46] However, in a couple of years, problems with awareness, severe hypertension during surgery, and other issues called into question the wisdom of using large doses of morphine for anesthesia, especially in more physically fit patients, such as those undergoing the new coronary artery bypass operation.[46,47] This led to many studies in animals evaluating large-dose fentanyl as an alternative opioid anesthetic and later in patients having cardiac surgery.[21,28,46,48,49] At first, cardiac anesthesiologists were skeptical of the advantages of large doses of fentanyl versus large doses of morphine, especially when some patients experienced truncal rigidity during induction of anesthesia with fentanyl.[7,47] However, with a little experience, these minor problems were solved, and within a year or two, high-dose fentanyl essentially replaced high-dose morphine as the technique of choice for patients having valvular and, a little later, coronary artery surgery in the early to mid-1980s.[7,46,47] Fentanyl's advantages over morphine were its greater potency and ease of use (it could be safely administered rapidly in a minute or less), its shorter onset and duration of action, and its absence of histamine release and lack of venodilation. As a result, inductions of anesthesia were faster. There was less hypo- and hypertension during induction throughout the entire surgical procedure and postoperatively; blood and crystalloid volume requirements were not increased, as occurred with morphine; and extubation and postoperative recovery occurred sooner.[46]

The clinical successes of large doses of fentanyl in cardiac and then vascular surgery in the late 1970s and early 1980s resulted in a dramatic increase in the sales of fentanyl as the branded product lost marketing exclusivity. Indeed, the sales of fentanyl in the United States increased 10-fold the first year (1981) the drug was off patent.[46] Rarely does this kind of an increase in sales occur with any drug going off patent, much less an opioid that was, at least at that time, only used in the perioperative period by anesthesiologists and their associates. Why did this happen? One reason was that fentanyl is easy and inexpensive to produce for the marketplace. In addition, before the reports of high-dose fentanyl anesthesia, fentanyl was rarely used in doses exceeding 50 μg for an entire operation. However, after the reports, fentanyl doses increased in cardiac operations to 50 to 100 μg/kg.

The marked increase in fentanyl usage throughout the world in the 1980s resulted in a number of events that would further improve the popularity of fentanyl, lead to other fentanyl-like compounds, increase the use of other opioids, and begin an entire new field of novel opioid drug delivery development.[46] The Janssen Company began the evolution by beginning to develop sufentanil and alfentanil. They also invited the author and then numerous other research anesthesiologists interested in opioids to study their new opioids in patients and also wild animals. De Lange, Stanley, Stanski, and many others began a series of studies in January of 1980 with alfentanil and sufentanil at the University of Leiden in The Netherlands that spread to many other medical centers in the United States and Europe for almost 2 decades, changing the way clinicians viewed and used fentanyl, the other fentanyls, and virtually all opioids.[46] It also resulted in the development of the "super fentanyls" as wild animal immobilization drugs and antiterrorist agents[6,33] and stimulated Glaxo to study other new opioids (that resulted in remifentanil) and Anaquest (of the British Oxygen Company) to develop its own series of opioids that are now available for wild animal immobilization.[26,46] In the 1980s, fentanyl began to be used intrathecally as part of some spinal anesthetics or epidurally for epidural anesthesia and analgesia.[7] It has become popular in these applications because its high lipid solubility appears to localize its effects better than morphine. Finally, Alza and Anesta (young drug delivery companies in the mid-1980s) began experiments with fentanyl in transdermal patches and oral transmucosal lozenges (lollipops).[17,43,50,51] The Alza researchers believed that transdermal fentanyl could be useful for acute pain after surgery and for patients with chronic pain who needed steady, sustained blood levels of a strong opioid. Oral transmucosal fentanyl was first developed to provide sedation, analgesia, and anxiolysis prior to surgery and later for breakthrough pain (BTP) episodes in patients who were opioid tolerant.

The New Fentanyl Drug Delivery Technologies

In the past 30 years, the cost of inventing, developing, getting approval for, and then marketing new drugs in the United States and throughout the world has markedly increased. In the early 1980s, the cost of this process was less than $75 million for the average drug. Today, it is more than $1 billion.[46] As a result, most large pharmaceutical companies can only afford to invest in new drugs that have the potential of being "blockbusters" (having possible sales of more than $1 billion per year). New drugs with potential sales of $200 million or lower are far less attractive for the largest pharmaceutical companies. In contrast, smaller pharmaceutical companies often focus on patenting and developing older, well-known drugs in newer drug delivery systems if those novel systems can provide advantages to patients and/or caregivers. The smaller companies do this because the cost of developing the older drugs in newer drug delivery systems today is much less expensive, sometimes only $30 to $50 million per drug.[46] In the second decade of the 21st century, the problem of developing new pain drugs or drug delivery concepts is becoming even more difficult as costs of development continue to escalate and the intense focus on cost containment by clinicians and hospitals and the difficulty for industry in getting sales personnel in front of clinicians are breaking apart many useful relationships that used to exist between industry and the clinical community.

Transdermal Fentanyl

The success in the early 1980s of one of the first transdermal drug delivery patches ever studied, scopolamine, convinced a then-small company, Alza Corporation, in northern California, to consider in the mid-1980s developing a fentanyl patch for patients with pain.[17,43,46] Alza was successful in creating a patch containing fentanyl (later called Duragesic) and getting it through the FDA approval process. It was first studied in opioid-naive patients with acute postoperative pain but produced too much respiratory depression.[11,17] When later evaluated in opioid-tolerant patients having cancer-induced chronic pain in the late 1980s and early 1990s, it proved useful and was approved by the FDA and European regulatory authorities.[46]

The next step for Alza was getting the product in the hands of oncologists and pain physicians. Because at that time they did not have a sales force, they tried to get the Janssen Company (by then a successful division of Johnson & Johnson, the huge conglomerate of healthcare companies) to sell their new product. Although the marketing and sales groups of Janssen were excited about the possibility of selling Duragesic, the first transdermal opioid approved for patients with cancer, Dr. Janssen was not convinced this new way of giving pharmaceutical products was not just a "gimmick." It was only after months of negotiation and an extensive market analysis that suggested Duragesic could be a very successful pain medicine that he consented and the product was launched. By the mid- to late 1990s, it became clear that transdermal fentanyl was a preferred way for many patients to get analgesia for the intense chronic pain of cancer and numerous other conditions. Duragesic proved to be one of the most successful analgesic pharmaceutical products ever developed, with sales in 2004 (its last year of patent life) exceeding $2.4 billion. The success of the fentanyl patch caused many generic companies to produce equivalents once it went off patent.[46]

Duragesic was successful in the management of chronic pain because it produced a steady-state blood level of fentanyl that lasted for 2 to 3 days with a single patch. It was much less useful for acute pain because it took 14 to 18 hours to get to a steady-state concentration,[46] and it could produce severe respiratory depression in opioid-naive patients even at the lowest doses available at that time. This prompted a number of investigators and later companies to study methods that would speed opioid passage across the skin, such as iontophoresis, which augments drug passage through the skin with a small electric current applied to salts such as morphine HCl and fentanyl citrate[5,46] and a number of mucosal surfaces. (Although a number of iontophoretic devices have been developed and shown to be effective in moving sufficient amounts of fentanyl across the skin to produce analgesia, none have so far been successful in achieving regulatory approval.)

Fentanyl Transmucosal Delivery

The idea of evaluating fentanyl for transmucosal delivery came about by chance, approximately 4 years following the recommendation of Dr. Paul Janssen to the author that he consider studying carfentanil (an ultrapotent cousin of fentanyl, also developed by Janssen) in some of the wild animals in the state of Utah. The author's studies, started in 1980, demonstrated that carfentanil was an ideal immobilizing drug when used in a dart delivery system for the rapid and safe immobilization of wild elk, moose, and numerous other ungulates.[6,33] Some years later, carfentanil was approved for this indication by the FDA and regulatory agencies of numerous other countries. These approvals and a number of publications by the author and other researchers studying carfentanil and other potent opioids stimulated U.S. government authorities to consider some of these compounds as potential antiterrorist agents[6,26,33,46] (T.H. Stanley, 1992, unpublished data provided by the author to numerous U.S. government agencies). The latter resulted in the author's receiving a number of U.S. government contracts to study carfentanil and other potent opioids for their immobilizing potential in numerous animal models. First rats, then dogs, and later ferrets were studied using all sorts of delivery techniques. A final evaluation was planned in Rhesus monkeys using an aerosol delivery system. During the studies in monkeys, a veterinarian colleague one day wondered whether

carfentanil could be injected into the sugar cubes that some of the study team were using that day in their coffee. He knew that monkeys love to suck on sugar cubes. He was also aware of the fear and anxiety monkeys experience when they are placed in a squeeze cage so that they can be safely given an intramuscular injection of drugs for induction of anesthesia. He wondered if a sugar cube loaded with carfentanil could be used as a safe and powerful sedative, allowing an intravenous infusion to be started or an intramuscular injection to be administered without the need of a squeeze cage and the huge associated emotional stress. An hour later, 2 monkeys were given sugar cubes filled with 2 different doses of carfentanil. The monkeys sucked on the sugar cubes until they were completely dissolved in their mouths over a period of 3 to 4 minutes. The monkey with the large dose of carfentanil became deeply narcotized. An awake endotracheal intubation was possible without the need for another medication. The monkey with the smaller dose of carfentanil became moderately sedated, but could still walk across a room (hand in hand) with his veterinarian keeper.

On an airplane flight later that day, the author wondered if something similar to carfentanil in sugar cubes could be developed for human patients, especially children, experiencing severe stress and anxiety prior to surgery. Some days later, the idea of fentanyl in a lozenge on a stick (a lollipop) was born as a premedication before surgery. (The idea of a lozenge on a stick or lollipop was important because it allowed patients or clinicians to titrate fentanyl noninvasively to a clinical end point—sedation or analgesia—and it also allowed a new patent to be obtained for this new method of use.) In 1984, Oralet, a "child friendly" sweetened, red lollipop-like product (Fig 5) was developed and presented to the Janssen Company as a product they should license, get through the FDA approval process, and sell. Janssen was in the process of getting alfentanil and sufentanil through the regulatory process in Europe and the United States and declined to become involved, although they assisted in getting an investigational new drug status for Oralet approved by the FDA. The author and his colleagues believed that the delivery of oral transmucosal fentanyl citrate (OTFC) was important and valuable. They reasoned it was simple, noninvasive, and easily titratable, and the unit could be quickly and easily removed by the patient or clinician when the desired effect (sedation or analgesia) was evident. They felt all the above was unique and useful, especially because the onset was rapid (5–15 minutes) and the duration of effect relatively short (1–2 hours). As a result, a small, new company, Anesta, was formed in the summer of 1985 in order to develop and get OTFC approved and into the marketplace.

Oralet achieved regulatory approval in 1993 for use as a premedication before surgery and painful procedures in children and adults.[4,46,50,51] It was introduced to clinicians later in 1993 but was never a commercial success. During clinical studies with Oralet in the late 1980s, a couple of clinicians at the University of Utah (Drs. Perry Fine and Michael Ashburn) raised the question of whether OTFC might be useful in patients with cancer being treated for moderate to severe pain with chronic opioid therapy who were experiencing episodes of BTP. Portenoy and colleagues had begun describing "breakthrough pain" and discussing its prevalence, impact on patients, and potential therapies for its treatment at approximately the same time.[39] Drs. Fine and Ashburn found that Oralet units used by patients with BTP could result in effective analgesia in 10 to 15 minutes, much faster than with any other opioid product available at that time.[3,20] They also found that when the patients rubbed OTFC units on their buccal mucosa until analgesia occurred, the patients usually did not need to consume the entire unit. Thus, the patients were able to titrate just the right amount of fentanyl for the analgesia they required at the moment the OTFC unit was used. These results were exciting and stimulated Anesta to seek a new indication for OTFC. After approximately 9 additional years and many studies, a different-looking OTFC unit, called Actiq (Fig 6), was approved by the FDA in 1998 for opioid-tolerant patients having breakthrough cancer pain. (Actiq was made to look different [more medicinal and less like a candy lollipop] because it was intended for

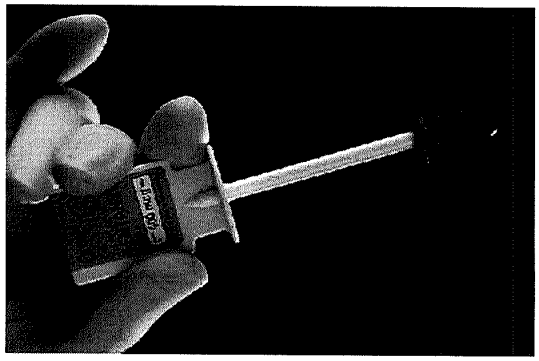


Figure 5. The Oralet buccal transmucosal delivery system of fentanyl.

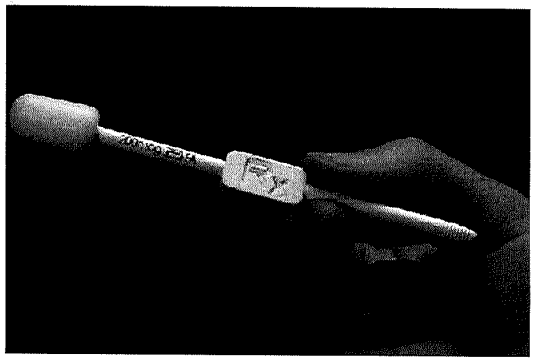


Figure 6. The Actiq buccal transmucosal delivery system of fentanyl.

out-of-hospital use, whereas Oralet was approved for use within a hospital or outpatient facility where control of the units was assumed to be better and misuse less likely.)

In the fall of 2000, Anesta was purchased by a larger pharmaceutical company, Cephalon, which was effective in making Actiq a significant commercial success. In its last year of patent life (2006), Cephalon sold more than $625 million of Actiq units. This success stimulated Cephalon, and other companies, to look at other methods of delivering fentanyl through the oral mucosa and, also, how they might minimize some of the limitations of Actiq, that is, its sugar content and potential cause of dental cavities and problems in diabetes, its slow dissolution, and the potential of shortening its onset of action to more effectively cover the BTP episode (Fig 7).

The Newer Rapid-Onset Opioid Delivery Systems

Actiq's commercial success convinced numerous companies to develop other rapid-onset opioid delivery systems[46] (Fig 8). Cephalon purchased a technology called OraVescent drug delivery and developed, got FDA approval for, and marketed an oral transmucosal buccal tablet that contained no sugar, called Fentora, in 2006. The OraVescent drug delivery technology generates a reaction that releases carbon dioxide when the tablet comes in contact with saliva. Transient pH changes accompanying this reaction optimize dissolution of the tablet (at a lower pH) as carbon dioxide is being released and, moments later when the tablet is dissolved and carbon dioxide is gone, optimize membrane permeation (at a higher pH).[16] The upshot of all of the above was that the OraVescent buccal tablet produced faster and higher blood levels of fentanyl that appeared to more effectively cover the BTP episode than equivalent does of Actiq.[16,37] Fentora was also a successful rapid-onset opioid product for Cephalon for the treatment of BTP and further stimulated the search for still better fentanyl rapid-onset delivery systems.

In the last 6 to 7 years, numerous companies have begun developing and selling generic forms of Actiq, as well as other fentanyl nasal, buccal, and sublingual transmucosal products for providing rapid-onset analgesia (Fig 4).[46] They include a sublingual tablet, a buccal soluble film, nasal and sublingual sprays, and others.[13,38,40,41] Most of these newer products use the citrated salt of fentanyl, and some may have an earlier onset and better bioavailability than Oralet and Actiq (Fig 4). One of these new products, the sublingual fentanyl spray, uses un-ionized (free) fentanyl, has an onset of action that is 5 minutes or less, has a bioavailability of

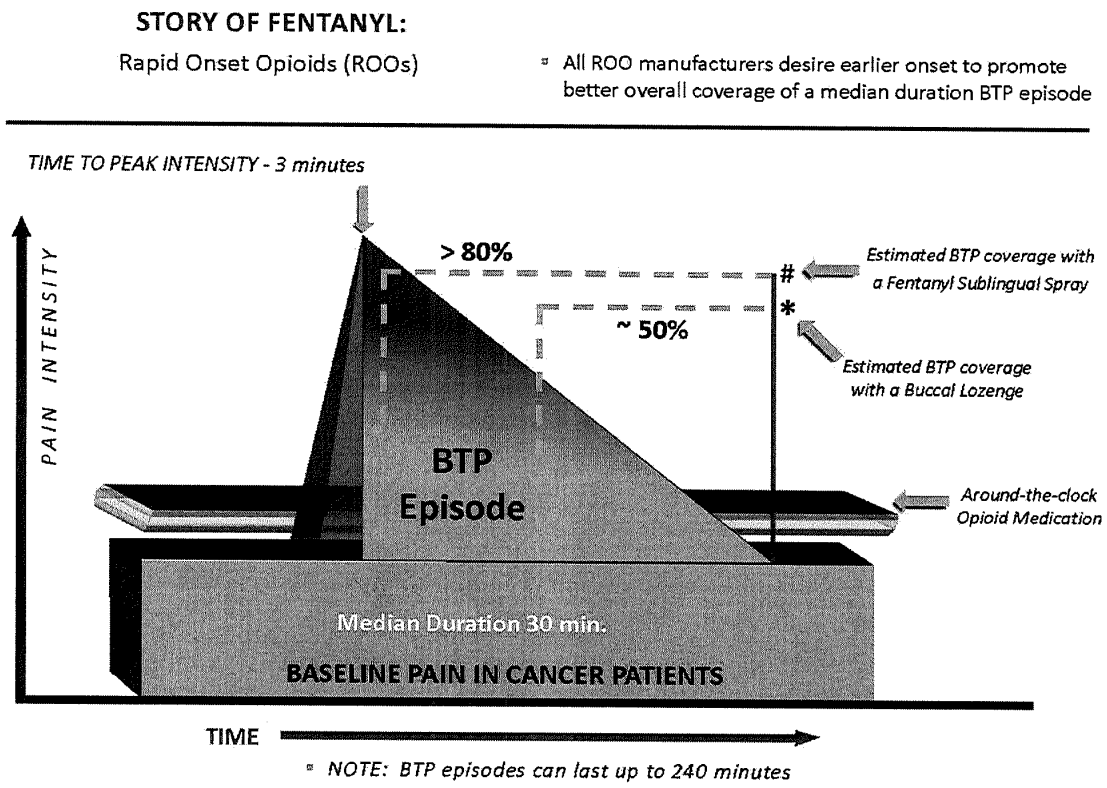


Figure 7. The estimated coverage of a median-duration BTP episode with OTFC buccal lozenge and a new sublingual fentanyl spray technology.

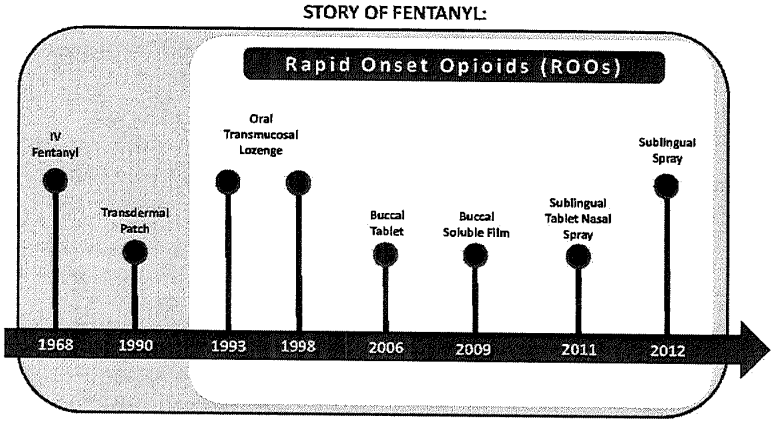


Figure 8. The history of the fentanyl rapid-onset opioids.

76%, and appears to cover approximately 80% or more of most BTP episodes (Figs 4 and 7).[35,40] It will be interesting to see the impact of this and the other new technologies and devices on patients with pain in the next few years. The early results are impressive.

Morbidity, Mortality, and Misuse of Fentanyl and the TIRF REMS Access Program

Overdoses of fentanyl with resulting severe respiratory depression, apnea, and death first appeared in the United States a few years after its approval in 1972 for use during anesthesia and the perioperative period.[1,8,23,34,44,52] Both misuse and illicit use by clinicians were reported. As more ways of administering the drug became available over the last 2 to 3 decades, more fentanyl-related deaths have occurred.[2,10,11,19,22,25,27,30,32,42] The increase in fatal fentanyl overdose has been due to misuse by patients, inappropriate prescriptions by clinicians, and increased illicit use and abuse of prescriptions of fentanyl as often occurs with the increased medical use of any opioid.[22,25,27,30]

The approval of the first oral transmucosal (rapid/immediate release) fentanyl product (Oralet), which was only approved for hospital use, was held up for some months in 1993 because of concerns about the possibility of unintentional overdoses of fentanyl. Although the incidence of respiratory depression after use of Oralet was rare, the FDA required that the company (Anesta) put in place a risk mitigation strategy prior to approval of the second OTFC product, Actiq, because this drug would be used by patients outside the hospital. In spite of that strategy, unintentional respiratory depression after use of Actiq has occurred. Because of this and continued problems with fentanyl overdosage with other TIRF products in the first decade of this century, on December 11, 2011, the FDA developed and put in place a single, shared system (shared by all companies, patients, providers, and pharmacists dealing with TIRF products) of risk evaluation and mitigation strategy (REMS) for the entire class of TIRF prescription medicine.[53] This "TIRF REMS Access Program" was developed to ensure safe use and access of the TIRF drugs for patients who need them and attempts to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to medication errors. The program attempts to accomplish the above by

1. Prescribing and dispensing TIRF medicines only to appropriate (opioid tolerant) patients
2. Preventing inappropriate conversion between fentanyl products
3. Preventing accidental exposure to children and others for whom TIRF medicines were not prescribed
4. Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose with TIRF medicines

All currently available TIRF medicines have either an individual or shared TIRF REMS system in place.

Unfortunately, deaths secondary to fentanyl and its analogs synthesized in clandestine laboratories and sold as heroin substitutes will not likely be reduced by the TIRF REMS program. Since 1979, a number of these illegal laboratories have been producing and selling fentanyl and its analogs to consumers involved in the illicit sale of the drug. An increasing number and percentile of the fentanyl overdose deaths in the United States in the last few years have been attributed to illicit versions of fentanyl produced by these clandestine laboratories.[22,27,30]

The Alternate Delivery Systems—Why Fentanyl?

A logical question any modern clinician could ask is, Why was fentanyl, rather than other potent lipid-soluble opioids such as sufentanil and carfentanil, chosen as the opioid first used for transdermal, oral (buccal and sublingual), and nasal transmucosal drug delivery when these systems were first evaluated in patients

with pain? Most of the other fentanyls had been synthesized and under development by the mid-1980s when the fentanyl patch and the first buccal lozenge (Oralet) were conceived. In addition, all the new fentanyls eventually approved for human patients, including sufentanil, alfentanil, and remifentanil, were available and on the market before the beginning of the 21st century, after which most of the rest of the transmucosal delivery systems began to be developed. This question becomes even more important when one considers that fentanyl is less potent, is less lipid soluble, and has a lower safety margin than sufentanil and carfentanil, issues that are considered pivotal in developing an alternative drug delivery system. The simple answer is that although fentanyl was less ideal than some of the newer fentanyl opioids, it was "good enough" and, even more important, it was well known, studied, and understood and thus far less of an investment risk than any of the newer opioids.

The Future

It is instructive to recognize that all of the newer delivery systems for administering fentanyl, from the first fentanyl transdermal patch, Duragesic, and the buccal transmucosal systems that began their development in the 1980s to all the TIRF products begun in the late 1990s and early 2000s, were initiated by entrepreneurs starting small, new companies. These entrepreneurs believed that their new way(s) of giving fentanyl would be useful for patients principally because it would be easier for the patient to be compliant (the patch), be less threatening (Oralet), or have a faster onset of action and/or be more pleasant to consume (Actiq and the rest of the TIRF products). Potency, lipid solubility, acid strength (pKa), the uniqueness of the formulation and delivery device, as well as the cost of the finished product, were believed to be the most important issues in each product's eventual success or failure. The entrepreneurs had to convince their investors that their devices were better than what was currently available and would be a significant commercial success and result in a good to great return on their investment. So far, the results are mixed. Oralet was a commercial failure whereas Duragesic, Actiq, and Fentora have been good to great successes. It is too soon to say much about the newer TIRF products. The continuing increases in the cost to develop these products and administrative regulations to get them FDA approved and into the marketplace raise serious questions of whether future entrepreneurs and their investors will be willing to take on the risks of going down that pathway with fentanyl or any other opioid. Of course, if one of the newer TIRF products or any other potent opioid (sufentanil) is a significant commercial success, that would likely stimulate others to try again.

Conclusion

Fentanyl, a potent rapid-acting synthetic opioid first synthesized more than 50 years ago, has become the opioid most commonly used intravenously for intraoperative analgesia throughout the world. This has occurred because the drug has minimal cardiovascular effects, does not result in increases in plasma histamine, is relatively short acting, is easy and inexpensive to synthesize and prepare for the marketplace, and is now familiar to clinicians working in perioperative medicine all over the planet. In the last 20 to 30 years, the development of novel, noninvasive drug delivery systems has enabled fentanyl, because of its physical characteristics and familiarity, to become extremely useful to pain physicians for around-the-clock opioid analgesia via transdermal patches and rapid-onset analgesia through nasal, buccal, and sublingual transmucosal drug delivery technologies. The early results of the impact of these new technologies and devices on patients with pain is encouraging, although the increase in morbidity, mortality, misuse, and abuse of fentanyl is concerning.

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FENTANYL CITRATE- fentanyl citrate injection, solution
Akorn, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FENTANYL CITRATE INJECTION safely and effectively. See full prescribing information for FENTANYL CITRATE INJECTION.
Fentanyl Citrate Injection, for intravenous or intramuscular use, CII
Initial U.S. Approval: 1968

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISK FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- **Fentanyl Citrate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. (5.2)**
- **Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of fentanyl. (5.3, 7, 12.3)**
- **Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.4, 7)**

RECENT MAJOR CHANGES

Boxed Warning	12/2016
Indications and Usage (1)	12/2016
Dosage and Administration (2)	12/2016
Contraindications (4)	12/2016
Warnings and Precautions (5)	12/2016

INDICATIONS AND USAGE

Fentanyl Citrate Injection is an opioid agonist indicated for: (1)

- analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- use as an opioid analgesic supplement in general or regional anesthesia.
- administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

DOSAGE AND ADMINISTRATION

- Fentanyl Citrate Injection should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids.
- Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available (2.1)
- Individualize dosing based on the factors such as age, body weight, physical status, underlying pathological condition, use of other drugs, type of anesthesia to be used, and the surgical procedure involved. (2.1)
- Initiate treatment in adults with 50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL). (2.2)
- Initiate treatment in children 2 to 12 years of age, with a reduced dose as low as 2 to 3 mcg/kg. (2.2)

DOSAGE FORMS AND STRENGTHS

Solution for injection (sterile): eq. to 50 mcg/mL fentanyl base; 2 mL, 5 mL, 10 mL, 20 mL ampules and 50 mL vial. (3)

CONTRAINDICATIONS

- Hypersensitivity to fentanyl. (4)

WARNINGS AND PRECAUTIONS

- Risks of Skeletal Muscle Rigidity and Skeletal Muscle Movement: Manage with neuromuscular blocking agent. See full prescribing information for more detail on managing these risks. (5.5)
- Severe Cardiovascular Depression: Monitor during dosage initiation and titration. (5.6)
- Serotonin Syndrome: Potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected. (5.7)
- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. (5.8)
- Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, or Head Injury: Monitor for sedation and respiratory depression. (5.9)

ADVERSE REACTIONS

Most common serious adverse reactions were respiratory depression, apnea, rigidity, and bradycardia. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-932-5676 or FDA at 1-800-FDA-1088 or www.fda.gov.medwatch.

DRUG INTERACTIONS

- Concomitant Use of CNS Depressants: May decrease pulmonary arterial pressure and may cause hypotension. See FPI for management instructions. For post-operative pain, start with the lowest effective dosage and monitor for potentiation of CNS depressant effects. (5.4, 7)
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Fentanyl Citrate Injection because they may reduce analgesic effect of Fentanyl Citrate Injection or precipitate withdrawal symptoms. (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm. (8.1)
- Lactation: Infants exposed to Fentanyl Citrate Injection through breast milk should be monitored for excess sedation and respiratory depression. (8.2)
- Geriatric Patients: Titrate slowly and monitor for CNS and respiratory depression. (8.5)

Revised: 11/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISK FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse

Fentanyl Citrate Injection exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing Fentanyl Citrate Injection, and monitor all patients regularly for the development of these behaviors and conditions *[see Warnings and Precautions (5.1)]*.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of Fentanyl Citrate Injection. Monitor for respiratory depression, especially during initiation of Fentanyl Citrate Injection or following a dose increase *[see Warnings and Precautions (5.2)]*.

Cytochrome P450 3A4 Interaction

The concomitant use of Fentanyl Citrate Injection with all cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in fentanyl plasma concentration. Monitor patients receiving Fentanyl Citrate Injection and any CYP3A4 inhibitor or inducer *[see Warnings and Precautions (5.3), Drug Interactions (7), Clinical Pharmacology (12.3)]*

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death *[see Warnings and Precautions (5.4), Drug Interactions (7)]*.

- **Reserve concomitant prescribing of Fentanyl Citrate Injection and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

1 INDICATIONS AND USAGE

Fentanyl Citrate Injection is indicated for:

- analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- use as a narcotic analgesic supplement in general or regional anesthesia.
- administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

Fentanyl Citrate Injection should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids.

- Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available.
- Individualize dosage based on factors such as age, body weight, physical status, underlying pathological condition, use of other drugs, type of anesthesia to be used, and the surgical procedure involved.
- Monitor vital signs routinely.

As with other potent opioids, the respiratory depressant effect of fentanyl may persist longer than the measured analgesic effect. The total dose of all opioid agonists administered should be considered by the practitioner before ordering opioid analgesics during recovery from anesthesia.

If Fentanyl Citrate Injection is administered with a CNS depressant, become familiar with the properties of each drug, particularly each product's duration of action. In addition, when such a combination is used, fluids and other countermeasures to manage hypotension should be available *[see Warnings and Precautions (5.4)]*.

Inspect parenteral drug products visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

2.2 Dosage

50 mcg = 0.05 mg = 1 mL

Premedication in Adults

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly 30 to 60 minutes prior to surgery.

Adjunct to General Anesthesia

See Dosage Range Charts below.

Table 1: Dosage Range Chart

TOTAL DOSAGE (expressed as fentanyl base)		
Low Dose — 2 mcg/kg (0.002 mg/kg) (0.04 mL/kg) For use in minor, but painful, surgical procedures. May also provide some pain relief in the immediate postoperative period.	**Moderate Dose** — 2 to 20 mcg/kg (0.002 to 0.02 mg/kg) (0.04 to 0.4 mL/kg). For use in more major surgical procedures, in addition to adequate analgesia, may abolish some of the stress response. Expect respiratory depression requiring artificial ventilation during anesthesia and careful observation of ventilation postoperatively is essential.	**High Dose** — 20 to 50 mcg/kg (0.02 to 0.05 mg/kg) (0.4 to 1 mL/kg). For open heart surgery and certain more complicated neurosurgical and orthopedic procedures where surgery is more prolonged, and the stress response to surgery would be detrimental to the well-being of the patient. In conjunction with nitrous oxide/oxygen has been shown to attenuate the stress response as defined by increased levels of circulating growth hormone, catecholamine, ADH and prolactin. Expect the need for postoperative ventilation and observation due to extended postoperative respiratory depression.
MAINTENANCE DOSAGE		

Low Dose — 2 mcg/kg (0.002 mg/kg) (0.04 mL/kg). Additional dosages infrequently needed in these minor procedures.	**Moderate Dose** — 2 to 20 mcg/kg (0.002 to 0.02 mg/kg) (0.04 to 0.4 mL/kg) - 25 to 100 mcg (0.025 to 0.1 mg) (0.5 to 2.0 mL) Administer intravenously or intramuscularly as needed when movement and/or changes in vital signs indicate surgical stress or lightening of analgesia.	**High Dose** — 20 to 50 mcg/kg (0.02 to 0.05 mcg/kg) (0.4 to 1.0 mL/kg). From 25 mcg (0.025 mg) (0.5 mL) to one half the initial loading dose as needed based on vital sign changes indicative of stress and lightening of analgesia. Individualize the dosage especially if the anticipated remaining operative time is short.

Adjunct to Regional Anesthesia

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly or slowly intravenously, over one to two minutes, when additional analgesia is required.

Postoperatively (recovery room)

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly for the control of pain, tachypnea and emergence delirium. The dose may be repeated in one to two hours as needed.

For Induction and Maintenance in Children 2 to 12 Years of Age

A reduced dose as low as 2 to 3 mcg/kg is recommended.

As a General Anesthetic

As a technique to attenuate the responses to surgical stress without the use of additional anesthetic agents, doses of 50 to 100 mcg/kg (0.05 to 0.1 mg/kg) (1 to 2 mL/kg) may be administered with oxygen and a muscle relaxant. In certain cases, doses up to 150 mcg/kg (0.15 mg/kg) (3 mL/kg) may be necessary to produce this anesthetic effect. It has been used for open heart surgery and certain other major surgical procedures in patients for whom protection of the myocardium from excess oxygen demand is particularly indicated, and for certain complicated neurological and orthopedic procedures.

3 DOSAGE FORMS AND STRENGTHS

Fentanyl Citrate Injection, USP 50 mcg/mL (equivalent to 50 mcg/mL Fentanyl base) is available as: 2 mL, 5 mL, 10 mL and 20 mL ampules.

4 CONTRAINDICATIONS

Fentanyl Citrate Injection is contraindicated in patients with:

- Hypersensitivity to fentanyl (e.g., anaphylaxis) *[see Adverse Reactions (6.2)]*

5 WARNINGS AND PRECAUTIONS

5.1 Addiction, Abuse, and Misuse

Fentanyl Citrate Injection contains fentanyl, a Schedule II controlled substance. As an opioid, Fentanyl Citrate Injection exposes users to the risks of addiction, abuse, and misuse *[see Drug Abuse and Dependence (9)]*.

Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when handling Fentanyl Citrate Injection. Strategies to reduce these risks include proper product storage and control practices for a C-II drug. Contact local state

professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product.

5.2 Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Adequate facilities should be available for postoperative monitoring and ventilation of patients administered anesthetic doses of Fentanyl Citrate Injection. It is essential that these facilities be fully equipped to handle all degrees of respiratory depression. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status *[see Overdosage (10)]*. Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids.

To reduce the risk of respiratory depression, proper dosing and titration of Fentanyl Citrate Injection are essential. As with other potent opioids, the respiratory depressant effect of Fentanyl Citrate Injection may persist longer than the measured analgesic effect. The total dose of all opioid agonists administered should be considered by the practitioner before ordering opioid analgesics during recovery from anesthesia.

Certain forms of conduction anesthesia, such as spinal anesthesia and some peridural anesthetics, can alter respiration by blocking intercostal nerves through other mechanisms *[see Clinical Pharmacology (12.2)]*. Fentanyl Citrate Injection can also alter respiration. Therefore, when Fentanyl Citrate Injection is used to supplement these forms of anesthesia, the anesthetist should be familiar with the physiological alterations involved, and be prepared to manage them in the patients selected for these forms of anesthesia.

Patients with significant chronic obstructive pulmonary disease or cor pulmonale, and those with a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive including apnea, even at recommended dosages of Fentanyl Citrate Injection. Elderly, cachectic, or debilitated patients may have altered pharmacokinetics or altered clearance compared to younger, healthier patients resulting in greater risk for respiratory depression.

Monitor such patients closely including vital signs, particularly when initiating and titrating Fentanyl Citrate Injection and when Fentanyl Citrate Injection is given concomitantly with other drugs that depress respiration. To reduce the risk of respiratory depression, proper dosing and titration of Fentanyl Citrate Injection are essential *[see Dosage and Administration (2.1)]*.

5.3 Risks of Concomitant Use or Discontinuation of Cytochrome P450 3A4 Inhibitors and Inducers

Concomitant use of Fentanyl Citrate Injection with a CYP3A4 inhibitor, such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir), may increase plasma concentrations of fentanyl and prolong opioid adverse reactions, which may exacerbate respiratory depression *[see Warnings and Precautions (5.2)]*, particularly when an inhibitor is added after a stable dose of Fentanyl Citrate Injection is achieved. Similarly, discontinuation of a CYP3A4 inducer, such as rifampin, carbamazepine, and phenytoin, in Fentanyl Citrate Injection-treated patients may increase fentanyl plasma concentrations and prolong opioid adverse reactions. When using Fentanyl Citrate Injection with CYP3A4 inhibitors or discontinuing CYP3A4 inducers in Fentanyl Citrate Injection-treated patients, monitor patients closely at frequent intervals and consider dosage reduction of Fentanyl Citrate Injection *[see Dosage and Administration (2.1), Drug Interactions (7)]*.

Concomitant use of Fentanyl Citrate Injection with CYP3A4 inducers or discontinuation of an CYP3A4 inhibitor could result in lower than expected fentanyl plasma concentrations and, decrease efficacy.

When using Fentanyl Citrate Injection with CYP3A4 inducers or discontinuing CYP3A4 inhibitors, monitor patients closely at frequent intervals and consider increasing the Fentanyl Citrate Injection dosage *[see Dosage and Administration (2.1), Drug Interactions (7)]*.

5.4 Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants

When benzodiazepines or other CNS depressants are used with Fentanyl Citrate Injection, pulmonary arterial pressure may be decreased. This fact should be considered by those who conduct diagnostic and surgical procedures where interpretation of pulmonary arterial pressure measurements might determine final management of the patient. When high dose or anesthetic dosages of Fentanyl Citrate Injection are employed, even relatively small dosages of diazepam may cause cardiovascular depression.

When Fentanyl Citrate Injection is used with CNS depressants, hypotension can occur. If it occurs, consider the possibility of hypovolemia and manage with appropriate parenteral fluid therapy. When operative conditions permit, consider repositioning the patient to improve venous return to the heart. Exercise care in moving and repositioning of patients because of the possibility of orthostatic hypotension. If volume expansion with fluids plus other countermeasures do not correct hypotension, consider administration of pressor agents other than epinephrine. Epinephrine may paradoxically decrease blood pressure in patients treated with a neuroleptic that blocks alpha adrenergic activity.

Profound sedation, respiratory depression, coma, and death may result from the concomitant use of Fentanyl Citrate Injection with benzodiazepines or other CNS depressants (e.g., nonbenzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, alcohol).

If the decision is made to manage postoperative pain with Fentanyl Citrate Injection concomitantly with a benzodiazepine or other CNS depressant, start dosing with the lowest effective dosage and titrate based on clinical response. Follow patients closely for signs and symptoms of respiratory depression, sedation, and hypotension. Fluids or other measures to counter hypotension should be available *[see Drug Interactions (7)]*.

5.5 Risks of Muscle Rigidity and Skeletal Muscle Movement

Fentanyl Citrate Injection may cause muscle rigidity, particularly involving the muscles of respiration. The incidence and severity of muscle rigidity is dose related. These effects are related to the dose and speed of injection. Skeletal muscle rigidity also has been reported to occur or recur infrequently in the extended postoperative period usually following high dose administration. In addition, skeletal muscle movements of various groups in the extremities, neck, and external eye have been reported during induction of anesthesia with Fentanyl Citrate Injection; these reported movements have, on rare occasions, been strong enough to pose patient management problems.

These effects are related to the dose and speed of injection and its incidence can be reduced by: 1) administration of up to 1/4 of the full paralyzing dose of a non-depolarizing neuromuscular blocking agent just prior to administration of Fentanyl Citrate Injection; 2) administration of a full paralyzing dose of a neuromuscular blocking agent following loss of eyelash reflex when Fentanyl Citrate Injection is used in anesthetic doses titrated by slow intravenous infusion; or, 3) simultaneous administration of Fentanyl Citrate Injection and a full paralyzing dose of a neuromuscular blocking agent when Fentanyl Citrate Injection is used in rapidly administered anesthetic dosages. The neuromuscular blocking agent used should be compatible with the patient's cardiovascular status.

5.6 Severe Cardiovascular Depression

Fentanyl Citrate Injection may cause severe bradycardia, severe hypotension including orthostatic hypotension, and syncope. There is increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics) *[see Drug Interactions (7)]*. In patients with

circulatory shock, Fentanyl Citrate Injection may cause vasodilation that can further reduce cardiac output and blood pressure. Monitor these patients for signs of hypotension after initiating or titrating the dosage of Fentanyl Citrate Injection.

5.7 Serotonin Syndrome with Concomitant Use of Serotonergic Drugs

Cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of fentanyl with serotonergic drugs. Serotonergic drugs include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT3 receptor antagonists, drugs that affect the serotonergic neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), and drugs that impair metabolism of serotonin (including MAO inhibitors, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue) *[see Drug Interactions (7)]*. This may occur within the recommended dosage range.

Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination, rigidity), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The onset of symptoms generally occurs within several hours to a few days of concomitant use, but may occur later than that. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected.

5.8 Adrenal Insufficiency

Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include non-specific symptoms and signs including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

5.9 Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, or Head Injury

In patients who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors), Fentanyl Citrate Injection may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of increasing intracranial pressure.

5.10 Risks of Use in Patients with Gastrointestinal Conditions

Fentanyl may cause spasm of the sphincter of Oddi. Opioids may cause increases in serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis for worsening symptoms.

5.11 Increased Risk of Seizures in Patients with Seizure Disorders

Fentanyl may increase the frequency of seizures in patients with seizure disorders, and may increase the risk of seizures occurring in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during Fentanyl Citrate Injection therapy.

5.12 Risks of Driving and Operating Machinery

Fentanyl Citrate Injection may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery after Fentanyl Citrate Injection administration.

5.13 Risks due to Interaction with Neuroleptic Agents

Many neuroleptic agents have been associated with QT prolongation, torsades de pointes, and cardiac arrest. Administer neuroleptic agents with extreme caution in the presence of risk factors for development of prolonged QT syndrome and torsades de pointes, such as: 1) clinically significant bradycardia (less than 50 bpm), 2) any clinically significant cardiac disease, including baseline prolonged QT interval, 3) treatment with Class I and Class III antiarrhythmics, 4) treatment with monoamine oxidase inhibitors (MAOI's), 5) concomitant treatment with other drug products known to prolong the QT interval and 6) electrolyte imbalance, in particular hypokalemia and hypomagnesemia, or concomitant treatment with drugs (e.g. diuretics) that may cause electrolyte imbalance.

Elevated blood pressure, with and without pre-existing hypertension, has been reported following administration of Fentanyl Citrate Injection combined with a neuroleptic. This might be due to unexplained alterations in sympathetic activity following large doses; however, it is also frequently attributed to anesthetic and surgical stimulation during light anesthesia.

ECG monitoring is indicated when a neuroleptic agent is used in conjunction with Fentanyl Citrate Injection as an anesthetic premedication, for the induction of anesthesia, or as an adjunct in the maintenance of general or regional anesthesia.

When Fentanyl Citrate Injection is used with a neuroleptic and an EEG is used for postoperative monitoring, the EEG pattern may return to normal slowly.

6 ADVERSE REACTIONS

The following serious adverse reactions are described, or described in greater detail, in other sections:

- Addiction, Abuse, and Misuse *[see Warnings and Precautions (5.1)]*
- Life-Threatening Respiratory Depression *[see Warnings and Precautions (5.2)]*
- Interactions with Benzodiazepines or Other CNS Depressants *[see Warnings and Precautions (5.4)*
- Severe Cardiovascular Depression *[see Warnings and Precautions (5.6)]*
- Serotonin Syndrome *[see Warnings and Precautions (5.7)]*
- Gastrointestinal Adverse Reactions *[see Warnings and Precautions (5.10)]*
- Seizures *[see Warnings and Precautions (5.11)]*

The following adverse reactions associated with the use of fentanyl were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

As with opioid agonists, the most common serious adverse reactions reported to occur with fentanyl are respiratory depression, apnea, rigidity, and bradycardia; if these remain untreated, respiratory arrest, circulatory depression or cardiac arrest could occur. Other adverse reactions that have been reported are hypertension, hypotension, dizziness, blurred vision, nausea, emesis, diaphoresis, pruritus, urticaria, laryngospasm and anaphylaxis.

It has been reported that secondary rebound respiratory depression may occasionally occur postoperatively.

When a tranquilizer is used with Fentanyl Citrate Injection, the following adverse reactions can occur: chills and/or shivering, restlessness, and postoperative hallucinatory episodes (sometimes associated with transient periods of mental depression); extrapyramidal symptoms (dystonia, akathisia, and oculogyric crisis) have been observed up to 24 hours postoperatively. When they occur, extrapyramidal symptoms can usually be controlled with anti-parkinson agents. Postoperative drowsiness is also frequently reported following the use of neuroleptics with fentanyl citrate.

Cases of cardiac dysrhythmias, cardiac arrest, and death have been reported following the use of

fentanyl citrate with a neuroleptic agent.

Serotonin syndrome: Cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of opioids with serotonergic drugs.

Adrenal insufficiency: Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use.

Anaphylaxis: Anaphylaxis has been reported with ingredients contained in Fentanyl Citrate Injection.

Androgen deficiency: Cases of androgen deficiency have occurred with chronic use of opioids *[see Clinical Pharmacology (12.2)]*.

7 DRUG INTERACTIONS

Table 2 includes clinically significant drug interactions with Fentanyl Citrate Injection.

Table 2: Clinically Significant Drug Interactions with Fentanyl Citrate Injection

Inhibitors of CYP3A4	
Clinical Impact:	The concomitant use of Fentanyl Citrate Injection and CYP3A4 inhibitors can increase the plasma concentration of fentanyl, resulting in increased or prolonged opioid effects, particularly when an inhibitor is added after a stable dose of Fentanyl Citrate Injection is achieved *[see Warnings and Precautions (5.3)]*. After stopping a CYP3A4 inhibitor, as the effects of the inhibitor decline, the fentanyl plasma concentration will decrease *[see Clinical Pharmacology (12.3)]*, resulting in decreased opioid efficacy or a withdrawal syndrome in patients who had developed physical dependence to fentanyl.
Intervention:	If concomitant use is necessary, consider dosage reduction of Fentanyl Citrate Injection until stable drug effects are achieved. Monitor patients for respiratory depression and sedation at frequent intervals. If a CYP3A4 inhibitor is discontinued, consider increasing the Fentanyl Citrate Injection dosage until stable drug effects are achieved. Monitor for signs of opioid withdrawal.
Examples:	Macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g. ketoconazole), protease inhibitors (e.g., ritonavir), grapefruit juice
CYP3A4 Inducers	
Clinical Impact:	The concomitant use of Fentanyl Citrate Injection and CYP3A4 inducers can decrease the plasma concentration of fentanyl *[see Clinical Pharmacology (12.3)]*, resulting in decreased efficacy or onset of a withdrawal syndrome in patients who have developed physical dependence to fentanyl *[see Warnings and Precautions (5.3)]*. After stopping a CYP3A4 inducer, as the effects of the inducer decline, the fentanyl plasma concentration will increase *[see Clinical Pharmacology (12.3)]*, which could increase or prolong both the therapeutic effects and adverse reactions, and may cause serious respiratory depression.
Intervention:	If concomitant use is necessary, consider increasing the Fentanyl Citrate Injection dosage until stable drug effects are achieved. Monitor for signs of opioid withdrawal. If a CYP3A4 inducer is discontinued, consider Fentanyl Citrate Injection dosage reduction and monitor for signs of respiratory depression.
Examples:	Rifampin, carbamazepine, phenytoin
Benzodiazepines and Other Central Nervous System (CNS) Depressants	
Clinical Impact:	The concomitant use of Fentanyl Citrate Injection with CNS depressants may result in decreased pulmonary artery pressure and may cause hypotension. Even small

	dosages of diazepam may cause cardiovascular depression when added to high dose or anesthetic dosages of Fentanyl Citrate Injection. As postoperative analgesia, concomitant use of Fentanyl Citrate Injection can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death.
Intervention:	As postoperative analgesia, start with a lower dose of Fentanyl Citrate Injection and monitor patients for signs of respiratory depression, sedation, and hypotension. Fluids or other measures to counter hypotension should be available. *[see Warnings and Precautions (5.4)].*
Examples:	Benzodiazepines and other sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, alcohol.
Serotonergic Drugs	
Clinical Impact:	The concomitant use of opioids with other drugs that affect the serotonergic neurotransmitter system has resulted in serotonin syndrome *[see Warnings and Precautions 5.7].*
Intervention:	If concomitant use is warranted, carefully observe the patient, particularly during treatment initiation and dose adjustment. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected.
Examples:	Selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT3 receptor antagonists, drugs that effect the serotonin neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), monoamine oxidase (MAO) inhibitors (those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue).
Monoamine Oxidase Inhibitors	
Clinical Impact:	MAOI interactions with opioids may manifest as serotonin syndrome or opioid toxicity (e.g., respiratory depression, coma) *[see Warnings and Precautions (5.2)]*
Intervention:	The use of Fentanyl Citrate Injection is not recommended for patients taking MAOIs or within 14 days of stopping such treatment.
Examples:	phenelzine, tranylcypromine, linezolid
Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics	
Clinical Impact:	May reduce the analgesic effect of Fentanyl Citrate Injection and/or precipitate withdrawal symptoms.
Intervention:	Avoid concomitant use.
Examples:	butorphanol, nalbuphine, pentazocine, buprenorphine
Muscle Relaxants	
Clinical Impact:	Fentanyl may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.
Intervention:	Monitor patients for signs of respiratory depression that may be greater than otherwise expected and decrease the dosage of Fentanyl Citrate Injection and/or the muscle relaxant as necessary.
Diuretics	
Clinical Impact:	Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone.
Intervention:	Monitor patients for signs of diminished diuresis and/or effects on blood pressure and increase the dosage of the diuretic as needed.
Anticholinergic Drugs	
Clinical Impact:	The concomitant use of anticholinergic drugs may increase risk of urinary retention and/or severe constipation, which may lead to paralytic ileus.
Intervention:	Monitor patients for signs of urinary retention or reduced gastric motility when Fentanyl Citrate Injection is used concomitantly with anticholinergic drugs.

Neuroleptics	
Clinical Impact:	Elevated blood pressure, with and without pre-existing hypertension, has been reported following administration of fentanyl combined with a neuroleptic *[see Warnings and Precautions (5.13)]*.
Intervention:	ECG monitoring is indicated when a neuroleptic agent is used in conjunction with Fentanyl Citrate Injection as an anesthetic premedication, for the induction of anesthesia, or as an adjunct in the maintenance of general or regional anesthesia.
Nitrous oxide	
Clinical Impact:	Nitrous oxide has been reported to produce cardiovascular depression when given with higher doses of Fentanyl Citrate Injection.
Intervention:	Monitor patients for signs of cardiovascular depression that may be greater than otherwise expected.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Prolonged use of opioid analgesics during pregnancy may cause neonatal opioid withdrawal syndrome. Available data with Fentanyl Citrate Injection in pregnant women are insufficient to inform a drug-associated risk for major birth defects and miscarriage.

In animal reproduction studies, fentanyl administration to pregnant rats during organogenesis was embryocidal at doses within the range of the human recommended dosing. No evidence of malformations was noted in animal studies completed to date [see Data].

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth.

Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea, and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn. Observe newborns for symptoms of neonatal opioid withdrawal syndrome and manage accordingly.

Labor or Delivery

Opioids cross the placenta and may produce respiratory depression and psycho-physiologic effects in neonates. An opioid antagonist, such as naloxone, must be available for reversal of opioid-induced respiratory depression in the neonate. Fentanyl Citrate Injection is not recommended for use in pregnant women during or immediately prior to labor, when other analgesic techniques are more appropriate. Opioid analgesics, including Fentanyl Citrate Injection, can prolong labor through actions which temporarily reduce the strength, duration, and frequency of uterine contractions. However, this effect is not consistent and may be offset by an increased rate of cervical dilation, which tends to shorten labor. Monitor neonates exposed to opioid analgesics during labor for signs of excess sedation and respiratory depression.

Data

Animal Data

Fentanyl has been shown to embryocidal in pregnant rats at doses of 30 mcg/kg intravenously (0.05 times the human dose of 100 mcg/kg on a mg/m^2 basis) and 160 mcg/kg subcutaneously (0.26 times the human dose of 100 mcg/kg on a mg/m^2 basis). There was no evidence of teratogenicity reported.

No evidence of malformations or adverse effects on the fetus was reported in a published study in which pregnant rats were administered fentanyl continuously via subcutaneously implanted osmotic minipumps at doses of 10, 100, or 500 mcg/kg/day starting 2-weeks prior to breeding and throughout pregnancy. The high dose was approximately 0.81 times the human dose of 100 mcg/kg on a mg/m^2 basis.

8.2 Lactation

Risk Summary

Fentanyl is present in breast milk. One published lactation study reports a relative infant dose of fentanyl of 0.38%. However, there is insufficient information to determine the effects of fentanyl on the breastfed infant and the effects of fentanyl on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Fentanyl Citrate Injection and any potential adverse effects on the breastfed infant from Fentanyl Citrate Injection or from the underlying maternal condition.

Clinical Considerations

Monitor infants exposed to fentanyl through breast milk for excess sedation and respiratory depression. Withdrawal symptoms can occur in breastfed infants when maternal administration of an opioid analgesic is stopped, or when breast-feeding is stopped.

8.3 Females and Males of Reproductive Potential

Infertility

Chronic use of opioids may cause reduced fertility in females and males of reproductive potential. It is not known whether these effects on fertility are reversible *[see Adverse Reactions (6.2), Clinical Pharmacology (12.2), Nonclinical Toxicology (13.1)]*.

8.4 Pediatric Use

The safety and efficacy of Fentanyl Citrate Injection in children under two years of age have not been established.

Rare cases of unexplained clinically significant methemoglobinemia have been reported in premature neonates undergoing emergency anesthesia and surgery which included the combined use of fentanyl, pancuronium, and atropine. A direct cause and effect relationship between the combined use of these drugs and the reported cases of methemoglobinemia has not been established.

8.5 Geriatric Use

Elderly patients (aged 65 years or older) may have increased sensitivity to fentanyl. In general, use caution when selecting a dosage for an elderly patient, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

Respiratory depression is the chief risk for elderly patients treated with opioids, and has occurred after large initial doses were administered to patients who were not opioid-tolerant or when opioids were co-administered with other agents that depress respiration. Titrate the dosage of Fentanyl Citrate Injection slowly in geriatric patients and monitor closely for signs of central nervous system and respiratory depression *[see Warnings and Precautions (5.2)]*.

Fentanyl is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

8.6 Hepatic Impairment

Fentanyl Citrate Injection should be administered with caution to patients with liver dysfunction because of the extensive hepatic metabolism. Reduce the dosage as needed and monitor closely for signs of respiratory depression, sedation, and hypotension.

8.7 Renal Impairment

Fentanyl Citrate Injection should be administered with caution to patients with kidney dysfunction because of the renal excretion of fentanyl citrate and its metabolites. Reduce the dosage as needed and monitor for signs of respiratory depression, sedation, and hypotension.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Fentanyl Citrate Injection contains fentanyl, a Schedule II controlled substance.

9.2 Abuse

Fentanyl Citrate Injection contains fentanyl, a substance with a high potential for abuse similar to other opioids including hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and tapentadol. Fentanyl Citrate Injection can be abused and is subject to misuse, addiction, and criminal diversion *[see Warnings and Precautions (5.1)]*.

Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and includes:

a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal.

Fentanyl Citrate Injection, like other opioids, can be diverted for non-medical use into illicit channels of distribution. Careful recordkeeping of prescribing information, including quantity, frequency, and renewal requests, as required by state and federal law, is strongly advised.

Risks Specific to Abuse of Fentanyl Citrate Injection

Abuse of Fentanyl Citrate Injection poses a risk of overdose and death. The risk is increased with concurrent use of Fentanyl Citrate Injection with alcohol and other central nervous system depressants.

Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

9.3 Dependence

Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects.

Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dosage reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity (e.g., naloxone, nalmefene), mixed agonist/ antagonist analgesics (e.g., pentazocine, butorphanol, nalbuphine), or partial agonists (e.g., buprenorphine). Physical dependence

may not occur to a clinically significant degree until after several days to weeks of continued opioid usage.

10 OVERDOSAGE

Clinical Presentation

Acute overdose with Fentanyl Citrate Injection can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations *[see Clinical Pharmacology (12.2)]*.

Treatment of Overdose

In case of overdose, priorities are the reestablishment of a patent and protected airway and institution of assisted or controlled ventilation, if needed. Employ other supportive measures (including oxygen and vasopressors) in the management of circulatory shock and pulmonary edema as indicated. Cardiac arrest or arrhythmias will require advanced life-support techniques.

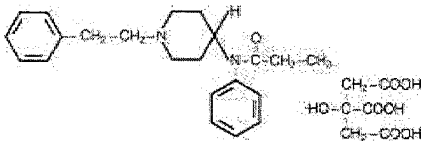
The opioid antagonists, naloxone or nalmefene, are specific antidotes to respiratory depression resulting from opioid overdose. For clinically significant respiratory or circulatory depression secondary to fentanyl overdose, administer an opioid antagonist. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to fentanyl overdose.

Because the duration of opioid reversal is expected to be less than the duration of action of fentanyl in Fentanyl Citrate Injection, carefully monitor the patient until spontaneous respiration is reliably reestablished. If the response to an opioid antagonist is suboptimal or only brief in nature, administer additional antagonist as directed by the product's prescribing information.

In an individual physically dependent on opioids, administration of the recommended usual dosage of the antagonist will precipitate an acute withdrawal syndrome. The severity of the withdrawal symptoms experienced will depend on the degree of physical dependence and the dose of the antagonist administered. If a decision is made to treat serious respiratory depression in the physically dependent patient, administration of the antagonist should be initiated with care and by titration with smaller than usual doses of the antagonist.

11 DESCRIPTION

Fentanyl Citrate Injection is an opioid agonist, available as a solution containing 50 mcg/mL eq. of fentanyl base, adjusted to pH 4.0 to 7.5 with sodium hydroxide. The chemical name is N-(1-phenethyl-4-piperidyl) propionanilide citrate (1:1). The molecular weight is 528.60. Its molecular formula is $C_{22}H_{28}N_2O \cdot C_6H_8O_7$, and it has the following chemical structure.



Fentanyl Citrate Injection, USP is a sterile, non-pyrogenic, preservative free aqueous solution for intravenous or intramuscular injection. The inactive ingredients in Fentanyl Citrate Injection include sodium hydroxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Fentanyl Citrate Injection is an opioid agonist, whose principal actions of therapeutic value are analgesia and sedation.

12.2 Pharmacodynamics

Effects on the Central Nervous System

Fentanyl produces respiratory depression by direct action on brain stem respiratory centers. The respiratory depression involves a reduction in the responsiveness of the brain stem respiratory centers to both increases in carbon dioxide tension and electrical stimulation.

Fentanyl causes miosis, even in total darkness. Pinpoint pupils are a sign of opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origins may produce similar findings). Marked mydriasis rather than miosis may be seen due to hypoxia in overdose situations.

Effects on the Gastrointestinal Tract and Other Smooth Muscle

Fentanyl causes a reduction in motility associated with an increase in smooth muscle tone in the antrum of the stomach and duodenum. Digestion of food in the small intestine is delayed and propulsive contractions are decreased. Propulsive peristaltic waves in the colon are decreased, while tone may be increased to the point of spasm, resulting in constipation. Other opioid-induced effects may include a reduction in biliary and pancreatic secretions, spasm of sphincter of Oddi, and transient elevations in serum amylase.

Effects on the Cardiovascular System

Fentanyl produces peripheral vasodilation which may result in orthostatic hypotension or syncope. Manifestations of histamine release and/or peripheral vasodilation may include pruritus, flushing, red eyes, sweating, and/or orthostatic hypotension.

Effects on the Endocrine System

Opioids inhibit the secretion of adrenocorticotropic hormone (ACTH), cortisol, and luteinizing hormone (LH) in humans. They also stimulate prolactin, growth hormone (GH) secretion, and pancreatic secretion of insulin and glucagon.

Chronic use of opioids may influence the hypothalamic-pituitary-gonadal axis, leading to androgen deficiency that may manifest as low libido, impotence, erectile dysfunction, amenorrhea, or infertility. The causal role of opioids in the clinical syndrome of hypogonadism is unknown because the various medical, physical, lifestyle, and psychological stressors that may influence gonadal hormone levels have not been adequately controlled for in studies conducted to date *[see Adverse Reactions (6)]*.

Effects on the Immune System

Opioids have been shown to have a variety of effects on components of the immune system in *in vitro* and animal models. The clinical significance of these findings is unknown. Overall, the effects of opioids appear to be modestly immunosuppressive.

Concentration–Efficacy Relationships

A dose of 100 mcg (0.1 mg) (2.0 mL) of Fentanyl Citrate Injection is approximately equivalent in analgesic activity to 10 mg of morphine or 75 mg of meperidine.

The minimum effective analgesic concentration will vary widely among patients, especially among patients who have been previously treated with potent agonist opioids. The minimum effective analgesic concentration of fentanyl for any individual patient may increase over time due to an increase in pain, the development of a new pain syndrome and/or the development of analgesic tolerance *[see Dosage and Administration (2.1)]*.

The onset of action of fentanyl is almost immediate when the drug is given intravenously; however, the maximal analgesic effect may not be noted for several minutes. The usual duration of action of the analgesic effect is 30 to 60 minutes after a single intravenous dose of up to 100 mcg (0.1 mg) (2 mL). Following intramuscular administration, the onset of action is from seven to eight minutes and the duration of action is one to two hours.

Concentration–Adverse Reaction Relationships

There is a relationship between increasing fentanyl plasma concentration and increasing frequency of dose-related opioid adverse reactions such as nausea, vomiting, CNS effects, and respiratory depression. In opioid-tolerant patients, the situation may be altered by the development of tolerance to opioid-related adverse reactions *[see Dosage and Administration (2.1, 2.2)]*.

The onset of action of fentanyl is almost immediate when the drug is given intravenously; however, the maximal respiratory depressant effect may not be noted for several minutes. As with longer acting opioid analgesics, the duration of the respiratory depressant effect of fentanyl may be longer than the analgesic effect. The following observations have been reported concerning altered respiratory response to CO_2 stimulation following administration of fentanyl citrate:

- Diminished sensitivity to CO_2 stimulation may persist longer than depression of respiratory rate. (Altered sensitivity to CO_2 stimulation has been demonstrated for up to four hours following a single dose of 600 mcg (0.6 mg) (12 mL) fentanyl citrate to healthy volunteers). Fentanyl frequently slows the respiratory rate, duration and degree of respiratory depression being dose-related.
- The peak respiratory depressant effect of a single intravenous dose of Fentanyl Citrate Injection is noted 5 to 15 minutes following injection *[see Warnings and Precautions (5.2)]*.

12.3 Pharmacokinetics

Fentanyl Citrate Injection is administered by the intravenous or intramuscular route. The pharmacokinetics of fentanyl can be described as a three-compartment model.

Distribution

Fentanyl plasma protein binding capacity decreases with increasing ionization of the drug. Alterations in pH may affect its distribution between plasma and the central nervous system. It accumulates in skeletal muscle and fat, and is released slowly into the blood. The volume of distribution for fentanyl is 4 L/kg. It has a distribution time of 1.7 minutes and redistribution time of 13 minutes.

Elimination

The terminal elimination half-life is 219 minutes.

Fentanyl, which is primarily transformed in the liver, demonstrates a high first pass clearance and releases approximately 75% of an intravenous dose in urine, mostly as metabolites with less than 10% representing the unchanged drug. Approximately 9% of the dose is recovered in the feces, primarily as metabolites.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term studies in animals to evaluate the carcinogenic potential of fentanyl citrate injection have not been conducted.

Mutagenesis

Studies in animals to evaluate the mutagenic potential of fentanyl have not been conducted.

Impairment of Fertility

Decreased pregnancy rates occurred in a multigenerational study in which pregnant rats were treated subcutaneously during the first 21 days of pregnancy with 160 mcg/kg to 1250 mcg/kg fentanyl (0.26 times to 2.0 times a human dose of 100 mcg/kg based on body surface area).

Studies in animals to characterize the effect of fentanyl on male fertility have not been conducted.

16 HOW SUPPLIED/STORAGE AND HANDLING

Fentanyl Citrate Injection, USP equivalent to 50 mcg fentanyl base per mL is available in single-dose glass containers as follows:

NDC 17478-030-02	100 mcg/2 mL (50 mcg/mL) in packages of 10
NDC 17478-030-05	250 mcg/5 mL (50 mcg/mL) in packages of 10
NDC 17478-030-10	500 mcg/10 mL (50 mcg/mL) in packages of 5
NDC 17478-030-20	1,000 mcg/20 mL (50 mcg/mL) in packages of 5
NDC 17478-030-25	100 mcg/2 mL (50 mcg/mL) in packages of 25
NDC 17478-030-55	250 mcg/5 mL (50 mcg/mL) in packages of 25
NDC 17478-031-50	2,500 mcg/50 mL (50 mcg/mL) in single pack

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light.

AKORN

Manufactured by: **Akorn, Inc.**
Lake Forest, IL 60045

AFCA0N Rev. 11/17

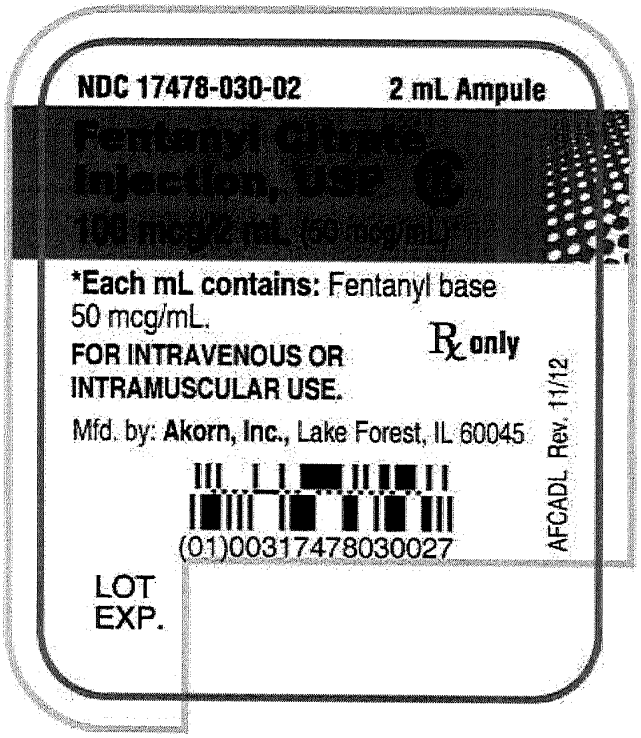
Principal Display Panel Text for Container Label:

NDC 17478-030-02 2 mL Ampule

Fentanyl Citrate

Injection, USP **CII**

100 mcg/2 mL (50 mcg/mL)*



Principal Display Panel Text for Carton Label:

NDC 17478-030-02 10 Ampules (2 mL each)

Fentanyl Citrate

Injection, USP **CII**

100 mcg/2 mL

(50 mcg/mL)*

FOR INTRAVENOUS OR INTRAMUSCULAR USE

Rx only Akorn Logo

Principal Display Panel Text for Container Label:

NDC 17478-031-50

Fentanyl Citrate

Injection, USP CII

2,500 mcg/50 mL

(50 mcg/mL)*

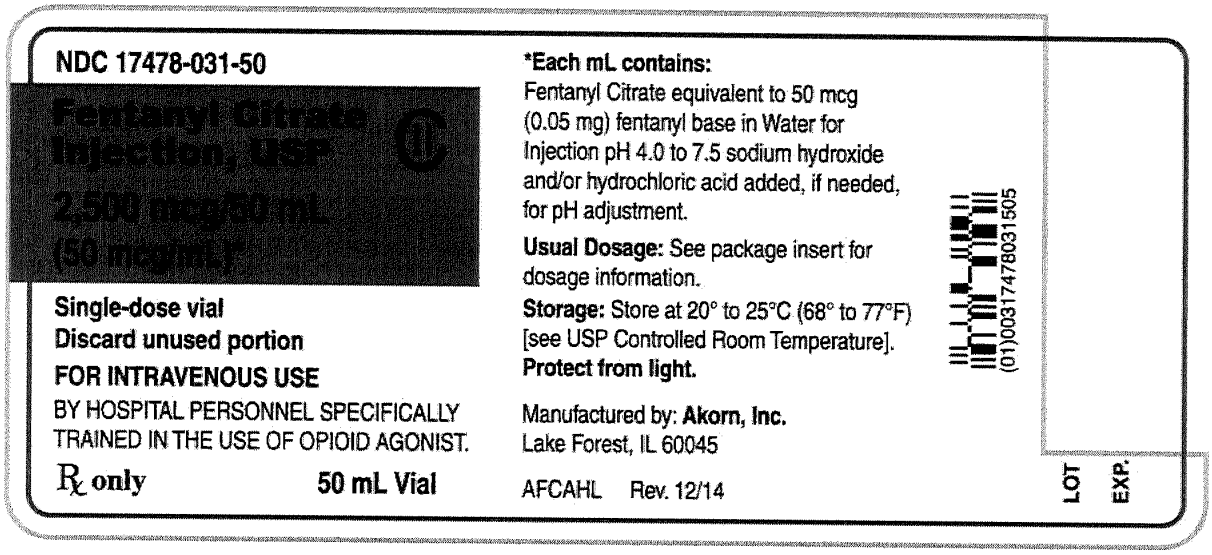
Single-dose vial

Discard unused portion

FOR INTRAVENOUS USE

BY HOSPITAL PERSONNEL SPECIFICALLY
TRAINED IN THE USE OF OPIOID AGONIST.

Rx ONLY 50 mL Vial



Principal Display Panel Text for Carton Label:

NDC 17478-031-50

Fentanyl Citrate

Injection, USP CII

2,500 mcg/50 mL

(50 mcg/mL)*

Single-dose vial

Discard unused portion

FOR INTRAVENOUS USE

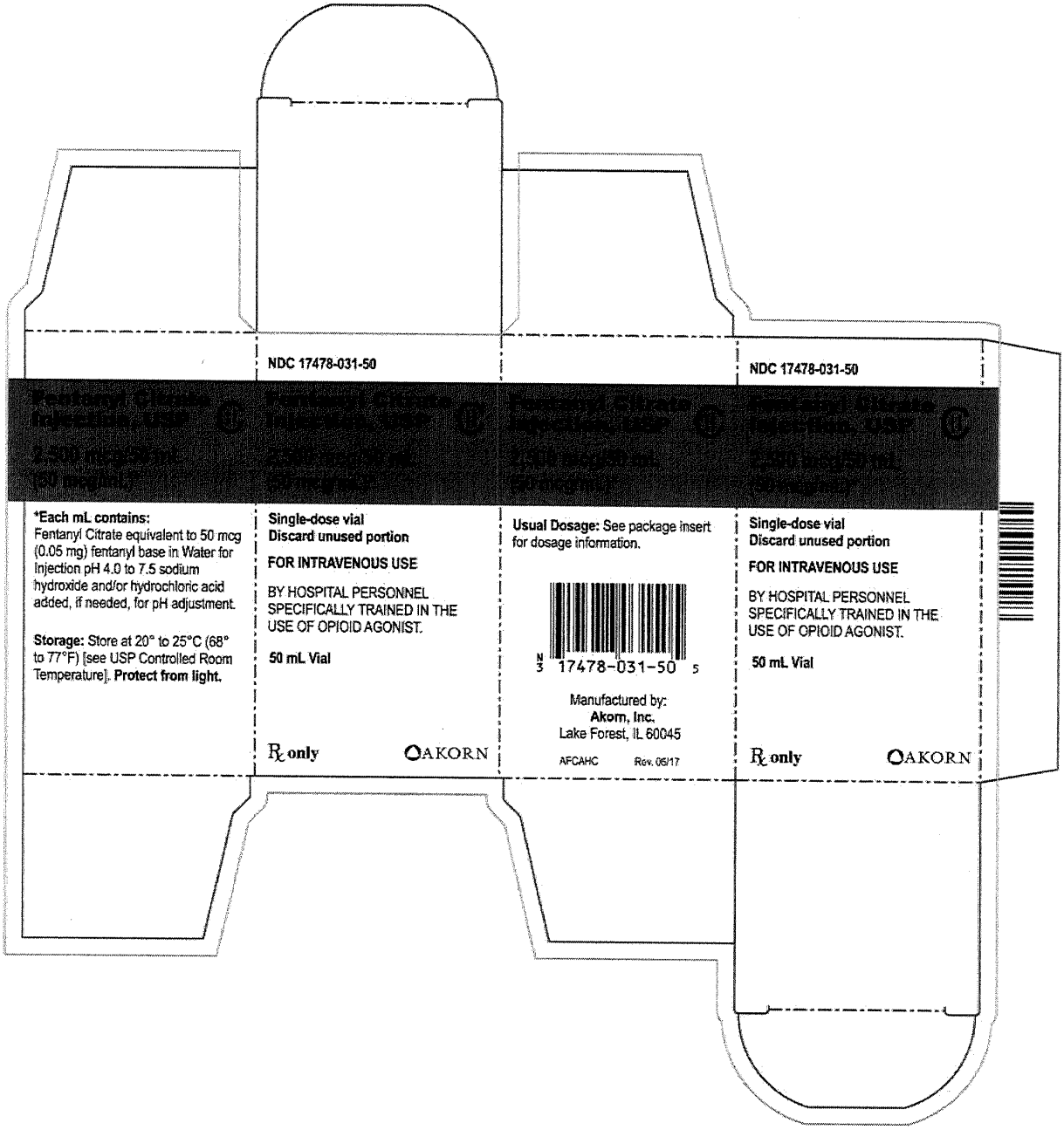
BY HOSPITAL PERSONNEL

SPECIFICALLY TRAINED IN THE

USE OF OPIOID AGONIST.

50 mL Vial

Rx ONLY Akorn Logo



FENTANYL CITRATE

fentanyl citrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:17478-030
Route of Administration	INTRAVENOUS, INTRAMUSCULAR	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FENTANYL CITRATE (UNII: MUN5LYG46H) (FENTANYL - UNII:UF599785JZ)	FENTANYL	50 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-030-02	10 in 1 CARTON	03/22/2012	
1		2 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:17478-030-05	10 in 1 CARTON	03/22/2012	
2		5 mL in 1 AMPULE; Type 0: Not a Combination Product		
3	NDC:17478-030-10	5 in 1 CARTON	03/22/2012	
3		10 mL in 1 AMPULE; Type 0: Not a Combination Product		
4	NDC:17478-030-20	5 in 1 CARTON	03/22/2012	
4		20 mL in 1 AMPULE; Type 0: Not a Combination Product		
5	NDC:17478-030-25	25 in 1 CARTON	03/22/2012	
5		2 mL in 1 AMPULE; Type 0: Not a Combination Product		
6	NDC:17478-030-55	25 in 1 CARTON	03/22/2012	
6		5 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016619	03/22/2012	

FENTANYL CITRATE

fentanyl citrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17478-031
Route of Administration	INTRAVENOUS	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FENTANYL CITRATE (UNII: MUN5LYG46H) (FENTANYL - UNII:UF599785JZ)	FENTANYL	50 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-031-50	1 in 1 CARTON	07/10/2017	
1		50 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016619	07/10/2017	

Labeler - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		063434679	PACK(17478-030, 17478-031) , LABEL(17478-030, 17478-031)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		155135783	MANUFACTURE(17478-030, 17478-031) , ANALYSIS(17478-030, 17478-031) , STERILIZE(17478-030, 17478-031)

Revised: 11/2017

Akorn, Inc.

EXHIBIT 4

The New York Times

Pfizer Blocks the Use of Its Drugs in Executions

By Erik Eckholm

May 13, 2016

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

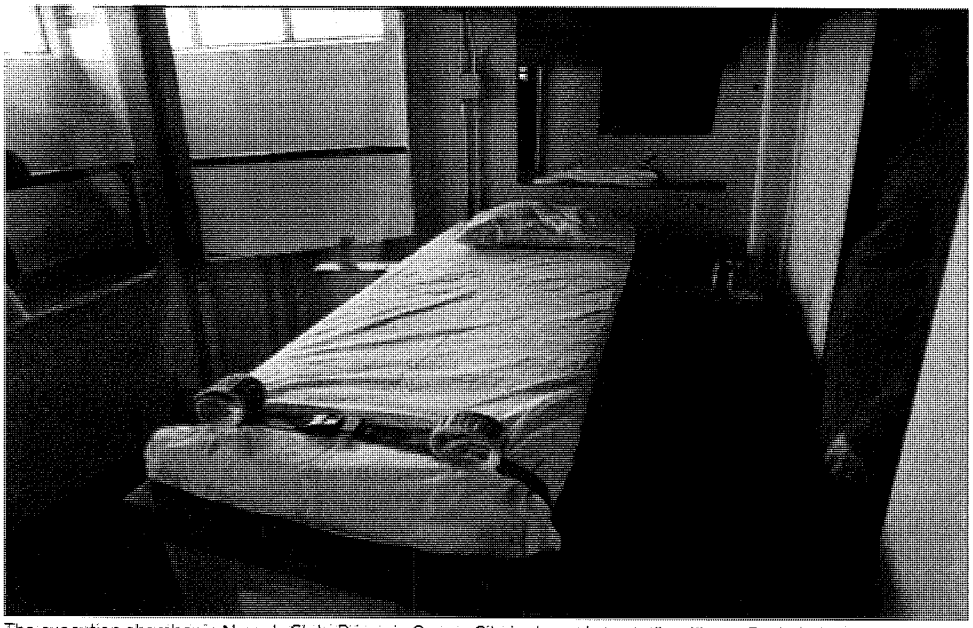
Texas, too, is apparently hedging its bets. Last fall, shipments of sodium thiopental, ordered by Texas and Arizona from an unapproved source in India, were seized in airports by federal officials.

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

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

EXHIBIT 5

Nevada receives no bids from companies to supply lethal-injection drugs



The execution chamber in Nevada State Prison in Carson City is shown in 2005. (Las Vegas Review-Journal)

By SANDRA CHEREB LAS VEGAS REVIEW-JOURNAL CAPITAL BUREAU
October 7, 2016 - 1:03 pm

CARSON CITY — Nevada prison officials said Friday 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 had expired. Not one response was received.

"We are confident the Purchasing Division solicited thoroughly for vendors," James Dzurenda, director of the Nevada Department of Corrections, said in a statement.

"Now we will work closely with the attorney general, the governor and the Legislature to examine our options and decide the best course of action moving forward."

Dzurenda in August told the state Board of Prison Commissioners chaired by Gov. Brian Sandoval that one of two drugs needed to execute a condemned inmate by lethal injection has expired and the drug company Pfizer refused to provide more supplies.

Nevada has used the drugs midazolam and hydromorphone to administer a lethal injection. Both are manufactured by Pfizer.

"Pfizer makes its products to enhance and save the lives of the patients we serve," the company said in a statement issued earlier this year. "Consistent with these values, Pfizer strongly objects to the use of its products as lethal injections for capital punishment."

The Nevada Legislature in the 2015 session approved spending $858,000 to build a new execution chamber at Ely State Prison, to replace the chamber in the now-closed Nevada State Prison in Carson City.

Officials have said that project is scheduled to be completed by Nov. 1 and the space will be used for storage and as an attorney-inmate meeting area if no executions are scheduled to go forward.

There are 81 inmates on Nevada's death row. No executions are on the immediate horizon. Without the supply of drugs, they could not be carried out even if one is ordered.

Under state law, Nevada is required to use lethal injection for executions. Changing the method Nevada uses to carry out executions would require approval by the state Legislature.

It's unknown what "options" Nevada officials might consider if drugs cannot be found.

Nevada is not alone in its inability to acquire drugs used to kill condemned inmates. In a recent article, Jennifer Horne with the Council of State Governments said dozens of states face the same dilemma. Some states are changing their protocols to use different drugs and some are trying to obtain drugs from foreign suppliers.

"Many states will have to change their method of execution, which means regulatory changes that have to be approved and lengthy court challenges." Richard Dieter, executive director of the Death Penalty Information Center, told Horne. "In many states, this could take months, if not years, delaying executions."

The last execution 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.

Contact Sandra Chereb at schereb@reviewjournal.com or 775-461-3821. Follow @SandraChereb on Twitter.

https://www.reviewjournal.com/post/110254

EXHIBIT 6

HIKMA
QUALITY

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

20 December 2016

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

Dear Mr. Laxalt,

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

We are extremely dismayed to learn that, despite our best efforts to ensure our medicines are used only for their intended medicinal purposes, some states continue to attempt to procure our products for use in lethal injection. Not only is this an off-label use and inconsistent with the FDA indication and contrary to our intention of manufacturing the product for the health and well-being of patients in need, but also it is completely counter to our values as an organization.

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

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

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

Sincerely,

Brooke S Clarke
VP Corporate Affairs

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

20 December 2016

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

Dear Governor Sandoval,

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1 New Burlington Place
London W1S 2HR
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Mr. James Dzurenda
Director
Department of Corrections
5500 Snyder Ave
P.O. Box 7011
Carson City, Nevada 89701
USA

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EXHIBIT 7

Nevada rejects Pfizer's demand to return execution drugs

By Ken Ritter Published 4:07 pm PST, Saturday, November 18, 2017

The state of Nevada is refusing pharmaceutical company Pfizer's demand to return a drug it manufactured and not use it in a planned lethal injection execution, a prison official said.

Nevada received a letter Oct. 4 similar to one received by officials in Nebraska and reported by the Omaha World-Herald, Nevada Department of Corrections spokeswoman Brooke Keast said.

The Nevada letter, obtained Friday by the Associated Press, seeks the return from the prisons pharmacy of the sedative diazepam or the opioid painkiller fentanyl made by Pfizer if they are intended for what the company calls "misuse" in an execution.

"Pfizer strongly objects to the use of its products as lethal injections for capital punishment," company executive Robert Jones said in the Oct. 4 letter, which promised to reimburse the state for the returned drug.

Pfizer announced in May 2016 it would block distribution of its products and those of its affiliate, Hospira, for executions in the 31 states in the U.S. with the death penalty. Company spokesman Steven Danehy in New York confirmed the authenticity of Jones' letter, but declined to comment about it.

Plans for Nevada's first execution in more than a decade — using a never-before-tried combination of diazepam, fentanyl and the muscle paralytic cisatracurium — were put on hold last week pending review by the state Supreme Court.

Diazepam is commonly known as Valium. Keast said the supply that Nevada received for the planned execution of twice-convicted murderer Scott Raymond Dozier was manufactured by Pfizer.

Invoice records show the drugs were obtained in late May from Cardinal Health, a company that Keast called the usual state prisons pharmacy supplier, at a combined cost of less than $500. Cardinal Health has not said if the company knew the intended use of the drugs.

"We are under no obligation, once we've made a purchase, to return it," Keast said.

In Nebraska, the Omaha World-Herald reported a similar Oct. 4 letter was among several documents released by the state Department of Corrections in response to public records requests from the newspaper and the American Civil Liberties Union of Nebraska.

Ken Ritter is an Associated Press writer.

EXHIBIT 8

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

12 December 2017

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

Dear Mr. Laxalt,

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

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

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

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

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

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12 December 2017

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

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12 December 2017

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5500 Snyder Ave,
P.O. Box 7011
Carson City, Nevada, 89701
USA

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Brooke S Clarke
VP Corporate Affairs

EXHIBIT 9

S (623) 478-8500

CardinalHealth

CARDINAL HEALTH
600 N 83RD AVE
TOLLESON, AZ 85353

PAGE 1 OF 1 ROUTE/STOP 307 / 010

RO

DEA RW-0263056 FED ID 68-0158739

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

REG NO.	CUST. DEA NO.	ORDER NO.	CUSTOMER P.O. NUMBER
CA00001	AS2995922	5265965	17XCO0039

ORDER DATE	CONF. NO.
9/28/17	03582

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

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

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

INVOICE SHIP DATE: 9/28/2017

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

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

Messages

121 This product is required by the FDA to be dispensed with a medication guide. To obtain a m
edication guide for this product, please visit http://www.fda.gov/Drugs/DrugSafety/ucm0857
29.htm

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

8351

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

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

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

307 / 010

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

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

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

EXHIBIT 10

10018739.1/000121

121/140 9:1

NEVADA DEPT OF CORRECTIONS
3955 W. RUSSELL RD-CASA GRANDE
CENTRAL PHARMACY
LAS VEGAS, NV 89118-0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AS2995922	10-31-2019	FEE EXEMPT

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	HOSPITAL/CLINIC	09-20-2016

NEVADA DEPT OF CORRECTIONS
3955 W. RUSSELL RD-CASA GRANDE
CENTRAL PHARMACY
LAS VEGAS, NV 89118-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (4/07)

EXHIBIT 11

Lewis Roca
ROTHGERBER CHRISTIE

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

775 823 2900 main
775 823 2929 fax
lrrc.com

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

July 11, 2018

VIA HAND DELIVERY

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

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

Dear Director Dzurenda:

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

Very truly yours,

Kristen L. Martini
Lewis Roca Rothgerber Christie LLP

KLM
Enclosure

hikma.

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR

T (0) 20 7399 2760

July 11th, 2018

The Honorable Brian Sandoval
Governor, State of Nevada

Mr. Adam Paul Laxalt
Attorney General, State of Nevada

Mr. James Dzurenda
Director, Nevada Department of Corrections

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

via Fax

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

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

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

(more)

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I look forward to receiving your response.

Sincerely,

Daniel Motto
Executive Vice President
Hikma/West-Ward Pharmaceuticals

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July 11, 2018

VIA HAND DELIVERY

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Attorney General, State of Nevada
5420 Kietzke Lane, Suite 202
Reno, Nevada 89511

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July 11th, 2018

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Governor, State of Nevada

Mr. Adam Paul Laxalt
Attorney General, State of Nevada

Mr. James Dzurenda
Director, Nevada Department of Corrections

Nevada State Capital Building
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via Fax

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Attorney General, State of Nevada

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

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

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

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

(more)

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

I look forward to receiving your response.

Sincerely,

Daniel Motto
Executive Vice President
Hikma/West-Ward Pharmaceuticals

EXHIBIT 12

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL

Effective Date: 06/11/2018

RPAPP0513

NDOC EXECUTION MANUAL INDEX

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

Effective Date: 06/11/2018

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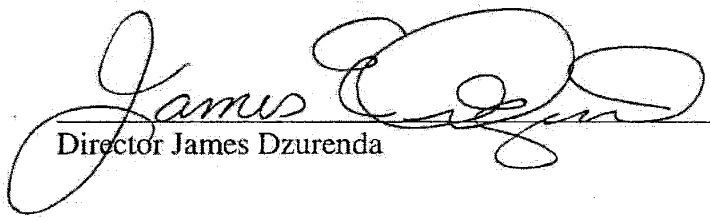
NDOC EXECUTION MANUAL

Effective Date: 06/11/2018

Signature Authority:



Director James Dzurenda

6/11/2018

Date

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 100
NEVADA LEGAL AUTHORITY

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: NO

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

The Attorney General's Office will be consulted to ensure that the legal authorities cited herein are up to date.

NEVADA REVISED STATUTES

100.01 PROCEEDINGS WHEN CONVICTION CARRIES DEATH PENALTY (NRS 176.345)

A. NRS 176.345 (Added to NRS by 1967, 1438; A 1977, 860; 1989, 390; 1999, 1048; 2001 Special Session, 218) states:

1. When a judgment of death has been pronounced, a certified copy of the judgment of conviction must be forthwith executed and attested in triplicate by the clerk under the seal of the court. There must be attached to the triplicate copies a warrant signed by the judge, attested by the clerk, under the seal of the court, which:

    a. Recites the fact of the conviction and judgment;

    b. Appoints a week, the first day being Monday and the last day being Sunday, within which the judgment is to be executed, which must not be less than 60 days nor more than 90 days from the time of judgment; and

    c. Directs the sheriff to deliver the prisoner to such authorized person as the Director of the Department of Corrections ("Director") designates to receive the prisoner, for execution. The prison must be designated in the warrant.

2. The original of the triplicate copies of the judgment of conviction and warrant must be filed in the office of the county clerk, and two of the triplicate copies must be immediately delivered by the clerk to the sheriff of the county. One of the triplicate copies must be delivered by the sheriff, with the prisoner, to such authorized person as the Director of the Department of Corrections designates, and is the warrant and authority of the Director for the imprisonment and execution of the prisoner, as therein provided and commanded. The Director shall return the certified copy of the judgment of

conviction to the county clerk of the county in which it was issued. The other triplicate copy is the warrant and authority of the sheriff to deliver the prisoner to the authorized person designated by the Director. The final triplicate copy must be returned to the county clerk by the sheriff with the sheriff's proceedings endorsed thereon.

100.02 EXECUTION OF DEATH PENALTY: METHOD; TIME AND PLACE; WITNESSES (NRS 176.355)

A. NRS 176.355 (Added to NRS by 1967, 1439; A 1977, 860; 1983, 1937; 1989, 390; 1995, 381; 2001 Special Session, 218), states:

1. The judgment of death must be inflicted by an injection of a lethal drug.

2. The Director of the Department of Corrections shall:

   a. Execute a sentence of death within the week, the first day being Monday and the last day being Sunday, that the judgment is to be executed, as designated by the district court. The Director may execute the judgment at any time during that week if a stay of execution is not entered by a court of appropriate jurisdiction.

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

   c. Be present at the execution.

   d. 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.

   e. Invite a competent physician, the county coroner, a psychiatrist and not less than six reputable citizens over the age of 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.

3. The execution must take place at the state prison.

4. A person who has not been invited by the Director may not witness the execution.

100.03 REQUEST FOR NOTIFICATION OF EXECUTION OF DEATH PENALTY; REQUEST TO ATTEND (NRS 176.357)

A. NRS 176.357 (Added to NRS by 1995, 318) states:

1. If after a conviction for murder a judgment of death has been pronounced, each member of the immediate family of the victim who is 21 years of age or older may submit a written request to the Director to be informed of the time, date and place scheduled for

the execution of the sentence of death. The request for notification may be accompanied by a written request to attend or nominate a representative to attend the execution.

2. As used in this section, "immediate family" means persons who are related by blood, adoption or marriage, within the second degree of consanguinity or affinity.

100.04 DIRECTOR OF DEPARTMENT OF CORRECTIONS TO MAKE RETURN ON DEATH WARRANT (NRS 176.365)

A. NRS 176.365 (Added to NRS by 1967, 1439; A 1977, 860; 2001 Special Session, 219) states:

1. After the execution, the Director of the Department of Corrections must make a return upon the death warrant to the court by which the judgment was rendered, showing the time, place, mode and manner in which it was executed.

100.05 WHEN EXECUTION OF DEATH PENALTY MAY BE STAYED (NRS 176.415)

A. NRS 176.415 (Added to NRS by 1967, 1440; A 1987, 1221; 2003, 768; 2007, 25; 2013, 686, 1756) states:

1. By the State Board of Pardons Commissioners as authorized in Section 14 of Article 5 of the Constitution of the State of Nevada;

2. By the Governor if the Governor grants a reprieve pursuant to Section 13 of Article 5 of the Constitution of the State of Nevada;

3. When a direct appeal from the judgment of conviction and sentence is taken to the Supreme Court;

4. By a judge of the district court of the county in which the state prison is situated, for the purpose of an investigation of sanity or pregnancy as provided in NRS 176.425 to 176.485, inclusive;

5. By a judge of the district court in which a motion is filed pursuant to subsection 5 of NRS 175.554, for the purpose of determining whether the defendant is mentally retarded; or

6. Pursuant to the provisions of NRS 176.0919 or 176.486 to 176.492, inclusive.

100.06 SANITY INVESTIGATION: FILING OF PETITION; STAY OF EXECUTION (NRS 176.425)

A. NRS 176.425 (Added to NRS by 1967, 1440; A 1977, 861; 1991, 1002; 2001 Special Session, 219) states:

1. If, after judgment of death, there is a good reason to believe that the defendant has become insane, the Director of the Department of Corrections to whom the convicted person has been delivered for execution may by a petition in writing, verified by a physician, petition a district judge of the district court of the county in which the state

prison is situated, alleging the present insanity of such person, whereupon such judge shall:

a. Fix a day for a hearing to determine whether the convicted person is insane;

b. Appoint two psychiatrists, two psychologists, or one psychiatrist and one psychologist, to examine the convicted person; and

c. Give immediate notice of the hearing to the Attorney General and to the district attorney of the county in which the conviction was had.

2. If the judge determines that the hearing on and the determination of the sanity of the convicted person cannot be had before the date of the execution of such person, the judge may stay the execution of the judgment of death pending the determination of the sanity of the convicted person.

100.07 SANITY INVESTIGATION: CONDUCT OF HEARING (NRS 176.435)

A. NRS 176.435 (Added to NRS by 1967, 1440; A 1977, 861; 2001 Special Session, 219) states:

1. On the day fixed, the Director of the Department of Corrections shall bring the convicted person before the court, and the Attorney General or the Attorney General's deputy shall attend the hearing. The district attorney of the county in which the conviction was had, and an attorney for the convicted person, may attend the hearing.

2. The court shall receive the report of the examining physicians and may require the production of other evidence. The Attorney General or the Attorney General's deputy, the district attorney, and the attorney for the convicted person or such person if the convicted person is without counsel may introduce evidence and cross-examine any witness, including the examining physicians.

3. The court shall then make and enter its finding of sanity or insanity.

100.08 EXECUTION OF JUDGMENT WHEN DEFENDANT FOUND SANE (NRS 176.445)

A. NRS 176.445 (Added to NRS by 1967, 1441; A 1977, 861; 2001 Special Session, 219) states:

1. If it is found by the court that the convicted person is sane, the Director of the Department of Corrections must execute the judgment of death; but if the judgment has been stayed, as provided in NRS 176.425, the judge shall cause a certified copy of the order staying the execution of the judgment, together with a certified copy of the judge's finding that the convicted person is sane, to be immediately forwarded by the clerk of the court to the clerk of the district court of the county in which the conviction was had, who shall give notice thereof to the district attorney of such county. Proceedings shall then be instituted in the last mentioned district court for the issuance of a new warrant of execution of the judgment of death in the manner provided in NRS 176.495.

100.09 SUSPENSION OF EXECUTION WHEN DEFENDANT FOUND INSANE; PROCEEDINGS ON RECOVERY OF SANITY (NRS 176.455)

A. NRS 176.455 (Added to NRS by 1967, 1441; A 1977, 861; 2001 Special Session, 219) states:

1. If it is found by the court that the convicted person is insane, the judge shall make and enter an order staying the execution of the judgment of death until the convicted person becomes sane, and shall therein order the Director of the Department of Corrections to confine such person in a safe place of confinement until the convicted person's reason is restored.

2. The clerk of the court shall serve or cause to be served three certified copies of the order, one on the Director, one on the Governor, for the use of the State Board of Pardons Commissioners, and one on the clerk of the district court of the county in which the conviction was had.

3. If the convicted person thereafter becomes sane, notice of this fact shall be given by the Director to a judge of the court staying the execution of the judgment, and the judge, upon being satisfied that such person is then sane, shall enter an order vacating the order staying the execution of the judgment.

4. The clerk of the court shall immediately serve or cause to be served three certified copies of such vacating order as follows: one on the Director, one on the Governor, for the use of the State Board of Pardons Commissioners, and one on the clerk of the district court of the county in which the conviction was had, who shall give notice thereof to the district attorney of such county, whereupon proceedings shall be instituted in the last mentioned district court for the issuance of a new warrant of execution of the judgment of death in the manner provided in NRS 176.495.

100.10 INVESTIGATION OF PREGNANCY: PROCEDURE; HEARING (NRS 176.465)

A. NRS 176.465 (Added to NRS by 1967, 1441; A 1977, 862; 2001 Special Session, 220) states:

1. If there is good reason to believe that a female against whom a judgment of death has been rendered is pregnant, the Director of the Department of Corrections to whom she has been delivered for execution shall petition a judge of the district court of the county in which the state prison is situated, in writing, alleging such pregnancy, whereupon such judge shall summon a jury of three physicians to inquire into the alleged pregnancy and fix a day for the hearing thereon, and give immediate notice thereof to the Attorney General and to the district attorney of the county in which the conviction was had.

2. The provisions of NRS 176.425 and 176.435 apply to the proceedings upon the inquisition, except that three physicians shall be summoned. They shall certify in writing to the court their findings as to pregnancy.

100.11 PROCEEDINGS AFTER INVESTIGATION: EXECUTION OF JUDGMENT; SUSPENSION OF EXECUTION; ISSUANCE OF WARRANT ON TERMINATION OF PREGNANCY (NRS 176.475)

A. NRS 176.475 (Added to NRS by 1967, 1442; A 1977, 862; 2001 Special Session, 220) states:

1. If it is found by the court that the female is not pregnant, the Director of the Department of Corrections must execute the judgment of death; but if a stay of execution has been granted pursuant to NRS 176.425 the procedure provided in NRS 176.445 is applicable.

2. If the female is found to be pregnant, the judge shall enter an order staying the execution of the judgment of death, and shall therein order the Director to confine such female in a safe place of confinement commensurate with her condition until further order of the court.

3. When such female is no longer pregnant, notice of this fact shall be given by the Director to a judge of the court staying the execution of the judgment. Thereupon the judge, upon being satisfied that the pregnancy no longer exists, shall enter an order vacating the order staying the execution of the judgment and shall direct the clerk of such court to serve or cause to be served three certified copies of such order, one on the Director, one on the Governor for the use of the State Board of Pardons Commissioners, and one on the clerk of the district court of the county in which the conviction was had, who shall give notice thereof to the district attorney of such county, whereupon proceedings shall be instituted in the last mentioned district court for the issuance of a new warrant of execution of the judgment in the manner provided in NRS 176.495.

100.12 ENTRY OF STAY OF EXECUTION AND NECESSARY ORDERS (NRS 176.488)

A. NRS 176.488 (Added to NRS by 1987, 1221; A 2001 Special Session, 221) states:

1. A stay of execution must be entered by the court in writing and copies sent as soon as practicable to the Director of the Department of Corrections, the warden of the institution in which the offender is imprisoned and the Office of the Attorney General in Carson City. The court shall also enter an order and take all necessary actions to expedite further proceeding before that court.

100.13 STAY OF EXECUTION FOLLOWING DENIAL OF APPEAL (NRS 176.491)

A. NRS 176.491 (Added to NRS by 1987, 1221; A 1989, 491) states:

1. Upon the denial of any appeal to the Supreme Court pursuant to chapter 34 or 177 of NRS, the Supreme Court shall dissolve any stay of execution previously entered. No stay of such execution may be entered or continued by the Supreme Court after the denial of an appeal pending the filing of a petition with a federal court or a petition for a writ of certiorari with the Supreme Court of the United States.

2. The entry of a stay of issuance of a remittitur in the Supreme Court does not prohibit the application of or the issuance of a warrant of execution by the district court in which the conviction was obtained.

3. To stay the execution of a sentence of death following the denial of any appeal to the Supreme Court pursuant to chapter 34 or 177 of NRS, a person under sentence of death must:

   a. Apply for and obtain a stay in the federal court in which the person applies for a writ of certiorari or habeas corpus; or

   b. Obtain a stay of execution pursuant to NRS 176.487.

100.14 NEW WARRANT GENERALLY (NRS 176.495)

A. NRS 176.495 (Added to NRS by 1967, 1442; A 1977, 863; 1989, 391; 2001 Special Session, 221; 2003, 2083) states:

1. If for any reason a judgment of death has not been executed, and it remains in force, the court in which the conviction was had must, upon the application of the Attorney General or the district attorney of the county in which the conviction was had, cause another warrant to be drawn, signed by the judge and attested by the clerk under the seal of the court, and delivered to the Director of the Department of Corrections.

2. The warrant must state the conviction and judgment and appoint a week, the first day being Monday and the last day being Sunday, within which the judgment is to be executed. The first day of that week must be not less than 15 days nor more than 30 days after the date of the warrant. The Director shall execute a sentence of death within the week the judgment is to be executed, as designated by the district court. The Director may execute the judgment at any time during that week if a stay of execution is not entered by a court of appropriate jurisdiction.

100.15 ORDER FOLLOWING APPEAL (NRS 176.505)

A. NRS 176.505 (Added to NRS by 1967, 1442; A 1977, 863; 1989, 491; 2001 Special Session, 221) states:

1. When a remittitur showing the affirmation of a judgment of death has been filed with the clerk of the court from which the appeal has been taken, the court in which the conviction was obtained shall inquire into the facts, and, if no legal reasons exist prohibiting the execution of the judgment, shall make and enter an order requiring the Director of the Department of Corrections to execute the judgment at a specified time. The presence of the defendant in the court at the time the order of execution is made and entered, or the warrant is issued, is not required.

2. When an opinion, order dismissing appeal or other order upholding a sentence of death is issued by the Supreme Court pursuant to chapter 34 or 177 of NRS, the court in which the sentence of death was obtained shall inquire into the facts and, if no legal reason exists prohibiting the execution of the judgment, shall make and enter an order requiring

the Director of the Department of Corrections to execute the judgment during a specified week. The presence of the defendant in the court when the order of execution is made and entered, or the warrant is issued, is not required.

3. Notwithstanding the entry of a stay of issuance of a remittitur in the Supreme Court following denial of appellate relief in a proceeding brought pursuant to chapter 34 or 177 of NRS, the court in which the conviction was obtained shall, upon application of the Attorney General or the district attorney of the county in which the conviction was obtained, cause another warrant to be drawn, signed by the judge and attested by the clerk under the seal of the court, and delivered to the Director of the Department of Corrections.

100.16 AUTHORITY TO POSSESS AND ADMINISTER DANGEROUS DRUG (NRS 454.213)

A. NRS 454.213*(1) (k)* states that "[a] drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by:" "[a]ny person designated by the head of a correctional institution." *See* NRS 454.213 [Effective January 1, 2012] (Added to NRS by 1979, 1682; A 1981, 60, 746; 1983, 1221, 1515, 1937; 1987, 952, 1657, 2215; 1989, 749; 1991, 1956; 1993, 1216, 2839; 1995, 725, 1691; 1999, 2720; 2001, 2, 789, 792; 2003, 2296; 2005, 2476; 2007, 1866; 2009, 1534; 2011, 1341, 2609, 3080, effective January 1, 2012)

100.17 FURNISHING DANGEROUS DRUG WITHOUT PRESCRIPTION PROHIBITED; PENALTY; EXCEPTIONS (NRS 454.221)

A. NRS 454.221(2)(f) states that "[t]he provisions of this section do not apply to the furnishing of any dangerous drug by:" "[a] pharmacy in a correctional institution to a person designated by the Director of the Department of Corrections to administer a lethal injection to a person who has been sentenced to death." *See* NRS 454.221 (Added to NRS by 1973, 1197; A 1975, 354; 1977, 673, 938; 1979, 594, 1676; 1981, 747; 1983, 453, 1938; 1985, 887, 1701; 1987, 1658; 1989, 1126; 1991, 795; 1993, 451, 2841; 1995, 301, 1292, 1329; 2001, 791; 2001 Special Session, 242; 2007, 1868)

THE CONSTITUTION OF THE STATE OF NEVADA

100.18 REMISSION OF FINES AND FORFEITURE; COMMUTATIONS AND PARDONS; SUSPENSION OF SENTENCE; PROBATION

A. Section 14 of Article 5 of the Constitution of the State of Nevada (Amended in 1950 and 1982) states:

1. The governor, justices of the supreme court, and attorney general, or a major part of them, of whom the governor shall be one, may, upon such conditions and with such limitations and restrictions as they may think proper, remit fines and forfeitures, commute punishments, except as provided in subsection 2, and grant pardons, after convictions, in all cases, except treason and impeachments, subject to such regulations as may be provided by law relative to the manner of applying for pardons.

2. Except as may be provided by law, a sentence of death or a sentence of life imprisonment without possibility of parole may not be commuted to a sentence which would allow parole.

3. The legislature is authorized to pass laws conferring upon the district courts authority to suspend the execution of sentences, fix the conditions for, and to grant probation, and within the minimum and maximum periods authorized by law, fix the sentence to be served by the person convicted of crime in said courts.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 101
MEDIA ACCESS

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: NO

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

The Public Information Officer (PIO) will be consulted to ensure that this manual is consistent with contemporary media procedures.

101.01 MEDIA REQUESTS FOR INTERVIEWS WITH CONDEMNED INMATE

A. Upon receiving notice that an execution has been scheduled, the Public Information Officer ("PIO") will determine whether the condemned inmate wants to receive requests from the media for interviews and if the condemned inmate's attorney will approve of media interviews.

B. If the condemned inmate is interested in receiving requests from the media for interviews and the condemned inmate's attorney approves of media interviews:

1. The condemned inmate must complete and sign an Inmate's Authorization for Photography, Recording or Publicity (DOC 3008) prior to the commencement of any media interview.

    a. A copy of the completed and signed Inmate's Authorization for Photography, Recording or Publicity (DOC 3008) will be placed in the condemned inmate's Institutional File.

2. The PIO may make direct contact with the condemned inmate when an interview is requested by a member of the media. This may be done without the required letters indicated within Section 120.07(3) of NDOC Administrative Regulation 120, entitled *News Media Contacts Press Releases*.

3. The media may conduct interviews with the condemned inmate one (1) week prior to the scheduled execution date. Interviews will take place in the Execution Holding Area designated for visits and interviews.

    a. The media may conduct interviews via telephone if the condemned inmate so desires.

b. The condemned inmate may terminate an interview at any time.

c. News media and media representative who wish to access NDOC institutions/facilities for purposes of interviewing the condemned inmate, must follow the procedures set forth herein and NDOC Administrative Regulation 120, entitled *News Media Contacts Press Releases* and all other applicable laws and NDOC regulations.

C. If the condemned inmate is not interested in receiving requests from the media for interviews and/or the condemned inmate's attorney does not approve of media interviews, the PIO will advise the media.

101.02 MEDIA ACCESS TO INSTITUTIONS/FACILITIES FOR PURPOSES OF INTERVIEWING A CONDEMNED INMATE

A. News media and other media representatives who wish to access a NDOC institution/facility for the purpose of interviewing a condemned inmate must submit a written request, on company letterhead, to the PIO that includes the following information:

1. Each person's full name, title and contact information;

2. The purpose of the interview including the name and NDOC ID# of the condemned inmate that the member(s) of their organization wishes to see;

3. The requested date, time and duration of the interview; and

4. If requesting to bring equipment, a list of proposed equipment including camera(s) and other recording device(s);

    a. News media or other media representatives who obtain prior authorization from the Warden to bring a camera or other recording device into the institution/facility must also complete and sign a Media Visit Information Sheet (DOC 046) prior to being allowed into the institution/facility.

B. The PIO will be responsible for reviewing written requests from news media and other media representatives for access to institutions/facilities for the purpose of interviewing a condemned inmate, and, if approved, facilitating, scheduling and coordinating such media interviews.

1. The PIO may request additional information and/or documentation from the news media/other media representative for the purpose of considering the written request for access to institutions/facilities for the purpose of interviewing a condemned inmate and/or facilitating, scheduling and coordinating such media interviews.

C. News media and other media representatives will only be granted access to the facility/institution subject to approval of time, manner and place restrictions relating to safety, security, discipline and the orderly operation of the prison, and consistent with preserving condemned inmate and staff rights to privacy.

1. News media and other media representatives will only be permitted to bring the pre-approved equipment which may include but is not limited to a camera or other recording device into the institution/facility. Prior authorization must be obtained from the Warden.

2. The safety, security and rights to privacy of NDOC employees, inmates, and approved visitors, and the safety, security and operations of the institution/facility are paramount.

3. The number of members of the news media and other media representatives and equipment (including cameras and recording devices) entering the institution/facility may be limited.

D. News media and other media representatives must provide positive identification. Foreign media, except for Canadians, must have an "I" Visa on their passport, prior to being allowed into the institution/facility.

E. News media and other media representatives must submit to a search of their person (i.e. clothed body search and metal detector inspection), vehicle or any other property, that they have brought onto NDOC property.

1. News media or other media representative will be required to complete and sign a Consent to Search (DOC 1615) prior to being allowed into the institution/facility.

F. News media and other media representatives must complete and sign a News Media Agreement (DOC 045) prior to being allowed into the institution/facility.

G. News media and other media representatives shall be escorted throughout the institution/facility by an Associate Warden to ensure compliance with NDOC regulations and for the security of the media team.

1. Interviews with a condemned inmate are subject to the visiting procedures and rules established by way of NDOC Administrative Regulation 719, Inmate Visitation, the AR 719 Visitation Manual, and the applicable institution/facility Operational Procedures.

   a. Failure to comply with all applicable rules and procedures may result in termination of the interview.

2. News media and other media representative interviews with a condemned inmate will take place in the Execution Holding Area designated for visits and interviews. The condemned inmate may be placed in restraints or the visit may be conducted in a non-contact visiting area.

3. Random access to the institution/facility not specific to the purpose of the visit (i.e. interviewing the condemned inmate) is prohibited.

4. In the event of an unusual occurrence or emergency, the interview with the condemned inmate will be suspended and the news media and other media representatives will be restricted to a designated area of the institution/facility.

101.03 MEDIA WITNESSES TO THE EXECUTION

A. The PIO is responsible for developing a list of potential media witnesses to the execution and submitting the list to the Director.

B. News media and other media representatives who wish to be considered as a potential media witness to the execution must submit a written request, on company letterhead, to the PIO within one (1) week of the execution warrant being issued that includes the pertinent information.

C. The Director, in his sole discretion, shall determine whether to approve a member of the news media or other media representative to be a witness to the execution.

1. A person who has not been invited by the Director may not witness the execution.

2. Courtroom artists will not be approved as media witnesses to the execution.

D. Media witnesses to the execution will not be permitted to take any cell phones, cameras, recording devices or any other personal items into the institution/facility where the execution will take place and/or any other pre-execution staging areas.

1. Any attempt to bring cellphones and/or recording or photography equipment (i.e. cameras or recording devices) into the institution/facility where the execution will take place and/or any other pre-execution staging areas will result in immediate revocation of the Director's previously issued invitation to witness the execution.

E. Media witnesses to the execution are not allowed to interview any other witnesses to the execution on NDOC property/prison grounds.

F. All members of the news media and other media representatives who expect to gain access onto institutional grounds must be pre-approved by the PIO. All members of the news media and other media representatives will be restricted to the area in the parking lot designated for the media and marked "MEDIA ONLY". Only those members of the news media and other media representatives who have been expressly invited by the Director to witness the execution will be allowed access through the Gatehouse per these procedures.

G. Members of the news media and all other media representatives will be required to leave institutional grounds within one (1) hour of the Media Witnesses group returning to their designated area of the parking lot at the conclusion of the condemned inmate's execution.

101.04 MEDIA INQUIRIES ON THE DATE OF THE EXECUTION

A. NDOC's PIO will distribute the telephone number designated to receive calls concerning the execution, via press release, 24 hours prior to the time of the scheduled execution.

B. Media inquiries on the date of the execution should be made only to the telephone number designated to receive calls concerning the execution. Information released will be via press releases prepared by the PIO.

1. A NDOC Execution Telephone Log will be maintained by the assigned individual manning the telephone.

2. The completed telephone log will be will be turned into the Warden's office. All documents, memorandums, the telephone log and any other correspondence pertaining to the execution will be retained in a file drawer of the Warden's Administrative Assistant.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 102
WITNESS SELECTION CRITERIA AND INSTRUCTIONS

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: NO

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

102.01 WITNESSES TO THE EXECUTION

A. The Director of the Department of Corrections ("Director") shall be present at the execution. NRS 176.355(2)(c).

B. The Director shall invite the following to be present at the execution (NRS 176.355(2)(e):

1. A competent Physician;
2. The County Coroner; (in White Pine County this person is the same as certain trained members of the White Pine County Sheriff's Department)
3. A psychiatrist;
4. Not less than six (6) reputable citizens over the age of 21 years.

In addition, the following may be invited to be present at the execution:

- The County Sheriff; (in White Pine County , certain members of the Sheriff's Department are trained as county coroner's)
- A local mortician;
- The spiritual advisor of the condemned inmate who is scheduled to be executed and/or the facility chaplain; and
- The District Attorney of the sentencing county.

C. Two weeks prior to the scheduled execution, the designated Warden will provide notification to the Department of Public Safety, Sheriff and Coroner in writing of the execution and request a police unit from both agencies to be on-site for the execution. A letter will be hand delivered to all three of those agencies by a NDOC staff member.

D. The Director, in his sole discretion, shall determine the maximum number of persons who may be present for the execution per NRS 176.355(2)(e). If all who are invited also elect to attend, there will be up to four specific groups of witnesses: Official witnesses, Victim witnesses, Media witnesses and Inmate Family members.

E. 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. NRS 176.355(2)(c).

1. The Director shall 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. NRS 176.355(2)(d).

F. A person who has not been invited by the Director may not witness the execution. NRS 176.355(4).

G. One week prior to scheduled execution date a confidential list of approved Official, Victim and Media Witnesses as well as Inmate Family members will be finalized and distributed to the Execution Management Team.

H. After the condemned inmate has been secured to the execution table and made ready for the final execution procedure, a person who has been invited by the Director as a witnesses will be permitted to view the execution.

102.02 WITNESSES PROCEDURE

A. A person who has been invited by the Director to witness the execution will be provided with individualized instructions two weeks prior to scheduled execution regarding the location and time that they will need to arrive prior to the execution to be checked-in and processed.

B. Witnesses to the execution must present proof of a valid current State or Federally issued photo identification (i.e. Driver's License, Passport, or Consular I.D.), and other vital information upon request, prior to being issued a Witness/Media Pass and being permitted to gain entry to the institution/facility where the execution will take place and/or any other pre-execution staging areas.

C. Witnesses to the execution must submit to a search of their person (i.e. clothed body search and metal detector inspection), vehicle or any other property, that they have brought onto NDOC property.

1. All witnesses and inmate family members will be required to complete and sign a Consent to Search (DOC 1615) prior to being allowed into the institution/facility.

D. No witness to the execution, including Media Witnesses, will be permitted to take any cameras, recording devices, cell phones, or personal items into the institution/facility where the execution will take place and/or any other pre-execution staging areas.

1. Any attempt to bring cellphones, recording or photography equipment (i.e. cameras or recording devices) into the institution/facility where the execution will take place and/or

any other pre-execution staging areas will result in immediate revocation of the Director's previously issued invitation to witness the execution.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 103
ACQUISITION AND PREPARATION OF DRUGS FOR LETHAL INJECTION

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: NO

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

103.01 LETHAL INJECTION PROTOCOL

A. Lethal drugs are to be used in the execution. Although the combination of drugs and doses listed below are lethal for most individuals, individual differences do exist. It shall be the responsibility of the Director to consult with the Chief Medical Officer in order to ensure that the selected lethal drug or combination of drugs and their dosages to be used in the execution are sufficient to cause death. The Director shall then select the drug, combination of drugs and dosages to be used for the execution. This information will not be withheld from the inmate or the public.

1. The NDOC Public Information Officer (PIO) will prepare and produce a statement on behalf of the Nevada Department of Corrections.

B. The Director will provide the condemned inmate with written notice of the drug or combination of drugs that will be used for the execution after a final decision has been made and no less than seven (7) calendar days prior to the first day of the week (i.e. Monday), as designated by the district court, that the judgment of death is to be executed.

1. If at any time after written notice of the drug or combination of drugs to be used for the execution has been provided to the condemned inmate, the Director determines that it is necessary to change the Lethal Injection Protocol identified and provided in CEM 110.02, a written notice of the Director's determination, which identifies the necessary changes to the Lethal Injection Protocol and an explanation as to the basis for such changes, will be immediately provided to both the condemned inmate and the condemned inmate's counsel of record.

C. The drug amounts specified below are designed for the execution of persons weighing 500 pounds or less. The drug amounts will be reviewed and revised, as necessary, for a condemned inmate exceeding 500 pounds.

103.02 ACQUIRING LETHAL DRUGS AND EQUIPMENT

A. After the Director makes the final decision as to the drug or combination of drugs that will be used for the scheduled execution, the designated Deputy Director/designated Warden will be responsible for:

1. Confirming that the equipment and materials necessary to properly conduct the execution is on site, immediately available for use and functioning properly.

2. Ensuring all medical equipment, including a backup cardiac monitor is on site, immediately available for use and functioning properly.

3. Ensuring that the drugs identified are acquired, arrive at Ely State Prison (ESP) no later than the day of execution and are properly stored. The drugs shall be stored in a secured locked area that is temperature regulated and monitored to ensure compliance with manufacturer specifications, under the direct control of the designated Warden.

103.03 PREPARATION OF LETHAL DRUGS

A. At the appropriate time, approximately two hours prior to the scheduled execution, the designated Warden shall transfer custody of the drugs to two members of the Security Team who have been selected by the designated Deputy Director as the Drug Administrators. The Drug Administrators will be two individuals who, based upon 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 then injecting the lethal drugs into the condemned inmate per these instructions when so ordered.

B. The quantity of the lethal drugs may not be changed without prior approval of the Director.

C. It is the responsibility of the Drug Administrators to prepare the lethal drugs. An Attending Physician or other properly trained and qualified medical professional will observe the Drug Administrators as they prepare the lethal drugs.

1. Both Drug Administrators shall complete detailed written reports describing the preparation and labeling of the lethal drugs.

a. The Drug Administrators shall be responsible for preparing and labeling the assigned syringes in a distinctive manner identifying the specific lethal drug contained in each syringe by (1) lethal drug name, (2) lethal drug amount and (3) assigned number. This information shall be preprinted on a label, with one label affixed to each syringe to ensure a label remains visible.

b. The syringes for each lethal drug by name will then be placed in an individual tray marked for all the syringes of that lethal drug. The labels for each tray and each syringe it contains will be colored to match: red in color for Midazolam, white in color for Fentanyl and blue in color for Cis-atracurium.

c. The drugs and their doses are to be prepared and labeled as follows:

i. Tray-1: Midazolam (labels to be red in color)

		DRUG	CONCENTRATION	SYRINGE	TOTAL
1.	#1-1	Midazolam	5mg/cc	10ml	50mg
2.	#1-2	Midazolam	5mg/cc	10ml	50mg
3.	#1-3	Midazolam	5mg/cc	10ml	50mg
4.	#1-4	Midazolam	5mg/cc	10ml	50mg
5.	#1-5	Midazolam	5mg/cc	10ml	50mg
6.	#1-6	Midazolam	5mg/cc	10ml	50mg
7.	#1-7	Midazolam	5mg/cc	10ml	50mg
8.	#1-8	Midazolam	5mg/cc	10ml	50mg
9.	#1-9	Midazolam	5mg/cc	10ml	50mg
10.	#1-10	Midazolam	5mg/cc	10ml	50mg

11. In the unlikely event that it is deemed necessary (see protocol in EM 110), additional syringes of Midazolam may be ordered by the Director, and then prepared and injected by the Drug Administrators. If ordered, additional syringes will be similarly labeled and numbered next in sequence, for example the next syringe would be numbered #1-11, then #1-12 and so on.

ii. Tray-2: Fentanyl (labels to be white in color)

		DRUG	CONCENTRATION	SYRINGE	TOTAL
1.	#2-1	Fentanyl	50mcg/cc	10ml	500mcg
2.	#2-2	Fentanyl	50mcg/cc	10ml	500mcg
3.	#2-3	Fentanyl	50mcg/cc	10ml	500mcg
4.	#2-4	Fentanyl	50mcg/cc	10ml	500mcg
5.	#2-5	Fentanyl	50mcg/cc	10ml	500mcg
6.	#2-6	Fentanyl	50mcg/cc	10ml	500mcg
7.	#2-7	Fentanyl	50mcg/cc	10ml	500mcg

8.	#2-8	Fentanyl	50mcg/cc	10ml	500mcg
9.	#2-9	Fentanyl	50mcg/cc	10ml	500mcg
10.	#2-10	Fentanyl	50mcg/cc	10ml	500mcg
11.	#2-11	Fentanyl	50mcg/cc	10ml	500mcg
12.	#2-12	Fentanyl	50mcg/cc	10ml	500mcg
13.	#2-13	Fentanyl	50mcg/cc	10ml	500mcg
14.	#2-14	Fentanyl	50mcg/cc	10ml	500mcg
15.	#2-15	Fentanyl	50mcg/cc	10ml	500mcg

16. In the unlikely event that it is deemed necessary (see protocol in EM 110), additional syringes of Fentanyl may be ordered by the Director, and then prepared and injected by the Drug Administrators. If ordered, additional syringes will be similarly labeled and numbered next in sequence, for example the next syringe would be numbered #2-16, then #2-17 and so on.

iii. Tray-3: Cis-atracurium (labels to be blue in color)

		DRUG	CONCENTRATION	SYRINGE	TOTAL
1.	#3-1	Cis-atracurium	2mg/1ml	10ml	20mg
2.	#3-2	Cis-atracurium	2mg/1ml	10ml	20mg
3.	#3-3	Cis-atracurium	2mg/1ml	10ml	20mg
4.	#3-4	Cis-atracurium	2mg/1ml	10ml	20mg
5.	#3-5	Cis-atracurium	2mg/1ml	10ml	20mg
6.	#3-6	Cis-atracurium	2mg/1ml	10ml	20mg
7.	#3-7	Cis-atracurium	2mg/1ml	10ml	20mg
8.	#3-8	Cis-atracurium	2mg/1ml	10ml	20mg
9.	#3-9	Cis-atracurium	2mg/1ml	10ml	20mg
10.	#3-10	Cis-atracurium	2mg/1ml	10ml	20mg

11. In the unlikely event that it is deemed necessary (see protocol in EM 110), additional syringes of Cis-atracurium may be ordered by the Director, and then prepared and injected by the Drug Administrators. If ordered, additional syringes will be similarly labeled and numbered next in

sequence, for example the next syringe would be numbered #3-11, then #3-12 and so on.

2. One Drug Administrator will prepare and label the lethal drug syringes. The second Drug Administrator will observe, verify the preparation, dosage and labeling of each syringe. The second Drug Administrator will then place the syringes in their correct trays for use.

3. The Drug Administrators shall prepare the designated lethal drugs and syringes so that the correct number of syringes are prepared and placed in each correctly labeled tray.

   a. To prepare each syringe for use, the Drug Administrator will draw the appropriate amount of supplied drug solution into each syringe so that the specified dose of each drug is made ready in each syringe.

      i. Midazolam will be used at a concentration of 5 milligrams per milliliter. For this drug, the specified doses to be prepared are 50 milligrams in 10 milliliter syringes. In order to achieve those doses, the Drug Administrator will draw ten (10) milliliters of the supplied solution into each 10 milliliter syringe labeled to contain Midazolam.

      ii. Fentanyl will be used at a concentration of 50 micrograms per milliliter. For this drug, the specified doses to be prepared are 500 micrograms in each 10 milliliter syringe. In order to achieve those doses, the Drug Administrator will draw ten (10) milliliters of the supplied solution into each 10 milliliter syringe labeled to contain Fentanyl.

      iii. Cis-actracurium will be used at a concentration of 2 milligrams per milliliter. For this drug, the specified doses to be prepared are 20 milligrams in each 10 milliliter syringe. In order to achieve those doses, the Drug Administrator will draw ten (10) milliliters of the supplied solution into each 10 milliliter syringe labeled to contain Cis-atracurium.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 104
LIST OF NEEDED EQUIPMENT, MATERIALS AND EXTERNAL/INTERNAL CONTACTS

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

104.01 NEEDED MEDICAL EQUIPMENT AND MATERIALS

A. One gel pillow
B. Twelve Bio-bags
C. Twelve white hand towels
D. Hot packs – 6 x 9 instant style
E. One box underpads
F. Portable suction machine and canister
G. Suction tubing
H. Resuscitator with bag and mask
I. Oxygen tank
J. Oxygen masks
K. Curved Laryngoscope
L. Trach tubes
M. Heplocks
N. Pulse Oximetry cable extension
O. Pulse Oximetry clip
P. Rolling medical stool (for use during setting of IV's)
Q. Portable stretcher, equipped with securing straps, one blanket and one pillow
R. Wheelchair
S. Automated external defibrillator (AED)
T. One stop watch
U. One stethoscope
V. Surgical shears
W. One flashlight
X. Four medium straight hemostats
Y. Four tourniquets
Z. Adhesive tape, both narrow and wide
AA. One roll of gauze
BB. Several gauze pads
CC. Alcohol

DD. Sponges
EE. One tongue depressor
FF. Four 18-gauge intercath needles, 1 ¾ inches long
GG. Four 20-gauge intercath needles, 1 ¾ inches long
HH. Four standard fluid administration tubing sets with "Y" injection site 3 to 4 inches long
II. Four extension sets 48 inches by 24 feet
JJ. Four injection needles, 20 gauge, 2 inches
KK. Twenty-four 10cc syringes for injection
LL. Eight 20cc syringes for sterile saline for injection
MM. Forty 18 gauge 1 ½ inch needles
NN. Six vials of sterile saline for injection
OO. Number of required vials of lethal drugs for injection
PP. Pre-printed Lethal Drug syringe labels
QQ. Twelve small Sharps containers
RR. 20 vials of NARCAN
SS. 20 vials of ROMAZICON
TT. Two sterile cut-down trays
UU. Two Electrocardiogram machines and two sets of leads
VV. EKG patches
WW. Extra-long EKG cables
XX. Two Blood Spill kits
YY. Facemasks with eye shields
ZZ. Surgical caps
AAA. Shoe covers
BBB. Non-latex surgical gloves
CCC. Chlorascrub swabs

104.02 NEEDED NON-MEDICAL EQUIPMENT AND MATERIALS

A. Digital audio recorder
B. Tripod & camera
C. [redacted] hand-held video cameras with power supplies
[redacted]
F. [redacted] Cell phones
G. [redacted] Satellite phone
H. Bullhorns
I. Parking barricades and traffic cones
J. Reflective Safety vests
K. Traffic directing light wands
L. Clipboards: 6 – Legal sized
M. Radio Battery charging stations – Gatehouse and Tower 3
N. Evidence kit with placards
O. Hand-scanners
P. Cell-sense detector
Q. Cleaning supplies – as allowed for unit cell cleaning

104.03 EXTERNAL/INTERNAL CONTACTS

A. [redacted] prior to the execution, the designated NDOC staff member will establish a service contract with [redacted] local Emergency Medical Technicians (EMTs).

B. [redacted] prior to scheduled execution, telephone notifications will be placed to the Department of Public Safety, the County Sheriff's Office, the County Coroner's Office and the local Mortuary notifying them of the pending execution.

C. [redacted] prior to the scheduled execution date [redacted] the Warden will make arrangements for the necessary medical equipment and lethal drugs to be provided.

1. Arrangements will be made for the pre-medication of the condemned inmate should he request sedation on the day of the scheduled execution.

2. It will be the responsibility of the [redacted] Team, with assistance provided by medical personnel, to ensure the cardiac monitor is in good working order and that medical equipment as necessary will be laid [redacted]

D. [redacted] the designated NDOC staff member will confirm arrangements with the Emergency Medical Technicians (EMTs), Attending Physician, County Coroner, Mortuary representative, Psychiatrist, inmate's Spiritual Advisor and facility Chaplain.

E. [redacted] an on-site meeting will be held with the EMTs, the County Coroner and the Attending Physician. The meeting will outline the events of the pending execution. Additionally, the location and type of cardiac monitor system will be shown.

F. [redacted] prior to scheduled execution, arrangements will be made for the Attorney General (or designee) to attend the execution at Ely State Prison.

G. [redacted] confidential telephone lists of appropriate government officials will be established, so that they may be immediately contacted via a land-line phone or a back-up cell phone. Restricted access phone lines for both types of phones will be established for the Governor's Office, Attorney General's office, Federal Court clerks, State Court clerks and 8th Judicial District Court Clerk for Judge Togliatti. [redacted] These numbers will be confidentially provided only to those groups concerned [redacted]

H. The Execution Area and Execution Area Chamber Room will each have a restricted access list. Authorization for access to these areas will be established by the Warden.

1. After the condemned inmate is moved to the Execution Area Holding Cell, [redacted] will not be used by any unauthorized person.

104.03 PREPARATION OF EXECUTION AREA WORKROOMS

A. All medical equipment will be checked for readiness and operational functionality by the [redacted] Team with the assistance of a qualified contracted EMT.

1. These checks will be performed:

a. [redacted] between scheduled executions;
b. [redacted] to a scheduled execution (prior to the final rehearsal);
c. [redacted] prior to the day of the scheduled execution;
d. [redacted] prior to the scheduled execution

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 105
SECURITY PLAN AND EXTRA DUTY STATIONS FOR THE EXECUTION OF THE DEATH PENALTY

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

105.01 SECURITY PLAN

A. The following security plan has been designated to provide complete safety and security coverage at Ely State Prison. It is designed with the highest level of protection for staff, visitors and witnesses during an execution of the death penalty.

B. Prior to the scheduled date of execution:

1. In order to prepare to implement this plan [redacted] training will be conducted to include operational planning, staff selection, assignments and training so that all members of each execution team will completely understand what is expected of them on the day of execution.

2. 'State Property' or 'No Trespassing' signs will be maintained along the perimeter of prison property so that it is clearly marked for demonstrators or observers.

3. A Medical Aid Station will be established for this event. [redacted]

4. At the State Route 490 top-of-the-hill entrance to the prison the Maintenance Department will [redacted] that only authorized personnel and approved witnesses will be admitted into the parking lot at the designated time.

5. The designated Associate Warden or Event Commander will provide copies [redacted]

C. On the scheduled date of execution:

1. [redacted] on the scheduled date of execution, the Exterior Team will be posted and this security plan will be in effect.

2. [redacted] all ESP staff members arriving at the institution will be directed to [redacted] where they will park and secure their vehicles. Staff members will then [redacted] Staff members will [redacted] entrance to the institution. At times of inclement weather, [redacted] This [redacted] staff parking plan will continue until the execution is completed and the institution has been returned to normal operations by the designated Associate Warden.

3. [redacted]

4. The meal plan for all inmates except the condemned inmate on the scheduled date of execution will follow the [redacted] meal schedule – the normally planned hot breakfast menu meal will be served [redacted] the regularly planned hot dinner menu meal will be served [redacted] with a cold, regularly planned lunch menu meal [redacted]

5. [redacted] on the day of a scheduled execution, the Maintenance and External Security teams will [redacted] separate parking area in the main parking lot: Media, Official & Victim Witnesses, VIP and Inmate Family. In addition, the Maintenance and External Security teams [redacted] for the purpose of conducting periodic briefings.

6. [redacted]

7. Authorized Official witnesses, Victim Family witnesses and Inmate Family members will be issued [redacted] after they have been processed and cleared by Gatehouse Officers.

8. Media witnesses will be issued [redacted] after they have been processed and cleared by Gatehouse Officers.

9. Any person not on the [redacted] WILL NOT be allowed entry onto Ely State Prison property.

10. [redacted] inmate and/or institutional visits, unscheduled deliveries, inmate transports (unless medically or operationally necessary) and work completed by outside contractors/vendors WILL NOT be allowed.

11. Authorized Media representatives and witnesses may arrive at the facility 5:00 p.m. on the day of a scheduled execution.

12. Authorized Inmate Family members and inmate's Spiritual Advisor may arrive at the facility at 10:00 a.m. on the day of a scheduled execution.

13. Authorized State Personnel may arrive at the facility [redacted] on the day of a scheduled execution.

14. The authorized County Coroner, Attending Physician, EMTs and Psychiatrist may arrive at the facility [redacted] on the day of a scheduled execution.

15. The authorized Mortuary representative may arrive at the facility [redacted]

105.02 EXTRA DUTY STATIONS

[redacted] The [redacted] Team will consist of [redacted] This team will be assigned [redacted] of Ely State Prison. [redacted]

1. [redacted] will be posted [redacted] respond quickly to problems that develop during the event such as if a demonstrator enters State property and refuses to be removed. If vandalism occurs [redacted] as appropriate will be notified and assistance requested.

2. [redacted]

3. [redacted]

4. Traffic Control Point #1 (TCP-1): [redacted] Officers will be assigned to the State Route 490 top-of-the-hill parking lot entrance.

5. Traffic Control Point #2 (TCP-2): [redacted] Officers will be assigned to direct any turn-around traffic at the traffic circle if required. Additionally, this team is responsible for the Official witnesses, Victim Family witnesses, and if invited Inmate Family members parking areas.

6. [redacted] Officers will be assigned to Tower 3/Sally-port. [redacted]

7. Media Witnesses Parking: [redacted] Officers will be assigned [redacted] Each Media group will be allocated an area that is approximately 10' x 10' for staging their equipment and conducting their newsfeed.

8. ESP Staff Parking: [redacted] Officers will be assigned [redacted]

9. Gatehouse: [redacted] Officers will be assigned to check all ID's, complete clothed body searches and clear persons through the scanners prior to entry into the facility. One of the Gatehouse Officers must be a female.

10. Escort Officers: [redacted] Officers will be assigned to provide escort from the parking lot to the Gatehouse and then to the areas specifically designated for each Officer's group. [redacted] groups include: Official Witnesses, Media Witnesses, Victim Family Witnesses, and if invited by the Director of NDOC, Inmate Family members.

11. There will be [redacted] additional [redacted] assignments.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 106
VICTIM FAMILY WITNESS SELECTION & INSTRUCTIONS

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

106.01 VICTIM FAMILY WITNESSES

A. 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. NRS 176.355(2)(c).

1. [redacted] prior to the execution date, the NDOC Victims Services Officer will notify the victim's family.

B. On the day of execution [redacted] Victim Family witnesses may arrive at Ely State Prison (ESP). They will be directed to park [redacted] The Victim Family Escort Officer will escort them from the parking lot to the Gatehouse. The Victim Services Officer will meet them at the ESP Gatehouse.

C. Following the required security checks, the Victim Services Officer and the Victim Family Escort Officer will escort the Victim Family [redacted].

D. Following a briefing regarding the execution protocols, the Victim Family Escort Officer will be directed by the Associate Warden of Programs to escort the Victim Family witnesses [redacted]

E. At the conclusion of the execution the Victim Family witnesses will be escorted [redacted] the Victim Services Officer and Victim Family Escort Officer will escort the Victim Family witnesses back to their designated area of the parking lot.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 107
WITNESS GROUPS PROCEDURE

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

107.01 WITNESS PROCEDURE

A. Nevada law, NRS 176.355(2)(e), states there must be at least six witnesses to attend an execution. The Director shall determine the maximum number of persons who may be present for the execution. He must approve all witnesses and other persons to be present.

B. [redacted] authorized Media and the invited Media Witnesses may begin arriving at the institution. They will be directed to park [redacted] behind the barricades.

C. [redacted] the Inmate Family members may begin arriving at ESP. They will be directed to park in designated spaces [redacted] They will be escorted to the Gatehouse by the Inmate Family Escort Officer and Classification Caseworker III (CCS III). After being processed in by Gatehouse Officers they will receive a briefing by the CCS III and then be escorted [redacted] the Inmate Family members will be escorted to wait [redacted] while the condemned inmate completes his last meal.

D. [redacted] the Attorney General (or designee) will arrive at Ely State Prison to witness the execution process. This individual will park [redacted] and proceed into the institution to meet with the Designated Warden and Associate Warden(s).

1. This individual will be able to view the execution [redacted]

E. [redacted] Official witnesses and Victim Family witnesses will arrive at the institution. A Victim Services Officer will be at the Gatehouse to meet the Victim Family witnesses. Both groups will be directed to park [redacted] Both witness groups will have an Escort Officer to take them to the Gatehouse to be processed in and given an I.D. card.

F. [redacted] the Official and Victim Family witnesses will be escorted by the Associate Warden of Programs, Victim Services Officer and designated Escort Officers from the Gatehouse [redacted]

1. [redacted] the Associate Warden of Programs will brief the Official and Victim witnesses on the execution protocol.

G. [redacted] invited Media Witnesses will proceed to the Gatehouse to be processed in and given an I.D. card. All other Media representatives will be instructed to remain [redacted] the parking lot behind the "MEDIA PARKING" barricade.

H. If both Inmate Family members and Victim Family witnesses will be present to view the execution, then the Inmate Family members will use Execution Area Viewing Room [redacted] and the Victim Family witnesses will use Execution Area Viewing Room [redacted] with the Official witnesses. If only the Inmate Family members or the Victim Family witnesses attend then the attending group will use Execution Area Viewing Room [redacted] and the Official witnesses will use Execution Area Viewing Room [redacted]

I. [redacted] at the direction of the Associate Warden of Programs, the Victim Witnesses Escort Officer will escort the Victim Witnesses to their designated Execution Area Viewing Room. The witnesses will not be allowed to take any cameras, recording devices, or any personal items into the witness area.

J. [redacted] the Associate Warden of Programs will escort the Official Witnesses to Execution Area Viewing Room [redacted] The witnesses will not be allowed to take any cameras, recording devices, or any personal items into the witness area. The condemned inmate's spiritual advisor and Institutional Chaplain will be allowed to witness the execution [redacted]

K. [redacted] the CCS III and the Inmate Family members Escort Officer will escort the Inmate Family members [redacted] to the Execution Area Viewing Room [redacted] The witnesses will not be allowed to take any cameras, recording devices, or any personal items into the witness area.

L. [redacted] the Official witnesses, Victim Family witnesses and Inmate Family members should be seated. None of the personnel involved in the execution should be in sight. The Associate Warden of Operations will notify the Public Information Officer (PIO) in the Gatehouse when it is time to bring the Media Witnesses to Execution Area Viewing Room [redacted] The PIO and Media Witnesses Escort Officer will then escort the Media Witnesses directly to Execution Area Viewing Room [redacted]

1. In Execution Area Viewing Room [redacted], the Associate Warden of Operations will brief the Media witnesses on the execution protocol.

M. Immediately following the execution Inmate Family members will be escorted [redacted]

N. They may elect to either be escorted to the parking lot or to wait [redacted] In either event, they must depart the property [redacted]

O. After the Inmate Family members have been escorted from their viewing room, the Media witnesses will be escorted by the PIO and Media Witnesses Escort Officer from Execution Area Viewing [redacted] to their designated parking area. The media must depart the institution property within one hour of their return to their designated area of the parking lot.

P. The Victim Family witnesses will be escorted from their designated Execution Area Viewing Room [redacted] by the Victim Services Officer and Escort Officer.

Q. The Official witnesses will then be escorted [redacted] They will meet briefly with the Associate Warden of Programs who will offer them the opportunity to participate in a debriefing session. Official witnesses may then depart institutional grounds.

R. After all Media has departed the property the Inmate Family members, if still [redacted] will be escorted to the parking lot so they may depart institutional grounds. After all other witnesses have departed institutional grounds, Victim Family witnesses will depart institutional grounds.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 108
COMMUTATION OR STAY OF EXECUTION

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

108.01 COMMUTATION OR STAY OF EXECUTION

A. [redacted] working with [redacted] will ensure that the following restricted access outside telephone lines [redacted] operate properly. [redacted] will ensure that there are [redacted] cell phones with classified phones numbers available for use should there be issues related to the land lines. These numbers will be confidentially provided only to those groups concerned [redacted] prior to a scheduled execution.

1. The Governor's direct line:
2. The Attorney General's direct line:
3. Federal Court Clerks direct line:
4. State Court Clerks direct line:
5. Judge Togliatti's direct line:

[redacted]

In addition to standard telephone lines and cell phones, a satellite phone will be available so that communications outside of the facility remains possible. This [redacted] will be provided [redacted]

B. In the event of a stay of execution, all preparations will cease and the Director will be immediately notified by the designated Warden.

C. It must be understood that after the infusion of the lethal drugs has begun the execution may still be stopped, but the inmate's respiratory and cardiovascular systems will be progressively more compromised.

1. If the execution is ordered to be stopped at any point after the infusion of the lethal drugs has begun, all reasonable attempts to save the inmate's life will be made by the Attending Physician and medical personnel present using equipment that will be made available for that possible contingency as noted in EM 104.01 – List of Needed Equipment, Materials and External/Internal Contacts.

2. If necessary, the inmate will be transported [redacted] for further stabilization and medical care.

D. If the condemned inmate has already been taken to the Execution Chamber room and a commutation or Stay of Execution order is received, the inmate shall be returned [redacted] All execution personnel shall remain on duty until released by the Associate Warden of Operations.

E. The Attorney General (or designee) shall be notified of the situation as soon as possible.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 109
EXECUTION PROCESS TIMELINE

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

109.01 OVERVIEW OF EXECUTION – 30 DAYS PRIOR

A. When an Order of Execution is received by the Department and the Director has set the date and time of the execution, if necessary, the condemned inmate will be transferred to ESP [redacted] prior to the scheduled execution. Upon arrival at the institution, the inmate will be photographed.

B. The Director of the Nevada Department of Corrections will appoint an Execution Review Committee (ERC) who will be responsible for the selection of Execution Assignment Positions. [redacted]

C. The designated Warden will ensure that written notification of the execution date and time has been made to the County Sheriff / County Corner via hand-delivered letters.

1. The letter to the County Sheriff's Department will ensure [redacted] the execution.

2. The letter to the County Coroner will ensure that the Coroner will be present at the execution and that they will be responsible for confirmation of the inmate's death and for pronouncing the time of death utilizing the atomic clock located in the Execution Chamber room.

D. There will be [redacted] teams: Execution Management, [redacted] Guest Witnesses, Medical Aid Station, and Debriefing. All participants not appointed by the Director, Deputy Director of Operations or ERC must be involved voluntarily and follow the guidelines for selections as outlined in the manual. A member of each team will be responsible for note taking. Timeline notations will occur [redacted]. All documents completed during any phase of the execution will be placed in an execution file to be forwarded to the Warden's Administrative Assistant' Office. Once all documents are collected they will be sent to the Deputy Director of Operations office for file retention. Teams will include the following:

1. Execution Management Team [redacted]
    a. One Warden
    b. Two Associate Wardens

[redacted]

5. Guest Witnesses Team (4 members)
    a. One Official Witnesses on-site representative [redacted]
    b. One Media Witnesses on-site representative – Public Information Officer
    c. One Victim Family on-site representative [redacted]
    d. One Inmate Family on-site representative (if inmate's family has been invited by the Director of NDOC) [redacted]

6. Medical Aid Station Team [redacted]

8. Debriefing Team [redacted]

E. The Deputy Director of Operations for the Nevada Department of Corrections will be responsible for the selection of the Warden, two Associate Warden's [redacted]

109.02 OVERVIEW OF EXECUTION – TWO WEEKS PRIOR

A. No later than two weeks prior to the scheduled execution the designated Deputy Director/designated Warden will meet with the condemned inmate to:

1. Conduct a detailed interview of inmate for preparation of the Death Certificate.
2. Attain inmate's final meal request from the standard NDOC Men's Menu.
3. Allow inmate to sign a DOC 3008 – Press Release form if he will be conducting interviews with the media.
4. Select personal spiritual advisor, if requested.
5. Select method of property disposition.

B. [redacted] will ensure the following Execution Area phones [redacted] operate so that internal and external phone calls may be placed and received. [redacted] will also ensure that the assigned cell phones operate correctly [redacted]

1. The Governor's line [redacted]
2. The Attorney General's line [redacted]
3. Federal Court Clerks line [redacted]
4. State Court Clerks line [redacted]
5. Judge Togliatti's direct line [redacted]

C. A completion of all maintenance inspections and repairs will be done [redacted] Maintenance inspections and repairs will also be completed [redacted] to include proper room temperature checks in all areas [redacted]

D. Arrangements will be made by the ASO II for [redacted] Sani-Huts to be delivered [redacted]

E. The Maintenance Supervisor will make arrangements for parking lot/facility entrance barricades to be delivered and set-up [redacted]

F. There will be a mandatory meeting regarding the execution operation plan status. [redacted]

109.03 OVERVIEW OF EXECUTION – ONE WEEK PRIOR

A. A notification of visiting programs and operational schedule changes that will affect facility operations on the day of the scheduled execution will be made via written memorandum. A memo will be sent to all units notifying all concerned that on the day of the event the institution will follow the [redacted] meal service schedule. The memorandum will be distributed to staff via Departmental Email. Inmates will be informed of these changes.

B. All staff involved in the execution process will meet [redacted] Detailed briefing on specific duties and responsibilities will be given followed by a full equipment check and event rehearsal. This equipment check includes testing [redacted] outside restricted access telephone lines and satellite phone.

C. ESP Food Service Manager/Culinary Sergeant will be notified in writing that they will be responsible for setting up beverages in the Gatehouse, Visiting Room and other designated areas as directed.

109.04 OVERVIEW OF EXECUTION – 48 HOURS PRIOR

A. If the condemned inmate has not already been moved to the Execution Holding Area [redacted] the following steps are to be taken. [redacted] prior to the scheduled execution, the assigned [redacted] Team [redacted] will report to the condemned man's living unit. One member [redacted] will be responsible for recording all movement by the condemned inmate using a hand-held camera.

1. They will take with them a complete set of new state-issue clothing consisting of a pair of jeans, short sleeved button-down shirt, socks, underwear and tennis shoes [redacted]

a. In the event of inclement weather a State-issued coat will be provided to the inmate [redacted].

2. They will enter the unit and proceed to the cell of the condemned inmate.

3. The condemned inmate will be positively identified [redacted]

4. The condemned inmate will be moved to a unit shower [redacted]

5. He will then put on the new set of State issued clothing consisting of a pair of jeans, short sleeved button-down shirt, socks, underwear and tennis shoes. No tee-shirt is to be issued or worn.

6. All of the condemned inmate's personal property will be loaded onto a cart. The condemned inmate and his property will then be escorted [redacted] The condemned inmate will be secured [redacted] His property will be thoroughly searched and inventoried in front of him [redacted] An inventory sheet will be completed and signed [redacted] and counter-signed by the condemned inmate.

7. The condemned inmate will not be allowed to bring with him any personal items.

8. Personal property will be handled in accordance with arrangements previously discussed with the condemned inmate and will follow departmental procedures.

9. The condemned inmate [redacted] will be placed in ankle and wrist restraints. If the Warden authorizes and the condemned inmate elects, the [redacted] Team will then take the condemned inmate to [redacted] yard time [redacted] and a shower.

[redacted] The [redacted] Team will take the condemned inmate to [redacted]

a. [redacted] yard first. He will be given [redacted] supervised yard time. [redacted] officers will maintain constant observation of the condemned inmate [redacted]

b. At the conclusion of yard time the condemned inmate will be restrained and moved to [redacted] a shower.

i. [redacted] will be supplied with shower shoes, soap, shampoo packet, comb, towel, toothpaste, toothbrush, cup, toilet paper. A new set of these items will be provided each time the condemned inmate is allowed to shower.

c. At the conclusion of his shower, the condemned inmate will be given another new set of clothing [redacted]. The

clothing will consist of a pair of jeans, short sleeved button-down shirt, socks, underwear and tennis shoes. No tee-shirt is to be issued or worn.

11. Following yard time and a shower the condemned inmate will be [redacted] escorted [redacted]. He will again be positively identified [redacted] and placed in the Execution Area Holding Cell.

    a. Direct visual observation of the condemned inmate will be maintained [redacted] At no time will the condemned inmate be out of visual observation [redacted]

B. Maintenance Department will ensure the institution's emergency generator and telephone battery back-up in the Execution Area are tested and functional. A check of room temperatures will be conducted in all locations of the Execution area. [redacted]

C. Necessary medical equipment will be laid out [redacted] The [redacted] Team [redacted] will participate and be responsible for checking the restraints that will be used during the execution. At this time all medical equipment to include the cardiac monitors will be checked for accountability and functionality.

D. [redacted] list will be generated and sent to necessary staff. Authorization for access to this area will be granted by the designated Warden or one of the designated Associate Wardens.

109.05 OVERVIEW OF THE DAY OF EXECUTION

A. [redacted] the condemned inmate will be served a standard NDOC Men's Menu breakfast tray and lunch sack.

    1. [redacted] Officers will report with the hand-held camera to the Culinary Department. [redacted] Officer will video the random selection of a breakfast styro and sack lunch for the condemned inmate. Delivery of these meals will be recorded from the time of their selection through to the time of delivery to the condemned inmate in the Execution Area Holding Cell.

B. [redacted] the [redacted] Team will offer the condemned inmate recreation yard time and a shower [redacted] Procedures as outlined in Sections 109.04A.10 and 109.04A.11 will be followed.

C. Once the condemned inmate has been returned to the Execution Area Holding Cell [redacted], he will be allowed to write letters, make phone calls and receive visits.

D. He will be asked if he desires a visit from his Spiritual Advisor or the Institutional Chaplain. The Institutional Chaplain will be assigned to the execution area the day of the execution.

1. The Spiritual Advisor and Chaplain are to remain in the [redacted] area in the time proceeding and following the execution. Should the inmate request a visit from either one, they will proceed to [redacted] where the inmate is located. A member of the [redacted] Team will remain in the room at all times.

2. Both the Spiritual Advisor and Chaplain may be present for the execution. [redacted]

E. [redacted] after being processed in and escorted [redacted] the condemned inmate family members may begin visiting with the condemned inmate.

F. [redacted] the Inmate Family members Escort Officer will escort the inmate's family [redacted]

G. [redacted] the [redacted] Team [redacted] will escort the Attending Physician to examine the condemned inmate. The Attending Physician will:

1. Assess the inmate's need for pre-execution sedatives. The doses will be orally administered with the first dose being offered to the condemned inmate at approximately four hours and the second oral dose being offered at approximately one hour prior to execution. This sedative pre-medication is not mandatory. Medical services personnel will administer the sedative pre-medication following NDOC policy and procedures. This sedative pre-medication is intended to provide a calming effect and shall not cause any lack of cognitive ability, incoherency or incompetence. The Attending Physician will determine the appropriate sedative and dosage.

2. Assess the condemned inmate's peripheral veins for IV placement. The veins of the lower arms are preferable, but the veins of the lower legs and neck should also be assessed. The Attending Physician will then advise the EMT performing the venipunctures.

H. [redacted] an [redacted] Officer will take the hand-held camera to the Culinary Department to video record the preparation and delivery of the condemned inmate's last meal exclusively by the Food Services Manager III and the Culinary Sergeant under camera. The menu for the last meal will match the inmate's previously selected menu choice from the standard NDOC Men's Menu. The preparation of the meal will be video recorded from the beginning of the meal preparation through to the delivery to the condemned inmate in the Execution Area Holding Cell.

I. [redacted] the condemned inmate will be offered the first prescribed pre-execution sedatives [redacted].

J. [redacted] the condemned inmate's last meal is to be served to him by the Food Services Manager and Culinary Sergeant under camera.

K. The condemned inmate may receive visits from his Spiritual Advisor/Chaplain, Attorney General (or designee), Director, Deputy Director, Warden or PIO following the completion of his last meal and until a time as determined by the designated Warden.

1. Any other visitors must be approved by the Director.

2. The [redacted] officers and the Official Execution Recorder will remain in the observation area from the start of the observation until they are relieved by the [redacted] Team [redacted]

L. The inmate will be allowed to send out letters and make final telephone calls to his immediate family and attorney-of-record. Additionally he will be able to send out letters to the media. Supplies for these letters will be provided [redacted].

M. [redacted] institutional count will be conducted. [redacted]

N. [redacted] conduct a telephone test on each of the [redacted] outside restricted access telephone lines and each of the [redacted] cell phones.

O. [redacted] the condemned inmate will be offered the second prescribed pre-execution sedative [redacted].

P. See *EM 110 Execution Procedure* for continued timeline.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 110
EXECUTION PROCEDURE

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

110.01 FINAL PREPARATION OF COMDENMED INMATE

[redacted]

1. The Warden will ensure that the Execution Area Viewing Room blinds are closed and that the Viewing Room lights are at full illumination.

2. The [redacted] Team [redacted] will relieve the [redacted] Officers [redacted]

   b. [redacted] officers will then move [redacted] The [redacted] Team [redacted] will move [redacted] to assist [redacted] officers with any issues that may arise before, during or after the execution.

3. The condemned inmate is placed in [redacted] restraints [redacted]

B. [redacted] the [redacted] Team [redacted] will inform the Warden that the condemned inmate is ready to enter the Execution Area Chamber Room.

C. [redacted] with permission of the Warden, the inmate is escorted [redacted] to the Execution Chamber Room [redacted], placed on the table and secured using soft restraints. The restraints that were used during escort will then be removed. A head support will be placed under the inmate's head and the table will be placed at a reverse Trendelenburg position. The [redacted] Team [redacted] will ensure the inmate is properly secured to the table and announce 'inmate secured'.

D. [redacted] the [redacted] Officers will post themselves in the Execution Chamber Room while the [redacted] Team [redacted] escorts [redacted] the EMT's into the Execution Chamber Room to set the IV lines and cardiac monitor leads.

1. The EMT will perform a venipuncture of both arms or alternate sites derived from the advice of the Attending Physician such as (in the order of preference) the condemned inmate's ankle, lower leg or neck.

   a. Using the appropriate gauge needle/catheter set (18 or 20 depending upon the size and condition of the vein at the intended venipuncture site) the EMT will perform a venipuncture of the condemned inmate's right arm (or alternate site derived from the advice of the Attending Physician). The venipuncture site should be selected as distal on the extremity as possible which will also accommodate at least a 20 gauge needle/catheter set. Should that site prove unsuccessful, a site proximal on the arm can then be selected and a second venipuncture re-attempted. When the venipuncture of the right arm is successful, the EMT will withdraw and appropriately discard the needle, connect the catheter tubing to the IV line, remove the tourniquet on the condemned inmate's upper arm and then check the patency of the venipuncture.

      i. The EMT will open the IV line flow-valve and observe for a free flow of saline inside the IV drip chamber.

      ii. The EMT will also observe the IV site for any unwanted swelling, discoloration or fluid seeping at the venipuncture site. If any of these problems are observed, the EMT will discontinue the IV at that site. If no problems are observed, the catheter/IV line will be secured with sufficient tape and set the IV flow at a rate sufficient to keep the vein open.

   b. The process set forth above in Section 110.01(D)(1)(a) will be repeated for the contralateral side or at another location on the same side to establish another adequate intravenous line.

2. If the EMT is unable to find an adequate vein in an arm, the venipuncture will occur into a vein of an ankle, lower leg or neck as advised by the Attending Physician. Once established and secure, a normal saline solution will then be infused at a slow rate in order to keep the vein open.

3. Once both venipunctures are successfully completed, cardiac leads will be attached to the condemned inmate by the EMT. The EMT will check [redacted] to ensure that the cardiac monitor is functioning properly. The cardiac monitor will then be turned off until the end of the process; there will be no dynamic cardiopulmonary electronic monitoring of the condemned inmate during the process.

E. [redacted] once these tasks have been accomplished successfully, the [redacted] Team and the EMT [redacted] will then exit the Execution Area Chamber Room [redacted]. The only person remaining with the condemned inmate will be the Warden.

F. [redacted] the Warden will direct the [redacted] Team [redacted] posted in the Execution Area Viewing Rooms to dim the lights. The Warden will then open the Execution Area Viewing Room blinds and advise the condemned inmate that those witnessing the execution may now hear his last words. A digital audio recorder will also record them.

110.02 EXECUTION OF CONDEMNED INMATE

A. [redacted] the Director will positively contact the Attorney General/designee and the Governor/designee in person or on their direct lines [redacted] in order to confirm a possible stay of execution, order, pardon or commutation of sentence. If none exists, the Director will inform the Warden to proceed with the execution.

B. Prior to the execution, the Warden will receive practical training in:

1. Measuring and reporting the condemned inmate's level of consciousness.

2. Monitoring the IV sites for signs of compromise.

C. Prior to the administration of lethal drugs, an Attending Physician or properly trained and qualified medical professional will enter the Execution Chamber Room behind a screen in order to monitor the condemned inmate's level of consciousness during the procedure.

D. The Warden will instruct the Drug Administrators to begin injecting the lethal drugs into the condemned inmate as specified below.

1. It must be understood that after the infusion of the lethal drugs has begun the execution may still be stopped, but the inmate's respiratory and cardiovascular systems will be progressively more compromised.

   a. If the execution is ordered to be stopped at any point after the infusion of the lethal drugs has begun, all reasonable attempts to save the inmate's life will be made by the Attending Physician and medical personnel present using equipment that will be made available for that possible contingency as noted in EM 104.01 – List of Needed Equipment, Materials and External/Internal Contacts.

   b. If necessary, the inmate will be transported [redacted] to the nearest emergency room for further stabilization and medical care.

2. If at any point, the Attending Physician determines that the condemned inmate's responses to the lethal drugs deviates from as expected, the Drug Administrators, Warden and Director will pause the procedure, close the Viewing Room window blinds and consult with the Attending Physician. Following the consultation with the Attending Physician, the Director will then decide how to proceed from that point. If the execution is to continue, the Viewing Room blinds will be reopened before proceeding.

3. From Workroom #1, in the following order and manner, a Drug Administrator will administer the lethal drugs while the Attending Physician and other medical personnel,

assisted by the Warden in the Chamber Room, closely observes and measures the level of consciousness of the condemned inmate.

a. Throughout the procedure the Warden, Attending Physician, and other medical personnel will evaluate the patency of the IV sites by ensuring that the IV drip chambers show continuous steady drips and that the IV sites show no signs of compromise. If the patency of one of the IV's is believed to be compromised, the medical professionals will inform the Drug Administrators to use the other, patent IV site. If both IV's appear to be compromised, the Warden will then consult with the Attending Physician before allowing the EMT to proceed with steps to re-establish patent IV access.

b. After the contents of each syringe has been administered, the syringe will be removed from the injection port and the syringe/needle unit will be placed in a new, small sharps container labeled and provided for that purpose.

c. From Tray-1, a Drug Administrator will obtain Midazolam syringes #1-1 through #1-10 containing 500 milligrams of Midazolam. The contents of the syringes will then be administered consecutively at the rate of one minute each.

   i. Two minutes after injecting the last syringe of Midazolam, the Attending Physician or other medical personnel will attempt to elicit an interpretable physical response to a verbal stimulus (i.e. move fingers, thumbs up, open eyes) and to a painful stimulus in the form of a medical grade pinch. If the condemned inmate does not respond to both attempts, the Attending Physician or other medical personnel will inform the Drug Administrator. The Drug Administrator will then begin injection of Fentanyl.

   ii. If, after the injection of the last syringe of Midazolam, the inmate shows a response to either stimulus, the Drug Administrator shall not proceed. The Director will consult with the Attending Physician. The Director will then decide the next course of action, which may include:

      1. Waiting and observing for an additional short period of time
      2. Initiating another IV
      3. Administering additional Midazolam to titrate to effect.
      4. Halting the execution
      5. Begin with the injection of Fentanyl if the IV is patent.

   iii. If the Director chooses actions 1, 2, and/or 3 above, after their completion the Attending Physician or other medical personnel will attempt to elicit an interpretable physical response to a verbal stimulus (i.e. move fingers, thumbs up, open eyes) and to a painful stimulus in the form of a medical grade pinch. If the condemned inmate does not respond to both attempts, the Attending Physician or other medical personnel will inform the Drug Administrator. The Drug Administrator will then begin injection of Fentanyl.

d. From Tray-2, a Drug Administrator will obtain Fentanyl syringes #2-1 through #2-10 containing 5,000 micrograms of Fentanyl. The contents of all syringes will then be

administered within two minutes. The injection of Fentanyl will be titrated to its desired effect in the following manner:

i. 90 seconds after the initial injection of 5,000 micrograms of Fentanyl, the Attending Physician or other medical personnel will attempt to elicit a response to painful stimuli (in the form of a medical grade pinch) from the condemned inmate. If the condemned inmate does not respond to the painful stimulus, the injection of Fentanyl will stop and the injection of Cis-atracurium will begin.

ii. If, after the initial 5,000 micrograms of Fentanyl have been injected, it is determined by the Attending Physician or other medical personnel that the inmate responded to painful stimuli, the Drug Administrator will obtain a supplemental dose of 2,500 micrograms of Fentanyl from syringes #2-11 through #2-15 and administer their contents over an additional two minutes.

iii. 90 seconds after the injection of the supplemental 2,500 micrograms of Fentanyl, the Attending Physician or other medical personnel will reattempt to elicit responses to painful stimuli. If the condemned inmate does not respond to this attempt the injection of Fentanyl will stop and the injection of Cis-atracurium will begin.

iv. If, after the injection of the supplemental 2,500 micrograms of Fentanyl, the inmate shows a response to painful stimuli, the Drug Administrator shall not proceed. The Director will consult with the Attending Physician. The Director will then decide the next course of action, which may include:

1. Waiting and observing for an additional short period of time
2. Initiating another IV
3. Administering additional Fentanyl to titrate to effect.
4. Halting the execution

v. If the Director chooses actions 1, 2, and/or 3 above, after their completion the Attending Physician or other medical personnel will attempt to elicit an interpretable physical response to a painful stimulus in the form of a medical grade pinch. If the condemned inmate does not respond, the Attending Physician or other medical personnel will inform the Drug Administrator. The Drug Administrator will then begin injection of Cis-atracurium.

e. From Tray-3, a Drug Administrator will obtain Cis-atracurium syringes #3-1 through #3-5 containing 100 milligrams of Cis-atracurium. The contents of all syringes will then be administered over 60 seconds. The injection of Cis-atracurium will be titrated to its desired effect in the following manner:

i. After the initial 100 milligrams of Cis-atracurium have been injected and five minutes have elapsed, the Drug Administer will administer a supplemental dose of 100 milligrams from supplemental syringes #3-6 through #3-10. The contents of the supplemental dose will then be administered over an additional 60 seconds.

f. After the administration of the supplemental dose of Cis-atracurium has been administered, the Attending Physician or other medical personnel in Workroom #1 will then turn on the cardiac monitor. The Attending Physician or other medical personnel will observe it until all signs of electrical activity of the heart have ceased.

E. When the lethal drugs have been injected as outlined above, and all electrical activity of the condemned inmate's heart has ceased (as shown by the cardiac monitor), and confirmed by the Attending Physician, the Coroner will be escorted to the execution room to confirm the condemned inmate is deceased and pronounce the time of death. Times recorded for the execution process will be recorded from clocks located in the Execution Area Chamber Room.

F. Immediately following the Coroner's pronouncement of death the Warden will close the Execution Area Chamber Room blinds and direct the posted Observation Team members to fully illuminate their assigned Viewing Room lights.

G. The two Drug Administrators who inject the lethal drugs into the IV lines will document the amount of each lethal drug administered and confirm that it was administered on form DRC 2001.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 111
POST-EXECUTION PROCEDURE

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

111.01 POST-EXECUTION PROCEDURE

A. Immediately following the announcement of the condemned inmate's official time of death, the Warden will close the Execution Area Viewing Room blinds and instruct [redacted] Officers posted in the Viewing Rooms to increase the Viewing Room lights to full illumination.

B. If present, Inmate Family members will be [redacted] escorted from their Viewing Room. [redacted] After the other groups have been escorted from their respective Viewing Rooms [redacted], Inmate Family members may elect to either be escorted out of the institution or to remain [redacted] until [redacted] Witnesses have departed.

C. Next, the Media Witnesses will be escorted by the Public Information Officer (PIO) and their Escort Officer from their Viewing Room, [redacted] out to their designated area [redacted] behind the barricades. A temporary structure suitable for a press briefing will be erected there. The PIO may elect to make an announcement at that time at that location.

D. Next, the Victim Family Witnesses will be escorted from their Viewing Room [redacted] Counseling services will be provided.

E. Next, the Official Witnesses will be escorted from their Viewing Room [redacted] Counseling services will be provided.

F. After all witness groups have left the Execution Area Viewing Rooms, the following procedures will be completed before the deceased inmate's body will be removed from the Execution Area Chamber Room [redacted]:

1. The Associate Warden of Operations will:

    a. Assist the County Coroner in completion of the Death Certificate. A copy will be made and will be placed in the execution file which will then be forwarded to the Warden's Administrative Assistant's office.

    b. Ensure that a Body Disposition document is completed in triplicate (original and two copies). The first copy will be signed by the mortuary vehicle driver and then retained in the execution file which will be forwarded to the Warden's Administrative Assistant's office. The original and the second copy will be provided to the mortuary driver.

    c. Ensure that a copy of the cardiac monitor's memory card or a recording from the cardiac monitor used to record the condemned inmate's heart activity to the time of death is to be placed in the execution file which will be forwarded to the Warden's Administrative Assistant's office for filing.

2. The White Pine County Coroner will:

    a. Collect items, including needles and tubing that were connected to the executed inmate.

    b. Take at least one photograph of the executed inmate's face for identification purposes.

3. The Drug Administrators will:

    a. Record the source and disposition of all solutions and syringes. Their records will indicate the amounts used and not used.

    b. The number of solutions that were used will be recorded by vial sequence number, lethal drug name and lethal drug volume.

4. A member of the State of Nevada Inspector General's office will:

    a. Collect all other execution related evidence that was not connected to the inmate's body, such as all used syringes and prepared syringes that were not used.

[redacted]

G. After the designated Associate Warden, Coroner, Drug Administrators and IG have completed their respective tasks related to processing the body and collecting evidence in the Execution Area Chamber Room, the [redacted] Team [redacted] will:

    1. Assist the Coroner with placing the deceased inmate's body in a body bag with a sealed identity tag.

2. Supervise the escort of the deceased inmate's body from the Execution Area Chamber Room [redacted]

3. After confirming that the Body Disposition document is properly signed by the mortuary driver, assist with placing the deceased inmate's body in the mortuary vehicle.

4. Escort the mortuary vehicle [redacted].

5. Confirm the identity of the deceased inmate by the sealed tag [redacted].

6. Upon order of the designated Associate Warden, release the deceased inmate's body [redacted] for transport [redacted].

H. All staff involved in the execution event will meet [redacted] for a mandatory debriefing. These staff members will be offered the services of clergy and/or psychologists of the Debriefing Team.

1. Assigned staff working the execution will be released from duty by the Event Commander, Associate Warden of Programs or Associate Warden of Operations.

2. The Execution Management Team Sergeant will provide a list of names of debriefing team members to the Warden along with vehicle descriptions and license plates, if available.

3. The Execution Management Team Sergeant will ensure that all resource materials for the debriefing sessions will be available at the institution.

I. All documents, memorandums, telephone records, logs and audio/video recordings related to the execution will be placed in an execution file to be forwarded to the Warden's Administrative Assistant's office. Once all execution items are collected and reviewed they will be sent to the Deputy Director of Operation's office for file retention.

NO ATTACHMENTS: SEE CEM 112 FOR ALL EXECUTION RELATED FORMS

NEVADA DEPARTMENT OF CORRECTIONS

EXECUTION MANUAL
EM 112
EXECUTION PROCESS FORMS

Effective Date: 06/11/2018

CONFIDENTIAL IN UN-REDACTED FORMAT: YES

AUTHORITY AND RESPONSIBILITY

The Director and designated Deputy Director will ensure that this manual is accurately revised and published upon order of the Governor prior to a scheduled execution.

112.01 EXECUTION PROCESS FORMS

[redacted]

D. Execution Telephone Log
E. Report and Schedule of Execution – Exhibit A
F. Body Identification Form

[redacted]

J. News Media Agreement
K. Consent to Search English/Spanish
L. Media Visit Information Sheet
M. Inmate Authorization for Photography, Recording for Publication

112.01D

NDOC EXECUTION TELEPHONE LOG

DATE	TIME	CALLER NAME	CALL ROUTED TO	COMMENTS

Employee Printed Name:_____ Employee Signature:_____

112.01E

NEVADA DEPARTMENT OF CORRECTIONS

Report and Schedule of Execution **EXHIBIT A**

Date _____

Report on the Legal Execution of: _____

Pursuant to the provisions of NRS 2000.030, 4(A) and NRS 176.345 and 176.355

As ordered on the ***(Date)*** day of ***(Month & Year)***

in the 7th Judicial District Court of the State of Nevada by the

Honorable ***(Judge's full name)*** , District Judge
At _____

On the _____ day of _____, 20XX

	Time Recorded
Inmate entered Execution Chamber	_____ AM/PM
Inmate strapped to table	_____ AM/PM
Door closed at	_____ AM/PM
Lethal doses of medication administered:	
Midazolam, Dosage: _____	_____ AM/PM
Fentanyl, Dosage: _____	_____ AM/PM
Fentanyl, Dosage: _____	_____ AM/PM
Cis-actracurium, Dosage: _____	_____ AM/PM
Inmate pronounced dead	_____ AM/PM
Body removed from Execution Chamber	_____ AM/PM

Submitted by: Reviewed by:

112.01E

Warden

County Corner

112.01F

NEVADA DEPARTMENT OF CORRECTIONS
ELY STATE PRISON

Body Identification Form

This will certifiy that I have, on this date, at ***(Time)***, received from Ely State Prison

the person of:

_____
Inmate's Name

_____
Inmate's Identification Number

DATED this _____ day of _____, 20XX

PRINTED NAME OF PERSON RECEIVING BODY

_____

SIGNATURE NAME OF PERSON RECEIVING BODY

_____

Title _____

Address _____

WITNESSED BY

(Print Name) _____
Signature _____

(Print Name) _____
Signature _____

(Print Name) _____
Signature _____

Distribution:
Warden Records Mortuary

112.01 J

Nevada Department of Corrections

News Media Agreement

I, _____, do hereby state that I am employed as a reporter or media representative for:

- print media such as a newspaper, magazine or periodical with local, national or international circulation.
- a television or radio news station which broadcasts locally, nationally or internationally.
- an internet blog, web-based media service or other bona fide news source.

My employer is: _____

My immediate supervisor is: _____

Who may be reached at (telephone):_____

- I have familiarized myself with NDOC Administrative Regulation 120 governing my conduct during interviews and visits within a prison. I agree to comply with the rules, both written and verbal, and direction given while inside the secured facility.

- I hereby waive my personal right to be free from search of my person or property so long as I remain within the boundaries of the grounds.

- I agree to provide no compensation, either direct or indirect, to the offender or his/her family for any interviews or correspondence. I further agree to respect the rights of privacy for all inmates and to obtain a release from any inmate before any photos or recordings are utilized or personal information derived from any interview or correspondence is used in any publication or broadcast.

- I recognize a visit to a facility presents certain hazards, and I agree to assume all ordinary and usual risks to my personal safety inherent in a visit to a facility of this type.

_____ _____

Media Signature Date

_____

Staff Signature

DOC 045 (11/16)

112.01K

NEVADA DEPARTMENT OF CORRECTIONS

CONSENT TO SEARCH

I, the undersigned, being free from coercion, duress, threats or force of any kind, do hereby freely and voluntarily consent to the search of my person, vehicle and other property which I have brought onto prison grounds. I agree that the search maybe conducted by duly authorized Correctional Officers of the Department of Corrections or by other law enforcement officers specifically authorized by the Warden. I understand that if I do not consent to the search of my person, vehicle or other property, I will be denied visitation on this date and may also be denied future visits pursuant to Administrative Regulation 719.

Inmate's Name_____ I.D. Number_____

Signed this _____ day of _____, 20_____, in the

City of _____, State of Nevada.

_____
Signature

_____
Print Name

_____
Street Address

_____
City, State, Zip code

Witnesses:

_____

_____

DOC-1615 [rev. 08/13]

112.01 K

DEPARTAMENTO DE CORRECCIONES DE NEVADA

CONSENTIMIENTO A REGISTRO PERSONAL

Yo, el abajo firmante, estando libre de coerción, de amenazas o presion, voluntariamente doy mi consentimiento a que registren mi persona, mi vehiculo o propiedad que e traido a los terrenos de esta prision. Estoy de acuerdo que sere registrado(a) por personal autorizado por el Departmento Correccional o otros especificamente autorizados por el director de esta prision. Entiendo que de no consentir a que me registren a mi, mi vehiculo o otra propiedad, se me negara la visita en esta fecha y tambien pueden negarme visitas en el futuro de acuerdo a la regulación administrativa 719.

Nombre del prisionero_____ Número de identificación _____

Firmado este _____ día de _____, 20_____, en la ciudad

de _____, Estado de Nevada.

_____
Nombre

_____
Firma

_____
Dirección de la calle

_____
Ciudad, estado, código postal

Testigos:

_____

_____

DOC-1615 [rev. 08/13]

112.01L

NEVADA DEPARTMENT OF CORRECTIONS

Procedures Governing Media at an Execution

WITNESS AT EXECUTION

There are six seats assigned for reporter witnesses in the execution chamber media witness room. To be as fair as possible, the occupants of the six seats will be chosen randomly and in accordance with the following guidelines:

A. Up to two print, radio or broadcast media representatives from the county of sentencing.

B. Up to two print, radio or broadcast media representatives from Nevada outside the county of sentencing.

C. One International Wire Service operating from and based in Nevada.

D. One media representative from Nevada, chosen dependent upon the circumstances of the particular execution.

Should we be unable to fill all six seats based on the above criteria, the NDOC PIO will consider the applicants and through lottery, will fill seats in a manner to represent varied counties throughout the State of Nevada.

The department cannot allow any witness to the execution, media or otherwise, to photograph, video or audio tape, or even sketch an image of the execution itself. No items other than a piece of identification will be allowed to come in with media representatives. No pens, paper or other items are allowed. Water will be provided and should any representative need writing materials, a small notepad and pen will be provided by the NDOCPIO.

For safety, security and privacy reasons, each media representative that is chosen to witness the execution must submit to a clothed pat searched and be scanned through a metal detector prior to entrance into the secured facility. The NDOC staff will make every effort to keep each member of the media safe, however, being inside of a prison introduces a level of risk and media representatives entering the prison must agree to acknowledge and accept that risk by signing the News Media Agreement. The agreement is attached for you to read and address any questions ahead of time.

Media witnesses to the execution will not be allowed to interview any other witnesses on prison grounds.

Any media representatives present in either the parking lot or inside as a witness should be familiar with NDOC Administrative Regulations 120 Media Access and 719 Inmate Visitation. Failure to adhere to the agency's policies and/or guidelines may result immediate removal from the facility or the grounds.

INMATE INTERVIEWS - 1 week prior to execution

Condemned inmates are allowed to be interviewed by media representatives. The inmate's attorney and the warden must authorize the interviews and they must take place within the last week prior to the execution. That said, we have already received too many requests to accommodate in one week and will have to limit the number of interviews to 4 in this case, which would take an estimated 6 hours of time to complete.

112.01L

NEVADA DEPARTMENT OF CORRECTIONS

Procedures Governing Media at an Execution

Any media wishing to be considered for an interview must let us know when submitting the pre-credentialing form. In this case, the 4 interviewees have already been chosen and approved by the inmate's attorney and the Warden. Three of those interviews already took place when there was a prior execution date set, and the fourth we have scheduled for the morning of Monday the week of the execution. Cameras or other equipment will be allowed into the institution as approved by the Warden.

Conservative dress is encouraged for all visitors. Clothing that is tight fitting, revealing, or made with see-through fabrics is not allowed. Please avoid jeans or blue clothing, no tobacco products or lighters allowed, no cell phones are allowed inside the institution.

Questions call Brooke Santina at 775-887-3309 or 775-350-0037.

112.01 L

NEVADA DEPARTMENT OF CORRECTIONS

Procedures Governing Media at an Execution

Media plays an important role keeping the public informed and their objective presence is vital to fair and thorough coverage of an execution. There are unique safety and security issues and other challenges presented at an execution due to the nature of the occurrence. Executions are not open to the public but witnesses are allowed under Nevada Revised Statutes 176.355 and the Department of Corrections (NDOC) Execution Protocol and Execution Directive 101 - Media Access.

July 11, 2017, at 8:00 PM, at Ely State Prison, Scott Raymond Dozier, 46, is scheduled to be put to death. His first-degree murder conviction was for the 2002 killing and dismemberment of Jeremiah Miller, 22. Miller's torso was found in a suitcase that had been dumped in a trash bin in Las Vegas, Nevada. The Eighth Judicial District Court ordered the execution.

There are two ways for media to be present at the execution.

- Staged in the parking lot
- As a witness inside the media room in the execution chamber.

ADVANCE CREDENTIALING

Either staged in the parking lot, or as a witness, all media representatives wishing to be onsite at Ely State Prison during the execution must be pre-credentialed and on the approved list at the gate. To be considered for either location, each media representative must complete and email a copy of the attached credentialing form to the NDOC PIO. It should be received no later than two weeks before scheduled execution, or by July 1st.

PARKING LOT STAGING - PRESS CONFERENCE

Media vehicles will be staged toward the back of the parking lot which will be assigned for media vehicles only and will be clearly marked. It is our intent to host a short press conference after the execution, weather permitting, near the parking lot staging area. No media or media vehicles will be allowed onsite prior to 5:00 PM on the day of the execution. Media must exit the parking lot no later than one hour after the post execution press conference is completed.

112.01 L

NEVADA DEPARTMENT OF CORRECTIONS

Procedures Governing Media at an Execution

Advance Credentialing Form

All media representatives must provide contact information to the Public Information Office at least two weeks prior to the date of the execution. Space is limited. Once capacity has been reached, no additional media representatives will be permitted to park onsite. Media will be allowed onsite not before 5:00 PM on July 11 and will have one hour after the close of the press conference to exit the premises.

PLEASE INDICATE YOUR PREFERENCES:

____ I'd like to be considered to INTERVIEW the inmate.

_____ I'd like to be considered to be a WITNESS to the execution.

_____ I'd like to park onsite and cover the press conference.

Number of vehicles you are arriving with: **# of Satelite Trucks**_____ **# of Passenger vehicles**_____

Name of Media Outlet/ Organization_____

Primary Attendee Name_____

Email Address:_____

Primary Phone#:_____ Secondary#:_____

Type of Organization Represented:

_TV/Cable _ Radio _Newspaper

_ Website _Freelance _Magazine

_Other (indicate

Names of other group members:

_____

_____

_____

Please print legibly and Email or fax this document with a copy of each attendee's Press ID (if one is issued by your organization) to:

Brooke Santina * Bsantina@doc.nv.gov * (775) 350-3307 * Fax (775) 887-3253

112.01 m

Nevada Department of Corrections

Inmate Media Consent Form

I, _____ _____
(Print Inmate Name) (NDOC #)

- O consent to be interviewed and/or photographed
- O do not consent to be interviewed and/or photographed

by_____
Name of interviewer or photographer

of_____
Name of news outlet or organization

on_____
Date / Location

I hereby waive confidentiality and consent to be photographed, recorded electronically, and/or interviewed for media coverage, publicity, website, or other special production.

I understand that I do not have to participate in this project and I may choose to discontinue the interview at any time and by doing so, I would therefore withdraw this consent.

I understand that I will receive no pay, royalties, merit credits or other form of compensation for participating in this project. I am free and voluntarily signing this authorization to participate in this project.

I understand that the Nevada Department of Corrections has no control of the use of my statement(s) and/or photographs in publications or broadcasts prepared by other organizations. On behalf of myself and my heirs and assigns, I release the State of Nevada and the Department of Corrections from any and all claims that may otherwise accrue to me as a result of the publication or broadcast of my statement(s) or photograph(s) obtained during this media opportunity.

_____
Inmate's Signature Date

_____
Staff Signature Title Date

DOC 046 (12/17)

EXHIBIT 13

Nevada Department of Corrections

Public Information Office: 775-887-3309
PIO Brooke Santina Cell: 775-350-0037

Update Regarding NDOC Process for Choosing Execution Drugs

For Immediate Release
July 6, 2018

The Nevada Department of Corrections (NDOC) is updating information in regards to the lethal injection protocol for the court-ordered execution of condemned murderer Raymond Scott Dozier.

According to NRS 176.355, the judgement of death must be inflicted by an injection of a lethal drug(s). When considering the drugs to be used for the ordered execution, NDOC Director James Dzurenda consulted with the-then State of Nevada Chief Medical Officer – at that time an anesthesiologist – who approved the drug protocol.

After the expiration of the drug Diazepam, it was necessary to change the lethal injection protocol. NDOC presented a revised execution protocol to the current Chief Medical Officer. The 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. As part of the execution protocol, an attending physician, who is a practicing physician in the State of Nevada, will attend the execution.

The Attorney General's office was consulted about the method of execution challenges, including by providing general advice about the proposed manual and drug protocol under legal precedent. The advice was premised on the medical recommendation of the State's Chief Medical Officer. The Nevada Department of Corrections relied on the legal advice from the Nevada Attorney General's Office.

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The Nevada Department of Corrections is committed to building a safer community by striving to incorporate progressive best practices in all aspects of corrections. NDOC houses nearly 14,000 persons with felony convictions in 18 facilities statewide. For more information visit www.doc.nv.gov.