No. 06-9

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

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

Plaintiff-Appellant,

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-Appellees.

BRIEF OF APPELLANT

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

EXECUTION SCHEDULED: 21 APRIL 2006, 2:00 A.M.

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STATEMENT OF JURISDICTION

This is an appeal by a North Carolina death row prisoner, Willie Brown, Jr., from the Final Order entered by the United States District Court for the Eastern District of North Carolina on 17 April 2006 denying Mr. Brown's Motion for Preliminary Injunction. The district court had jurisdiction over this matter, filed pursuant to 28 U.S.C. § 1983, under 28 U.S.C. §§ 1331, 1343, 2201, and 2202. The Notice of Appeal was filed 17 April 2006. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Whether factual determinations made by the district court in its Final Order were clearly erroneous because these findings were not supported by substantial evidence, disregarded substantial evidence that would have necessitated a contrary conclusion, and were contrary to the clear weight of the evidence considered in light of the entire record.

2. Whether the conclusion of the district court was an abuse of discretion because it rests upon clearly erroneous findings of material fact.

STATEMENT OF THE CASE

I. Pertinent Procedural History

Mr. Brown filed this action pursuant to 42 U.S.C. § 1983, challenging the protocol and procedures Defendants intend to employ to carry out his execution by lethal injection, scheduled for 21 April 2006. Specifically, Mr. Brown alleges that Defendants are determined to use an inadequate protocol for anesthesia as a precursor to carrying out his death sentence, and as a result, he faces an unacceptable and unnecessary risk of suffering excruciating pain during the course of his execution in violation of his right to be free from cruel and unusual punishment under the Eighth and Fourteenth Amendments of the United States Constitution. Mr. Brown makes no attack on his conviction or the validity of his sentence to death by lethal injection.

On 28 February 2006, Mr. Brown filed a Motion for Preliminary Injunction, seeking narrowly drawn equitable relief to prevent Defendants from carrying out his execution using their intended inadequate protocol for inducing and maintaining anesthesia, pending resolution of the merits of his claims under Section 1983. Following the close of briefing, the district court held a hearing on 6 April 2006 to hear the arguments of counsel. Thereafter, on 7 April 2006, the court entered an order denying Mr. Brown's Motion for Preliminary Injunction, "on the condition that there are present and accessible to Plaintiff throughout the execution personnel with sufficient medical training to ensure that Plaintiff is in all respects unconscious prior to and at the time of" administration of the painful lethal chemicals used to effectuate his death. (7 April 2006 Order at 14.) Defendants were further required to file a notice setting forth information

regarding the plans and qualifications of personnel who would participate in the execution in the manner articulated by the order by noon on 12 April 2005. (*Id.* at 15.)

Defendants timely filed their Notice and Response to 7 April 2006 Order. This Notice described the actions taken by Defendants to purchase a bispectral index monitor ("BIS monitor") and to include the use of this device in a revised execution protocol. (Defs.' Notice at 2, 4.) On 14 April 2006, Mr. Brown filed and served his objection to Defendants' Notice, raising, among other things, the fact that Defendants' intended use of the BIS monitor as the sole method of measuring Mr. Brown's consciousness during the execution was directly contrary to the manufacturer's indications for use, the guidelines of the American Society of Anesthesiologists, and even the prior opinions of Defendants' own expert witness. Thus, used in the manner proposed by Defendants, the BIS monitor cannot be relied upon to ensure that anesthesia was properly administered, maintained, and monitored under Defendants' protocol such that Mr. Brown will be rendered fully unconscious and will not suffer excruciating pain during the course of his execution.

On 17 April 2006, the district court entered its Final Order denying Plaintiff's Motion for Preliminary Injunction. From this order, Mr. Brown now appeals.

II. Nature of the Case

In its 7 April 2006 order, the district court evaluated Mr. Brown's Motion for Preliminary Injunction under the familiar four-prong standard articulated in *Blackwelder v. Furniture Co. v. Seileg Mfg. Co.*, 550 F.2d 189 (4th Cir. 1977). With respect to the first factor, the irreparable harm to the plaintiff if the injunction is denied, the court concluded:

> If 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. Moreover, if the

> State of North Carolina is permitted to execute Brown as scheduled on April 21, 2006, Brown will be deprived of any opportunity to pursue this action to seek redress in the event he suffers a torturous death.

(7 April 2006 Order at 12-13.) Recognizing that "[t]he inability to obtain damages from the State in a § 1983 action reduces the showing necessary to establish irreparable harm," *Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353, 360 (4th Cir. 1991), the district court found that "the likelihood of harm to Brown far exceeds the likelihood of harm to Defendants." (7 April 2006 Order at 12.)

Mr. Brown's evidence regarding likelihood of irreparable harm, combined with his showing of likelihood of success on the merits, which included "evidence of a kind that is different from that presented in the cases previously considered by this and other courts," prompted the Court to impose certain conditions "to ensure that the State, if it chooses to go forward with executing Brown, does so in a manner that comports with the Eighth Amendment." (*Id.* at 8, 13.) As articulated in the 7 April 2006 Order, the district court concluded that the substantial questions raised by Mr. Brown regarding the unnecessary and unacceptable risk of excessive pain under Defendants' existing protocol "could be resolved by the presence of medical personnel who are qualified to ensure that Plaintiff is unconscious at the time of his execution." (*Id.* at 14.) Plaintiff's expert anesthesiologist has agreed that the requirement of suitably trained medical personnel "represents a very positive and reasonable step that, if implemented in a meaningful way, greatly reduces the risk of an inhumane execution." (Third Heath Aff. ¶ 12.)

In an effort to respond to the grave risk of irreparable harm recognized by the district court and to comply with that court's directive, the Defendants revised their execution protocol. At the time of filing of Mr. Brown's Amended Complaint, the lethal injection process in North

Carolina involved the pushing five sets of identical syringes into two intravenous lines leading to the inmate's body. The first set of two syringes contains a total of 3000 milligrams of (1500 milligrams each) sodium pentothal, an ultra-short acting barbiturate that quickly puts the inmate to sleep. The second set of two syringes contains saline to flush the IV line clean. The third set contains a total of 40 milligrams (20 milligrams each) of pancuronium bromide (Pavulon), a chemical paralytic agent that results in total muscle paralysis. The fourth set contains a total of 160 millequivalents of potassium chloride, a salt solution that causes cardiac arrest. The fifth set contains saline to flush the IV lines clean. *See* North Carolina Department of Correction "Execution Method," *available at* http://www.doc.state.nc.us/dop/deathpenalty/method.htm.

Upon a signal from the Warden, both sets of syringes are injected simultaneously in order "one" through "five," with each succeeding chemical solution introduced within a few seconds after the injection of the immediately preceding chemical solution is completed. Under Defendants' protocol, registered nurses and EMTs are responsible for preparing the syringes and inserting intravenous catheters into the inmate's veins ([First] Polk Aff. ¶¶ 6(b), (c)); however, each of the actual injections, including the sodium pentothal used to induce anesthesia, is administered by an individual with no medical training who is selected from the Warden's staff. (Polk Dep. at 103, Ex. A to Errata Sheet at 3.) These members of the execution team are separated from the inmate by a curtain running through the execution chamber. (*See* Diagram (attached as Ex. A to Pl.'s Reply Supp. Prelim. Injunction).)

As summarized by the district court in its Final Order, Defendants protocol has now been revised in the following respects:

> 1. Defendants have purchased a bispectral index (BIS) monitor, which is commonly used to analyze electroencephalogram (EEG) waves, or brain waves, to monitor the level of consciousness in patients undergoing a variety of surgical procedures;

2. Under the revised protocol, defendants will utilize the BIS monitor to measure the level of plaintiff's consciousness throughout the execution process;

3. Defendants will be prepared to administer additional qualities of sodium pentothal if plaintiff is not unconscious based on readings of the BIS monitor after the initial 3000 mg. of sodium pentothal has been injected into the body.

(17 April 2006 Order at 4.) More particularly, the Defendants propose to place the BIS monitor in an observation room adjacent to the execution chamber where its display can be read by a licensed registered nurse and licensed physician following the initial injection of sodium pentothal. (Defs.' Notice at 2, 4.)

Without altering its prior findings regarding the serious concerns raised by Plaintiff's evidence regarding the risk of needless and conscious suffering due to improper administration and monitoring of anesthesia, the district court determined that the Defendants' response was satisfactory and denied Mr. Brown's Motion for Preliminary Injunction. The 17 April 2006 Order reiterates that the district court, like Mr. Brown, is concerned "the improper techniques or other errors would lead to failed administration of sodium pentothal rendering plaintiff paralyzed but able to perceive pain at later stages of the execution." (17 April 2006 Order at 6.) Thus, "without the safeguards required under the [7 April 2006 Order], the questions raised by plaintiff would be so 'serious, substantial, difficult and doubtful' as to require 'more deliberate investigation.'" (*Id.* at 3 (quoting *Rum Creek*, 926 F.2d at 359).)

ARGUMENT

Following its review of the revised protocol, the district court concluded that "plaintiff's concerns about human error are greatly mitigated by the use of this independent check on plaintiff's level of consciousness before the potentially pain-inducing injections of pancuronium bromide and potassium chloride begin." (Order at 6.) The district court further concluded that:

> The State's use of the BIS monitor, the execution team's resulting awareness of the level of consciousness of the plaintiff, and the administration, if necessary, of additional quantities of sodium pentothal to ensure that plaintiff is unconscious prior to the administration of lethal drugs, together satisfy this court that defendants have substantially complied with the terms of the court's April 7, 2005 order, and that the balance of hardships under *Blackwelder* now favors the State and counsels against issuance of a preliminary injunction and stay in this case.

(*Id.*) Thus, the district court's conclusion that the balance of hardships has shifted in Defendants' favor is predicated entirely on the revisions to the protocol set forth in Defendants' 12 April 2006 Notice.

Although the district court's findings of fact with regard to the newly revised protocol are not set out separately in its 17 April 2006 Order, the district court appears to rely in large part on its findings with respect to the following three factual issues:

(1) Ability to Verify and Respond to Appellant's Level of Consciousness. (Order at 5.)

(2) Training of the Execution Team. (Order at 5.)

(3) Reliability of the BIS Monitor. (Order at 6.)

As outlined in greater detail below, these findings are clearly erroneous and should be set aside because they are ill-supported by the evidentiary record before the district court. Fed. R. Civ. P. 52(a) (requiring findings of fact in support of decisions refusing preliminary injunction and providing that such findings are set aside if "clearly erroneous.") "A factual finding is clearly erroneous when the 'reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.'" *Provident Life & Accident Ins. Co. v. Cohen*, 423 F.3d 413, 418 (4th Cir. 2005) (quoting *United States v. United States Gypsum Co.*,

333 U.S. 364, 395 (1948)). Specifically, when reviewing a district court's findings for clear error this Court has held:

> we tend to focus on four avenues in which the district court may go awry in arriving at its factual findings: (1) the district court labored under an improper view or misconception of the appropriate legal standard; (2) the district court's factual determinations are not supported by substantial evidence; (3) the district court disregarded substantial evidence that would militate a conclusion contrary to that reached; and (4) the district court's conclusion is contrary to the clear weight of the evidence considered in light of the entire record.

Jiminez v Mary Washington College, 57 F.3d 369, 379 (4th Cir. 1995). Here, the district court's findings concerning the appellee's proposed protocol should be set aside because they are not supported by supported by substantial evidence, the district court disregarded Mr. Brown's substantial evidence concerning the inadequacies of the proposed protocol, and the clear weight of the evidence, considered in light of the entire record, is contrary to the district court's findings and requires that a preliminary injunction issue.

Indeed, it appears that the district court ignored the evidentiary record when it reweighed the balance of hardships. The district court's conclusion that the proposed revision now tips the balance of hardships against the issuance of equitable relief is not supported by the findings of fact, nor could the district court have made such findings on the record before it. As such, the district court's refusal to grant preliminary injunction is an abuse of its discretion. *Bryte v. Am. Household*, 429 F.3d 469, 475 (4th Cir. 2005) ("A district court abuses its discretion if its conclusion is guided by erroneous legal principles, or if it rests upon a clearly erroneous factual finding."); *Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189, 193 (4th Cir. 1977) ("When the grant or denial of interim injunctive relief is reviewed, it is simplistic to say or imply, as we sometimes do, that it will be set aside only if an abuse of discretion can be shown.

For there is, of course, the possibility that the court below has either failed to exercise its discretion in some respect or else exercised it counter to established equitable principles. A judge's discretion is not boundless and must be exercised within the applicable rules of law or equity.") (citations omitted).

I. The District Court Abused Its Discretion By Denying Preliminary Injunctive Relief Based on Clearly Erroneous Findings of Fact Concerning the Ability to Verify and Respond to Mr. Brown's Level of Consciousness.

With respect to the BIS monitor's impact on the Defendants' ability to verify and respond Mr. Brown's level of consciousness, the district court found:

> Under the revised protocol, whether the medical professionals monitor the BIS monitor from the execution chamber or an adjoining room (one designed especially for carrying out and monitoring the execution process, no less) will have no impact on the likelihood that the plaintiff will feel pain. Wherever the medical professionals are located, they will be able to verify that plaintiff is unconscious after administration of sodium pentothal or, if he remains conscious at that time, they will be able to bring about the injection of additional sodium pentothal until plaintiff is rendered fully unconscious.

(Order at 5.) This finding of fact is clearly erroneous in view of the substantial evidence before the district court with respect to the use of the BIS monitor to verify unconsciousness and the efficacy of Defendants' proposed response in the event that the BIS monitor does not reflect an adequate level of unconsciousness.

A. Verification of Unconsciousness.

The district court's finding that the Defendants' proposed protocol will allow verification of the Mr. Brown's level of unconsciousness is contrary to the clear weight of the evidence establishing that while a BIS monitor can be a helpful adjunct to the assessment of anesthesia it is not medically accepted practice to use the BIS monitor as intended by the Defendants' – as the sole indicator of the level of consciousness. According to Mark J. S. Heath, M.D., a board-

certified anesthesiologist and Assistant Professor of Clinical Anesthesiology at Columbia University:

> [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.

(Third Heath Aff. ¶ 8.) Although Dr. Heath frequently, but not always, uses a BIS monitor when providing anesthesia to his surgical patients he explains that:

> [He] would not, however, rely exclusively on a BIS monitor to assure me of a patient's anesthetic depth. It is *just one tool, among many*, that [he] use[s] and integrate[s] when providing patient care.

(*Id.* ¶ 5 (emphasis added).)

Likewise, Philip G. Boysen, M.D., FACP, FCCP, FCCM, a board certified anesthesiologist, Professor of Medicine and Anesthesiology, Executive Associate Dean for Graduate Medical Education at the University of North Carolina School of Medicine at Chapel Hill, and former Chair of the Department of Anesthesiology explains:

> The 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 Affidavit ¶ 4 (emphasis added).) Dr. Boysen makes clear that "the BIS monitor should always be used in conjunction with direct visual and tactile monitoring of the patient and conventional monitoring techniques (such as blood pressure, heart rate, and respiratory rate)." (*Id.* at ¶ 5.)

Similarly, Nancy Bruton-Maree, CRNA, a Certified Registered Nurse Anesthetist and a Registered Nurse licensed to practice in North Carolina who is the Program Director of the

Raleigh School of Nurse Anesthesia and a Visiting Assistant Professor at the School of Nursing at the University of North Carolina at Greensboro, explained:

> To my knowledge, there is no one piece of technology that is used alone to monitor physical parameters for assessment of anesthetic depth.

(Third Maree Aff. ¶ 7.)

These expert opinions are further supported by the statements of Aspect Medical Systems, Inc. ("Aspect"), the manufacturer of the BIS Monitor purchased by Defendants. (Kelley Aff. ¶ 9.) On its website, Aspect clearly states:

> 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 also 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.

Likewise, "Practice Advisory for Intraoperative Awareness and Brain Function Monitoring" *Anesthesiology*, Vol. 104, No. 4, 847 (Apr. 2006) (attached as Exhibit 1 to Third Heath Aff.), recently adopted by the American Society of Anesthesiologists specifically evaluates the use of brain functioning monitoring technology, such as BIS monitors, and offers guidance regarding the use of these devices directly contrary to the Defendants' intention to use the BIS monitor in isolation, without other monitoring modalities or interpretation by personnel with appropriate training in anesthesia. 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.). 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." (*Id.* at 851, 854).

> 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.

Echoing the ASA's conclusions, the American Association of Nurse Anesthetists ("AANA") issued a model policy for CRNAs regarding the "Prevention and Monitoring of Unintended Awareness Under General Anesthesia" which establishes 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 (emphasis added).

Further evidence that the BIS monitor should not be the sole method for assessing anesthetic depth is found in the fact that the BIS monitor is not required by the medically accepted standard of care for monitoring consciousness with the administration of anesthesia. (Second Boysen Aff. at ¶ 3; Third Heath Aff. at ¶ 6; Third Maree Aff. at ¶ 8.) Specifically, Dr. Heath explains that:

> a significant controversy exists within the anesthesiology community regarding the utility and efficacy of brain function monitoring and that use of a BIS monitor is not the standard of care for anesthesiology practice. While there are many anesthesiologists who use BIS monitors in their clinical practice, there are also many anesthesiologists who do not use BIS monitors and do not believe that these monitors have an important place in clinical care. Many of my colleagues in the Department of Anesthesiology at Columbia University Medical Center use BIS monitors and many do not. Some of the operating rooms at Columbia are equipped with BIS monitors, or other brain function monitors, and some operating rooms are not.

(Third Heath Aff. ¶ 6. *See also*, Third Maree Aff. ¶ 8.)

Likewise, with respect to use of brain function monitoring devices, like the BIS monitor, the ASA's Practice Advisory for Intraoperative Awareness and Brain Function Monitoring 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 . . . .

Anesthesiology, Vol. 104, No. 4, at 855 (emphasis added).[1]

The clear weight of the evidence, when considering the entire record before the district court, establishes that Defendants' proposed protocol calls for the use of the BIS monitor as the only indicator of Mr. Brown's level of consciousness in contravention of medically accepted standards for its use. Accordingly, the district court clearly erred in finding that the protocol will enable Defendants' to verify Mr. Brown's level of consciousness.

The district court apparently ignored Aspect's own statement concerning Defendants' proposed use of Aspect's BIS monitor. Specifically, Scott D. Kelley, M.D., Vice President and Medical Director of Aspect Medical Systems, Inc., and a board certified anesthesiologist who practices at Brigham and Women's Hospital, a Harvard Medical School Affiliate, explains that "[b]oth Aspect and standard anesthesia treatises recommend that medical professionals integrate

[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.").

the BIS monitoring with their own direct observation of the patient (along with traditional monitoring – i.e. blood pressure, heart rate, respiratory rate, etc.)" (Kelley Aff. ¶ 18.) However, as Dr. Kelley notes, "[t]he Defendants' Notice and Response and the supporting Affidavits indicate that the 'licensed registered nurse' and the ' licensed physician' will be at a remote location from the Plaintiff and may be relying excessively – or even solely – on the BIS monitor readings rather than clinical observations."[2] (*Id.* ¶ 19.)

Indeed, Ms. Maree, based on her tour of the execution chamber, observation room, and witness room, identified barriers to employing the multiple modalities that are medically necessary for assessing anesthesia. (First Maree Aff. ¶¶ 8,10.) Specifically, she states:

> In my professional opinion, the setup of the execution chamber renders it impossible for the personnel administering the anesthesia to the inmate to identify and remedy possible problems with its administration. Specifically, the presence of the curtain between the inmate and the execution personnel blocks visual access to the site of the IV. One possible complication that arises when attempting to administer a large volume of intravenous fluids in a short amount of time is that a vein may rupture. This results in the fluid remaining in the tissue rather than circulating through the bloodstream. Without visual access to the IV sites, the execution personnel would not know if this complication occurred.

(*Id.* ¶ 8.) Likewise, Ms. Maree describes the barriers to direct monitoring of consciousness from the observation room where Defendants propose to place the BIS monitor as well as from the witness room as follows:

> Finally, after touring the execution chamber, it is my opinion that neither Warden Polk, nor any other member of the execution team, can observe an abnormality or malfunction in the lethal injection process and halt the execution. While I do not know where Warden Polk is physically located during the execution, I do know that he cannot be everywhere that he would need to be in order to identify a problem. If he is located in the chamber behind the curtains with the executioners, he cannot see the IV site and cannot

[2] It bears note that had Dr. Kelley known the Defendants' true purpose for purchasing the BIS monitor, he would have acted to prevent the sale. (Kelley Aff. ¶ 22.)

> identify problems there. If he is in the observation room, he can see at best only the head of the inmate, and cannot see the inmate's right arm or the lines and other equipment administering the IV fluids. If he is in the witness room, he is not close enough for a meaningful view of the inmate's arm, nor does he have the medical training to identify a problem with the IV site. Nor can he see the other equipment. Indeed, there is no one person who can see the IV site, the inmate, and the IV lines and other equipment, as would be necessary to safely induce and monitor an appropriate plane of anesthesia.

(*Id.* ¶ 10.) There is no evidence that Defendants' proposed protocol will address these visual barriers to proper assessment of Mr. Brown's level of consciousness.

B. Response to Consciousness.

In addition to the district court's erroneous finding that the Defendants' addition of a BIS monitor will verify Mr. Brown's level of consciousness, the district court's finding concerning the efficacy of Defendants' proposed response in the event that the BIS monitor does not reflect an adequate level of unconsciousness is contrary to the clear weight of the evidence before the district court. As now proposed, if anesthesia is improperly administered by the execution team such that the reading on the BIS monitor fails to fall below an appropriate level, the only response called for under the Defendants' protocol is for the non-medical personnel administering the sodium pentothal to administer more. However, this single response fails to address any of the concerns raised by Ms. Maree, outlined above, concerning the manner in which the anesthetic is administered. (*See also*, First Heath Aff. ¶ 30.) Ms. Maree observed that:

> nothing in the Notice or the Affidavits address my concerns regarding the maintenance of the integrity of the IV sites throughout the administration of the drugs. An infiltration is not always obvious. No steps have been taken to monitor IV sites for infiltration or to identify what will be done in the event that infiltration occurs.

(Third Maree Aff. ¶ 11.) Quite to the contrary, the only evidence before the district court concerning Defendants' proposed response to a BIS monitor reading indicating an inappropriate level of consciousness is for the same 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.

Finally, the district court's finding that Defendants' protocol contemplates use of the BIS monitor to verify Mr. Brown's level of consciousness at the time that potassium chloride is administered is not supported by the evidence. (17 April 2006 Order at 6.) As set out by Warden Polk, the proposed protocol only indicates that the BIS monitor will be read after the administration of the initial 3000 mg dose of sodium pentothal and before the administration of pancuronium bromide. (Second Polk Aff. ¶ 6.4.) As described by Warden Polk, this protocol includes no provision for further readings of the BIS monitor after administration of the pancuronium bromide and before the potassium chloride. Further, it 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.

Therefore, the district court's finding that the Defendants' revised protocol provided for constitutionally sufficient verification of Mr. Brown's level of unconsciousness and response to a potential state of consciousness is clearly erroneous as it is not supported by substantial evidence, disregarded substantial evidence that would militate a conclusion to the contrary, and/or is actually contrary to the clear weight of the evidence considered in light of the entire record in this action. Accordingly, this finding should be set aside and this Court should find the district court abused its discretion in denying the equitable relief sought by Mr. Brown.

II. The District Court Abused Its Discretion By Denying Preliminary Injunctive Relief Based on Clearly Erroneous Findings of Fact Concerning the Training of the Execution Team.

With respect to the training of the individuals charged under the Defendants' new protocol with reading and responding to the data provided by the BIS monitor, the district court found:

> The court is also satisfied that the licensed registered nurse and licensed physician used by defendants in plaintiff's execution will be satisfactorily trained and fully capable of reading the BIS monitor and responding appropriately to the data they receive.

(17 April 2006 Order at 5.) This finding is not supported by substantial evidence in the record, disregards substantial evidence that militates a contrary conclusion, and is contrary to the clear weight of the evidence in the record. The district court clearly erred in making this finding of fact and its reliance on this finding in denying Mr. Brown preliminary injunctive relief was an abuse of the district court's discretion.

A. Training and Experience Required to Induce and Maintain an Adequate Plane of Anesthesia.

There is ample evidence in the record that extensive and specialized training is required in North Carolina, and in the United States generally, to induce and monitor an appropriate plane of anesthesia:

> [T]he provision of anesthetic care is performed only by personnel with advanced training in the medical subspecialty of Anesthesiology. This is because the administration of anesthetic care 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.)

Moreover, the record provides that the assessment of aesthetic depth and the corresponding maintenance of that state is both medical science and "art." (Third Heath Aff.

¶ 9.) This specialized skill is acquired through both extensive education and hands-on experience:

> "[G]eneral anesthesia is administered by physicians who have completed residency training in the specialty of Anesthesiology, and by CRNAs. Physicians and nurses who have not completed the requisite training to become anesthesiologists or CRNAs are not permitted to provide general anesthesia. It is critical to understand that the great majority of physicians and nurses and other health care professionals do not possess the requisite training, skills, experience, and credentials to provide general anesthesia. . . . Conversely, a physician who is not an anesthesiologist or a nurse who is not a CRNA should not be permitted to provide general anesthesia within the prison (or anywhere else in North Carolina)."

([First] Heath Aff. ¶ 33.) With respect to procedures like lethal injection, which require deep sedation or general anesthesia, the North Carolina Medical Board has stated that "[a]nesthesia should be administered by an anesthesiologist or a CRNA supervised by a physician. The physician who performs the surgical or special procedure should not administer the anesthesia. The anesthesia provider should not be otherwise involved in the surgical or special procedure." (*Id.* ¶ 34.)

B. The District Court's Finding of Training and Experience.

The district court expressly stated that it was satisfied that the registered nurse and physician used by Defendants "*will be* satisfactorily trained" to read the BIS monitor and capable of "responding appropriately to the data they receive." (17 April 2006 Order at 5 (emphasis added).). Respectfully, there is no evidence of the training that the registered nurse or physician will receive with regard to the BIS monitor. Moreover, by couching its finding in the future tense, the district court acknowledged that the record contained no information regarding the present training of such personnel in the use of the BIS monitor.

The Notice Defendants filed with the district court simply states that the execution protocol has been revised to include the use of the BIS monitor to "measure the Plaintiff's level

of consciousness." (Defs.' Notice at 2.) This revision calls for the attachment of the BIS monitor to the Mr. Brown, and the operation and interpretation of the monitor by a licensed registered nurse and licensed physician from an observation room adjacent to the execution chamber. (Defs.' Notice at 2; Second Polk Aff. ¶ 6.) However, the only evidence suggesting that mere licensure as a registered nurse or physician enables these individuals to operate and interpret the BIS monitor is a statement by Dr. Dershwitz that the BIS monitor can be operated and the values obtained, recorded, and interpreted by a registered nurse. (Third Dershwitz Aff. ¶ 8.) Dr. Dershwitz does not explain the factual basis for this statement.

To the contrary, a CRNA with extensive experience in the teaching of nurses has stated that proper use of a BIS monitor requires education, training, and experience in anesthetic care as well as proper training and experience in the use of the BIS monitor. (Third Maree Aff. ¶ 9.) Similarly, two practicing clinical anesthesiologists have explained that additional, specialized training is required for proper use of the BIS monitor while inducing anesthesia: "The use of the BIS monitor requires an understanding of its role in making clinical decisions and integration of the data provided with all other available sources of clinical information" by an anesthesiologist or CRNA. (Second Boysen Aff. ¶ 4.) "[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." (Third Heath Aff. ¶ 10.)

The evidence in the record before the district court included guidelines also issued by the ASA and AANA and the considerations for use distributed by the manufacturer of the device. Each of these authorities state that additional and specific training is required for the clinical use

of the BIS monitor. Scott M. Kelley, M.D., a board-certified anesthesiologist and the Vice President and Medical Director of Aspect Medical Systems, Inc. ("Aspect"), the maker of the BIS monitoring technology, stated that the BIS monitor "is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use." (Kelley Aff. ¶ 12.) Dr. Kelley also expressed Aspect's specific concern that the Defendants' proposed use of the BIS monitor may result in its operation "by persons lacking appropriate training." (*Id.* ¶ 21.)

Further, in October 2005, the ASA approved a "Practice Advisory for Intraoperative Awareness and Brain Function Monitoring," which specifically evaluated the use of brain function monitoring technology, such as BIS monitors, and offered guidance regarding the use of these devices. This document included numerous statements that refute Defendants' proposal to use the BIS monitor without interpretation by personnel with appropriate training in anesthesia. *See* Practice Advisory for Intraoperative Awareness and Brain Function Monitoring, *Anesthesiology*, Vol. 104, No. 4, 847, 851, 854 (Apr. 2006) (attached as Ex. 1 to Third Heath Aff.). 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 clinical use" and emphasizes 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_TSMenu TargetType=4&ucNavMenu_TSMenuID=6&id=712; (*see also* Third Maree Aff. ¶ 6.)

Equally important, however, is the fact that the record is completely devoid of any evidence that the registered nurse or physician are capable of "responding appropriately" to the data generated by the BIS monitor. Presumably, this statement by the district court was referring to the possibility that the Mr. Brown may require further anesthesia. As discussed above in Section II.A, there is ample evidence from experts in the field of anesthesia, that only persons with that specialized training, well beyond that of licensed physicians and registered nurses, are qualified to induce or maintain a plane of anesthesia. There is no evidence in the record that the registered nurse or licensed physician employed by Defendants have the requisite training or experience to induce and maintain a plane of anesthesia sufficient to ensure the humaneness of Mr. Brown's execution. As stated by Dr. Heath, "[a] physician, registered nurse, or any person, who lacks extensive hands-on clinical immersive formal training in the art and science of assessing and maintaining anesthetic depth cannot possibly meet any reasonable standard of care, regardless of whether or not a BIS monitor is available." (Third Heath Aff. ¶ 13.)

Therefore, it is clear that the district court's finding that the registered nurse and physician used by Defendants "will be satisfactorily trained" to read the BIS monitor and capable of "responding appropriately to the data they receive" is not supported by substantial evidence, disregards substantial evidence that militates a contrary conclusion and is contrary to the clear weight of the evidence in the record.

C. District Court's Finding of Ethical Conflict.

To the extent the district court based its determination on a finding that Mr. Brown was attempting "to force a conflict of medical ethics by taking the issue of the positioning of medical

professionals in and around the execution chamber, and dressing it in constitutional clothes;" (17 April 2006 Order at 4-5), such a finding was clearly erroneous as it is contrary to the record in the case. The only evidence in the record before the district court regarding any such conflict, to the extent it exists, does not suggest it presents any problem for the Defendants. The only statement addressing this issue provides that "Warden Polk would not encounter significant difficulty in recruiting and contracting for an adequately trained physician to provide the general anesthetic that necessarily must precede the administration of sodium thiopental and pancuronium bromide." ([First] Heath Aff. ¶ 43.) There was absolutely no evidence that the protocol sought by the Mr. Brown would present any ethical "conflict" which would result in Defendants being unable to recruit or contract personnel with the requisite training.

Moreover, the Defendants have never suggested or argued that they have been, or would be, unable to locate a medical professional with adequate training to personally induce, monitor, and maintain the requisite plane of anesthesia as is both necessary and required to protect Mr. Brown's constitutional rights. Further, the Defendants' ability to employ a licensed physician and registered nurse to observe the BIS monitor actually suggests that no such ethical "conflict" exists. This physician and nurse are subject to the same ethical constraints as a medical professional with credentialed, licensed, and proficient in the field of anesthesiology. Moreover, long before the filing of Mr. Brown's Amended Complaint, a physician has been present in the observation room to read the heart monitor and possibly to pronounce death. (Polk Dep. pp. 113-14; Defs.' Notice at 3.) As such, it is not certain what "conflict of medical ethics" was referred to by the district court; however, to the extent it was relied upon, such reliance was clearly erroneous.

D. District Court's Finding Regarding More Specific Information.

The district court found that there was "no reasonable basis for plaintiff to demand more specific information than" the Defendants' plan to use a licensed registered nurse and a licensed physician, particularly in light of the need "to maintain the confidentiality of the identities of medical personnel who participate in executions." (17 April 2006 Order at 5.) However, nearly in the same breath, the Court stated that it was satisfied that the registered nurse and physician "will be satisfactorily trained" to operate and interpret the BIS monitor. (*Id.*)

It is difficult to imagine that the physician and registered nurse "will be satisfactorily trained" when no such training was a part of the revised protocol submitted by the Defendants. However, the district court's verb tense seems to concede, as multiple experts have opined, that such specific training is required to operate and interpret the BIS monitor. And yet, the district court found a demand to disclose more specific information about the training by, or qualification of, the physician and registered nurse unreasonable.

If the district court's basis for denying access to this information rests on the need to maintain the confidentiality of the identities of the medical personnel taking part in the execution, it is important to note that Mr. Brown has never sought, or argued it was reasonable, to reveal the names or personal identification information of these medical professionals. (Am. Compl. ¶ 5 ("[I]t is Plaintiff's understanding that Defendants' will not reveal the identities of these persons.").) Mr. Brown has only sought, and continues to only seek, the objective qualifications and training of the medical professionals taking part in his execution to ensure that he will not consciously suffer excruciating pain in violation of his Eight Amendment rights. Therefore, to the extent the district court relied upon the finding that Mr. Brown's request for more specific information regarding the training and qualifications of the medical professionals

participating in his execution was unreasonable, that too was clearly erroneous and not supported by the record in this action.

III. The District Court Abused Its Discretion By Denying Preliminary Injunctive Relief Based on Clearly Erroneous Findings of Fact Concerning the Reliability of the BIS Monitor.

The district court found as fact that:

> Whatever concerns might be raised about this 'machine,' or about the propriety of using it in executions, it is apparent to this court that the BIS monitor has been used reliability for a decade and is used in many anesthesia procedures across the country to determine an individual's level of consciousness.

(17 April 2006 Order at 6.) This finding is clearly erroneous in light of overwhelming evidence in the record, completely disregarded by the district court, demonstrating that the BIS monitor, used in the manner intended by Defendants, cannot be relied upon to definitely determine a patient's level of consciousness. As previously discussed, the evidence before the district court uniformly stresses the need for appropriately trained medical personnel to exercise clinical judgment in interpreting the BIS monitor in conjunction with other observation and diagnostic modalities. (*See e.g.*, Third Heath Aff. ¶¶ 7-9; Second Boysen Aff. ¶¶ 4-5; Third Marec Aff. ¶ 7; Kelley Aff. ¶ 15.) Such cautions are based upon an appreciation of the limitations of the BIS monitor and are intended to enhance the reliability of the assessment. The determination of the district court that the BIS monitor can be expected to function reliably without such safeguards finds no support in the record and is thus clearly erroneous.

With its statement deriding "whatever concerns might be raised" about the monitor and the propriety of using it in the manner proposed, the district court glosses over and disregards substantial evidence, unrebutted by Defendants, calling into question the reliability of the BIS monitor as the sole means of assessing consciousness. In fact, a recent study specifically found

that "[a]nesthesia providers should not rely exclusively on the BIS monitor when assessing depth of anesthesia." Niedhart, Dagmar J., et al., "Intraoperative Reproducibility of the BISxp® Monitor," *Anesthesiology*, Vol. 104, No. 2, 242 (Feb. 2006) (attached as Ex. 2 to Third Heath Aff.). Researchers applied two BIS electrode strips to the forehead of the same patient and compared the results for consistency. Considering only those readings "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. With respect to the reliability of the BIS monitor as a monitor of anesthetic depth, the authors concluded:

> 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; (*see also* Third Heath Aff. ¶ 18).

The district court also failed to address Mr. Brown's evidence that that nature of the chemicals used in Defendants' lethal injection protocol impair the reliability of the BIS monitor as a means of assessing Mr. Brown's level of consciousness throughout his execution. As explained by Dr. Heath, the BIS monitor "is like all medical instruments in that it is subject to artifactual interference." (Third Heath Aff. ¶ 24.) One study relied upon by Dr. Heath found that when subjects were administered a neuromuscular blocking agent, the same category of chemical as the pancuronium bromide included in Defendants' execution protocol, the value displayed by the BIS monitor decreased to levels as low as 33, despite the fact that no anesthetic

drugs were administered and the subjects remained *fully conscious* throughout the experiment. Messner, M., et al., "The Bispectral Index Declines During Neuromuscular Block in Fully Awake Patients," *Anesthesia & Analgesia*, 2003; 97:488-91 (attached as Ex. 5 to Third Heath Aff.). These results support Dr. Heath's conclusion that "[i]n 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." (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."); Third Marce Aff. ¶ 10 ("The BIS monitor does not always give a reliable reading.").) There was no evidence before the district court to counter this showing of unreliability.

Furthermore, the district court's 17 April 2006 Order fails to even acknowledge the evidence submitted by Mr. Brown that Defendants' own expert, the only person who appears to advocate the use of the BIS monitor in the manner proposed, has expressed concerns about the efficacy and reliability of the monitor in this context. As recently as February of this year, Dr. Dershwitz 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 as Ex. B to Pl.'s Objection).) Significantly, Dr. Dershwitz also opined 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).)

These statements call into question Defendants' claim that a BIS monitor, used as the sole measure of consciousness in protocol, can reliably "prevent the possibility of the inmate being awake during the administration of the pancuronium or potassium chloride." (Third Dershwitz Aff. ¶ 11.) In making this assertion, Dr. Dershwitz does not indicate that there has been any testing of the machine, as he specifically recommended, to establish its efficacy and reliability under the conditions Defendants propose. The inconsistent opinions of Defendants' only expert witness only underscore that the clear weight of the evidence before the district court established that the addition of a BIS monitor as the only measure of consciousness, divorced from any direct monitoring or clinician judgment by a medical professional, does not mitigate Mr. Brown's substantial concerns that anesthesia will not be properly administered under Defendants' protocol, resulting in needless suffering during the execution.

The record contains no evidence to dispute Mr. Brown's evidence "that currently there exists no single device that provides a fully reliable and accurate 'readout' of the level of consciousness or anesthetic plane." (Third Heath Aff. ¶ 24.) Instead, it is virtually universally acknowledged that neither the BIS monitor, nor any other device, can substitute for the skill, judgment, and experience of appropriately trained medical personnel. (*Id.* at ¶¶ 8, 9, 15.) *See also* Press Release, American Society of Anesthesiologists, *Report on Awareness Under General Anesthesia Says Anesthesiologists 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."). The opinions of Mr. Brown's experts are also consistent with and informed by standards of care in North Carolina. Specifically, Dr. Heath refers to a news article stating:

"When told about the state's proposal, Dr. Richard Pollard of Charlotte, president of the N.C. Society of Anesthesiologist, laughed out loud . . . These monitors cannot guarantee that a patient is asleep." Andrea Weigl, *News &Observer*, "Prisons offer machine as monitor; Officials hope a judge's order concerning lethal injection will be satisfied" (Apr. 13, 2006) (attached as Ex. 3 to Third Heath Aff.).

Finally, the district court's determination that "the BIS monitor has been used reliably for a decade" ignores the undisputed evidence that the manufacturer of this monitor expressly disclaims the level of certainty suggested by the court. The Operating Manual that is shipped by the manufacturer with each BIS monitor includes an explicit warning about the "potential false readings, which: 'may be caused by poor skin contact . . ., muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference.'" (Kelley Aff. ¶ 14.) For this reason, Aspect repeatedly stresses that 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 15; "Considerations for Using BIS," *available at* http://www.aspectmedical.com/resources/proc_cards/or/components_anesthesia.htm; "BIS Vista Monitoring System Operating Manual" at iii, *available at* http://inservice.aspectmedical.com/vista/manual/manual.pdf.)

In sum, record viewed in its entirety, provides no support for the finding made by district court regarding reliability of the BIS monitor under conditions proposed by Defendants. In arriving at this determination, the district court disregard the substantial, and indeed uncontroverted, evidence that weighed in favor of a contrary conclusion.

CONCLUSION

In conclusion, the district court abused its discretion by denying preliminary injunctive relief based on clearly erroneous findings of fact concerning the ability to verify and respond to appellant's level of consciousness, the training of the execution team, and the reliability of the BIS monitor. The district court's findings concerning the Defendant's proposed protocol should be set aside because they demonstrate complete disregard for Mr. Brown's substantial evidence concerning the inadequacies of the proposed protocol. The clear weight of this evidence, when considered in light of the entire record, is contrary to the district court's refusal to grant equitable relief and requires the issuance of a preliminary injunction. The district court's conclusion that the proposed revision now tips the balance of hardships against the issuance of equitable relief is not supported by the findings of fact, nor could the district court make such findings of facts on the record before it. The district court's refusal to grant preliminary injunction is an abuse of its discretion.

Therefore, Mr. Brown requests that the Court reverse the district court's decision and remand with instructions to issue a preliminary injunction enjoining Defendants from using their inadequate proposed anesthesia protocol in the course of Mr. Brown's execution.

Respectfully submitted this the 18th day of April 2006.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing BRIEF OF APPELLANT was served upon Defendants by electronic transmission to the following counsel:

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