

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

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RUIZ, ET AL, Plaintiff,	)	IN THE DISTRICT COURT
VS.	)	TRAVIS COUNTY, TEXAS
TDCJ, ET AL, Defendant.	)	345TH JUDICIAL DISTRICT

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**EMERGENCY MOTION FOR TEMPORARY INJUNCTION**

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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.

APPEARANCES

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AND

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FOR THE INTERVENOR ARTHUR BROWN JR. :

**MR. BENJAMIN WOLFF**  
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## EMERGENCY MOTION FOR TEMPORARY INJUNCTION

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## 1 PROCEEDINGS

2 January 10, 2023

07:21AM 2  
07:23AM 3 THE COURT: Let me call for hearing Cause  
10:10AM 4 No. D-1-GN-22-7149 Wesley Ruiz, John Balentine, Robert  
10:10AM 5 Fratta versus Texas Department of Criminal Justice, Et  
10:10AM 6 Al.

10:10AM 7 Your appearances for the record, please.

10:10AM 8 MR. KURSMAN: Good morning, Your Honor.  
10:10AM 9 Alex Kursman for Petitioners Balentine and Ruiz. This  
10:11AM 10 morning Ms. Swiergula filed an order with the Court  
10:11AM 11 asking for pro hac vice admission for myself and my  
10:11AM 12 colleague, Hayden Nelson-Major. I just want to make sure  
10:11AM 13 that order was granted before the hearing begins.

10:11AM 14 THE COURT: I am told that that has been  
10:11AM 15 filed. I'll need to, yeah, take that up and get that  
10:11AM 16 signed. We might take a little break after we do  
10:11AM 17 appearances since that order -- I'll take appearances and  
10:11AM 18 then I'll see if there's any objection. I don't think  
10:11AM 19 there should be.

10:11AM 20 I'm going to ask everyone as you give your  
10:11AM 21 appearances or if you go through, because I have so many  
10:11AM 22 counsel appearing this morning, if everyone could go  
10:11AM 23 through and change their name and include who they  
10:11AM 24 represent. It may not all show up and it may not be  
10:12AM 25 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

10:36AM 1 legal duty here. There is a valid court order issuing a  
10:36AM 2 death warrant and there's a statute that says TDCJ shall  
10:36AM 3 carry out lethal injection.

10:36AM 4 Similar challenges have been raised in the  
10:36AM 5 federal courts, as we've laid out in our briefing. The  
10:36AM 6 Fifth Circuit has repeatedly rejected challenges to  
10:36AM 7 TDCJ's use of pentobarbital, including challenges that  
10:37AM 8 allege that pentobarbital is expired. Those have been  
10:37AM 9 rejected by the Fifth Circuit.

10:37AM 10 To be entitled to injunctive relief the  
10:37AM 11 Petitioners have to prove three elements, the first of  
10:37AM 12 which is they have to show that they have a cause of  
10:37AM 13 action. For the reasons I've just said and for the  
10:37AM 14 reasons laid out in our brief, they haven't satisfied the  
10:37AM 15 first element or the second element, which is that they  
10:37AM 16 have a probable right to relief.

10:37AM 17 The last element is they have to show a  
10:37AM 18 probable imminent irreparable injury. Now, you're going  
10:37AM 19 to hear evidence from their -- or testimony from their  
10:37AM 20 expert talking about what may happen, what she thinks  
10:37AM 21 will happen. She applies pharmaceutical standards in  
10:37AM 22 reaching those conclusions. And as I've just discussed,  
10:37AM 23 the pharmaceutical standards in the USP do not apply to  
10:37AM 24 this situation because we're not treating injury, illness  
10:37AM 25 or disease.

10:37AM 1 And lastly, Your Honor, because this is a  
10:37AM 2 challenge to the method of execution, the United States  
10:38AM 3 Supreme Court has added another standard on top of the  
10:38AM 4 injunctive relief standard that the Petitioners have to  
10:38AM 5 meet, and that is found in Blaze vs. Rees. The  
10:38AM 6 Petitioners have to show that the State's lethal  
10:38AM 7 injection creates a demonstrated risk of severe pain.

10:38AM 8 Your Honor, the TDCJ has carried out  
10:38AM 9 executions using pentobarbital under the same testing  
10:38AM 10 process that it uses now over 70 times. It has carried  
10:38AM 11 out lethal injection over 90 times. What the Petitioners  
10:38AM 12 describe has never happened; it simply has never  
10:38AM 13 happened. The drugs that TDCJ possesses and uses and  
10:38AM 14 sends to labs to get tested are -- and the Petitioners'  
10:38AM 15 own evidence shows that it was retested as recently as  
10:38AM 16 January of 2022 -- it's proven to be potent and  
10:38AM 17 effective.

10:38AM 18 The other factors that might be relevant to  
10:39AM 19 therapeutic uses of drugs simply don't matter for  
10:39AM 20 purposes of a lethal injection. And for that reason we  
10:39AM 21 believe that their request for injunctive relief and  
10:39AM 22 declaratory relief should be denied.

10:39AM 23 THE COURT: Thank you. All right. Well,  
10:39AM 24 before we begin, I'm certainly aware of the Court of  
10:39AM 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

10:46AM 1 Pharmacopeia?

10:46AM 2 A. You must be familiar with the USP because it  
10:46AM 3 basically provides guidance on our everyday activities;  
10:46AM 4 everything from how we compound, how we handle  
10:46AM 5 medications, storage conditions. A lot of really good  
10:46AM 6 references is in USP.

10:46AM 7 Q. Are you familiar with USP Chapter 797?

10:46AM 8 A. Yes, absolutely. It is a subject matter that I  
10:46AM 9 have been teaching for years. And USP Chapter 797  
10:46AM 10 basically governs or provides guidance on how to perform  
10:46AM 11 sterile compounding in 503A regulated environment.

10:46AM 12 Q. And are you familiar with USP Chapter 790?

10:46AM 13 A. Yes, absolutely. USP Chapter 790 describes how  
10:47AM 14 to perform visual inspection for injectables.

10:47AM 15 Q. And are you familiar with USP Chapter 711?

10:47AM 16 A. Yes. Yes, that's another very good compounding  
10:47AM 17 method that describes how to perform sterility testing on  
10:47AM 18 the products that are compounded.

10:47AM 19 Q. Dr. Almgren, have you served as an expert in  
10:47AM 20 litigation before, an expert in pharmacy?

10:47AM 21 A. Yes.

10:47AM 22 MR. KURSMAN: Your Honor, we would move to  
10:47AM 23 have Dr. Almgren qualified as an expert in pharmacy  
10:47AM 24 compounding, United States Pharmacopeia and extending  
10:47AM 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

10:50AM 1 pharmacological activity would be. Typically when you  
10:50AM 2 have medications that expired, the further away they are  
10:50AM 3 from the date when they were prepared, the more chances  
10:50AM 4 there are that the medication will not work as expected.

10:50AM 5 I looked at the data related to the  
10:50AM 6 pentobarbital and I saw how the TDCJ is trying to extend  
10:50AM 7 the beyond-use date using the assay testing, but that is  
10:50AM 8 not appropriate; and actually the potency of the drug  
10:50AM 9 might be much lower than what was determined, and so the  
10:50AM 10 potency may be affected. Typically as the medication  
10:50AM 11 sits for a long time -- and of course I'm not sure, but  
10:50AM 12 it does not appear that the storage conditions are really  
10:51AM 13 well-monitored for those medications.

10:51AM 14 That also brings up another concern,  
10:51AM 15 because medications, if they are stored in conditions  
10:51AM 16 where the temperature changes, humidity changes, they may  
10:51AM 17 be exposed to light; all of that has impact on medication  
10:51AM 18 quality. And of course, the medications are expired, to  
10:51AM 19 begin with, and then they are, you know, exposed to all  
10:51AM 20 of these unknown conditions. So the chances of those  
10:51AM 21 medications not functioning as they are supposed to are  
10:51AM 22 really high.

10:51AM 23 Q. Is one of the probable risks that the drugs  
10:51AM 24 will fall out of solution?

10:51AM 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,

11:27AM 1 but if that drug is maybe close to expiring, maybe it's  
11:27AM 2 expired, it's been around for a while, it has most likely  
11:27AM 3 passed its expiry, you will start seeing degradants,  
11:27AM 4 which is of course a natural process with any medication.  
11:27AM 5 That's why we have expiration dates, because we can only  
11:27AM 6 guarantee their quality and their activity up to the  
11:27AM 7 expiry. And so once you start getting past the expiry,  
11:27AM 8 you will start seeing degradants forming.

11:27AM 9           What you see in this example, you see the  
11:27AM 10 separation of the degradant from the analyte. So in the  
11:27AM 11 first example the degradant is basically part of the  
11:27AM 12 analyte because it's a different method. So this is a  
11:27AM 13 stability indicating method and your elution time in the  
11:27AM 14 mobile phase, the chemicals that basically help to kind  
11:27AM 15 of separate out your degradants are being used to  
11:27AM 16 basically see if there is any degradation.

11:28AM 17           So if you had a fresh drug, if you had  
11:28AM 18 pentobarbital that you just purchased from the  
11:28AM 19 manufacturer, you will not see the degradant at all. Or  
11:28AM 20 you may see a tiny little peak that would not really  
11:28AM 21 impact your total size of the analyte peak. But as the  
11:28AM 22 drugs degrade over time, you will start seeing these  
11:28AM 23 degradants and that's exactly what is shown here.

11:28AM 24           So you see this degradant that's a peak. I  
11:28AM 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

11:57AM 1

11:57AM 2

BY MS. O'LEARY:

11:57AM 3

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.

11:57AM 4

11:57AM 5

11:57AM 6

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

11:57AM 7

11:57AM 8

A. That's correct.

11:57AM 9

11:57AM 10

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?

11:57AM 11

11:57AM 12

A. Right.

11:57AM 13

11:57AM 14

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

11:57AM 15

11:57AM 16

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.

11:58AM 17

11:58AM 18

11:58AM 19

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

11:58AM 20

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.

11:58AM 21

11:58AM 22

11:58AM 23

THE STENOGRAPHER: Yes, I'm here.

11:58AM 24

THE COURT: Ok. Thank you. Proceed.

11:58AM 25

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

12:07PM 1 challenge before under the four state statutes that are  
12:07PM 2 at issue in this complaint; so therefore, the 8th  
12:07PM 3 Amendment standards are completely irrelevant and not  
12:07PM 4 before this Court.

12:07PM 5 I would next like to turn to the arguments  
12:07PM 6 that Respondents have made about the various state  
12:07PM 7 statutes at issue here. I would like to go through each  
12:07PM 8 statute individually, but I would like to first note that  
12:07PM 9 one overarching theme runs throughout all of the  
12:07PM 10 arguments that Respondents have made. That is,  
12:07PM 11 essentially that they are above the law and that when  
12:07PM 12 carrying out executions state statutes do not apply to  
12:07PM 13 their conduct. They urge that as long as lethal  
12:07PM 14 injection is the method used, but no ultra vires claims  
12:07PM 15 can lie with respect to the drugs or how they are  
12:07PM 16 administered.

12:07PM 17 If this argument is accepted, essentially  
12:07PM 18 it would mean that Respondents are immune, automatically  
12:07PM 19 immune from any state statute or constitutional  
12:07PM 20 restraints from carrying out an execution. Discretion is  
12:08PM 21 bound by the law, no matter how much power Respondents  
12:08PM 22 wish to afford themselves. And when carrying out  
12:08PM 23 official duties state actors must comply with statutory  
12:08PM 24 framework. That's the entire point of the ultra vires  
12:08PM 25 doctrine. And I would argue that compliance with the law

12:08PM 1 is of paramount importance when the State is doing  
12:08PM 2 something so serious and final as taking a life.

12:08PM 3 I would like to turn to the Texas Pharmacy  
12:08PM 4 Act. Ms. O'Leary suggested that the Texas Pharmacy Act  
12:08PM 5 does not apply because it only applies in the context of  
12:08PM 6 treating patients for treatment. In support of this  
12:08PM 7 argument they rely on one of the two stated legislative  
12:08PM 8 purposes that are found in the Texas Pharmacy Act, and  
12:08PM 9 those appear at Texas Occupational Code  
12:08PM 10 Section 551.002(c).

12:08PM 11 In making this argument they completely  
12:08PM 12 ignore the other stated legislative purpose of the Texas  
12:09PM 13 Pharmacy Act, and that is to regulate and control the  
12:09PM 14 practice of pharmacy. Respondents have elected to use a  
12:09PM 15 method of execution that relies on the practice of  
12:09PM 16 pharmacy. As such, application of the Texas Pharmacy  
12:09PM 17 Act, the lethal injection context is completely  
12:09PM 18 consistent with the legislative purpose of the act.

12:09PM 19 Furthermore, there's a statement that  
12:09PM 20 appears along with the legislative purposes which states  
12:09PM 21 that the act was enacted to ensure that the practice of  
12:09PM 22 pharmacy receive the confidence of the public. Here that  
12:09PM 23 goal is also of paramount importance. The public must be  
12:09PM 24 confident that the drugs used to carry out executions are  
12:09PM 25 compounded in a professional way and will not cause pain

12:09PM 1 and suffering.

12:09PM 2 Respondents cite a number of Administrative  
12:09PM 3 Code provisions to further argue that the Pharmacy Act  
12:10PM 4 does not apply here. They cite language which  
12:10PM 5 unfortunately only applies to nonsterile compounding, and  
12:10PM 6 thus Dr. Almgren explained the pentobarbital in TDCJ's  
12:10PM 7 possession applies to sterile compounded preparations, so  
12:10PM 8 those provisions are also irrelevant.

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

12:11PM 20 And I would also like to note that the  
12:11PM 21 pharmacist that actually prepares the drugs for TDC is  
12:11PM 22 also named as a respondent in this action, and is the  
12:11PM 23 proper respondent in this action as well.

12:11PM 24 So for those reasons the arguments that  
12:11PM 25 Respondents have made about the applicability of the

12:11PM 1 Texas Pharmacy Act are inaccurate and inconsistent with  
12:11PM 2 the plain language, as well as the legislative purpose of  
12:11PM 3 the Texas Pharmacy Act.

12:11PM 4 I would like to move on to the Controlled  
12:11PM 5 Substances Act unless Your Honor has questions about the  
12:11PM 6 applicability of the Pharmacy Act.

12:11PM 7 THE COURT: No. Go ahead.

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

12:12PM 18 Respondents urge that they fall under this  
12:12PM 19 provision simply because they are carrying out an  
12:12PM 20 execution. However, they are asking this Court to  
12:12PM 21 completely disregard the explicit limitation in this  
12:12PM 22 provision which says that state actors may possess  
12:12PM 23 controlled substances when enforcing only two kinds of  
12:12PM 24 laws: The Controlled Substance Act or a customs law.  
12:12PM 25 When Respondents carry out executions, they are clearly

12:12PM 1 doing neither; therefore, this exemption does not cover  
12:12PM 2 their conduct.

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

12:13PM 16           I first note that this provision doesn't  
12:13PM 17 speak of administration of the controlled substance.  
12:13PM 18 Petitioner's CSA claim is related to the administration  
12:14PM 19 of a controlled substance; so therefore, the provision  
12:14PM 20 doesn't even reach the conduct at issue. But  
12:14PM 21 furthermore, the statute is clear that, even if you  
12:14PM 22 possess a DEA license, your conduct with respect to the  
12:14PM 23 covered activities must still be in conformance with the  
12:14PM 24 statute.

12:14PM 25           I would also note that Respondents haven't

12:14PM 1 offered any evidence to demonstrate that they have a  
12:14PM 2 valid DEA license. We have received several DEA forms in  
12:14PM 3 response to Public Information Act requests. We don't  
12:14PM 4 have any information about the actual DEA license they  
12:14PM 5 claim to possess and whether that encompasses schedule II  
12:14PM 6 controlled substances which pentobarbital, in fact, is.

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

12:15PM 19           Similarly, the arguments they made with  
12:15PM 20 respect to the Food, Drug and Cosmetic Act similarly find  
12:15PM 21 no basis in the plain language of the statute. They  
12:15PM 22 argue that they are immune and above the FDCA because  
12:15PM 23 they are not introducing drugs into commerce; however,  
12:15PM 24 they cite no statutory provision that supports this  
12:15PM 25 reading and the prescription requirement in the FDCA

12:16PM 1 contains no such language. Again, Respondents are asking  
12:16PM 2 this Court to rewrite the statutes and create exceptions  
12:16PM 3 for their conduct that simply do not exist.

12:16PM 4           And lastly with respect to the Texas Penal  
12:16PM 5 Code, Respondents argue that they are exempt from this  
12:16PM 6 statute as well because they are carrying out executions.  
12:16PM 7 Respondents have cited no legal authority for this  
12:16PM 8 argument whatsoever. Perhaps sensing that that argument  
12:16PM 9 is without any statutory foundation, they argue that  
12:16PM 10 their conduct is nonetheless justified because they  
12:16PM 11 reasonably believe that they were not subject to the  
12:16PM 12 Texas Penal Code. However, that belief can no longer be  
12:16PM 13 reasonable since the filing of this action in which it  
12:16PM 14 was specifically detailed how their conduct violates that  
12:16PM 15 statute.

12:16PM 16           So having addressed Respondents' arguments  
12:16PM 17 about the applicability of the statutes, I briefly wanted  
12:16PM 18 to return to the factual record. Dr. Almgren's testimony  
12:17PM 19 involved, you know, a significant number of technical  
12:17PM 20 terms and concepts. However, distilled to its essence,  
12:17PM 21 there's a number of rather simple facts at issue here and  
12:17PM 22 we believe that the record that was just introduced  
12:17PM 23 demonstrates that they are unrebutted and clear. And  
12:17PM 24 that is that TDCJ receives pentobarbital in two different  
12:17PM 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 respond 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

12:28PM 1 execution where any abnormal pain or suffering has been  
12:28PM 2 observed. The sounds, movements, eye movements, all of  
12:28PM 3 those details are described for each execution. And  
12:28PM 4 since I can't prove a negative, the Petitioners have the  
12:28PM 5 burden here. They haven't presented that a single  
12:28PM 6 execution in Texas history, and not since 2013 when  
12:28PM 7 single does pentobarbital began its use, has this  
12:28PM 8 terrible problem that they are describing ever occurred.

12:28PM 9           Additionally, Your Honor, the Pharmacy Act,  
12:28PM 10 the categories are listed in the statute, it's laid out  
12:28PM 11 in our briefing; it applies to certain categories of  
12:28PM 12 actors. It applies to a provider prescribing medications  
12:28PM 13 to their patient, it provides a pharmacy compounding  
12:29PM 14 solutions for another pharmacy. Categories like that;  
12:29PM 15 certainly no category that TDCJ or its actors fall into.  
12:29PM 16 The controlled substances --

12:29PM 17           THE COURT: What about -- let me ask about  
12:29PM 18 the Pharmacy Act. What about the second --  
12:29PM 19 Ms. Nelson-Major told me was the second legislative, the  
12:29PM 20 purpose of the Pharmacy Act was to regulate pharmacies  
12:29PM 21 and pharmaceuticals consistent with the purposes of the  
12:29PM 22 act. Because they are used for execution purposes, is it  
12:29PM 23 your position that the Respondents are taken out of  
12:29PM 24 requirements to comply with the Pharmacy Act? Is there  
12:29PM 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.

12:32PM 1 Now, if you look at the Code of Criminal  
12:32PM 2 Procedure, the statute directs TDCJ to carry out  
12:32PM 3 executions by lethal injection. Now, implicit in that  
12:32PM 4 mandate is that a lethal injection is going to be  
12:32PM 5 conducted using a controlled substance. That's the only  
12:32PM 6 humane way to do it; that's the only type of substance  
12:32PM 7 that could be effective for lethal injection. And so  
12:32PM 8 that mandate implicitly requires TDCJ to administer a  
12:33PM 9 controlled substance. It also implicitly requires that  
12:33PM 10 substance to be administered without a prescription from  
12:33PM 11 a medical provider because a medical provider cannot  
12:33PM 12 ethically prescribe a medication to kill somebody.  
12:33PM 13 Hippocratic oath.

12:33PM 14 THE COURT: Mr. Kursman, hold on. You will  
12:33PM 15 have a chance to respond.

12:33PM 16 Go ahead, Ms. O'Leary.

12:33PM 17 MS. O'LEARY: They have the hippocratic  
12:33PM 18 oath. Nursing and non-doctor medical providers have  
12:33PM 19 similar ethical responsibilities. They cannot write a  
12:33PM 20 prescription that is meant as a lethal does to kill  
12:33PM 21 somebody. And so when we have a statute from the  
12:33PM 22 legislature directing TDCJ to administer a lethal dose of  
12:33PM 23 a controlled substance, that context matters. That is  
12:33PM 24 authority that has to be done, and implicitly that means  
12:33PM 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

12:36PM 1 bunch of purported facts that were never introduced into  
12:37PM 2 evidence. One of those purported facts were that doctors  
12:37PM 3 can't write a prescription. Well, not only was that not  
12:37PM 4 produced in evidence; it simply not true. Other states,  
12:37PM 5 including the State of Tennessee, obtains a prescription  
12:37PM 6 for every execution. So we have no way to challenge  
12:37PM 7 these facts, these purported facts, that Ms. O'Leary has  
12:37PM 8 just stated because she hasn't entered any of these in  
12:37PM 9 evidence.

12:37PM 10 Every fact that was entered today in  
12:37PM 11 evidence was from the Petitioners and every single one of  
12:37PM 12 those facts went virtually un rebutted. We have proven by  
12:37PM 13 clear evidence that the Respondents are violating all of  
12:37PM 14 the statutes that we had named; therefore, we would  
12:37PM 15 request that you grant the requested preliminary  
12:37PM 16 injunction. Thank you, Your Honor.

12:37PM 17 THE COURT: Thank you. All of the  
12:37PM 18 decisions I make on the Bench are important. I have to  
12:38PM 19 say this one weighs on me particularly heavily, given the  
12:38PM 20 exigent nature of the requested relief, which requires me  
12:38PM 21 to make a decision in the next few hours, as well as --  
12:38PM 22 well, just as well as what's at issue here. I want to go  
12:38PM 23 back and look at a couple of these statutes. I'll get  
12:38PM 24 you-all a ruling within the next -- no later than two  
12:38PM 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 Intervenors 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.

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(Proceedings concluded.)



**REPORTER'S CERTIFICATE**

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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            
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