IN THE SUPREME COURT OF FLORIDA

NO. SC11-1387

MANUEL VALLE,

Appellant,

v.

STATE OF FLORIDA,

Appellee.

DEATH WARRANT SIGNED

SUPPLEMENTAL INITIAL BRIEF OF APPELLANT

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PRELIMINARY STATEMENT

This proceeding involves the appeal of an order summarily denying Mr. Valle's successive Rule 3.851 motion. All other references are self-explanatory or otherwise explained herein.

REQUEST FOR ORAL ARGUMENT

Mr. Valle is presently under a death warrant. This Court has not hesitated to allow oral argument in other warrant cases in a similar procedural posture. A full opportunity to air the issues through oral argument would be more than appropriate in this case, given the seriousness of the claims involved, as well as Mr. Valle's pending execution date. Mr. Valle, through counsel, urges that the Court permit oral argument.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

STATEMENT OF THE FACTS

On July 25, 2011, this Court relinquished jurisdiction of the instant matter to the circuit court for the purpose of conducting an evidentiary hearing regarding the efficacy of pentobarbital as an anesthetic in the amount prescribed by Florida's lethal injection procedures. This Court also ordered the DOC to produce correspondence from Lundbeck, Inc., the sole manufacturer of pentobarbital.

The circuit court held a status conference on July 26, 2011 and both parties agreed to submit witness and exhibit lists that same day. The circuit court required both the State and Mr. Valle to proffer the anticipated testimony of each witness. After Mr. Valle filed his witness list and an amended witness list, the State moved to strike 7 of Mr. Valle's witnesses.[1]

On July 27, 2011, the circuit court held a hearing on the State's motion to strike and thereafter granted the motion. The evidentiary hearing began on July 28, 2011.

Mr. Valle presented **Matt Schulz**, an attorney with the capital habeas unit of Federal Defender's Office for the Middle District of Alabama (T. 7/28 29) who represented Eddie Powell, a death-sentenced Alabama inmate. Mr. Schulz witnessed the execution of Mr. Powell on June 16, 2011, with Federal Defender

[1] The State specifically moved to strike Russell Hosford, Jennifer Parker, Timothy Cannon, Edwin G. Buss, Rana Wallace, the Primary Executioner and the Second Executioner.

Christine Freeman. Mr. Schulz felt that Powell was handling his execution about as well as he could possibly expect someone to handle it, so he was not in any sort of distress other than just obviously the general anxiety about what was coming (T. 7/28 36).

Mr. Schulz had never been to the execution chamber before and did not know what to expect (T. 7/28 38). Also present in the execution chamber were the guard who brought them into the room, Ms. Freeman and three members of the press. There were additional witnesses who Mr. Schulz could not see (T. 7/28 40). Mr. Schulz explained that the witness room was separated from the chamber by a window, which was covered by a curtain when he arrived (T. 7/28 40). He sat right in front of the window. Mr. Powell was in the middle of the execution chamber, already on the gurney. He was strapped down, and covered by a number of white sheets tightly wrapped around him. Mr. Schulz could not see Mr. Powell's feet below the sheets (T. 7/28 40-41). He could see most of Mr. Powell's body, approximately seven or eight feet away. Mr. Schulz faced the left side of Mr. Powell's body. He could see the entire left side of Mr. Powell's face, his arms which were strapped to extensions on the gurney (T. 7/28 41-42). Mr. Schulz observed two guards and a chaplain in the chamber. The warden then entered the room, read the death warrant, and asked if Mr. Powell had any last words. The warden placed the microphone close to Mr. Powell's face and Mr. Powell

apologized for the pain that he had caused the victim's family and his own (T. 7/28 43). Mr. Powell did not appear to be in any distress at that time (T. 7/28 43).

After Mr. Powell's last statement, the warden stated the execution would now be carried out. He walked behind Mr. Powell and Mr. Schulz was not able to see the warden after that point. There was a wall behind Mr. Powell and the IV lines ran into and/or around the wall, so Mr. Schulz was not able to see the warden or know when they were injecting the lethal drugs (T. 7/28 44). Mr. Schulz described what he saw:

> After approximately one minute, Mr. Powell all of the sudden jerked his head up and kind of his upper body also jerked up rather abruptly. He looked to be pressing -- it looked as though his upper body was pressing against the restraints, and he had a real look of confusion on his face. He looked around, and then looked down at the chaplain, and he particularly had a look of confusion when he looked down at the chaplain, and then he began -- about the only way I can describe it is it look as though he was clenching his jaw and flexing the muscles in his face and in his neck quite strenuously. It's -- that looked as though -- I don't know whether it was his arteries actually throbbing or if it was just because of the muscles flexing, but it looked as though his artery was pumping and blood was sort of pumping into his face at that point, and that lasted for about a minute in and of itself, and then he -- at that point, his eyes started to kind of glaze over and rolled into the back of his head, and then his head went back down in what appeared to be involuntary at that point.
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> He appeared to be restrained clear throughout his lower and upper body…I was really only looking at his upper body, so it looked like -- kind of like his shoulders were pressing up against the restraints.
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> After a few minutes, a guard approached Mr. Powell and then sort of bent down a little towards him and yelled very loudly, "Eddie, Eddie, Eddie," and there was no response, and then the guard ran his -- it looked like he ran his finger kind of lightly over Mr. Powell's left eyelash, and there was, again, no response.

(T. 7/28 46-49). Mr. Schulz noted that Mr. Powell's eyes were open, but, by the end of the procedure which lasted 20 to 25 minutes, they appeared to be fully closed (T. 7/28 49).

Mr. Schulz explained that, to his knowledge, Alabama uses a three-drug cocktail in their lethal injection procedures and that they recently announced they were switching from sodium thiopental to pentobarbital (T. 7/28 51). Mr. Schulz was surprised that the process would have taken so long (T. 7/28 58). He could see from the clock in the execution chamber that it took 20 to 25 minutes (T. 7/28 59).

The State presented **John Harper**, a 23-year employee of the Georgia Diagnostic Prison in Jackson, Georgia (T. 7/28 88-89).[2] Mr. Harper has attended twenty-eight lethal injection executions in Georgia, including the execution of Roy Blankenship on June 23, 2011 (T. 7/28 89). During the Blankenship execution, Mr. Harper was in the mechanical room behind the actual execution chamber. Mr. Harper explained that there's a witness area separated from the execution chamber

[2] Mr. Valle moved to strike the testimony of the State's witnesses Jacqueline Martin and John Harper, because their testimony was offered to rebut the testimony that would have been offered by Mr. Valle's witnesses, who the court had excluded upon argument by the State (8/2 at 28).

by a wall of windows. Behind that chamber, there's another window that leads into the mechanical room where he was situated. Between the mechanical room and the gurney is a one-way (or a two-way) mirror - you can see out but you can't see in (T. 7/28 90).

Mr. Harper was approximately 86 inches from the head of the gurney (T. 7/28 90). He could see Mr. Blankenship's left side (T. 7/28 91). About 5 seconds after the injection of the first syringe, Mr. Harper saw Mr. Blankenship look at his left arm, then his right. He then made a noise that Mr. Harper described as a "grunt." Mr. Harper did not see Mr. Blankenship move after the consciousness check (T. 7/28 91-92).

Mr. Harper explained that he was not as close to the inmate as the witnesses in the first row. He could hear, but could not tell what was being said (T. 7/28 96). Mr. Blankenship's execution was the first Mr. Harper had witnessed involving pentobarbital (T. 7/28 98). Mr. Harper has never been trained in, and has no knowledge about pentobarbital (T. 7/28 98). He could not, or would not, estimate the size of the mechanical room in which he was situated (T. 7/28 99). Mr. Harper's duties during the execution involved communicating on the telephone with two command posts, letting them know what was happening (T. 7/28 100). While his view of the inmate is "mostly" unobstructed (T. 7/28 100), people would walk in front of him. There were approximately eight people in the mechanical

room, including the person actually pushing the syringes (T. 7/28 100).

Mr. Harper had indicated in an affidavit that there were two stopwatches in the mechanical room, however, he testified that he did not observe those stopwatches and relied on the clock in the execution chamber for his time line (T. 7/28 101-102). While present at the execution of Mr. Blankenship, Mr. Harper was on the telephone, there were people in front of him at times, and he saw the person pushing the syringes and he was taking notes (T. 7/28 102-103).

Mr. Blankenship moved to look at his left arm within 5 seconds of the first syringe being pushed (T. 7/28 103). While he could not estimate the length of the IV tubing, Mr. Harper did not believe that this was enough time for the drug to actually reach the inmate (T. 7/28 105). Approximately five seconds after looking at his arm, Mr. Blankenship laid his head back (T. 7/28 106). Mr. Harper does not know what chemical is in each of the syringes (T. 7/28 107).

The State also presented **Dr. Jacqueline Martin**, who testified by telephone from New York. Dr. Martin is a deputy chief medical examiner at the Georgia Bureau of Investigations where she has been employed since 2001 (T. 7/28 123). Dr. Martin performs autopsies and performs some administrative duties. In the course of her responsibilities as a medical examiner for the State of Georgia, Dr. Martin witnessed the execution of Roy Blankenship. She had witnessed two other executions (T. 7/28 124).

Dr. Martin was seated in the witness area, in the front row by the window separating the witness area from the execution chamber. She estimated she was about five feet away from the inmate (T. 7/28 125). Dr. Martin stated that she did not have a clear and unobstructed view of Mr. Blankenship, but then indicated she could see him clearly (T. 7/28 125-126). She described what she saw:

> When he -- when the warden left, about two to three minutes later, Mr. Blankenship looked to his left arm, he made some movement of his mouth, and then looked to his right arm, and then -- well, he kind of laid -- well, pushed his head towards the pillow and stayed put.

(T. 7/28 129). Dr. Martin opined that she did not observe Mr. Blankenship to be in any pain (T. 7/28 136).

Dr. Martin does not treat living patients and does not have experience in anesthesia (T. 7/28 134). She does not practice surgery or anesthesiology. Her only experience in a surgical setting witnessing somebody who's been sedated or induced anesthetically was as a medical student in 1984 or 1985 (T. 7/28 134). She does not recall how many times she might have witnessed someone being induced. Blankenship was the first execution that that she witnessed where pentobarbital was used (T. 7/28 135).

The Georgia Bureau of Investigation, who employs Dr. Martin, is a law enforcement agency (T. 7/28 137). After the Blankenship execution, the Georgia state attorney's office asked Dr. Martin to produce an affidavit (T. 7/28 138).

Dr. Martin described Mr. Blankenship’s facial expressions during the

execution:

> Mr. Blankenship, when he first looked towards his left hand, he opened and closed his mouth like he was chewing. He had no teeth -- no natural teeth, it was somewhat awkward, and then he went -- did the same thing looking to his right arm, and then he closed his mouth and stayed put.

(T. 7/28 140).

Dr. David Waisel, testified that he is an anesthesiologist at Boston Children's Hospital and medical ethicist (T. 8/2 49). Dr. Waisel performs "perioperative care," which includes anesthetizing patients for surgery. Dr. Waisel has been an anesthesiologist for 18 years, and has attended to approximately 15,000 to 20,000 patients (T. 8/2 40). In addition to his practice, Dr. Waisel is an associate professor at Harvard Medical School, lectures trainees and is in charge of the fellowship. As a medical ethicist, Dr. Waisel performs services for patients and families, as well as consulting with institutions on matters related to development of policy and quality of care (T. 8/2 43). In addition to being board certified in anesthesiology, Dr. Waisel has written approximately 30 peer-reviewed articles and numerous other contributions to publications regarding medical ethics and anesthesiology.

Dr. Waisel has consulted with capital defendants regarding lethal injection issues and testified in three states (T. 8/2 46). Dr. Waisel was contacted by Mr. Valle's counsel in early July, 2011. He reviewed the Florida lethal injection

protocols from 2007 and June 2011. In Dr. Waisel's opinion, the protocol's change from sodium thiopental to pentobarbital is significant (T. 8/2 49).

As an anesthesiologist, Dr. Waisel is familiar with both pentobarbital and sodium thiopental (T. 8/2 49). The purpose of pentobarbital is to anesthetize the inmate prior to the injection of pancuronium, which paralyzes the inmate mostly for cosmetic reasons, and potassium chloride to stop the heart, which would be excruciatingly painful if the inmate were not anesthetized (T. 8/2 50).

Dr. Waisel testified that the improper administration of pentobarbital could result in the inmate not being adequately anesthetized. This would result in paralysis, which would be a "horrible" and "terrifying" feeling and "probably hellish" experience (T. 8/2 50-51).

Both sodium thiopental and pentobarbital are classified as barbiturates, however, they are used in extremely different ways and are not interchangeable (T. 8/2 52). Both were developed in the late 1920's, early 1930's. By the early 1950's, sodium thiopental became the standard drug for intravenous injection of anesthesia in over 95% of patients. As a result, sodium thiopental was studied extensively.

On the other hand, pentobarbital was not used for induction of anesthesia and is not widely studied. Dr. Waisel testified that there are only two studies, one from 1948 and one from 1951, examining pentobarbital for induction of anesthesia in relatively healthy patients.

Pentobarbital became a “niche drug,” used in the intensive care unit for patients who had very bad seizures that could not be stopped any other way, to stop the electrical activity of the brain to prevent the brain from being injured (T. 8/2 54) Pentobarbital was also used for patients with swollen brains to decrease the electrical activity and the need of the brain for energy to help decrease damage to the brain. Pentobarbital might also be used for sedation in children receiving radiographic scans, but it has been replaced by better drugs for that use (T. 8/2 54).

Besides these “niche” uses, pentobarbital was used “extraordinarily infrequently” in the operating room to provide brain protection when an interruption of blood flow to the brain was anticipated (T. 8/2 54). However, sodium thiopental was used “nearly exclusively” for that purpose because it was a very common drug (T. 8/2 54). Moreover, when pentobarbital was used in those circumstances where patients required brain silence, an anesthetic was administered first (T. 8/2 56).

Because of its extensive use, Dr. Waisel “can't imagine there is a drug we know better in anesthesiology then sodium thiopental (T. 8/2 57). It has been tested in all sorts of patients, with all sorts of diseases, and all sorts of clinical situations, by novices and by experts. Because of this, we know its strengths and how to mitigate its weaknesses” (T. 8/2 59).

While “nothing about [sodium thiopental] will surprise us,” (T. 8/2 59), the

same cannot be said for pentobarbital, which is only used in narrow circumstances (T. 8/2 60). Moreover, pentobarbital has been researched in the context of those narrow uses, but not in use for induction of anesthesia, because it was not used in that manner (T. 8/2 60). The information on pentobarbital is "appropriately dismal" because it is not used for anesthesia (T. 8/2 60).

Prior to June 8, 2011, the Florida lethal injection procedures called for five grams of sodium thiopental. The new lethal injection protocol calls for the use of five grams of pentobarbital. However, as Dr. Waisel explained, the dosages are not proportional. A 500 milligram dose of thiopental would anesthetize a 220 pound man, thus a dose of five grams is ten times the amount of the upper dose for induction of anesthesia (T. 8/2 61). However, with pentobarbital the upper dose for sedation, not for anesthesia, is 500 milligrams for an unspecified weight. That is also ten times the dose, but for sedation, which is significantly different than anesthesia (T. 8/2 61). In fact, the package insert for pentobarbital does not state that pentobarbital is to be used, or is approved for, the induction of anesthesia (T. 8/2 62).

Dr. Waisel explained that the package insert is "the truth, the bible for what we know." (T. 8/2 63). The Food and Drug Administration approves the package inserts for drugs, which lists the uses, effects and complications associated with its use (T. 8/2 64). According to the package insert, there is no average intravenous

dosage of pentobarbital that can be relied on to produce similar effects in different patients (T. 8/2 67). The commonly used initial dose for the 70 kilo adult is 100 milligrams (T. 8/2 67). "If necessary, additional small increments of the drug may be given up to a total of, from 200 to 500-milligrams for normal adults.

However, there is a “vast” difference between sedation and anesthesia (T. 8/2 68). It is probably best to think of sedation and anesthesia on a continuum from being wide awake to being completely anesthetized and being able to do an operation. In “conscious sedation,” the patient can respond to voices, can make movements, and will respond to varying levels of pain (T. 8/2 68). As the patient gets closer to anesthesia, the amount of stimulus required to have the patient respond is increased. A greater stimulus will cause a response by the patient whereas lesser stimulus will not (T. 8/2 68).

Dr. Waisel explained that trainees often will see a patient as quiet and still, assume that the patient is anesthetized, do something stimulating or painful. This results in the patient responding by grabbing whatever part of the body is being stimulated (T. 8/23 at 69). Dr. Waisel also explained that one cannot extrapolate an appropriate does of pentobarbital for anesthesia based on the upper limit dose because we do not have the data to know that (T. 8/2 70). This would only be done in the most extreme circumstances where there was no alternative (T. 8/2 70).

Pentobarbital is manufactured by a company called Lundbeck. Dr. Waisel

reviewed several letters from Lundbeck to officials in several states, including Florida, warning against the off-label use of pentobarbital (T. 8/2 71). As Dr. Waisel explained, such a manufacturer's warning is unusual. Nearly always, the FDA issues initial warnings and the drug manufacturers follow with their own statement (T. 8/2 72). Dr Waisel explained that "I take any of these warnings very very serious, and so if the manufacturer chooses to do this in and of itself, I give it the highest regard." (T. 8/2 72). If he, as an anesthesiologist, received such a warning about a drug, he would "absolutely not use it" absent "an absolute hail Mary situation" (T. 8/2 72).

Dr. Waisel explained that the change in Florida's lethal injection protocol from sodium thiopental to pentobarbital was "very significant" (T. 8/2 74) because:

> We're taking a drug that we know everything about, replacing it with a drug which we know nothing, almost nothing, about in terms of inducing anesthesia in otherwise healthy people. In addition, when we think about how errors happen, this increases the likelihood of errors and subsequent harm to the inmate -- substantial harm, dramatically.
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> The community knowledge of sodium thiopental provided a bulwark against substantial harm . . . When you have, as we've seen in other cases, a high risk procedure where there are many points where there could be errors, not having a bulwark, especially at the end exposes the inmate to extraordinary risk.

(T. 8/2 74).

Dr. Waisel had the opportunity to speak to Greg Bluestein, a witness to the

execution of Roy Blankenship in Georgia[3] (T. 8/2 75). Dr. Waisel also reviewed several affidavits of other witnesses to the Blankenship execution, including Eddie Ledbetter and Mitchell Peace, also journalists (T. 8/2 76). In addition, when consulting on the DeYoung case in Georgia, Dr. Waisel reviewed affidavits of approximately 13 employees of the Georgia Department of Corrections who witnessed the Blankenship's execution.

Blankenship was executed under Georgia's protocol, which calls for the use of pentobarbital (T. 8/2 80). Based on his review of the witnesses' affidavits, Dr. Waisel concluded that "Mr. Blankenship suffered extremely during the execution." (T. 8/2 78). By report, Blankenship looked to his one arm in pain and looked to the other arm in pain. He then grimaced, jerked his head up, continued breathing and mouthing words for up to three-minutes (T. 8/2 78-79). Dr. Waisel explained that this three minute span was significant in two ways. First, while some patients, while being induced under anesthesia, may make movements for the first 15 seconds or so, the movements are not focused or localized as Blankenship's were

[3] The State made a motion in limine "to preclude Dr. Waisel from being used as a conduit for hearsay," specifically regarding Dr. Waisel's conversations with Associated Press reporter Mr. Bluestein, who witnessed the execution of Roy Blankenship in Georgia on June 23, 2011, as well as the other affidavits Dr. Waisel reviewed with respect to the Blankenship execution (T. 8/2 6). Mr. Bluestein, a reporter for the Associated Press, was not available to testify due to journalist privilege and the policies of his employer. Attorneys for the Associated Press indicated that Mr. Bluestein would be available only if subpoenaed and would claim journalist's privilege (T. 8/2 9).

(T. 8/2 79). Second, if pentobarbital worked as the state claimed, this would last for the first 3 seconds when the drug reaches the body, not for three minutes, which is not how the state claims pentobarbital works.

On cross-examination, Dr. Waisel testified that “phase induction” involves rendering a patient unconscious at the beginning of some surgical procedure, and induction of anesthesia is normally accomplished with intravenous drugs, but rarely just one (T. 8/2 82). For the duration or the of the surgical procedure, anesthesia is often maintained with a balanced anesthetic, which includes an inhaled anesthetic (T. 8/2 82). Sodium thiopental is no longer available (T. 8/2 70).

Sodium thiopental is an ultra short acting barbiturate. Pentobarbital is classified as both a short acting and an intermediate acting barbiturate (T. 8/2 85). These classifications refer to the length that the drugs are effective, not to the rate at which they take effect (T. 8/2 85). Pentobarbital did not become the favored drug back before the 1950's because its effects last longer than sodium thiopental (T. 8/2 85).

Pentobarbital is used to control seizures. One of the primary objectives of seizure control using pentobarbital is to achieve burst suppression in the brain if the seizure is severe and intractable (T. 8/2 86). Burst suppression can be determined with the use of an EEG (T. 8/2 87). Dr. Waisel explained that the initial doses of pentobarbital to start are well established, because you want to start on the

lower end to build effect. The EEG is used as a monitor to help decide the appropriate amount of pentobarbital for this person who has a brain injury of some sort.

Dr. Waisel opined that 5,000 milligrams of pentobarbital, if delivered intravenously, in the time frame of Florida's lethal injection protocol would most likely achieve burst suppression "in the scenario of a patient who has brain damage, such as intractable seizures, such as a swollen brain." (T. 8/2 89). However, there is no data of the affect of pentobarbital in a patient who does not have brain damage, intractable seizures, or brain swelling, so Dr. Waisel was not able to opine in that context (T. 8/2 90). While the dosages for burst suppression in people with injured brains is established, Dr. Waisel cautioned that in those situations, the patient is monitored and the dose is titrated to affect (T. 8/2 93). "We don't just give a dose and walk away." (T. 8/2 94).

Anesthesiologists always monitor the patient closely. When they use a drug that we know less about, there is even greater vigilance (T. 8/2 97). We do not have the body of information about pentobarbital for induction of general anesthesia in healthy people (Id).

Dr. Alan Dershwitz testified for the State. Dr. Dershwitz is an anesthesiologist (T. 8/2 103). In addition to practicing anesthesiology, Dr. Dershwitz has taught pharmacology to medical students and anesthesiology

residents. Dr. Dershwitz has testified as a witness in court proceedings more than 20 times, always for the state (T. 8/2 105).

Dr. Dershwitz explained that pentobarbital is used primarily to treat either intractable seizures or to induce barbiturate coma, and it is occasionally used as a sedative (T. 8/2 111). The typical indication for inducing barbiturate coma is for brain protection when the brain is going to be deliberately deprived of oxygen, such as during certain surgical procedures or when the person has suffered head trauma, carbon monoxide poisoning or something like that, that also puts the brain at risk (T. 8/2 111). Typically the introduction of a barbiturate coma involves an intravenous dose of pentobarbital that is titrated to a particular intermittent flat line tracing on an electroencephalogram, called burst suppression (T. 8/2 112). When a patient undergoes surgery, in most cases Dr. Dershwitz gives a dose based upon the patient's body weight of an intravenous drug that's different from a barbiturate, then evaluates the patient's response a short time later to see what the initial dose actually produced in the patient (T. 8/2 112). Anesthesia is different than burst suppression because anesthesia is a lighter plane or lesser degree of unconsciousness than burst suppression (T. 8/2 113). The range of doses necessary to achieve burst suppression in different people "is quite large" and not everyone requires the same dose (T. 8/2 114). Factors may include things like age, the size of the person and "underlying genetics that we still do not have a good handle on."

(T. 8/2 115).

Dr. Dershwitz opined that a dose of 5,000 milligrams of pentobarbital "is far in excess of any dose that would be used in a human for any reason that I could think of." (T. 8/2 117). The primary pharmacological effects of this dose involve the cardiovascular system and the respiratory system (T. 8/2 117). This would cause a flat-line EEG and it will also cause the person to stop breathing and the blood pressure to fall dramatically (T. 8/2 117).

It possible for a patient who is in the operating room on the operating table who has been anesthetized in the process to move and it sometimes happens, but it is usually a reflex mechanism (T. 8/2 118). It is also possible for the patient's eyes to remain open (T. 8/2 118).

Dr. Dershwitz explained that pentobarbital is not FDA approved for use as a general anesthetic (T. 8/2 120). No company has submitted the necessary data to the FDA to obtain such approval. In addition, pentobarbital is a not a short-acting barbiturate, so its effects would cause "an excessively large hangover in most patients if it were used for general anesthesia." (T. 8/2 120). Dr. Dershwitz explained there is nothing unusual about an off-label use of a drug, and that it is common in medicine (T. 8/2 121).

On cross-examination, Dr. Dershwitz recalled that he has testified regarding lethal injection in several jurisdictions, "somewhere in the teens, but I don't have

that information in front of me right now." (T. 8/2 126). He has also provided affidavits when asked and has provided expert reports to various states around the country, if asked (T. 8/2 127). Dr. Dershwitz denies that he has consulted with states regarding their execution procedures, "because it is not permissible for a physician to be an advisor or a consultant. My role is that of an expert witness, and I provide expert testimony in the context of litigation." (T. 8/2 128). Dr. Dershwitz refuses to discuss his position on the death penalty with anyone publicly or privately (T. 8/2 129). Dr. Dershwitz charges $3,500 per day for his testimony, as well as hourly for his time for work done in preparation (T. 8/2 130).

Dr. Dershwitz has used pentobarbital "a few times, a few being single digits, to either induce a barbiturate coma in one of my own patients or assisting one of my colleagues who had the same goal." (T. 8/2 131). He has not used it since a few years ago (T. 8/2 131). He has not done original research on pentobarbital, nor has he done any research into barbiturates (T. 8/2 132). When he has used pentobarbital, it was usually to produce a barbiturate coma in a patient who is already anesthetized with something else (T. 8/2 132).

Dr. Dershwitz has testified in the past regarding the comparison between thiopental and pentobarbital in use of lethal injection procedures. When asked if he testified previously that thiopental is better than pentobarbital for executions, Dr. Dershwitz refuses to answer:

> In order to answer that question, I'd have to draw a comparison that I am no longer allowed to do. However, the written record is extensive and I stand behind the answers I gave in the past, and I cannot answer that question today.

(T. 8/2 134-5).

Dr. Dershwitz recalled previously testifying in *Dickens v. Napolitano*. In that case, Dr. Dershwitz was asked, "Do you agree that pentobarbital could be used as a painless drug to kill an inmate?" He responded, "Probably, but as I wrote in my expert report, commenting on Dr. French's writings, Pentobarbital given by the IV route is uncommonly used in humans and we have very, very little high quality high resolution kinetic data on pentobarbital in humans, and we have even less pharmacodynamic data." (T. 8/2 138). While he stands by everything he said, he refused to answer whether he recalled that testimony because "I will no longer answer questions that draw comparisons between pentobarbital and thiopental, because it puts my board certification in anesthesiology at risk." (T. 8/2 138).

In *Dickens*, Dr. Dershwitz further explained that:

> There is no reason to think pentobarbital wouldn't work, but neither I, nor anyone else on Earth, could draw the high resolution graphs for pentobarbital that I drew for thiopental, because in order to do so, we need human studies that don't exist. Let me just follow up with one more statement. The contention that pentobarbital is longer lasting is silly, and anyone who makes that contention doesn't understand the kinetics.
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> We also want to know what are the respiratory effects, what are the

> hemodynamic effects, and, again, we've got a lot of animal data on pentobarbital, much less human data, where there's a huge body of data using thiopental.
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> I should also add, in the context of using thiopental for brain protection, the usual dosage in an average size person is about three grams, so not quite as high as what Arizona is going to use, but the dose that many other states are using for lethal injection. There's no clinical scenario in which equivalent doses of pentobarbital are also used. So, again, we have much more research experience, we have much more clinical experience using thiopental at this dosage range, and I see no scientific reason to defensibly argue for changing it.

(T. 8/2 139-140).

Dr. Dershwitz also recalled his testimony in *Alderman* that he could not recall the last time he used pentobarbital, but it was probably for ICU sedation when he was a resident (T. 8/2 143). The most common intravenous anesthetic used in Dr. Dershwitz's practice today is Propofol (T. 8/2 149).

Dr. Dershwitz testified that a dose of 5000 mg of pentobarbital would not "definitely" be fatal (T. 8/2 150-151). There are no high resolution pharmacokinetic, pharmacodynamic studies of pentobarbital that would permit him to draw the detailed high resolution graph such as the one he had previously submitted as exhibits in litigation regarding sodium thiopental (T. 8/2 151).

ARGUMENT

ARGUMENT I: THE STATE OF FLORIDA'S LETHAL INJECTION STATUTE, FLA. STAT. § 922.105, AND THE EXISTING PROCEDURE THAT THE STATE OF FLORIDA UTILIZES FOR LETHAL INJECTION VIOLATE ARTICLE II, SECTION 3 AND ARTICLE I, SECTIONS 9 AND 17 OF THE FLORIDA CONSTITUTION, AND THE EIGHTH AMENDMENT TO THE U.S. CONSTITUTION

The substitution of pentobarbital for sodium thiopental as an anesthetic is not inconsequential. Mr. Valle has established that the use of pentobarbital in the lethal injection drug sequence introduces an unknown variable into an already deficient system and creates a substantial risk of serious harm. Dr. Waisel best explained the risk created by the use of pentobarbital:

> We're taking a drug that we know everything about, replacing it with a drug which we know nothing, almost nothing, about in terms of inducing anesthesia in otherwise healthy people. In addition, when we think about how errors happen, this increases the likelihood of errors and subsequent harm to the inmate—substantial harm, dramatically.

(T. 8/2 73). As Dr. Waisel's testimony demonstrated, there are serious risks associated with the DOC's choice of pentobarbital for use as an anesthetic: unlike sodium thiopental which is widely used in surgical settings, pentobarbital has never been tested on human beings for the purpose of inducing an anesthetic coma. Pentobarbital has not been FDA-approved for the induction of anesthesia, has no relevant clinical history, and has no relevant clinical reference doses by which to determine an appropriate dosage for a clinically adequate depth of anesthesia to avoid the excruciating pain and suffering caused by an injection of pancuronium

bromide and potassium chloride. Therefore, an essential bulwark, i.e., the community knowledge of sodium thiopental, has been eliminated (T. 8/2 73-74). Instead, the State is left with a high risk procedure where there are many points where there could be errors and not having the initial bulwark exposes the inmate to extraordinary risk (T. 8/2 74).[4]

This Court remanded the case for a hearing "solely on Valle's claim regarding the efficacy of pentobarbital **as an anesthetic** in the amount prescribed by Florida's protocol." *Valle v. State*, Case No. SC11-1387 (Fla. July 25, 2011) (emphasis added). Yet, there was a fundamental misperception of the problems associated with the use of pentobarbital in the context of an execution and consequently, there was a schism between the available evidence and the lower court's conception of the question presented. This became clear during the closing arguments when the trial court queried, "Let me ask you this, there's a five-gram

[4] Dr. Waisel explained that in the medical field and other high risk organizations seeking high reliability, the possibility of error is analogized to Swiss cheese:

> Imagine, if you will, several Swiss cheese lined up for an error to occur, often times there are multiple bulwarks to prevent the error. When an error occurs, it makes it through one hole of the Swiss cheese, then the other hole in another Swiss cheese, then the third hole…

(T. 8/2 73). Dr. Waisel compared sodium thiopental to a piece of regular cheese with a small hole, whereas he described pentobarbital as a piece of Swiss cheese with "one huge hole." (T. 8/2 73).

dosage, and yet Ohio[5] puts people six feet under after five grams. How can anybody feel anything if they are dead? And that's my question." It is apparent that the lower court did not understand the purpose of pentobarbital in Florida's protocols. Ultimately, the court concluded that

> The defendant has failed to show that the substitution of pentobarbital as an anesthetic violated the Eighth Amendment's prohibition of cruel and unusual punishment. Defendant has attempted to use evidence of two (2) earlier executions (Powell and Blankenship) to show that the administration of 5,000 mg of pentobarbital causes needless suffering in and of itself, and that the pentobarbital dose does not adequately render an inmate unconscious, thereby leading to needless suffering. The evidence presented did not establish substantial risk of serious harm from pentobarbital, or even that inmates who were executed earlier necessarily suffered any harm, much less serious harm, from intravenous administration of pentobarbital.

Order at 20. Mr. Valle's Eighth Amendment is not premised upon an assertion that the introduction of pentobarbital "in and of itself" presents a substantial risk of harm; rather, the issue is whether pentobarbital will be a sufficient safeguard against Mr. Valle experiencing the excruciating pain of the second and third drug.

It cannot be emphasized enough that the most vital component of Florida's three-drug lethal injection procedure that safeguards against the risk of infliction of

[5] Unlike Florida, Ohio uses a one-drug protocol which renders the issues significantly different than those presented here. Importantly, Ohio now has a de facto moratorium due to the Federal District Court's opinion in *Cooey v. Kasich*, et. al., No. 2:09-cv-242 (S.D. Ohio July 8, 2011).

gratuitous pain is a reliable method by which to ensure that the condemned inmate is sufficiently anesthetized. Previously this Court found that the most constitutionally significant of the three drugs used in the procedures was sodium thiopental, the ultra short-acting anesthetic, because "it was undisputed that if pancuronium bromide or potassium chloride [ ] are injected into a conscious person, significant pain would result from each of the chemicals." *Lightbourne v. McCollum*, 969 So. 2d 326, 344-45 (Fla. 2007). Simply put, the sodium thiopental was an indispensible part of the process. *See also Baze v. Rees*, 128 S. Ct. 1520 (2008).

After Hospira, Inc. stopped making sodium thiopental, a number of states across the country abandoned the use of the anesthetic and began experimenting with a sedative, pentobarbital, before the introduction of pancuronium bromide and potassium chloride. Pentobarbital (Nembutal) is a short-acting barbiturate approved by the Food and Drug Administration (FDA) for the treatment of seizures, preoperative (and other) sedation (T. 8/2 54). Although both drugs are classified as barbiturates, pentobarbital and sodium thiopental are not interchangeable (T. 8/2 52). Florida chose to formally adopt the use of the sedative pentobarbital in place of sodium thiopental on June 8, 2011. The issue in Florida is very different from the issue in states, such as Ohio, that use pentobarbital alone in a one-drug procedure without following it with two extremely painful drugs. In

other words, in Florida, the efficacy of pentobarbital **as an anesthetic** cannot be considered in a vacuum, because its role is not to cause death, but to prevent the condemned inmate from feeling the excruciating pain and suffering of the second and third drugs.

Ensuring that the condemned inmate is adequately anesthetized protects against the serious harm that will result from the injection of the second and third drug into a conscious person. Dr. Waisel's testimony comparing the breadth of knowledge about sodium thiopental versus the extreme dearth of knowledge about pentobarbital for inducing anesthesia demonstrated that pentobarbital does not protect against the substantial risk of serious harm that comes from the injection of pancuronium bromide and potassium chloride. Dr. Waisel testified that there is no drug that is known better than sodium thiopental because of the extensive research and testing and use of the drug:

> It has been tested in all sorts of patients, with all sorts of diseases, and all sorts of clinical situations, by novices, by experts. We know where it's weak points are. We know where it's strengths are. We know how to mitigate the weaknesses. Nothing about that drug will surprise us.

(T. 8/2 58). In contrast, there is simply not the same kind of data available for pentobarbital because 1) its use has been far less frequent, confined to very narrow situations (T. 8/2 53-54), and 2) research has been done primarily in those narrow situations, and not on its use for induction of anesthesia (T. 8/2 58-59).

Based on the significant dearth of research with respect to pentobarbital, Dr.

Waisel testified he did not have sufficient data to extrapolate a dose that is appropriate for anesthesia. According to the package insert for pentobarbital,[6] there is no average intravenous dosage of pentobarbital that can be relied on to produce similar effects in different patients (T. 8/2 67). The commonly used initial dose for sedation of a 70 kilo adult is 100 milligrams (T. 8/2 67). "If necessary, additional small increments of the drug may be given up to a total of, from 200 to 500-milligrams for normal adults." Therefore, the upper dose **for sedation, not for anesthesia,** is 500 milligrams for an unspecified weight. That is one tenth the dose prescribed in the lethal injection procedures, but **for sedation**, which is significantly different than anesthesia. (T. 8/2 67).[7] In fact, the package insert for pentobarbital does not state that pentobarbital is to be used, or is approved for, the induction of anesthesia (T. 8/2 62).

Importantly, there is a "vast" difference between sedation and anesthesia (T. 8/2 68). It is probably best to think of sedation and anesthesia on a continuum from

[6] Dr. Waisel explained that the package insert is "the truth, the bible for what we know." (T. 8/2 63). The Food and Drug Administration approves the package inserts for drugs, which lists the uses, effects and complications associated with its use (T. 8/2 64).

[7] In contrast, a 500 milligram dose of sodium thiopental would anesthetize a 220 pound man, thus a dose of five grams is ten times the amount of the upper dose of induction of anesthesia (8/2 61). Dr. Waisel made clear that 5 grams of sodium thiopental is not the functional equivalent of 5 grams of pentobarbital for the purpose of inducing anesthesia.

being wide awake to being completely anesthetized and being able to do an operation. In "conscious sedation," the patient can respond to voices, can make movements, and will respond to varying levels of pain. (T. 8/2 68) As the patient gets closer to anesthesia, the amount of stimulus required to have the patient respond is increased. A greater stimulus will cause a response by the patient whereas lesser stimulus will not (T. 8/2 68). Dr. Waisel explained that trainees often will see a patient as quiet and still, assume that the patient is anesthetized, then do something stimulating or painful. This results in the patient responding by grabbing whatever part of the body is being stimulated (T. 8/2 69). The lower court misunderstood or ignored these distinctions.

Dr. Waisel warned that there are serious issues with the adequacy of monitoring for continuing consciousness of the condemned inmate after the pentobarbital is injected, "**particularly in light of lack of information available about how fast pentobarbital takes effect in a lethal injection scenario**" (Report of Dr. Waisel at 9) (emphasis added). Dr. Waisel's warnings highlight the flawed reasoning of the circuit court asking "How can anybody feel anything if they are dead?" The court misunderstands that the proper question is: At what point along the continuum between awake and ultimately death, are the second and third drugs administered? Because there are "gradations of consciousness and anesthesia…an inmate may appear unconscious but may be able to perceive pain or may have

some awareness." *Id*. Just as medical trainees assume a patient is anesthetized because he is quiet and still, so too are "unqualified individuals [ ] very likely to miss subtle signs of inadequate anesthesia that highly qualified, certified individuals will recognize." *Id*. Significantly, the procedures do not specify how the condemned inmate's consciousness will be assessed and monitored in light of the new and unknown drug.

Dr. Waisel also testified about the information contained in the letters from Lundbeck, Inc., the sole FDA-approved manufacturer of pentobarbital, to Governor Scott and the DOC. Def. Exh. A. The Lundbeck letters corroborate Dr. Waisel's opinion: "The use of pentobarbital outside of the approved labeling has not been established. As such, Lundbeck cannot assure the associated safety and efficacy profiles in such instances. For this reason, we are concerned about its use in prison executions." Def. Exh. A. Lundbeck urged Florida to stop using pentobarbital in its executions. The circuit court rejected the Lundbeck letters on the basis that they are "of no legal significance and carr[y] no weight." Order at 6. Additionally, the circuit court found that "[t]here was no mention of medical evidence or anything relevant to the court's inquiry." Order at 6.

The court appeared to base its rejection of the Lundbeck letters on Lundbeck's position that the use of its product in executions contradicts the philosophy behind their business—to provide therapies that improve people's

lives—ignoring the scientific and medical reasons for Lundbeck to have concerns about the drugs safety and efficacy in executions. The circuit court also ignored that Dr. Waisel testified that it is highly unusual for a drug manufacturer to issue this sort of warning. Rather, the normal course is for the FDA to conduct the initial work and issue a warning, which the manufacturer will then follow with its own statement (T. 8/2 71). Dr. Waisel further stated that as an anesthesiologist, he would take a warning issued directly from a manufacturer very seriously, give it the highest regard, and absolutely not use the drug. Yet, the DOC has failed to even consider the manufacturer's warnings. Therefore, DOC cannot be held blameless in this analysis.

The circuit court concluded that Dr. Waisel's testimony regarding the efficacy of pentobarbital in Florida's lethal injection procedures was "based on speculation and, is therefore, inherently unreliable." Order at 9.[8] The circuit court's

[8] Additionally, the circuit court faults Dr. Waisel because "[a]t the very least, he does not establish a reasonable effective, readily implemented alternative to pentobarbital." Order at 9, citing *Baze v. Rees*. The circuit court apparently misread the *Baze* plurality opinion. The *Baze* plurality opinion concluded that a method of execution is unconstitutional if (1) it presents a "substantial risk of serious harm" or an "objectively intolerable risk of harm"; **or** (2) a state refuses to adopt alternative procedures that are "feasible, readily implemented," and will "significantly reduce a substantial risk of severe pain." *Baze v. Rees*, 128 S. Ct. 1520, 1530–32 (2008) (plurality opinion). Contrary to what the circuit court finds, *Baze* does not impose an obligation on Mr. Valle to assert the method by which the State should kill him. Mr. Valle has never advocated an alternative procedure; he has alleged that Florida's procedures are unconstitutional under the substantial risk of serious harm standard. Additionally, the circuit court is faulting Dr. Waisel from

wholesale rejection of Dr. Waisel's testimony and complete acceptance of Dr. Dershwitz's testimony was erroneous. The circuit court failed to consider that Dr. Dershwitz's opinion is truly based on speculation and must therefore be inherently unreliable. In fact, the testimony of Dr. Waisel and Dr. Dershwitz were wholly consistent with respect to the use of pentobarbital and the lack of research and study of the drug. The only issue on which their opinions diverged centered on Dr. Waisel's testimony that he could not speculate as to how 5 grams of pentobarbital would effect a healthy person because there was insufficient data to do so (T. 8/2 93-94), whereas Dr. Dershwitz had no problem speculating in that regard (T. 8/2 117).

Dr. Dershwitz testified on cross-examination that his personal experience with pentobarbital is limited to having "used it a few times, a few being single digits, to either induce a barbiturate coma in one of my own patients or assisting one of my colleagues who had the same goal" (T. 8/2 131). He further clarified:

> When I've used pentobarbital it is usually to produce a barbiturate coma in a patient who is already anesthetized with something else. The plan was to continue the barbiturate coma postoperatively, and typically that requires using an intravenous drug, because the inhaled drugs that we use during anesthesia require machinery and equipment that is not available outside of the operating room.

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giving advice on an effective alternative, when he is prohibited from doing so by the American Board of Anesthesiology and the American Medical Association, as Dr. Dershwitz explained during his testimony (T. 8/2 110, State's Ex. 2).

(T. 8/2 132-33). Dr. Dershwitz also testified that he has "not done any original research on pentobarbital" and has not personally conducted any research on barbiturates (T. 8/2 132).

Dr. Dershwitz has never used pentobarbital to induce anesthesia. He has never administered pentobarbital to a healthy person. He testified that pentobarbital is "used primarily to treat either intractable seizures or to induce barbiturate coma, and it is occasionally used as a sedative." (T. 8/2 110-11). Dr. Dershwitz explained that the typical indication for inducing a barbiturate coma is when the brain is going to be deliberately deprived of oxygen in certain surgical procedures, or when the brain has already suffered some insult, such as by head trauma or carbon monoxide poisoning (T. 8/2 111).

The circuit court's order reflects that it misunderstood entirely the significance of Dr. Dershwitz's previous testimony in other proceedings, stating "Dr. Dershwitz admitted that he had previously testified in the Dickens and Alderman cases about the efficacy of sodium thiopental. However, that drug is no longer available and has not been, to his knowledge, for some two (2) years or more." Order at 14.

While the circuit is correct that Dr. Dershwitz testified previously about the efficacy of sodium thiopental, most significantly, Dr. Dershwitz questioned the efficacy of pentobarbital for the very same reasons that Dr. Waisel questions the

use of pentobarbital here. Specifically, Dr. Dershwitz previously testified "Pentobarbital given by the IV route is uncommonly used in humans and we have very, very little high quality high resolution kinetic data on pentobarbital in humans, and we have even less pharmacodynamic data" (T. 8/2 138). Dr. Dershwitz's previous testimony went into much greater detail comparing sodium thiopental to pentobarbital:

> DR. DERSHWITZ: There is no reason to think pentobarbital wouldn't work, **but neither I, nor anyone else on Earth, could draw the high resolution graphs for pentobarbital that I drew for thiopental, because in order to do so, we need human studies that don't exist.** Let me just follow up with one more statement. The contention that pentobarbital is longer lasting is silly, and anyone who makes that contention doesn't understand the kinetics.
>
> Q: The research of thiopental is important for the purpose of determining how long it will be effective in keeping someone unconscious; is that correct?
>
> DR. DERSHWITZ: That's only partially it. **We also want to know what are the respiratory effects, what are the hemodynamic effects, and, again, we've got a lot of animal data on pentobarbital, much less human data**, where there's a huge body of data using thiopental. I should also add, in the context of using thiopental for brain protection, the usual dosage in an average size person is about three grams, so not quite as high as what Arizona is going to use, but the dose that many other states are using for lethal injection. **There's no clinical scenario in which equivalent doses of pentobarbital are also used**.

(T. 8/2 139-40) (emphasis added).

Despite Dr. Dershwitz's very limited use of pentobarbital, his testimony that "the range in doses, even amongst normal people is quite large" (T. 8/2 114), his

testimony that pentobarbital is uncommonly used in humans and his testimony regarding the lack of data available regarding the use of pentobarbital in humans, Dr. Dershwitz opined that five grams of pentobarbital would "definitely" be fatal (T. 8/2 117). This is perhaps the most speculative testimony presented at the hearing. On cross-examination, Dr. Dershwitz clarified that "Perhaps definite is a little strong, but let me phrase it this way. Neither I, nor any experienced anesthesiologist, could imagine any person surviving that sort of dose, **but we have never attempted to do so clinically**" T. 8/2 149.) (emphasis added). By his own testimony, Dr. Dershwitz has no testing, research or data on which to base this testimony.

Furthermore, whether the introduction of a large dose of pentobarbital will be fatal is not the issue; the issue is whether the use of a sedative will result in a state of unconsciousness such that the inmate will not feel pain. There is not only a substantial risk that it will not but there is no evidence that it will. The bottom line is that both Dr. Waisel and Dr. Dershwitz agree that there is no data to support the use of pentobarbital as an anesthetic in the context of an execution, let alone any context. This highlights the experimental nature of the use of pentobarbital. The use of inmates for medical experiments has long been considered abhorrent in a civilized society. *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 183-84 (2d Cir. 2009) *cert. denied*, 130 S. Ct. 3541 (2010) ("[T]he norm prohibiting nonconsensual

medical experimentation on human subjects has become firmly embedded and has secured universal acceptance in the community of nations.").

Mr. Valle also presented evidence regarding two recent executions using pentobarbital where the pentobarbital did not work as the State says it will. Eddie Duvall Powell was executed in Alabama on June 16, 2011 by a three drug protocol that included pentobarbital as the first drug (T. 7/28 33; 50). Mr. Valle called Matt Schulz, Powell's counsel, to testify about what he observed during Powell's execution. Schultz was seated in a witness room about seven or eight feet from where Powell lay on the gurney, and was situated so that he could see the left side of Powell's body (T. 7/28 42). Schultz testified that after Powell made his last statement, the warden told the witnesses that the execution would now be carried out (T. 7/28 43-44). At that point, a chaplain approached Powell, who was already restrained on the gurney, and began praying (T. 7/28 45). Powell then took a deep breath and laid his head back (T. 7/28 45). Schultz then testified that

> And after approximately one minute, **he all of the sudden jerked his head up and kind of his upper body also jerked up rather abruptly.** He looked to be pressing—it looked as though his upper body was pressing against the restraints, and he had a real look of confusion on his face. He looked around, and then looked down at the chaplain, and he particularly had a look of confusion when he looked down at the chaplain, and then he began—**about the only way I can describe it is it look as though he was clenching his jaw and flexing the muscles in his face and in his neck quite strenuously.** It's—that looked as though —I don't know whether it was his arteries actually throbbing or if it was just because of the muscles flexing, but it looked as though his artery was pumping and blood was sort of

> pumping into his face at that point, and that lasted for about a minute in and of itself, and then he—at that point, his eyes started to kind of glaze over and rolled into the back of his head, and then his head went back down in what appeared to be involuntary at that point.

(T. 7/28 46-47) (emphasis added). After a couple of minutes, Powell's eyes slightly opened again, but Schulz testified that by the end of the execution, 20 to 25 minutes later, they did appear to be fully closed (T. 7/28 49).

The circuit court dismissed Schultz's testimony as speculative and concluded that "without more specific testimony or expert testimony it is of little value to the court in consideration of the question at hand." Order at 5. The court's rejection of Schultz's testimony was in error. Schultz's testimony was confined to his factual observations of the Powell execution. There is simply no basis for rejecting it as speculative. While Schultz did not know exactly when the drugs were injected—and did not speculate—Powell's movements for a minute after lying still for a minute are not consistent with the pentobarbital working the way the State says it should, which is certainly germane to the issue at hand. The State presented no evidence regarding the Powell execution.

Mr. Valle also presented evidence that the execution of Roy Blankenship in Georgia on June 23, 2011, was botched. Dr. Waisel testified that after the execution, he interviewed AP reporter Greg Bluestein, who witnessed the execution (T. 8/2 75). Dr. Waisel also reviewed affidavits written by Mitchell Peace and Eddie Ledbetter, two other reporters who witnessed the execution, and

affidavits written by approximately 13 employees of the Georgia Department of Corrections who witnessed or participated in Blankenship's execution. (T. 8/2 75). Based on the information Dr. Waisel reviewed, he opined that "Mr. Blankenship suffered extremely during the execution." (T. 8/2 78).

By report, Blankenship looked to his one arm in pain and looked to the other arm in pain. He then grimaced, jerked his head up, continued breathing and mouthing words for up to three-minutes (T. 8/2 78-79). Dr. Waisel explained that this three minute span was significant in two ways. First, while some patients, while being induced under anesthesia, may make movements for the first 15 seconds or so, the movements are not focused or localized as Blankenship's were (T. 8/2 79). Second, if pentobarbital worked as the State claimed, this would last for the first 15 seconds once the drug reaches the body, not for three minutes.

The State presented two witnesses, Georgia DOC employee John Harper, and Dr. Jacqueline Martin of the Georgia Bureau of Investigations, who witnessed the Blankenship execution and testified that they did not observe any indications that Blankenship was in pain or suffered. Harper testified that 5 seconds after the injection of the first drug, Blankenship looked at his left arm (T. 7/28 92). Harper further testified that he never saw Blankenship exhibit any signs of distress, but he did hear him grunt. (T. 8/2 92) The circuit court concluded that "[o]f all the witnesses on the issue of the Blankenship execution, Harper is the most credible on

this topic" because "[h]e actually could hear and could see the pushing of the syringes and was keeping a timing log." Order at 10.

The circuit court's conclusions about Harper's credibility are not supported by the record. Harper testified on cross-examination that his role during the execution was to communicate with two different command posts via landline telephone throughout the execution, giving them information about what was happening (T. 7/28 100). He also wrote down notes, or a time log, of what happened throughout the execution, and in order to do that, he observed the executioner push each syringe (T. 7/28 102-03). Harper also testified that his view of Blankenship was not completely unobstructed and that during the course of the execution, people walked between him and Blankenship (T. 7/28 100). Finally, although Harper testified that it was 5 seconds after the administration of the first syringe that Blankenship looked at his left arm, Harper did not believe that 5 seconds was enough time for the drug to get to his arm. He testified that it took an additional 5 seconds from the point of looking at his left arm to be completely unconscious. However, he also testified that he had not been trained in the effects of pentobarbital and did not know the length of the IV tubing (T. 7/28 105). The circuit court's decision to credit the testimony of a Georgia DOC employee - who has a strong personal interest in maintaining his employment, and who was communicating on the phone with two different command posts, watching the

executioner push the syringes, and taking notes, while people were walking between him and the inmate, thereby obstructing his view - was blatant error. This error is obvious when contrasted against the testimony of Dr. Waisel, who obtained information from an AP reporter whose sole purpose in witnessing the execution was to be a neutral observer reporting the facts, who had an unobstructed view of the inmate, and who was not distracted by other tasks or communications during the execution.

The circuit court's conclusion that Mr. Valle has failed to meet his burden under the *Baze* standard is erroneous. Under the circuit court's reasoning, the only way that Mr. Valle—or any other condemned inmate—could possibly meet this standard is to wait for series of executions so obviously botched that no DOC or court could deny it or to commission a research study on the effect on otherwise healthy human beings of an injection of 5,000 mg of pentobarbital followed by 200 mg of pancuronium bromide and 120 mEq of potassium chloride. Yet this is not what *Baze* requires. *Baze* does not require an inmate to prove that he will certainly be subject to cruel and unusual punishment. Rather, *Baze* requires condemned inmates to demonstrate that a method of execution will cause a **substantial risk of serious harm** in order prove an Eighth Amendment violation. *Baze v. Rees*, 128 S. Ct. 1520, 1531 (2008). It is not disputed that if the pentobarbital does not sufficiently anesthetize Mr. Valle, he will suffer agonizing pain from the

pancuronium bromide and potassium chloride. Mr. Valle presented evidence that the pentobarbital did not work as the State says it should in the executions of Eddie Powell and Roy Blankenship. Mr. Valle presented evidence about the complete dearth of scientific knowledge or research on pentobarbital as an anesthetic induction agent. Mr. Valle has met the *Baze* standard.

Furthermore, due to the extremely limited scope of this Court's relinquishment, Dr. Waisel was not able to testify about how the switch to pentobarbital affects the other aspects of Florida's lethal injection procedures, although he discussed them in his written report. The fact remains that substitution of pentobarbital for sodium thiopental cannot be considered in a vacuum. "The combination of significant unknowns from a lack of clinical history related to using pentobarbital to induce anesthesia, inadequate implementation of procedural safeguards and a cavalier attitude toward lethal injection puts the inmate at risk for serious undue pain and suffering." (Report of Dr. Waisel at 3). The most critical aspects of Florida's lethal injection process—specifically, the administration of the drugs, the assessment of consciousness, and the monitoring of the inmate for consciousness throughout the procedure—remain inadequate to protect against a substantial risk of harm. Adding an untested and likely problematic drug, whose own manufacturer has warned about its unreliability exacerbates an already dysfunctional procedure. Although this Court has previously declared Florida's

lethal injection procedures constitutional in *Lightbourne v. State*, 969 So. 2d 326 (Fla. 2007), the substitution of pentobarbital in the lethal injection procedures calls into question the adequacy of the entire protocol and calls into question that decision.

ARGUMENT II: MR. VALLE WAS DENIED A FULL AND FAIR EVIDENTIARY HEARING IN VIOLATION OF HIS CONSTITUTIONAL RIGHT TO DUE PROCESS UNDER THE FIFTH AND FOURTEENTH AMENDMENTS TO THE U.S. CONSTITUTION AND CORRESPONDING PROVISIONS OF THE FLORIDA CONSTITUTION.

Due process requires a reasonable opportunity to be heard in a full and fair adversarial proceeding. *Cleveland Bd. Of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985) ("essential principle of due process is that a deprivation of life . . . be preceded by notice and opportunity for **hearing appropriate to the nature of the case**") (emphasis added). Mr. Valle is being denied his right to make the record *he* feels is "necessary for the full and fair consideration of the merits of the case." *Taylor v. Crawford*, 445 F. 3d 1095 (8th Cir. 2006).

A. The striking of Mr. Valle's witnesses was error

On July 25, 2011, this Court rejected the summary denial of Mr. Valle's challenge to Florida's use of pentobarbital and found that Mr. Valle's allegations warranted an evidentiary hearing on his claim "regarding the efficacy of pentobarbital as an anesthetic in the amount prescribed by Florida's protocol." July 25, 2011 Order. Additionally, this Court specifically directed the DOC to produce

correspondence and documents from Lundbeck, Inc., the sole manufacturer of pentobarbital.

On July 26, 2011, Mr. Valle submitted his witness list which included seven DOC employees, including Secretary Edwin Buss. The State filed a motion to strike all seven DOC witnesses and the lower court granted the motion. The trial court's striking of these witnesses prior to the start of the hearing was an abuse of discretion and denied Mr. Valle due process. The public records that were disclosed pursuant to this Court's July 25 order reveal that DOC employees Rana Wallace, Jennifer Parker, and Russell Hosford were provided copies of the letter from Lundbeck voicing concerns about the use of pentobarbital in lethal injections, or were in at least in possession of the letter so that they may take the appropriate action. Timothy Cannon and Secretary Edwin Buss have, at the very least, constructive knowledge of the fact that Lundbeck cannot guarantee the safety or efficacy of pentobarbital in the execution of human beings. Florida's lethal injection procedures require periodic reassessment of the protocols, including consideration of new medical research. Whether Timothy Cannon, Rana Wallace, and Secretary Buss have fulfilled these duties goes to the core of the *Baze* inquiry and the factual issues that this Court remanded for further development. These facts can only be established through the testimony of DOC officials.

In order to obtain relief on his Eighth Amendment challenge, Mr. Valle must

establish

> (1) the State is being deliberately indifferent (2) to a condition that poses a substantial risk of serious harm to him. *Farmer v. Brennan,* 511 U.S. 825, 828, 114 S. Ct. 1970, 128 L.Ed. 2d 811 (1994). As a plurality of the Supreme Court summarized, "to prevail on such a claim there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.' " *Baze v. Rees,* 553 U.S. 35, 50, 128 S. Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion) (quoting *Farmer,* 511 U.S. at 842, 846 & 847 n. 9, 114 S. Ct. 1970).

Powell v. Thomas, 641 F.3d 1255, 1257 (11th Cir. 2011) *cert. denied,* 131 S. Ct. 2487 (U.S. 2011). DOC's consideration of, or failure to consider, the Lundbeck letters is relevant to a determination of the safety and efficacy of pentobarbital. These documents establish that Lundbeck's position is clearly one of concern for the safety and efficacy of pentobarbital as an anesthetic component in lethal injection executions. Thus, the extent to which DOC either considered or "were deliberately indifferent to" the concerns of the manufacturer goes to the heart of the analysis of Mr. Valle's challenge to the use of pentobarbital under *Baze*. As a result of the exclusion of these witnesses, the lower court again found that the letters have no legal significance.

Timothy Cannon's testimony is necessary on several points which reflect directly on the safety and efficacy of the use of pentobarbital in the lethal injection procedures. First, the lethal injection procedures require that **all** team members shall be instructed on the effects of **each** lethal chemical. June 8, 2011 Procedures

at p.3, ¶ 4. The procedures also require that the chemicals, including pentobarbital, are correct and current. Procedures p. 4, ¶ 6. To the extent the pentobarbital is not correct, current or compliant with federal and state law, this renders pentobarbital ineffective and unsafe.

Mr. Valle maintains that the source of the pentobarbital, specifically from where it was obtained, and whether it was obtained legally, remains relevant to its safety and efficacy, particularly in light of the fact that the sole manufacturer of pentobarbital, Lundbeck, has recently instituted restricted distribution procedures to prevent U.S. prisons from obtaining the drug for use in executions. David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, New York Times (July 1, 2011) (emphasis added). These issues fall directly within this Court's remand for a hearing on the issue of the safety and efficacy of pentobarbital. If the only FDA approved source of pentobarbital is Lundbeck, and Lundbeck restricts access to their product, DOC must seek the drug from a non-FDA approved source. The failure to comply with federal regulations regarding the importation of controlled substances creates a substantial risk that imported pentobarbital will be adulterated, counterfeit, or otherwise ineffective, resulting in disastrous consequences.

Furthermore, while Florida's lethal injection procedures provide for a consciousness check after the injection of pentobarbital, the procedures do not delineate the method for assessing consciousness. Dr. Waisel expressed concerns

regarding the assessment of consciousness as a result of DOC's change from sodium thiopental to pentobarbital. In his report, Dr. Waisel voiced serious concerns about the inadequacy of monitoring for patency of the intravenous line, pointing out the risk of such inadequacies in the protocol. Report of Dr. Waisel at 8-9. Dr. Waisel also warned that there are serious issues with the adequacy of monitoring for continuing consciousness of the condemned inmate after the pentobarbital is injected, "particularly in light of lack of information available about how fast pentobarbital takes effect in a lethal injection scenario" (Report of Dr. Waisel at 9) (emphasis added). Because Mr. Valle was not afforded an opportunity to examine the necessary witnesses,[9] it remains unknown whether the protocol's method of assessment of consciousness has been changed to accommodate the significant differences between pentobarbital and sodium thiopental.

When Mr. Valle agreed to provide the State with a brief proffer of the anticipated testimony of the witnesses he intended to call, he did not agree that he was required to make a showing of relevancy prior to calling witnesses. Mr. Valle is not required to do so. The proper time to make an objection as to the relevance of testimony is at the time the testimony is offered. Pre-trial determinations of the

[9] Mr. Valle has been denied access to public records which would allow him to narrow the witnesses he would present at the hearing and has had no opportunity for discovery of these issues prior to the hearing.

admissibility of evidence are typically reserved for evidence that will be highly prejudicial to the moving party. C. Earhardt, Florida Evidence § 104.5 (2011 Edition). Pursuant to Fla. Stat. § 90.104(a) "a proper objection must state the specific reason for excluding the evidence. *Id.* at § 104.2.[10] Specifically, "[t]he objection that evidence is incompetent, irrelevant and immaterial is not a specific objection." *Id*. The lower court abused its discretion when striking Mr. Valle's witnesses before the evidentiary hearing. As a result, Mr. Valle was denied the necessary factual development that this Court ordered.

B. The exclusion of witness affidavits

Mr. Valle was further denied due process during the evidentiary hearing. At the start of the hearing, Mr. Valle proffered an affidavit and newspaper article written by Associated Press Reporter Greg Bluestein. Mr. Bluestein witnessed the Georgia execution of Roy Blankenship, during which he saw Mr. Blankenship repeatedly jerk his head, grimace, make a startled face, blink rapidly, and mouth words for about three minutes after the injection of pentobarbital. In his affidavit, Mr. Bluestein acknowledges that he wrote an account of Mr. Blankenship's execution for the AP news wire, indicated where the article could be found online

[10] *See also Atlantic Coast Line R. Co. v. Shouse*, 91 So. 2d 90, 95 (Fla. 1922) ("The rule which obtains in this state as to objection to the admission of evidence is that the grounds to the objection must be specific, and when objection is based upon and confined to particular grounds no other grounds of objection will ordinarily be entertained.")

and affirmed that AP stories are routinely posted online in the regular course of business of reporting the news. Mr. Bluestein further attested that a true and accurate copy of his online story was attached to the affidavit.

Following the initial proffer of these affidavits, when the hearing resumed on August 2, Mr. Valle argued that the affidavit and article be admitted as evidence. Counsel explained that Mr. Bluestein had been contacted and requested to testify at the hearing. Counsel was referred to attorneys for the Associated Press who asserted that Mr. Bluestein would refuse to testify based on the shield law, common law and constitutional privileges.

The Journalist's Privilege is recognized by Fla. Stat. § 90.5015, which grants to professional journalists the qualified privilege not to testify to information obtained in the normal scope of their employments. The section also provides that business records maintained or produced by a professional journalist my be authenticated for admission in evidence upon a showing, by affidavit of the journalist, that the record is a true and accurate copy of the original and that the copy truly and accurately reflects the observations and facts contained therein. Fla. Stat. § 90.5015(6). Mr. Valle obtained and submitted such an affidavit authenticating the newspaper article written by Mr. Bluestein. That affidavit authenticated the attached article written by Mr. Bluestein and verified that Mr. Bluestein wrote the article.

Mr. Valle moved that the affidavit of Eddie Ledbetter be admitted as evidence for similar reasons. Mr. Ledbetter is the Assistant Editor for the Statesboro Herald in Statesboro, Georgia who also witnessed the Blankenship execution. Mr. Ledbetter reported that Mr. Blankenship jerked and twinged after the administration of the pentobarbital, that he jerked his arms twice, lifted his head from the gurney and, while looking at his right arm, he appeared to say "Ow." Mr. Blankenship continued to mumble after his head dropped back down to the gurney. Mr. Ledbetter's affidavit affirmed that he wrote an article for his newspaper based on his account of the execution, provided the link for the article on the newspaper's website and stated that articles are routinely posted online in the regular course of business of reporting the news. Mr. Ledbetter also attested to the truth and accuracy of the attached article.

The court's refusal to admit these affidavits was error.

C. The admission of the State's witnesses

Due to the unavailability of Mr. Valle's expert witness at the start of the hearing, Mr. Valle agreed that the State could present its witnesses out of turn. The State presented two witnesses to Mr. Blankenship's execution: John Harper, a 23-year employee for the Georgia Department of Corrections and Jacqueline Martin, an assistant medical examiner for the Georgia Bureau of Investigations. The State offered these witnesses to rebut Mr. Valle's assertions that the

Blankenship execution was botched. Subsequently, Mr. Valle sought to have admitted the affidavits of Mr. Bluestein and Mr. Ledbetter, to which the State objected. The court sustained the State's objection. This was error.

As counsel explained, Mr. Bluestein would not appear to testify due to the policies of his employer, the Associated Press, and a claim of journalist's privilege. Moreover, under the truncated schedule, there was simply not enough time to secure him as an out-of-state witness and properly serve him a subpoena in a foreign jurisdiction. Mr. Valle's inability to call Mr. Bluestein was not due to his choice. Rather, it resulted from the Associated Press policies regarding journalist's privilege, the complications of securing out-of-state witnesses and the truncated schedule, none of which is attributable to Mr. Valle.

After the lower court ruled the Bluestein and Ledbetter affidavits inadmissible, Mr. Valle moved to strike State witnesses John Harper and Dr. Martin. The sole purpose of these witnesses' testimony was to rebut the affidavits of Mr. Bluestein and Mr. Ledbetter regarding the Blankenship execution that the court had ruled were inadmissible. Therefore, the testimony of the State's witnesses regarding what they observed at the Blankenship execution, offered to rebut Mr. Valle's evidence that was never admitted, was irrelevant. Despite the fact that these witnesses were being called to rebut evidence that was never presented, the lower court denied Mr. Valle's motion and, in fact, relied on the State's

witnesses in denying him relief. Order at 18-19.

The circuit court's denial of a full and fair hearing violated Mr. Valle's rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution and corresponding provisions of the Florida Constitution. As a result of these numerous errors, Mr. Valle was denied the full and fair evidentiary hearing, appropriate to the nature of the case, that this Court ordered.

CONCLUSION

In light of the foregoing arguments, Mr. Valle submits that this Court should find Florida's lethal injection procedures unconstitutional under the Eighth Amendment or, in the alternative, he should be granted a full and fair evidentiary hearing.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true copy of the foregoing has been furnished by electronic mail and United States Mail to Sandra Jaggard, Assistant Attorney General, 444 Brickell Ave., Suite 650 Miami, Florida 33131 this 20th day of July, 2011.

_____
SUZANNE MYERS KEFFER
Chief Assistant CCRC-South

CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that this petition is typed in Times New Roman 14 point font, in compliance with Fla. R. App. P. 9.210(a) (2).

_____
SUZANNE MYERS KEFFER
Chief Assistant CCRC-South