

HOW LETHAL INJECTION REFORM CONSTITUTES IMPERMISSIBLE RESEARCH ON PRISONERS

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This essay exposes how recent attempts at lethal injection reform have involved unethical and illegal research on prisoners. States are varying the doses and types of drugs used, developing methods designed for non-medical professionals to administer medical procedures, and gathering data or made provision for the gathering of data to learn from executions gone wrong. When individual prisoners are executed under these conditions, states are conducting research on them. Conducting research or experimentation on prisoners in the process of reform is problematic because it violates ethical frameworks and state laws.

The Supreme Court has recently taken up the challenge of elucidating the standard for determining the constitutionality of lethal injection. If the Court suggests an approach to lethal injection reform that is akin to some of the more thoughtful and cautious approaches other courts have proposed, the Court's decision may also contravene state laws or ethical precepts regarding research with prisoners. Thus, this paper provides important limitations on the kinds of reform that may be permissible and outlines the open questions that must be addressed before it can be determined whether the risks and uncertainties involved in lethal injection can be remedied.

INTRODUCTION

The Supreme Court recently granted certiorari in order to elucidate a standard for applying the Eighth Amendment's prohibition on cruel and unusual punishment to determine the constitutionality of execution by lethal injection.¹ Before this decision, execution by lethal injection had come to a halt in eleven states as a result of dramatic evidence of the potential problems with its implementation.² These problems led some courts to conclude that, as currently practiced, the lethal injection system is broken and runs a substantial risk of involving cruel and

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¹ Baze v. Rees, No. 07-5439, 2007 U.S. LEXIS 9066, at *1 (U.S. September 25, 2007).

² Lethal injections have been halted in California, Florida, Missouri, South Dakota, Arkansas, Delaware, Kentucky, Louisiana, Maryland, North Carolina, and Ohio. The Eighth Circuit reversed a lower court opinion halting lethal injections in Missouri, however, and this decision is currently being challenged for rehearing en banc.

unusual punishment.³ States applied varying standards for evaluating lethal injection, such as “wanton infliction of pain,” “excessive pain,” “unnecessary pain,” “substantial risk,” “unnecessary risk,” and “substantial risk of wanton and unnecessary pain.”⁴ These standards reflect confusion in the courts about how to determine what, precisely, is wrong with lethal injection. In misguided attempts to resolve the uncertainty about the amount of risk of pain inherent in existing lethal injection protocols, many states began to reform their current lethal injection procedures.

Yet in the extensive litigation and debate over lethal injection, one important issue has been entirely neglected: attempts to reform lethal injection necessarily require states to experiment with different procedures and revise their lethal injection protocols, and thereby to conduct research on prisoners. The process of revision and reform therefore comes into conflict with regulations or policies governing research on prisoners, with which states must comply.⁵ Thus, attempts to develop appropriate lethal injection protocols in a manner that constitutes experimentation on prisoners could require the use of many prisoners as test subjects, in violation of state policies, regulations, and ethical precepts. Furthermore, this conflict may ultimately be irresolvable.

The potential scope of this problem is large. Several states are conducting impermissible research on prisoners, and the number of prisoners involved, although decreasing each year, is troubling. In 2006, fifty-two people were put to death by lethal injection; sixty people were put to

³ See, e.g., *Morales v. Tilton*, 465 F. Supp. 972, 974 (N.D. Cal. 2006). Additionally, some states, such as Florida, have attempted to reform lethal injection protocols without prior court intervention. See, e.g., Final Report, Governor’s Commission on Administration of Lethal Injection, March 1, 2007, available <http://www.law.berkeley.edu/clinics/dpclinic/Lethal%20Injection%20Documents/Florida/lethalinjectionfinalreport.pdf> (last accessed August 22, 2007).

⁴ Petition for Writ of Certiorari at 1, *Baze*, No. 07-5439 (July 11, 2007).

⁵ See Appendix 1 for Table 1 (Listings of states, regulations governing research with prisoners, and cases requiring reform of lethal injection).

death in this manner in the previous year.⁶ Since the reinstatement of the death penalty in 1976, lethal injection has been used on 897 inmates.⁷

In this paper, I will first explain how lethal injection protocols were developed and how they have generally been implemented. Next, I will discuss the development of laws governing research with prisoners. I will then analyze how the laws governing research with prisoners in California, Florida, Ohio, South Dakota, North Carolina, Tennessee, and Maryland operate to ban those states' approaches to reform and attempts to revise their lethal injection protocols. In the penultimate section, I will address potential objections to these arguments, and I will conclude with an examination of whether and how the conflict between the need for reform and the impermissibility of research on prisoners might be resolved.

I. DEVELOPMENT OF LETHAL INJECTION PROTOCOLS

In 1977, Oklahoma pioneered the first lethal injection protocol.⁸ The protocol was developed by two state legislators, State Senator Bill Dawson and House Representative Bill Wiseman.⁹ These two politicians approached medical societies for help in devising lethal injection protocols, but their requests for assistance were denied.¹⁰ Wiseman and Dawson then contacted Dr. A. Jay Chapman, Oklahoma's Chief Medical Examiner, whose initial response was to demur because his expertise was in "dead bodies but not [] in getting them that way."¹¹ Nevertheless, Wiseman and Dawson persuaded Dr. Chapman to give his assistance, and he devised a process that would involve an intravenous saline drip, into which a lethal chemical would be introduced.¹² The lethal chemicals he proposed were an ultra-short-acting barbiturate

⁶ Ellyde Roko, *Note: Executioner Identities: Toward recognizing a right to know who is hiding beneath the hood*, 75 FORDHAM L. REV. 2791, 2796 (April 2007).

⁷ *Id.*

⁸ Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 FORDHAM L. REV. 47, 64 (2007).

⁹ *Id.*

¹⁰ *Id.* at 65.

¹¹ *Id.* (quoting an email from A. Jay Chapman).

¹² *Id.*

and a chemical paralytic.¹³ Chapman further suggested that the procedure use sodium thiopental as the barbiturate and chloral hydrate as the chemical paralytic.¹⁴ However, the protocol was designed to be vague and not specify the specific chemicals that would be used; at the time, it was not clear when lethal injection would be implemented, or what drugs would be available at the time it was put into practice.¹⁵

Dr. Stanley Deutsch developed a similar protocol that may also have served as a basis for subsequent lethal injection methods.¹⁶ Dr. Deutsch was initially approached by Dawson to devise a method of lethal injection that was relatively inexpensive and more humane than the alternative, which at the time was electrocution.¹⁷ Dr. Deutsch suggested the use of two drugs: an ultra-short-acting barbiturate followed by a drug that would create “a long duration of paralysis.”¹⁸

Legislation implementing a lethal injection protocol based on Chapman’s recommendations passed the Oklahoma Senate on March 2, 1977 and the Oklahoma House of Representatives on April 20, 1977.¹⁹ However, it is unclear whether Dr. Deutsch’s input actually informed Oklahoma’s protocol, because he provided the senators with information after the initial passage of the statute.²⁰ At the time, officials with the Department of Corrections were not certain what drugs would be used in implementing the statute; they assumed that new and better drugs might be available when the statute was put into practice.²¹ The drugs that were used by the Department of Corrections varied over time. In May of 1978, the execution procedures used in Oklahoma specified the following: “The execution shall be by means of a continuous, intravenous administration of a lethal quantity of sodium thiopental combined with either tubo-

¹³ *Id.* at 66.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Deborah W. Denno, *When Legislatures Delegate Death: The troubling paradox behind state uses of electrocution and lethal injection and what it says about us*, 63 OHIO ST. L.J. 63, 97 (2002).

¹⁸ *Id.* at 95.

¹⁹ Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 FORDHAM L. REV. 47, 70-71 (2007).

²⁰ *Id.*

²¹ *Id.* at 72.

curarine or succinylcholine chloride or potassium chloride which is an ultrashort-acting barbiturate combination with a chemical paralytic agent.”²² In 1981, Chapman assisted the Department of Corrections once more in creating a lethal injection protocol by adding a third drug to the cocktail—potassium chloride.²³ By 2004, the Department of Corrections used sodium thiopental and vecuronium bromide, followed by potassium chloride.²⁴

Lethal injection protocols vary somewhat from state to state. Although some states do not specify a particular combination of drugs in their lethal injection statutes, in practice, all states administer injections of a sequence of three drugs modeled after Oklahoma’s three-drug protocol.²⁵ The first drug is a dose of sodium thiopental that would not necessarily be lethal in the time allotted for execution, but that is intended to induce an anesthetic state.²⁶ The second chemical is pancuronium bromide, a neuromuscular blocking agent.²⁷ Pancuronium bromide only serves to paralyze the inmate, and does not render the inmate unconscious or unable to feel pain.²⁸ The final chemical administered is potassium chloride, which is the agent that typically causes death by inducing cardiac arrest.²⁹ All states also use a saline solution in between the administration of each chemical to prevent the sodium thiopental and the neuromuscular blocking agent from mixing and forming a precipitate which could occlude the IV line.³⁰ If an inmate is

²² Oklahoma Policy Statement No. P-090900, *Procedures for Carrying Out the Death Sentence* (July 29, 1977), on file with author.

²³ Denno, *supra* note 19, at 73.

²⁴ Oklahoma Policy No. P-040301-01, *Procedures for the Execution of Inmates Sentenced to Death*, (Aug. 7, 2006), on file with author.

²⁵ Ty Alper, *Lethal Incompetence: Lethal injection litigation is exposing more than torturous executions*, THE CHAMPION, Sept.-Oct. 2006 at 41; *see also* Denno, *supra* note 19, at 18. New Jersey requires that a two-drug combination be used, but there is a formal moratorium on executions currently in place. *See* N.J. Stat. Ann. § 2C:49-2 (2007) (“[P]unishment shall be imposed by continuous, intravenous, administration until the person is dead of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent in a quantity sufficient to cause death.”); Mark Sherman, *Associated Press, Reconvening U.S. Justices To Review Lethal Injection: New term to include appeal by two Kentucky inmates*, STAR-LEDGER, Sept. 26, 2007, at A3 (“New Jersey, which has not put anyone to death since 1963, has a formal moratorium on executions.”).

²⁶ Denno, *supra* note 19, at 77.

²⁷ *Id.* at 49.

²⁸ *Id.*

²⁹ *Id.*

³⁰ Denno, *supra* note 17, at 95.

not sufficiently anesthetized after the administration of the first drug, “the inmate may suffer excruciating suffocation caused by a paralyzing dose of pancuronium bromide *and* the heart attack induced by the potassium chloride,” but because the inmate would be unable to move, he would be unable to communicate the experience of suffering to execution witnesses.³¹

In clinical practice, the use of anesthesia is carefully regulated, has been tested in clinical trials, and is administered by practitioners who undergo years of specialized training.³² By contrast, the use of anesthesia in lethal injection in the United States has not been developed with prior testing in clinical trials.³³ Many inmate-specific issues may complicate the administration of anesthesia in the context of an execution, including the fact that a person anticipating an execution might be fearful or anxious in a manner that would impede the effect of the anesthesia, or the likelihood that inmates with histories of chronic substance abuse may have a high tolerance for sedatives and may require larger than normal doses for any anesthetic effect.³⁴

A nationwide survey of lethal injection protocols conducted through the use of questionnaires in 2001, and repeated in 2005, determined that the criteria set out in most lethal injection protocols failed to specify necessary information, which “heightened the likelihood that a lethal injection would be botched.”³⁵ Additionally, the details that were provided often included errors.³⁶ In 2005, the study’s author found that there is not a national consensus on how to

³¹ Alper, *supra* note 23, at 41 (emphasis in original).

³² See American Society of Anesthesiologists, Patient Education Brochure: The Medical Specialty of Anesthesiology, <http://www.asahq.org/patientEducation/specialty.htm> (last visited Aug. 28, 2007).

³³ By contrast to the development of lethal injection protocols in the United States, the Chinese government went through a series of tests of lethal injection protocols on human subjects in order to develop its current system. See Elizabeth Weil, *The Needle and the Damage Done*, N.Y. TIMES MAGAZINE, Feb. 11, 2007, at 46. Although China’s approach may have been ethically suspect, the development of lethal injection protocols in the United States was not based on scientific data, and appears to have developed based on various hypotheses about what might constitute a more humane form of execution.

³⁴ Mark J. S. Heath, et al., Correspondence *Inadequate Anesthesia in Lethal Injection for Execution*, 366 LANCET 1073, 1074 (2005).

³⁵ Denno, *supra* note 19, at 28.

³⁶ *Id.*

conduct lethal injection, and that the details of protocols are often left to be worked out by Department of Corrections personnel.³⁷

II. RECENT PROBLEMS WITH EXECUTIONS BY LETHAL INJECTION

Not only has the process by which lethal injection was developed raised concerns, but problems with lethal injection have also been dramatically demonstrated. Since 1985, at least thirty lethal injections have been prolonged because executioners had great difficulty finding suitable veins in which to inject the cocktail of drugs.³⁸ Several inmates have shown signs of experiencing significant pain after administration of lethal injection.³⁹ In 1998, Texas conducted the longest execution on record—the execution lasted for two hours.⁴⁰ In May 2006, the State of Ohio ran into several difficulties during the execution of Joseph Clark.⁴¹ According to reports made by members of the execution team, they initially took several minutes to find a vein in which to inject the drugs.⁴² The vein then collapsed, and Mr. Clark had to sit up and inform the execution team that the procedure was not working.⁴³ An autopsy revealed that Mr. Clark had nineteen needle puncture marks and signs of paravenous injection of drugs.⁴⁴ A medical examiner in Michigan who reviewed Mr. Clark’s execution called the persons inserting IV catheters “incompetent.”⁴⁵ All told, Mr. Clark’s execution lasted for ninety minutes.⁴⁶

Later that year, Angel Diaz’s execution in Florida lasted a full thirty-four minutes before the declaration of death.⁴⁷ Mr. Diaz continued to move, squint, grimace, and attempt to speak

³⁷ *Id.*

³⁸ Michael L. Radelet, *Some Examples of Post-Furman Botched Executions*, <http://www.deathpenaltyinfo.org/article.php?scid=8&did=478> (last visited Sept. 21, 2007).

³⁹ *Id.*

⁴⁰ Denno, *supra* note 19, at 18. As late as 2006, Ohio conducted the second longest execution by lethal injection ever recorded—a ninety-minute procedure.

⁴¹ Andrew Welsh-Huggins, *Inmate Sought Injection Alternative During Execution*, CHI. TRIB., May 12, 2006, at C6.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Woman Sues U.S. Prison Over Son’s 86-minute Execution*, AGENCE FRANCE PRESSE, July 3, 2007.

⁴⁵ *Id.*

⁴⁶ Welsh-Huggins, *supra* note 41, at C6.

⁴⁷ Gary Fineout, *Executioners Missed Vein with Lethal Cocktail, Report Says*, MIAMI HERALD, Dec. 15, 2006.

after the first injection was thought to have been administered.⁴⁸ An autopsy revealed that the medical personnel inserting the IVs into Mr. Diaz failed to place the IVs inside his veins.⁴⁹ The tip of each IV pierced the veins and was placed in the soft tissue of his arms.⁵⁰ As a result, the chemicals were injected directly into the tissue of Mr. Diaz's arms, and he sustained internal chemical blisters that were approximately one foot in length.⁵¹ The failure on the part of the execution team to deliver the execution drugs to Mr. Diaz's venous system effectively, and instead into his arm tissue, prevented any of the drugs, and especially the anesthetic drug, from taking effect as intended.⁵² Exacerbating the already devastating problem of misplacement of the IVs, the execution team failed to administer the drugs in the correct order, likely resulting in Mr. Diaz feeling the excruciating effects of pancuronium bromide before the effects of thiopental.⁵³

In hearings in a recent California lethal injection case, the court noted that "anomalies in six execution logs raise substantial questions as to whether certain inmates may have been conscious when pancuronium bromide or potassium chloride was injected."⁵⁴ In fact, the court noted that, based on the heart rates recorded in an execution log, there was a high likelihood that in the California execution of Robert Lee Massie on March 27, 2001, Massie may have been awake when injected with potassium chloride, which, if true, would indicate that Massie experienced tremendous suffering before his death.⁵⁵

III. THE HISTORY OF RESEARCH WITH PRISONERS

Research "refers to a class of activities designed to develop or contribute to generalizable knowledge."⁵⁶ By contrast, medical practice involves "a class of activities designed solely to

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Id.

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Chris Tisch, *Doctor: Execution flawed at start*, ST. PETERSBURG TIMES, Feb. 13, 2007, at 1B.

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Id.

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Id.

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Botched Execution Spurs State Changes, CHI. TRIB., Aug. 5, 2007, at C10.

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Tisch, *supra* note 33, at 1B.

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Morales v. Tilton, 465 F. Supp. 972, 984 (N.D. Cal. 2006).

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Id.

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ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 3 (1986).

enhance the well-being of an individual patient or client.”⁵⁷ The critical distinction here is that standard medical practice typically requires a reasonable expectation of success and is aimed at improving the health of one particular patient, whereas research is aimed at developing knowledge that can be used to benefit society. In other words, the distinction between medical practice and research is not solely based on the uncertainty of the outcome. Although medical practice may involve some uncertainty because of individual variation in physiology or behavior,⁵⁸ uncertainty about some important scientific question is what drives the conduct of research. To develop knowledge about a scientific or medical question that can be generalized to many others, however, individual subjects involved in research take on some risk of being harmed. This risk of harm is what raises the most salient ethical issues in research with human subjects: “By placing some people at risk of harm for the good of others, clinical research has the potential for exploitation of human subjects. Ethical requirements for clinical research aim to minimize the possibility of exploitation by ensuring that research subjects are not merely used but are treated with respect while they contribute to the social good.”⁵⁹

Over the long history of research in the United States, research conducted on prisoners has unfortunately involved many examples of exploitation. During the 1950s, researchers studied more than one hundred inmates in the Ohio state prison system by injecting them with live cancer cells in order to determine how the human body killed off cells.⁶⁰ “From 1962 to 1966, . . . 33 pharmaceutical companies tested 153 experimental drugs at Holmesburg Prison in Philadelphia, including a Retin-A (tretinoin) study in which researchers did not seek informed consent and

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Ezekiel J. Emanuel, David Wendler, Christine Grady, *What Makes Clinical Research Ethical?*, 283 JAMA 27101-27111, 2701 (2000).

⁶⁰ Allen M. Hornblum, *They Were Cheap and Available*, 315 BRIT. MED. J., Nov. 29, 1997, at 1437-1441, for this example and others, available at http://www.bmj.com/cgi/content/full/315/7120/1437?ijkey=b58ac42465f33c5c9a41f9fb3d63ac1662dd6fa0&keytype=tf_ipsecsha#R33 (citing *Cancer by the needle*, NEWSWEEK, June 4, 1956, 67).

prisoners were not adequately treated for pain.”⁶¹ In fact, prior to the early 1970s, “approximately 90% of all pharmaceutical research was conducted on prisoners.”⁶² Yet, the studies described above and other scandals, such as the Tuskegee experiment,⁶³ led the public to become wary of medical experimentation on institutionalized populations.⁶⁴ Consequently, the practice of research with prisoners in the United States began to come under increasing scrutiny in the 1960s.⁶⁵ Several states and the Federal Bureau of Prisoners took the drastic step of banning research on prisoners altogether, citing concerns of “exploitation, secrecy, danger and the impossibility of obtaining informed consent.”^{66, 67}

In 1987, perhaps also in response to public concerns about exploitation, the American Correctional Association (“ACA”), an association that develops standards for accreditation for

⁶¹ Lawrence O. Gostin, *Biomedical Research Involving Prisoners: Ethical values and legal regulation*, 297 JAMA 737-740, 737 (2007).

⁶² *Id.*

⁶³ Amy L. Fairchild & Ronald Bayer, *Uses and Abuses of Tuskegee*, 284 SCIENCE 5416, 919-921, at 919 (May 7 1999) (Beginning in 1932, the United States Public Health Service (PHS) conducted a forty-year study of the long-term effects of syphilis. The PHS drew its subjects from poor African-American men afflicted with the disease, but failed to inform any of the 399 participants about their diagnosis, the possibilities for treatment, or what they could do to prevent transmitting the disease to others. When the study began, the available treatments were toxic and of questionable efficacy. However, in 1947, treatment by penicillin became the standard of care to cure the diseases. The researchers continued with the study in order to obtain data they knew they could not obtain otherwise, and even thwarted efforts by the study participants to obtain treatment. In 1972, the story was leaked to the press, and the study was finally terminated.)

⁶⁴ Hornblum, *supra* note 57, at 1437.

⁶⁵ NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS, RESEARCH INVOLVING PRISONERS, at 3 (1976), *as reprinted in* 42 Fed. Reg. 3076-77 (1977) [hereinafter REPORT].

⁶⁶ Gostin, *supra* note 58, at 737. Additionally, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research was formed in the mid 1970s to make recommendations for research regulations. The National Commission developed recommendations that ultimately resulted in regulations to protect children, pregnant women, and prisoners, codified at 45 C.F.R. 46 (2005).

⁶⁷ Significantly, there could be collateral harm from research on lethal injection being performed on death row prisoners. African American distrust of research and the medical profession is well-documented. See J. Wasserman, M.A. Flannery, J.M. Clair, *Raising the Ivory Tower: The Production of Knowledge and Distrust of Medicine Among African Americans*, 33 J. OF MED. ETHICS 177-180, 177 (2007). Additionally, African Americans are disproportionately represented on death row. See, e.g., Amnesty International, (“While [African Americans] make up 12 per cent of the national population, they account for more than 40 per cent of the country’s current death row inmates, and one in three of those executed since 1977.”); see generally U.S. DEPT OF JUSTICE, THE FEDERAL DEATH PENALTY SYSTEM: A STATISTICAL SURVEY (1988-2000) (2000). Thus, the fact that Departments of Correction are conducting research in which a greater burden of risk is being borne by African American defendants may exacerbate the distrust that many African Americans feel towards research and the practice of medicine.

departments of correction across the country, ratified a mandatory standard that prohibits the use of prisoners for medical, pharmaceutical, or cosmetic experimentation.⁶⁸ This standard was last reviewed and amended in 2003.⁶⁹ Accreditation by the ACA depends upon compliance with ACA standards, which suggests that in order to receive ACA accreditation, state Departments of Correction would have to adopt this standard prohibiting medical, pharmaceutical, or cosmetic research.⁷⁰

IV. STATE-BY-STATE ANALYSIS OF LETHAL INJECTION REFORM AND POST-RESEARCH REGULATIONS

A. CALIFORNIA

On December 15, 2006, Judge Jeremy Fogel of the Northern District of California determined that “California’s lethal-injection protocol—as actually administered in practice—create[s] an undue and unnecessary risk that an inmate will suffer pain so extreme that it offends the Eighth Amendment.”⁷¹ In particular, the court noted that “anomalies in six execution logs raise substantial questions as to whether certain inmates may have been conscious when pancuronium bromide or potassium chloride was injected.”⁷² In general, the court found that the protocol lacked “reliability and transparency.”⁷³ Judge Fogel also concluded that the system

⁶⁸ American Correctional Association, A.C.A. Standard #4-4402 (January 2003, 4th ed.). This is a mandatory standard. *See* A.C.A. Policy, http://www.aca.org/government/policyresolution/view.asp?ID=38&origin=results&QS='PoliciesAndResolutionsYMGHFREName=research&reversesearch=false&viewby=50&union=AND&startrec=1&top_parent=360.

⁶⁹ *Id.*

⁷⁰ American Correctional Association, Explanation of How to Seek Accreditation, *available at* <http://www.aca.org/standards/seeking/> (last visited Mar. 23, 2007).

⁷¹ *Morales v. Tilton*, 465 F. Supp. 972, 974 (N.D. Cal. 2006). Judge Fogel previously denied a stay in the case, but required that medical professionals trained in anesthesia be present at the execution. This was appealed, and the Ninth Circuit further required that these medical professionals intervene and aid with the execution in the event something went wrong. In response, the American Medical Association issued a statement that it would be unethical for physicians to participate in the administration of lethal drugs during an execution. Because no physicians could be found to participate in the execution after this directive, *Morales*’ execution was effectively stayed indeterminately. The December 15th ruling has suggested an approach the state can take to reform the lethal injection system, and the state has subsequently devised a new protocol attempting to comply with the court’s ruling.

⁷² *Id.* at 980.

⁷³ *Id.* at 981.

could be fixed,⁷⁴ and directed the state to revise its procedures and correct the flaws in its lethal injection system.

The court explicitly deemed the state’s prior attempts to reform its lethal injection protocol inadequate. Previously, the state had “tweaked” the protocol by adjusting the dosages of the three drugs in the lethal injection protocol and requiring the continuous infusion of sodium thiopental into an inmate throughout the procedure.⁷⁵ The court was particularly troubled by the fact that the changes were not systematic, and that the parties making the changes did not consider several important issues, including the training of the members of the execution team, the administration of drugs, and monitoring or preparation of adequate execution logs and other records.⁷⁶

Aside from these procedural deficiencies, the court found the previous protocol inadequate because the record before the court was “replete with evidence that in actual practice [the protocol] does not function as intended.”⁷⁷ The court required the Governor’s office carefully revise the lethal injection procedures by undertaking:

a thorough review of the lethal-injection protocol, including, *inter alia*, the manner in which the drugs are injected, the means used to determine when the person being executed has lost consciousness, and the quality of contemporaneous records of executions, such as execution logs and electrocardiograms, likely will be necessary. To be meaningful, such a review may require consultation with independent experts and with other jurisdictions, and it must be undertaken with openness to the idea of making significant improvements in the “infrastructure” of executions.⁷⁸

The court additionally suggested that the state could modify the protocol such that it requires the administration of an anesthetic agent alone in sufficiently large doses to cause death.⁷⁹

⁷⁴ *Id.* at 977.

⁷⁵ *Id.* at 979.

⁷⁶ *Id.*

⁷⁷ *Id.* at 979.

⁷⁸ *Id.* at 975.

⁷⁹ *Id.* at 983-84.

On May 15, 2007, the State of California responded with a revised operational procedure for execution by lethal injection. Under its own terms, the procedure is to “be reviewed and/or revised annually in the month of June or at additional times as needed.”⁸⁰ The procedure provides “the direction and process for execution by lethal injection,” and cites California Penal Code Section 3604(a), which permits the Department of Corrections to specify “the substance or substances to be injected in a lethal quantity sufficient to cause death.”⁸¹ The statute does not specify what these substances are, the order in which they should be injected, or the appropriate doses. Presumably, the Department of Corrections may change the procedure at any time without legislative amendment. More recently, a Marin County Superior Court has held that the state of California must comply with the Administrative Procedures Act and publish its lethal injection protocol to obtain public comment.⁸²

Turning to the features of California’s proposed revised lethal injection protocol at issue here, the protocol designates the Associate Warden of the Specialized Housing Division as the Lethal Injection Team Administrator, who is assigned with the bulk of the managerial and other duties.⁸³ Additionally, the procedure describes a new lethal injection facility that is under construction in the California State Prison at San Quentin.⁸⁴ The procedure creates teams of prison officials responsible for security, intravenous access, infusion, and record keeping.⁸⁵ It also sets minimal criteria for determining the composition of these teams, such as excluding

⁸⁰ San Quentin Operational Procedure 0-770-1 (May 15, 2007) at 1, <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/California/Morales/Morales%20Dist%20Ct/2007.05.15%20protocol%20review.pdf> (last visited Sept. 25, 2007) [hereinafter May 2007 Procedure].

⁸¹ *Id.* at 2.

⁸² Weinstein H. Judge bars new plan for executions. *Los Angeles Times*. November 1, 2007:B3. Incidentally, Judge Fogel has also stayed the proceedings in *Morales*, pending the outcome of the Supreme Court litigation. *See Morales v. Tilton*, No. 06-00219 (N.D. Cal. Nov. 5, 2007) (Order granting parties’ joint request to vacate case management schedule).

⁸³ *Id.* at 2.

⁸⁴ *Id.* at 3.

⁸⁵ *Id.* at 9.

individuals who have disciplinary infractions on their records from participating in executions.⁸⁶ The protocol also mandates lethal injection simulation on a monthly basis.⁸⁷ This regular training is designed to identify “[p]otential problems and recommendations for avoidance or resolution.”⁸⁸

The record-keeping and documentation requirements for the protocol are extensive. An individual designated as the litigation coordinator “is responsible for the security of all documents generated prior to, during, and after the Lethal Injection process.”⁸⁹ In fact, “[e]ach element of the Lethal Injection Protocol will be documented by a member of the Record Keeping Team.”⁹⁰ Immediately after an execution has been conducted, the Lethal Injection Team Leader must fill out an execution report, and each team member must document his or her “actions and observations during the execution.”⁹¹ Logs are to be kept by the teams responsible for security, the intravenous lines, infusion, and the emergency operations center.⁹² The associate warden, in the Specialized Housing Division, is tasked with referring the inmate for a “vein assessment to determine the size, location, and resilience of the veins in the inmate’s anticubital [sic] areas.”⁹³ The protocol also instructs that alternative insertion sites such as the forearm, wrist, back of the hand, top of the foot, and ankle, lower leg, or other appropriate locations may be considered if the forearm is not an appropriate injection site.⁹⁴ The associate warden must schedule “[d]aily training and preparedness exercises on each of the three days prior to the execution,”⁹⁵ and, in concert with the Lethal Injection Team Leader, must obtain the necessary chemicals.⁹⁶ The

⁸⁶ *Id.* at 9.

⁸⁷ *Id.*

⁸⁸ *Id.* at 12.

⁸⁹ *Id.* at 14; *see also id.* at 49 (“The Litigation Coordinator will (a) Assemble all appropriate reports and maintain the Master Execution File of records regarding the execution in the Litigation Coordinator’s office.”)

⁹⁰ *Id.*; *see also id.* at 19.

⁹¹ *Id.* at 15.

⁹² *Id.* at 16.

⁹³ *Id.* at 23. “Antecubital” refers to the “inner or front surface of the forearm.” *See* Merriam-Webster Medical Dictionary, *available at* <http://www2.merriam-webster.com/cgi-bin/mwmednlm?book=Medical&va=antecubital>.

⁹⁴ May 2007 Procedure, *supra* note 80, at 24.

⁹⁵ *Id.* at 36.

⁹⁶ *Id.* at 38.

protocol does not appear to state how many hours before an execution the inmate's last meal will be served.⁹⁷

The administration of the injection itself is governed by a unique procedure, one which does not describe any basis in standard medical practice or mention any evidence supporting the effectiveness of the procedure. The procedure involves two trays of eight color-coded syringes, one primary tray and one back-up tray.⁹⁸ A record keeper must observe and document the preparation of the cocktail of drugs.⁹⁹ The Intravenous Team ensures that the restraints placed on the inmate do not interfere with inserting the catheters, and then instructs a member of the team in the infusion room to initiate the IV drip.¹⁰⁰ Further, a member of the Intravenous Team has the responsibility of assessing the inmate's consciousness throughout the execution from within the execution room.¹⁰¹ Two intravenous catheters are to be inserted, one of which is designated as the primary catheter.¹⁰² The chemicals on the primary tray are to be injected into the inmate through the primary catheter.¹⁰³

The process starts with the insertion of syringe #1, which is a 60 cubic centimeter syringe containing 1.5 grams of sodium thiopental.¹⁰⁴ A member of the record keeping team then begins a ten-minute countdown.¹⁰⁵ In the meantime, a member of the intravenous team assesses the inmate by "brush[ing] the back of his/her hand over the condemned inmate's eyelashes, and speak[ing] to and gently shak[ing] the condemned inmate."¹⁰⁶ If the inmate is unresponsive, then he is deemed to be unconscious.¹⁰⁷ Once this determination is made, another 1.5 grams of sodium

⁹⁷ *Id.*
⁹⁸ *Id.* at 42.
⁹⁹ *Id.*
¹⁰⁰ *Id.*
¹⁰¹ *Id.*
¹⁰² *Id.* at 47.
¹⁰³ *Id.*
¹⁰⁴ *Id.* at 47.
¹⁰⁵ *Id.*
¹⁰⁶ *Id.* at 47-48.
¹⁰⁷ *Id.* at 48.

thiopental is injected into the inmate.¹⁰⁸ Subsequently, a saline flush is administered, and at this point, the inmate’s consciousness is re-assessed by the same eyelash-brushing and shaking method.¹⁰⁹ If the inmate is determined to be conscious, the injection through the primary catheter is discontinued, and the sequence is repeated through the back-up catheter using the materials on the back-up tray.¹¹⁰ If the member of the intravenous team determines that the inmate is unconscious, the chemicals designed to cause death are administered.¹¹¹ First, 50 milligrams of pancuronium bromide (the chemical that causes paralysis) are injected.¹¹² Then another saline flush is administered, and two doses of 100 ml of potassium chloride are administered.¹¹³ Throughout this process, team members are required to document their observations.¹¹⁴ If the inmate is still alive after being injected with all of the chemicals, the process is restarted with the chemicals from the back-up tray.¹¹⁵ Finally, after the execution, the Intravenous Team is required to “crimp closed and disconnect all intravenous lines,” but not to remove them; the lines are to be left in place in case the Marin County Coroner is required to review them.¹¹⁶

There are no dramatic differences between this protocol and the previous protocols—the same chemicals are used, and in the same sequence, but in slightly different amounts. The new protocol requires a larger dose of sodium thiopental than the protocol developed in March 6, 2006, but a smaller dose than was used in the 2003 version of the protocol, a larger dose of pancuronium bromide, and less potassium chloride.¹¹⁷ Significantly, these attempts to modify,

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 49.

¹¹⁷ Compare May 2007 Procedure, *supra* note 80, at 1 with San Quentin Operational Procedure 0-770-1 (March 6, 2006) at 25 (requiring the injection of 6.5 gm. sodium thiopental, 40 mg. pancuronium bromide, and 240 m.Eq. potassium chloride). See also San Quentin Operational Procedure 0-77901 (June 13, 2003) at 26 (requiring the injection of 5.0 gm. sodium thiopental, 50 mgm. per 50 cc. pancuronium bromide, and 50 ml/Eq potassium chloride),

reform, and fix California’s lethal injection protocol contravene a provision of the California Penal Code, which provides that “no biomedical research shall be conducted on any prisoner in this state.”¹¹⁸

Principles of statutory construction guide courts in the application and interpretation of statutes. A court must first “look to the language of the statutes, giving the words their usual and ordinary meaning.”¹¹⁹ “If the words are unambiguous, ‘we presume the lawmakers meant what they said, and the plain meaning of the language governs.’”¹²⁰ To determine whether lethal injection procedures would be prohibited under the California Penal Code, courts applying these principles to the penal code sections governing research with prisoners would first examine whether the meaning of the statutory text is ambiguous. The statutory language is unambiguous in its prohibition of biomedical research on all prisoners in the state of California.

Legislative intent is also consistent with this interpretation. Until 1985, the statute prohibited biomedical research performed “without the informed consent of the prisoner”, which is a much more permissive approach to research; under this language, some biomedical research would be allowed as long as the prisoner entered into the study voluntarily.¹²¹ The legislators deleted this phrase in 1985, changing their relatively permissive stance on research to a prohibition with only two limited exceptions.¹²² Additionally, one limited exception that remained in the law in 1985 was repealed in 1995.¹²³ Courts presume “that the Legislature by deleting an express provision of a statute intended a substantial change in the law.”¹²⁴ The

[http://www.law.berkeley.edu/clinics/dpclinic/Lethal%20Injection%20Documents/California/Morales/Morales%20Dist%20Ct.Cp/Ex%20A%20to%20TRO%20motion%20\(Procedure%20No.%20770\).pdf](http://www.law.berkeley.edu/clinics/dpclinic/Lethal%20Injection%20Documents/California/Morales/Morales%20Dist%20Ct.Cp/Ex%20A%20to%20TRO%20motion%20(Procedure%20No.%20770).pdf)

¹¹⁸ CAL. PENAL CODE § 3502 (2007).

¹¹⁹ Roland v. Superior Court, 124 Cal. App. 4th 154, 162 (2004) (citing People v. Lawrence, 25 Cal. 4th 219, 230-31 (2000)).

¹²⁰ *Id.* (quoting Day v. City of Fontana, 25 Cal. 4th 268, 272 (2001)).

¹²¹ CAL. PENAL CODE § 3502 (2007) (1985 Amend. notes).

¹²² *Id.*

¹²³ *Id.* This exception permitted research on wards of the state with regard to nutritional supplements, such as vitamins.

¹²⁴ People v. Dillon, 668 P.2d 697, 712 (Cal. 1983) (quoting People v. Valentine, 169 P.2d 1, 14 (Cal. 1946) and citing People v. Schmel, 126 Cal. Rptr. 317, 319 (Cal. Ct. App. 1975)).

legislature's deletion of these exceptions to the statute therefore reflects its intention to make the statute more protective of prisoners and the prohibition on research more absolute.¹²⁵

In 1989, the legislature further modified the statute to ensure that prisoners were not prevented from accessing medically-indicated drugs or treatments.¹²⁶ The legislature added Penal Code section 3502.5, under which physicians may provide prisoners with medically-indicated drugs that are only available through research or that are considered investigational new drugs.¹²⁷ However, the drug must be in the patient's best medical interest, and the patient's informed consent is necessary.¹²⁸ The legislature amended the statute upon finding that, "state law designed to protect prisoners from inappropriate medical experimentation has had the unintended effect of preventing prisoners from having access to drugs or treatments which might be required for good medical care."¹²⁹ To avoid this outcome, the legislature created an exception under which an experimental drug may be provided strictly for the purpose of treating a patient who has a medical need for that drug. Thus, this modification reflects an important distinction drawn by legislators between allowing the use of an experimental intervention for an individual prisoner's benefit (or the provision of research as treatment), and prohibiting the conduct of biomedical research for other purposes, including to collect data for the benefit of society.

Turning to the language used in the statute itself, biomedical research is defined as "research relating to or involving biological, medical, or physical science."¹³⁰ Thus, the term "biomedical" broadly encompasses scientific investigation, and specifically refers to medical

¹²⁵ See, e.g., *People v. Corey*, 581 P.2d 644, 648 (Cal. 1978) (concluding that by deleting an statutory exception for peace officers engaged in part-time patrol for private employers, the Legislature intended that the statute should apply broadly to all police officers, regardless of whether they were engaged in public or private employment at the time of the violation); *Krikorian v. Barry*, 242 Cal. Rptr. 312, 318 (Cal. Ct. App. 1987) (determining that the deletion of a qualification regarding mandatory reporters of child abuse "evidences a legislative intention to grant absolute immunity to persons required to report suspected cases of child abuse").

¹²⁶ CAL. PENAL CODE § 3501 (2007) (1985 Amend.).

¹²⁷ CAL. PENAL CODE § 3502.5 (2007) (1989 Amend.).

¹²⁸ CAL. PENAL CODE § 3502.5 (2007) (1989 Amend. notes).

¹²⁹ *Id.*

¹³⁰ CAL. PENAL CODE § 3500 (2007).

research. The term “research” refers to “a class of activities designed to develop or contribute to generalizable knowledge such as theories, principles, or relationships, or the accumulation of data on which they may be based, that can be corroborated by accepted scientific observation and inferences.”¹³¹ Furthermore, a “research protocol” is “a formal document setting forth the explicit objectives of a research project and the procedures of investigation designed to reach those objectives.”¹³² The plain language of the statute therefore suggests that an activity would be prohibited if it relates to medical science; results in the production of a formal document that provides details, parameters, and the purposes of the activity; has explicit objectives to develop or contribute to knowledge that can be applied generally; and is designed to reach those objectives.¹³³

The revised lethal injection protocol developed by the state of California clearly shares these features of research. First, it involves medical science in that it requires the injection of a combination of drugs in order to cause the cessation of bodily functions and ultimately, death. Second, it is designed to contribute to generalizable knowledge by developing procedures that can be used to execute future inmates within constitutional parameters. The protocol’s objective is “to establish appropriate guidelines for the execution of condemned inmates in compliance with the laws of the State of California and the United States.”¹³⁴ More specifically, the protocol is an attempt to reform the previous lethal injection protocol by delineating new procedures for the “care, treatment, and management of condemned inmates,” “for the selection, training, and oversight of the Lethal Injection Team,” “specific duties and responsibilities of personnel,” and

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Compare id.* (describing and prohibiting biomedical research) with Cal. Penal Code § 3501 (2007) (describing and permitting behavioral research). In section 3500(a), “behavioral research” is defined as “studies of human behavior, emotion, adaptation, conditioning, and response in a program designed to test hypotheses through the collection of objective data.”

¹³⁴ May 2007 Procedure, *supra* note 80, at 1.

“[t]o ensure direct supervision and managerial oversight of the Lethal Injection process.”¹³⁵

Thus, the changes in the protocol are designed to create procedures that can work for the lethal injection process as it is applied to future inmates and in accord with the law. In other words, the protocol is designed as an attempt to codify generalizable knowledge about the lethal injection process that can make the process effective and legal for all inmates who undergo it. Yet the method by which this reform is occurring offers no guarantee of success and relies on untested elements that may or may not work. Moreover, the protocol itself anticipates that it will work imperfectly as it is subject to revision at least annually, but perhaps more often than that.

The elements of the protocol that are still being tested include: (1) the presence of non-medical professionals; (2) the administration of drugs in particular amounts, in a particular combination, and within a certain amount of time after eating; and (3) the conditions that inmates may have and how the protocol will be modified in response.¹³⁶ Moreover, the protocol is designed to reach its objectives by requiring massive amounts of data-gathering and at least annual revision of its terms.

One untested element of California’s lethal injection protocol is the administration of euthanasia by non-medical professionals. The Department of Corrections is testing novel methods designed to allow non-medical professionals to administer medical procedures safely and effectively. Judge Fogel stated a preference for a medical professional to administer the anesthesia and be involved in the administration of lethal injection. However, because the American Medical Association, the American Nurses’ Association, the American Society of Anesthesiologists, and the National Commission on Correctional Health Care have propounded ethical guidance that opposes the participation of their members in executions,¹³⁷ medical

¹³⁵ *Id.*

¹³⁶ Additionally, the State of California has built a new lethal injection facility at San Quentin that is meant to correct some of the problems that arose in the past. *See id.* at 3. This may be another experimental element of the protocol.

¹³⁷ Roko, *supra* note 6, at 2799-2800.

professionals who are willing to assist with lethal injection have become very difficult to find.¹³⁸ Therefore, Judge Fogel noted that non-medical professionals and those who have not received formal medical training may be able to administer lethal injection. The revised protocol involves methods for administering lethal injection such as having two trays of injections that are color-coded and designed to be administered in order, and specifying that the inmate's eyelashes be brushed and that he be gently spoken to and shaken—methods that seem to be tailored to a non-medical professional. Additionally, these procedures are to be practiced at regular intervals and revised as needed.

By contrast to the minimal requirements placed on non-medical professionals monitoring an inmate's consciousness, the American Society of Anesthesiologists has rigorous standards for basic anesthetic monitoring.¹³⁹ These basic requirements include that qualified anesthesia personnel must be present and the patient's oxygenation, ventilation, circulation, and temperature must be continually evaluated.¹⁴⁰ The presence of qualified anesthesia personnel is a significant protection for patients undergoing anesthesia because to be qualified requires years of training and experience.¹⁴¹ The novel training of non-medical professionals by the California Department of Corrections to perform medical procedures in a safe and effective fashion does not appear to be based on evidence or experience of training medical professionals, and is set to be revised at least annually. Without evidence to believe that non-medical professionals will be able to perform these tasks safely and effectively, the development of these procedures will necessarily involve a process of biomedical research, under the statutory definitions.¹⁴²

¹³⁸ *Id.* at 2800.

¹³⁹ *See generally* American Society of Anesthesiologists, Standards for Basic Anesthetic Monitoring (Oct. 25, 2005), <http://www.asahq.org/publicationsAndServices/standards/02.pdf>.

¹⁴⁰ *Id.* at 1.

¹⁴¹ *See* American Society of Anesthesiologists, Patient Education Brochure: The Medical Specialty of Anesthesiology, <http://www.asahq.org/patientEducation/specialty.htm> (last visited Aug. 28, 2007).

¹⁴² *See* CAL. PENAL CODE § 3500 (2007).

The dosages of the drugs being administered are also experimental. Contrary to Judge Fogel’s recommendation following the extensive evidentiary hearings he held on the matter,¹⁴³ the Department of Corrections modified the amounts of drugs in a seemingly ad-hoc fashion.¹⁴⁴ The new protocol does not offer an explanation of why these dosage amounts were chosen, nor does it cite any authority or evidence for this decision.¹⁴⁵ Additionally, the new protocol does not indicate how long after eating an inmate could be executed, despite the fact that the consumption of food too soon before the administration of an anesthetic can cause an inmate to choke.¹⁴⁶ Although the protocol makes provisions for medical examinations of the prisoners and various sites on which injections may occur, it does not specify procedures for inmates who present particular physical conditions that may make it difficult to administer an injection. “[P]hysicians have particular difficulty finding suitable veins among individuals with diabetes, heavily pigmented skin, obesity, or extreme muscularity, as well as the very nervous or drug users. Nearly one quarter of prison inmates’ veins may be inaccessible ‘because they are deep, flat, covered by fat or damaged by drug use.’”¹⁴⁷ Given these uncertainties, and the fact that it is unclear how the California Department of Corrections made the determination that these procedures would be safe and effective for inmates, it is possible, if not probable, that the administration of these procedures will lead to difficulties with executions in the future. It appears that the Department of Corrections is prepared for such an eventuality and plans to revise the protocol at least annually if problems arise. The test subjects who will be experiencing firsthand these hiccups and deficiencies in the protocol are the inmates who will be executed under its direction.

¹⁴³ Morales v. Tilton, 465 F. Supp. 972, 983-84 (N.D. Cal. 2006) (noting that a large enough dose of the anesthetic would likely be the most effective and painless way to cause death).

¹⁴⁴ See *supra* note 14.

¹⁴⁵ See *supra* note 80, at 47-48.

¹⁴⁶ Denno, *supra* note 17, at 123 (“[I]f the inmate ingests food or drink six-to-eight hours before the execution, the inmate may choke or gag when sodium thiopental is injected.”)

¹⁴⁷ *Id.* at 109-110 (quoting Thomas O. Finks, *Lethal Injection: An uneasy alliance of law and medicine*, 4 J. LEGAL MED. 383, 397 (1983)).

Furthermore, large amounts of data are to be gathered under the new protocol. Given the long history of problems with executions in general¹⁴⁸ and lethal injections in particular, courts seem to be anticipating that it will take some time to perfect lethal injection, and that record-keeping will assist in the process. California's revised procedure also reflects these concerns, as it provides for a Litigation Coordinator, intravenous lines being kept in place after an execution is over, and logs and record-keeping by members of the various teams involved in the execution. Perhaps keeping detailed records of an execution could create some accountability that may, in turn, encourage more responsibility by the execution team, but it could also detract from the attention that a member of the execution team pays to an inmate during an execution. In the event that something does go wrong, the fact that detailed records were kept would do nothing to help the inmate who was suffering, and the need for record-keeping could further cause a delayed response in case something goes wrong. Even assuming that one person was designated to be the record-keeper, that person would be prevented from responding and helping the team address the crisis at hand. Critically, the fact that the records are kept by the Litigation Coordinator suggests that the goal of this record-keeping has to do with future legal challenges. To demonstrate to a court that a procedure has been developed that is constitutional, effective, and generalizable to other inmates, records of individual executions are necessary. The detailed record-keeping is a requirement with an eye to future litigation and future refinement of the lethal injection protocol, and is not merely in place to ensure that any individual execution avoids the risk of cruel and unusual punishment.¹⁴⁹ These records will help determine what new problems arise and how to

¹⁴⁸ See Radelet, *supra* note 38.

¹⁴⁹ Although the state of California is attempting to keep elements of the new protocols and changes secret, *see, e.g.,* Morales v. Tilton, No. 06-00219, (N.D. Cal. Jan. 16, 2007) (state motion for a protective order for the deliberative process of producing a new lethal injection protocol), which would prevent the public dissemination of information that typically constitutes research, it is not clear that this secrecy is constitutional. However, there is a historic right of access to judicial proceedings that requires some degree of publicity for criminal proceedings. In *Richmond Newspapers v. Virginia*, the United States Supreme Court found that “[t]o work effectively, it is important that society’s criminal process ‘satisfy the appearance of justice,’ and the appearance of justice can best be provided by allowing people to observe it.” 448 U.S. 555, 571-72 (1980). Moreover, the Court noted that, the First Amendment disfavors governmental limitations on the dissemination of information. 448 U.S. at 575-76 (“[T]he First

fix them, thereby enabling the Department of Corrections to utilize the experiences of prisoners whose executions have not gone as planned to improve the process. Thus, this data-gathering is designed to take the knowledge from the use of untested procedures on inmates, codify it, and use it to generalize and generate new and improved procedures that can be defended in the context of litigation, which can be accurately described as research.

The one exception to the California Penal Code's prohibition on research with prisoners does not apply to the process of reforming lethal injection. The exception provides that prisoners may have access to experimental treatment when a "physician determines that access to that drug is in the best medical interest of the patient, and the patient has given informed consent."¹⁵⁰ In interpreting this statute, its plain language seems to indicate that a drug may be given to a prisoner if it is in the prisoner's best interests. If lethal injection reform is in the prisoner's best medical interests because it improves the process of lethal injection, at first glance, it seems possible that this statutory exception would cover lethal injection reform. However, it strains the notion of treatment to allow the experimental provision of a drug that causes death to be considered in the best interests of the patient. Moreover, legislative history counsels against such an interpretation of the statute. The legislature clarified that in crafting this exception, "it is the intent of the Legislature by this act to provide prisoners access to certain investigational drugs or

Amendment goes beyond protection of the press and the self-expression of individuals to prohibit government from limiting the stock of information from which members of the public may draw." (quoting *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 783 (1978)). In the case of *Globe Newspaper Co. v. Superior Court*, the Court allowed some restrictions on public access to trial proceedings provided that the state demonstrate a compelling reason for secrecy and that the closure of proceedings to the public is narrowly tailored to serving that compelling reason. 457 U.S. 596, 513 (1982). Additionally, the Ninth Circuit has explained that, "[i]ndependent public scrutiny - made possible by the public and media witnesses to an execution - plays a significant role in the proper functioning of capital punishment. An informed public debate is critical in determining whether execution by lethal injection comports with 'the evolving standards of decency which mark the progress of a maturing society.'" *Cal. First Am. Coalition v. Woodford*, 299 F.3d 868, 876 (9th Cir. 2002) (quoting *Trop v. Dulles*, 356 U.S. 86, 101 (1958)). The constitutional considerations favoring public access and scrutiny regarding capital punishment weigh in favor of ensuring public access to information about lethal injection protocols to enable appropriate public scrutiny. Thus, the outcomes of the process of refining lethal injection protocols will likely be disseminated to the public, as research results typically are.

¹⁵⁰ CAL. PENAL CODE § 3502.5 (2007).

treatments on the same basis that they are made available to patients outside the prison setting.”¹⁵¹ Lethal injection is not made available to patients outside the prison setting even when patients are prepared to give their informed consent; voluntary active euthanasia is against the law in California and most other jurisdictions.¹⁵² Therefore, the exception for experimental treatment would not apply to lethal injection research on prisoners.

The California Penal Code therefore applies to prohibit the methods by which the California Department of Correction is attempting to reform its lethal injection procedures. The intent and letter of the statutory provisions in the California Penal Code are in accord here: prisoners should be protected from biomedical interventions that may expose them to excessive risk. One potential argument to the contrary is that the California Penal Code also provides acceptable methods for the punishment of death including “intravenous injection of a substance or substances in a lethal quantity sufficient to cause death, by standards established under the direction of the Department of Corrections.”¹⁵³ A court may find that these two sections should be harmonized, and the intent of the legislature could not have been to prohibit lethal injections. If a court were to make such a finding, however, it would have to redefine the intent of the legislature narrowly so as to avoid a particular outcome, and ignore the more general intent of the legislature to prevent risky biomedical experimentation on prisoners. Furthermore, what is at issue here is the attempt by the California district court to reform lethal injection procedures (not the statute permitting execution by lethal injection. The only way to fix this broken system is not permitted under the California Penal Code.

¹⁵¹ *Id.*

¹⁵² CAL. PENAL CODE § 401(2007) (“Every person who deliberately aids, or advises, or encourages another to commit suicide, is guilty of a felony.”); *see also* Wash. v. Glucksberg, 521 U.S. 702, 716 (U.S. 1997) (noting that most Western democracies have a blanket prohibition on active euthanasia and that California has banned assisted suicide since 1974); *Vacco v. Quill*, 521 U.S. 793, 796 (U.S. 1997) (noting that “[i]n New York, as in most States, it is a crime to aid another to commit or attempt suicide”).

¹⁵³ CAL. PENAL CODE § 3604 (2007).

One objection to this interpretation of California's Penal Code is that if the intent of the prohibition on research with prisoners is to prevent exploitation of prisoners, this is not a concern that is relevant to the practice of lethal injection. The worries about lethal injection are whether it constitutes cruel and unusual punishment under the Constitution, not whether the method of administering lethal injection takes unfair advantage of some prisoners for the benefit of other people. Again, however, the concern regarding the *administration* of lethal injection is not the relevant concern here. It is the attempt to *reform* lethal injection that may well be exploitative of some inmates for the benefit of other people. The first few inmates who receive lethal injections after the protocol is modified will be test subjects for novel procedures.

In sum, although Judge Fogel's ruling is premised on the belief that the lethal injection protocols can be fixed and is designed to minimize the risks associated with lethal injections, the fact remains that because "individuals react differently to drugs and medicines, it is impossible for a court to determine in advance whether a particular inmate will suffer unnecessary pain during his execution by lethal injection."¹⁵⁴ Moreover, "[t]he state is also unable to test any proposed lethal injection procedures on human subjects to learn its effects with any certainty" in advance of trying out the new procedure on an inmate for the very first time.¹⁵⁵ The first few inmates to be executed under the revised protocol will be taking on risks related to an unknown and novel procedure with the hope that this procedure will be proven to be effective and constitutional. And therein lies the very problem that the California Penal Code seeks to prevent. Experimenting with dosages of (lethal) drugs on human subjects to determine what the harmful side effects might be, what types of problems might arise, and whether the drugs are efficacious in this combination and in different types of people is prohibited under the California Penal Code.

¹⁵⁴ Ellen Kreitzberg & David Richter, *But Can it Be Fixed? A Look at Constitutional Challenges to Lethal Injection Executions*, 47 SANTA CLARA L. REV. 445, 477 (2007).

¹⁵⁵ *Id.*

The process of conducting research involves determining *how* biomedical interventions can be safely administered. In its absence, the California Department of Correction is still being required to find a way to minimize the risks of the administration of lethal injection, to design a protocol for its administration, to publish this protocol, and ultimately, to administer this new protocol in prisoners and document its effects. Therefore, the problem that the State of California cannot avoid is that the only way to improve the lethal injection protocol systematically and effectively, and to minimize the risk of improper administration of lethal injections, is to conduct research on prisoners.

B. FLORIDA

In Florida, after the dramatic problems that occurred during the execution of Angel Diaz, Governor Jeb Bush suspended executions by lethal injection and appointed a commission to determine what procedures can be implemented constitutionally; this commission recently issued a report with findings about the errors in the most recent execution and recommendations about how to improve the process.¹⁵⁶ The Florida commission produced a final report on March 1, 2007.¹⁵⁷ The commission was specifically asked to develop findings and conclusions regarding the errors that occurred during the execution of Angel Diaz in December of 2006,¹⁵⁸ and the members of the commission concluded that the lethal injection “protocols as written are insufficient to properly carry out an execution when complications arise.”¹⁵⁹

The Florida commission recommended that the Florida Department of Corrections (DOC) consider revising its protocols and specifically that the DOC, “[i]mplement written policies, practices, and procedures related to ensuring optimal supervision and management of every lethal injection procedure by the appropriate procedure,” and devise “a comprehensive,

¹⁵⁶ THE GOVERNOR’S COMMISSION ON ADMINISTRATION OF LETHAL INJECTION, FINAL REPORT WITH FINDINGS AND RECOMMENDATIONS (March 1, 2007), <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Florida/lethalinjectionfinalreport.pdf> (last visited Sept. 25, 2007).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 5.

¹⁵⁹ *Id.* at 8.

systematic procedure for ensuring that persons selected to perform these official duties related to carrying out lethal injections are suitably qualified.”¹⁶⁰ The commission further concluded that the DOC should “[d]evelop and implement procedures which require that any step or function which is required to be documented on a checklist;” “[d]evelop and implement procedures to monitor and document all stages of the lethal injection process;” ensure that one agent is present at executions who is responsible for “documenting and keeping a detailed log as to what occurs in the Chemical Room at a minimum of 30 second intervals;” and ensure that another agent is present in the Witness Room to keep a detailed a log of events in the “Death Chamber” at a minimum of 30 second intervals.¹⁶¹ Moreover, the commission made several recommendations for the development of procedures regarding access to the inmate’s veins, closed circuit monitoring of the inmate’s face and IV access points, and the administration of the lethal chemicals.¹⁶² The commission also suggested that the DOC “on an ongoing basis explore other more recently developed chemicals for use in a lethal injection execution with specific consideration and evaluation of the need of a paralytic drug like pancuronium bromide in an effort to make the lethal injection procedure less problematic.”¹⁶³

These recommendations, designed to improve the lethal injection procedure, required systematic modifications to the method of execution. The commission’s recommendation of ongoing exploration of the use of other chemicals suggests that this is an ongoing process of refinement and data-gathering. In particular, the gathering of large amounts of observational data required by the commission suggests that the application of the protocol to any given inmate will in part be a process used to gather information that can be used to improve the process for future executions.

¹⁶⁰ *Id.* at 9.

¹⁶¹ *Id.* at 10.

¹⁶² *Id.* at 11.

¹⁶³ *Id.* at 13.

Following these recommendations, the Florida Department of Corrections issued a new protocol for execution by lethal injection on July 31, 2007.¹⁶⁴ The new protocol requires that there be a primary executioner and a secondary executioner, and that team members be selected from certain categories of trained medical professionals, if necessary.¹⁶⁵ In order to ensure compliance with the procedure, extensive records are to be kept, including checklists that must be followed throughout and signed by the warden afterwards.¹⁶⁶ Two Florida Department of Law Enforcement officers are to be present at each execution, one of whom would sit in the Execution Booth; the other officer is to observe from the execution chamber.¹⁶⁷ Their purpose is to keep detailed logs of the procedure, with entries made at a minimum of two minute intervals.¹⁶⁸ The same three drug cocktail that is used by other states is required in the Florida protocol.¹⁶⁹ The record-keeping is also systematic, and the warden must sign a record of the execution and send it to the Secretary of State.¹⁷⁰ The Secretary of the Florida Department of Corrections is required to review the lethal injection procedure at least every two years, but more frequently if necessary.¹⁷¹ This review is to take into account medical literature, legal jurisprudence, and protocols and experience from other jurisdictions.¹⁷² The fact that a review and revision of the protocol may occur at least as often as once every two years suggests that Florida is gathering data from its experience of lethal injection and using this data to develop knowledge about how to conduct lethal injection more humanely.¹⁷³

¹⁶⁴ Florida Department of Corrections, Execution by Lethal Injection Procedures (July 31, 2007), <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Florida/DOC/August%201%202007%20Lethal%20Injection%20Protocol.pdf> (last visited Sept. 25, 2007).

¹⁶⁵ *Id.* at 4.

¹⁶⁶ *Id.* at 4.

¹⁶⁷ *Id.* at 5.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* at 6-7.

¹⁷⁰ *Id.* at 14.

¹⁷¹ *Id.* at 14.

¹⁷² *Id.*

¹⁷³ Lethal injection litigation in Florida circuit courts has suggested that there is a further need for modifications to the Department of Corrections' revised protocol. *State v. Lightbourne*, No. 81-170-CF-A-01 (Fla. Cir. Ct. July 31, 2007) (order granting temporary stay), *available at* <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Florida/Lightbourne/2007.07.31%>

The State of Florida prohibits medical, cosmetic or pharmaceutical experimental testing, and “any other health-related experimental procedure,” unless the procedure is necessary for treating the inmate when standard therapy is insufficient.¹⁷⁴ To interpret statutes such as these, Florida law provides that “when the language of the statute is clear and unambiguous and conveys a clear and definite meaning, there is no occasion for resorting to the rules of statutory interpretation and construction; the statute must be given its plain and obvious meaning.”¹⁷⁵ Florida’s prohibition on medical testing is clear and unambiguous, with only one exception designed to allow inmates to access therapies for which they have a medical need. The drafters of the statute used very general language, choosing the term “testing” instead of “research” or “experimentation,” which would describe more specific activities. Additionally, the prohibited activity can be medical, cosmetic, or pharmaceutical. Moreover, even if these three categories were insufficient to describe an activity that might involve experimentation with prisoners, the legislature added a final modifier by prohibiting “any other health-related experimental procedure.”

It is also important to note that, “where it is possible, courts must give full effect to all statutory provisions and construe related statutory provisions in harmony with one another.”¹⁷⁶ Applying this principle, the Florida Supreme Court has clarified that two related statutory provisions may still be in harmony so long as the enforcement of one provision does not render

[20Lightbourne%20Order.pdf](#); *but see* State v. Lightbourne, No. 81-170-CF-A-01 (Fla. Cir. Ct. Sept. 10, 2007) (order denying defendant’s all writs petition to declare Florida’s lethal injection procedure unconstitutional), *available at* <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Florida/Lightbourne/09.10.07.FL.1Lightbourne.orderofdenial.pdf>.

¹⁷⁴ FLA. ADMIN. CODE ANN. R. 4-4402 (“No offender in the custody of or under the supervision of the department will be utilized for medical, cosmetic or pharmaceutical experimental testing or any other health-related experimental procedure. This does not preclude individual treatment of an offender based on her/his need for a specific medical procedure that is not generally available.”) (4-4402, 4-ACRS-4C-20, Dept. of Corrections Procedure no. 207.001(12)).

¹⁷⁵ Holly v. Auld, 450 So. 2d 217, 219 (Fla. 1984) (quoting A.R. Douglass, Inc. v. McRainey, 137 So. 157, 159 (Fla. 1931)).

¹⁷⁶ Knowles v. Beverly Enters.-Fla., Inc., 898 So. 2d 1, 8 (Fla. 2004).

the other meaningless.¹⁷⁷ These principles of statutory construction may be relevant because Florida Statute section 922.105 provides that “[a] death sentence shall be executed by lethal injection, unless the person sentenced to death affirmatively elects to be executed by electrocution.”¹⁷⁸ As the court held in *Knowles v. Beverly Enterprises-Florida, Inc.*, however, the apparent conflict is not a reason to construe the statute in a manner other than its plain language suggests. Like the court concluded in *Knowles*, the application of the statute prohibiting research would not necessarily make the state’s ability to conduct lethal injection meaningless. Rather, the current approach taken by the state of Florida to reform the lethal injection protocol involves untested medical procedures that are to be tested on inmates who are on death row. The process of review required by courts and the governor has initiated a great deal of change in the system, and the Department of Correction now must develop new procedures designed to avoid the problems that the previous procedures faced. These procedures involve medical or pharmaceutical testing because they require the injection of a cocktail of drugs. The process by which these procedures are being improved will require systematically overhauling the current system and collecting data on the outcomes of the new system. Thus, this process of reform (and not the lethal injection statute itself) requires medical or pharmaceutical testing on inmates, and therefore, the process of reform violates Florida law.

C. OHIO

Fifteen inmates have joined a class action suit challenging the constitutionality of Ohio’s lethal injection procedure.¹⁷⁹ A three-judge panel in the Sixth Circuit Court of appeals ordered dismissal of the suit, finding it procedurally barred.¹⁸⁰ This ruling was upheld by an *en banc* panel, but the petitioners have filed a petition for certiorari at the United States Supreme

¹⁷⁷ *Id.*

¹⁷⁸ Fla. Stat. § 922.105 (2007).

¹⁷⁹ *Cooey v. Taft*, No. 04-1156 (S.D. Ohio Nov. 22, 2006) (order granting John Spirko’s motion to intervene and denying motion for preliminary injunction) at 1.

¹⁸⁰ *Id.* at 8.

Court.¹⁸¹ The district court stayed the case, but is allowing other inmates to join the suit.¹⁸² Additionally, another district court determined that it has jurisdiction to determine whether death can be precluded as a sentencing option in a particular case because lethal injection—the only method of execution permitted in Ohio—is unconstitutional.¹⁸³ All of this activity may be superseded, however, by the Supreme Court’s decision in *Baze v. Rees*.

In the meantime, Ohio has modified its lethal injection protocol.¹⁸⁴ Prompted by the ninety minutes that it took to complete Joseph Clark’s execution and concerns raised that Clark suffered through his execution,¹⁸⁵ the Ohio Department of Rehabilitation and Correction conducted a review of its lethal injection procedures.¹⁸⁶ The review did not involve any medical professionals, and the Board made the following five recommendations: (1) eliminating time limits for executions to reduce pressure on the execution team, (2) including three “hands-on” medical reviews of the prisoner prior to the execution, (3) “making every effort” to proceed with executions only when there are two intravenous (“I.V.”) lines inserted—one in each of the prisoner’s arms, (4) using a low pressure saline drip to keep the I.V. lines open, and (5) continuing to have staff observe the delivery of drugs through the I.V. lines.¹⁸⁷ The stated goal of these refinements was to “lessen the probabilities of the recurrence of the problems” that occurred in Clark’s execution.¹⁸⁸

The Ohio Department of Rehabilitation and Correction prohibits “medical, pharmaceutical, and/or cosmetic” research on prisoners unless it can be characterized as a

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *State v. Rivera*, No. 04-CR-065940 (Ct. Com. Pl. July 24, 2007) (order granting temporary stay), available at <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Ohio/Rivera/RiveraRipenessOrder072407.pdf>.

¹⁸⁴ Alan Johnson, Review leads to 5 ideas for ending execution errors, Columbus Dispatch, June 29, 2006, at <http://www.dispatch.com/dispatch/contentbe/dispatch/2006/06/29/20060629-D5-00.html>.

¹⁸⁵ *See supra* Part III (Recent Problems with Executions by Lethal Injection).

¹⁸⁶ *See id.*; *see also* Ohio Death Penalty Information, http://ohiodeathpenaltyinfo.typepad.com/ohio_death_penalty_inform/romell_broom/index.html (last visited Aug. 27, 2007) (search the blog for the text of the letter).

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

“treatment opportunity, rather than as participation in an experimental project.”¹⁸⁹ Moreover, the risks posed by the research “must be minimal or non-existent.”¹⁹⁰ By modifying the approach to execution by lethal injection, and in particular by changing to a low pressure saline drip, the Ohio Department of Correction and Rehabilitation is engaging in an experimental project, trying different medical approaches to develop a method that will not have the same problems as the previous method. Even so, the Department’s experimental project is not permitted under its own policies regarding research; it fails to provide adequate protection for the human subjects involved.

Ohio law requires courts to interpret statutes according to the plain meaning of the words used.¹⁹¹ “Unless words are otherwise defined or a contrary intent is clearly expressed, we give words in a statute their plain and ordinary meaning.”¹⁹² Because the Ohio Department of Correction and Rehabilitation does not define the terms it uses, there are no statutory definitions that allow for interpretation of the words beyond their plain meaning. In addition to explicit definition of terminology in a statute, if the court “ascertain[s] that an adherence to the plain and ordinary meaning of the word would defeat the legislative purpose in the enactment of the statute . . . the strict letter of an act must yield to its evident spirit and purpose.”¹⁹³ The Ohio Department of Rehabilitation and Correction states that prisoners under its jurisdiction “should not be used as a population of convenience;” provides exceptions where it would be of medical benefit to a prisoner to participate in research or would cause minimal, if any, harm; and furthermore

¹⁸⁹ Ohio Dept. of Rehabilitation & Correction, Human Subjects Research Review Process: Detailed description, http://www.drc.state.oh.us/web/hsrrc_review.htm (Mar. 31, 2006) (last visited Aug. 27, 2007) [hereinafter Human Subjects Research Review Description].

¹⁹⁰ *Id.*

¹⁹¹ For states with Department of Correction policies against research with prisoners, principles of statutory interpretation may seem to be inapplicable. However, because an Ohio court interpreting a Department of Correction policy did employ principles of statutory construction, in the interest of thoroughness, the analysis of Department of Correction policies in this paper incorporates principles of statutory interpretation. *See, e.g.,* Call v. Ohio Dep’t. of Rehab. & Corr., No. 06AP-1057, 2007 Ohio 2655, at *7 (Ohio Ct. App. 10th 2007) (upholding a lower court interpretation of a Department of Rehabilitation & Correction policy applying principles of statutory construction).

¹⁹² Hughes v. Ohio DOC, 868 N.E.2d 246, 250 (Ohio 2007) (internal citations omitted).

¹⁹³ Ohio Ass’n of Pub. Sch. Employees v. Twin Valley Local Sch. Dist. Bd. of Educ., 451 N.E.2d 1211, 1214 (Ohio 1983) (internal citations and quotations omitted).

prohibits payment to inmates for research participation in order to ensure that prisoners will not be coerced into being research subjects.¹⁹⁴ Thus, the Ohio Department of Rehabilitation and Correction has clearly expressed its intent to prevent the unfair treatment of prisoners, which is entirely consistent with an interpretation of the policy that blocks attempts to reform lethal injection that would constitute medical or pharmaceutical research on prisoners.

Ohio's revised lethal injection protocol incorporates novel elements such as three medical hands-on reviews of the prisoner before an execution, recommendations that two intravenous lines be inserted before an execution can proceed, using a low pressure saline drip to keep the intravenous lines open, and having these medical procedures performed by non-medical professionals who are following a protocol developed by committee members who are also not medical professionals. These refinements are meant to avoid future problems in executions by changing elements of the medical or pharmaceutical procedures involved. Developing new procedures such as these and creating a novel method for non-medical professionals to administer them involves medical or pharmaceutical experiments on prisoners to see how the protocol can be improved. Modifying medical protocols, testing these revised protocols on death row inmates, and all the while attempting to develop a system that will work in the future is a form of medical or pharmaceutical research on prisoners.

D. SOUTH DAKOTA

On August 29, 2006, the governor of South Dakota issued a stay of execution for a death row inmate, Donald Moeller, because the existing statute governing lethal injection had last been updated in 1984 and required a two-drug protocol (most states use a three-drug protocol that also incorporates potassium chloride).¹⁹⁵ In particular, the statute previously required that, “[t]he punishment of death shall be inflicted by the intravenous administration of a lethal quantity of an

¹⁹⁴ Human Subjects Research Review Description, *supra* note 187.

¹⁹⁵ Carson Walker, *First S.D. Execution Looms in Decades*, Associated Press Online, July 11, 2007; *see also Gov. Rounds Issues Statement on the Stay of Execution for Elijah Page*, S.D. STATE NEWS, available at <http://www.state.sd.us/news/printDoc.aspx?i=7722>.

ultra-short-acting barbiturate in combination with a chemical paralytic agent and continuing the application thereof until the convict is pronounced dead by a licensed physician according to accepted standards of medical practice.”¹⁹⁶

To remedy this problem, the South Dakota legislature recently amended section 23A-27A-32 to vest greater discretion in the warden to decide what combination of drugs he or she would use in a lethal injection protocol.¹⁹⁷ The new law states that, “The warden, subject to the approval of the secretary of corrections, shall determine the substances and the quantity of substances used for the punishment of death. An execution carried out by intravenous injection shall be performed by a person trained to administer the injection who is selected by the warden and approved by the secretary of corrections.”¹⁹⁸ Thus, the new law allows for the warden to create a new protocol and determine—in any manner of his choosing but subject to approval by the secretary of corrections—a cocktail of drugs to be administered as a lethal injection.¹⁹⁹ Moreover, this law indicates that the administration of lethal injection “in the manner required by this section may not be construed to be the practice of medicine.”²⁰⁰ On July 11, 2007, South Dakota executed Elijah Page pursuant to this new law.²⁰¹

The South Dakota Department of Health’s Correctional Health Services branch has a policy that was most recently revised on April 1, 2007.²⁰² The purpose of this policy is “[t]o protect inmates from being used in any research.”²⁰³ The policy states that, “The South Dakota Department of Health Correctional Health Care policy forbids any involvement or participation in

¹⁹⁶ S.D. CODIFIED LAWS § 23A-27A-32 (2007 amendment notes). This inconsistency was also challenged by inmate Donald Moeller in a habeas petition. *See Moeller v. Weber*, No. 04-4200, 2006 U.S. Dist. LEXIS 64761, at * 7 (S.D. S.D. Sept. 8, 2006).

¹⁹⁷ Monica Davey, *Execution in South Dakota, Delayed a Year by Debate on Method, is First in Six Decades*, N.Y. TIMES, July 13, 2007.

¹⁹⁸ S.D. CODIFIED LAWS § 23A-27A-32 (2007), available at <http://legis.state.sd.us/statutes/DisplayStatute.aspx?Type=Statute&Statute=23A-27A-32>.

¹⁹⁹ S.D. CODIFIED LAWS § 23A-27A-32 (2007 amendment).

²⁰⁰ *Id.* (emphasis added). Notably, research is expressly not the practice of medicine.

²⁰¹ Davey, *supra* note 195.

²⁰² South Dakota Department of Health, Correctional Health Services Policy P-I-07, “Medical and Other Research” (April 1, 2007), (on file with author).

²⁰³ *Id.*

medical or other research involving inmates. This includes direct as well as indirect research.”²⁰⁴ From its plain language, the policy serves as a broad prohibition on any type of research with prisoners. Furthermore, the intent of the policy is consistent with the plain language of the policy—the purpose states a general intention to prevent the use of prisoners in research.

The South Dakota Supreme Court has “repeatedly stated that when the terms of a statute are clear, certain and unambiguous in their meaning, it is the function of the court to give them effect and not to amend the statute to avoid or produce a particular result.”²⁰⁵ Additionally, the South Dakota Supreme Court has explained that:

While it is fundamental that we must strive to ascertain the real intention of the lawmakers, it is equally fundamental that we must confine ourselves to the intention as expressed in the language used. To violate the rule against supplying omitted language would be to add voluntarily unlimited hazard to the already inexact and uncertain business of searching for legislative intent.²⁰⁶

There is a long-established rule, however, that amendment of a statute reveals the intent of the legislature to narrow or broaden the terms of the statute and the rights that it grants.²⁰⁷ The South Dakota courts have clarified that where two statutes conflict, ambiguity may be created.²⁰⁸ “Ambiguity is a condition of construction, and may exist where the literal meaning of a statute leads to an absurd or unreasonable conclusion.”²⁰⁹ In such cases, courts turn to legislative intent to interpret the statutes at issue.²¹⁰

²⁰⁴ *Id.*

²⁰⁵ Matter of Sales Tax Refund Applications of Black Hills Power & Light Co., 298 N.W.2d 799, 802 (S.D. 1980) (superseded by statute as explained in Van Emmerik v. Montana Dakota Utils. Co., 332 N.W.2d 279, 281-82 (S.D. 1983)).

²⁰⁶ S.D. Subsequent Injury Fund v. Cas. Reciprocal Exch., 589 N.W.2d 206, 211 (S.D. 1999).

²⁰⁷ *Id.* at 210 (quoting In re Dwyer, 207 N.W. 210, 212 (S.D. 1926)).

²⁰⁸ Sales Tax Refund Applications, 298 N.W.2d 799, 802-03 (S.D. 1980) (superseded by statute as explained in Van Emmerik v. Mont. Dakota Utils. Co., 332 N.W.2d 279, 281-82 (S.D. 1983)).

²⁰⁹ *Id.*

²¹⁰ MGA Ins. Co., Inc. v. Goodsell, 707 N.W.2d 483, 487 (2005) (“There are instances when it is necessary to look beyond the express language of a statute in determining legislative intent. Most notably, when the language is ambiguous, unclear, or if confining ourselves to the express language would produce an absurd result.”)

Interpreting the plain language of the statute and intent of lawmakers leads to the conclusion that the legislature intended to vest a great deal of discretion in the warden regarding lethal injection protocols. Given that the Department of Correction has a policy prohibiting medical research, however, this policy binds the warden to refrain from performing medical research. Because the warden's discretion must be exercised in accordance with the policies of the Department of Correction, the apparent conflict of laws is not necessarily an actual conflict. The method of administration of lethal injection, and of reform of the system, should take account of the policy against biomedical research with prisoners. Not only should there be good evidence for the new protocol before it is implemented in prisoners, but subsequent approaches should be designed to prevent an individual inmate's suffering; not for the purpose of obtaining generalizable knowledge.

E. NORTH CAROLINA

In 2006, an inmate named Willie Brown challenged the constitutionality of North Carolina's lethal injection protocol, contending that the protocol was inadequate to ensure that he was sufficiently anesthetized prior to the final lethal injection.²¹¹ On April 7, 2006, a district court judge found that the State ran the risk of violating the Eighth Amendment to the Constitution if it proceeded with the protocol.²¹² The court conditionally denied Brown's request for a preliminary injunction, however, provided that the state retain qualified and trained personnel at his execution to administer the anesthesia.²¹³ On April 12, the state of North Carolina responded with a proposal for "a revised protocol that uses a bispectral index (BIS) monitor, a device that, according to the State, can monitor Brown's level of consciousness during the execution procedure," and the requirement that a licensed registered nurse and a licensed

²¹¹ Brown v. Beck, Case No. 5:06-3018, 2006 U.S. Dist. LEXIS 60084, at *3 (E.D.N.C. April 7, 2006).

²¹² *Id.* at 13-14.

²¹³ *Id.*

physician would be present to read the BIS monitor.²¹⁴ The State's proposed use of the BIS monitor was supported by the affidavit of Dr. Mark Dershwitz, who advocated in North Carolina that using the BIS monitor would "beyond a reasonable degree of medical certainty, that the utilization of the BIS monitor . . . will prevent the possibility of the inmate being awake."²¹⁵ However, this contradicted his testimony just weeks earlier, in which he indicated that BIS monitors should not be used in executions for the following reason: "[A]lthough I have not done the experiment myself nor do I think has anybody else, [] I think it's a really important experiment to do in an animal, but I predict that the sort of dose of potassium chloride that is used in a judicial execution will cause widespread depolarization which will be picked up by the BIS monitor and misinterpreted as EEG activity."²¹⁶

On February 6, 2007, the North Carolina Council of State approved a new "Execution Protocol."²¹⁷ Under this protocol, a lethal injection involves "the administration of a lethal quantity of an ultrashort-acting barbiturate, such as sodium pentothal, in combination with a chemical paralytic agent, such as pancuronium bromide, and potassium chloride into the veins of a condemned prisoner."²¹⁸ The inmate's degree of consciousness is "observed visually" and tracked with a bispectral index (BIS) monitor, which interprets brainwaves.²¹⁹ The warden has the task of halting the administration of the drugs after the first injection of the ultrashort-acting barbiturate and a subsequent injection of not less than 30 ml of a saline solution to clean the equipment, in order to confirm that there is a "very high probability of unconsciousness" because the value displayed on the BIS monitor is sufficiently low.²²⁰ The protocol provides the example of a value below 60 as a value that is sufficient to indicate a very high probability of

²¹⁴ Brown v. Beck, 445 F.3d 752, 754 (4th Cir. 2006) (Michael, J., dissenting).

²¹⁵ See Third Affidavit of Dershwitz, Brown v. Beck, No. 5:06-03018, at ¶ 11 (E.D.N.C. April 12, 2006).

²¹⁶ Dershwitz Rebuttal report, Walker v. Johnson, No. 05-934, at 5 (E.D. Va. Feb. 3, 2006).

²¹⁷ Connor v. N.C. Council of State, 07-GOV-0238, In the Office of Administrative Hearings (August 9, 2007) at 8, ¶ 31.

²¹⁸ *Id.* at 9.

²¹⁹ *Id.*

²²⁰ *Id.* at 10.

unconsciousness.²²¹ Upon ascertaining that there is a sufficient value on the machine, the warden is to resume the lethal injection process.²²² If not, the warden directs the administration of repeated doses of the ultrashort-acting barbiturate until the reading on the BIS monitor is sufficiently low.²²³

North Carolina’s lethal injection protocol does not provide much guidance on how the machine should be used, and only provides the suggestion that a reading below 60 is sufficiently low. It does not indicate that a reading below 60 is mandatory or that there is some other method of determining what value demonstrates a very high probability of unconsciousness. Yet once the warden determines that there is a very high probability of unconsciousness, a chemical paralytic agent, such as pancuronium bromide, is injected to paralyze the inmate’s muscles.²²⁴ Following that, an injection of potassium chloride is administered for the purpose of interrupting nerve impulses to the heart to stop the beating of the inmate’s heart and cause his death.²²⁵ Finally, a fifth injection of a saline solution is administered to flush the equipment used for lethal injection.²²⁶

The protocol also requires that a licensed medical doctor be present at executions to monitor the essential body functions of the inmate, to notify the warden if the inmate demonstrates indications that he is experiencing “undue pain or suffering,” at which point the warden would stop the execution.²²⁷ Thus, the protocol explicitly contemplates that the lethal injection procedure might fail to prevent pain and suffering, and that a medical professional is needed in case of such an outcome. It should be noted, however, that the protocol does not require the physician to examine the BIS monitor after the administration of the anesthesia; that decision is left to the warden alone. Additionally, the North Carolina Medical Board has

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.* at 11. Additionally, the physician is responsible for certifying death.

determined that although physicians may be present during an execution, they may not participate.²²⁸ Moreover, the Medical Board determined that “any physician who engages in any verbal or physical activity . . . that facilitates the execution may be subject to disciplinary action by this board.”²²⁹

The district court found the use of this machine sufficed to remedy the problems with lethal injection, and the Fourth Circuit Court of Appeals affirmed this decision.²³⁰ Willie Brown was executed under this new protocol on April 21, 2006, but the protocol was not followed to the letter—the licensed physician present at Brown’s execution was not trained to read the BIS monitor values, was not asked to do so at the execution, and did not in fact do so.²³¹

On August 9, 2007, an administrative law judge (ALJ) determined that the execution protocol was inadequate to ensure that inmates would be prevented from experiencing undue pain during the execution.²³² The ALJ found that “[r]eliance on the BIS alone for intraoperative anesthetic management is not recommended by its manufacturer,” and that without some exercise of clinical judgment to confirm the meaning of the reading on the BIS monitor, it would be dangerous to proceed.²³³ Furthermore, the ALJ found that both pancuronium bromide and potassium chloride would result in excruciating pain if administered while an inmate is conscious.²³⁴ The protections ensuring that an inmate is unconscious when these drugs are administered are therefore the most critical to ensure the constitutionality of lethal injection.²³⁵ The ALJ concluded that inmates “are entitled to the presence of medical personnel who are appropriately placed, trained, and qualified to help ensure that they are unconscious and unable to

²²⁸ North Carolina Medical Board Position Statement Regarding Capital Punishment (January 2007), available at <http://www.ncmedboard.org/Clients/NCBOM/Public/index.htm>.

²²⁹ Connor at 6, ¶ 14.

²³⁰ *Id.*

²³¹ *Id.* at 6, ¶ 12.

²³² *Id.* at 15.

²³³ *Id.* at 12.

²³⁴ *Id.*

²³⁵ *Id.*

feel pain prior to and at the time of the administration of any pancuronium bromide or potassium chloride.”²³⁶

The ALJ additionally determined that North Carolina public policy in favor of the death penalty cannot be “stymied by a non-binding position statement” of the North Carolina Medical Board,²³⁷ but took exception to the provision of the protocol allowing the execution to proceed after the Warden noted that the BIS monitor displayed a level of 60 or below for two reasons.²³⁸ First, there is a need for a nurse or doctor to exercise clinical judgment in determining unconsciousness.²³⁹ Second, the administration of a paralytic agent is likely to prevent an inmate from demonstrating that he or she is conscious.²⁴⁰ The ALJ was persuaded “that the proposed protocol does not ensure that inmates will be rendered unconscious prior to and throughout the period during which lethal drugs are injected into their bloodstream, such that they will be prevented from perceiving pain during their execution.”²⁴¹ Therefore, he ordered that the North Carolina Council of State reconsider its Execution Protocol.²⁴² In the most recent development in North Carolina, a court enjoined that the North Carolina Medical Board from taking disciplinary action against physicians who participate in executions.²⁴³

The BIS is a novel technology, and even “the role of brain-function monitors in the prevention of intraoperative awareness is controversial.”²⁴⁴ Anesthesiologist Scott Kelley, a vice president of the company selling the machine, said that it was inappropriate to extrapolate from data about anesthesia in surgical patients with a medical professional present to the use of the

²³⁶ *Id.* at 13.

²³⁷ *Id.* at 14.

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Id.* at 15.

²⁴³ N.C. Dep’t of Corr. v. N.C. Med. Bd., No. 07-CVS-3574, at 5 (N.C. Sept. 21, 2007) (order granting plaintiff’s request for declaratory relief to enjoin enforcement of disciplinary standards). Interestingly, although the court noted that physician participation was crucial to the administration of lethal injection, the court also determined that “[a] judicial execution is not a medical event or medical procedure.” *Id.*

²⁴⁴ Robert Steinbrook, *New Technology, Old Dilemma—Monitoring EEG Activity During Executions*, 354 NEW ENG. J. MED. 2525 (2006).

machine in lethal injection.²⁴⁵ Thus, under the new protocol, inmates are anesthetized and monitored by a machine in a manner that was neither recommended by the manufacturers nor tested on human or animal subjects. The protocol also fails to require the exercise of clinical judgment by a physician as a protection for inmates.

North Carolina's policy on research with prisoners adopts the Federal Regulations governing research on prisoners,²⁴⁶ and one of its requirements would prohibit lethal injection. The Federal Regulations define "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."²⁴⁷ Additionally, the regulations clarify that "[a]ctivities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."²⁴⁸ In North Carolina, the words of a statute such as this are interpreted "in accordance with their plain meaning unless the statute provides an alternative meaning."²⁴⁹ Additionally, "[i]n construing the ordinary and plain meaning of disputed terms, this Court has used 'standard, nonlegal dictionaries' as a guide."²⁵⁰ However, because the Federal regulations provide a definition for research, that definition would prevail over dictionary definitions.

The use of a machine untested for the purpose of monitoring unconsciousness during executions, with or without a medical professional present, is a novel use that may have unknown risks the manufacturer did not anticipate. To determine what those risks are and how to minimize

²⁴⁵ *Id.*

²⁴⁶ North Carolina Department of Correction, Research and Planning, "Conducting Research within the North Carolina Department of Correction," <http://www.doc.state.nc.us/rap/ResearchGuidelines.pdf> (last visited Aug. 7, 2007).

²⁴⁷ 45 C.F.R. 46.102(d) (2007).

²⁴⁸ *Id.*

²⁴⁹ *Malloy v. Zoning Bd. of Adjustment*, 573 S.E.2d 760, 762 (N.C. Ct. App. 2002) (quoting *Kilpatrick v. Village Council*, 530 S.E.2d 338, 343 (N.C. Ct. App. 2000)).

²⁵⁰ *C. D. Spangler Constr. Co. v. Industrial Crankshaft & Engineering Co.*, 388 S.E.2d 557, 568 (N.C. 1990) (quoting *Ins. Co. v. Ins. Co.*, 146 S.E.2d 410, 416 (1966) and citing *Waters v. Lumber Co.*, 20 S.E. 718, 720 (1894)).

those risks would require some investigation of this new technique. Further, this investigation is systematic because the North Carolina Department of Corrections delineates the procedures that are to be followed in each execution in stepwise fashion and requires the use of a machine to monitor unconsciousness.²⁵¹ However, it is not entirely clear that this activity will contribute to generalizable knowledge. The fact that the ALJ has required reconsideration of the protocol to remedy its deficiencies, namely that the procedures may be insufficient to determine that an inmate is truly unconscious, suggests that North Carolina will have to take a more careful approach in the future. Moreover, because this approach will have to be improved in a manner that can be approved by the ALJ, it will require documentation and detail. As with the states discussed above, it is likely that the state will present evidence of how the procedure was conducted in the context of future litigation to support its approach. To do so, the state must acquire data and present it in the form of generalizable knowledge—after all, if the data only applied to one individual execution, it would not suffice to reassure courts that the lethal injection process was being conducted within the strictures of the Eighth Amendment.

Incidentally, North Carolina’s restriction on research requires informed consent from participants and certification from the Office of Human Research Protections, both of which have most likely not been followed by the North Carolina Department of Corrections to date.²⁵² A further requirement is that “the risks involved in the research are equivalent to risks that would be accepted by nonprisoner volunteers.”²⁵³ It seems impossible to imagine that nonprisoner volunteers would accept the risks of undergoing an injection that is designed to be lethal, will be monitored by a machine untested for this purpose, and that may not work as planned.²⁵⁴

²⁵¹ See NORTH CAROLINA DEPT. OF CORRECTION, EXECUTION METHOD (2007), <http://www.doc.state.nc.us/DOP/deathpenalty/method.htm>.

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ Additionally, the Federal Regulations regulating prisoner research state that “Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.” 45 C.F.R. 46.305(4) (2007). Thus, an equal protection challenge alleging

Therefore, North Carolina may have revised its lethal injection protocol to avoid the pitfall of not having any monitoring of anesthetic depth, only to contravene its own regulations governing research with prisoners.

F. TENNESSEE

In Tennessee, lethal injections were stayed on February 1, 2007, by order of the governor, to allow a ninety day review of deficiencies in the lethal injection protocol.²⁵⁵ The governor specifically directed the Commission of Correction to review the existing lethal injection protocol, “do research and perform an analysis of the best practices used by other states,” and develop new protocols for administering the death penalty in Tennessee.²⁵⁶ A new lethal injection protocol was developed, and the moratorium on executions imposed by the governor expired on May 2, 2007.²⁵⁷ The committee decided to retain its three-drug protocol in the face of medical testimony that a one-drug protocol would be safer and engender less risk of conscious suffering for the condemned.²⁵⁸ The protocol was changed to require a certain degree of training in the people administering drugs through an I.V.²⁵⁹ The new protocol has a “contemporaneous documentation” requirement, under which a member of the I.V. team is required to “document the administration of the three-drug protocol during an execution.”²⁶⁰

Finally, the committee decided that if access to an inmate’s veins could not be

that the death penalty is being unfairly implemented could also support allegations that the lethal injection protocol violates the regulation requiring equitable selection of prisoners.

²⁵⁵ *Workman Executed by Lethal Injection*, NewsChannel5.com, May 9, 2007, available at <http://www.newschannel5.com/Global/story.asp?S=6489589>. See also STATE OF TENNESSEE, EXECUTIVE ORDER OF FEBRUARY 1, 2007, <http://www.tennesseeanytime.org/governor/AdminCMSServlet?action=viewFile&id=969> (last visited Sept. 25, 2007).

²⁵⁶ STATE OF TENNESSEE, EXECUTIVE ORDER OF FEBRUARY 1, 2007, <http://www.tennesseeanytime.org/governor/AdminCMSServlet?action=viewFile&id=969> (last visited Sept. 25, 2007).

²⁵⁷ Leslie Schulman, *Tennessee Resumes Lethal Injection Executions after Moratorium Expires*, JURIST PAPER CHASE, May 9, 2007, available at: <http://jurist.law.pitt.edu/paperchase/2007/05/tennessee-resumes-lethal-injection.php>.

²⁵⁸ *Workman v. Bredesen*, 486 F.3d 896, 902 (6th Cir. 2007).

²⁵⁹ *Id.*

²⁶⁰ *Id.*

ensured, a physician would continue to be required to perform a “cut-down” procedure, or to make an incision to enable another member of the team to administer the injection.²⁶¹ The committee characterized its work as determining “best practices” for lethal injection procedures.²⁶² However, the circuit court reviewing the committee’s work characterized it as a comprehensively-conducted “adoption, implementation, and refinement of a lethal injection procedure.”²⁶³ On May 7, 2007, Philip Workman was executed under this new protocol.²⁶⁴

On September 19, 2007, a district court judge reviewed the process by which the Commission of Correction and the Commissioner developed its new protocol and found that the new protocol were insufficient to protect inmates from cruel and unusual punishment.²⁶⁵ The court noted that the committee’s recommendations to switch to a one-drug protocol, provide for the adequate training of personnel, and incorporate a method for monitoring anesthetic depth were overruled by the Commissioner, who therefore knowingly disregarded excessive risk.²⁶⁶

Under Tennessee Department of Correction Policy number 114.02(I), “The use of inmates for medical, pharmaceutical, or cosmetic experiments is prohibited. This does not preclude treatment of an inmate based on his/her need for a specific medical procedure which is not generally available.”²⁶⁷ The policy applies to all Department of Correction staff and inmates and to all persons proposing and/or participating in research activities within the Department of Correction.²⁶⁸ Although the Tennessee Department of Correction does not define the term “experiment,” it does define two terms: research and informed consent.²⁶⁹ The policy defines research as follows: “Any project which involves the collection of data from files or records

²⁶¹ *Id.*

²⁶² *Id.* at 9.

²⁶³ *Id.* at 10.

²⁶⁴ *Workman Executed by Lethal Injection, supra* note 251. For the revised lethal injection protocol, see: Tennessee Department of Correction, Report on Administration of Death Sentences in Tennessee, April 2007, <http://tennessean.com/assets/pdf/DN71684430.PDF> (last visited Sept. 25, 2007).

²⁶⁵ *Harbison v. Little*, No. 3:06-01206, 2007 U.S. Dist. LEXIS 72410, at 32 (M.D. Tenn. 2007).

²⁶⁶ *Id.* at 10, 32, 91.

²⁶⁷ Tennessee Dept. of Correction Policy #114.02 (June 1, 2004), at 3, <http://www.state.tn.us/correction/pdf/researchform.pdf> (last visited Sept. 25, 2007).

²⁶⁸ *Id.* at 1.

²⁶⁹ *Id.* at 1.

maintained within the department and/or the testing, observation, interviewing, or manipulation of the behavior of an inmate or staff for the purpose of conducting surveys, evaluative studies, and/or hypothesis testing.”²⁷⁰

Tennessee courts would interpret this language by first determining whether it is ambiguous.²⁷¹ “If the statutory language is clear and unambiguous, we apply its plain meaning in its normal and accepted use and without a forced interpretation that would limit or expand the statute's application.”²⁷² Additionally, “[w]hen called upon to construe a statute, courts must take care not to unduly restrict a statute's application or conversely to expand its coverage beyond its intended scope.”²⁷³ “If, however, a statute is ambiguous, capable of conveying more than one meaning, we look to the entire statutory scheme to determine legislative intent.”²⁷⁴ Also, courts are to avoid any interpretation of a statute that would lead to absurd results.²⁷⁵

The Department of Correction policy is clear and unambiguous. Although the term “experiment” is not defined, the statute indicates that the prohibition on medical, pharmaceutical, or cosmetic experimentation does not preclude treatment with a medical procedure that is not generally available. Thus, the term experiment can be construed to refer to activities involving medical procedures that are not treatment. The use of the disjunctive “or” indicates that the legislature chose to make the statute broadly restrictive of any of the three kinds of experimentation listed. Additionally, because the lethal injection protocol requires the use of medical procedures, namely the placement of intravenous lines and the injection of pharmaceutical drugs in lethal doses, it is medical and pharmaceutical in nature. The plain meaning of experiment, moreover, is “the action of trying something or putting it to the test; a

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Id.

²⁷¹ Wells v. Tenn. Bd. of Regents, No. 2005-0093782007, 2007 LEXIS 647, at *8 (Tenn. 2007).

²⁷² *Id.* (citing Eastman Chem. Co. v. Johnson, 151 S.W.3d 503, 507 (Tenn. 2004)).

²⁷³ *Id.* (citing Houghton v. Aramark Educ. Res., Inc., 90 S.W.3d 676, 678 (Tenn. 2002)).

²⁷⁴ *Id.* (citing Sallee v. Barrett, 171 S.W.3d 822, 828 (Tenn. 2005)).

²⁷⁵ Abdur'Rahman v. Bredesen, 181 S.W.3d 292, 313 (Tenn. 2005) (citing McClellan v. Bd. of Regents of the State Univ., 921 S.W.2d 684, 689 (Tenn. 1996)).

test, a trial” or “a procedure or course of action tentatively adopted without being sure that it will achieve its purpose.”²⁷⁶ Taking care neither to restrict this definition unduly nor to apply it too expansively, it is applicable to Tennessee’s lethal injection protocol.

The fact that the three-drug protocol has been refined after comprehensive study and will now involve “contemporaneous documentation” suggests that the administration of this medical procedure that has not been tested systematically is medical experimentation, not treatment of an inmate based on his or her need for a specific medical procedure. It is hard to imagine how medically-needed treatment could possibly be construed to include a state-sanctioned lethal injection, particularly when the first precept of medicine is to do no harm.²⁷⁷ This procedure has been adopted, but the emphasis on documentation also indicates that the Department of Correction is testing it and is unsure whether the procedure will achieve its intended purpose. In particular, the documentation of the execution as it is ongoing can serve no helpful purpose for the inmate, but is instead designed to determine what problems arise so they can be fixed for the future. Therefore, the Department of Corrections, in executing Phil Workman, violated its own policies prohibiting experimentation on prisoners. The subsequent decision in *Harbison v. Little* illustrates the fact that problems such as inadequate training, inappropriate procedures to monitor unconsciousness, and the choice of drugs involved excessive risk. The Tennessee Department of Correction thus employed Mr. Workman as an unwitting subject in a research project, and the data they gathered about his execution will no doubt be used to continue to modify and improve the lethal injection protocol.

One counterargument to this analysis is that if a reviewing court determined that the statutory language was ambiguous, that court could look to the existing statutory scheme and

²⁷⁶ Shorter Oxford English Dictionary 894 (5th ed. 2002).

²⁷⁷ American Medical Association, Policy E-2.06 (Capital Punishment) (August 15, 2005) (explaining how physician participation in lethal injection violates the basic ethical principle that “the [medical] profession [is] dedicated to preserving life when there is hope of doing so...”), <http://www.ama-assn.org/ama/pub/category/8419.html> (last viewed Aug. 29, 2007).

determine that the fact that there is a statute authorizing execution by lethal injection,²⁷⁸ and that invalidating that statute with a Department of Correction policy would lead to an absurd result. In *Abdur'Rahman v. Bredesen*, the Supreme Court of Tennessee concluded that allowing the Nonlivestock Humane Death Act, which relates to euthanizing nonlivestock animals, to prohibit the Department of Correction's approach to lethal injection would lead to an absurd result.²⁷⁹ The reasons given by the court included that the Act was meant to apply to agencies that were created for the care of animals, and not agencies such as the Department of Correction.²⁸⁰ Additionally, the court concluded that if the Act did apply to lethal injection, then "lethal injections of death row inmates may be carried out only by veterinarians or other technicians described in this Act."²⁸¹

By contrast, applying the Department of Correction's own policy regarding research with prisoners to the group to whom it was targeted (i.e., Department of Correction personnel) would not lead to an absurd result. Had executions been treated as medical experimentation on inmates and subjected to the rigorous review typically required of such experiments, many of the dramatic mistakes in executions, and the concerns that inmates have suffered excruciating pain as a result, might not have occurred. Likewise, the Department of Correction policy does not necessarily conflict with the existing statutory scheme. As argued earlier, although the provision of lethal injection is allowed in the statutory scheme, the manner in which lethal injection is being reformed is not dictated by the statutory scheme. It is this approach to reforming and modifying lethal injection and collecting data that contravenes the Department of Correction's own policies. Such a result, though perhaps unanticipated or unfortunate, is far from absurd.

G. MARYLAND

²⁷⁸ TENN. CODE ANN. § 40-23-114 (2007).

²⁷⁹ *Abdur'Rahman v. Bredesen*, 181 S.W.3d 292, 312 (Tenn. 2005).

²⁸⁰ *Id.* at 313.

²⁸¹ *Id.*

Maryland's executions have been halted because the Court of Appeals determined that lethal injection was being used without an established protocol and therefore failed to comply with the Maryland Administrative Procedures Act (APA).²⁸² In order to comply with the APA, the state would have to develop procedures under the guidance of the Maryland attorney general, a legislative committee, and providing opportunity for notice and comment by the public.²⁸³ Alternatively, the court held that the legislature could pass legislation to exempt lethal injection protocols from the APA.²⁸⁴ However, the legislature was unable to pass a bill to that effect.²⁸⁵ More recently, the governor of Maryland has placed the protocol on hold in an effort to pressure the legislature to abolish the death penalty.²⁸⁶

Under Maryland state regulations, the managing official of an adult correctional institute "shall have a written policy prohibiting the use of an inmate for medical, pharmaceutical, or cosmetic experiments."²⁸⁷ The only exception provided in the regulations is that they "do[] not preclude the individual treatment of a consenting inmate based on the need for a specified medical procedure which is not generally available."²⁸⁸ Moreover, the Maryland Department of Public Safety and Correctional Services "does not participate in research that depends on the use of inmates or detainees in medical or cosmetics experiments, or for pharmaceutical testing."²⁸⁹

²⁸² See *Evans v. State*, 914 A.2d 25, 80-81 (Md. 2006) (citing MD. CODE ANN., STATE GOV'T. § 10-101 (2007)).

²⁸³ Jeannie Shawl, *Maryland High Court Rules Lethal Injection Procedures Subject to Public Review*, JURIST PAPER CHASE NEWSBURST, December 19, 2006, at: <http://jurist.law.pitt.edu/paperchase/2006/12/maryland-high-court-rules-lethal.php>.

²⁸⁴ *Id.*

²⁸⁵ See John Wagner and Eric Rich, *O'Malley's Inaction Irks Prosecutors; Delay in New Rules Creates Block, Gives Hope to Law's Opponents*, WASH. POST, July 8, 2007, at C11.

²⁸⁶ Vesna Jaksic, *More Lawmakers Take a Stand Against Death Penalty*, NAT'L L. J. (March 6, 2007), available at <http://www.law.com/jsp/article.jsp?id=1173101904578> (last visited Sept. 25, 2007).

²⁸⁷ MD. CODE ANN. (Standards: Inmate Safety) § 12.14.04.02.C (2007).

²⁸⁸ *Id.*

²⁸⁹ Maryland Dept. of Public Safety & Correctional Services, Research—Data and Resources (2006), at <http://www.dpscs.state.md.us/publicinfo/opprs.shtml#answ11>.

In Maryland, courts first look to the plain meaning of a statute to determine its correct interpretation.²⁹⁰ If the statute is unambiguous, the plain language of the statute is taken to effectuate the legislature’s intent, and “[t]he cardinal rule of statutory interpretation is to ascertain and effectuate the intent of the Legislature.”²⁹¹ When a statute is ambiguous, meaning that there are two or more reasonable interpretations of the statute, then “the job of this Court is to resolve that ambiguity in light of the legislative intent, using all the resources and tools of statutory construction at our disposal.”²⁹² The other tools commonly available to construe statutes include: “the structure of the statute, including its title; how the statute relates to other laws; the legislative history, including the derivation of the statute; comments and explanations regarding it by authoritative sources during the legislative process, and amendments proposed or added to it; the general purpose behind the statute; and the relative rationality and legal effect of various competing constructions.”²⁹³

The statutory language prohibiting medical or pharmaceutical experimentation is clear and unambiguous. Again, as discussed above, there is some potential for ambiguity in the use of the term “experimentation,” which is not defined by the statute. Looking to the other terms in the statute, the administration of a drug to an inmate to improve his or her health is the only exception provided to the rule. This suggests that the rest of the statute prohibits other uses of experimental drugs provided to an inmate in a manner that may have unknown consequences and for reasons other than the inmate’s need for a medical procedure. Additionally, because a court has held state regulations applicable to the lethal injection protocol (e.g., the Administrative Procedures Act), this leaves little doubt that the state regulations for research on prisoners are applicable in this context. Thus, as with lethal injection protocols in California, Florida, South

²⁹⁰ Carroll v. Konits, No. 117, 2007 Md. LEXIS 466, *38-*39 (Md. July 27, 2007) (citing State Dept. of Assessments and Taxation v. Maryland-Nat’l Capital Park & Planning Comm’n, 702 A.2d 690, 696 (Md. 1997) and Montgomery County v. Buckman, 636 A.2d 448, 452 (Md. 1994)).

²⁹¹ *Id.* at *38.

²⁹² *Id.* at *40.

²⁹³ *Id.* at *40-*41.

Dakota, North Carolina, and Tennessee, attempts to reform Maryland's lethal injection protocols will contravene its prohibitions on medical experimentation, especially to the extent that the protocol becomes more systematic and requires the collection of data for knowledge that can be generalized to future executions or for the purposes of future litigation.

V. OBJECTIONS

A. IS LETHAL INJECTION REFORM RESEARCH OR QUALITY CONTROL?

Proponents of lethal injection may argue that lethal injection should not be thought of as research, but rather as punishment. This distinction, however, ignores the fact that the arguments above relate to the process of reform of lethal injection, and not to the practice of lethal injection. Arguably, the administration of lethal injection prior to the attempts to reform the procedure would not be considered research. It is the changes described herein, such as alteration of dosages and data-gathering, that lead to the implication that Departments of Corrections are conducting research on prisoners.

Alternatively, Departments of Corrections may argue that the attempts at reform are merely quality control and thus distinct from research. Quality control or innovation is described as an activity that "aims to improve health care quality and outcomes through local innovations and adaptation in the processes and systems of care."²⁹⁴ If these activities are being undertaken at local levels and are designed to improve different systems, based on their different contexts, then some argue that they are distinct from research. Research is typically defined as "a systematic investigation . . . designed to develop or contribute to generalizable knowledge."²⁹⁵ This distinction could imply that regulations governing research should not apply to local attempts to conduct quality control.

²⁹⁴ Christine Grady, *Quality Improvement and Ethical Oversight*, 146 ANNALS OF INT. MED. 9, 680, 680 (Apr. 16, 2007).

²⁹⁵ *Id.* (citing U.S. Code of Federal Regulations, 45 C.F.R. 46.102(d), *available at* <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> (last visited Sept. 25, 2007)).

However, this distinction is difficult to keep clear. Even those who argue for distinctions between quality improvement and research are unable to avoid the conclusion that the two overlap.²⁹⁶ In addition to the difficulty of maintaining a distinction between quality control and research, the activities are similar in that both warrant protections of the individuals who face increased risks by participating in them. In particular,

Both activities encompass a heterogeneous set of data-gathering and data-generating activities whose goals extend beyond the immediate interests of the participants. Surely, great care and attention are required for any activity whose purpose extends beyond what is directly needed for the care of an individual patient and that might add burden or incur risk.²⁹⁷

Moreover, as previously discussed, the regulations governing research with prisoners do not draw the kinds of subtle distinctions that separate research from quality control. Instead, they operate to prohibit medical experimentation on prisoners rather broadly. Again, the efforts at issue here involve attempts to modify the process of lethal injection, gather data on the new methods being employed, release this data in public fora, and review and improve the lethal injection process with the goal of making the process Constitutional and able to survive litigation. These are unlikely to be the kinds of activities that can be neatly classified as quality control and thereby rendered exempt from regulations prohibiting or severely restricting medical research on prisoners. In other words, even if there are elements of quality control motivating states to make change in their lethal injection protocols, states are nevertheless conducting research on prisoners.

B. IS LETHAL INJECTION REFORM A MEDICAL PROCEDURE?

Another objection may be that since doctors are not ethically permitted to perform lethal injection (or euthanasia in the United States), such an activity cannot be *medical* in the views of doctors themselves. This argument is flawed for at least three reasons. First, with regard to statutory interpretation, the relevant definitions of research are included in the statute, and what

²⁹⁶ J. Lynn, et al., *The Ethics of Using Quality Improvement Methods in Health Care*, 146 ANN. INTERN. MED. 669, 669-70 (May 1, 2007).

²⁹⁷ *Id.*

physicians might think is irrelevant. Second, lethal injection is a medical procedure, and physicians' objections to lethal injection do not turn on whether the procedure is medical or not—they rely on the fact that, in these cases, a medical procedure is being employed to do harm.²⁹⁸ Third, as previously discussed, much of the debate about lethal injection has centered on the ability of a non-medical professional to perform a medical procedure in the absence of medical training. In fact, one of the seminal problems with the current administration of lethal injection is that the procedure is a medical one, but that the professional organizations governing the people with the relevant training have ethical qualms about their participation.

VI. CONSIDERATIONS FOR FUTURE REFORM ATTEMPTS

For states whose attempts to reform lethal injection violate their regulations prohibiting research with prisoners, one response could be to amend their regulations to exempt lethal injection reform. This may be a particularly appealing solution for states or policymakers who believe that once a prisoner has been sentenced to death, concerns about any additional exploitation are immaterial. However, state execution procedures are subject to certain limitations. The Eighth Amendment to the Constitution prohibits cruel and unusual punishment and thereby limits how an execution can be conducted. Similarly, the laws governing research with prisoners place important boundaries on how executions by lethal injection should be conducted.

States could also turn to alternative methods of execution. Nebraska, for instance, still employs the electric chair.²⁹⁹ Other states have lethal gas as a viable method of execution.³⁰⁰ Other methods of execution have fallen into disfavor, perhaps because of public perception that

²⁹⁸ See Priscilla Ray, *AMA Opposes Physician Involvement in Executions*, American Medical Association (2006), <http://www.ama-assn.org/ama/pub/category/16007.html>

²⁹⁹ See NEB. REV. STAT. § 29-2532 (2006).

³⁰⁰ *But see* *Fierro v. Gomez*, 77 F.3d 301, 309 (9th Cir. 1996) (determining that “[t]he district court’s findings of extreme pain, the length of time this extreme pain lasts, and the substantial risk that inmates will suffer this extreme pain for several minutes require the conclusion that execution by lethal gas is cruel and unusual.”), *vacated and remanded for further proceedings in light of statutory elimination of lethal gas as an option for execution by Gomez v. Fierro*, 519 U.S. 918 (1996)).

these methods are inhumane and that medicalization of executions may be provide a less painful and more civilized alternative.³⁰¹ It is not clear whether the arguments in this paper would apply to reform of other forms of execution. The fact that execution by lethal injection involves medical procedures is what makes it subject to state prohibitions on medical research. However, it is possible that other methods of execution, such as hanging, firing squad, electric chair, guillotine, and lethal gas would still come into conflict with state laws that have extremely broad prohibitions on research with prisoners that are not limited to medicine.³⁰²

Biomedical interventions necessarily involve risk and uncertainty, and research is the process by which interventions are tested to determine whether the ratio of risks to benefits is acceptable. The approach to research in the United States, and even throughout the world, has a long history of exploitation and scandal. Throughout this history of research with human subjects, ethical and legal guidance for research has evolved in an effort to avoid the crises of the past. This guidance can be helpful in approaching the question of whether death by lethal injection can fit into our policies regarding the criminal justice system.

Like the conduct of biomedical research in the field of medicine, the use of biomedical interventions in criminal justice should undergo a process of systematic data-gathering and research before it can be determined whether lethal injection can be constitutional. Rather than have legislatures devise loopholes to existing laws governing research, and instead of moving towards the proliferation a multiplicity of different appellate standards governing lethal injection, some national consensus must be reached on lethal injection. Other commentators have suggested that a nationwide commission should be established to determine what risks and uncertainties are associated with lethal injection.³⁰³ Presumably, such a commission would be charged with examining the existing data, determining what further data are needed, and

³⁰¹ See Michael Madow, *Forbidden Spectacle: Executions, the Public, and the Press in Nineteenth Century New York*, 43 BUFFALO L. REV. 461, 486-90 (1995).

³⁰² See, e.g., CAL. PENAL CODE § 3500 (prohibiting research on prisoners relating to “physical science”).

³⁰³ Denno, *supra* note 8, at 118-20.

delineating how these data can be collected. Significantly, this commission could take any number of approaches to this question, including examining data about the practice of euthanasia in countries that permit it, and perhaps even conducting research on people undergoing euthanasia in those countries that would be relevant to understanding how to conduct lethal injection.³⁰⁴

For some of the reasons previously discussed, however, it is possible that such a commission would be unable to develop a constitutionally sound lethal injection procedure. The commission may determine that the only people qualified to conduct lethal injection are physicians, but the predominant professional organizations have determined that direct physician participation in lethal injections is unethical.³⁰⁵ Additionally troubling is the fact that there may be some level of irreducible risk inherent in the administration of lethal injection. Data from analogous settings suggest that this may be the case. Even under ideal conditions where a trained anesthesiologist is present to monitor a patient, there is a risk of intraoperative awareness such that patients are conscious and experience pain throughout a surgical operation.³⁰⁶ A study of 535 cases of euthanasia performed in the Netherlands, where euthanasia is legal, demonstrated that technical problems with the practice of euthanasia occurred in five percent of cases and

³⁰⁴ It is not clear how conducting research on different methods of administering lethal injection in prisoners could meet with the prohibition on cruel and unusual punishment. For one thing, it may be prohibitively difficult to obtain informed consent for prisoners to participate in such research.

³⁰⁵ See, e.g., Priscilla Ray, *AMA Opposes Physician Involvement in Executions*, American Medical Association (2006), <http://www.ama-assn.org/ama/pub/category/16007.html>; American Nurses Association Committee on Ethics, *Ethics and Human Rights Position Statements: Nurses' Participation in Capital Punishment* (1994), <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Professional%20Associations/ANA%20Position%20Statement%20Nurses'%20Participation%20in%20Capital%20Puni...pdf>; Orin F. Guidry, *Message from the President: Observations Regarding Lethal Injection* (2006), <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Professional%20Associations/Observations%20Regarding%20Lethal%20Injection.pdf>; National Association of Emergency Medical Technicians, *Position Statement on EMT and Paramedic Participation in Capital Punishment* (2006), <http://www.naemt.org/aboutNAEMT/capitalpunishment.htm>.

³⁰⁶ See, e.g., J. Bruhn, et al., *Depth of Anesthesia Monitoring: What's available, what's validated, and what's next*, 97 *British J. of Anesthesia* 85, at 86 (2006) (noting that incidence of awareness under anesthesia is alarmingly high and ranges from 0.13% to 0.18% in adults); American Society of Anesthesiologists Task Force on Intraoperative Awareness, *Practice Advisory for Intraoperative Awareness and Brain Function Monitoring*, at 1 (October 25, 2005) (reporting an intraoperative awareness rate of 0.1-0.2% in all surgical patients), available at [http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/California/Morales/Morales%20Dist%20Ct.Cp/Ex%20to%20Heath%20Decl%20\(ASA%20Advisory%20re%20intraoperative%20awareness\).pdf](http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/California/Morales/Morales%20Dist%20Ct.Cp/Ex%20to%20Heath%20Decl%20(ASA%20Advisory%20re%20intraoperative%20awareness).pdf).

complications occurred in three percent of cases.³⁰⁷ It may be that the conditions under which lethal injection is conducted, which to date have involved execution teams with significantly less training than that obtained by medical professionals, necessarily involve some higher level of risk of pain than these studies have demonstrated. Simply put, there may be no acceptable way to conduct lethal injection.

Regardless, the current approach is untenable—it may lead to dramatic inconsistencies in the practice of lethal injection without furthering our knowledge of the risks involved. In order to determine whether lethal injection is constitutional, it will take a systematic, careful analysis of the risks involved in lethal injection—the type of determination that states have not attempted to make to date, and that they may lack the expertise or objectivity to undertake. This investigation cannot involve prisoners without some attention to the ethical issues involved to minimize risks and the possibility of exploitation. In addition, it will also require democratic deliberation about these risks and a societal determination about the acceptability risks and uncertainty involved. Given the controversial nature of the death penalty itself, the lethal injection question cannot take hidden approaches to reform that fail to acknowledge the trade-offs that are being made. Whether we can determine the level of risk to an acceptable level of certainty may be a scientific determination, but whether that risk is sufficiently low to be consistent with the Constitutional prohibition on cruel and unusual punishment is a public affair.

VII. CONCLUSION

One interesting implication of the analysis above is that state regulations on research with prisoners should be revised. This largely unexplored effect of regulations governing research with prisoners highlights the fact that there may be problems with these regulations. In particular, they may be too restrictive in a manner that prohibits prisoners from receiving potential benefits from medical research. The Institute of Medicine recently issued a report calling for reform of

³⁰⁷ Johanna H. Groenewoud, et al., *Clinical Problems with the Performance of Euthanasia and Physician-Assisted Suicide in the Netherlands*, 342 *NEW ENG. J. OF MED.* 551, Table 3 (Feb. 24, 2000).

the Federal regulations governing research with prisoners, and these recommendations may apply even more forcefully to state regulations.³⁰⁸ Somewhat ironically, overprotective laws that may prevent prisoners from receiving benefits from participating in research have not been applied to protect prisoners in the context of execution. Yet these laws should operate to ensure that states and prison officials are not experimenting on prisoners by subjecting them to substantial risk of pain and suffering as they try to improve an execution system that may not withstand Constitutional scrutiny.

States that have determined that lethal injection, as practiced, violates the Constitutional prohibition on cruel and unusual punishment have painted themselves into a corner by also placing stringent restrictions on research on prisoners. These states are in a situation where they have recognized that they cannot continue conducting executions as they have, but they are unable to do anything about it without contradicting their own policies, regulations, and/or penal codes. Moreover, even states that are modifying their procedures in an ad-hoc manner, using procedures to gather data in order to publicly present this data in future litigation to reform the process over time, are likely to be conducting research on prisoners.

Furthermore, nearly all of the states that currently permit execution by lethal injection have regulations governing research with prisoners. By implication from the arguments above, these regulations may operate to prohibit reform of execution by lethal injection in states that have not yet determined that reform is necessary. If the Supreme Court finds that lethal injection is error-prone, it is possible that these states are also conducting experimentation or research on prisoners in violation of their own regulations. Certain types of regulations are more restrictive than others and would be more likely to prohibit lethal injection in states that are not attempting to reform their protocols. By incorporating medical procedures into the process of execution,

³⁰⁸ COMMITTEE ON ETHICAL CONSIDERATIONS FOR REVISIONS TO DHHS REGULATIONS FOR PROTECTION OF PRISONERS INVOLVED IN RESEARCH, ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS (2006).

states have made the process of execution subject to restrictions on medical research, and they cannot ignore the effect of their own regulations on their approaches to lethal injection.

The implications for this analysis are perhaps most salient for the upcoming Supreme Court decision in *Baze v. Rees*. Determining the likelihood of the risks of a medical procedure requires an examination of evidence. If there is insufficient evidence to determine the level of risk, medical research is the way to resolve the question. These fundamental medical concepts have not been explored in litigation over lethal injection to date, but underlie many of the questions that the Supreme Court has taken up in *Baze*.³⁰⁹ Furthermore, if the Supreme Court's analysis requires an approach to reform similar to the approaches undertaken by California and Florida, research regulations and policies in many states would prohibit Departments of Correction from abiding by the Supreme Court decision. Whatever standard the Court sets for evaluating lethal injection, it must take account of the fact that the approach to reform and the changes it requires cannot involve unethical and impermissible research on prisoners.

³⁰⁹ See *Baze v. Rees*, No. 07-5439, 2007 U.S. LEXIS 9066, at *1 (U.S. September 25, 2007). The questions before the Supreme Court are:

- I. Does the Eighth Amendment to the United States Constitution prohibit means for carrying out a method of execution that create an unnecessary risk of pain and suffering as opposed to only a substantial risk of the wanton infliction of pain?
- II. Do the means for carrying out an execution cause an unnecessary risk of pain and suffering in violation of the Eighth Amendment upon a showing that readily available alternatives that pose less risk of pain and suffering could be used?
- III. Does the continued use of sodium thiopental, pancuronium bromide, and potassium chloride, individually or together, violate the cruel and unusual punishment clause of the Eighth Amendment because lethal injections can be carried out by using other chemicals that pose less risk of pain and suffering?

All of these questions require consideration of the arguments contained herein.

APPENDIX 1

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
CALIFORNIA	<p>“Except as provided in Section 1706 of the Welfare and Institutions Code, no biomedical research shall be conducted on any prisoner in this state.” Cal. Penal Code § 3502.</p>	<p>“California’s lethal-injection protocol—as actually administered in practice—create[s] an undue and unnecessary risk that an inmate will suffer pain so extreme that it offends the Eighth Amendment.” <i>Morales v. Tilton</i>, 465 F. Supp. 972, 974 (N.D. Cal. 2006).</p>
FLORIDA	<p>“No offender in the custody of or under the supervision of the department will be utilized for medical, cosmetic or pharmaceutical experimental testing or any other health-related experimental procedure. This does not preclude individual treatment of an offender based on her/his need for a specific medical procedure that is not generally available.” Fla. Admin. Code Ann. R. 4-4402.</p>	<p>“Protocols as written are insufficient to properly carry out an execution when complications arise.” THE GOVERNOR’S COMMISSION ON ADMINISTRATION OF LETHAL INJECTION, FINAL REPORT WITH FINDINGS AND RECOMMENDATIONS (Mar. 1, 2007).</p>
OHIO	<p>“Research on inmates that is medical, pharmaceutical, and/or cosmetic is prohibited, unless all of the following conditions are true: 1) there is a clear benefit to the individual inmate based on his/her need for a specific medical procedure or pharmaceutical that is not generally available, and 2) the inmate suffers from a medical condition for which all conventional treatment modalities and alternatives have been exhausted, and 3) the only remaining treatment is the one being proposed as part of the medical or pharmaceutical experiment, and 4) the treatment will have an immediate therapeutic benefit to the participant. If these conditions are met, the ODRC may authorize participation as a treatment opportunity, rather than as participation in an experimental project.” Ohio Dept. of Rehabilitation & Correction, Human Subjects Research Review Process: Detailed</p>	<p>One district court is considering arguments on the constitutionality of lethal injection; a class action lawsuit has been stayed pending the outcome of a petition for writ of certiorari. <i>Cooley v. Taft</i>, No. 04-1156 (S.D. Ohio Nov. 22, 2006); <i>State v. Rivera</i>, No. 04-CR-065940 (Ct. Com. Pl. July 24, 2007).</p>

	description, http://www.drc.state.oh.us/web/hsrrc_review.htm .	
SOUTH DAKOTA	“The South Dakota Department of Health Correctional Health Care policy forbids any involvement or participation in medical or other research involving inmates. This includes direct as well as indirect research.” South Dakota Department of Health, Correctional Health Services Policy P-I-07, “Medical and Other Research” (April 1, 2007).	Governor issued a stay of execution to modify the lethal injection protocol from requiring a two-drug cocktail to the three-drug cocktail used by most states. The lethal injection statute was amended by the legislature. S.D. CODIFIED LAWS § 23A-27A-32 (2007 amendment notes).
NORTH CAROLINA	Research must abide by the Code of Federal Regulations, 45 C.F.R. 46.306(a)(2), and seven additional criteria: “(1) the research is in one of the categories of permissible research (see above). (2) there cannot be any undue incentives as a consequence of taking part. (3) the risks involved in the research are equivalent to risks that would be accepted by nonprisoner volunteers; (4) procedures for the selection of subjects within the prison are fair to all prisoners and that prison authorities or other prisoners cannot intervene in the selection. (5) information about the project is written at a level that prisoners can understand. (6) that there is no gain, nor perception of gain, for a prisoner taking part, and that there is no penalty, nor perception of a penalty, for a prisoner saying “no.” (7) adequate provision is made for follow-up examination or care after the end of their participation, if needed.” North Carolina Department of Correction, Research and Planning, “Conducting Research within the North Carolina Department of Correction,” http://www.doc.state.nc.us/rap/ResearchGuidelines.pdf .	A district court judge found that the State ran the risk of violating the Eighth Amendment to the Constitution if it proceeded with a protocol in which a doctor would not be present at the execution; North Carolina added the use of mechanical monitoring of anesthetic depth and proceeded with executions. Brown v. Beck, 445 F.3d 752 (4th Cir. 2006).
TENNESSEE	“The use of inmates for medical, pharmaceutical, or cosmetic experiments is prohibited. This does not preclude treatment of an inmate based on his/her need for a specific medical procedure which is not generally available.” Tennessee Dept. of Correction Policy #114.02 (June 1, 2004), http://www.state.tn.us/correction/pdf/researchform.pdf .	“The plaintiff’s pending execution under Tennessee’s new lethal injection protocol violates the Eighth Amendment to the United States Constitution. The new protocol presents a

		substantial risk of unnecessary pain.” Harbison v. Little, No. 3:06-01206, 2007 U.S. Dist. LEXIS 72410, at 55-56 (M.D. Tenn. 2007).
MARYLAND	The managing official of an adult correctional institute “shall have a written policy prohibiting the use of an inmate for medical, pharmaceutical, or cosmetic experiments.” The only exception provided in the regulations is that they “do[] not preclude the individual treatment of a consenting inmate based on the need for a specified medical procedure which is not generally available.” Md. Code Ann. [Standards: Inmate Safety] § 12.14.04.02.C (2007).	Executions halted for failure to comply with the Administrative Procedures Act when developing the lethal injection protocol. <i>See</i> Evans v. State, 914 A.2d 25, 80-81 (Md. 2006).