Exhibit A

SUPPLEMENTAL EXPERT REPORT OF DR. MICHAELA ALMGREN

1. The attorneys who represent death-sentenced prisoner Clarence Dixon asked me to submit an expert opinion in this case. I offered an initial expert report on March 10, 2022. I am now supplementing the opinions that I offered in that initial report based on my review of additional documents (attached hereto as Exhibit 4), which are a partial component of stability reports.

2. My experience, qualifications, testimony in prior cases, and fee schedule for this case are set forth in my initial report and accompanying exhibits.

3. More documents, studies, and other pertinent information may become available to me at a later date, and I reserve the right to take such materials into account and to modify or supplement my opinions accordingly. I may also be present at hearings or at trial and may consider any testimony or other evidence related to my opinions and modify/supplement my opinions accordingly.

I. The stability data provided do not include—and cannot be used—to assign a beyond-use date of the compounded pentobarbital because they contain insufficient information.

4. The Arizona Department of Corrections, Rehabilitation and Reentry Order Manual Chapter: 700, Department Order 710—Execution Procedures and attachments ("the Manual") specifies that the assigned Beyond Use Date (BUD) of the lethal chemical used must be past the execution date.

5. What is labelled as "stability data" provided in the alleged "stability report" is insufficient to be used for the assignment of BUD, as it does not contain all the required information needed for the determination of a parenteral drug's expiry. Thus, the Arizona

Department of Corrections is not in compliance with its own requirements as specified in the Manual.

6. A typical stability study is very carefully designed to address all quality aspects of the medication that need to be considered to assure that the drug maintains its integrity and thus its pharmacological properties over a time period defined by the study. Since the stability studies are used to extend the expiry of the medication, it is important to examine the medication degradation profile as it changes over time.

II. The "stability data" lack many basic elements of a typical stability study specific for compounded parenteral medication and are insufficient to extend the drug's BUD.

7. No information on the stability study design was provided. The stability study design must be specified in a test protocol, which usually accompanies the stability study results to provide information about the storage conditions, test methodology, quality requirements, container sizes, batch sizes, container closure systems used, etc. All study parameters are carefully selected and examined as they are important to consider when it comes to the drug compounding, packaging, and storage. For example, if a study examines a certain container type with a specific container closure, the stability study findings only apply to this specific container type and closure, and a new study has to be performed if a different type of container closure (i.e., new vial cap) is used.

8. It is also crucial to examine multiple samples of the compounded drug, preferably from multiple batches, to demonstrate that the drug preparations are uniform, and that the results of the study are reproducible even when testing different batches. Typically, three batches are used in a typical study, at a minimum.

9. The results provided in the "stability report" do not specify what samples were used, whether the samples were from the same batch or different, how many vials were tested and what type of storage container and container closure is used for these samples.

10. The study data provided do not specify what compounding recipe was used to prepare this compound, which is important to note in order to identify this study with the specific product. Findings for each stability study are only applicable to a specific compounding recipe; if any ingredient changes are made, which includes changes in the excipients used, a new stability study needs to be initiated.

11. The study data provided does not outline the testing strategy of the timing intervals. According to the records, the sample was received on 9/24/2021. But there is no information regarding when the preparation was compounded and what the initial assay value was, as the first assay test was not performed until 12/28/2021. Most commonly when executing stability studies, the samples are tested initially, then tested monthly to establish some understanding of the drug's degradation process. There are no reports submitted from the samples being tested in October 2021 or November 2021. It is also not clear whether the samples were stored correctly during that time.

III. Since pentobarbital is a relatively complex preparation, it is important to design the stability study carefully to assure that the drug is tested correctly, and the correct BUD is assigned.

12. Compounded pentobarbital contains unstable excipients in varying amounts, which are prone to evaporation, oxidation, and precipitation. This can lead to unwanted changes of the compounded drug quality, resulting in changes in pharmacological activity.

13. The excipients, as well as the active pharmaceutical ingredient (API) itself are also rather sensitive to environmental conditions, which can cause the compound to degrade, or cause

the API to form a precipitate. A precipitate is usually formed when a drug starts forming solid crystals and comes out of solution, most often due to changes in temperature or the pH of the solution. This can be a serious quality concern, as injection of a solution containing particles may lead to directly causing severe tissue injury and thromboembolism, which can be extremely painful. Furthermore, if the drug has precipitated out of solution, the potency of the injection will be lower, but it may not be detected necessarily when assay is performed, as the API is still present, just not in pharmacologically applicable state due to crystallization.

14. The study design for this preparation should be detailed and specific to assure that the quality requirements for this medication are met at all test points. Testing methodology should also be provided and included in the protocol to assure the validity of the results provided by the contract laboratory.

IV. The "stability data" points in the "stability report" provided for review are not complete, because only the assay was performed.

15. The stability reports are incomplete because only the assay was performed, which only provides information on the potency of the drug.

16. According to the USP monograph for pentobarbital injection, additional tests should also be performed to assure that the medication meets all quality requirements. Additionally, further USP quality requirements for all injectable drugs are specified in USP Chapter 1.

17. One of the important tests listed in the drug monograph, but missing in the purported stability report, is the pH of the compound. The pH is crucial because the wrong pH can result in formation of precipitant, leading to reduction or loss of pharmacological activity of the drug. It can also cause tissue irritation and damage, causing severe pain when infused.

18. Visual inspection should also be performed to assure that the drug does not contain particulate matter, which could indicate the formation of precipitant. Also, any change in color or general appearance should be noted as they can also signal significant changes in drug quality. There is no indication that a visual inspection of the compounded drug was conducted.

19. The presence of impurities should also be examined, especially since the initial quality of the pentobarbital API cannot be verified. (No data for the API were provided. Appropriate data would include origin of the API; Certificate of Analysis for the API, indication of whether the API is of pharmaceutical grade, etc..) There is no information about whether the compounded drug was examined for contaminants or impurities.

20. Sterility should be confirmed for this parenteral preparation to assure that the medication is not contaminated by any microorganisms. Certain microorganisms may alter the quality of active ingredients or excipients, leading to unpredictable pharmacological activity. The sterility of the drug should be tested at the beginning of the stability study, followed by a test of the last sample/study endpoint to demonstrate that the preparation maintained sterility during the entire study. No sterility data has been provided.

V. Due to the lack of information about the origin of the pentobarbital API, it is important to generate the information pertaining to the initial quality of the API by testing the API according to the requirements specified in the USP monograph for pentobarbital.

21. The assay for pentobarbital API is specified in the USP monograph and should be performed. The acceptance criteria are relatively stringent, and it is important that the API meets these requirements.

22. In addition to the assay, impurities testing needs to be performed. Assays do not test for impurities; they indicate potency of the drug. But impurities can also have impact on pharmacology of the medication. Sometimes impurities present in the drug can be

pharmacologically active and some can have opposing effect on the activity of the active ingredient. This makes pharmacodynamics and pharmacokinetic properties of the drug unpredictable.

VI. A well-designed stability protocol addressing all the information needed to extend the BUD of the compounded pentobarbital should be performed.

23. A proper stability protocol needs to be specific in terms of sampling, storage conditions, container, drug formulation, testing frequency and methodology to assure that all quality concerns are addressed, and the BUD established is true and correct.

24. While the assay results reported in the "stability report" indicate that the drug has the potency as specified in the USP monograph, unfortunately this information alone is not sufficient to assume that the compounded medication's BUD can be extended. There are other parameters such as pH, visual inspection, impurities assay and sterility studies that need to be also included—and for which no information was provided—in order to offer a complete and accurate picture of the drug quality and provide assurance that the medication will perform as expected. The presence of pharmacologically active impurities, precipitant or microbial contamination cannot be ruled out at this time. Any of those factors can cause changes in pharmacology, pharmacokinetic and pharmacodynamic activity of the drug leading to unpredictable effects. This in turn can lead to unnecessary pain and suffering when injected.

VII. Conclusion

25. The "stability data" provided is insufficient to establish the BUD of the compounded pentobarbital because the study did not include data from a number of additional tests set forth in the USP monograph for pentobarbital that are necessary to the determination of a parenteral drug's expiry. Consequently, it is not possible to determine whether the compounded drug that the Arizona Department of Corrections intends to use in Mr. Dixon's execution is

appropriate for this use. Based on the information the Department provided, it appears that the Department is out of compliance with its own requirements as specified in the Manual.

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March 31st, 2022