IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:06-CT-3018-H

WILLIE BROWN, JR., N.C. DOC #0052205,

Plaintiff,

v.

THEODIS BECK, Secretary, North Carolina Department of Correction, and MARVIN POLK, Warden, Central Prison, Raleigh, North Carolina, and UNKNOWN EXECUTIONERS, Individually, and in their Official Capacities,

Defendants.

OBJECTION TO DEFENDANTS' NOTICE AND RESPONSE TO 7 APRIL 2006 ORDER

Plaintiff Willie Brown, Jr., N.C. DOC #0052205, (hereinafter "Plaintiff"), through counsel, hereby submits this objection to the Defendants' Notice and Response to 7 April 2006 Order.

STATEMENT OF THE CASE

This matter is before the Court on Plaintiff's Amended Complaint filed 8 March 2006. Plaintiff filed this action pursuant to 42 U.S.C. § 1983, challenging the protocol and procedures Defendants intend to employ to carry out Plaintiff's execution by lethal injection. Following extensive briefing by the parties, a status conference on 27 March 2006 and a hearing on 6 April 2006, the Court issued an Order on 7 April 2006 conditionally denying Plaintiff's Motion for Preliminary Injunction.

This Order concluded that Plaintiff had offered evidence raising "serious questions" concerning the adequacy of Defendants' intended protocol for administering, monitoring, and

maintaining anesthesia during the course of Plaintiff's execution by lethal injection. (Order at 12.) The Court further concluded that Plaintiff's execution could:

> proceed as scheduled on April 21, 2006, on the condition that there are present and accessible to Plaintiff throughout the execution personnel with sufficient training to ensure that Plaintiff is in all respects unconscious prior to and at the time of the administration of any pancuronium bromide or potassium chloride. Should Plaintiff exhibit effects of consciousness at any time during the execution, such personnel shall immediately provide appropriate medical care so as to insure Plaintiff is immediately returned to an unconscious state.

(*Id.* at 14.)

On 12 April 2006, Defendants filed with the Court and served upon Plaintiff their Notice and Response to 7 April 2006 Order, indicating that Defendants have now revised their execution protocol to incorporate the use of a bispectral index monitor ("BIS monitor"). In accordance with the deadlines set forth in the Court's 7 April 2006 Order, Plaintiff submits the following objection to the revised protocol proposed by Defendants.

ARGUMENT

Plaintiff objects to the revised protocol proposed by Defendants on the grounds that it: (1) fails to comply with the terms of this Court's Order and (2) fails to address the serious questions raised by Plaintiff's evidence and recognized by the Court regarding the effect of Defendants' anesthesia protocol.

I. DEFENDANTS' PROPOSED PROTOCOL IS NOT RESPONSIVE TO OR COMPLIANT WITH THE TERMS OF THIS COURT'S ORDER.

After careful consideration of the evidence and arguments of the parties, this Court concluded that the questions raised by Plaintiff regarding the Defendants' protocol for inducing, maintaining, and monitoring anesthesia "could be resolved by the presence of medical personnel who are qualified to ensure that Plaintiff is unconscious at the time of his execution." (Order at

14.) To this end, the Order directed the Defendants to provide for the presence of "personnel with sufficient medical training" and to "file with this Court and serve upon Plaintiff a notice setting forth the plans and qualifications of such personnel." (*Id.* at 14-15.) The conditions imposed by this Court provided a well-reasoned and medically appropriate means of ensuring that Plaintiff's execution will be conducted humanely and in accordance with the requirement of the Eighth Amendment.

However, in responding to the Court's Order, Defendants have offered no information to establish the sufficiency of the medical training for the available medical personnel, and they have set forth no plans that would permit such personnel to "immediately provide appropriate medical care" in the event that Plaintiff exhibits signs of consciousness at any time during the execution. Defendants have elected not to accept the Court's conditions and have instead selected an entirely different means of monitoring anesthesia, the BIS monitor. The addition of this machine also does not respond to or satisfy the directive of this Court. Contrary to the Court's Order, the Defendants' proposed protocol does not require the presence of any additional personnel with sufficient medical training to ensure that Plaintiff is unconscious. The only personnel contemplated by Defendants' new protocol are those who would have participated prior to the Court's 7 April 2006 Order. The only addition to Defendants' protocol intended to address concerns regarding Plaintiff's level of consciousness is a BIS machine, which will be applied by a registered nurse and interpreted by a registered nurse and physician located in an observation room outside the execution chamber. This is plainly insufficient.

Moreover, even if the Court were to find that this monitoring protocol could be sufficient, which is denied, Defendants' Notice and Response still provides no information whatsoever regarding the qualifications of the specific registered nurse and physician who will supposedly

ensure unconsciousness during the course of Plaintiff's execution. The evidence previously offered by Plaintiff in support of his Motion for Preliminary Injunction demonstrates that the administration and monitoring of anesthesia "is complex and risky, and can only be safely performed by individuals who have completed the extensive requisite training to permit them to provide anesthesia services." (First Heath Aff. ¶ 32.) Defendants have failed to provide any information to indicate that *any* of the personnel participating in Plaintiff's execution will be credentialed, licensed, and proficient in the practice of anesthesiology. Furthermore, though Defendants now propose to rely upon a BIS monitor to assess Plaintiff's level of consciousness, they have failed to state whether the personnel operating the BIS monitor have had any training or prior clinical experience with this device.

Defendants' proposed protocol fails to respond to the Court's directive that sufficiently trained medical personnel "are present and accessible to Plaintiff." According to Defendants, "[a] licensed registered nurse and the licensed physician *are positioned in the observation room* beside the Cardiac Monitor Defibrillator. . . . The BIS monitor will be located such that it can be observed and its values read by both medical professionals." (Defs.' Notice at 3.) A nurse and physician located in a separate room cannot be deemed "accessible" to Plaintiff and therefore fail to comply with the conditions set forth in the Order. The fact that the only medical personnel identified in Defendants' Notice and Response are located in a separate observation room also indicates that Defendants have failed to satisfy the Court's condition that trained medical personnel "*immediately* provide appropriate medical care to Plaintiff" in the event that he exhibits effects of consciousness. (Order at 14 (emphasis added).) Communication between separate rooms will necessarily involve some degree of delay that could be avoided if medical personnel were directly accessible to Plaintiff in the manner contemplated by this Court's Order.

Defendants have also failed to identify protocols to be followed in the event that there are problems in the administration of anesthesia requiring communication between personnel in the observation room and personnel within the execution chamber, such as who should initiate the communication and who is responsible for responding. The absence of such protocols unnecessarily impairs the immediacy of response to foreseeable problems during the execution.

The proposed protocol submitted by Defendants further fails to comply with the requirement that "such personnel," referring to personnel with sufficient medical training, shall "provide appropriate medical care so as to insure Plaintiff is immediately returned to an unconscious state." (*Id.*) Under Defendants' proposed plan, the only personnel who will respond in the event that the BIS reading fails to fall below accepted levels are the "the execution team employed by Defendants," who will "continue to administer sodium pentothal." (Defs.' Notice at 4.) As previously established, the personnel who are responsible for administering the injections of sodium pentothal are they are volunteers selected by the Warden from among his staff, and these individuals have no medical training or expertise. (Polk Dep. at 103, Exhibit A to Errata Sheet at 3.) Thus, as now proposed, if anesthesia is improperly administered by the execution team such that the reading on the BIS machine fails to fall below an appropriate level, the only response called for under the Defendants' protocol is for the non-medical personnel to continue administering anesthetic, presumably using the same improper techniques and repeating the same errors that lead to the initial failed administration. Accordingly, Defendants' protocol fails to ensure that Plaintiff will be rendered or immediately returned to an unconscious state, as required by the Court's Order.

The Court has directed that Defendants monitor and respond in the event that "Plaintiff exhibits effects of consciousness *at any time during the execution*." (Order at 14 (emphasis

added).) Review of Defendants' proposed protocol indicates that the BIS monitor display will be read by personnel "after the initial dose of 3000 mg of sodium pentothal" and that "the execution team employed by Defendants will not administer any quality of pancuronium bromide to Plaintiff until such time at the BIS monitor reading falls below '60.'" (Defs.' Notice at 4.) As described by Defendants, this protocol includes no provision for further readings of the machine after administration of the pancuronium bromide and potassium chloride and gives no indication how, or in fact whether, execution personnel would respond if the BIS monitor displayed a reading above "60" during the later stages of the execution. The protocol thus completely ignores the Court's condition that Defendants develop plans "to insure Plaintiff is immediately returned to an unconscious state" if he exhibits signs of consciousness at the time of administration of subsequent chemicals.

In sum, the Court's Order offered appropriate conditions that would have allowed the execution to proceed, thereby respecting the State's interest in proceeding with its judgment, while at the same time responding to the serious concerns raised by Plaintiff's evidence. Defendants ignored the Court's conditions. They have not complied with the terms of the Order. Moreover, as will be discussed in greater detail below, they have failed to address the substantial concerns raised by Plaintiff that he faces an unacceptable and unnecessary risk of conscious suffering during his execution in violation of the Eighth Amendment due to Defendants' failure to (1) ensure that the personnel responsible for administering anesthesia are appropriately trained and qualified; (2) adopt medically appropriate standards for administering and monitoring anesthesia; (3) provide opportunities for direct monitoring of the inmate; and (4) make provision for foreseeable contingencies that may arise during execution.

The Court's 7 April 2006 Order, which was based upon its review of the evidence and consideration of the parties' arguments, did not invite Defendants to circumvent the conditions imposed by the Court by designing an alternative method that Defendants felt would address the serious questions raised by Plaintiff. Yet, this is exactly what Defendants have done. While it is true that under different circumstances, Defendants could attempt, through discovery and litigation, to demonstrate that their incorporation of the BIS monitor eliminates the deficiencies raised by Plaintiff's Amended Complaint and Motion for Preliminary Injunction, this demonstration is not appropriate under the circumstances of this case. As is described in detail below, Plaintiff does not believe that Defendants' proposed protocol is constitutionally sufficient, and more importantly, this Court's Order does not contemplate that Defendants should be allowed to proceed with Plaintiff's execution, now less than one week away, using an entirely new protocol, not previously considered by the Court or the Plaintiff at any time during the briefing and argument of this matter.

Thus, because Defendants have failed to comply with the terms of this Court's Order by giving notice of their plans to proceed with Plaintiff's execution *in the manner outlined by the Court*, a preliminary injunction including a stay of execution should immediately issue without the necessity of further proceedings.

II. DEFENDANTS' PROPOSED USE OF THE BIS MONITOR DOES NOT ALLEVIATE THE SUBSTANTIAL CONCERNS RAISED BY PLAINTIFF'S EVIDENCE.

In support of his Motion for Preliminary Injunction, Plaintiff presented evidence that Defendants' protocol created a serious risk that anesthesia would not be appropriately administered and that Plaintiff would consciously suffer excruciating pain during the course of his execution in violation of his Eighth Amendment rights. After considering this evidence, the

Court concluded that Plaintiff "raised substantial questions as to whether North Carolina's execution protocol creates an undue risk of excessive pain." (Order at 13-14.) Instead of complying with the terms of the Court's Order, Defendants now propose to "incorporate the use of the BIS monitor . . . to insure the unconsciousness of the Plaintiff." (Defs.' Notice at 4.) However, the available evidence, including guidelines issued by the American Association of Anesthesiology ("ASA") and American Association of Nurse Anesthetists ("AANA"), the considerations for use distributed by the manufacturer of the device, and the opinions of Plaintiff's expert anesthesiologists and certified registered nurse anesthetist, demonstrates that, as proposed by Defendants, use of the BIS machine does not comply with medically accepted standards of care and fails to ensure that anesthesia will be properly administered such that Plaintiff will be rendered fully unconscious prior to injection of the painful lethal chemicals.

A. The BIS Monitor Is Intended to be Used as an Adjunct to Other Patient Monitoring and Cannot Substitute for Direct Monitoring and Exercise of Clinical Judgment of a Properly Qualified Medical Professional.

According to Plaintiff's expert anesthesiologist Mark J. S. Heath, M.D.:

> [I]t is virtually universally accepted and understood by all anesthesiologists that the BIS monitor and other brain function monitors cannot be used as the sole method for assessing anesthetic depth. Instead, BIS monitors are only to be used as part of a suite of monitors and devices to help assemble an overall assessment of anesthetic depth.
>
> This assessment of anesthetic depth can only be properly and accurately and reliably undertaken by an individual with considerable specialized clinical training, and in the United States it is generally performed by highly specialized nurses and physicians – certified registered nurse anesthetists ("CRNAs") and anesthesiologists.

(Third Heath Aff. ¶¶ 8-9.) Defendants' proposed use of the BIS monitor—in isolation, without direct monitoring or the exercise of skill or judgment by personnel with appropriate training in anesthesia—is utterly inconsistent with this understanding of the function of the device.

Defendants' use also directly contradicts the manufacturer's guidelines for use of the BIS monitor and the positions of the national organizations devoted to raising and maintaining standards of practice in the field of anesthesiology.

The following statement appears on the website of Aspect Medical Systems, Inc. ("Aspect"), the maker of the BIS monitoring technology: "**Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical signs. Reliance on the BIS alone for intraoperative anesthetic management is not recommended.**" Aspect Medical Systems, Considerations for Using BIS, *available at* http://www.aspectmedical.com/resources/proc_cards/or/components_anesthesia.htm. This statement appears prominently in the operating manuals that accompany the BIS monitors sold by Aspect. *See* A-2000 BIS Monitoring System Operating Manual, *available at* http://www.aspectmedical.com/assets/Documents/pdf/070-0015-040121A2kmanrev302.pdf; BIS Vista Monitoring System Operating Manual at iii, *available at* http://inservice.aspectmedical.com/vista/manual/manual.pdf. Similarly, the "Clinician's Guide to Bispectral Index" published by Aspect Medical Systems includes the following statement regarding product use:

> It is important to note that reliance on BIS monitoring alone for intraoperative anesthetic management is not recommended. Clinical judgment is crucial when interpreting BIS data. Patient assessment should include evaluation and correlation of BIS data with hemodynamic and other monitoring data as well as observation of clinical signs. The BIS value should be thought of as an additional piece of information that must be interpreted in the context of all other information available for patient assessment.

"Monitoring Level of Consciousness During Anesthesia and Sedation: A Clinician's Guide to the Bispectral Index" at 4-12, *available at* http://www.aspectmedical.com/assets/documents/pdf/complete_bis_handbook.pdf. The Guide further states:

> In the operating room, dramatic changes in blood pressure and heart rate are not infrequent and require the anesthesia provider to

> make rapid diagnostic assessments and timely interventions. BIS monitoring provides new data that can facilitate decision-making and management techniques in many of these situations. ***BIS monitoring is not a substitute for keen clinical judgment.*** However, using BIS information as part of their assessment, clinicians can make more informed decisions about the dosing and balance of anesthetic agents and other adjuvant therapies such as analgesics, epidural anesthesia and cardioactive agents, especially in patients at increased risk.

Id. at 1-3 (emphasis added).

Scott M. Kelley, M.D., a board-certified anesthesiologist and the Vice President and Medical Director of Aspect, confirms that Defendants' proposed use of the BIS monitor is medically inappropriate and contrary to the intended use of the product. Regarding the Defendants' purchase of the BIS monitor, Dr. Kelley states:

> Earlier this week, representatives of the Defendants purchased [a] BIS monitor, an Aspect A-2000 EEG Monitor with BIS, by calling Aspect's 1-800 telephone sales number. In response to standard inquiries from Aspect's telephone sales team, those representatives of the Defendants indicated that they were purchasing the Aspect BIS monitor for use in operating rooms, mobile operating rooms and intensive care units and never indicated in any way that they intended to use it in connection with the execution of the Plaintiff.

(Kelley Aff. ¶ 9.) The Operating Manual that was shipped by Aspect to Defendants "clearly indicates that: 'the BIS monitor is intended for use on . . . patients within a hospital or medical facility providing patient care,'" conditions that will not be observed under Defendants' intended use of the product. (*Id.* ¶ 10.) Moreover, according to Dr. Kelley, the BIS monitor has never been approved by the FDA for the use contemplated by Defendants:

> While the Defendant Polk notes in his Second Affidavit, ¶ 3, that "the BIS monitor has been approved by the Food and Drug Administration ("FDA") for multiple purposes," he does not indicate that the intended uses submitted to the FDA by Aspect and the "cleared indications" by the FDA have always related solely to the provision of therapeutic care to patients by trained doctors and nurses.

(*Id.* ¶¶ 11, 12.)

Dr. Kelley has expressed concerns that that the personnel who will read the BIS monitor under Defendants' protocol will be physically separated from the Plaintiff and "may be relying excessively – or even solely – on the BIS monitor readings rather than clinical observations" and may not have received appropriate training in the use of the BIS monitor. (*Id.* ¶¶ 19, 20.) In sum, "Aspect's concern is that its product may be employed by the Defendants in a manner that is entirely contrary to its intended use, its cleared indications for use and its Operating Manual. Aspect is further concerned that the BIS monitor may be operated by persons lacking appropriate training." (*Id.* ¶ 21.) Under these circumstances, had Dr. Kelley known the Defendants' true purpose for purchasing the BIS monitor, he would have acted to prevent the sale. (*Id.* ¶ 22.)

In October 2005, the ASA approved a "Practice Advisory for Intraoperative Awareness and Brain Function Monitoring" recently adopted by the ASA, which specifically evaluates the use of brain functioning monitoring technology, such as BIS monitors, and offers guidance regarding the use of these devices. This document includes numerous statement that refute Defendants' assertion that a BIS monitor can be used in isolation, without other monitoring or interpretation by personnel with appropriate training in anesthesia, to ensure the Plaintiff will achieve an adequate plane of anesthesia prior to the injection of pancuronium bromide and potassium chloride. While all individuals participating in the ASA Task Force "agree that clinical techniques (*e.g.*, checking for purposeful or reflex movement) are valuable and should be used to assess intraoperative consciousness," participants did not agree that "a brain activity monitor is valuable and should be used to assess intraoperative depth of anesthesia for all patients." Practice Advisory for Intraoperative Awareness and Brain Function Monitoring, *Anesthesiology*, Vol. 104, No. 4, 847, 851, 854 (Apr. 2006) (attached as Exhibit 1 to Third Heath Aff.).

Based upon its review of available literature and opinions, the ASA Task Force reached the following conclusion regarding the assessment of consciousness: "Intraoperative monitoring of depth of anesthesia, for the purpose of minimizing the occurrence of awareness, should rely on multiple modalities, including clinical techniques (*e.g.*, checking for clinical signs such as purposeful or reflex movement) and conventional monitoring systems (*e.g.*, electrocardiogram, blood pressure, HR, end-tidal anesthetic analyzer, capnography). *Id.* at 854. With respect to use of brain function monitoring devices, like the BIS monitor, the Advisory states:

> ***The general clinical applicability of these monitors in the prevention of intraoperative awareness has not been established.*** Although a single randomized clinical trial reported a decrease in the frequency of awareness in high-risk patients, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness in high-risk patients undergoing general anesthesia. In addition, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness for any other group of patients undergoing general anesthesia. . . . It is the consensus of the Task Force that brain function monitoring is not routinely indicated for patients undergoing general anesthesia . . . .

Id. at 855 (emphasis added).[1]

These conclusions are echoed by the AANA, which issued a model policy for CRNAs regarding the "Prevention and Monitoring of Unintended Awareness Under General Anesthesia." This model policy requires "[t]he Department of Anesthesiology [to] provide and document training of individual anesthesia providers on the consciousness monitoring system prior to

[1] Press releases issued by the ASA in connection with the adoption and publishing of the Practice Advisory stress the importance of direct monitoring of patients by appropriately trained anesthesia professionals. *See* Press Release, American Society of Anesthesiologists, *Pre-surgery Communication Comforts and Empowers Patients* (Mar. 31, 2006), *available at* http://www.asahq.org/news/asanews040306.htm ("The advisory states that patients should be monitored with clinical techniques and conventional monitors such as electrocardiograms, vital signs and gas analyzers. Newer devices called 'brain function monitors' may also be used at the discretion of the individual anesthesiologist."); Press Release, American Society of Anesthesiologists, *Report on Awareness Under General Anesthesia Says Anesthesiologist Have Multiple Tools and Approaches for Minimizing Risks* (Oct. 25, 2005), *available at* http://www.asahq.org/news/news102505.htm ("[T]he most important monitor in the operating room is the anesthesiologist, who has 12 years of medical training and a wealth of experience to draw on when deciding what is appropriate for each individual patient.").

clinical use" and that "[s]ound clinical judgment should always be used when interpreting the consciousness monitor in conjunction with other available clinical signs." American Association of Nurse Anesthetists, Model Policy for "Prevention and Management of Unintended Awareness Under General Anesthesia" (Apr. 13, 2005), *available at*, http://www.aana.com/News.aspx?ucNavMenu_TSMenuTargetID=62&ucNavMenu_TSMenuTargetType=4&ucNavMenu_TSMenuID=6&id=712; (*see also* Third Maree Aff. ¶ 6). Moreover, in a patient education brochure jointly issued by the ASA and AANA, these organizations emphasize that "no monitoring device can replace the judgment and skill of an anesthesia professional who has years of training and clinical experience." *Patient Awareness Under General Anesthesia – What Is It?*, *available at* http://www.asahq.org/patientEducation/Awarenessbrochure.pdf.

Consistent with all of the standards and recommendations cited above, Plaintiff's anesthesiology experts uniformly opine that Defendants' proposed use of the BIS monitor as the sole indicator of Plaintiff's level of consciousness is contrary to accepted medical standards. Dr. Heath has stated that use of the BIS monitor during executions by lethal injection "would only be acceptable if there were also a properly qualified medical professional in place to integrate the readout of the BIS monitor with other methods of assessing anesthetic depth." (Third Heath Aff. ¶ 7.) As further explained by Dr. Heath:

> The skill, experience, and judgment that goes into the assessment of anesthetic depth can not be imparted in any other way than by undergoing this extensive hands-on training. In addition to all of the science that must be mastered, there is an "art" to the assessment of anesthetic depth, and this acquired skill, talent, and experience can not be replaced by machines, let alone by a single device such as a BIS monitor.

(*Id.* at ¶ 9.) Dr. Philip G. Boysen agrees that "[t]he BIS monitor is not a stand alone monitor, but only one part of the many sources of clinical information that can be relied upon by anesthesiologists or CRNAs when delivering anesthetic drugs." (Second Boysen Aff. ¶ 4.)

Thus, "[a]ccepted standards of care in North Carolina do not permit the BIS monitor to be used as a substitute for direct monitoring by medical professionals with adequate training and expertise in the practice of anesthesia." (*Id.* ¶ 5.) Nancy Bruton-Maree, CRNA, reaches the same conclusion regarding Defendants' proposed use of the BIS monitor:

> To my knowledge, there is no one piece of technology that is used alone to monitor physical parameters for assessment of anesthetic depth. Assessment of anesthetic depth requires properly qualified and trained medical personnel to use multiple monitoring techniques. Properly qualified medical personnel would not rely solely on a BIS monitor.

(Third Maree Aff. ¶ 7.)

Indeed, the medical literature and manufacturer recommendations reviewed by Plaintiff's counsel have revealed no documents or opinions that would support Defendants' proposed use of the BIS monitor as the sole indictor of Plaintiff's level of consciousness, other than the Third Affidavit of Mark Dershwitz, M.D., Ph.D. However, though Dr. Dershwitz now advocates the use of a BIS monitor in the Defendants' execution protocol, he has previously expressed concerns about the effectiveness of this device when used to assess consciousness during an execution by lethal injection. In connection with *Baze v. Rees*, Franklin Circuit Court, No. 04-CI-01094, Dr. Dershwitz testified as follows regarding the use of a BIS monitor in this context:

> Now, you asked me about the possibility of employing a BIS monitor during an execution to confirm that the inmate would be unconscious. And I see one theoretic problem with that, . . . knowing what I know about how potassium chloride acts, since the BIS monitor is measuring very, very tiny voltages on the forehead that are coming from the brain, when the potassium chloride causes widespread stimulation of skeletal muscles, I expect that those voltages that will be produced will overwhelm the EEG voltage that the monitor is trying to measure . . .

(Transcript,[2] *Baze v. Rees*, Franklin Circuit Court, No. 04-CI-01094 (Ky. Cir. Ct. May 2, 2005) (attached hereto as Exhibit A) at A-7.) When questioned in more detail regarding the effect of potassium chloride on the BIS monitor, Dr. Dershwitz stated, "So what I think is going to happen if a BIS monitor were used for an execution, is once the potassium chloride caused skeletal muscle to be stimulated, the digital read out from the BIS monitor, I believe, will go blank." (*Id.* at A-7, A-8.)

In a rebuttal expert report filed in February of this year, Dr. Dershwitz reiterated these conclusions and cautioned against the use of a BIS monitor to measure level of consciousness during executions by lethal injection: "The administration of a large does of potassium chloride will cause widespread depolarization (biologically-generated electrical signals) throughout the body. I predict that the BIS monitor would be unable to assess the level of consciousness following potassium chloride administration." (Dershwitz Rebuttal Report, *Walker v. Johnson*, No. 1:05cv934, at 4-5 (E.D. Va. Feb. 3, 2006) (attached hereto as Exhibit B).) Significantly, Dr. Dershwitz also opines that "[i]t would be possible to test my hypothesis in an anesthetized animal. Prior to such an experiment being performed, however, ***it would not be prudent to recommend the use of the BIS monitor during lethal injections***." (*Id.* at 5 (emphasis added).)

Defendants have offered no evidence that there have been any testing of the BIS monitor, *as recommended by their own expert*, to establish the effectiveness and reliability of the device in measuring an inmate's level of consciousness during execution by lethal injection. Defendants nevertheless propose to use the BIS monitor in the precise manner Dr. Dershwitz found to be inappropriate on two prior occasions. Furthermore, given this Court's explicit condition that

[2] The official court record of the proceeding in *Baze v. Rees* is maintained in the form of video-recordings consisting of several videocassette tapes. For the convenience of the Court, Plaintiff has attached as Exhibit A portions of a written record transcribed from the video-recordings. Exhibit A also includes a Transcriber's Certification attesting to the accuracy of the written transcript. Should the Court wish to view the original video-recording of Dr. Dershwitz's testimony, it will be promptly furnished by Plaintiff.

Defendants "ensure that Plaintiff is in all respects unconscious prior to and at the time of the administration of any pancuronium *or potassium chloride*" (Order at 14), the testimony of Dr. Dershwitz expert establishes that the BIS monitor cannot be relied upon to assess consciousness throughout the execution process.

B. Because the Reliability of the BIS Monitor Has Not Been Established Defendants' Proposed Protocol Fails to Obviate the Serious Questions Raised by Plaintiff.

In a Practice Advisory published earlier this month, the ASA specifically concluded that "[t]he general clinical applicability of [brain function monitors such as the BIS monitor] has not been established." Practice Advisory for Intraoperative Awareness and Brain Function Monitoring, *Anesthesiology*, Vol. 104, No. 4, 847, 855 (Apr. 2006) (attached as Exhibit 1 to Third Heath Aff.). More specifically, the ASA Task Force reported:

> [C]ase reports suggest that routine intraoperative events (*e.g.*, administration of depolarizing muscle relaxants, activation of electromagnetic equipment or devices, patient warming or planned hypothermia) may interfere with BIS functioning. Two case reports were found that reported patients experiencing intraoperative awareness despite monitored values indicating an adequate depth of anesthesia. Finally, still other case reports suggested that certain patient conditions may affect BIS values.

Id. at 852.

Like the ASA, Dr. Heath concludes that "the clinical roles of BIS monitors, and other brain function monitors, are not yet fully established or defined, and . . . the issue remains a matter of considerable debate and discussion within the profession of anesthesiology." (Third Heath Aff. ¶ 6.) Dr. Heath also describes potential inaccuracies in the readings displayed by the BIS monitor that make it inappropriate for use in the manner proposed by Defendants:

> In some cases a BIS monitor can indicate a deep plane or level of anesthesia when in fact the patient is demonstrably fully awake, aware, and conscious. Indeed, BIS readout values that are far below 60, the value proposed by the D.O.C. as being suitable for

> administering the agony-inducing drugs pancuronium and potassium, can be observed in individuals who have received no anesthetic agent and who are fully conscious. See Messner, M., et al., "The Bispectral Index Declines During Neuromuscular Block in Fully Awake Patients," *Anesthesia & Analgesia*, 2003; 97:488-91, attached as Exhibit 5. This is just one of the reasons why it is so important that the BIS monitor not be used as a "stand-alone" device to assess anesthetic depth, but instead must be used only in conjunction with a broader suite of monitors, instruments, and observation techniques. Assessing anesthetic depth by looking solely at a BIS monitor would be as dangerous and absurd as driving a bus by looking only at the speedometer.

(Third Heath Aff. ¶ 24; *see also* Second Boysen Aff. ¶ 7 ("I am aware of reported instances of patients regaining consciousness or awareness while using the BIS monitor as one modality to monitor the 'plane of anesthesia.' Therefore, this device cannot guarantee that a patient is in fact unconscious following administration of anesthesia.").)

The opinions of Plaintiff's experts are confirmed by a recent study measuring the reliability of BIS monitors. Researchers applied two BIS electrode strips to the forehead of the same patients and compared the results for consistency. Niedhart, Dagmar J., et al., "Intraoperative Reproducibility of the BISxp® Monitor," *Anesthesiology*, Vol. 104, No. 2, 242 (Feb. 2006) (attached as Exhibit 2 to Third Heath Affidavit). Considering only those reading "that differed uninterruptedly for at least 30 s[econds]," the study found that "10.7% of the time, the BISxp® devices suggested different anesthetic planes from each other, which would suggest different anesthetic management." *Id.* at 247-48. These results lead the authors to the following conclusion:

> In summary, the results of this study suggest that the BISxp® does not consistently display intrapatient reproducibility. These results are at variance with the manufacturer's claim that the BIS® monitor provides a reproducible and "reliable single number that represents each patient's level of consciousness." The results of this study reinforce the sentiment expressed on the Aspect Medical Web site: "Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical

> signs. Reliance on the BIS alone for intraoperative anesthetic management is not recommended."

Id. at 248.

C. The Revised Protocol Proposed by Defendants Fails to Provide Any Information Demonstrating that the Personnel Responsible for Operating the BIS Monitor Possess Adequate Training and Experience.

Even if the BIS monitor, when used in isolation as the sole measure of anesthetic depth, could reliably assess an inmate's level of consciousness during execution — a claim that is contradicted by medical guidelines, the manufacturer's specifications for use, and even the prior testimony of Defendants' own expert — Defendants' proposed protocol would still be inadequate because it fails to specify whether the specific personnel operating the BIS monitor have had any training or prior clinical experience with this device. Indeed, Dr. Dershwitz's suggestion that any registered nurse would have the requisite skill and training to apply and interpret the BIS monitor is refuted by each of Plaintiff's experts, including Ms. Maree, a CRNA with extensive experience in the teaching of nursing professionals.

According to Ms. Maree, "[i]n order for one to make proper use of a BIS monitor as part of monitoring anesthesia, one must be educated, trained, credentialed, and experienced in anesthetic care and properly trained and experienced in the use of the BIS monitor." (Third Maree Aff. ¶ 9.) Based upon her review of the Defendants' Notice and Affidavits, she does "not see any information to suggest that the execution team members are appropriately qualified to monitor anesthesia in general, or to use the BIS monitor in particular." (*Id.*) Dr. Heath concurs, stating that:

> [T]he clinical utility of the BIS monitor for anesthesiologists derives in significant part from spending many hours personally observing the readouts of the BIS monitor in conjunction with the continuous real-time flow of multiple modalities of observation and diagnostic information and information from other monitoring devices . . . A person who has not gone through this process of

> learning, through experience, to use the BIS monitor as part of their clinical anesthesiology practice *should under no circumstances attempt to use a BIS monitor on their own.*

(Third Heath Aff. ¶ 10 (emphasis added).)

By failing to provide any information regarding the training and/or experience of personnel in the use of the BIS monitor or in the practice of anesthesiology generally, Defendants have failed to comply with this Court's condition that "personnel with sufficient medical training" be present and accessible to ensure that Plaintiff "is in all respects unconscious" prior to the administration of the paralyzing pancuronium bromide and excruciating potassium chloride injections.

D. The Addition of the BIS Monitor Does Not Address the Defendants' Failure to Make Provision for Foreseeable Problems that May Arise During Execution.

As discussed in Section I above, in the event that anesthesia is improperly administered such that the BIS monitor fails to drop below Defendants' threshold number, it appears that the only response permitted under the protocol is the re-administration of sodium pentothal by execution personnel who possess no medical training whatsoever. Thus, Defendants' response does not call for, or even allow, the provision of "appropriate medial care so as to insure that Plaintiff is immediately returned to an unconscious state." (Order at 14.) This problem is only exacerbated by the fact that Defendants' proposed protocol places the medical personnel observing the BIS monitor outside the execution chamber, delaying any conceivable response to problems that may occur during the administration of anesthesia.

According to Dr. Heath:

> It is also very important to note that the DOC intends to place the BIS monitor outside of the execution chamber and run the lead for the monitor into the chamber. Contrary to inferential arguments by Dr. Dershwitz, the induction of general anesthesia should never be undertaken from a separate or remote location that lacks optimal

> visual surveillance of the procedural field. Instead, in order to meaningfully monitor and control anesthetic depth the anesthesia care provider needs to be immediately adjacent to the patient, within arm's length from the patient's upper body and head when inducing anesthesia. I strongly believe that it is reckless and negligent to contemplate the induction of general anesthesia, and the monitoring of anesthetic depth during the execution process, from a separate location—with or without a BIS monitor.

(Third Heath Aff. ¶ 22.) By failing to include any opportunities for direct monitoring of Plaintiff and immediate access by appropriately trained medical personnel, Defendants' protocol needlessly increases the risk that Plaintiff will not be fully anesthetized and will experience excruciating pain during the course of his execution.

Similarly, Ms. Maree notes in her Affidavit that "nothing in the Notice or Affidavits address my concerns regarding the maintenance of the integrity of the IV sites throughout the administration of the drugs." (Third Maree Aff. ¶ 11.) Though a BIS reading above "60" following injection of 3000 mg of sodium pentothal would necessarily indicate that the drug has not been successfully delivered into the inmate's circulation, Defendants' protocol fails to include any measures to identify or remedy the source of the administration problem. As Ms. Maree explains, "[a]n infiltration is not always obvious. No steps have been taken to monitor IV sites of infiltration or identify what will be done in the event that infiltration occurs." (*Id.*) Furthermore, though Defendants now intend to use the BIS monitor as the sole means of assessing Plaintiff's level of consciousness during the course of his execution, they have offered no plan for assessing consciousness in the event that the BIS monitor malfunctions or otherwise fails to provide a accurate reading.

This Court recognized that, "[i]f the alleged deficiencies do, in fact, result in inadequate anesthesia prior to execution, there is no dispute that Brown will suffer excruciating pain as a result of the administration of pancuronium bromide and potassium chloride." (Order at 12.)

Such an execution would be inhumane and in violation of the Eighth Amendment. Nevertheless, Defendants' proposed protocol continues to call for the administration of anesthesia without medically accepted safeguards to ensure unconsciousness in direct violation of this Court's 7 April 2006 Order. This protocol is unacceptable.

CONCLUSION

For the foregoing reasons, Defendants' Notice and Response to 7 April 2006 Order fails to comply with the terms or the intent of this Court's Order. Plaintiff respectfully requests that a preliminary injunction, including a stay of execution, issue immediately.

Respectfully submitted this the 14th day of April 2006.

/s/ J. Donald Cowan, Jr.
J. Donald Cowan, Jr.
N.C. State Bar No. 0968
Attorney for Plaintiff
SMITH MOORE LLP
Post Office Box 21927
Greensboro, NC 27420
Telephone: (336) 378-5200
Telecopier: (336) 378-5400
Email: don.cowan@smithmoorelaw.com

/s/ Laura M. Loyek
Laura M. Loyek
N.C. State Bar No. 28708
Attorney for Plaintiff
SMITH MOORE LLP
Post Office Box 27525
Raleigh, NC 27611
Telephone: (919) 755-8700
Telecopier: (919) 755-8800
Email: laura.loyek@smithmoorelaw.com

CERTIFICATE OF SERVICE

This is to certify that on this date, I electronically filed the foregoing **REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** with the Clerk of Court using the CM/ECF system, which will send notification of such filing to counsel of record:

Thomas J. Pitman, Special Deputy Attorney General (tpitman@ncdoj.com)
James P. Smith, Special Counsel (jpsmith@ncdoj.com)
North Carolina Department of Justice
114 West Edenton Street
Raleigh, North Carolina 27602

This the 14th day of April, 2006.

/s/ Laura M. Loyek
Laura M. Loyek
Attorney for Plaintiff