**DECLARATION OF MARK J.S. HEATH, M.D.**

The undersigned, Mark, J.S. Heath, M.D., being of lawful age, states the following:

1. I am an Assistant Professor of Clinical Anesthesiology at Columbia University in New York City. I received my Medical Doctorate degree from the University of North Carolina at Chapel Hill in 1986 and completed residency and fellowship training in Anesthesiology in 1992 at Columbia University Medical Center. I am Board Certified in Anesthesiology, and am licensed to practice medicine in New York State. My work consists of approximately equal parts of performing clinical anesthesiology (specializing in cardiothoracic anesthesiology), teaching residents, fellows, and medical students, and managing a neuroscience laboratory. As a result of my training and research I am familiar with and proficient in the use and pharmacology of the chemicals used to perform lethal injection. I am qualified to do animal research at Columbia University and am familiar with the American Veterinary Medical Association's guidelines for animal research and animal euthanasia.

2. Over the past several years as a result of concerns about the mechanics of lethal injection as practiced in the United States, I have performed many hundreds of hours of research into the techniques that are used during this procedure. I have testified as an expert medical witness regarding lethal injection in courts in California, Missouri, Maryland, Tennessee, Georgia, Kentucky, Virginia, Oklahoma, and Indiana in the following cases: *Morales v. Tilton*, Nos. 06-219-JF-RS, C-06-926-JF-RS (N.D. Cal.); *Taylor v. Crawford*, No. 05-4173-CV-C-FJG (W.D. Mo.); *Patton v. Jones*, No. 06-CV-00591-F (W.D. Okla.); *Evans v. Saar*, 06-CV-00149-BEL (D. Md.); *Baker v. Saar*, No. WDQ-05-3207 (D. Md.); *Reid v. Johnson*, No. 3:03CV1039 (E.D. Va.); *Abdur'Rahman v. Bredesden*, No. 02-2336-III (Davidson County Chancery Ct., Ky.); *Commonwealth v. Lamb*, CR05032887-00 (Rockingham County Cir. Ct., Ky.), *State v. Nathaniel Code*, No. 138860 (1st Judicial District Court of La. for Caddo Parish); and *Timberlake (Intervenor Woods) v. Donahue*, No. 06-cv-01859-KLY-WTL (S.D. Ind.) I have also filed affidavits or declarations that have been revised by courts in the above states and also in Pennsylvania, New York, Alabama, North Carolina, South Carolina, Ohio, Texas, Missouri, Connecticut, Arkansas, Delaware, Nevada, and Montana, and by the United States Supreme Court.

3. I have reviewed the execution protocols and autopsy data (when available) from each of the above referenced states and the federal government. Additionally, I have reviewed execution protocols and/or autopsy data from Florida, Idaho, Oregon, and Arizona.

4. As a result of the discovery process in other litigation, I have participated in inspections of the execution facilities in Maryland, Missouri, California, Delaware, North Carolina, Texas, Alabama and the Federal Execution Facility in Terre Haute, Indiana. During court proceedings, I have heard testimony from prison wardens who are responsible for conducting executions by lethal injection.

5. I have testified before the Nebraska Senate Judiciary Committee regarding proposed legislation to adopt lethal injection. I have testified before the Pennsylvania Senate Judiciary Committee regarding proposed legislation to prohibit the use of pancuronium bromide or other neuromuscular blockers in Pennsylvania's lethal injection protocol, and have testified before the Maryland House and Senate Judiciary Committees regarding legislation on the administrative procedures that govern the creation of lethal injection protocols. I have also testified before the South Dakota House Committee on State Affairs regarding proposed legislation to amend the lethal injection statute. Most recently, I testified before the Florida Governor's Commission on Administration of Lethal Injection as part of the Commission's review of the method in which lethal injection protocols are administered by the Florida Department of Corrections.

6. My research regarding lethal injection has involved extensive conversations with recognized experts in the fields of anesthesiology, toxicology and forensic pathology, and correspondence with Drs. Jay Chapman and Stanley Deutsch, the physicians responsible for introducing lethal injection as a method of execution in Oklahoma.

7. My qualifications are further detailed in my curriculum vitae, a copy of which is attached hereto as Exhibit 1 and incorporated herein.

8. I hold all opinions expressed in this declaration to a reasonable degree of medical certainty unless otherwise specifically noted.

9. In preparing this declaration, I have referred to and relied on:

- My training and experience as a practicing physician and anesthesiologist;

- My research into lethal injection, including media and witness accounts of executions, media accounts of legislative and governmental activities related to lethal injection, and materials reviewed in litigation;
- A document entitled "Report on Administration of Death Sentences in Tennessee" prepared by the TDOC;
- A document entitled " Executive Order by the Governor, Number 43, An order directing the Department of Correction to complete a comprehensive

review of the manner in which the death penalty is administered in Tennessee";

- A document entitled "Execution procedures for lethal injection" that bears the seal of the Tennessee Department of Correction. This document was emailed to me on April 30, 2007 by an attorney named Paul Bottei, Assistant Federal Defender, with the representation that it is the "new" and current lethal injection protocol promulgated by the TDOC;
- The American Veterinary Medical Association (AVMA "2000 Report of the AVMA Panel on Euthanasia";
- Email correspondence amongst members of a group of personnel involved in revising the TDOC lethal injection protocol

## I. Introductory comments on the Tennessee lethal injection protocol and its deficiencies

10. It is useful to think of the procedure of lethal injection as comprising the following four stages: (1) The first stage is achieving intravenous access. (2) The second stage is the administration of general anesthesia (sodium thiopental). (3) The third stage is the administration of a neuromuscular blocking agent that has a paralyzing effect to ensure the execution appears serene and peaceful (pancuronium bromide). (4) The fourth stage is the execution through the administration of potassium chloride which kills the prisoner by stopping his heart.

11. Further, it is useful to highlight the two principal problems that can result in an inhumane execution: A) the obtaining of IV access, which when done improperly has resulted in painful mutilation in previous executions, and which requires demonstrated proficiency and skill, and B) failure to produce and maintain adequate general anesthesia so that the agonizing effects of pancuronium and potassium are not experienced by the prisoner. It is important to recognize that the discretionary use by the TDOC of pancuronium and potassium makes the anesthetic component of the procedure a matter of extreme importance.

12. The current TDOC protocol contains unacceptable deficiencies in both of these areas. The problematic features of the Tennessee lethal injection protocol render it deficient with respect to minimum standards of safe care, deficient with respect to acceptable standards of veterinary care, and deficient with respect to the lethal injection practices of other states, as recognized by Courts, Committees, and Departments of Corrections.

13. It is important to understand that lethal injection is performed on animal such as dogs and cats with great frequency, with reliability, and in ways that are humane. Thus, the problem with Tennessee's lethal injection protocol is not that lethal injection is in itself necessarily inhumane, but rather that the manner in which Tennessee currently plans to undertake lethal injection is gratuitously fraught with unnecessary and avoidable risk, principally because it deviates from acceptable and legal standards of veterinary euthanasia.

14. The Tennessee statute providing for execution by lethal injection does not set forth any particular drug as part of the execution process. Specifically, the relevant part of the statute reads as follows:

> 40-23-114. Death by lethal injection — Election of electrocution.
>
> (a) For any person who commits an offense for which the person is sentenced to the punishment of death, the method for carrying out this sentence shall be by lethal injection.

15. Unlike the statues of many other states, there is no affirmative direction regarding the types of lethal substances to be used. Thus, the selection of lethal substances on the part of the TDOC is completely discretionary. The TDOC could, should it chose to, evaluate and select different lethal substances, with an eye towards reducing and eliminating the risks that are necessarily conferred by the use of pancuronium and potassium.

16. As in other states, Tennessee's method of execution by lethal injection involves the sequential administration of three separate drugs.

17. The TDOC protocol specifies the drugs used for execution by lethal injection to be the following (page 38-39):

- The intended dose of sodium thiopental is 5 grams, administered in divided doses from 4 syringes.
- The intended dose of pancuronium is difficult for me to discern, because the protocol describes the concentration of pancuronium to be "100mg/ml" (bottom of page 38). I am not aware of pancuronium being supplied in such a high concentration, and

suspect that this is an error in the written procedure. Based on my clinical experience with pancuronium and based on lethal injection protocols from other states, pancuronium is supplied in concentrations of one fiftieth to one hundredth of the TDOC's intended use, namely 1 mg/ml or 2 mg/ml. I think it is more likely the case that rather than administering a total of 10,000 mg of pancuronium (100cc of 100mg/ml), as currently specified in the protocol, the TDOC hopes to administer 100mg of pancuronium in 100 cc, in divided doses from two syringes. I note parenthetically that, if indeed this is an error in the protocol, it is illustrative of the fact that, despite what was likely intended to be a rigorous process of recursive scrutiny of its documentation, unanticipated and undetected errors do occur.

- The intended dose of potassium chloride appears to be 200 milliequivalents (mEq), although this is not explicitly stated, and instead would have to be inferred from the "recipe" that is provided.
- Three injections of 50 cc of saline solution are also reported to be part of the process.
- It appears that TDOC employees mix the drugs used in the execution. The TDOC does not require that the drugs be mixed or prepared by a licensed pharmacist or physician.
- The drugs, and intervening flushes of saline solution, are intended to be delivered serially, one after another, using a total of eleven syringes.
- Of note, there is no description whatsoever of the actual mechanics of the administration of the drugs (page 65). Instead, the protocol elides the necessary step-by-step instructions, moving from "The Warden gives the signal to proceed and the Executioner begins to administer the first chemical…." to "Following the completion of the lethal injection process…" This is non-sensical, and it is also a departure from the written protocols of many other states, which describe in detail the intended mechanical steps to be taken during the sequence of injections. While Tennessee's omission might in theory be acceptable if the drugs were to be administered by an individual possessing the requisite demonstrated professional experience to undertake this activity, it is in fact not acceptable if it is the case that it is being done by personnel who lack such experience and qualifications. I know this from, among other things, my experience teaching medical students and junior anesthesiology residents in the operating room. Despite a significant degree of immersion in the clinical setting, medical students and junior anesthesiology residents often initiate or make critical errors in their

handling and use of intravenous tubing, injection sites, and syringes. Part of my job, as a practitioner in a teaching hospital, it to intercept such errors on the part of junior personnel, to apprise them of their errors, and to instruct them on how to avoid, detect, and correct such errors. It is not acceptable, under any standard, to permit personnel who have not undergone such elbow-to-elbow training to perform lethal injection, particularly in view of the inclusion of pancuronium and potassium in the currently proposed procedure.

18. The intravenous ("IV") catheters are to be inserted by a team of persons whom the TDOC represents as having, at some time, training or background as emergency medical technicians. The TDOC has not presented any information which shows that these persons are currently licensed or credentialed as an emergency medical technicians or whether placement of IV lines is currently part of any team members' regular occupation or duties. The protocol does not require that the injection team members be qualified in any particular way. The absence of currency with IV access procedures would render the IV team unqualified to perform IV access in an execution context.

19. The TDOC asserts that "[t]he method of finding a suitable blood vessel and maintaining a flow through that blood vessel are considered to be medical matters that will be addressed through standard medical methods and procedures."

20. If the IV team is unsuccessful in placing a catheter in each of the condemned inmate's arms, "cut-down" procedures will be initiated.

21. The TDOC does not monitor the condemned inmate to ensure that he or she has been adequately anesthetized.

22. Based upon my review of the foregoing material and my knowledge of and experience in the field of anesthesiology, I have formed several conclusions with respect TDOC's protocol for carrying out lethal injections. These conclusions arise both from the details disclosed in the materials I have reviewed and available at this time and from medically relevant, logical inferences drawn from the details in those materials. My principal conclusions are as follows:

23. The TDOC's intention to perform a surgical cut-down on a condemned inmate in the event their injection team is unable to achieve peripheral venous access without first trying the less painful and less invasive method of percutaneous access represents a profound departure from "standard medical methods" that the TDOC purports to apply to venous

access. It also constitutes a departure from the standard of care used in executions in other states.

24. The TDOC injection team as described is not qualified to mix and prepare execution drugs or syringes. The TDOC's apparent failure to require drug mixing and syringe preparation by a licensed pharmacist invites failure through under dosage of critical drugs. Numerous other states appropriately require the use of a licensed pharmacists to prepare and dispense the drugs and the syringes.

25. The TDOC's failure to understand the rudiments of drug dosing (made evident by its depiction of the preparation of the drugs) raise serious concerns about the TDOC's ability to reliably prepare the required drug amounts.

26. The TDOC's failure to have appropriately qualified and trained personnel monitor the condemned inmate after the administration of thiopental to ensure that there has been no IV access issue and to assure that the inmate has reached an appropriate plane of anesthesia prior to the administration of drugs which would cause suffering is contrary to all standards of practice for the administration of anesthetic drugs and creates a severe and unnecessary risk that the condemned will not be adequately anesthetized before experiencing asphyxiation and/or the pain of potassium chloride injection. This failure represents a critical and unacceptable departure from the standards of medical care and veterinary care, and falls below the lethal injection protocols of other states.

27. Pancuronium bromide (or any other similar neuromuscular blocking agent) is not statutorily required as part of a Tennessee lethal injection, it serves no legitimate medical purpose during execution, and it will, with certainty, cause great suffering if administered to an inadequately anesthetized person. The inclusion of such an agent adds a severe and unnecessary risk of masking body movements that could signal condemned inmate distress during execution.

28. Potassium is not statutorily required as part of a Tennessee lethal injection, it serves no legitimate medical purpose during execution, and it will, with certainty, cause great suffering if administered to an inadequately anesthetized person.

29. As described above, it useful to divide the procedure of lethal injection into four stages. The first stage is achieving intravenous access. The second stage is the administration of general anesthesia. The third stage is the administration of neuromuscular blocking agent that has a paralyzing effect to ensure the execution appears serene and peaceful. The fourth

stage is the execution through the administration of potassium chloride which kills the prisoner by stopping his heart. For purposes of this discussion about the risks of the execution process, it is helpful to consider the execution process in reverse order.

## II. Potassium Chloride Causes Extreme Pain

30. I have reviewed execution logs and electrocardiogram ("EKG") strips from executions around the country. These data show clearly that in the great majority of cases the administration of potassium chloride disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and causes death by cardiac arrest. In other words, condemned inmates are alive until killed by the administration of potassium chloride.

31. The TDOC apparently intends to inject 200 milliequivalents (meq)[1] of potassium chloride to cause death; this is a highly concentrated dose.

32. There is no medical dispute that intravenous injection of concentrated potassium chloride solution, such as that administered by the TDOC, causes excruciating pain. The vessel walls of veins are richly supplied with sensory nerve fibers that are highly sensitive to potassium ions. There exist other chemicals which can be used to stop the heart and which do not cause pain upon administration.

33. Even though the statute authorizing lethal injection in Tennessee does not require the use of potassium, the TDOC has nevertheless selected potassium chloride to cause cardiac arrest. Thus, the TDOC has exercised its discretion and chosen a means of causing death that causes extreme pain upon administration, instead of selecting available, equally effective yet essentially painless medications for stopping the heart. In so doing, the TDOC has assumed the responsibility of ensuring, through all reasonable and feasible steps, that the prisoner is sufficiently anesthetized and cannot experience the pain of potassium chloride injection.

34. A living person who is to be intentionally subjected to the excruciating pain of potassium injection must be provided with adequate anesthesia.

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[1] The TDOC's protocol calls for the use of 100 ***milligrams*** of potassium chloride. The TDOC protocol is presumably in error since 100 milligrams of potassium chloride is unlikely to constitute a lethal dose and would likely not cause death within a minute, as routinely occurs in executions following the administration of potassium chloride. The TDOC must intend to say that it will give 100 milliequivilants of potassium chloride. The TDOC's inability to understand the dosages of the drugs it intends to administer is just another example of the failures in protocol and failures in qualification and skill and professionalism of the persons involved in the execution process in Tennessee.

This imperative is of the same order as the imperative to provide adequate anesthesia for any person or any prisoner undergoing painful surgery. Given that the injection of potassium is a scheduled and premeditated event that is known without any doubt to be extraordinarily painful, it would be unconscionable and barbaric for potassium injection to take place without the provision of sufficient general anesthesia to ensure that the prisoner is rendered and maintained unconscious throughout the procedure, and it would be unconscionable to allow personnel who are not properly trained in the field of anesthesiology to attempt to provide or supervise this anesthetic care.

35. Indeed, the need for proper medical anesthetic care before death by potassium chloride is so well understood that standards for animal euthanasia require that euthanasia by potassium chloride be performed only by one qualified to assess anesthetic depth:

> It is of utmost importance that personnel performing this technique [euthanasia by potassium chloride injection] are trained and knowledgeable in anesthetic techniques, and ***are competent in assessing anesthetic depth*** appropriate for administration of potassium chloride intravenously. ***Administration of potassium chloride intravenously requires animals to be in a surgical plane of anesthesia characterized by loss of consciousness, loss of reflex muscle response, and loss of response to noxious stimuli.***

*2000 Report of the American Veterinary Medical Association Panel on Euthanasia*, 218 (5) J. AM. VET. MED. ASS'N 669, 681 (2001) (emphasis added). As result of the TDOC's failure to assess anesthetic depth and its failure to provide personnel who are competent in assessing anesthetic depth, the TDOC protocol for executing humans is unacceptable for the euthanasia of animals.

36. Tennessee's own laws regarding veterinary euthanasia reflect and underscore the hazards of the use of both pancuronium and potassium:

> "**(a)** Sodium pentobarbital and such other agents as may be specifically approved by the rules of the board of veterinary medicine shall be the only methods used for euthanasia of nonlivestock animals by public and private agencies, animal shelters and other facilities operated for the collection, care and/or euthanasia of stray,

neglected, abandoned or unwanted nonlivestock animals."

And

**"(c)** Succinylcholine chloride, curare, curariform mixtures, strychnine, nicotine, chloral hydrate, magnesium or **potassium** or **any substance which acts as a neuromuscular blocking agent**, or any chamber which causes a change in body oxygen may not be used on any nonlivestock animal for the purpose of euthanasia."

(emphasis added) (note: pancuronium is a neuromuscular blocking agent, and its paralytic effects are indistinguishable from curare and curariform mixtures).

## III. Administration of Neuromuscular Blocking Agents Is Medically Unnecessary and Causes an Extreme Risk of Suffering

37. The TDOC likely hopes to administer 100 milligrams of pancuronium bromide (as described above, the drug preparation instructions on page 38 dictate otherwise). Pancuronium bromide is one of a class of drugs called neuromuscular blocking agents. Such agents paralyze all voluntary muscles, but do not affect sensation, consciousness, cognition, or the ability to feel pain and suffocation. The effect of the pancuronium bromide is to render the muscles (including the diaphragm which moves to permit respiration) unable to contract. It does not affect the brain or sensory nerves.

38. Clinically, the drug is used to ensure a patient is securely paralyzed so that surgical procedures can be performed without muscle contraction. Anesthetic drugs are administered before neuromuscular blocking agents so that the patient does not consciously experience the process of becoming paralyzed and losing the ability to breathe. Thus, in any clinical setting where a neuromuscular blocker is to be used, a patient is anesthetized and monitored to ensure anesthetic depth throughout the duration of neuromuscular blocker use. To assess anesthesia, a trained medical professional, either a physician anesthesiologist or a nurse anesthetist, provides close and vigilant monitoring of the patient, their vital signs, using various diagnostic indicators of anesthetic depth. The appropriate procedures for monitoring a patient undergoing anesthesia and who is about to be administered a drug which masks the ability to convey distress are detailed in the American Society of Anesthesiology's recently published *Practice Advisory for Intraoperative Awareness and Brain*

*Function Monitoring*, 104 Anesthesiology 847, 850-51 (Apr. 2006) (describing preoperative and intraoperative measures for gauging anesthetic depth, including close monitoring of sites of IV access). *See also ASA Standards for Basic Anesthetic Monitoring* (Oct. 25, 2005). TDOC's procedure, to the extent disclosed, indicates that, contrary to all medical practice, no one, let alone a properly trained individual, assesses anesthesia prior to the administration of pancuronium bromide.

39. It is important to understand that pancuronium bromide does not cause unconsciousness in the way that an anesthetic drug does; rather, if administered alone, a lethal dose of pancuronium bromide would cause a condemned inmate to lose consciousness only after he or she had endured the excruciating experience of suffocation. It would totally immobilize the inmate by paralyzing all voluntary muscles and the diaphragm, causing the inmate to suffocate to death while experiencing an intense, conscious desire to inhale. Ultimately, consciousness would be lost, but it would not be lost as an immediate and direct result of the pancuronium bromide. Rather, the loss of consciousness would be due to suffocation, which would be preceded by the torment and agony caused by suffocation. This period of torturous suffocation would be expected to last at least several minutes and would only be relieved by the onset of suffocation-induced unconsciousness. The experience, in onset and duration and character, would be very similar to that of being suffocated by having one's nose and mouth blocked off. However, there would be the additional element of being unable to move or writhe or communicate the agony.

40. Based on the information presently available, this type of problem has occurred in other states. But before commenting on specific executions, I think it is important to explain how assessing the degree of consciousness that may have been felt in an execution differs from assessing consciousness in a clinical context. In the clinical context, anesthesiologists closely monitor patients for signs of awareness, and conduct post-operative interviews to assess to what extent a patient may have consciously experienced any part of his or her surgical procedure. The American Society of Anesthesiologists has recently commented that "[i]ntraoperative awareness cannot be measured during the intraoperative phase of general anesthesia, because the recall component of awareness can only be determined postoperatively by obtaining information directly from the patient." *See Practice Advisory for Intraoperative Awareness and Brain Function Monitoring*, 104 Anesthesiology 847, 850 (Apr. 2006).

41. Neither monitoring nor post-process interviews take place with an execution; we can therefore never know with absolute certainty the degree of consciousness felt in an execution. But, to the extent we can know, after the fact, we look for signs of intravenous access problems, physical

reaction to the process, and postmortem blood concentrations of anesthetic drugs. Based on the information presently available, this information suggests terrible problems have occurred during some executions. For example, in the State of Oklahoma's execution of Loyd LaFevers in 2001, witnesses observed an infiltration (a problem with intravenous access) in the intravenous (IV) line delivering the anesthetic thiopental. This problem was confirmed by the Medical Examiner's office notes attached to Mr. LaFevers's autopsy file. Witnesses to Mr. LaFevers's execution observed movements that they described as convulsions or seizures lasting for many minutes. A similar problem appears to have occurred in the 2006 execution of Mr. Angel Diaz in Florida which lasted 34 minutes. An autopsy of Mr. Diaz showed that the veins in each arm had through and through punctures showing that the IV lines were improperly seated in his veins and that he had chemical burns on both arms from what was most likely an infiltration of the drugs into his muscle tissue. During execution, observers report Mr. Diaz moved and tried to mouth words. Given the sequence of drugs he was administered, the only drug that could have caused chemical burns would be thiopental. Governor Bush has ordered a review of Mr. Diaz's execution, and the Commission charged with evaluating his execution has issued its final report. There is, however, still ongoing commentary about the Diaz execution and of lethal injection in Florida in general, and until that process has run its course I believe it would be premature to draw firm conclusions about exactly what took place. However, it is virtually certain that there was a deep failure to achieve the goal of a smooth execution, that something went disastrously wrong with the administration of the drugs, that the executioners were slow to confront and address the problems with the IV drug delivery and catheters, and that Mr. Diaz did not experience the sort of rapid humane death that is the intended result of the lethal injection procedure. These kinds of inadequate anesthesia experiences have resulted from the completely avoidable problem of poorly designed protocols for the delivery of anesthetic drugs, and the gratuitous inclusion of neuromuscular blocking agents like pancuronium bromide, which I will discuss in full below.

42. When thiopental is not properly administered in a dose sufficient to cause loss of consciousness for the duration of the execution procedure, it is my opinion held to a reasonable degree of medical certainty, that the use of paralytic drugs such as pancuronium or pancuronium bromide will cause conscious paralysis, suffocation, and the excruciating pain of the intravenous injection of concentrated potassium chloride, such as Mr. LaFevers and Mr. Diaz likely experienced.

43. There is no legitimate reason for including pancuronium bromide in the execution process and assuming the foregoing risks. Because potassium

chloride causes death in executions by lethal injection, there is no rational place in the protocol for pancuronium bromide; the drug simply serves no function in the execution process. Its inclusion, therefore, only adds risk, with no medical benefit.

44. Because of the concerns enumerated above, medical practitioners eschew the use of neuromuscular blocking agents in circumstances similar to that of executions, end of life care:

> NMBAs [neuromuscular blocking agents] possess no sedative or analgesic activity and can provide no comfort to the patient when they are administered at the time of withdrawal of life support. Clinicians cannot plausibly maintain that their intention in administering these agents in these circumstances is to benefit the patient. Indeed, unless the patient is also treated with adequate sedation and analgesia, the NMBAs may ***mask the signs of acute air hunger*** associated with ventilator withdrawal, ***leaving the patient to endure the agony of suffocation in silence and isolation***. Although it is true that families may be distressed while observing a dying family member, the best way to relieve their suffering is by reassuring them of the patient's comfort through the use of adequate sedation and analgesia.
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> * * *
>
> As a general rule, therefore, ***pharmacologic paralysis should be avoided at the end of life***. Robert D. Truog et al., *Recommendations for end-of-life care in the intensive care unit: The Ethics Committee of the Society of Critical Care Medicine*, 29(12) CRIT. CARE MED. 2332, 2345 (2001) (emphasis added).

45. Indeed, even the creator of the original "triple drug" lethal injection protocol, Dr. Jay Chapman, now questions whether his initial contribution warrants reconsideration in light of the problems that have been brought to light nationwide. In a CNN article place online on April 30, 2007 Dr. Chapman is quoted as saying "It may be time to change it," Chapman said in a recent interview. "There are many problems that can arise ... given the concerns people are raising with the protocol it should be re-examined." Regarding the pancuronium, the article states "When asked why he included the asphyxiation drug in his formula, Chapman answered, "It's a good question. If I were doing it now, I would probably eliminate it."

http://www.cnn.com/2007/HEALTH/04/30/lethal.injection/index.html

46. Additionally, the TDOC lethal injection protocol provides no information about the timing of the injections. A problem encountered in other states is that unless the timing is carefully planned, movements that might be cause by potassium will occur (if at all) before pancuronium has had time to cause paralysis. Given that the TDOC has not taken steps to establish a regime for properly timing the injections, the risks of pancuronium are assumed without any clear reason to believe it will achieve its stated purpose of preventing movement (which, as described above, is not in the first place a legitimate purpose).

## III. The TDOC's Administration of General Anesthesia Fails to Adhere to a Minimum Standard of Care

47. Because of the potential for an excruciating death created by the use of potassium chloride and the risk of conscious asphyxiation created by the use of the pancuronium bromide, it is necessary to induce and maintain a deep plane of anesthesia. The circumstances and environment under which anesthesia is to be induced and maintained in a Tennessee execution create, needlessly, a significant risk that inmates will suffer. It is my opinion, stated to a reasonable degree of medical certainty, that the lethal injection procedures selected by the TDOC subject condemned inmates to an increased and unnecessary risk of experiencing excruciating pain in the course of execution.

48. Presumably, because of the TDOC's awareness of the potential for excruciating pain evoked by potassium, the protocol plans for the provision of general anesthesia by the inclusion of thiopental. When successfully delivered into the circulation in sufficient quantities, thiopental causes sufficient depression of the nervous system to permit excruciatingly painful procedures to be performed without causing discomfort or distress. Failure to successfully deliver into the circulation a sufficient dose of thiopental would result in a failure to achieve adequate anesthetic depth and thus failure to block the excruciating pain.

49. The TDOC's procedures do not comply with the medical standard of care for inducing and maintaining anesthesia prior to and during a painful procedure. Likewise, the TDOC's procedures are not compliant with the guidelines set forth by the American Veterinary Medical Association for the euthanasia of animals

### The Dangers of Using Thiopental as an Anesthetic

50. Thiopental is an ultrashort-acting barbiturate that is intended to be delivered intravenously to induce anesthesia. In typical clinical doses, the

drug has both a quick onset **and short duration**, although its duration of action as an anesthetic is dose dependant.

51. When anesthesiologists use thiopental, we do so for the purposes of temporarily anesthetizing patients for sufficient time to intubate the trachea and institute mechanical support of ventilation and respiration. Once this has been achieved, additional drugs are administered to maintain a "surgical depth" or "surgical plane" of anesthesia (i.e., a level of anesthesia deep enough to ensure that a surgical patient feels no pain and is unconscious). The medical utility of thiopental derives from its ultrashort-acting properties: if unanticipated obstacles hinder or prevent successful intubation, patients will likely quickly regain consciousness and resume ventilation and respiration on their own.

52. The benefits of thiopental in the operating room engender serious risks in the execution chamber. The duration of unconcsiousness provided by thiopental is dose-dependent. However, if the intended amount of thiopental fails to reaches the condemned inmate's brain (as can occur as a result of an infiltration, leakage, mixing error, or other causes), and the condemned inmate receives a near surgical dose of thiopental, the duration of narcosis will be brief and the inmate could reawaken during the execution process. Then, a condemned inmate in Tennessee would suffer the same fate that apparently befell Mr. Angel Diaz in Florida who was intended to receive a 5 gram dose of thiopental just as Mr. Workman is intended to receive, but who did not, and then apparently experienced a conscious or semi-conscious response to the execution process.

53. Many foreseeable situations exist in which human or technical errors could result in the failure to successfully administer the intended dose. The TDOC's procedure both fosters these potential problems and fails to provide adequate mechanism for recognizing these problems, and it does these things needlessly and without legitimate reason.

## Drug Administration Problems

54. Examples of problems that could occur (and which have occurred in executions) that could prevent the proper administration of thiopental include, but are not limited to, the following:

a. **Errors in Drug Preparation.** Thiopental is delivered in powdered form and must be mixed into an aqueous solution prior to administration. This preparation requires the correct application of pharmaceutical knowledge and familiarity with terminology and abbreviations. Calculations are also required, particularly if the protocol requires the use of a concentration of drug that differs from that which is normally used. Recently drug

preparation problems were revealed in the State of Missouri, which was using a board-certified physician to prepare drugs. *See* Excerpts of Transcript of June 12, 2006 Bench Trial, at 30-39, *Taylor v. Crawford*, No. 05-4173-CV-C-FJG (W.D. Mo.). The TDOC's apparent use of the injection team to prepare the drugs and syringes heightens these risks. That risk is compounded by the TDOC protocol which does not set out the drug amounts in an intelligible fashion.

b. **Error in Labeling of Syringes.** It is of paramount importance that the drugs in an execution be given in the correct order. If the drugs are mislabeled, it greatly increases the chances the drugs will not administered in the correct order. The TDOC's apparent use of the injection team to prepare the drugs and syringes heightens these risks.

c. **Error in Selecting the Correct Syringe.** As presently configured, the TDOC protocol uses the serial injection of fluid from eleven syringes. With that number of syringes it would be easy to make a mistake in selecting the correct syringe. Medication errors are widespread within the clinical arena, and it is recognized by all health care professionals that the most important step in preventing medication errors is the acceptance of the fact that they can and do occur. In the context of lethal injection it is equally important to recognize the possibility of medication errors, particularly given the gratuitous use of pancuronium and potassium. The proposed TDOC procedures do not recognize the possibility of error. The proper way to detect error during the induction of general anesthesia is to assess anesthetic depth and thereby ensure that the drugs have exerted their intended and predicted effects.

d. **Error in Correctly Injecting the Drug into the Intravenous Line**. If the syringe holding the drug is turned in the wrong direction, a retrograde injection of the drug into the IV fluid bag rather than into the inmate will result. Even experienced anesthesiologists sometimes make this error, and the probability of this error occurring is greatly increased in the hands of inexperienced personnel.

e. **The IV Tubing May Leak.** An "IV setup" consists of multiple components that are assembled by hand prior to use. If the drugs are not at the bedside, which they are not in Tennessee, but are instead in a different room then it will be impossible to maintain visual surveillance of the full extent of IV tubing so that such leaks may be detected. The configuration of the death chamber and the relative positions of the executioners and the inmate in Tennessee will hinder or preclude such surveillance, thereby causing a failure to detect a leak. Leaking IV lines have been noted in executions in other states. The induction of general anesthesia in the medical context, and I believe in the veterinary context, is always a

"bedside procedure"; it is never conducted by the administration of drugs in tubing in one room that then is intended to travel into the body of a person in another room.

f. **Incorrect Insertion of the Catheter.** If the catheter is not properly placed in a vein, the thiopental will enter the tissue surrounding the vein but will not be delivered to the central nervous system and will not render the inmate unconscious. This condition, known as infiltration, occurs with regularity in the clinical setting. Recognition of infiltration requires continued surveillance of the IV site during the injection, and that surveillance should be performed so as to permit correlation between visual observation and tactile feedback from the plunger of the syringe. One cannot reliably monitor for the presence of infiltration through a window from another room. One cannot monitor a syringe site if it is covered in gauze (as Tennessee does when using a cut down). There have been occasions where departments of correction have failed to recognize infiltrations during execution. In Oklahoma an infiltration in the catheter delivering the anesthetic thiopental was reported (followed by condemned inmate convulsions). Another such occurrence has been reported during the Florida execution of Angel Diaz. These occurrences appear to have directly contributed to the condemned inmates' conscious experience of the execution process.

g. **Migration of the Catheter.** Even if properly inserted, the catheter tip may move or migrate, so that at the time of injection it is not within the vein. This would result in infiltration, and therefore a failure to deliver the drug to the inmate's circulation and failure to render the inmate unconscious.

h. **Perforation or Rupture or Leakage of the Vein.** During the insertion of the catheter, the wall of the vein can be perforated or weakened, so that during the injection some or all of the drug leaves the vein and enters the surrounding tissue. The likelihood of rupture occurring is increased if too much pressure is applied to the plunger of the syringe during injection, because a high pressure injection results in a high velocity jet of drug in the vein that can penetrate or tear the vessel wall. Recently, during the Clark execution in Ohio, the Department of Corrections there failed to recognize that the condemned's veins had "collapsed", causing the inmate to reawaken during the execution process and the condemned inmate to plead "Can't you just give me something by mouth to end this." *See* Jim Provance, *Problematic execution draws questions: Correction official to appear before panel*, TOLEDO BLADE (May 17, 2006).

i. **Excessive Pressure on the Syringe Plunger.** Even without damage or perforation of the vein during insertion of the catheter, excessive pressure on the syringe plunger during injection can result in tearing, rupture, and

leakage of the vein due to the high velocity jet that exits the tip of the catheter. Should this occur, the drug would not enter the circulation and would therefore fail to render the inmate unconscious. The TDOC protocol provides no information about the rate or speed of injections, meaning that there are no instructions to prevent the lay executioners from pushing the syringe plungers in a manner that injures the vein and causes failed delivery of some or all of the thiopental dose.

j. **Securing the Catheter.** After insertion, catheters must be properly secured by the use of tape, adhesive material, or suture. Movement by the inmate, even if restrained by straps, or traction on the IV tubing may result in the dislodging of the catheter. If this were to occur under a sheet or under gauze, it would not be detected, and the drug would not enter the inmate's circulation and would not render the inmate unconscious.

k. **Failure to Properly Loosen or Remove the Tourniquet.** A tourniquet is used to assist in insertion of an IV catheter. Failure to remove such tourniquets from the arm or leg after placement of the IV catheter will delay or inhibit the delivery of the drugs by the circulation to the central nervous system. This may cause a failure of the thiopental to render and maintain the inmate in a state of unconsciousness.

l. **Impaired Delivery Due to Restraining Straps.** Restraining straps may act as tourniquets and thereby impede or inhibit the delivery of drugs by the circulation to the central nervous system. This may cause a failure of the thiopental to render and maintain the inmate in a state of unconsciousness. Even if the IV is checked for "free flow" of the intravenous fluid prior to commencing injection, a small movement within the restraints on the part of the inmate could compress the vein and result in impaired delivery of the drug. It has been noted in at least one execution by lethal injection that the straps hindered the flow of drugs. *See* Editorial, *Witnesses to a Botched Execution*, ST. LOUIS POST-DISPATCH, at 6B (May 8, 1995).

55. These types of drug administration problems are not uncommon in the practice of medicine. A number of medical publications detail exactly these types of administration issues. For example, the National Academy of Sciences Institute on Medicine has just published the report of the Committee on Identifying and Preventing Medication Errors, which details the rates of drug preparation and administration errors in hospital setting and concludes "[e]rrors in the administration of IV medications appear to be particularly prevalent." PREVENTING MEDICATION ERRORS: QUALITY CHASM SERIES 325-60 (Philip Aspden, Julie Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Eds. 2006); *id*. at 351. Likewise a recent study shows that "drug-related errors occur in one out of five doses given to patients in hospitals." *See* Bowdle, T. A., *Drug Administration Errors from the ASA*

*[Am. Soc. Anesthesiologists] Closed Claims Project*, 67(6) ASA NEWSLETTER, 11-13 (2003). This study recognizes that neuromuscular blockers have been administered to awake patients and to those who have had inadequate doses of general anesthetic. *Id*.

56. In the practice of medicine, preventing pain and/or death as a result of these common drug administration problems is achieved by having persons in attendance who have the training and skill to recognize problems when they occur and the training and skill to avert the negative consequences of the problems when they arise.

**The Need for Adequate Training in Administering Anesthesia**

57. Because of these foreseeable problems in administering anesthesia, in Tennessee and elsewhere in the United States, the provision of anesthetic care is performed only by personnel with advanced training in the medical subspecialty of Anesthesiology. The establishment of a surgical plane of anesthesia is a complex task which can only reliably be performed by individuals who have completed the extensive requisite training to permit them to provide anesthesia services. *See Practice Advisory for Intraoperative Awareness and Brain Function Monitoring*, 104 Anesthesiology 847, 859 Appendix 1 (Apr. 2006) (recommending the use of "multiple modalities to monitor depth of anesthesia'). If the individual providing anesthesia care is inadequately trained or experienced, the risk of these complications is enormously increased. The President of the American Society of Anesthesiologists, writing about lethal injection, recently stated that "the only way to assure [a surgical plane of anesthesia] would be to have an anesthesiologist prepare and administer the drugs, carefully observe the inmate and all pertinent monitors, and finally to integrate all this information." Orin F. Guidry, M.D., *Message from the President: Observations Regarding Lethal Injection* (June 30, 2006).

58. In Tennessee and elsewhere in the United States, general anesthesia is administered by physicians who have completed residency training in the specialty of Anesthesiology, and by nurses who have undergone the requisite training to become Certified Registered Nurse Anesthetists (CRNAs). Physicians and nurses who have not completed the requisite training to become anesthesiologists or CRNAs are not permitted to provide general anesthesia.

59. In my opinion, individuals providing general anesthesia in the Tennessee prison should not be held to a different or lower standard than is set forth for individuals providing general anesthesia in any other setting in Tennessee. Specifically, the individuals providing general anesthesia within Tennessee's prisons, including during execution procedures, should

possess the experience and proficiency of anesthesiologists and/or CRNAs. Conversely, a physician who is not an anesthesiologist or a nurse who is not a CRNA or any person who lacks the requisite training and credentials should not be permitted to provide general anesthesia within Tennessee's prisons (or anywhere else in Tennessee or the United States).

60. There is no evidence, at this time, that any person on the TDOC's injection team has any training in administering anesthesia, or, if personnel are given training, what that training might be. The absence of any details as to the training, certification, or qualifications of injection personnel raises critical questions about the degree to which condemned inmates risk suffering excruciating pain during the lethal injection procedure. The great majority of nurses are not trained in the use of ultrashort-acting barbiturates; indeed, this class of drugs is essentially only used by a very select group of nurses who have obtained significant experience in intensive care units and as nurse anesthetists. Very few paramedics are trained or experienced in the use of ultrashort-acting barbiturates and/or pancuronium. Based on my medical training and experience, and based upon my research of lethal injection procedures and practices, inadequacies in these areas elevate the risk that the lethal injection procedure will cause the condemned to suffer excruciating pain during the execution process. Failure to require that the injection team have training equivalent to that of an anesthesiologist or a CRNA compounds the risk that inmates will suffer excruciating pain during their executions.

61. In addition to apparently lacking the training necessary to perform a lethal injection, the TDOC's protocol imposes conditions that exacerbate the foreseeable risks of improper anesthesia administration described above, and fails to provide any procedures for dealing with these risks. Perhaps most disturbingly, the protocol makes no mention of the need for effective monitoring of the inmate's condition or whether he is anesthetized and unconscious. After IV lines are inserted and the execution begins, it appears that the injection team will be in a different room from the prisoner, and thus will not have the ability to monitor the IV deliver system and catheter sites as they would if they were at "the bedside". Accepted medical practice, however, dictates that trained personnel are physically situated so that they can monitor the IV lines and the flow of anesthesia into the veins through visual and tactile observation and examination. The apparent lack of any qualified personnel present in the chamber during the execution thwarts the execution personnel from taking the standard and necessary measures to reasonably ensure that the thiopental is properly flowing into the inmate and that he is properly anesthetized prior to the administration of the pancuronium bromide and potassium. Other states have taken steps to place personnel with medical backgrounds actually

within the execution chamber for the purpose of monitoring the IV delivery system during the injection process.

62. In my opinion, having a properly equipped, trained, and credentialed individual examine the inmate after the administration of the thiopental (but prior to, during, and after the administration of pancuronium, until the prisoner is pronounced dead) to verify that the inmate is completely unconscious would substantially mitigate the danger that the inmate will suffer excruciating pain during his execution. This is the standard of care, and in many states the law, set forth for dogs and cats and other household pets when they subjected to euthanasia by potassium injection. Yet the TDOC protocol does not apparently provide for such verification.

63. Indeed, it appears that departments of correction around the country are now agreeing that some assessment of anesthetic depth is required to insure a humane execution. As a result of my participation in lethal injection litigations around the country I have become aware that the State of Indiana and the State of Florida now concede that some attempt at measuring or assessing anesthetic depth should be performed. Additionally, in Missouri, a federal district judge has ordered that an appropriately qualified person assess anesthetic depth. While Judge Fogel in California has not, to my understanding, issued a final decision regarding the evidence presented to him, it is clear from his discussion of the case that he recognizes that the use of drugs that cause great pain or suffering (such as pancuronium and potassium) places a heightened burden on the execution team and the state to properly monitor and maintain adequate anesthetic depth.

## IV. Unqualified Persons Establishing Intravenous Access

64. The first step in the lethal injection process is creating effective intravenous access for drug delivery. The subsequent administration of the anesthetic drugs can only be successful if IV access is properly achieved. But the TDOC has put in place a protocol that exacerbates the risk that IV access will not be adequately achieved. Tennessee states that the persons starting IV lines have EMT training, but has offered no information about whether those persons are or ever have been licensed as EMTs, the currency of their licenses, or the frequency with which they insert IV catheters. There have been problems in other states, most notably the Diaz execution in Florida, wherein the personal professional qualifications of the personnel providing IV access had not been subjected to adequate scrutiny.

65. When peripheral IV access is not possible, the TDOC will use a cut down to achieve venous access. A “cut-down” is a complex medical procedure requiring equipment and skill that are not accounted for in Tennessee’s

protocol on cut down procedures. It has a very high probability of not proceeding properly in the absence of adequately trained and experienced personnel, and without the necessary equipment. If done improperly, the "cut-down" process can result in very serious complications including severe hemorrhage (bleeding), pneumothorax (collapse of a lung which may cause suffocation), nerve injury, and severe pain. It is well documented that lethal injection procedures in other states require the use of central intravenous lines. As is widely recognized in the medical community, administration of intravenous medications and the management of intravenous systems are complex endeavors with significant risks and complications.

66. Cut-down procedures are an outdated method of achieving venous access for the administration of anesthetic drugs. The cut-down procedure has been virtually completely supplanted by the "percutaneous" technique for achieving central venous access. The percutaneous technique is less invasive, less painful, less mutilating, faster, safer, and less expensive than the cut-down technique. I have personally never used the cut-down technique to achieve intravenous access for drug delivery to a patient. The cut-down technique is still used in clinical situations that are not pertinent to executions by lethal injection, including emergency scenarios where there has been extensive blood loss, and in situations involving very small pediatric patients and premature infants. These are the only situations in which I have seen colleagues perform cut-down procedures for the administration of drugs. That Tennessee intends to use a cut down procedure on Mr. Workman if it can not successfully place peripheral IVs after 4 attempts is unconscionable. To use a cut-down as the backup method of achieving IV access would defy contemporary medical standards and would be a violation of any modern standard of decency. The ready availability of a superior alternative technique for achieving central IV access, should it be necessary, means that the TDOC's adherence to the outdated cut-down method would represent the gratuitous infliction of pain and mutilation to the condemned prisoner. Most other states have abandoned the use of the cutdown procedure as a means of obtaining IV access during executions.

66. It is my opinion that, to reasonably minimize the risk of severe and unnecessary suffering during the TDOC's execution by lethal injection, there must be: proper procedures that are clear and consistent; qualified personnel to ensure that anesthesia has been achieved prior to the administration of pancuronium bromide and potassium chloride; qualified personnel to select chemicals and dosages, set up and load the syringes, administer "pre-injections," insert the IV catheter, and perform the other tasks required by such procedures; and adequate inspection and testing of the equipment and apparatus by qualified personnel. The TDOC's

procedures for implementing lethal injection, to the extent that they have been made available, provide for none of the above.

67. An additional concern is that the TDOC protocol deliberately withholds important information about the properties of the execution drugs from the execution personnel. On page 35 of the lethal injection manual (entitled "Brief explanation of the chemicals used in lethal injection") it:

-Describes thiopental, but neglects the critical information that in clinically used doses it is ultra-short acting (i.e. it wears off very rapidly, well within the time frame of lethal injection executions if less than the intended dose is received by the condemned). Further, it neglects important information in the thiopental package insert regarding the potentially extremely painful consequences of infiltration or intra-arterial injection of thiopental. All personnel using thiopental need to be fully cognizant of this risk of its use and prepared to immediately remedy the consequences of such an event.

-Describes pancuronium, but neglects the critical information that it will prevent the personnel from ascertaining if the prisoner is suffering, or if there has been a failure to provide adequate anesthesia. Omission of this information, in a document that is purported to provide lay executioners with necessary information, is duplicitous and unconscionable.

-Describes potassium chloride, but neglects the critical information that, in the concentrations specified by the protocol, it would necessarily cause excruciating pain in a person who was not adequately anesthetized. Again, omission of this information, in a document that is purported to provide lay executioners with necessary information, is duplicitous and unconscionable.

## V. Conclusions

68. Overall, evaluation of the proposed TDOC lethal injection procedures reveal several problematic themes:

1 – the absence of a physician to supervise the use of the high-risk drugs pancuronium and potassium. Other states recognize their need to rely upon physicians to oversee the administration of pancuronium and potassium. By contrast, in Tennessee the physician is physically remote from the procedure, standing in a garage, and offering no more protection than would a potted plant.

2 – the use of pancuronium, which confers high risk of torturous death, which prevents the detection by witnesses and execution personnel of inadequate anesthesia, and which is speciously justified by a need to

prevent witnesses seeing movement when no such steps are taken for electrocution in Tennessee or other states.

3 – the absence of any articulated recognition that the establishment and maintenance of anesthetic depth is essential for the non-cruel completion of the execution procedure. There are no participating personnel who are capable of monitoring anesthetic depth, and there are no directives in the written protocol that would instruct such personnel, if they were present, to actually undertake the assessment of anesthetic depth. Other states, and courts, and committees, have recognized that given the use of torture-causing drugs such as pancuronium and potassium, it is essential that meaningful and effective steps be in place to ensure that adequate anesthesia is established and maintained.

4 – IV access – as described above, the "back-up" plan of using a cut-down, a mutilating surgical procedure, is unacceptable.

69. Based on my research into methods of lethal injection used by various states and the federal government, and based on my training and experience as a medical doctor specializing in anesthesiology, it is my opinion stated to a reasonable degree of medical certainty that, given the apparent absence of a central role for a properly trained professional in TDOC's execution procedure, the characteristics of the drugs or chemicals used, the failure to understand how the drugs in question act in the body, the failure to properly account for foreseeable risks, the design of a drug delivery system that exacerbates rather than ameliorates the risk, the TDOC has created an revised execution protocol that does little to nothing to assure they will reliabily achieve humane executions by lethal injection.

70. Given that the TDOC announced its new execution protocols on May 1, 2007, and that Mr. Workman's execution is scheduled for May 9, 2007, this declaration was, of necessity, prepared with limited time. I reserve the right to continue to review the TDOC execution policies and procedures and revise my opinion accordingly.

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

DATED this 3rd day of May, 2007.

Mark J.S. Heath, M.D.