

EXHIBIT 13

REPORTER'S RECORD
VOLUME 1 OF 1 VOLUME
TRIAL COURT CAUSE NO. D-1-N-22-7149

RUIZ, ET AL,
Plaintiff,

VS.

TDCJ, ET AL,
Defendant.

) IN THE DISTRICT COURT
)
) TRAVIS COUNTY, TEXAS
)
) 345TH JUDICIAL DISTRICT

EMERGENCY MOTION FOR TEMPORARY INJUNCTION

On the 10th day of January, 2023, the following proceedings came on to be heard in the above-entitled and numbered cause before the Honorable Catherine A. Mauzy Judge Presiding, held in Austin, Travis County, Texas REMOTELY VIA VIDEOCONFERENCE:

Proceedings reported by machine shorthand.

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PROCEEDINGS

January 10, 2023

THE COURT: Let me call for hearing Cause

No. D-1-GN-22-7149 Wesley Ruiz, John Balentine, Robert Fratta versus Texas Department of Criminal Justice, Et Al.

Your appearances for the record, please.

MR. KURSMAN: Good morning, Your Honor.

Alex Kursman for Petitioners Balentine and Ruiz. This morning Ms. Swiergula filed an order with the Court asking for pro hac vice admission for myself and my colleague, Hayden Nelson-Major. I just want to make sure that order was granted before the hearing begins.

THE COURT: I am told that that has been filed. I'll need to, yeah, take that up and get that signed. We might take a little break after we do appearances since that order -- I'll take appearances and then I'll see if there's any objection. I don't think there should be.

I'm going to ask everyone as you give your appearances or if you go through, because I have so many counsel appearing this morning, if everyone could go through and change their name and include who they represent. It may not all show up and it may not be possible, but we can try.

10:12AM 1 Mr. Kursman and Ms. Swiergula, and who else
10:12AM 2 do I have, please.

10:12AM 3 MS. NELSON-MAJOR: This is Hayden
10:12AM 4 Nelson-Major with the Federal Community Defender Office
10:12AM 5 in the Eastern District of Pennsylvania on behalf of John
10:12AM 6 Balentine and Wesley Ruiz.

10:12AM 7 MR. WILSON: Good morning, Your Honor.
10:12AM 8 Daniel Wilson with Sussman Godfrey as additional counsel
10:12AM 9 for Ruiz and Balentine, and I filed a notice of
10:12AM 10 appearance this morning.

10:12AM 11 THE COURT: Thank you.

10:12AM 12 (Zoom audio distortion)

10:12AM 13 MR. SCHARDL: Good morning, Your Honor.
10:12AM 14 This is Tivon Schardl from the Federal Defender Office
10:12AM 15 here in Austin for Robert Fratta.

10:12AM 16 THE COURT: Thank you.

10:12AM 17 MR. WOLFF: Good morning, Your Honor. My
10:12AM 18 name is Benjamin Wolff. I'm with the Office of Capital
10:13AM 19 and Forensic Writs, and along with Paul Manser, who is
10:13AM 20 federal habeas counsel, we represent Arthur Brown, Jr.
10:13AM 21 We filed a petition intervention yesterday.

10:13AM 22 MS. O'LEARY: Good morning, Your Honor.
10:13AM 23 Leah O'Leary from the Attorney General's Office. I
10:13AM 24 represent TDCJ, Brian Collier, Bobby Lumpkin and Kelly
10:13AM 25 Strong, the Respondents.

10:13AM 1 THE COURT: Thank you.

10:13AM 2 Anyone else? Before I begin, I need to
10:13AM 3 look at those pro hac vice --

10:13AM 4 MR. MARSHALL: This is Ed Marshall. I'm
10:13AM 5 also here on behalf of Respondents.

10:13AM 6 THE COURT: Thank you, Mr. Marshall.

10:13AM 7 All right. Before -- I need to look at
10:13AM 8 those pro hac vice orders and get those filed. Let me
10:13AM 9 just ask, does anyone have any objection to those? I
10:14AM 10 have not had a chance to look at those yet.

10:14AM 11 MS. O'LEARY: No objection, Your Honor. I
10:14AM 12 believe they are filed as unopposed.

10:14AM 13 THE COURT: Okay, great. I'll take a
10:14AM 14 little break. Let me give you some preliminary
10:14AM 15 announcements. I'll take a break and get those signed so
10:14AM 16 that we can proceed. We are holding today's hearing
10:14AM 17 today remotely on the Zoom platform.

10:14AM 18 (Court's COVID instructions.)

10:14AM 19 MR. KURSMAN: We have an expert witness
10:14AM 20 that needs to be through by 1:30 eastern time.

10:14AM 21 THE COURT: That's fine. I'm assuming,
10:16AM 22 Ms. O'Leary, you don't have an objection to that.

10:16AM 23 MS. O'LEARY: Our position is going to be
10:16AM 24 that we don't need to reach the expert at all. We also
10:16AM 25 have some housekeeping matters like objections to

10:16AM 1 exhibits that have been filed.

10:16AM 2 And we'd like to understand the scope of
10:16AM 3 the hearing. The hearing has only been noticed for Mr.
10:16AM 4 Fratta's amended emergency motion for temporary
10:16AM 5 injunction. So we haven't been noticed to hear the
10:16AM 6 original petition in the case, and we just want to make
10:16AM 7 sure that we understand that correctly.

10:16AM 8 THE COURT: We'll get to all those
10:16AM 9 housekeeping matters in a minute. Let me take care of
10:16AM 10 those pro hac vice motions and orders. I'm going to take
10:17AM 11 a short break and in the meantime you-all can stand by.
10:17AM 12 Let me get those orders taken care of and then we'll go
10:17AM 13 right into the housekeeping matters, into the evidence,
10:17AM 14 realizing that we have a witness who needs to be done by
10:17AM 15 12:30 our time. Thank you.

10:17AM 16 (Whereupon There was a Break in the Proceedings)

10:22AM 17 THE COURT: I've reviewed the motions for
10:22AM 18 pro hac vice for Mr. Kursman and Ms. Nelson-Major and I
10:22AM 19 have signed those and we'll get those filed. So now
10:22AM 20 let's begin. We can go ahead and begin with any
10:22AM 21 housekeeping matters that we need to take up.

10:22AM 22 MS. O'LEARY: Yes, Your Honor. We have
10:22AM 23 some objections to the exhibits that were uploaded last
10:22AM 24 night. We can address those now or I'm happy to address
10:22AM 25 them as we go, as Petitioners try to offer them.

10:22AM 1 THE COURT: Go ahead, Mr. Kursman.

10:22AM 2 MR. KURSMAN: That is -- I think it's more
10:22AM 3 appropriate if they are objected to as offered. We
10:22AM 4 wanted to introduce six of those exhibits prior to
10:23AM 5 offering our witness based on stipulations with
10:23AM 6 Respondents, and those would be Exhibits 6, 7, 8, 9, 10
10:23AM 7 and 11. Respondents agreed to stipulate to the
10:23AM 8 following, that if a record custodian was called to
10:23AM 9 testify, they would testify to the following:

10:23AM 10 That the record was made at or near the
10:23AM 11 time by or from information transmitted by someone with
10:23AM 12 knowledge, that the record was kept in the course of
10:23AM 13 regularly conducted business activity and that making the
10:23AM 14 record was a regular practice of that activity.

10:23AM 15 Respondents also agree to stipulate to the
10:23AM 16 accuracy and authenticity of those exhibits. So
10:23AM 17 Petitioners would move to admit Exhibits 6, 7, 8, 9, 10
10:23AM 18 and 11.

10:23AM 19 THE COURT: Ms. O'Leary.

10:23AM 20 MS. O'LEARY: Respondents do so stipulate
10:23AM 21 and we have no objection to the admission of 6 through
10:24AM 22 10.

10:24AM 23 THE COURT: Through 11.

10:24AM 24 MS. O'LEARY: I'm sorry; was it 11?

10:24AM 25 THE COURT: I heard Mr. Kursman offering 6,

10:24AM 1 7, 8, 9, 10 and 11.

10:24AM 2 MR. KURSMAN: Yes. No. 11, Ms. O'Leary, is
10:24AM 3 the TDCJ protocol.

10:24AM 4 MS. O'LEARY: I'm sorry; I didn't see that
10:24AM 5 one. TDCJ's execution procedure, may I ask if it's the
10:24AM 6 current version, revision?

10:24AM 7 MR. KURSMAN: Yes, Ms. O'Leary. It's the
10:24AM 8 version that was sent to us pursuant to the requests.

10:24AM 9 MS. O'LEARY: We have no objection to
10:24AM 10 admission of No. 11 then.

10:24AM 11 THE COURT: All right. Then Petitioner's
10:24AM 12 Exhibits 6 through 11 are admitted without objection. I
10:24AM 13 agree that the rest -- if you don't have agreements on
10:24AM 14 them, let's just take up your objections to any other
10:24AM 15 exhibits as they come up.

10:24AM 16 MS. O'LEARY: Yes, Your Honor.

10:24AM 17 The other issue, before the Petitioners put
10:25AM 18 on their expert, is we have some argument to make as to
10:25AM 19 why the Court doesn't need to consider the expert's
10:25AM 20 opinion on the factual issues in the case. So if the
10:25AM 21 Court is amenable, I'm happy to present that right now.

10:25AM 22 THE COURT: Well, yes, go ahead and do
10:25AM 23 that, then I'm going to ask for brief openings. I've
10:25AM 24 reviewed I believe almost all the pleadings, almost all
10:25AM 25 of them. And again, apologies that this came up in the

10:25AM 1 middle of -- I was moving yesterday, so I didn't have
10:25AM 2 much technology set up. I'm going to try to read all of
10:25AM 3 the pleadings.

10:25AM 4 So let's go ahead and start with that
10:25AM 5 argument, Ms. O'Leary.

10:25AM 6 MS. O'LEARY: Yes, Your Honor. The
10:25AM 7 Petitioners intend to introduce expert testimony from
10:25AM 8 I'll just say a pharmaceutical expert to discuss
10:25AM 9 expiration dates and beyond-use dates of the drug that
10:25AM 10 TDCJ uses for lethal injection. The Court does not need
10:26AM 11 to get into the question of whether the drugs are, quote,
10:26AM 12 expired or whether they are being used beyond-use date,
10:26AM 13 which is contested.

10:26AM 14 But even if, for argument's sake, the Court
10:26AM 15 assumes that the drugs are expired or are being used
10:26AM 16 beyond the beyond-use date -- the Court can assume that
10:26AM 17 to be true -- but first the Court should instead
10:26AM 18 recognize that the Petitioners haven't stated a cause of
10:26AM 19 action here. And so even if factually there's a factual
10:26AM 20 dispute or assumption that the asserted facts are true,
10:26AM 21 without a cause of action the Court can't issue an
10:26AM 22 injunction here and no declaratory relief is available.

10:26AM 23 This is an ultra vires action against TDCJ
10:26AM 24 officials. The basis of the ultra vires asserted conduct
10:26AM 25 is they have violated certain state statutes such as the

10:26AM 1 Texas Pharmacy Act. As we have laid out in our briefing,
10:26AM 2 none of the statutes that the Petitioners have cited
10:27AM 3 actually apply to TDCJ's use of pentobarbital lethal
10:27AM 4 injection; they simply don't apply. They also cite
10:27AM 5 things like the Texas Penal Code. There's clear
10:27AM 6 exceptions to each of those statutes that exempt TDCJ or
10:27AM 7 exempt this situation from those standards. And so
10:27AM 8 without demonstrating that there's a potential, at least
10:27AM 9 a potential ultra vires claim here, there's no reason to
10:27AM 10 get into the factual disputes about whether the drugs are
10:27AM 11 beyond a beyond-use date.

10:27AM 12 And I'm happy to go through each of those
10:27AM 13 state statutes if the Court wants to hear that now, and
10:27AM 14 that includes the Texas Pharmacy Act, the Texas
10:27AM 15 Controlled Substance Act, the Penal Code and the Texas
10:27AM 16 Food, Drug and Cosmetics Act.

10:27AM 17 THE COURT: Mr. Kursman, you want to
10:27AM 18 respond to that, please.

10:27AM 19 MR. KURSMAN: Sure, Your Honor.

10:27AM 20 So all of those issues were briefed in our
10:27AM 21 initial petition in Respondents' response and in our
10:28AM 22 reply. I think we can get into those in more detail
10:28AM 23 after Dr. Almgren testifies if Your Honor would like, but
10:28AM 24 I think those are pretty well-briefed in all of our
10:28AM 25 pleadings.

10:28AM 1 Ms. O'Leary began with saying that we
10:28AM 2 didn't state a cause of action, but then describes the
10:28AM 3 cause of action that we stated in our petition. And I'm
10:28AM 4 sure Your Honor is fully aware of what that is, as we
10:28AM 5 filed that petition weeks ago.

10:28AM 6 THE COURT: Yes, I am. I've read your
10:28AM 7 petition.

10:28AM 8 So that objection is overruled,
10:28AM 9 Ms. O'Leary. All right.

10:28AM 10 Then let's begin, Mr. Kursman, or whoever
10:28AM 11 is going to make argument with brief opening statements.

10:28AM 12 MR. KURSMAN: Sure, Your Honor.

10:28AM 13 The Texas Department of Criminal Justice
10:28AM 14 planned to administer expired drugs to Petitioners
10:28AM 15 Fratta, Ruiz, Balentine and Brown during their
10:28AM 16 executions. These drugs expired anywhere from 630 days
10:29AM 17 ago to over 1,300 days ago. You will hear that when
10:29AM 18 drugs are this old the pharmacological property of the
10:29AM 19 drugs themselves change. So although the drugs may be
10:29AM 20 labeled pentobarbital, because they are hundreds or
10:29AM 21 thousands of days past their expiration date, the
10:29AM 22 pharmacological effects of those drugs may not be
10:29AM 23 pentobarbital at all.

10:29AM 24 You will also hear when drugs are this old
10:29AM 25 there's a high risk that they fall out of solution. What

10:29AM 1 this means is that the drug themselves become grainy. So
10:29AM 2 instead of injection of a liquid into a vein, the drug
10:29AM 3 themselves will contain solid particles, and when
10:29AM 4 injected into one of the prisoner's veins, it will cause
10:29AM 5 burning at the injection site. Because of these risks
10:29AM 6 the Texas statutes that we outlined in our petition
10:29AM 7 protect against administering expired drugs to humans.
10:30AM 8 Under the statutes in Texas outlined in our petition, it
10:30AM 9 is unlawful to administer expired drugs to human beings.

10:30AM 10 TDCJ acknowledges that these statutes
10:30AM 11 exist, they implicitly concede that these drugs are
10:30AM 12 expired, but they claim to be above the law. They say
10:30AM 13 that these statutes don't apply to them because the drugs
10:30AM 14 are being used for an execution. There is no legal
10:30AM 15 support for that argument. TDCJ and individuals who work
10:30AM 16 for TDCJ are not above the law. They, too, must follow
10:30AM 17 the laws of practice, even during an execution.

10:30AM 18 After hearing the evidence this Court
10:30AM 19 should grant a temporary injunction prohibiting TDCJ from
10:30AM 20 administering expired drugs to Messrs. Fratta, Ruiz,
10:30AM 21 Balentine and Brown.

10:31AM 22 THE COURT: Thank you.

10:31AM 23 Ms. O'Leary.

10:31AM 24 MS. O'LEARY: Your Honor, I just want to
10:31AM 25 comment, Mr. Kursman is asking for relief for Mr. Ruiz

10:31AM 1 and Balentine. We have not been noticed on their
10:31AM 2 petition for today's hearing; we've only been noticed on
10:31AM 3 Mr. Fratta's request for temporary injunction. And so I
10:31AM 4 think that their idea of what this hearing is covering is
10:31AM 5 different from ours. And I just, again I ask for clarity
10:31AM 6 from the Court on whether we are hearing the original
10:31AM 7 petition today, which again was not noticed.

10:31AM 8 THE COURT: Well, I think the amended
10:31AM 9 request -- I should have -- I skipped over attorney for
10:31AM 10 Mr. Fratta, Mr. Schardl. I should let him speak, as
10:31AM 11 well. But so I think the -- what was noticed is clearly
10:31AM 12 we wouldn't be here but for the original petition; it's
10:31AM 13 the underlying pleadings. I'm willing to hear all of it.
10:31AM 14 I'm going to let Mr. Kursman, participate; Mr. Schardl,
10:31AM 15 as well.

10:32AM 16 I guess I should let you go ahead and make
10:32AM 17 a statement before Ms. O'Leary goes on.

10:32AM 18 MR. SCHARDL: Thank you very much, Your
10:32AM 19 Honor. I have nothing to add to what Mr. Kursman said or
10:32AM 20 to what the Court just said.

10:32AM 21 THE COURT: Thank you.

10:32AM 22 All right, Ms. O'Leary.

10:32AM 23 MS. O'LEARY: Yes, Your Honor. It's
10:32AM 24 important to be aware of the context and timing in which
10:32AM 25 we find ourselves in court today. Mr. Fratta's death

10:32AM 1 sentence became final in 2011. TDCJ has been using
10:32AM 2 compounded single drug pentobarbital for lethal injection
10:32AM 3 since 2013, using the current testing and retesting
10:32AM 4 processes that are currently in place since 2013. So at
10:32AM 5 any time over the past nine years the Petitioners could
10:32AM 6 have raised this claim; but instead we find ourselves in
10:32AM 7 a hearing hours before Mr. Fratta's scheduled execution.

10:32AM 8 It's also important to note that there's an
10:32AM 9 active writ of prohibition in the case that prevents --
10:32AM 10 it orders this Court to refrain from issuing any order
10:33AM 11 purporting to stay an execution. And even if an order
10:33AM 12 doesn't say that it stays an execution, it can have that
10:33AM 13 effect; and so we just want to point out that is still in
10:33AM 14 place.

10:33AM 15 And again, the Court doesn't need to go
10:33AM 16 into the factual assertions in the case because the
10:33AM 17 Petitioners haven't demonstrated a cause of action. They
10:33AM 18 wrote ultra vires on their petition; so they have picked
10:33AM 19 out a cause of action, but they haven't asserted any
10:33AM 20 facts that would allow this Court to find that any
10:33AM 21 official acted in an ultra vires manner.

10:33AM 22 An ultra vires action cannot lie where
10:33AM 23 there is discretion. The Respondents are statutorily
10:33AM 24 required to carry out lethal injection, and that is in
10:33AM 25 the Code of Criminal Procedure. The statute gives

10:33AM 1 Director Bobby Lumpkin discretion in deciding how to
10:33AM 2 carry out lethal injection.

10:33AM 3 The State is indeed regulated on how it
10:33AM 4 carries out a lethal injection and it is regulated by the
10:34AM 5 8th Amendment, which is not a cause of action that's been
10:34AM 6 raised here. It is not regulated by things like the
10:34AM 7 Texas Pharmacy Act or the Food, Drug and Cosmetic Act.

10:34AM 8 Petitioners allege that Respondents have
10:34AM 9 violated the Texas Pharmacy Act. If the Court looks at
10:34AM 10 the statute, it describes who the statute applies to.
10:34AM 11 The pharmaceutical standards are codified in Texas law
10:34AM 12 and again, they specify who they apply to. They do not
10:34AM 13 apply to TDCJ, its officials or lethal injection.

10:34AM 14 For example, the Texas Pharmacy Acts states
10:34AM 15 it applies to a provider prescribing a medication to a
10:34AM 16 patient. That's obviously something that doesn't apply
10:34AM 17 here. And right in the introduction of the Texas
10:34AM 18 Pharmacy Act it says that it, "Regulates the practice of
10:34AM 19 pharmacy and licensing pharmacies that are engaged in
10:35AM 20 distribution of prescription drugs and devices that are
10:35AM 21 used in diagnosing illness, injury or disease."

10:35AM 22 That is not something that is happening
10:35AM 23 when TDCJ is carrying out lethal injection. We're not
10:35AM 24 treating anything, we're not providing any kind of
10:35AM 25 therapeutic treatment or drugs. We're not treating

10:35AM 1 illness, injury or disease. And so right from the
10:35AM 2 introduction of the Pharmacy Act, it's clear that it does
10:35AM 3 not apply to TDCJ.

10:35AM 4 The Texas Controlled Substances Act,
10:35AM 5 there's a clear exception that involves the licensing to
10:35AM 6 possess controlled substances. There's a clear exception
10:35AM 7 for employees of the State engaged in the enforcement of
10:35AM 8 law or carrying out an official duty.

10:35AM 9 Additionally, TDCJ has a DEA license to
10:35AM 10 possess pentobarbital. The Petitioners have copies of
10:35AM 11 the DEA order forms they appended back to their original
10:35AM 12 petition. So for those reasons, the Controlled
10:35AM 13 Substances Act doesn't apply to TDCJ.

10:35AM 14 The Texas Food, Drug and Cosmetic Act is a
10:36AM 15 consumer protection statute. It regulates labelling,
10:36AM 16 branding and other safety mechanisms for products that
10:36AM 17 are introduced into commerce. That is not what is
10:36AM 18 happening in lethal injection. We don't need to be
10:36AM 19 concerned with consumers who are reading the labels on
10:36AM 20 lethal doses of pentobarbital.

10:36AM 21 And lastly, Petitioners allege that TDCJ
10:36AM 22 officials are violating the Penal Code because they are
10:36AM 23 bringing a controlled substance into a correctional
10:36AM 24 facility. There is a clear exception in the Penal Code
10:36AM 25 for officials carrying out legal duties, and they have a

1 legal duty here. There is a valid court order issuing a
2 death warrant and there's a statute that says TDCJ shall
3 carry out lethal injection.

4 Similar challenges have been raised in the
5 federal courts, as we've laid out in our briefing. The
6 Fifth Circuit has repeatedly rejected challenges to
7 TDCJ's use of pentobarbital, including challenges that
8 allege that pentobarbital is expired. Those have been
9 rejected by the Fifth Circuit.

10 To be entitled to injunctive relief the
11 Petitioners have to prove three elements, the first of
12 which is they have to show that they have a cause of
13 action. For the reasons I've just said and for the
14 reasons laid out in our brief, they haven't satisfied the
15 first element or the second element, which is that they
16 have a probable right to relief.

17 The last element is they have to show a
18 probable imminent irreparable injury. Now, you're going
19 to hear evidence from their -- or testimony from their
20 expert talking about what may happen, what she thinks
21 will happen. She applies pharmaceutical standards in
22 reaching those conclusions. And as I've just discussed,
23 the pharmaceutical standards in the USP do not apply to
24 this situation because we're not treating injury, illness
25 or disease.

1 And lastly, Your Honor, because this is a
2 challenge to the method of execution, the United States
3 Supreme Court has added another standard on top of the
4 injunctive relief standard that the Petitioners have to
5 meet, and that is found in Blaze vs. Rees. The
6 Petitioners have to show that the State's lethal
7 injection creates a demonstrated risk of severe pain.

8 Your Honor, the TDCJ has carried out
9 executions using pentobarbital under the same testing
10 process that it uses now over 70 times. It has carried
11 out lethal injection over 90 times. What the Petitioners
12 describe has never happened; it simply has never
13 happened. The drugs that TDCJ possesses and uses and
14 sends to labs to get tested are -- and the Petitioners'
15 own evidence shows that it was retested as recently as
16 January of 2022 -- it's proven to be potent and
17 effective.

18 The other factors that might be relevant to
19 therapeutic uses of drugs simply don't matter for
20 purposes of a lethal injection. And for that reason we
21 believe that their request for injunctive relief and
22 declaratory relief should be denied.

23 THE COURT: Thank you. All right. Well,
24 before we begin, I'm certainly aware of the Court of
25 Criminal Appeals order and I understand that I am

10:39AM 1 prohibited from issuing any order that purports to stay
10:39AM 2 the scheduled executions, and I would not assume to do
10:39AM 3 so. This is a separate matter having to do with an
10:39AM 4 injunction on the use of what the Plaintiffs allege are
10:39AM 5 expired drugs that do not meet certain standards set out
10:39AM 6 in various civil statutes, so we'll proceed with that
10:39AM 7 evidence.

10:39AM 8 Mr. Kursman, if you would like to call your
10:39AM 9 first witness.

10:39AM 10 MR. KURSMAN: Thank you, Your Honor.
10:39AM 11 Before I do, could I just ask that we be given time to
10:39AM 12 respond to Ms. O'Leary's legal arguments?

10:39AM 13 THE COURT: Yes, go ahead. After -- you
10:40AM 14 want to call your witness -- yes.

10:40AM 15 MR. KURSMAN: Petitioners call Dr. Michaela
10:40AM 16 Almgren.

10:40AM 17 MICHAELA ALMGREN,
10:40AM 18 having been duly first sworn, testified as follows:

10:40AM 19 DIRECT EXAMINATION

10:40AM 20 BY MR. KURSMAN:

10:40AM 21 Q. Dr. Almgren, can you introduce yourself to the
10:40AM 22 Court.

10:40AM 23 A. So my name is Michaela Almgren. I'm a clinical
10:40AM 24 associate professor of pharmacy at the University of
10:40AM 25 South Carolina College of Pharmacy. I'm a licensed

10:40AM 1 pharmacist in South Carolina and a few other states and I
10:40AM 2 have really vast experience in sterile compounding.

10:40AM 3 When I was a student I was a pharmacy
10:40AM 4 technician working in a hospital performing sterile
10:40AM 5 compounding. When I graduated I was a pharmacist in a
10:40AM 6 large teaching hospital performing duties of a sterile
10:41AM 7 compounding pharmacist. I worked in oncology, I worked
10:41AM 8 in home infusion, all of those fields involving sterile
10:41AM 9 compounding.

10:41AM 10 I also teach CE, continuing educational
10:41AM 11 courses to pharmacists that deal with this subject matter
10:41AM 12 of sterile compounding. I'm very familiar with sterile
10:41AM 13 compounding under 503A regulations. And most recently I
10:41AM 14 became a pharmacist as a part of my clinical assignment
10:41AM 15 with the university as a 503B pharmacy. And so I also
10:41AM 16 have vast experience now in sterile compounding
10:41AM 17 regulations as they are related to 503B pharmacy.

10:41AM 18 I also have pharmaceutical industry
10:41AM 19 experience because prior to going to pharmacy school I
10:41AM 20 actually went to -- I worked for a number of drug
10:41AM 21 companies and I worked as an analytical chemist. So I
10:41AM 22 have this analytical chemistry experience, I have a
10:41AM 23 master's degree -- I have a college degree in biology and
10:42AM 24 chemistry. I have a master's degree in pharmaceutical
10:42AM 25 sciences in pharmacy and I also have a doctorate in

10:42AM 1 pharmacy.

10:42AM 2 Q. And Dr. Almgren, can you just briefly describe
10:42AM 3 for the Court what a pharmacist does?

10:42AM 4 A. So it really depends, because the area of
10:42AM 5 pharmacy practice is very vast. So you can be a clinical
10:42AM 6 pharmacist working in a hospital, you can be a retail
10:42AM 7 pharmacist working in Rite Aid or a Walgreen's dispensing
10:42AM 8 and working directly with the public. My area of
10:42AM 9 expertise is sterile compounding and so what I do is, I
10:42AM 10 prepare medications based on physicians' orders for
10:42AM 11 patients.

10:42AM 12 Q. Can you tell the Court what sterile compounding
10:42AM 13 means?

10:42AM 14 A. So sterile compounding involves preparation of
10:42AM 15 drugs where you start with either a sterile drug -- this
10:42AM 16 would be considered low risk compounding where you start
10:43AM 17 with maybe a vial of drug that comes from the
10:43AM 18 manufacturer and, according to the doctor's orders, you
10:43AM 19 will perhaps dilute the medication or maybe turn it from
10:43AM 20 an injection into an infusion. So you are going to add
10:43AM 21 it to an IV bag. So that would be considered low risk
10:43AM 22 compounding.

10:43AM 23 Then you have a medium risk compounding
10:43AM 24 that involves more complex procedures. So if I was
10:43AM 25 compounding a total parenteral nutrition product, so

10:43AM 1 something that contains a number of additives -- so maybe
10:43AM 2 I'll add 10 or 12 additives -- that would be considered a
10:43AM 3 medium risk compounding.

10:43AM 4 Then there is high risk compounding. And
10:43AM 5 according to USP 797, the guidance that basically
10:43AM 6 provides all of the regulations for 503A pharmacies in
10:43AM 7 regards to sterile compounding, the high risk compounding
10:43AM 8 involves starting with a nonsterile product that would be
10:43AM 9 maybe an API active pharmaceutical ingredient that you
10:44AM 10 will weigh out, measure out in some way and then you're
10:44AM 11 going to dilute it and prepare a sterile product
10:44AM 12 basically by sterilizing it. You prepare it, you maybe
10:44AM 13 add an additive or two and then you go in to either
10:44AM 14 filter, sterilize it, make it sterile or you could
10:44AM 15 autoclave it, depending on the product itself.

10:44AM 16 Q. Do you also have experience with extending
10:44AM 17 beyond-use dates of --

10:44AM 18 A. Yes.

10:44AM 19 Q. -- medications?

10:44AM 20 A. Yes, I do. Of course, in a 503B environment we
10:44AM 21 have to follow CGAP regulations, so we extend beyond-use
10:44AM 22 dates according to that. I also worked in a hospital
10:44AM 23 teaching pharmacy, and so we extended beyond-use dates
10:44AM 24 according to USP 797.

10:44AM 25 Q. Did you prepare a CV in connection with this

10:44AM 1 case?

10:44AM 2 A. I'm sorry; you broke up.

10:44AM 3 Q. Did you prepare a CV in connection with this
10:44AM 4 case?

10:44AM 5 A. Yes, I did. Yes, I'm sorry. Yes.

10:45AM 6 Q. I'm going to show you what's marked as
10:45AM 7 Petitioner's Exhibit 1.

10:45AM 8 MS. O'LEARY: Your Honor, Respondents
10:45AM 9 object to Exhibit 1 as hearsay.

10:45AM 10 THE COURT: Mr. Kursman.

10:45AM 11 MR. KURSMAN: Your Honor, because this is a
10:45AM 12 bench preliminary injunction hearing, we were thinking
10:45AM 13 that it would be -- it would streamline both this
10:45AM 14 presentation and whatever argument happens later on on
10:45AM 15 Ms. Almgren's expertise, but we're happy to just go
10:45AM 16 further through Ms. Almgren's expertise.

10:45AM 17 THE COURT: That's all right, no. The
10:45AM 18 objection will be overruled and the CV will be admitted.

10:45AM 19 Q. (Mr. Kursman) Dr. Almgren, are you familiar
10:45AM 20 with the United States Pharmacopeia?

10:46AM 21 A. Yes, of course. It's a -- basically it governs
10:46AM 22 a lot of the pharmacy practice, pharmaceutical industry.
10:46AM 23 It's a really excellent reference for practice.

10:46AM 24 Q. And can you tell the Court why it's important
10:46AM 25 for a pharmacist to be familiar with the United States

1 Pharmacopeia?

2 A. You must be familiar with the USP because it
3 basically provides guidance on our everyday activities;
4 everything from how we compound, how we handle
5 medications, storage conditions. A lot of really good
6 references is in USP.

7 Q. Are you familiar with USP Chapter 797?

8 A. Yes, absolutely. It is a subject matter that I
9 have been teaching for years. And USP Chapter 797
10 basically governs or provides guidance on how to perform
11 sterile compounding in 503A regulated environment.

12 Q. And are you familiar with USP Chapter 790?

13 A. Yes, absolutely. USP Chapter 790 describes how
14 to perform visual inspection for injectables.

15 Q. And are you familiar with USP Chapter 71?

16 A. Yes. Yes, that's another very good compounding
17 method that describes how to perform sterility testing on
18 the products that are compounded.

19 Q. Dr. Almgren, have you served as an expert in
20 litigation before, an expert in pharmacy?

21 A. Yes.

22 MR. KURSMAN: Your Honor, we would move to
23 have Dr. Almgren qualified as an expert in pharmacy
24 compounding, United States Pharmacopeia and extending
25 beyond-use dates.

10:47AM 1 THE COURT: She's so accepted. You may
10:47AM 2 proceed.

10:47AM 3 Q. (Mr. Kursman) Dr. Almgren, were you retained
10:47AM 4 in this case by Petitioners' counsel?

10:47AM 5 A. Yes.

10:47AM 6 Q. Were you asked to provide an opinion about this
10:47AM 7 case?

10:47AM 8 A. Yes.

10:47AM 9 Q. Can you tell the Court what you were asked to
10:48AM 10 provide an opinion about?

10:48AM 11 A. So I was provided a number of documents to
10:48AM 12 review and basically assess whether the beyond-use date
10:48AM 13 on the products that I used are -- is appropriate.

10:48AM 14 Q. Were you asked to reach a conclusion about
10:48AM 15 whether the pentobarbital in TDCJ's possession is
10:48AM 16 expired?

10:48AM 17 A. Yes, I was asked to analyze and basically see
10:48AM 18 if I -- what are my thoughts on the expiry of those
10:48AM 19 products, yes.

10:48AM 20 Q. And what is your opinion on whether the
10:48AM 21 pentobarbital in TDCJ's possession is expired?

10:48AM 22 A. Those products are well beyond expiry. The way
10:48AM 23 that the TDCJ extends beyond-use dating is not
10:48AM 24 appropriate. This is not how you are supposed to extend
10:48AM 25 beyond-use dating on drugs.

10:48AM 1 Q. Do you hold that opinion to a reasonable degree
10:48AM 2 of scientific certainty?

10:48AM 3 A. Absolutely.

10:49AM 4 Q. Can you tell the Court what documents you
10:49AM 5 reviewed to come to that opinion?

10:49AM 6 A. So I looked at the -- I guess the documents are
10:49AM 7 listed in my testimony, in my report. But some of the
10:49AM 8 key documents that I looked at were some of the
10:49AM 9 analytical reports that were provided that basically show
10:49AM 10 the potency and some of the testing results of the drugs,
10:49AM 11 as well as I reviewed I guess the storage logs for the
10:49AM 12 drugs themselves.

10:49AM 13 Q. Were you also asked to opine on whether there
10:49AM 14 was a risk of harm that can be caused by the
10:49AM 15 administration of the expired compounded pentobarbital?

10:49AM 16 A. Yes, that's correct.

10:49AM 17 Q. Did you provide an opinion?

10:49AM 18 A. I did.

10:49AM 19 Q. And can you describe for the Court what that
10:49AM 20 opinion is?

10:49AM 21 A. Well, the drugs that are currently in
10:49AM 22 possession, as far as I know from the records that I was
10:50AM 23 provided, all appear to be well-beyond expiry, well
10:50AM 24 beyond expiration date. And with those types of
10:50AM 25 medications, it's really difficult to tell what the

1 pharmacological activity would be. Typically when you
2 have medications that expired, the further away they are
3 from the date when they were prepared, the more chances
4 there are that the medication will not work as expected.

5 I looked at the data related to the
6 pentobarbital and I saw how the TDCJ is trying to extend
7 the beyond-use date using the assay testing, but that is
8 not appropriate; and actually the potency of the drug
9 might be much lower than what was determined, and so the
10 potency may be affected. Typically as the medication
11 sits for a long time -- and of course I'm not sure, but
12 it does not appear that the storage conditions are really
13 well-monitored for those medications.

14 That also brings up another concern,
15 because medications, if they are stored in conditions
16 where the temperature changes, humidity changes, they may
17 be exposed to light; all of that has impact on medication
18 quality. And of course, the medications are expired, to
19 begin with, and then they are, you know, exposed to all
20 of these unknown conditions. So the chances of those
21 medications not functioning as they are supposed to be
22 really high.

23 Q. Is one of the probable risks that the drugs
24 will fall out of solution?

25 A. There is a good probable. The reason for that

10:51AM 1 is the medication itself, pentobarbital, is not water
10:51AM 2 soluble, so it is not your typical type of medication.
10:51AM 3 People think, oh, you just take the vial, add some normal
10:51AM 4 saline, dissolve it; here it is in liquid and you go
10:51AM 5 ahead and inject it.

10:51AM 6 Pentobarbital is actually not water
10:51AM 7 soluble. So what you have to do is, you have to adjust
10:52AM 8 the pH of the solution and you have to dissolve the
10:52AM 9 pentobarbital powder in alcohol, and so this way you are
10:52AM 10 making it to come into the solution. But what happens in
10:52AM 11 time is the pH will shift because of, like I said, the
10:52AM 12 environmental exposure, just time itself; also alcohol,
10:52AM 13 as we all know, will evaporate over time. The
10:52AM 14 concentration of that will shift, as well, and all of
10:52AM 15 that can potentially lead to the drug degrading, coming
10:52AM 16 out of solution.

10:52AM 17 I would like to see the vials of the drug.
10:52AM 18 I have no doubt that every one of them have changed color
10:52AM 19 from the original. You know, it's supposed to be clear
10:52AM 20 colored solution. You know, looking at the records that
10:52AM 21 I was provided, I have no doubt at all that those vials
10:52AM 22 are probably yellow by now, and that just shows the signs
10:52AM 23 of degradation.

10:52AM 24 Q. And if the drug falls out of solution, does
10:52AM 25 that cause pain at the injection site?

10:52AM 1 A. Oh, absolutely. Medications, if there is any
10:53AM 2 precipitation -- this is the whole point of USP
10:53AM 3 Chapter 790. You perform visual inspection to make sure
10:53AM 4 that the medications do not have any precipitant form in
10:53AM 5 them. Because if you inject medication that has
10:53AM 6 particulate matter in them, if you inject them
10:53AM 7 intravenously, it definitely can cause pain, burning at
10:53AM 8 injection site. A lot of times you will have occlusion
10:53AM 9 of the blood vessels and that can cause severe pain.

10:53AM 10 I have read literature because I do a lot
10:53AM 11 of assessments, clinical assessments for my 503B pharmacy
10:53AM 12 appointment. So I a lot of times assess clinical risks
10:53AM 13 of medication that contains particulate matter, and they
10:53AM 14 can have very severe outcomes. Patients can get a
10:53AM 15 stroke, embolism, those types of things from having
10:53AM 16 particulates in a solution.

10:53AM 17 Q. I'm going to show you what's marked as
10:54AM 18 Plaintiff's Exhibit 2. Do you recognize this exhibit?

10:54AM 19 A. Yes.

10:54AM 20 MS. O'LEARY: Respondents object to this
10:54AM 21 exhibit, Your Honor. It is inadmissible hearsay. Expert
10:54AM 22 reports are typically inadmissible without a non-hearsay
10:54AM 23 purpose, and this doesn't fall within any of the
10:54AM 24 exclusions or exceptions in Rule 801 or 803.

10:54AM 25 In re: Commitment of Johnson, Delamar vs.

10:54AM 1 Fort Worth Mountain Bikers Association, these are just a
10:54AM 2 handful of cases that exclude expert reports. Regardless
10:54AM 3 of whether the expert is testifying, the report itself is
10:54AM 4 hearsay.

10:54AM 5 THE COURT: Mr. Kursman.

10:54AM 6 MR. KURSMAN: Your Honor, we are just
10:54AM 7 attempting to streamline this presentation because
10:54AM 8 there's not a jury; but, of course, we are willing to
10:54AM 9 just go into the details of the report rather than enter
10:54AM 10 it, if you would like.

10:54AM 11 THE COURT: The objection is sustained.

10:55AM 12 Q. Aside from the documents that you discussed
10:55AM 13 earlier that you relied on, did you rely on any
10:55AM 14 scientific sources in coming to your conclusions?

10:55AM 15 A. Absolutely. This is typically what I do. I
10:55AM 16 mean, I have a lot of experience working in analytical
10:55AM 17 chemistry for almost ten years and working in industry
10:55AM 18 and working in a pharmacy. I do have vast experience,
10:55AM 19 but I typically prefer to find scientific arguments that
10:55AM 20 will support, you know, whatever my findings are.

10:55AM 21 Q. I'm going to show you what's marked as
10:55AM 22 Plaintiff's Exhibit 3. Do you recognize Plaintiff's
10:55AM 23 Exhibit 3?

10:55AM 24 A. Yes, that's USP Chapter 797.

10:55AM 25 MS. O'LEARY: Your Honor, Respondents

10:55AM 1 object to Exhibits 3, 4, 5, which are all similar to the
10:56AM 2 one that we see here, as hearsay. They also have
10:56AM 3 improper foundation; there's no authentication. There's
10:56AM 4 nothing to show that these standards apply in Texas.
10:56AM 5 When Texas has standards, they are codified. There are
10:56AM 6 pharmacy standards codified in the Texas Administrative
10:56AM 7 Code and this is not a copy of the administrative code
10:56AM 8 so...

10:56AM 9 THE COURT: Sorry, Ms. O'Leary. You froze
10:56AM 10 there for a second. You got cut off.

10:57AM 11 (Brief pause.)

10:57AM 12 MS. O'LEARY: As I was saying, Exhibits 3,
10:57AM 13 4 and 5, each are inadmissible hearsay, they don't fall
10:57AM 14 within one of the exceptions or exemptions, and the
10:57AM 15 expert has not linked this to what is applicable in
10:57AM 16 Texas, which is found in the Texas Administrative Code.

10:57AM 17 MR. KURSMAN: Your Honor, I think if I ask
10:57AM 18 another question maybe it would clear this up.

10:57AM 19 THE COURT: All right, go ahead.

10:57AM 20 Q. (BY MR. KURSMAN) Is this a source that is
10:57AM 21 ordinarily relied upon by experts in your field?

10:57AM 22 A. Absolutely. This is something that we use
10:57AM 23 across the country. This is something that pharmacists
10:57AM 24 in Texas, South Carolina, anywhere in the United States
10:57AM 25 use. Yes, this is a very common standard.

10:57AM 1 As a matter of fact, if you work in any
10:58AM 2 kind of a health system, pharmacy setting, you have to
10:58AM 3 comply with the JCAHO regulations and, of course, this is
10:58AM 4 one of the requirements. So this is a very widely
10:58AM 5 accepted standard of practice.

10:58AM 6 MR. KURSMAN: So we would move to admit
10:58AM 7 Exhibit 3 under Rule 703.

10:58AM 8 MS. O'LEARY: The Respondents continue to
10:58AM 9 object based on hearsay, Your Honor.

10:58AM 10 THE COURT: How do you responded to the
10:58AM 11 hearsay objection, Mr. Kursman?

10:58AM 12 MR. KURSMAN: Your Honor, I believe
10:58AM 13 Rule 703 allows documents in that experts rely on if it's
10:58AM 14 relied upon ordinarily by experts in their field, and
10:58AM 15 Dr. Almgren testified it was. So I believe it comes in
10:58AM 16 under 703.

10:58AM 17 THE COURT: The objection is overruled.
10:58AM 18 Exhibit 3 is admitted.

10:58AM 19 Q. (Mr. Kursman) Dr. Almgren, let me show you
10:58AM 20 what is marked as Plaintiff's Exhibit 4. Do you
10:59AM 21 recognize this exhibit?

10:59AM 22 A. Yes, yes. This is USP Chapter 71. It
10:59AM 23 describes how to perform sterility tests on products that
10:59AM 24 are sterile compounds.

10:59AM 25 Q. Is this a source that is ordinarily relied upon

10:59AM 1 by experts in your field?

10:59AM 2 A. Absolutely, yes.

10:59AM 3 MR. KURSMAN: I move to admit Petitioner's
4 Exhibit 4.

5 THE COURT: Mr. Marshall, are you taking
6 over? I don't see Ms. O'Leary.

7 MR. MARSHALL: Ms. O'Leary is attempting to
8 restart her computer.

9 THE COURT: Let's give her a moment to do
10 that.

10:59AM 11 MR. MARSHALL: Your Honor, I'm perfectly
10:59AM 12 willing to follow along with the testimony here. If
10:59AM 13 we're going to examine the witness, I will be the one
10:59AM 14 asking the questions so...

10:59AM 15 THE COURT: Well, if you are going to be
10:59AM 16 the one asking the questions, you need to be making the
11:00AM 17 objections; we don't go back and forth. Ms. O'Leary had
11:00AM 18 started with making the objections, so I assumed she
11:00AM 19 would be doing the cross-examination. You don't get to
11:00AM 20 tag team. Let's wait for Ms. O'Leary to get back,
11:00AM 21 please.

11:01AM 22 MS. O'LEARY: I apologize for that.

11:01AM 23 THE COURT: That's all right.

11:02AM 24 Mr. Kursman had offered Exhibit 4.

11:02AM 25 MS. O'LEARY: Your Honor, Respondents

11:02AM 1 object for the same reasons as 3.

11:02AM 2 THE COURT: No. 4 will be admitted.

11:02AM 3 Q. (Mr. Kursman) I'm just going to ask is this a
11:02AM 4 source -- I think I did ask while Ms. O'Leary was gone.
11:02AM 5 This is a source that is ordinarily relied upon by --

11:02AM 6 THE COURT: Hold on. Before you go on, I
11:02AM 7 can see your the -- there you go.

11:02AM 8 Q. (Mr. Kursman) This is a source that is
11:02AM 9 ordinarily relied upon by experts in your field?

11:02AM 10 A. Yes.

11:02AM 11 MR. KURSMAN: We will move to admit
11:02AM 12 Petitioner's Exhibit 4.

11:02AM 13 THE COURT: I had just admitted 4 a moment
11:02AM 14 ago. You can move on from that.

11:02AM 15 Q. (Mr. Kursman) Dr. Almgren, I want to show you
11:02AM 16 Petitioner's Exhibit 5. Do you recognize this exhibit?

11:03AM 17 A. Yes, I do.

11:03AM 18 Q. Can you describe for the Court what this
11:03AM 19 exhibit is?

11:03AM 20 A. So this is the USP chapter that describes how
11:03AM 21 to perform visual inspection for visible particulates in
11:03AM 22 the injections. It's very commonly used. We use it in
11:03AM 23 the hospital when we examine and prepare medications.
11:03AM 24 I've used it in industry, used it in pharmacy, in 503B
11:03AM 25 setting. It's very commonly used by pharmacists.

11:03AM 1 MR. KURSMAN: I would move to admit
11:03AM 2 Petitioner's Exhibit 5.

11:03AM 3 THE COURT: Ms. O'Leary.

11:03AM 4 MS. O'LEARY: Respondents object to 5 on
11:03AM 5 the same basis as 3 and 4; hearsay.

11:03AM 6 THE COURT: No. 5 is admitted.

11:03AM 7 Q. (Mr. Kursman) Dr. Almgren, in your initial
11:03AM 8 testimony you described commercially manufactured drugs
11:04AM 9 versus compounded drugs. Can you -- first, is there a
11:04AM 10 difference between the two?

11:04AM 11 A. Yes, there is absolutely a big difference
11:04AM 12 between the two. Typically your commercially prepared
11:04AM 13 medications undergo very rigorous testing.

11:04AM 14 You know, think about medications that are
11:04AM 15 made by Baxter and Pfizer. When they make those, let's
11:04AM 16 say, sterile preparations, they make thousands, tens of
11:04AM 17 thousands of dosages. And so, of course, they have to
11:04AM 18 have a very strict and a good manufacturing control,
11:04AM 19 quality control over their products. You know, the
11:04AM 20 medications are tested multiple times throughout the
11:04AM 21 manufacturing process. At the beginning, throughout you
11:04AM 22 want to assure there is continuity and uniformity that
11:04AM 23 the sterility is tested properly and all that. So the
11:04AM 24 manufacturing process is very strictly controlled. We
11:04AM 25 use CGMP regulations from the FDA that basically oversee

11:05AM 1 this process and they are very detailed, very vigorous.

11:05AM 2 By comparison, when you perform sterile
11:05AM 3 compounding in a 503A setting, let's say in the hospital
11:05AM 4 or in a pharmacy, the 503A compounding does not have
11:05AM 5 those controls in place. All we have is USP Chapter 797,
11:05AM 6 and that is what we follow. And so in Chapter 797, you
11:05AM 7 know, when you read for example how beyond-use dating is
11:05AM 8 established, it's much shorter because you don't have as
11:05AM 9 much control over the compounds as you do when you follow
11:05AM 10 CGMP.

11:05AM 11 You know, when I teach my pharmacy students
11:05AM 12 I always compare, I tell them, "You know when we talk
11:05AM 13 about USP Chapter 797, it's kind of like the high school
11:05AM 14 level regulations; then when you are looking at the CGMP,
11:05AM 15 it's kind of like the doctorate level regulations." Like
11:05AM 16 they are really strict, very specific, you know, and they
11:05AM 17 are really made to, you know, to promulgate really good
11:06AM 18 control over the entire manufacturing process.

11:06AM 19 THE COURT: Doctor, let me stop you. Tell
11:06AM 20 me, what does CGMP stand for?

11:06AM 21 THE WITNESS: Yes, absolutely. So CGMP
11:06AM 22 stands for Current Good Manufacturing Practices, and
11:06AM 23 those are specified in the Food, Drug and Cosmetic Act.
11:06AM 24 I think it's in the Federal Register. Chapter 210, 211
11:06AM 25 specify specifically sterile compounding practices.

11:06AM 1 And like I said, the CGMP, the Current Good
11:06AM 2 Manufacturing Practices are practices that are
11:06AM 3 implemented by pharmaceutical manufacturers and also 503B
11:06AM 4 compounders, so both of those. Because of the sizes of
11:06AM 5 batches, you have to have a much more strict control over
11:06AM 6 your process, over your compounding or manufacturing
11:06AM 7 process because your medications go to thousands of
11:06AM 8 patients.

11:06AM 9 So on the other end of the spectrum you
11:07AM 10 have USP Chapter 797 that provides you the basics on how
11:07AM 11 to perform compounding, sterile compounding, to prepare
11:07AM 12 safe drugs for individual patients.

11:07AM 13 Q. (Mr. Kursman) Does USP also describe how to
11:07AM 14 extend the beyond-use dates of compounded drugs?

11:07AM 15 A. It does touch upon that, yes.

11:07AM 16 Q. And does it also describe what the beyond-use
11:07AM 17 date of compounded drugs would be?

11:07AM 18 A. Yes, absolutely. And this is very crucial
11:07AM 19 because, again, when you think about manufacturing you
11:07AM 20 have so many controls in place; with compounding you
11:07AM 21 don't. It's really the pharmacist or the pharmacy
11:07AM 22 technician who is compounding, so those beyond-use dates
11:07AM 23 will be much shorter than your traditional expiry of the
11:07AM 24 manufactured medications. You know, by comparison
11:07AM 25 manufactured drugs, they may have expired a couple of

11:07AM 1 years, two to three years.

11:07AM 2 I work for a 503B compounding drug company
11:08AM 3 and so we perform compounding under 503B regulations. So
11:08AM 4 we follow CGMP, and none of our beyond-use dates are past
11:08AM 5 180 days. So even though we have strict control over our
11:08AM 6 process, we still don't extend the beyond-use date past
11:08AM 7 180 days, just out of caution.

11:08AM 8 And then you have USP Chapter 797 that,
11:08AM 9 again as I said, the regulations are different and the
11:08AM 10 control of the process of the compounding isn't as good
11:08AM 11 because, as I said, those are small batches typically
11:08AM 12 made for one or two patients by pharmacists in a
11:08AM 13 hospital. It's not your big, you know, manufacturing,
11:08AM 14 automated system where there is very little human
11:08AM 15 interaction. The compounding is all human interaction,
11:08AM 16 so a lot of potential for error, a lot of potential for
11:08AM 17 contamination. So because of that, your beyond-use dates
11:09AM 18 are going to be significantly shorter; typically in days
11:09AM 19 or hours.

11:09AM 20 Q. And are the drugs in TDCJ's possession
11:09AM 21 commercially manufactured drugs or are they compounded
11:09AM 22 drugs?

11:09AM 23 A. They are compounded drugs. That's what it says
11:09AM 24 in their records.

11:09AM 25 Q. And what does it mean for a drug to be

11:09AM 1 compounded?

11:09AM 2 A. That basically means that it was probably a
11:09AM 3 pharmacist or pharmacy technician who prepared it. It is
11:09AM 4 not commercially manufactured, an automated system.

11:09AM 5 Q. And are these sterile compounded drugs?

11:09AM 6 A. They need to be sterile because they are going
11:09AM 7 to be injected into a patient. So, of course, they need
11:09AM 8 to be sterile.

11:09AM 9 Q. According to the USP, what is the maximum
11:09AM 10 beyond-use date for a sterile compounded drug?

11:09AM 11 A. So according to USP Chapter 797, if you keep
11:09AM 12 the medication deeply frozen -- so that means it's in a
11:10AM 13 minus 10 to minus 25 degree type of deep freeze setting
11:10AM 14 -- it is good for 45 days.

11:10AM 15 Q. And the three exhibits I showed you previously,
11:10AM 16 Exhibits 3, 4 and 5, which were USP 797, 790 and 71, are
11:10AM 17 those guidelines that pharmacists follow when performing
11:10AM 18 sterile compounding of drugs?

11:10AM 19 A. Yes. Yes, of course.

11:10AM 20 Q. Are the vials of pentobarbital in TDCJ's
11:10AM 21 possession considered high risk sterile compounds?

11:10AM 22 A. My assumption is that they are high risk
11:10AM 23 compounds, yes.

11:10AM 24 Q. Can you tell the Court why?

11:10AM 25 A. Because they are most likely -- they have been

11:10AM 1 prepared from the API, from the powdered drug. So if you
11:10AM 2 are starting with an API that's typically nonsterile, you
11:10AM 3 are going to weigh out the medication, you are going to
11:10AM 4 prepare the solution. As I described earlier, this is a
11:11AM 5 non-water soluble drug, so more technically advanced in
11:11AM 6 terms of how you prepare it. And so the medication is
11:11AM 7 prepared and then put in the vials, and so then it has to
11:11AM 8 be sterilized prior to being put in vials.

11:11AM 9 Q. And I believe you testified this a minute ago
11:11AM 10 about all compounded drugs, but what is the maximum
11:11AM 11 beyond-use date for high risk sterile compounds?

11:11AM 12 A. It is the same. It's 45 days. So 45 days in
11:11AM 13 deep freeze, yes.

11:11AM 14 Q. And what if they are not in deep freeze?

11:11AM 15 A. Then, depending on the storage conditions,
11:11AM 16 24 hours if they are stored in room temperature -- that's
11:11AM 17 for high risk compounds -- and 72 hours, or 3 days, if
11:11AM 18 they are stored in refrigerator.

11:11AM 19 Q. And what chapter of the USP should be followed
11:11AM 20 for compounding of high risk sterile compounds?

11:11AM 21 A. It's USP Chapter 797.

11:11AM 22 Q. I'm going to show you again Plaintiff's
11:12AM 23 Exhibit 3. And is this USP 797 we are looking at right
11:12AM 24 here?

11:12AM 25 A. Yes, it is.

11:12AM 1 Q. Now, if we go to Page 33 of Exhibit 3, do you
11:12AM 2 see where it says the maximum beyond-use dates of
11:12AM 3 compounded drugs?

11:12AM 4 A. Yes. All the way on the bottom it says, "High
11:12AM 5 risk level compounded sterile products." It says, "Not
11:12AM 6 more than 24 hours at room temperature, three days at
11:12AM 7 cold and 45 in solid frozen state."

11:12AM 8 Q. Now I'm going to show you what's previously
11:12AM 9 been admitted as Plaintiff's Exhibit 6. Do you recognize
11:13AM 10 this exhibit?

11:13AM 11 A. Yes, I do.

11:13AM 12 Q. And did you rely on this exhibit in forming
11:13AM 13 your opinion?

11:13AM 14 A. Yes, I did.

11:13AM 15 Q. I'm going to take you to -- do you see the date
11:13AM 16 that says 3-18-21?

11:13AM 17 A. Yes. 3-18-21, received from supplier line.
11:13AM 18 Yes, I see it.

11:13AM 19 Q. According to these records, this is the last
11:13AM 20 time that TDCJ received 50 milliliter vials of
11:13AM 21 pentobarbital?

11:13AM 22 A. That's what it appears to be, from the records
11:13AM 23 that I was given.

11:13AM 24 Q. So according to the USP, when would the 50
11:13AM 25 milliliter vials of pentobarbital have expired?

11:13AM 1 A. So if this medication was stored in deep
11:13AM 2 freeze, that would be good for 45 days. So 3-18-21 -- I
11:14AM 3 would say sometime early May of 2021 is when this
11:14AM 4 medication would have expired.

11:14AM 5 Q. I'm going to show you Plaintiff's Exhibit 7.
11:14AM 6 Do you recognize this exhibit?

11:14AM 7 A. Yes.

11:14AM 8 Q. And what is this exhibit?

11:14AM 9 A. So this appears to be the storage inventory of
11:14AM 10 the pentobarbital vials that have 100 milliliter volume.

11:14AM 11 Q. And do you see the entry that says 4-29-19?

11:14AM 12 A. Yes. That's when I'm assuming the six vials
11:14AM 13 were received, or six vials were -- let me see -- oh, 15
11:14AM 14 vials were received from the supplier and added into the
11:14AM 15 inventory.

11:14AM 16 Q. And according to these records, 4-29-19 is the
11:14AM 17 last time TDCJ received 100 milliliters vials of
11:14AM 18 pentobarbital?

11:15AM 19 A. That's what it appears to be.

11:15AM 20 Q. According to USP, when would have the 100
11:15AM 21 milliliter vials in TDCJ's possession have expired?

11:15AM 22 A. Sometime in mid June of 2019.

11:15AM 23 Q. Based on your review of the records, has TDCJ
11:15AM 24 been following the USP when extending the beyond-use date
11:15AM 25 of pentobarbital in its possession?

11:15AM 1 A. No. Because what they appear to be doing is
11:15AM 2 they just basically test the medication and if it appears
11:15AM 3 that potency is there, then they somehow -- and I'm not
11:15AM 4 really sure what the reasoning is -- they are just
11:15AM 5 extending it beyond that. But you know, there are a lot
11:15AM 6 of flaws in that particular methodology, number one being
11:15AM 7 the fact that when you tested one vial from one batch,
11:16AM 8 that is not representative of all of the other vials and
11:16AM 9 all of the other batches that you have in possession.

11:16AM 10 So it's very important to have good quality
11:16AM 11 manufacturing process like when you do 503B compounding
11:16AM 12 or sterile compounding, you know, manufacturing where you
11:16AM 13 have large batches and you have contact uniformity. When
11:16AM 14 you are doing small scale, there's no guarantee that
11:16AM 15 other vials are exactly the same. So that's one concern.

11:16AM 16 The other concern that I have is the fact
11:16AM 17 that when you are testing the potency using an assay, the
11:16AM 18 methodology that's used to test for the actual potency,
11:16AM 19 the strength is not appropriate. You have to use a
11:16AM 20 method that looks at the stability and looks at the
11:16AM 21 degradation of the product, especially when these
11:16AM 22 products are so old and expired.

11:17AM 23 Your stability indicating method will show
11:17AM 24 you if there are any other potential degradants in the
11:17AM 25 product itself. And those would be bundled in with the

11:17AM 1 main drug in an assay, so you would not be able to see
11:17AM 2 them.

11:17AM 3 Q. So in layman's terms, can you describe for the
11:17AM 4 Court what TDCJ is doing to purportedly extend the B-U
11:17AM 5 date of the pentobarbital in their possession?

11:17AM 6 A. So from what I can tell from the records that
11:17AM 7 are provided for my review, they basically test the drug
11:17AM 8 and if it still has what they assume is the correct
11:17AM 9 potency, which we are not really sure that it does, they
11:17AM 10 just say all of the vials are still good, regardless
11:17AM 11 whether they are 50 ml vials or 100 ml vials and they
11:17AM 12 just somehow assign it the further date out.

11:17AM 13 But that's completely inappropriate,
11:17AM 14 because what you need to do is you need to do a stability
11:18AM 15 study that basically will determine what is the proper
11:18AM 16 span for the medications expiring. So if you perform a
11:18AM 17 stability study, then you will be able to project the
11:18AM 18 dates forward. But you can't do that as you go; that's
11:18AM 19 not a correct way of doing it. You can't just assume
11:18AM 20 that next time we test it, it probably will be fine; it's
11:18AM 21 fine between now and the next date.

11:18AM 22 Q. And did they perform all the tests that are
11:18AM 23 required under the United States Pharmacopeia?

11:18AM 24 A. No. I also did not see all of the tests that
11:18AM 25 they are supposed to do, and one that really concerns me

11:18AM 1 is actually pH. PH is a concerning one because, number
11:18AM 2 one, if the pH is not appropriate the drug may fall out
11:18AM 3 of solution -- and you may say, "Oh, I don't see
11:18AM 4 anything," because you may have microcrystal formation.
11:18AM 5 There is actually potential for these difficult-to-see
11:18AM 6 particles to be formed that you may not see with the
11:18AM 7 naked eye.

11:18AM 8 And so they may -- so they really should
11:19AM 9 perform pH to assess that the drug still has the pH that
11:19AM 10 it's supposed to have. And of course, pH itself, if it's
11:19AM 11 inappropriate, it can cause burning and pain at the
11:19AM 12 injection site. So pH is definitely something that needs
11:19AM 13 to be tested.

11:19AM 14 And also the sterility that they have
11:19AM 15 performed or they had the contract lab to perform is done
11:19AM 16 via scan RDI, which is a technology that provides quicker
11:19AM 17 turnaround. It's a quick technology, but it is not as
11:19AM 18 accurate. And in particular, it does not capture a lot
11:19AM 19 of times some of the long-term microorganisms, some of
11:19AM 20 the fungus, some of the microorganisms that you will only
11:19AM 21 see in USP 71 methodology. So the sterility is not
11:19AM 22 tested via correct method, either.

11:19AM 23 Q. I want to show you what is marked as
11:19AM 24 Plaintiff's Exhibit 8. Do you recognize this exhibit?

11:20AM 25 A. Yes.

11:20AM 1 Q. Do you see it's from August 12, 2022?

11:20AM 2 A. Yes, that's correct.

11:20AM 3 Q. Can you see it's from TDCJ?

11:20AM 4 A. Yes.

11:20AM 5 Q. Do you see that on August 12, 2022, the
11:20AM 6 beyond-use date of the 2.5 gram vials in TDCJ's
11:20AM 7 possession was assigned at October 9, 2022, and
11:20AM 8 December 8, 2022?

11:20AM 9 A. Yes, that's correct.

11:20AM 10 Q. Do you see that on that same date the 5 gram
11:20AM 11 vials had beyond-use date or purported beyond-use date of
11:20AM 12 12-8-2022?

11:20AM 13 A. That's correct.

11:20AM 14 Q. Now I'm going to point you to Plaintiff's
11:20AM 15 Exhibit 9 which has already been admitted. Do you
11:20AM 16 recognize this exhibit?

11:20AM 17 A. Yes.

11:20AM 18 Q. Do you see it's an e-mail from TDCJ on
11:20AM 19 November 29, 2022?

11:20AM 20 A. Yes.

11:21AM 21 Q. Do you see that the beyond-use dates for
11:21AM 22 pentobarbital changed from that last e-mail?

11:21AM 23 A. Right.

11:21AM 24 Q. Can you tell the Court what those beyond-use
11:21AM 25 dates now are assigned by TDCJ?

11:21AM 1 A. They seem to be projected way out, far out. We
11:21AM 2 are talking about September of 2023 and November of 2023.
11:21AM 3 That's a really significant change from the previous
11:21AM 4 beyond-use date.

11:21AM 5 Q. Do you know how TDCJ extended the beyond-use
11:21AM 6 dates of the pentobarbital in their possession?

11:21AM 7 A. Unless they performed a stability study, I
11:21AM 8 would say incorrectly, because there's no really other
11:21AM 9 way of assigning beyond-use dates out far like this.

11:21AM 10 Like I said, we compound in my pharmacy, we
11:21AM 11 compound medications according to 503B, according to CGMP
11:21AM 12 regulations and we don't typically assign BUD's past
11:22AM 13 180 days. So it's really impressive they are able to
11:22AM 14 extend the BUD this far out, but I would really wonder
11:22AM 15 what type of documentation they have that they are able
11:22AM 16 to do so.

11:22AM 17 Q. Now I'm going to show you what's marked as
11:22AM 18 Plaintiffs Exhibit 10 which has previously been admitted.
11:22AM 19 Have you reviewed Plaintiff's Exhibit 10 before?

11:22AM 20 A. Yes.

11:22AM 21 Q. Have you reviewed what testing has been done by
11:22AM 22 the laboratory for TDCJ's pentobarbital?

11:22AM 23 A. Yes, that's correct. This is an assay that was
11:22AM 24 performed.

11:22AM 25 Q. What they have done, is that the proper way to

11:22AM 1 extend the beyond-use dates of drugs according to the
11:22AM 2 USP?

11:22AM 3 A. No. No, this is not the assay that you should
11:22AM 4 use. This assay is traditionally used when you are
11:22AM 5 performing quality control or maybe when you receive the
11:22AM 6 raw material. So when you receive an API, active
11:22AM 7 pharmaceutical ingredient, maybe from a manufacturer, you
11:22AM 8 are going to do a compounding activity, you are going to
11:22AM 9 receive the API and you will have it tested by a contract
11:23AM 10 lab to make sure that it has the potency that you need.

11:23AM 11 So once you have that, then you are going
11:23AM 12 to compound it and maybe at the end of your compounding
11:23AM 13 procedure you will send out a sample to test it again.
11:23AM 14 But this is all -- this assay is typically used to just
11:23AM 15 verify that the drug has the potency that it has.

11:23AM 16 Q. Based on the testing that you reviewed by the
11:23AM 17 pharmacy or the laboratory, would it be appropriate to
11:23AM 18 extend the beyond-use dates of the pentobarbital as far
11:23AM 19 out as TDCJ has done?

11:23AM 20 A. Using this methodology, no. You need to
11:23AM 21 perform a stability indicating assay. And the stability
11:23AM 22 indicating assay is the proper methodology that will
11:23AM 23 explore how well is your drug holding up; are there any
11:23AM 24 degradants that are potentially forming. And so you need
11:23AM 25 to perform the stability indicating assay that will

11:23AM 1 analyze quality of a drug that, you know, you are looking
11:24AM 2 at potentially extending the BUD for.

11:24AM 3 Q. What I'm going to show you now, can you explain
11:24AM 4 what this chart shows to the Court?

11:24AM 5 A. Sure. So this is an example from just when you
11:24AM 6 run your typical run-of-the-mill assay. So you want to
11:24AM 7 know what is the potency of my medication, you want to
11:24AM 8 know what is the -- how many milligrams of pentobarbital
11:24AM 9 is in my solution, or any drug for that matter.

11:24AM 10 So what you will do is, this is a
11:24AM 11 chromatography example from a HPLC, High Precision Liquid
11:24AM 12 Chromatograph. It's a system that basically analyzing --
11:24AM 13 a very commonly used system in pharmaceutical industry
11:25AM 14 and pharmacy in general.

11:25AM 15 So what happens is, you will analyze your
11:25AM 16 medication. You will have a curve, so you are going to
11:25AM 17 use for standards that will create a calibration curve so
11:25AM 18 you can quantitate what -- you know, how much of the
11:25AM 19 analyte you have. So you are going to create -- you
11:25AM 20 purchase your USP standards from USP that basically you
11:25AM 21 can confirm that it is the correct medication. And so
11:25AM 22 you use the standards, you will make a calibration curve.
11:25AM 23 And then you use this calibration curve to quantitate
11:25AM 24 your recovery, to see that your drug that you compounded
11:25AM 25 has the appropriate potency. So that's what this is.

11:25AM 1 So this is an example of your HPLC method
11:25AM 2 that's used to analyze your finished product or maybe
11:25AM 3 your API. You're just looking strictly for potency; you
11:25AM 4 want to see how much of the drug is in a solution.

11:25AM 5 Q. And this is the testing that TDCJ is doing to
11:26AM 6 extend their beyond-use dates?

11:26AM 7 A. I believe so, because it was listed at the
11:26AM 8 bottom where they basically -- in the report, the
11:26AM 9 analytical report, it said which methodology they used
11:26AM 10 and they refer to USP; I think it's 624, which is an HPLC
11:26AM 11 analysis. And of course, you will get more detail if you
11:26AM 12 go into a monograph for the pentobarbital. It will give
11:26AM 13 you details of how to perform this analytical method.

11:26AM 14 But again, the monograph for the
11:26AM 15 pentobarbital injection provides guidance on how to
11:26AM 16 perform just a regular assay. So that's what this is.
11:26AM 17 This is an example of an assay. You are just
11:26AM 18 quantitating how much pentobarbital was in there and you
11:26AM 19 are assuming that it's all just pure pentobarbital.

11:26AM 20 Q. Can you describe for the Court what this
11:26AM 21 picture shows?

11:26AM 22 A. This is as great example of a stability
11:26AM 23 indicating assay. So in this case what you are seeing
11:26AM 24 is, it could be exactly the same sample that you the saw
11:26AM 25 on the previous example. So it may be exactly same drug,

1 but if that drug is maybe close to expiring, maybe it's
2 expired, it's been around for a while, it has most likely
3 passed its expiry, you will start seeing degradants,
4 which is of course a natural process with any medication.
5 That's why we have expiration dates, because we can only
6 guarantee their quality and their activity up to the
7 expiry. And so once you start getting past the expiry,
8 you will start seeing degradants forming.

9 What you see in this example, you see the
10 separation of the degradant from the analyte. So in the
11 first example the degradant is basically part of the
12 analyte because it's a different method. So this is a
13 stability indicating method and your elution time in the
14 mobile phase, the chemicals that basically help to kind
15 of separate out your degradants are being used to
16 basically see if there is any degradation.

17 So if you had a fresh drug, if you had
18 pentobarbital that you just purchased from the
19 manufacturer, you will not see the degradant at all. Or
20 you may see a tiny little peak that would not really
21 impact your total size of the analyte peak. But as the
22 drugs degrade over time, you will start seeing these
23 degradants and that's exactly what is shown here.

24 So you see this degradant that's a peak. I
25 mean, in this case the peak is almost probably about

11:28AM 1 80 percent the size of the analyte peak. So this would
11:28AM 2 be completely different and this could be a different
11:28AM 3 chemical and most likely is a very different structure
11:28AM 4 that might not have any of the pharmacologic activity of
11:28AM 5 your analyte.

11:28AM 6 Q. So can you describe in layman's terms for the
11:28AM 7 Court what a degradant is?

11:28AM 8 A. So a degradant is basically a chemical entity
11:29AM 9 that just develops from whatever you have, let's say a
11:29AM 10 pentobarbital molecule. Over time it just -- it gets
11:29AM 11 exposed to light, maybe a different temperature, and so
11:29AM 12 it kind of falls apart and the structures change.

11:29AM 13 So eventually these other chemicals that
11:29AM 14 are being formed from the mother analyte, from the
11:29AM 15 original peak, these other peaks that are being formed,
11:29AM 16 these are different chemicals. At times -- I was looking
11:29AM 17 at some literature to see the degradation process of
11:29AM 18 pentobarbital and I do believe I included it in my expert
11:29AM 19 report as well. There is an example of degradation of
11:29AM 20 pentobarbital.

11:29AM 21 But what happens, the pentobarbital
11:29AM 22 actually breaks down into some of the entities that
11:29AM 23 initially when you are preparing pentobarbital from raw
11:29AM 24 materials -- so those chemicals that you made it from --
11:29AM 25 those are the chemicals that it basically goes back to.

11:29AM 1 So it kind of falls apart into those.

11:30AM 2 Q. So is pentobarbital known to have degradants
11:30AM 3 that form over time?

11:30AM 4 A. Yes. Yes, of course. Yes, a majority of the
11:30AM 5 medications do.

11:30AM 6 Q. And when those degradants form over time, do
11:30AM 7 they have the same pharmacological effect as
11:30AM 8 pentobarbital itself?

11:30AM 9 A. No, they do not. A lot of times they are not
11:30AM 10 studied just because, you know, there is really -- we
11:30AM 11 don't use medications that are past expiry, so we
11:30AM 12 typically don't study them in great detail.

11:30AM 13 But I was curious and I looked up a couple
11:30AM 14 because, like I said, those are actually, for
11:30AM 15 pentobarbital, those are actually drugs that they started
11:30AM 16 with. I shouldn't say drugs; they are chemicals that
11:30AM 17 they started with and then they synthesized the
11:30AM 18 pentobarbital.

11:30AM 19 So some of them do have some described
11:30AM 20 activity and, if I remember correctly, one of them was
11:30AM 21 stimulating the pancreas. Like they do not have any more
11:30AM 22 pharmacological activity of the pentobarbital; they are
11:30AM 23 very different structures.

11:30AM 24 Q. And the potency testing that was done by the
11:31AM 25 pharmacy employed by TDCJ, did they do testing to detect

11:31AM 1 the degradants?

11:31AM 2 A. I don't believe so because they use the
11:31AM 3 standard assay method, and the assay method is not a
11:31AM 4 stability indicating method. So it's a different method.
11:31AM 5 So when they run the assay, they will just see one peak.
11:31AM 6 That peak could actually be containing all of these other
11:31AM 7 degradants, but you don't see them because you are using
11:31AM 8 different methods. So you are not eluting, you are not
11:31AM 9 separating out all of the degradants; instead you are
11:31AM 10 just running it as a one-peak. So it will appear as a
11:31AM 11 one-peak and in reality it could be serial peaks that you
11:31AM 12 are just not seeing.

11:31AM 13 Q. Now I'm going to show you again Plaintiff's
11:31AM 14 Exhibit 7. If I take you to Page 3 of Plaintiff's
11:31AM 15 Exhibit 7, can you tell the Court the last time TDCJ
11:32AM 16 returned a vial to the lab to test the 100 milliliters
11:32AM 17 vials of pentobarbital?

11:32AM 18 A. So it appears on here it was all the way on the
11:32AM 19 bottom. December 20, 2021, return to supplier or -- yes,
11:32AM 20 I think so.

11:32AM 21 Q. If you look at Page 4, which is the very last
11:32AM 22 page, were there any times after December 20, 2021, that
11:32AM 23 TDCJ returned one of the 100 milliliter vials to the
11:32AM 24 laboratory to be tested?

11:32AM 25 A. No, there does not appear to be.

11:32AM 1 Q. Now let's turn to Exhibit 6 which is already
11:32AM 2 been admitted. And if I take you to Page 2, can you tell
11:32AM 3 the Court the last time TDCJ returned a 50 milliliter
11:33AM 4 vial to the supplier to be tested?

11:33AM 5 A. It appears it is September 30, 2022. That's
11:33AM 6 what it says, "Return to supplier."

11:33AM 7 Q. Do you also see, I believe it says 9-30-2022,
11:33AM 8 as well, "Return to supplier"?

11:33AM 9 A. Yes, 9-30-2022, "Return to supplier." That's
11:33AM 10 correct.

11:33AM 11 Q. And that would have been between the two
11:33AM 12 e-mails that I showed you before, correct; the e-mail on
11:33AM 13 August 12, 2022, and the e-mail on 11-29-22 from TDCJ?

11:33AM 14 A. Yes, that's correct.

11:33AM 15 Q. So from August 12, 2022 when TDCJ sent that
11:33AM 16 first e-mail to 11-29-2022, were any of the 100
11:34AM 17 milliliter vials returned to the supplier?

11:34AM 18 A. I don't believe so.

11:34AM 19 Q. If none of those vials were returned to the
11:34AM 20 supplier, could there be a scientific basis to extend the
11:34AM 21 BUD of the 100 milliliter vials?

11:34AM 22 A. No, absolutely not, because that's a couple of
11:34AM 23 different sizes, a potentially different container,
11:34AM 24 container closure. So all that, it's not just the drug
11:34AM 25 itself, but you know you have a potential different

11:34AM 1 compounding process. You definitely have a different
11:34AM 2 container size and volume. All of that would require its
11:34AM 3 own testing to be able to project -- or not even project,
11:34AM 4 but to test the assay to figure out what is the potency.

11:34AM 5 Q. But even though in your expert opinion there
11:34AM 6 was no scientific basis based on your review of the
11:34AM 7 records, you saw that TDCJ nevertheless extended the BUD
11:34AM 8 of the 100 milliliter or 5 gram vials of pentobarbital?

11:35AM 9 A. They did, but I am not really sure how they
11:35AM 10 could have done that with what they are supposed to be
11:35AM 11 doing. They did not follow the proper procedures.

11:35AM 12 Q. Now let's talk about the 50 milliliter vials.
11:35AM 13 You just testified a minute ago that TDCJ transferred 102
11:35AM 14 vials during the period of the two e-mails, right?

11:35AM 15 A. Yes.

11:35AM 16 Q. In terms of extending the BUD for all 50
11:35AM 17 milliliter vials, even if they did the correct testing on
11:35AM 18 those two vials, would it be consistent after correct
11:35AM 19 testing on two vials to extend the entire batch of the 50
11:35AM 20 milliliter vials?

11:35AM 21 A. No, because they are not representative. Also
11:35AM 22 I'm concerned, I'll be honest, that does not seem to be
11:36AM 23 -- of course there's a redacted portion, so maybe that's
11:36AM 24 what data is hiding. But it does not appear that there
11:36AM 25 is a very good control, inventory control in terms of lot

11:36AM 1 numbers.

11:36AM 2 And so it would be very crucial to test, if
11:36AM 3 you have any testing performed, that it really relates to
11:36AM 4 vials you tested. It does not relate to different
11:36AM 5 batches and different products, different sizes or
11:36AM 6 anything like that; those are just the ones that you
11:36AM 7 tested.

11:36AM 8 Q. Now based on your review of the records, did
11:36AM 9 TDCJ test the pH of the pentobarbital?

11:36AM 10 A. No, it was not included in the report.

11:36AM 11 Q. Is that required to extend the BUD under the
11:36AM 12 USP?

11:36AM 13 A. Absolutely, yes, all of the testing that's
11:36AM 14 listed in the monograph -- so when you have a
11:36AM 15 pentobarbital injection monograph that's listed in the
11:36AM 16 USP compounding, it lists all that needs to be performed,
11:36AM 17 and pH is one of them. So whenever you perform any kind
11:36AM 18 of stability studies, you will make sure that your
11:37AM 19 stability study results will meet all of the USP
11:37AM 20 monograph requirements.

11:37AM 21 Q. Based upon your review of the records, was
11:37AM 22 visual inspection performed to extend the BUD of the
11:37AM 23 pentobarbital?

11:37AM 24 A. It was not recorded on the report.

11:37AM 25 Q. Is this required by USP?

11:37AM 1 A. Yes, it is.

11:37AM 2 Q. Can you tell the Court why visual inspection is
11:37AM 3 important?

11:37AM 4 A. Visual inspection is very important in
11:37AM 5 particular with injectable drugs because you need to
11:37AM 6 examine it in case there is any formation of
11:37AM 7 precipitation.

11:37AM 8 Q. Dr. Almgren, we discussed this a bit before,
11:37AM 9 but did TDCJ test at all for sterility?

11:37AM 10 A. Yes, it did appear that they did test the
11:37AM 11 sterility of the products.

11:37AM 12 Q. Was it the correct test for sterility?

11:37AM 13 A. No, it was not correct. They were using scan
11:37AM 14 RDI instead of the required method in USP 71 that is
11:38AM 15 specified in a monograph for pentobarbital injection.

11:38AM 16 Q. Now, let's talk about TDCJ's record keeping in
11:38AM 17 relation to the pentobarbital. Can you describe for the
11:38AM 18 Court how drugs are removed from storage when they are
11:38AM 19 tested?

11:38AM 20 A. In the case of TDCJ or just the regular how?

11:38AM 21 Q. In TDCJ; meaning does it just show that they
11:38AM 22 are re-sent to the supplier?

11:38AM 23 A. Yes, that's what appears. So they basically
11:38AM 24 take them out of the inventory, then it appears it says,
11:38AM 25 "Return to supplier." What's really not good is the fact

11:38AM 1 that they don't have really any storage details about the
11:38AM 2 temperature, how the drugs are actually stored. And then
11:38AM 3 when they are transferred, if they are being shipped to
11:38AM 4 the supplier, are they in frozen state, are they in a
11:39AM 5 refrigerator? None of that is documented and it just
11:39AM 6 says, "Return to supplier."

11:39AM 7 Q. Now I'm going to show you again Exhibit 7.
11:39AM 8 We're going to go to Page 3. Do you see on 9-8-20 they
11:39AM 9 returned a vial to the supplier?

11:39AM 10 A. Yes, I do see that.

11:39AM 11 Q. Then if you go to Exhibit 10 which has already
11:39AM 12 been admitted, I'm going to take you to Page 3. Do you
11:39AM 13 see on 9-18-2020 they tested a vial?

11:39AM 14 A. Yes, that's correct.

11:40AM 15 Q. Now if we go back to Exhibit 7 that you just
11:40AM 16 saw before, do you see on 1-21-21 a vial was returned?

11:40AM 17 A. Yes. I saw that, yes. The assumption I'm
11:40AM 18 making is that a vial was sent out to the supplier who
11:40AM 19 then sent it off to be tested. The drug was tested and
11:40AM 20 then it was returned back and put back into inventory,
11:40AM 21 which is completely inappropriate. You cannot return
11:40AM 22 medication after it was tested back into inventory by --
11:40AM 23 you would never, you should never use it in a patient,
11:40AM 24 never use it in a person because the medication could be
11:40AM 25 tampered with.

11:40AM 1 It was not stored properly, it was opened,
11:40AM 2 a portion of it was removed for testing. There's a very
11:40AM 3 good potential for bacterial contamination or, for that
11:41AM 4 matter, physical or chemical contamination, as well. So
11:41AM 5 vials like that should never be returned; that should
11:41AM 6 have been disposed of.

11:41AM 7 Q. And is that practice consistent with the USP,
11:41AM 8 to test a vial and then return it?

11:41AM 9 A. No. No, you would never do that. It's not
11:41AM 10 consistent with the USP, FDA, pharmacy general practice,
11:41AM 11 you know, aseptic technique. All of those would direct
11:41AM 12 you to not use vials that have been opened and tested.

11:41AM 13 Q. Now let me direct your attention again to
11:41AM 14 Exhibit 7. You see it says "Expired"?

11:41AM 15 A. Yes.

11:41AM 16 Q. And one vial was taken out of storage?

11:41AM 17 A. Yes.

11:41AM 18 Q. What does that tell you as an expert in
11:41AM 19 pharmacy?

11:41AM 20 A. It's actually extremely mind boggling, I'll be
11:41AM 21 honest with you, because I don't understand how you can
11:42AM 22 have one vial that's expired. How did you identify that
11:42AM 23 this vial expired, how were you able to determine by
11:42AM 24 looking at it that it's expired and why were there not
11:42AM 25 other vials within the same batch that were also expired.

11:42AM 1 I think it's very poor practice and there
11:42AM 2 should be, if nothing else, some form of explanation of
11:42AM 3 why this vial was expired. But that's very disturbing
11:42AM 4 because it just tells me that the folks who are handling
11:42AM 5 these medications, my assumption is they probably looked
11:42AM 6 at a vial and maybe saw some physical changes that made
11:42AM 7 them expire this. But you never just expire one vial.

11:42AM 8 If one vial has -- you see some type of
11:42AM 9 changes, you're going to expire all within the same lot.
11:42AM 10 Because there's a very good chance that all of them are
11:42AM 11 going through the same chemical changes or physical
11:42AM 12 changes as this one; you may just not be able to quite
11:42AM 13 see them, but they may definitely be happening.

11:42AM 14 Q. In your career as a pharmacist has there ever
11:42AM 15 been a situation where you had one vial expired but the
11:43AM 16 rest of the batch was not?

11:43AM 17 A. No, no. We would not do that. I mean, if one
11:43AM 18 expires, all expire.

11:43AM 19 Q. Dr. Almgren, based on the documents you have
11:43AM 20 reviewed and on your professional experience, what is
11:43AM 21 your scientific opinion about the pentobarbital in TDCJ's
11:43AM 22 possession?

11:43AM 23 A. It is expired. It is well beyond the
11:43AM 24 beyond-use date, and there's really no way to tell what
11:43AM 25 state the medication is in, if it's, you know -- how much

11:43AM 1 of it is actually still pentobarbital, how much of it is
11:43AM 2 degradants. It's difficult to tell because it has not
11:43AM 3 been analyzed using a stability method.

11:43AM 4 Q. Do you hold this opinion to a reasonable degree
11:43AM 5 of scientific certainty?

11:43AM 6 A. I do.

11:43AM 7 MR. KURSMAN: I have nothing further, Your
11:43AM 8 Honor.

11:43AM 9 THE COURT: Could you go ahead and unshare
11:44AM 10 your screen. I need to give Ms. Hayes a break. And I'm
11:44AM 11 cognizant of the doctor's time before we do that, so I
11:44AM 12 need to take at least a 10-minute break because my court
11:44AM 13 reporter can't keep going.

11:44AM 14 Let me ask counsel for Mr. Brown, do you
11:44AM 15 have questions for this witness or are we going to go
11:44AM 16 directly to the State?

11:44AM 17 MR. SCHARDL: Nothing from Mr. Fratta, Your
11:44AM 18 Honor.

11:44AM 19 MR. WOLFF: Nothing for Mr. Brown. Thank
11:44AM 20 you, Your Honor.

11:44AM 21 THE COURT: Thank you. Let's be on break
11:44AM 22 for ten minutes.

11:44AM 23 (Whereupon There was a Break in the Proceedings)

11:57AM 24 THE COURT: All right, Ms. O'Leary.

11:57AM 25 MS. O'LEARY: Yes, Your Honor.

CROSS-EXAMINATION

BY MS. O'LEARY:

Q. Good morning, Dr. Almgren. I just have a few questions and I'll try to make it quick because I know you are on a quick turnaround.

You have not worked in a pharmacy where you compounded lethal doses of a drug; is that accurate?

A. That's correct.

Q. You testified earlier that it is really difficult to assess what the pharmacological activity might be in TDCJ's supply of drugs; is that accurate?

A. Right.

Q. Are you familiar with a study conducted by a Priest Geisbuhler where he [sic] studied injectable sodium pentobarbital stability at room temperature?

A. I am, and actually I read it last night just to make sure that I'm up-to-date on all of the literature, so yes.

Q. Okay good. So let me get to the table here.

THE COURT: Hold on one second. I'm sorry. I should have asked Ms. Hayes -- I need to make sure Ms. Hayes is with us.

THE STENOGRAPHER: Yes, I'm here.

THE COURT: Ok. Thank you. Proceed.

MS. O'LEARY: Thank you, Your Honor.

11:58AM 1 Q. (Ms. O'Leary) In that study the person who
11:58AM 2 conducted the study says that about 15 to 25 milligrams
11:58AM 3 of pentobarbital is a lethal dose. Is that consistent
11:58AM 4 with your understanding of pentobarbital?

11:58AM 5 A. I guess so.

11:58AM 6 Q. You are not familiar with what would be a
11:58AM 7 lethal dose of pentobarbital?

11:58AM 8 A. No, no. I mean yeah -- yeah, I mean
11:58AM 9 pentobarbital is a very potent drug.

11:58AM 10 Q. Okay. And so if 15 to 25 milligrams is a
11:59AM 11 lethal dose, are you aware that TDCJ uses about 10 times
11:59AM 12 that to conduct lethal injection?

11:59AM 13 A. Right. I'm assuming you use a whole 50? What
11:59AM 14 do you normally use? Is it a vial?

11:59AM 15 Q. So it's five grams and five more grams as a
11:59AM 16 backup.

11:59AM 17 A. Right.

11:59AM 18 Q. In that same study the lab conducted studies of
11:59AM 19 compounded pentobarbital solution, which is similar to
11:59AM 20 what we're discussing today. Did you see the part where
11:59AM 21 he -- his finding is that the chemical degradation occurs
11:59AM 22 at about half a percent per year for sodium pentobarbital
11:59AM 23 compound?

11:59AM 24 A. So I would like to point out one thing, and I'm
11:59AM 25 not sure that we can share the document in any way

11:59AM 1 because it appears like maybe you have it on paper.

12:00PM 2 If you read that study, if you will start

12:00PM 3 -- I think it's on maybe, it's on the first page. The

12:00PM 4 study starts off by discussing the two methods that they

12:00PM 5 have used. Can you -- I wish -- can I look? I have that

12:00PM 6 study on my computer. Would it be okay for me to open it

12:00PM 7 so we can talk about the same study together? I have the

12:00PM 8 study right here.

12:00PM 9 Q. Well, let me just re-ask the question.

12:00PM 10 THE COURT: No, ma'am. Doctor, just let

12:00PM 11 Ms. O'Leary ask her question, please.

12:00PM 12 Q. (Ms. O'Leary) Do you agree that that finding

12:00PM 13 concludes that it degrades at half a percent per year?

12:00PM 14 A. No, they use incorrect method. So there are

12:00PM 15 two methods --

12:00PM 16 Q. I'm sorry. That's not my question.

12:00PM 17 MR. KURSMAN: Objection, Your Honor. If

12:00PM 18 Ms. O'Leary is going to ask these questions, I would just

12:00PM 19 ask that she allow Dr. Almgren to answer those questions.

12:00PM 20 THE COURT: Well, I think Dr. Almgren, she

12:00PM 21 did answer it. She said no, she did not agree.

12:00PM 22 Ms. O'Leary can ask her next question.

12:01PM 23 Q. (Ms. O'Leary) Your explanation, Doctor, is

12:01PM 24 that was the finding, but you disagree with the methods.

12:01PM 25 Is that what you mean?

12:01PM 1 A. That's exactly what I mean. When you read the
12:01PM 2 article, they quote two separate methods. So they have a
12:01PM 3 method by Morley and Elrod and they have a method by is
12:01PM 4 it Reef? There are two different methods. So the method
12:01PM 5 that they use is the one by Morley and Elrod, and that
12:01PM 6 method is actually your analytical method that you use
12:01PM 7 for confirmation of analyte.

12:01PM 8 The second method that is used by, like I
12:01PM 9 said, I think it's Reef and --- I can't remember; there
12:01PM 10 are a couple of other authors on the other method. That
12:01PM 11 is the stability indicating method. And they did not use
12:01PM 12 that one, so they don't explain in that particular study
12:01PM 13 based on what they chose, the Method One. But they just
12:01PM 14 performed Method One, which is not stability indicating;
12:01PM 15 it does provide the guidance on how to perform an assay.

12:02PM 16 So that's why I disagree with them being
12:02PM 17 able to assess the degradation being 0.5 percent per
12:02PM 18 year. Because if you are not using correct method, what
12:02PM 19 they are really just showing is that, using the regular
12:02PM 20 analytical method, they are seeing some degradation as
12:02PM 21 well. I think an actual stability indicating method
12:02PM 22 would probably show a higher percentage of degradation.

12:02PM 23 Q. So that first method, is that the method that
12:02PM 24 TDCJ uses in their testing that you also disagree with,
12:02PM 25 the standard assay?

12:02PM 1 A. So I would have to look, honestly, because I do
12:02PM 2 not know 100 percent. It sounds like the method that's
12:02PM 3 used, but I could not confirm it without actually seeing
12:02PM 4 chromatography and seeing the settings what buffer they
12:02PM 5 use, elution method. There are a lot of details that
12:02PM 6 would have to be confirmed.

12:02PM 7 Q. Okay. That's fine if you are not sure.

12:02PM 8 So one last question about this study, the
12:02PM 9 finding was that the pentobarbital solution had a --
12:03PM 10 let's see what the terminology is -- it was good for as
12:03PM 11 long as six years. And my question for you is, do you
12:03PM 12 agree that that was the finding even if you don't -- if
12:03PM 13 you disagree with the method, that's fine; you have
12:03PM 14 already said that -- but that was the finding of this
12:03PM 15 particular study; is that right?

12:03PM 16 A. That study is incorrect. You know, if you read
12:03PM 17 through that study --

12:03PM 18 MS. O'LEARY: I'll object to nonresponsive,
12:03PM 19 Your Honor.

12:03PM 20 THE COURT: Sustained. Doctor, just listen
12:03PM 21 to her questions and answer her specific questions,
12:03PM 22 please.

12:03PM 23 A. Can you restate the question again? I'm sorry.

12:03PM 24 Q. I believe you gave the answer. You disagree
12:03PM 25 with the methods but the finding was, in fact, that it

12:03PM 1 was good for six years?

12:03PM 2 A. No, it's not.

12:03PM 3 Q. Okay.

12:03PM 4 A. Can I comment why I think it's not correct?

12:03PM 5 THE COURT: Not at this point, ma'am. You
12:03PM 6 may have a chance when we go on, but not now.

12:04PM 7 MS. O'LEARY: I pass the witness, Your
12:04PM 8 Honor.

12:04PM 9 THE COURT: Mr. Kursman, do you have any
12:04PM 10 follow-up?

12:04PM 11 MR. KURSMAN: Just very briefly.

12:04PM 12 REDIRECT EXAMINATION

12:04PM 13 BY MR. KURSMAN:

12:04PM 14 Q. Dr. Almgren, can you tell the Court why that's
12:04PM 15 not correct?

12:04PM 16 A. Yes. It is incorrect because if you are using
12:04PM 17 incorrect method, analytical method, you are not going to
12:04PM 18 be able to assess stability. So that's my number one
12:04PM 19 comment.

12:04PM 20 Number two concern is, if you read that
12:04PM 21 study, it also talks about how the authors were unable to
12:04PM 22 explain why they were not seeing changes, greater changes
12:04PM 23 in potency when they were seeing changes in color. And
12:04PM 24 typically change in color is a major concern and, as a
12:04PM 25 matter of fact, per USP you would not be able to use a

12:04PM 1 drug that changed color, as in you need to -- the color
12:04PM 2 of the drug indicates that there are some changes
12:04PM 3 happening.

12:04PM 4 And so the fact that they noted and they
12:04PM 5 did measurements trying to capture the change in color
12:04PM 6 over time, the fact that they noted they saw changes but
12:04PM 7 they were not able to explain how come the potency didn't
12:05PM 8 change is just a true indication that study was not done
12:05PM 9 correctly.

12:05PM 10 I also want to point out one more thing.
12:05PM 11 They really were not looking at USP standards and this
12:05PM 12 drug being used in humans. This study was strictly
12:05PM 13 focused on the fact that this drug was used for animal
12:05PM 14 studies. And so I think that they were trying to kind of
12:05PM 15 justify why they are using this drug past expiry and
12:05PM 16 making sure it is potent enough for animals. So I think
12:05PM 17 that that was their -- the intent was not here to extend
12:05PM 18 beyond-use date for human use.

12:05PM 19 MR. KURSMAN: I have nothing further, Your
12:05PM 20 Honor.

12:05PM 21 THE COURT: Ms. O'Leary, do you have
12:05PM 22 anything further?

12:05PM 23 MS. O'LEARY: Sorry, Your Honor. I have no
12:05PM 24 further questions for this witness.

12:05PM 25 THE COURT: May this witness be excused?

12:05PM 1 MR. KURSMAN: Yes, Your Honor.

12:05PM 2 THE COURT: All right. Thank you, Doctor.
12:05PM 3 I hope we can get you to your class on time. Thank you
12:05PM 4 for your time and your testimony. You may be excused,
12:06PM 5 which means you may log off of Zoom, if you'd like.

12:06PM 6 Mr. Kursman, do you want to respond, now
12:06PM 7 that we've gotten the doctor's testimony, to the legal
12:06PM 8 points Ms. O'Leary made previously or do you have any
12:06PM 9 other evidence you would like to present first?

12:06PM 10 MR. KURSMAN: Yeah, I do, Your Honor.
12:06PM 11 Could I turn to Ms. Nelson-Major who will respond to the
12:06PM 12 statutory arguments made?

12:06PM 13 THE COURT: Yes. That's fine.

12:06PM 14 Ms. Nelson-Major.

12:06PM 15 MS. NELSON-MAJOR: Good afternoon, Your
12:06PM 16 Honor. I would like to begin by responding to the
12:06PM 17 argument that Ms. O'Leary made in her opening statement
12:06PM 18 that Blaze vs. Rees provides applicable legal standard
12:06PM 19 here in that the temporary injunction should not issue
12:06PM 20 because we have not proffered an alternative to the use
12:06PM 21 of expired pentobarbital.

12:06PM 22 This is not an 8th Amendment challenge.
12:06PM 23 Petitioners are not challenging the protocol and they are
12:06PM 24 not challenging the use of compounded pentobarbital in
12:06PM 25 general. No prisoner in Texas has brought a similar

1 challenge before under the four state statutes that are
2 at issue in this complaint; so therefore, the 8th
3 Amendment standards are completely irrelevant and not
4 before this Court.

5 I would next like to turn to the arguments
6 that Respondents have made about the various state
7 statutes at issue here. I would like to go through each
8 statute individually, but I would like to first note that
9 one overarching theme runs throughout all of the
10 arguments that Respondents have made. That is,
11 essentially that they are above the law and that when
12 carrying out executions state statutes do not apply to
13 their conduct. They urge that as long as lethal
14 injection is the method used, but no ultra vires claims
15 can lie with respect to the drugs or how they are
16 administered.

17 If this argument is accepted, essentially
18 it would mean that Respondents are immune, automatically
19 immune from any state statute or constitutional
20 restraints from carrying out an execution. Discretion is
21 bound by the law, no matter how much power Respondents
22 wish to afford themselves. And when carrying out
23 official duties state actors must comply with statutory
24 framework. That's the entire point of the ultra vires
25 doctrine. And I would argue that compliance with the law

1 is of paramount importance when the State is doing
2 something so serious and final as taking a life.

3 I would like to turn to the Texas Pharmacy
4 Act. Ms. O'Leary suggested that the Texas Pharmacy Act
5 does not apply because it only applies in the context of
6 treating patients for treatment. In support of this
7 argument they rely on one of the two stated legislative
8 purposes that are found in the Texas Pharmacy Act, and
9 those appear at Texas Occupational Code
10 Section 551.002(c).

11 In making this argument they completely
12 ignore the other stated legislative purpose of the Texas
13 Pharmacy Act, and that is to regulate and control the
14 practice of pharmacy. Respondents have elected to use a
15 method of execution that relies on the practice of
16 pharmacy. As such, application of the Texas Pharmacy
17 Act, the lethal injection context is completely
18 consistent with the legislative purpose of the act.

19 Furthermore, there's a statement that
20 appears along with the legislative purposes which states
21 that the act was enacted to ensure that the practice of
22 pharmacy receive the confidence of the public. Here that
23 goal is also of paramount importance. The public must be
24 confident that the drugs used to carry out executions are
25 compounded in a professional way and will not cause pain

1 and suffering.

2 Respondents cite a number of Administrative
3 Code provisions to further argue that the Pharmacy Act
4 does not apply here. They cite language which
5 unfortunately only applies to nonsterile compounding, and
6 thus Dr. Almgren explained the pentobarbital in TDCJ's
7 possession applies to sterile compounded preparations, so
8 those provisions are also irrelevant.

9 And I want to specifically address the
10 regulation at the heart of claim one of Petitioners'
11 complaint, and that appears at Administrative Code
12 Section 291.133(b)(9). That's the regulation which
13 prohibits the administration of an expired drug. The
14 only drug that a pharmacist is authorized to administer
15 is Epinephrine. So therefore, Respondents' argument that
16 this provision only applies to pharmacists is clearly
17 inconsistent with the plain language of the statute.
18 It's obviously intended to reach conduct by individuals
19 other than pharmacists.

20 And I would also like to note that the
21 pharmacist that actually prepares the drugs for TDC is
22 also named as a respondent in this action, and is the
23 proper respondent in this action as well.

24 So for those reasons the arguments that
25 Respondents have made about the applicability of the

1 Texas Pharmacy Act are inaccurate and inconsistent with
2 the plain language, as well as the legislative purpose of
3 the Texas Pharmacy Act.

4 I would like to move on to the Controlled
5 Substances Act unless Your Honor has questions about the
6 applicability of the Pharmacy Act.

7 THE COURT: No. Go ahead.

8 MS. NELSON-MAJOR: Respondents argue that
9 they are immune from the Controlled Substances Act
10 because they are carrying out an execution. For this
11 broad exception they cite Health and Safety Code
12 Section 481.062(a)(4) and argue that they need not comply
13 with the Controlled Substances Act. However, that
14 subsection provides that a state actor may possess a
15 controlled substance if they are lawfully engaged in the
16 enforcement, and I quote, "of a law relating to a
17 controlled substance or drug or to a customs law."

18 Respondents urge that they fall under this
19 provision simply because they are carrying out an
20 execution. However, they are asking this Court to
21 completely disregard the explicit limitation in this
22 provision which says that state actors may possess
23 controlled substances when enforcing only two kinds of
24 laws: The Controlled Substance Act or a customs law.
25 When Respondents carry out executions, they are clearly

1 doing neither; therefore, this exemption does not cover
2 their conduct.

3 Alternatively, Respondents argue that they
4 are immune from the CSA because they possess a DEA
5 license. Again, they are asking the Court to rewrite the
6 play language of this exception. That exception they
7 cite appears at Section 481.061 of the Controlled
8 Substances Act. They seem to argue that this provision
9 means that anyone with a DEA license is automatically
10 immune and exempt from compliance with the CSA. This is
11 absolutely not true. The provision they cite says that a
12 person with a DEA license may "possess, manufacture,
13 distribute, analyze, dispense or conduct research with a
14 substance to extent authorized by the chapter and in
15 conformity with the chapter."

16 I first note that this provision doesn't
17 speak of administration of the controlled substance.
18 Petitioner's CSA claim is related to the administration
19 of a controlled substance; so therefore, the provision
20 doesn't even reach the conduct at issue. But
21 furthermore, the statute is clear that, even if you
22 possess a DEA license, your conduct with respect to the
23 covered activities must still be in conformance with the
24 statute.

25 I would also note that Respondents haven't

1 offered any evidence to demonstrate that they have a
2 valid DEA license. We have received several DEA forms in
3 response to Public Information Act requests. We don't
4 have any information about the actual DEA license they
5 claim to possess and whether that encompasses schedule II
6 controlled substances which pentobarbital, in fact, is.

7 And in addition to those two arguments I
8 would also note that the Controlled Substance Act has an
9 explicit exception for humane society and animal control
10 personnel to possess pentobarbital for the use in
11 euthanizing animals, and that appears at Health and
12 Safety Code Section 481.11(b). And no similar exception
13 exists that would authorize Respondents to possess
14 pentobarbital without a prescription for use in
15 executions. So therefore, the arguments that Respondents
16 made that they are immune and above the Controlled
17 Substance Act fail and are inconsistent with the plain
18 language of that statute.

19 Similarly, the arguments they made with
20 respect to the Food, Drug and Cosmetic Act similarly find
21 no basis in the plain language of the statute. They
22 argue that they are immune and above the FDCA because
23 they are not introducing drugs into commerce; however,
24 they cite no statutory provision that supports this
25 reading and the prescription requirement in the FDCA

1 contains no such language. Again, Respondents are asking
2 this Court to rewrite the statutes and create exceptions
3 for their conduct that simply do not exist.

4 And lastly with respect to the Texas Penal
5 Code, Respondents argue that they are exempt from this
6 statute as well because they are carrying out executions.
7 Respondents have cited no legal authority for this
8 argument whatsoever. Perhaps sensing that that argument
9 is without any statutory foundation, they argue that
10 their conduct is nonetheless justified because they
11 reasonably believe that they were not subject to the
12 Texas Penal Code. However, that belief can no longer be
13 reasonable since the filing of this action in which it
14 was specifically detailed how their conduct violates that
15 statute.

16 So having addressed Respondents' arguments
17 about the applicability of the statutes, I briefly wanted
18 to return to the factual record. Dr. Almgren's testimony
19 involved, you know, a significant number of technical
20 terms and concepts. However, distilled to its essence,
21 there's a number of rather simple facts at issue here and
22 we believe that the record that was just introduced
23 demonstrates that they are unrebutted and clear. And
24 that is that TDCJ receives pentobarbital in two different
25 sized vials: 50 milliliters, and 100 milliliters, and

12:17PM 1 that TDCJ last received new 100 milliliter vials in April
12:17PM 2 of 2019 and last received 50 milliliter vials in March
12:17PM 3 of 2021.

12:17PM 4 Dr. Almgren explained that these are
12:17PM 5 considered high risk sterile compounded preparations and
12:17PM 6 that the USP sets forth careful and detailed expiration
12:17PM 7 dates for these high risk preparations. And those are
12:18PM 8 24 hours at room temperature, three days in refrigeration
12:18PM 9 and 45 days in a solid frozen state.

12:18PM 10 All vials in TDCJ's possession are expired.
12:18PM 11 That record is undisputed, as per USP. The 100
12:18PM 12 milliliter vials expired in June of 2019. The 50
12:18PM 13 milliliter vials expired in May of 2021.

12:18PM 14 You also heard Dr. Almgren explain how
12:18PM 15 Respondents claimed to extend the beyond-use dates beyond
12:18PM 16 what is recognized as a scientifically valid deadline,
12:18PM 17 and that is by on occasion sending out a vial for a
12:18PM 18 potency test alone, then claiming to extend the
12:18PM 19 expiration date of all the vials in their possession for
12:18PM 20 up to 11 months at a time.

12:18PM 21 You also heard Dr. Almgren explain these
12:18PM 22 actions violate USP and Respondents have violated USP
12:19PM 23 upon initial compounding of pentobarbital in TDCJ's
12:19PM 24 possession. There is no record that any vial was ever
12:19PM 25 subjected to pH testing or to a visual inspection and

12:19PM 1 that when TDCJ performed sterility test they, in fact,
12:19PM 2 performed the wrong test.

12:19PM 3 You also heard Dr. Almgren clearly explain
12:19PM 4 that these vials as a matter of pharmaceutical science
12:19PM 5 are expired and have been expired between 20 and
12:19PM 6 43 months.

12:19PM 7 You also heard Dr. Almgren explain that the
12:19PM 8 methods that Respondents use to claim to extend the
12:19PM 9 beyond-use dates are completely unscientific and invalid.
12:19PM 10 But the only valid way to extend the expiration date of a
12:19PM 11 drug is with a stability indicating test and that the
12:19PM 12 potency test that TDCJ does is not a stability indicating
12:19PM 13 test and will give a false picture of how potent the
12:19PM 14 drugs are.

12:20PM 15 Rather TDCJ uses the potency test alone and
12:20PM 16 claims to extend the beyond-use dates. Even if you could
12:20PM 17 use the potency test alone, which you cannot, Dr. Almgren
12:20PM 18 explained that the way that TDCJ is using these potency
12:20PM 19 tests is further invalid under the USP. It is invalid to
12:20PM 20 take a vial from one batch and then say, based on the
12:20PM 21 test of that one vial, all of the vials in your
12:20PM 22 possession are expired. That is not a scientific method
12:20PM 23 or conclusion to reach.

12:20PM 24 Dr. Almgren offered the conclusion that
12:20PM 25 these drugs are expired under USP and that the beyond-use

12:20PM 1 date must be disregarded that Respondents have claimed to
12:20PM 2 admit.

12:20PM 3 In their response to the emergency motion,
12:20PM 4 Respondents seem to disregard the clear conclusions under
12:20PM 5 USP and instead have offered their own definition of when
12:21PM 6 a drug is considered expired. They claim that for
12:21PM 7 purposes of an execution a drug is unexpired if it
12:21PM 8 retains sufficient potency -- and I want to quote the
12:21PM 9 language -- so that it is "Quickly effective so that no
12:21PM 10 pain or suffering will be experienced."

12:21PM 11 Even if that was a definition, that was
12:21PM 12 acceptable under USP or the Texas Pharmacy Act, the
12:21PM 13 evidence demonstrates that they are not meeting their own
12:21PM 14 standard of expiration. Dr. Almgren was clearly
12:21PM 15 explaining that even if a drug returns a test result on a
12:21PM 16 potency test in a sufficient range, it nonetheless poses
12:21PM 17 risk of harm and suffering upon administration.

12:21PM 18 So therefore, even accepting Respondents'
12:21PM 19 own definition of an expired drug, these drugs are
12:21PM 20 expired. So in this way the record demonstrates that
12:21PM 21 Respondents are in violation of multiple state statutes
12:22PM 22 when they procure, compound, maintain and then administer
12:22PM 23 the pentobarbital in TDCJ's possession.

12:22PM 24 Each of the failures that I just outlined
12:22PM 25 to comply with USP is a violation of the Pharmacy Act.

12:22PM 1 First the Pharmacy Act requires compliance with USP on
12:22PM 2 initial compounding; Respondents are not doing that. USP
12:22PM 3 says that expired drugs may not be administered;
12:22PM 4 Respondents are not doing that. And USP says that you
12:22PM 5 may not prepare amounts of a compounded drug in excess of
12:22PM 6 what you reasonably expect to administer prior to an
12:22PM 7 expiration date. In other words, USP and the Pharmacy
12:22PM 8 Act prohibits stockpiling drugs. That is what
12:22PM 9 Respondents are doing. That's a further violation of
12:22PM 10 USP.

12:22PM 11 And the Pharmacy Act and the Texas
12:23PM 12 Controlled Substances Act, the Texas Food, Drug and
12:23PM 13 Cosmetics Act, the Texas Penal Code all require a
12:23PM 14 prescription to possess, distribute or administer
12:23PM 15 pentobarbital. No prescriptions have been produced to us
12:23PM 16 in response to multiple Public Information Act requests;
12:23PM 17 therefore, Respondents lack legal authority under these
12:23PM 18 statutes to administer pentobarbital to Petitioners.

12:23PM 19 So I've just outlined the causes of action
12:23PM 20 stated in the complaint, how the evidence introduced
12:23PM 21 today demonstrates a probable right to relief under each
12:23PM 22 of these claims. And I would like to briefly touch on
12:23PM 23 the evidence that demonstrates that, absent this Court's
12:23PM 24 intervention, Petitioners will suffer probable imminent
12:23PM 25 irreparable injury.

12:23PM 1 As Dr. Almgren explained, as a drug
12:23PM 2 degrades it can turn into a completely different compound
12:23PM 3 that will act upon the body in a way that pentobarbital
12:24PM 4 is not intended to act, and that as a drug ages
12:24PM 5 precipitants form and that those precipitants can cause
12:24PM 6 pain at the injection site and can clog IV lines. It
12:24PM 7 also appears and is worth noting again that TDCJ has not
12:24PM 8 subjected any of the vials in its possession to --

12:24PM 9 THE COURT: I'm sorry. To what? What did
12:24PM 10 you say? I missed the last part.

12:24PM 11 MS. NELSON-MAJOR: I was saying it's worth
12:24PM 12 noting in this context again that Respondents have not
12:24PM 13 subjected, based on the records before us, any of the
12:24PM 14 vials to pH testing. And that's significant because as a
12:24PM 15 drug ages pH can change, and that can lead to a whole
12:24PM 16 host of issues, including pain upon injection and further
12:24PM 17 causing degradants and particulates to form.

12:24PM 18 Dr. Almgren also discussed how Respondents'
12:24PM 19 handling of the drugs exposes the vials to contaminants
12:25PM 20 which can cause vomiting, nausea, pain, renal failure and
12:25PM 21 Dr. Almgren also explained that these risks increase the
12:25PM 22 further past the expiration date you are.

12:25PM 23 And because Petitioners can't be adequately
12:25PM 24 redressed for the risk of these harms absent this Court's
12:25PM 25 intervention -- because if these harms occurred during

12:25PM 1 their execution, Petitioners will obviously be dead and
12:25PM 2 no longer able to pursue a form in which to have these
12:25PM 3 important allegations heard.

12:25PM 4 Therefore, this Court should grant the
12:25PM 5 request for a temporary injunction and issue an order
12:25PM 6 prohibiting Respondents from procuring, possessing,
12:25PM 7 distributing or administering pentobarbital to
12:25PM 8 Petitioners in violation of the Texas Pharmacy Act, the
12:25PM 9 Texas Controlled Substances Act, the Texas Penal Code,
12:25PM 10 and the Texas Food, Drug and Cosmetics Act. Therefore,
12:26PM 11 the record adequately demonstrates the issuance of the
12:26PM 12 temporary injunction is justified and necessary in this
12:26PM 13 case. Thank you, Your Honor.

12:26PM 14 THE COURT: Thank you, Ms. Nelson-Major.
12:26PM 15 Ms. O'Leary.

12:26PM 16 MS. O'LEARY: Yes, Your Honor. I'll just
12:26PM 17 respondent to a couple of those points, if I may.

12:26PM 18 First, even if Blaze vs. Rees didn't apply
12:26PM 19 -- which is the Supreme Court case that sets the standard
12:26PM 20 for challenges to the method of execution, which this
12:26PM 21 case can certainly be categorized as that -- even if this
12:26PM 22 didn't apply, an injunction requires they show a probable
12:26PM 23 irreparable imminent injury. And an injury, when it
12:26PM 24 comes to lethal injection, is that it's going to cause
12:26PM 25 more pain than it normally would. And by "normally

12:26PM 1 would" I mean it doesn't feel --

12:26PM 2 THE COURT: Isn't that violative of the
12:26PM 3 penal statutes that govern how executions are supposed to
12:27PM 4 be carried out?

12:27PM 5 MS. O'LEARY: I'm sorry, Your Honor. The
12:27PM 6 Code of Criminal Procedure is the lethal injection
12:27PM 7 statute.

12:27PM 8 THE COURT: Okay. All right.

12:27PM 9 MS. O'LEARY: And the provision of the
12:27PM 10 penal code that Petitioners allege is being violated is
12:27PM 11 bringing a controlled substance into a correctional
12:27PM 12 facility.

12:27PM 13 THE COURT: All right. Go ahead.

12:27PM 14 MS. O'LEARY: The Petitioners cannot show
12:27PM 15 an imminent injury because they cannot show that any pain
12:27PM 16 or suffering is going to be experienced beyond just what
12:27PM 17 it feels like to have blood drawn when the IV's are
12:27PM 18 placed.

12:27PM 19 THE COURT: How would anyone -- other than
12:27PM 20 the expert testimony I've heard today from a
12:27PM 21 pharmacologist, how could that ever be established?

12:27PM 22 MS. O'LEARY: Well, Your Honor, the media
12:27PM 23 and witnesses are present at every single execution and
12:28PM 24 they describe what they see in every execution. The
12:28PM 25 Petitioners haven't presented evidence of a single

1 execution where any abnormal pain or suffering has been
2 observed. The sounds, movements, eye movements, all of
3 those details are described for each execution. And
4 since I can't prove a negative, the Petitioners have the
5 burden here. They haven't presented that a single
6 execution in Texas history, and not since 2013 when
7 single does pentobarbital began its use, has this
8 terrible problem that they are describing ever occurred.

9 Additionally, Your Honor, the Pharmacy Act,
10 the categories are listed in the statute, it's laid out
11 in our briefing; it applies to certain categories of
12 actors. It applies to a provider prescribing medications
13 to their patient, it provides a pharmacy compounding
14 solutions for another pharmacy. Categories like that;
15 certainly no category that TDCJ or its actors fall into.
16 The controlled substances --

17 THE COURT: What about -- let me ask about
18 the Pharmacy Act. What about the second --
19 Ms. Nelson-Major told me was the second legislative, the
20 purpose of the Pharmacy Act was to regulate pharmacies
21 and pharmaceuticals consistent with the purposes of the
22 act. Because they are used for execution purposes, is it
23 your position that the Respondents are taken out of
24 requirements to comply with the Pharmacy Act? Is there
25 an exception in the Pharmacy Act that says for purposes

12:29PM 1 of execution we don't have to comply with those
12:29PM 2 provisions?

12:29PM 3 MS. O'LEARY: There is not an explicit
12:29PM 4 exception that says "executions," Your Honor, but
12:29PM 5 certainly there are -- that is the general stated
12:30PM 6 purpose. It says, "To regulate the practice of pharmacy
12:30PM 7 and licensing pharmaceuticals who engage in the practice
12:30PM 8 of treating illness, injury or disease." And so the --
12:30PM 9 then it lists categories of actors that it applies to.
12:30PM 10 In case the stated overall purpose is too broad or not
12:30PM 11 specific enough, then it goes on to list who it applies
12:30PM 12 to. And it certainly doesn't apply to TDCJ, it doesn't
12:30PM 13 apply to lethal doses of pentobarbital, things that are
12:30PM 14 not used for therapeutic purposes.

12:30PM 15 THE COURT: Let me ask you another
12:30PM 16 question. Why does TDCJ test the drugs in its possession
12:30PM 17 periodically? If they are not worried about the
12:30PM 18 efficacy, the potency, the stability of those drugs, why
12:30PM 19 are they even tested?

12:30PM 20 MS. O'LEARY: We certainly can't say that
12:30PM 21 they are not worried about the potency or efficacy, Your
12:31PM 22 Honor. They are not doing that in order to comply with
12:31PM 23 the Texas Pharmacy Act; they are doing that to comply
12:31PM 24 with the 8th Amendment, to be sure they have effective,
12:31PM 25 potent drugs when it's time to use them, because

12:31PM 1 certainly they are interested in carrying out executions
12:31PM 2 in the most humane way possible. And they are regulated
12:31PM 3 by the 8th Amendment; they are not regulated by
12:31PM 4 pharmaceutical standards.

12:31PM 5 THE COURT: But isn't the pharmacist,
12:31PM 6 whoever compounded the drugs, aren't they regulated by
12:31PM 7 those standards? Is it your position that once they are
12:31PM 8 put out and given to TDCJ that, therefore, none of the
12:31PM 9 pharmaceutical regulations apply and, therefore, the
12:31PM 10 Respondents can just take some drugs, they are out of
12:31PM 11 date, and use them however they see fit?

12:31PM 12 MS. O'LEARY: No, Your Honor. The
12:31PM 13 confidential pharmacy and whoever is conducting the lab
12:31PM 14 testing for TDCJ, they simply don't fall into these
12:31PM 15 categories under the Pharmacy Act. They are not
12:32PM 16 dispensing a drug for a Class A pharmacy, to the
12:32PM 17 practitioner for the office's use. They just don't fall
12:32PM 18 into those categories, because the Pharmacy Act was not
12:32PM 19 written to cover this kind of situation, and so the
12:32PM 20 categories it describes don't capture it.

12:32PM 21 Another point, Your Honor, that I think is
12:32PM 22 important to discuss is that ultra vires claims cannot
12:32PM 23 lie if there is conflicting statutory authority. An
12:32PM 24 ultra vires claim is for an official who is acting
12:32PM 25 without authority.

1 Now, if you look at the Code of Criminal
2 Procedure, the statute directs TDCJ to carry out
3 executions by lethal injection. Now, implicit in that
4 mandate is that a lethal injection is going to be
5 conducted using a controlled substance. That's the only
6 humane way to do it; that's the only type of substance
7 that could be effective for lethal injection. And so
8 that mandate implicitly requires TDCJ to administer a
9 controlled substance. It also implicitly requires that
10 substance to be administered without a prescription from
11 a medical provider because a medical provider cannot
12 ethically prescribe a medication to kill somebody.
13 Hippocratic oath.

14 THE COURT: Mr. Kursman, hold on. You will
15 have a chance to respond.

16 Go ahead, Ms. O'Leary.

17 MS. O'LEARY: They have the hippocratic
18 oath. Nursing and non-doctor medical providers have
19 similar ethical responsibilities. They cannot write a
20 prescription that is meant as a lethal does to kill
21 somebody. And so when we have a statute from the
22 legislature directing TDCJ to administer a lethal dose of
23 a controlled substance, that context matters. That is
24 authority that has to be done, and implicitly that means
25 certain things. And so the medical provider can't be

12:33PM 1 directly involved in the prescription.

12:33PM 2 So each of these acts that the
12:34PM 3 Petitioner -- the statutes that the Petitioners have
12:34PM 4 listed, they are citing to portions that require a
12:34PM 5 prescription from a provider. And while clever, as the
12:34PM 6 Court of Criminal Appeals noted, it conflicts with the
12:34PM 7 statute that directs TDCJ to carry out lethal injection.
12:34PM 8 And so whether there's conflicting statute, it cannot be
12:34PM 9 said that these officials are acting without authority.

12:34PM 10 And then I'll address Dr. Almgren quickly.
12:34PM 11 She acknowledged a scientific study that she had read
12:34PM 12 just last night. That study found that compounded
12:34PM 13 pentobarbital has a shelf life of up to six years, that
12:34PM 14 it degrades at half a percent per year and she disagrees
12:34PM 15 was the methodology, and that's fine. It's another study
12:34PM 16 by another pharmaceutical scientist. Reasonable minds
12:34PM 17 can differ, even when it comes to scientific methodology.
12:34PM 18 So that is the only point that I want to make with
12:34PM 19 Dr. Almgren, is that her methodology is different and
12:35PM 20 because the Pharmacy Act doesn't apply to TDCJ, the
12:35PM 21 methodology that she prefers does not have to be used
12:35PM 22 here.

12:35PM 23 Additionally, the USP, United States
12:35PM 24 Pharmacologica [sic], only portions of that are codified
12:35PM 25 in the administrative code, so the exhibits we saw citing

12:35PM 1 to the USP, we don't know if those are actually codified.
12:35PM 2 The USP is not a statute and certainly someone cannot act
12:35PM 3 ultra vires by violating standards, United States
12:35PM 4 standards for pharmacology.

12:35PM 5 The penal code -- just very quickly.
12:35PM 6 Petitioners in their argument said that we cited no
12:35PM 7 authority at all to say that we're exempt from the Penal
12:35PM 8 Code. But we cited 9.21(a) of the Penal Code that
12:35PM 9 specifically says that a state official carrying out a
12:36PM 10 legal court order for a legal process can do what they
12:36PM 11 need to, even if it violates the Penal Code. So that
12:36PM 12 exception is quite clear.

12:36PM 13 And again, even if it wasn't, when you have
12:36PM 14 a conflicting statute like the one that directs the
12:36PM 15 director of TDCJ correctional institutions to carry out a
12:36PM 16 lethal injection, implicitly he has to take certain
12:36PM 17 action in order to comply with that statute. And that
12:36PM 18 means administering pentobarbital without a prescription
12:36PM 19 and in a correctional facility. And unless the Court has
12:36PM 20 any other questions, that concludes my argument.

12:36PM 21 THE COURT: Thank you. I'll let the
12:36PM 22 Petitioners close the argument. I don't know if it's
12:36PM 23 Mr. Kursman or Ms. Nelson-Major.

12:36PM 24 MR. KURSMAN: Sure, Your Honor.

12:36PM 25 What you heard from Ms. O'Leary was just a

1 bunch of purported facts that were never introduced into
2 evidence. One of those purported facts were that doctors
3 can't write a prescription. Well, not only was that not
4 produced in evidence; it simply not true. Other states,
5 including the State of Tennessee, obtains a prescription
6 for every execution. So we have no way to challenge
7 these facts, these purported facts, that Ms. O'Leary has
8 just stated because she hasn't entered any of these in
9 evidence.

10 Every fact that was entered today in
11 evidence was from the Petitioners and every single one of
12 those facts went virtually un rebutted. We have proven by
13 clear evidence that the Respondents are violating all of
14 the statutes that we had named; therefore, we would
15 request that you grant the requested preliminary
16 injunction. Thank you, Your Honor.

17 THE COURT: Thank you. All of the
18 decisions I make on the Bench are important. I have to
19 say this one weighs on me particularly heavily, given the
20 exigent nature of the requested relief, which requires me
21 to make a decision in the next few hours, as well as --
22 well, just as well as what's at issue here. I want to go
23 back and look at a couple of these statutes. I'll get
24 you-all a ruling within the next -- no later than two
25 hours. I understand what the deadlines are and I

12:38PM 1 understand the importance of the ruling I'm about to
12:38PM 2 make.

12:38PM 3 I also am very clear and cognizant of the
12:38PM 4 Court of Criminal Appeal's opinion and I would -- do not
12:38PM 5 purport in any way to attempt to stay or set aside the
12:38PM 6 sentences that have been leveled against the Petitioners
12:38PM 7 and the Intervenor or to attempt to stay their execution
12:39PM 8 dates.

12:39PM 9 I think the State -- I haven't heard any
12:39PM 10 evidence about whether or not the State can get anymore
12:39PM 11 unexpired pentobarbital. The State is certainly entitled
12:39PM 12 to carry out the executions that have been ordered with
12:39PM 13 unexpired drugs. What I'm going to decide is whether or
12:39PM 14 not the State is permitted to use expired drugs, and I'll
12:39PM 15 get you an order and a decision just within the next
12:39PM 16 couple of hours. It will be e-mailed to all counsel.

12:39PM 17 Thank you-all very much. You may be
12:39PM 18 excused.

12:39PM 19 MR. WILSON: Your Honor, if I may. Daniel
12:39PM 20 Wilson. Throughout the hearing we've been preparing a
12:39PM 21 potential proposed order that tracks a lot of what I've
12:39PM 22 heard. Would the Court find that helpful?

12:39PM 23 THE COURT: Yes. Both sides are invited to
12:39PM 24 send me proposed orders. Please send them to my
12:39PM 25 submission e-mail address.

(Proceedings concluded.)

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REPORTER'S CERTIFICATE

STATE OF TEXAS }
COUNTY OF TRAVIS }

I, Leah Hayes, Official Court Reporter in and for the 419th District Court of Travis County, State of Texas, do hereby certify that the above and foregoing contains a true and correct transcription of all portions of evidence and other proceedings requested in writing by counsel for the parties to be included in this volume of the Reporter's Record, in the above-styled and numbered cause, all of which occurred REMOTELY VIA VIDE CONFERENCE and were reported by me.

I further certify that this Reporter's Record of the proceedings truly and correctly reflects the exhibits, if any, offered in evidence by the respective parties.

WITNESS MY OFFICIAL HAND this the 15th day of January, 2023.

/s/ Leah Hayes
Leah Hayes, Texas CSR No. 3973
Expiration Date: 07/31/2023
Texas Certified Realtime Reporter
Official Court Reporter
419th District Court
Travis County, Texas
Austin, Texas 78701
(512) 854-9329

EXHIBIT 14

Catherine Clare Bernhard

attorney

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Seagoville, Texas 75159

972-294-7262

Fax-972-421-1604

ccb@ccbernhardlaw.com

September 8, 2023

TDCJ Executive Services
Public Information Request
Huntsville, Texas 77342

Via email transmission to pia@tdcj.texas.gov

Re: Jedidiah Murphy, scheduled for execution October 10, 2023

To Whom it May Concern:

I represent Jedidiah Murphy who is scheduled for execution on October 10, 2023. In my capacity as Mr. Murphy's counsel and on his behalf, pursuant to the Texas Public Information Act ("the Act"), the Texas Constitution, and the First, Fourth, Eighth and Fourteenth Amendments to the United States Constitution, I am requesting the following information.

I. Any and all records containing information regarding the location of drugs intended for use in lethal injection executions, including but not limited to:

1. The name of the Texas Department of Criminal Justice (TDCJ) Unit where such drugs are kept in the regular course of business, including on August 24 and August 25, 2023, and
2. The area or wing of such TDCJ Unit where such drugs are kept in the regular course of business, including on August 24 and August 25, 2023.

II. Any and all records containing information regarding the fire at the TDCJ Huntsville Unit on or around August 25, 2023 (“the fire”), including but not limited to:

1. The area(s) of the Huntsville Unit that were affected by the fire, including by heat, smoke, or electrical outages,
2. The area(s) of the Huntsville Unit that were affected by efforts or actions undertaken to extinguish the fire,
3. The proximity of any drugs intended for use in lethal injection executions to any areas affected by the fire,
4. Whether the rooms, spaces, or areas where drugs intended for use in lethal injection executions are kept were affected in any way by the fire, including by fire, smoke, excessive heat or efforts undertaken to extinguish the fire, and
5. Whether the execution chamber and adjacent rooms were affected in any way by the fire, including by fire, smoke, excessive heat or efforts undertaken to extinguish the fire

The term “records,” as used in this request, includes records in practically any medium, including: paper; film; a magnetic, optical, solid state or other device that can store an electronic signal; tape; Mylar; and any physical material on which information may be recorded, including linen, silk, and vellum. *See* Tex. Gov’t Code § 552.002(b). Section 552.002(c) specifies that “[t]he general forms in which the media containing public information exist include a book, paper, letter, document, e-mail, Internet posting, text message, instant message, other electronic communication, printout, photograph, film, tape, microfiche, microfilm, photostat, sound recording, map, and drawing and a voice, data, or video representation held in computer memory.

Public Information defined by the Act includes “any electronic communication created, transmitted, received or maintained on any device if the communication is in connection with the transaction of official business.” *See* Tex. Gov’t Code § 552.002(a-2).

Moreover, the “characterization of the information as ‘public information’ under the Act is not dependent on whether the requested records

are in the possession of an individual, rather than a governmental body, or whether a governmental body has a particular policy or procedure that establishes a governmental body's access to the information. If information was made, transmitted, maintained, or received in connection with a governmental body's official business, the mere fact that the governmental body does not possess the information does not take the information outside the scope of the Act." See Public Information Act Handbook, pp. 16-17.

I look forward to your timely response.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Bernhard", with a stylized, cursive script.

Catherine Clare Bernhard

EXHIBIT 15

Subject: RE: PIA request
From: PIA <PIA@tdcj.texas.gov>
Date: 9/19/2023, 4:15 PM
To: Catherine Clare Bernhard <cbernhard@sbcglobal.net>

Your request was received on 9/8/2023 and sent for processing.

We are allowed 10 full business days (Monday through Friday and excluding holidays) to process all requests, which means that your request is currently on day # 8.

All requests are processed in the order in which they are received, not on the basis of need or urgency.

We appreciate your patience.

Regards,
Texas Department of Criminal Justice - PIA
Open Records Coordinator
Executive Services

From: Catherine Clare Bernhard <cbernhard@sbcglobal.net>
Sent: Tuesday, September 19, 2023 4:10 PM
To: PIA <PIA@tdcj.texas.gov>
Subject: Re: PIA request

CAUTION: This email was received from an EXTERNAL source, use caution when clicking links or opening attachments.
If you believe this to be a malicious and/or phishing email, please contact the Information Security Office (ISO).

The below and attached PIA was sent on September 8, 2023 and to date, I have not received any response.

The Public Information Act requires that the governmental body must produce the requested information "promptly." Gov't Code 552.221. Given that my client is scheduled for execution in three weeks, the delay in your response is neither prompt nor reasonable. If you intend to seek an Attorney General opinion, please advise immediately, so that I have time to respond. Regardless of the fact that the Act gives you 10 days to request such an opinion, in these circumstances the unnecessary use of the full period flouts the language and the spirit of the Act.

Catherine Clare Bernhard

attorney
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Seagoville, Texas 75159

972-294-7262
fax - 972-421-1604
cbernhard@sbcglobal.net

www.ccbernhardlaw.com



On 9/8/2023 7:51 AM, Catherine Clare Bernhard wrote:

Please see attached.

--

Catherine Clare Bernhard

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EXHIBIT 16

Subject: RE: PIA request
From: Amy Lee <Amy.Lee@tdcj.texas.gov>
Date: 9/22/2023, 8:20 AM
To: "cbernhard@sbcglobal.net" <cbernhard@sbcglobal.net>

Ms. Bernhard,

On September 8, 2023, the Texas Department of Criminal Justice (TDCJ) received your request under Chapter 552 of the Texas Government Code, the Public Information Act (PIA), seeking information pertaining to the fire at the TDCJ Huntsville Unit on or around August 25, 2023. Some of the responsive information is excepted from disclosure under the PIA and therefore not releasable.

This email is to advise you that the TDCJ has requested a decision from the Office of the Attorney General (OAG) who will determine whether certain information responsive to your request should be made available to you, or any other member of the public. Attached please find a copy of the request for decision submitted to the OAG. A copy of our written comments will also be provided once submitted.

Contact this office if you have any questions.

Amy Lee
Project Coordinator
Office of the General Counsel - TDCJ

The information contained in this email and any attachments is intended for the exclusive use of the addressee(s) and may contain confidential, privileged, or proprietary information. Any other use of these materials is strictly prohibited. This email shall not be forwarded outside the Texas Department of Criminal Justice, Office of the General Counsel, without the permission of the original sender. If you have received this material in error, please notify me immediately by telephone and destroy all electronic, paper, or other versions.

From: Catherine Clare Bernhard <cbernhard@sbcglobal.net>
Sent: Friday, September 8, 2023 7:52 AM
To: PIA <PIA@tdcj.texas.gov>
Subject: PIA request

CAUTION: This email was received from an EXTERNAL source, use caution when clicking links or opening attachments.
If you believe this to be a malicious and/or phishing email, please contact the Information Security Office (ISO).

Please see attached.

--

Catherine Clare Bernhard

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— Attachments: —

2023-09-07 - Murphy PIA re Fire.pdf	96.7 KB
Notification Letter re RFD-Catherine Bernhard 09.08.23.pdf	96.8 KB
Request for Decision-Catherine Bernhard 09.08.23.pdf	105 KB

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Appendix 2

Ex Parte Jedidiah Isaac Murphy, W-0002323-D (194th Dist. Ct. Oct. 5, 2023)

CAUSE NO. W00-02424-M(D)

EX PARTE	§	IN THE 194TH JUDICIAL
JEDIDIAH ISAAC MURPHY,	§	DISTRICT COURT
APPLICANT	§	DALLAS COUNTY, TEXAS

ORDER

Before the Court is Applicant's "Application for Writ of Habeas Corpus Under Article I, § 12 of the Texas Constitution & Texas Code of Criminal Procedure Article 11.05," the State's responsive "Motion to Send Subsequent Writ to Court of Criminal Appeals," and the Applicant's "Opposition to State's Motion to Send Writ to Court of Criminal Appeals." For the reasons stated below, the Court denies the Application and the State's motion.

In several grounds, Applicant maintains that TDCJ's procurement, possession, distribution and administration of expired and/or fire-damaged drugs for purposes of Applicant's execution violates both constitutional and statutory standards requiring relief. In *Glossip*, the Supreme Court held "that prisoners cannot successfully challenge a method of execution unless they establish that the method presents a risk that is 'sure or very likely to cause serious illness and needless suffering, and give rise to sufficiently imminent dangers.'" *Glossip v. Gross*, 576 U.S. 863, 877 (2015) (quoting *Baze v. Rees*, 553 U.S. 35, 50 (2008) (plurality opinion)). Applicant's claims fail to meet the threshold for relief.

Therefore, Applicant's "Application for Writ of Habeas Corpus Under Article I, § 12 of the Texas Constitution & Texas Code of Criminal Procedure Article 11.05" is denied. Accordingly, the State's responsive "Motion to Send Subsequent Writ to Court of Criminal Appeals" is denied.

The Clerk of the Court is **ORDERED** to immediately transmit to the Court of Criminal Appeals certified copies of the following documents:

1. Applicant's "Application for Writ of Habeas Corpus under Article I, § 12 of the Texas Constitution & Texas Code of Criminal Procedure Article 11.05," filed on September 27, 2023, in cause number W-002424-D;
2. The State's Motion to Send Subsequent Writ to Court of Criminal Appeals;


3. Applicant's Opposition to State's Motion to Send Writ to Court of Criminal Appeals;
4. A copy of the order scheduling Applicant's execution for October 10, 2023; and
5. The Court's instant order.

The Clerk is further **ORDERED** to transmit a copy of this order to counsel of record for both Applicant and Respondent:

Catherine Bernhard
P.O. Box 506
Seagoville, Texas 75159
cbernhard@sbcglobal.net

Ali M. Nasser
District Attorney Pro Tem
Post Office Box 12548, Capital Station
Austin, Texas 78711
Ali.Nasser@oag.texas.gov

SIGNED this 5 day of October, 2023.



ERNEST WHITE, JUDGE
194TH JUDICIAL DISTRICT COURT
DALLAS COUNTY, TEXAS

Appendix 3

Ex Parte Jedidiah Isaac Murphy, No. AP-77,116 (Tex. Crim. App. Oct. 10, 2023)



SHARON KELLER
PRESIDING JUDGE

BARBARA P. HERVEY
BERT RICHARDSON
KEVIN P. YEARY
DAVID NEWELL
MARY LOU KEEL
SCOTT WALKER
MICHELLE M. SLAUGHTER
JESSE F. MCCLURE, III
JUDGES

COURT OF CRIMINAL APPEALS

P.O. BOX 12308, CAPITOL STATION
AUSTIN, TEXAS 78711

DEANA WILLIAMSON
CLERK
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SIÂN SCHILHAB
GENERAL COUNSEL
(512) 463-1597

October 9, 2023

Presiding Judge 194th District Court
133 N. Riverfront Boulevard, Lb 26
Dallas, Tx 75207

* Delivered Via E-Mail *

Re: Murphy, Jedidiah Murphy
CCA No. AP-77,116
Trial Court Case No. W00-02424-M(D)

The court has issued an opinion on the above referenced cause number.

Sincerely,

A handwritten signature in black ink that reads 'Deana Williamson'.

Deana Williamson, Clerk

cc: Catherine Clare Bernhard (Delivered Via E-Mail)
District Clerk Dallas County (Delivered Via E-Mail)
District Attorney Dallas County (Delivered Via E-Mail)
Benjamin Wolff (Delivered Via E-Mail)
Edward L. Marshall (Delivered Via E-Mail)
Timothy Fitzpatrick (Delivered Via E-Mail)



IN THE COURT OF CRIMINAL APPEALS OF TEXAS

NO. AP-77,116

EX PARTE JEDIDIAH ISAAC MURPHY, Applicant

**ON DIRECT APPEAL FROM DENIAL OF WRIT OF HABEAS CORPUS
UNDER ARTICLE I, § 12 OF THE TEXAS CONSTITUTION AND TEXAS CODE
OF CRIMINAL PROCEDURE 11.05 IN CAUSE NO. W00-02424-M(D)
FROM THE 194TH JUDICIAL DISTRICT COURT
DALLAS COUNTY**

***Per curiam.* YEARY, J., filed a dissenting opinion. NEWELL and WALKER, JJ., dissented.**

OPINION

Applicant appeals from a trial court order denying relief on the claims raised in his Application for Writ of Habeas Corpus Under Article I, § 12 of the Texas Constitution and Texas Code of Criminal Procedure Article 11.05.¹ Applicant raises four points of error. After reviewing the issues, we find the points to be without merit. Consequently, we affirm the trial court's order denying relief.

¹ References to Articles in this opinion are to the Texas Code of Criminal Procedure unless otherwise specified.

I. *Background*

Applicant was convicted and sentenced to death in June 2001 for the capital murder of 80-year-old Bertie Cunningham. *See* TEX. PENAL CODE §19.03(a). The evidence showed that on October 4, 2000, Cunningham went shopping at a mall in Plano, Texas. She was returning to her Garland home when Applicant forced her at gunpoint to give him a ride. Ultimately, Applicant forced Cunningham into the trunk of her car and shot her. Applicant then drove Cunningham's car around and used her credit cards to buy alcohol and beer, among other things. At some point, he picked up his niece and two of her school-age friends. He later dropped off his niece, and he and the boys continued driving around. Ultimately, he bought them both motorized scooters before taking them home. He eventually removed Cunningham from the trunk and dumped her in a creek.

This Court affirmed the judgment and sentence on direct appeal. *Murphy v. State*, 112 S.W.3d 592 (Tex. Crim. App. 2003). This Court also denied relief on the claims raised in Applicant's initial habeas application and dismissed his subsequent applications as abuses of the writ. *Ex parte Murphy*, No. WR-70,832-01 (Tex. Crim. App. Mar. 25, 2009) (not designated for publication); *Ex parte Murphy*, No. WR-70,832-02 (Tex. Crim. App. Mar. 21, 2012) (not designated for publication); *Ex parte Murphy*, No. WR-70,832-05 (Tex. Crim. App. Oct. 4, 2023) (not designated for publication).

II. *The Original Writ Application Filed in the Trial Court*

In the original application filed in the trial court, Applicant raised several claims

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for relief in which he asserted that the Texas Department of Criminal Justice's (TDCJ's) procurement, possession, distribution, and administration of drugs used for executions violated both constitutional and statutory requirements. He asserted that the trial court should give him relief so that he would not be made to suffer cruel and unusual punishment in violation of the Constitution.

III. *The Trial Court's Ruling*

The trial court noted the *Glossip* ruling from the United States Supreme Court in which that Court held "that prisoners cannot successfully challenge a method of execution unless they establish that the method presents a risk that is 'sure or very likely to cause serious illness and needless suffering,' and give rise to 'sufficiently imminent dangers.'" *Glossip v. Gross*, 576 U.S. 863, 877 (2015). The court concluded that Applicant failed to meet the threshold for relief.

IV. *Applicant's Arguments on Appeal and the Court's Analysis*

In his first point of error, Applicant complains that the trial court erred in denying the writ without first affording him an evidentiary hearing. Applicant acknowledges that there is generally no right to a hearing on a writ of habeas corpus. However, he asserts that a hearing was necessary in this case because it "was the only way that [he] could obtain the evidence to prove his claims."

Applicant's conclusory statements that a hearing was the only way to obtain discovery does not make the statements true. Without more, Applicant has failed to show

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that the trial court abused its discretion in failing to hold a hearing. Applicant's first point of error is overruled.

In his second point of error, Applicant asserts that the trial court "failed to address all of the claims [he] raised in arguing that his execution with fire-blighted expired drugs violates the law." To begin with, this claim assumes unproven "facts." Throughout Applicant's pleadings, he asserts "facts" "on information and belief." But he has not shown that either "fire-blighted" or "expired" drugs will be used on him in his execution. Recently addressing claims substantially similar to those raised in Applicant's state habeas application, the federal district court noted that a laboratory report dated nearly a month after the fire showed two lots of pentobarbital that passed potency and sterility tests. The court stated,

While it is unclear from the record whether this report encompasses all of the pentobarbital currently in TDCJ's possession [or] if the drugs tested are the ones to be used in [Applicant's] execution, it does undermine [Applicant's] argument that all of TDCJ's pentobarbital was damaged in the Huntsville fire. As a result, [Applicant's] claim that the so-called "fire-blighted" pentobarbital is sure or very-likely to cause serious illness or suffering is meritless.

Murphy v. Lumpkin, No. 1:23-cv-01199-RP-SH, ECF 9 at *5 (W.D. Tex. Oct. 6, 2023).

That same report is currently in the record before this Court.

Returning to Applicant's assertion that the trial court failed to address all of his claims, we note that the trial court observed that Applicant had raised several grounds. It subsequently held, "Applicant's claims fail to meet the threshold for relief." By all

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indications, the trial court ruled on all of Applicant's claims. The court is not required to explicitly and separately set out its reasoning on every argument made, and Applicant has failed to show this Court exactly what claims he believes the trial court failed to address. Without more, Applicant's second point of error is overruled.

Applicant complains in his third point of error that the trial court erred in denying the writ "because attempting to execute [Applicant] with fire-blighted, expired pentobarbital violates the United States Constitution." Again, Applicant's claim assumes unproven "facts." Although Applicant "on information and belief" asserts his manner of execution will be unconstitutional, he presents no evidence to support it. Additionally, as the trial court pointed out, the U.S. Supreme Court adopted a two-element showing in order to raise a method-of-execution claim. First, the defendant must show that the method to be used "presents a risk that is 'sure or very likely to cause serious illness and needless suffering,' and give rise to 'sufficiently imminent dangers,'" and second, the defendant "must identify an alternative [execution method] that is 'feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain.'" *Glossip*, 576 U.S. at 877. Applicant failed to make this showing. Point of error three is overruled.

Applicant asserts in his fourth point of error that the trial court erred in denying the writ "because TDCJ's violation of state laws protecting him from unnecessary pain violates the Due Process Clause, the Eighth Amendment, and the Equal Protection

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Clause.” Specifically, Applicant first argues in this point that he “has a right to life that may not be extinguished without due process.” But Applicant’s death sentence was achieved and upheld through due process. A method-of-execution claim, which is what Applicant is actually arguing, does not decide an applicant’s “right to life.” And under *Glossip*, in order to show that a method of execution is cruel and unusual under the Eighth Amendment, an applicant must show that it is “sure or very likely to cause serious illness and needless suffering,” not just “unnecessary pain.”

Applicant further argues that the State is violating the Equal Protection Clause because of its deliberate use of disparate practices between death-sentenced and other-sentenced Texas prisoners. But the Equal Protection Clause requires that similarly situated persons be treated alike. *See City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985). Death-sentenced inmates are not similarly situated to other-sentenced inmates with respect to being executed. Point of error four is overruled.

V. Conclusion

Finding no reversible error in the proceedings below, we affirm the trial court’s order denying relief on Applicant’s Application for Writ of Habeas Corpus Under Article I, § 12 of the Texas Constitution and Texas Code of Criminal Procedure Article 11.05. No motions for rehearing will be entertained and the Clerk is instructed to immediately issue mandate.

Delivered: October 9, 2023
Do Not Publish



In the Court of Criminal Appeals of Texas

No. AP-77,116

EX PARTE JEDIDIAH ISAAC MURPHY, *Applicant*

On Direct Appeal from Denial of Writ of Habeas Corpus Under
Article I, § 12 of the Texas Constitution and Texas Code of
Criminal Procedure Article 11.05 in Cause No. W00-02424-M(D)
From the 194th Judicial District Court of Dallas County

YEARY, J., filed a dissenting opinion.

Appellant filed what purports to be an original application for the writ of habeas corpus in the district court. In that pleading, he claimed his application was authorized by Article I, Section 12, of the Texas Constitution and by Texas Code of Criminal Procedure Article 11.05.

TEX. CONST. Art. I, § 12; TEX. CODE CRIM. PROC. art. 11.05. Appellant sought by his pleading to have the district court grant an injunction against his execution, which is to be implemented by the administration of certain drugs that Appellant contends the State should be prohibited from using. The trial court denied relief on the basis that Appellant failed to meet the threshold burden required by the United States Supreme Court in *Glossip v. Gross*, 576 U.S. 863, 877 (2015).

Appellant now seeks to appeal the decision of the district court denying relief on his application. There is no general constitutional right to appeal criminal cases. *See Phynes v. State*, 828 S.W.2d 1, 2 (Tex. Crim. App. 1992). Appellant points to no authority suggesting that he has a right to appeal the decision of the trial court. As a result, this Court lacks a sufficient basis to conclude that its appellate jurisdiction has been properly invoked. Appellant's attempted appeal should be dismissed.

Even more importantly, by his purported application for habeas relief, Appellant sought to have the district court enjoin his execution. But this Court seems to have previously decided that “any order by another state court purporting to stay an execution unlawfully circumvents the exclusive jurisdiction of the Court of Criminal Appeals

in a death-penalty conviction.” *Ex parte Alba*, 256 S.W.3d 682, 690 n.19 (Tex. Crim. App. 2008) (Cochran, J., concurring) (*citing State ex rel. Holmes v. Third Court of Appeals*, 885 S.W.2d 389, 395–96 (Tex. Crim. App.1994)). Therefore, regardless of the merits of Appellant’s claim, the district court would have been without authority to grant the relief he requested.

Perhaps Appellant could have properly litigated his claim by resort to an application for the writ of mandamus or prohibition in this Court. But he has not attempted to do that. He has not even filed either: (1) a subsequent writ pursuant to Code of Criminal Procedure Article 11.071; or (2) an original application for the writ of habeas corpus in this Court, which we might conceivably have treated as an attempted invocation of our original jurisdiction to issue the writs of mandamus or prohibition.

I would dismiss the appeal. Because the Court instead affirms the district court’s denial of relief on the merits, I respectfully dissent.

FILED:
DO NOT PUBLISH

October 9, 2023