

D-1-GN-22-007149

Cause No. _____

WESLEY RUIZ, and
JOHN LEZELL BALENTINE,
Petitioners,

v.

TEXAS DEPARTMENT OF
CRIMINAL JUSTICE,
BRYAN COLLIER,
BOBBY LUMPKIN,
KELLY STRONG,
UNKNOWN PHARMACY and
PHARMACISTS,
UNKNOWN EXECUTIONERS and
DRUG PROCURERS,
Respondents.

§
§
§
§
§
§
§
§
§
§
§
§
§
§

IN THE DISTRICT COURT

OF TRAVIS COUNTY, TEXAS

345TH, DISTRICT COURT

____ **JUDICIAL DISTRICT**

**PETITIONERS’ ORIGINAL VERIFIED PETITION AND APPLICATION FOR
TEMPORARY INJUNCTION, DECLARATORY RELIEF, AND PERMANENT INJUNCTION**

Petitioners Wesley Ruiz and John Lezell Balentine file this Original Verified Petition and Application for Temporary Injunction, Declaratory Relief, and Permanent Injunction (“Petition”), against the Texas Department of Criminal Justice (“TDCJ”), Bryan Collier, in his official capacity as the Executive Director of TDCJ, Bobby Lumpkin, in his official capacity as the Director of the Correctional Institutions Division of TDCJ, Kelly Strong, in her official capacity as Senior Warden of the Huntsville Unit, Unknown Pharmacy and Pharmacists, and Unknown Executioners and Drug Procurers, in their official capacities (collectively, “Respondents”), to prohibit Respondents from using expired drugs to execute Petitioners. In support of their Petition, Petitioners respectfully show the following:

I. INTRODUCTION

1. Respondents intend to execute Petitioner Wesley Ruiz on February 1, 2023, and Petitioner John Lezell Balentine on February 8, 2023, pursuant to a one-drug pentobarbital

execution protocol.

2. Absent this Court's intervention, Respondents will execute Mr. Ruiz and Mr. Balentine with unlawfully obtained and long-expired pentobarbital. TDCJ acquires pentobarbital in 50ml vials and 100ml vials. The 50ml vials of pentobarbital in TDCJ's possession expired over twenty months ago and the 100ml vials of pentobarbital expired over forty-three months ago. Given the age of the drugs and Respondents' failure to comply with statutory requirements, the pentobarbital Respondents intend to use to execute Mr. Ruiz and Mr. Balentine will act unpredictably, obstruct IV lines during the execution, and cause unnecessary pain.

3. In seeking to execute Mr. Ruiz and Mr. Balentine with these drugs, Respondents have acted and continue to act without legal authority and in violation of the Texas Pharmacy Act, the Texas Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Penal Code. This action seeks to enjoin Respondents' *ultra vires* compounding, procuring, possessing, distributing, and administration of compounded pentobarbital in violation of these statutes.

4. Petitioners are not challenging their convictions or sentences of death in this action. Nor are Petitioners arguing that the use of pentobarbital violates their state or federal constitutional rights to be free from cruel and unusual punishment. Nor are Petitioners seeking a stay of execution.

5. Rather, Petitioners ask this Court to ensure that Respondents act with legal authority and comply with existing statutory frameworks when compounding, procuring, possessing, distributing, and administering lethal injection drugs. Injunctive relief is necessary to ensure that Respondents do not continue to compound, procure, possess, distribute, or administer expired compounded pentobarbital to Mr. Ruiz and Mr. Balentine in violation of the Texas Pharmacy Act, the Texas Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Penal Code.

II. DISCOVERY

6. Petitioners intend to conduct discovery in accordance with Tex. R. Civ. P. 190.3 (Level 2), or in accordance with Tex. R. Civ. P. 190.4 (Level 3) if the Court believes a discovery control plan should be tailored to the circumstances of this specific suit.

7. The documents attached to this Petition demonstrate Petitioners' entitlement to the temporary injunctive relief they seek. Petitioners intend to introduce these documents and testimony from Dr. Michaela Almgren, *see ex. D*, Report of Michaela Almgren, Pharm.D., M.S, at the temporary injunction hearing and do not believe that additional discovery is necessary prior to that hearing. However, Petitioners intend to request that Respondents provide any documentary evidence and notice of any testimony they will seek to introduce at the temporary injunction hearing.

8. Additional discovery may be warranted prior to a final trial on the merits of Petitioners' request for permanent injunctive relief.

III. PARTIES

9. Petitioner Wesley Ruiz is a person within the jurisdiction of the State of Texas. He is currently under a sentence of death and confined at the Polunsky Unit in Livingston, Texas. His execution is scheduled for February 1, 2023. Pursuant to Tex. Civ. Prac. Rem. Code § 30.014, the last three digits of Mr. Ruiz's social security number are 650.

10. Petitioner John Lezell Balentine is a person within the jurisdiction of the State of Texas. He is currently under a sentence of death and confined at the Polunsky Unit in Livingston, Texas. His execution is scheduled for February 8, 2023. Pursuant to Tex. Civ. Prac. Rem. Code § 30.014, the last three digits of Mr. Balentine's social security number are 878.

11. Respondent TDCJ is a Texas state agency responsible for, among other things, managing and administering "correctional facilities based on constitutional and statutory standards." Tex. Gov't Code § 494.001. Respondent TDCJ can be served with citation and process by serving

Bryan Collier, Executive Director, TDCJ at 209 West 14th Street, 5th Floor, Price Daniel Building, Austin, TX 78701.

12. Respondent Bryan Collier is sued only in his official capacity as the Executive Director of TDCJ. Respondent Collier can be served with citation and process by serving him at 209 West 14th Street, 5th Floor, Price Daniel Building, Austin, TX 78701.

13. Respondent Bobby Lumpkin is the Director of the Correctional Institutions Division of TDCJ and determines and supervises the manner by which death sentenced individuals are executed. Tex. Code Crim. Proc. art. 43.14(a). He is sued in his official capacity only. Respondent Lumpkin can be served with citation and process by serving him at 209 West 14th Street, 5th Floor, Price Daniel Building, Austin, TX 78701.

14. Respondent Kelly Strong is the Senior Warden of the Huntsville Unit, where executions take place. She is sued in her official capacity only. Respondent Strong can be served with citation and process by serving her at 209 West 14th Street, 5th Floor, Price Daniel Building, Austin, TX 78701.

15. Respondent Unknown Pharmacy is a pharmacy that compounds, tests, and dispenses pentobarbital at the direction of TDCJ. Respondent Unknown Pharmacists are employed by Unknown Pharmacy and are sued in their official capacity only. Respondents Unknown Pharmacy and Pharmacists can be served with citation and process by serving TDCJ at 209 West 14th Street, 5th Floor, Price Daniel Building, Austin, TX 78701.

16. Respondents Unknown Executioners and Drug Procurers are employed by TDCJ, obtain lethal injection drugs on behalf of TDCJ, and carry out executions in Texas. Petitioners do not know their identities because TDCJ conceals them. They are sued in their official capacity only. Respondents Unknown Executioners and Drug Procurers can be served with citation and process by serving TDCJ at 209 West 14th Street, 5th Floor, Price Daniel Building, Austin, TX 78701.

IV. JURISDICTION AND VENUE

17. This Court’s jurisdiction to enter declaratory and injunctive relief is established by Tex. Civ. Prac. & Rem. Code § 37.001, *et seq.*, and Tex. Civ. Prac. & Rem. Code § 65.001, *et seq.*

18. Moreover, Petitioners confer jurisdiction on this Court by challenging the *ultra vires* acts of Respondents who are government officials, *see City of El Paso v. Heinrich*, 284 S.W.3d 366 (Tex. 2009), and government contractors whose actions are effectively attributable to government officials, *see GTECH Corp. v. Steele*, 549 S.W.3d 768, 786 (Tex. App. 2018), *aff’d sub nom. Nettles v. GTECH Corp.*, 606 S.W.3d 726 (Tex. 2020).

19. Suits to require government entities or officials to comply with statutory provisions are not barred by sovereign immunity. *Heinrich*, 284 S.W.3d at 372.

20. Venue is proper in Travis County pursuant to Tex. Civ. Prac. & Rem. Code § 15.005 and § 65.023.

V. EXHAUSTION OF ADMINISTRATIVE REMEDIES

21. Mr. Ruiz exhausted his administrative remedies prior to filing this Petition. *See Ex. A, Declaration of Wesley Ruiz Regarding Exhaustion of Administrative Remedies.*

22. On September 26, 2022, Mr. Ruiz submitted a “Step 1” grievance raising claims related to the drugs that Respondents intend to use at his execution. *Id.* at ¶ 5.

23. The “Step 1” grievance was denied on October 13, 2022. *Id.* at ¶ 6.

24. Mr. Ruiz was not provided with a copy of the decision until October 20, 2022. *Id.* at ¶ 7.

25. Mr. Ruiz subsequently submitted a “Step 2” grievance on October 31, 2022. *Id.* at ¶ 8.

26. On November 17, 2022, Mr. Ruiz received a written decision denying his “Step 2” grievance, *id.* at ¶ 9, thereby fully exhausting his administrative remedies. Tex. Gov’t Code §

501.008(d)(1).

27. Mr. Balentine also exhausted his administrative remedies prior to filing this Petition. *See Ex. B, Declaration of John Lezell Balentine Regarding Exhaustion of Administrative Remedies.*

28. On October 10, 2022, Mr. Balentine submitted a “Step 1” grievance related to the drugs that Respondents intend to use at his execution. *Id.* at ¶ 5.

29. The “Step 1” grievance was denied on October 13, 2022. Mr. Balentine was not provided with a copy of the decision until October 20, 2022. *Id.* at ¶ 6.

30. Mr. Balentine subsequently submitted a “Step 2” grievance on October 31, 2022. *Id.* at ¶ 7.

31. Mr. Balentine’s “Step 2” grievance was denied on November 17, 2022, *id.* at ¶ 8, thereby fully exhausting his administrative remedies. Tex. Gov’t Code § 501.008(d)(1).

32. This action was filed twenty-seven days after Mr. Balentine and Mr. Ruiz received the final written decisions denying their “Step 2” grievances and is, therefore, timely. *See Tex. Civ. Prac. & Rem. Code § 14.005(b).*

33. In the alternative, Petitioners’ claims fall within exceptions to the exhaustion requirement, including, but not limited to:

- a. Petitioners bring claims against government entities and government officials in their official capacities for prospective declaratory and injunctive relief challenging Respondents’ *ultra vires* actions that violate statutory provisions. Exhaustion of administrative remedies is not required because TDCJ’s grievance system is not equipped to resolve these questions of state law.
- b. Exhaustion of administrative remedies is not required because TDCJ’s grievance system is not equipped to provide the remedy that Petitioners seek.

VI. FACTS

34. Under Texas law, TDCJ Respondents¹ have the authority and duty to establish and administer a lethal injection protocol. The Texas Code for Criminal Procedure provides:

Whenever the sentence of death is pronounced against a convict, the sentence shall be executed at any time after the hour of 6 p.m. on the day set for the execution, by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death and until such convict is dead, such execution procedure to be determined and supervised by the director of the correctional institutions division of the Texas Department of Criminal Justice.

Tex. Code Crim. Proc. art. 43.14(a). “No torture, or ill treatment, or unnecessary pain, shall be inflicted upon a prisoner to be executed under the sentence of the law.” Tex. Code Crim. Proc. art. 43.24.

35. Respondent Lumpkin adopted the current execution protocol on April 21, 2021. *See* Ex. C, TDCJ Execution Protocol.

36. The current execution protocol requires that individuals be executed by lethal injection using 5 grams of pentobarbital. *Id.* at 10.

37. Pentobarbital is a Schedule II controlled substance. Tex. Health & Safety Code § 481.032; *Schedule of Controlled Substances*, 45 Tex. Reg. 2249 (March 27, 2020).

A. Every Vial of Pentobarbital in TDCJ’s Possession Is Expired.

38. In September 2013, TDCJ began purchasing and carrying out executions using compounded—as opposed to commercially manufactured—pentobarbital.

39. TDCJ Respondents rely on Unknown Pharmacy and Pharmacists to compound and test their pentobarbital.

¹ “TDCJ Respondents” refers to Respondents TDCJ, Collier, Lumpkin, Strong, and Unknown Executioners and Drug Procurers.

40. When a drug is commercially manufactured, it is subjected to extensive quality control and testing to ensure that the quality, potency, and purity of the drug is stable until its expiration date. Ex. D, Report of Michaela Almgren, Pharm.D., M.S at ¶ 6. These measures are product specific. *Id.* at ¶ 7.

41. On the other hand, when drugs are compounded, pharmacists use Active Pharmaceutical Ingredients (“APIs”) to prepare smaller batches of a medication. *Id.* at ¶ 8.

42. API refers to an active drug ingredient, usually in a concentrated powder form. *Id.*

43. Generally, drugs are compounded in a pharmacy that specializes in sterile compounding because specific equipment and training are required to prepare the sterile products correctly. *Id.* at ¶ 8.

44. Sterile compounding must follow the strict guidelines set forth in the United States Pharmacopeia (“USP”). *Id.* at ¶ 9.

45. USP is a compendium of quality requirements, specifications, and practices that apply to the practice of the pharmacy. USP sets the standards for the pharmaceutical industry. *Id.* at ¶¶ 9, 11.

46. If USP guidelines are not followed it can lead to medication contamination, patient harm, and unpredictable drug effects. *Id.* at ¶ 11.

47. USP directs how pharmacists are to determine the Beyond Use Date (“BUD”), or expiration date of the compounded product. *Id.* at ¶ 10.

48. The expiry or BUD of a compounded drug is significantly shorter than its commercially available equivalent because compounded drugs do not undergo the same extensive quality testing as commercially available products. *Id.*

49. According to the USP, the maximum BUD for high-risk compounded sterile preparations, like the pentobarbital in TDCJ’s possession, are:

- 24 hours, if stored at room temperature between 20° and 25°C;
- 72 hours, if kept refrigerated at temperature range between 2° and 8°C, or
- 45 days, if kept in a solid, frozen state at temperature range -25° and -10°C.

Id. at ¶¶ 10, 14-15.

50. It appears that TDCJ stores the compounded pentobarbital at room temperature. *See* Ex. E, Lab Reports.

51. Therefore, the BUD of the pentobarbital in TDCJ's possession is 24 hours.

52. In other words, after 24 hours at room temperature, the pentobarbital is expired as per the USP.

53. TDCJ acquires pentobarbital in 50ml and 100ml vials.

54. TDCJ last received 50ml vials of pentobarbital on March 18, 2021. Ex. F, Huntsville Unit Storage Inventory Logs, Pentobarbital (2.5 grams); *see also* Ex. G, DEA Forms 12.

55. All of the 50ml vials of pentobarbital currently in TDCJ's possession are from the batch received by TDCJ on March 18, 2021.

56. As of the time of filing of this Petition, the 50ml vials in TDCJ's possession are at least 636 days old.

57. The 50ml vials are well over the BUD limit of 24 hours (or 45 days if kept frozen). Ex. D, Report of Dr. Almgren ¶ 17.

58. Therefore, every 50ml vial in TDCJ's possession is expired as per the USP.

59. TDCJ last received 100ml vials of pentobarbital on April 29, 2019. Ex. H, Huntsville Unit Storage Inventory Logs, Pentobarbital (5 grams); *see also* Ex. G, DEA Forms, p. 9.

60. All of the 100ml vials of pentobarbital currently in TDCJ's possession are from the batch received by TDCJ on April 29, 2019.

61. As of the time of filing of this Petition, the 100ml vials in TDCJ's possession are at least 1,325 days old.

62. The 100ml vials are well over the BUD limit of 24 hours (or 45 days if kept frozen). Ex. D, Report of Dr. Almgren ¶ 18.

63. Therefore, every 100ml vial in TDCJ's possession is expired as per the USP.

B. The Pentobarbital in TDCJ's Possession Was Not Subject to All of the Tests Required by USP.

64. In addition to being expired, the pentobarbital in TDCJ's possession was not subject to all of the tests required by USP.

65. The USP also specifies that the pH of compounded pentobarbital should be tested and be between 9.0 and 10.5. *Id.* at ¶ 31.

66. pH can shift over time, which can accelerate the breakdown of the pentobarbital molecules and lead to the formation of precipitants.

67. None of the analytical reports TDCJ has produced indicate that the pH of the pentobarbital in its possession has ever been tested. Ex. E, Lab Reports.²

68. None of the analytical reports TDCJ has produced indicate that any of the pentobarbital has been subject to a visual inspection for particulates as required by USP Chapter <790>.

69. The pentobarbital in TDCJ's possession was tested for sterility but the wrong methodology was used, and the results are, therefore, not valid under USP. Even if the sterility test

² Counsel for Petitioners have submitted multiple Public Information Act requests related to the lethal injection drugs in TDCJ's possession. The most recent such request sought, among other things, the results of all testing generated between January 1, 2013, and November 17, 2022. On November 29, 2022, TDCJ provided counsel for Petitioners with seven pages of testing reports. *See* Ex. E. Allegations regarding the quantity of drugs in TDCJ's possession, age of each batch of drugs, the types of testing performed on the drugs, and dates on which vials were last subjected to testing are based on those reports.

results were valid, which they are not, that testing, along with the other testing completed by TDCJ, cannot extend the BUD of the pentobarbital in its possession. *See infra* IV. C.

C. Respondents May Not Use Expired Pentobarbital to Execute Mr. Ruiz and Mr. Balentine.

70. A drug that has surpassed its BUD is at risk of stability and sterility failings.

According to the USP, such drugs must not be used. Ex. D, Report of Dr. Almgren at ¶ 20.

71. Pharmacological activity of expired drugs is unpredictable but in general the effectiveness will decrease over time. *Id.*

72. Some of the drug degradants may have their own pharmacological activity, typically completely different from the original drug. *Id.* at ¶¶ 20, 24, 27.

73. Expired medications can cause nausea, vomiting, acute renal failure, and other severe side effects. *Id.* at ¶ 20.

74. The Food and Drug Administration also strongly advises against the use of any expired medication. *Id.*

D. Claims by Respondents to “Extend” the Expiration Dates are Unscientific and Invalid.

75. On several occasions, TDCJ has removed a vial of pentobarbital from its existing stockpile and returned the individual vial to Respondents Unknown Pharmacy and Pharmacists. *See* Exs. F, H, Huntsville Unit Storage Inventory Logs.

76. Respondents Unknown Pharmacy and Pharmacists in turn subject these single vials to potency testing. Potency testing, also referred to as assay testing, measures the amount of API in a sample.

77. On several occasions, TDCJ Respondents have claimed to “extend” the BUD of the expired compounded pentobarbital currently in TDCJ’s possession based on the results of potency testing alone.

78. This is an unscientific and invalid approach to extending the BUD of a compounded drug. Ex. D, Report of Dr. Almgren ¶¶ 21-23.

79. The only valid means to assess whether and how long the BUD of a drug can be extended beyond the BUD limits imposed by Chapter 797 of the USP is to perform stability-indicating studies. *Id.* at ¶¶ 23, 25-27.

80. A stability-indicating test, unlike a potency test, is capable of determining whether there has been any degradation of the drug. *Id.* at ¶ 26.

81. The method used to test the potency of TDCJ's compounded pentobarbital is not a stability-indicating test. *Id.* at ¶¶ 23, 25.

82. A stability-indicating test is capable of separating the drug API from degradation residues, i.e., the impurities that form in the vial over time, and will show the true potency of the drug. *Id.* at ¶¶ 23, 24-26.

83. A stability-indicating test will reveal the presence of degradants, which likely lower the potency of the API and may change solubility, pH, and other drug qualities, all of which can impact how the drug functions on the body. *Id.* at ¶¶ 24, 30.

84. Pentobarbital degrades over time and those degradants do not have the same pharmacologic effect as pentobarbital. *Id.* at ¶ 27.

85. TDCJ has purported to extend the BUD of multiple vials based on the results of a potency test performed on a single vial.

86. Even if potency testing were a valid basis on which to extend a drug's BUD, which it is not, USP makes clear that the results from tests conducted post-compounding on one vial are not applicable to other vials from the same batch. *See id.* at ¶ 28. For example, TDCJ may not extend the BUD of an entire batch of pentobarbital based on a test of a single vial from that batch.

87. USP also dictates that test results performed on a particular vial are not applicable to

vials from other batches. *Id.* at ¶ 29. For example, TDCJ may not extend the BUD of the batch of 100ml vials of pentobarbital obtained on April 29, 2019, based on a test of a single 50ml vial obtained on March 18, 2021.

88. Contrary to Respondents' faulty claims that they extended the BUD of their lethal injection chemicals, all the pentobarbital in TDCJ's possession expired long ago.

89. The vials that TDCJ "returned" to the Unknown Pharmacy and Pharmacists are on occasion shipped back to TDCJ after testing and placed back into storage for use in future executions. Once a sterile vial is opened for testing, any drug not consumed in testing must be wasted given the risk of contamination and potential for tampering. *Id.* at ¶¶ 33-34.

E. Respondents Did Not Even Follow Their Own Unscientific and Invalid Process When Concocting the Expiration Dates that They Currently Claim.

90. As of August 12, 2022, Respondents claimed that the 50ml vials in TDCJ's possession expired on October 9, 2022, or December 8, 2022, and that all 100ml vials in TDCJ's possession expired on December 8, 2022. Ex. I, Email from Amy Lee, Office of the General Counsel – TDCJ (Aug. 12, 2022).

91. On November 29, 2022, TDCJ's general counsel's office informed Petitioners that Respondents were claiming to have yet again extended the BUD of the pentobarbital vials, and were now claiming that all 50ml vials in TDCJ's possession expire on September 27, 2023, and all 100ml vials expire on November 1, 2023. Ex. J, Email from Amy Lee, Office of the General Counsel – TDCJ (Nov. 29, 2022).

92. Respondents, however, did not subject any pentobarbital in its possession to potency testing between August 12, 2022, and November 29, 2022. *See* Ex. E, Lab Reports.

93. In fact, it appears that December 9, 2021, was the last time any 50ml vial was tested for potency and January 17, 2022, was the last time any 100ml vial was tested for potency. *Id.*

94. Having failed to conduct any recent potency testing, Respondents apparently abandoned their own unscientific and invalid process when purporting to extend the pentobarbital's BUD well into 2023.

95. It is unclear what, if any, alternative method or grounds Respondents relied on when calculating the most recent alleged BUDs.

F. TDCJ Acquires Pentobarbital Without a Prescription and in Large Quantities that Cannot Be Used Prior to the Expiration Date.

96. Based on information and belief, Respondents do not obtain or receive a prescription from a medical practitioner when ordering pentobarbital for use in executions.

97. TDCJ purchases compounded pentobarbital for use in executions in batches that have ranged from nine to twenty-four vials. Ex. G, DEA Forms, 1, 5, 7, 9, 12.

98. TDCJ stockpiles compounded pentobarbital, meaning that it obtains more pentobarbital than it can reasonably expect to use prior to its BUD.

VII. SUMMARY OF RELEVANT LAW

A. The Texas Pharmacy Act

99. The Texas Pharmacy Act recognizes that it is a “matter of public interest and concern” that “only qualified persons be permitted to engage in the practice of pharmacy” and that practice of pharmacy receive the “confidence of the public.” Tex. Occ. Code § 551.002(b). To that end, the Pharmacy Act “control[s] and regulat[es] the practice of pharmacy.” *Id.* at § 551.002(c)(1).

100. Under the Pharmacy Act, compounding must be done in compliance with “applicable United States Pharmacopoeia guidelines, including the testing requirements.” Tex. Occ. Code § 562.153(2). To compound and deliver a compounded preparation, a pharmacy must comply with applicable USP standards. 22 Tex. Admin. Code § 291.133(f)(1)(D)(ii).

101. Consistent with the USP, a drug “shall not be stored or transported or begin to be

administered to a patient” after its BUD has passed. 22 Tex. Admin. Code § 291.133(b)(9). The BUD “shall be determined as outlined in Chapter 797” of the USP. 22 Tex. Admin. Code § 291.133(d)(9)(A)(iii).

102. The Pharmacy Act permits a pharmacy to “dispense and deliver a reasonable quantity of a compounded drug to a practitioner for office use by the practitioner.” Tex. Occ. Code § 562.152. “Reasonable quantity” means an amount that “does not exceed the amount a practitioner anticipates may be used in the practitioner’s office before the expiration date of the drug.” Tex. Occ. Code § 562.151(3)(A).

103. Except in limited circumstances, only licensed pharmacists are authorized to dispense, distribute, or transfer prescription drugs from one person to another. Tex. Occ. Code §§ 558.001(c), 551.004.

104. Unless incident to research, teaching, or chemical analysis, compounding must be authorized by a prescription from a medical practitioner. Tex. Occ. Code § 551.003(9); *see also* 22 Tex. Admin. Code § 291.133(d)(1)(A).

105. It is permissible to compound a drug that is commercially available, such as pentobarbital, only if three conditions are satisfied:

- (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet individual patient’s needs;
- (ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and
- (iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

22 Tex. Admin. Code § 291.133(d)(1)(C).

106. The unavailability of the commercially available drug must be documented prior to compounding, including, “maintaining a copy of the wholesaler’s notification showing back-

ordered, discontinued, or out-of-stock items.” 22 Tex. Admin. Code § 291.133(d)(1)(D).

B. Texas Controlled Substances Act

107. The Texas Controlled Substances Act (“CSA”) provides that, other than in an emergency, a person “may not dispense or administer a controlled substance without an electronic prescription.” Tex. Health & Safety Code § 481.074(b).

108. The CSA further specifies that the prescription must issue from a “practitioner”³ in the normal course of medical practice. *See* Tex. Health & Safety Code § 481.071(a).

109. A prescription for a Schedule II drug, such as pentobarbital, must contain the date the prescription issued, the substance and quantity prescribed, the intended use, the practitioner’s name, and the name, address, and date of birth of the person for whom the substance is prescribed. Tex. Health & Safety Code § 481.075(e)(1).

110. The CSA also prohibits a pharmacist from dispensing a controlled substance if the pharmacist “knows or should have known that the prescription was issued without a valid patient-practitioner relationship” or on any occasion “except under a valid prescription and in the course of professional practice.” Tex. Health & Safety Code § 481.074(a).

111. Although the CSA contains multiple exemptions, none apply to TDCJ’s acquiring, possession, distributing, dispensing, or administering of pentobarbital in connection with

³ In relevant part, the CSA defines a “practitioner” as:

- (A) a physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;
- (B) a pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state, . . .
- (D) an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order a drug or device.

Tex. Health & Safety Code § 481.002(39).

executions. *See, e.g.*, Tex. Health & Safety Code § 481.061, .062, .065.

112. The CSA explicitly authorizes animal control and humane society personnel to possess pentobarbital under certain circumstances for “the purpose of destroying injured, sick, homeless, or unwanted animals.” Tex. Health & Safety Code § 481.111(b).

113. No analogous provision exists authorizing TDCJ Respondents to possess pentobarbital for use in executions.

C. Texas Food, Drug, and Cosmetic Act

114. The Texas Food, Drug, and Cosmetic Act likewise requires the issuance of a prescription in order to dispense any drug for which the federal Food, Drug, and Cosmetic Act (“FDCA”) requires a prescription. Tex. Health & Safety Code § 431.113(c)(1).

115. Under the federal FDCA, a prescription is required to dispense pentobarbital. 21 U.S.C. § 353(b)(1).

D. Texas Penal Code

116. Under Texas Penal Code § 38.11(a)(1), it is an offense for any person to “provide” (or to possess with intent to provide) a controlled substance “to a person in the custody of a correctional facility or civil commitment facility, except on the prescription of a practitioner.”

117. The Texas Penal Code uses the same definition of “practitioner” as the Controlled Substances Act. *See* Tex. Penal Code § 38.11(f)(1) (citing Tex. Health & Safety Code § 481.002).

VIII. CAUSES OF ACTION

**Count One – Texas Pharmacy Act
Respondents Are Without Legal Authority to Procure, Possess, Distribute, or
Administer Expired Pentobarbital**

118. Petitioners reallege and incorporate by reference the allegations contained in the above paragraphs.

119. According to the BUD set by Chapter 797 of the USP, every vial of pentobarbital

currently in TDCJ's possession expired between twenty and forty-three months ago.

120. The Texas Pharmacy Act prohibits the use of expired compounded pentobarbital.

121. Therefore, Respondents' procurement, possession, distribution, and future administration of the pentobarbital in their possession to Mr. Balentine and Mr. Ruiz violates the Texas Pharmacy Act.

122. Respondents are without legal authority to procure, possess, distribute or administer expired pentobarbital to Petitioners.

123. Petitioners seek a declaration that Respondents' aforementioned actions violate the Texas Pharmacy Act.

124. Petitioners seek to enjoin Respondents from continuing to procure, possess, distribute or administer expired pentobarbital to Petitioners in violation of the Texas Pharmacy Act.

Count Two – Texas Pharmacy Act
Respondents Acted and Continue to Act Without Legal Authority When Compounding, Procuring, Possessing, Distributing, and Administering Pentobarbital

125. Petitioners reallege and incorporate by reference the allegations contained in the above paragraphs.

126. Respondents acted and continue to act without legal authority when compounding, procuring, possessing, distributing, and administering compounded pentobarbital without a prescription issued by a practitioner.

127. Respondents acted and continue to act without legal authority when they compound, procure, possess, distribute, and administer compounded pentobarbital that was not subject to the standards and tests required by USP.

128. Respondents acted and continue to act without legal authority by compounding and obtaining pentobarbital in an amount in excess of what could reasonably be administered prior to the BUD set by Chapter 797 of the USP.

129. Respondents acted and continue to act without legal authority when compounding and obtaining pentobarbital that is essentially a copy of FDA-approved injectable pentobarbital without (a) establishing the FDA-approved version is not commercially available, and (b) providing a prescription documenting a specific need for the compounded version of the drug.

130. Therefore, Respondents' compounding, procurement, possession, distribution, and future administration of the pentobarbital in their possession to Mr. Balentine and Mr. Ruiz violates the Texas Pharmacy Act.

131. Petitioners seek a declaration that Respondents' aforementioned actions violate the Texas Pharmacy Act.

132. Petitioners seek to enjoin Respondents from continuing to compound, procure, possess, distribute, or administer pentobarbital to Petitioners in violation of the Texas Pharmacy Act.

Count Three – Texas Controlled Substances Act
Respondents Do Not Have Legal Authority to Dispense or
Administer Pentobarbital to Petitioners

133. Petitioners reallege and incorporate by reference the allegations contained in the above paragraphs.

134. TDCJ Respondents do not have a valid prescription to dispense or administer pentobarbital, a Schedule II controlled substance, to Petitioners.

135. Such a prescription is required by Tex. Health & Safety Code § 481.074(b).

136. Unknown Pharmacy and Pharmacists know or should have known that no valid prescription exists. Unknown Pharmacy and Pharmacists are therefore prohibited from dispensing pentobarbital to TDCJ Respondents. Tex. Health & Safety Code § 481.074(a).

137. Petitioners seek a declaration that Respondents' aforementioned actions violate the Texas Controlled Substances Act.

138. Petitioners seek to enjoin Respondents from dispensing and/or administering pentobarbital to Petitioners in violation of the Texas Controlled Substances Act.

Count Four – Texas Food, Drug, and Cosmetic Act
Respondents Do Not Have Legal Authority to Dispense or Administer Pentobarbital to Petitioners

139. Petitioners reallege and incorporate by reference the allegations contained in the above paragraphs.

140. Respondents do not have a valid prescription to dispense or administer pentobarbital, a Schedule II controlled substance, to Petitioners.

141. Such a prescription is required by Tex. Health & Safety Code § 431.113(c)(1).

142. Petitioners seek a declaration that Respondents' aforementioned actions violate the Texas Food, Drug, and Cosmetic Act.

143. Petitioners seek to enjoin Respondents from dispensing or administering pentobarbital to Petitioners in violation of the Texas Controlled Substances Act.

Count Five – Texas Penal Code § 38.11(a)
Respondents Do Not Have Legal Authority to Provide or Administer Pentobarbital to Petitioners

144. Petitioners reallege and incorporate by reference the allegations contained in the above paragraphs.

145. Respondents are in possession of pentobarbital, a controlled substance, and intend to administer it to Petitioners.

146. Respondents do not have a prescription related to such administration and, therefore, are acting in violation of Texas Penal Code § 38.11(a)(1) and without legal authority.

147. Petitioners seek a declaration that Respondents aforementioned actions violate the Texas Penal Code.

148. Petitioners seek to enjoin Respondents from continuing to possess pentobarbital with the intent to administer it to Petitioners in violation of the Texas Penal Code.

IX. APPLICATION FOR EMERGENCY TEMPORARY INJUNCTION

149. Petitioners seek a temporary injunction, and permanent injunction to stop the Respondents' *ultra vires* and unlawful administration of expired pentobarbital into Petitioners during their executions.

150. The function of a temporary injunction is to maintain the status quo rather than adjudicate the matter on the merits. *In re M-I L.L.C.*, 505 S.W.3d 569, 576 (Tex. 2016) (quotations omitted).

151. A plaintiff seeking a temporary injunction must plead and prove three specific elements: "(1) a cause of action against the defendant[s]; (2) a probable right to relief sought; and (3) a probable imminent and irreparable injury in the interim." *Butnaru v. Ford Motor Co.*, 84S.W.3d 198, 204 (Tex. 2020) (citation omitted).

152. Petitioners meet all the elements necessary for immediate injunctive relief with respect to their claims described above. First, Petitioners state valid causes of action against each Respondent.

153. Second, Petitioners establish a probable right to relief sought. A plaintiff need not prove that he will prevail at trial for a temporary injunction to issue; instead he must only show that he is "likely to succeed on final determination on the merits." *Six Brothers Concrete Pumping, LLC v. Tomczak*, No. 01-21-00161-CV, 2022 WL 3031350 at * 4 (Tex. App. Aug. 2, 2022). To meet that burden, a plaintiff must only "present some evidence that, under the applicable rules of law, tends to support its cause of action." *Id.* (citations omitted).

154. For the reasons detailed above, there is a substantial likelihood that Petitioners will prevail after a trial on the merits because Respondents' *ultra vires* acquisition, storage, and

administration of expired compounded pentobarbital is in violation of the statutes as described above. At the very least, Petitioners presented evidence that supports their causes of action and tends to prove that Respondents are violating applicable rules of law.

155. Third, if this Court does not issue a temporary injunction, Petitioners will suffer irreparable injury. “An injury is irreparable if the injured party cannot be adequately compensated in damages or if the damages cannot be measured by any certain pecuniary standard.” *Butnaru*, 84 S.W.3d at 204. If Respondents are permitted to administer expired pentobarbital into Petitioners, there is a risk of severe injury at the site of injection. Ex. D, Report of Dr. Almgren at ¶ 17. Additionally, expired drugs like the ones at issue here have unpredictable action, potential harm, and unwanted side effects. *Id.*

156. Petitioners cannot be adequately compensated for such damages because, if these harms occur during their executions, Petitioners will be dead before they can seek redress. For that reason, a temporary injunction should issue to maintain the status quo, and prohibit Respondents from executing Petitioners with expired drugs until this matter is adjudicated so that the Court can rule on Petitioners’ request for a permanent injunction while they are still alive.

157. Petitioners do not seek a stay of execution. Instead, they seek injunctive barring Respondents from unlawfully executing them with expired drugs.

X. PRAYER AND SUMMARY OF RELIEF REQUESTED

158. For the foregoing reasons, Petitioners request that the Court grant the following relief:

- a. Upon a hearing, a temporary injunction prohibiting Respondents from continuing to compound, procure, possess, distribute or administer pentobarbital to Petitioners in violation of the Texas Pharmacy Act, the Texas Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Penal Code.

- b. After trial, a permanent injunction prohibiting Respondents from continuing to compound, procure, possess, distribute or administer pentobarbital to Petitioners in violation of the Texas Pharmacy Act, the Texas Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Penal Code.
- c. Declaratory judgment that Respondents' actions violate the Texas Pharmacy Act, the Texas Controlled Substances Act, the Texas Food, Drug, and Cosmetic Act, and the Texas Penal Code.
- d. All other relief, general and special, at law and in equity, as the Court may deem necessary and proper.

Dated: December 14, 2022.

Respectfully Submitted,

/s/ Peter Walker

Peter Walker
Alex Kursman*
Assistant Federal Defenders
Federal Community Defender Office
for the Eastern District of Pennsylvania
Suite 545 West, The Curtis Building
601 Walnut Street
Philadelphia, PA 19106
(215) 928-0520
peter_walker@fd.org
alex_kursman@fd.org

Jennae Swiergula
Texas Defender Service
1023 Springdale Road, Building 14, Suite E
Austin, Texas 78721
(512) 320-8300
jswiergula@texasdefender.org.

**Pro hac vice forthcoming*

*Attorneys for Petitioners Wesley Ruiz and
John Lezell Balentine*