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*45 Am. Crim. L. Rev. 1101***LENGTH:** 28466 words**ARTICLE:** HOW LETHAL INJECTION REFORM CONSTITUTES IMPERMISSIBLE RESEARCH ON PRISONERS**NAME:** Seema Shah ***BIO:**

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SUMMARY:

... As states develop lethal injection procedures through modifications and adjustments, test those procedures in an attempt to find a constitutionally sound procedure that can be generalized to future inmates, gather data on the tests of these procedures, and then disseminate the results of their investigations to courts and to the public, they are conducting medical research on prisoners. ... 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." ... Moreover, gathering systematic data would require methods such as setting a rigid timeframe during which relevant data from executions would be collected, setting criteria for which evidence is relevant, adjusting for variation in subjects that may make them more or less susceptible to the outcome being studied, and using statistical methods to determine the relevant number of test subjects needed to arrive at a definitive answer. ... 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. ... Because there is no reason to anticipate that it would pose risks of pain and suffering, research on a single, lethal injection of anesthesia may be more acceptable than research on the current protocols, whether conducted in the U.S. or abroad.

HIGHLIGHT: *This Article 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 making provisions 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 state laws and ethical principles.

The Supreme Court has recently taken up the challenge of elucidating the standard for determining the constitutionality of lethal injection. The Court's fractured decision suggests that states may need to conduct lethal injection reform to develop procedures substantially similar to those used in Kentucky. It follows that the Court's decision may lead states to contravene state laws or ethical precepts regarding research with prisoners. Thus, this Article 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.

TEXT:

[*1101] INTRODUCTION

The Supreme Court recently issued a fractured decision in the case of *Baze v. Rees* allowing Kentucky's lethal injection procedures to stand and articulating standards for applying the Eighth Amendment's prohibition on cruel and unusual punishment to execution by lethal injection. n1 Execution by lethal injection had previously come to a halt in eleven states as a result of dramatic evidence of its [*1102] potential to cause excruciating pain and prolongation of death. n2 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 unusual punishment. n3 States have 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." n4 These standards reflected considerable confusion in the courts about how to evaluate lethal injection. In attempts to resolve the uncertainty and concern about the risk of pain inherent in existing lethal injection protocols, many states began to reform their current lethal injection procedures.

The Supreme Court decision in *Baze* may resolve some of the controversy in the short-term. A majority of justices agreed that the petitioners did not carry their burden to show that Kentucky's lethal injection protocol is unconstitutional, and further signaled that states that refuse to change their methods when there are feasible alternatives presented to them may be in violation of the constitution. n5 Yet, the long-term picture is much more unclear. The justices are in considerable disagreement about the correct standard for evaluating lethal injection procedures. n6

In all of the extensive litigation and debate over lethal injection, one important issue has been entirely neglected. This Article will argue that in their attempts to reform lethal injection, states have experimented with different procedures and revised their lethal injection protocols, thereby conducting 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. n7 Thus, attempts to develop appropriate lethal injection protocols in a manner that constitutes experimentation on prisoners have required the use of prisoners as research subjects in a manner that violates state laws and ethical precepts. The Supreme Court's ruling in *Baze* may exacerbate this problem by prompting states [*1103] to reform their procedures. Future attempts at reform may be similarly problematic and, indeed, without substantive changes in state law and regulations, this conflict may ultimately be irresolvable.

The potential scope of this problem is vast. 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 death the previous year. n8 In all, 897 inmates have been put to death using lethal injection since the reinstatement of the death penalty in 1976. n9

In Part I of this Article, I will first provide some background on how lethal injection protocols were developed, how they are currently implemented, and what problems have arisen. In Part II, I will provide a definition of research and apply that definition to lethal injection reform, as well as clarify two areas of conceptual confusion with a discussion of

quality control and what counts as a medical procedure. In Part III, I will analyze how the laws governing research with prisoners apply to California and Florida, two of the states which have undertaken extensive reform efforts, and Kentucky, the state involved in the litigation currently before the Supreme Court (while briefly noting how these arguments would apply to other states). In Part IV, I will address the ethical problems in the conduct of execution research on prisoners, and in Part V, I will respond to a potential objection to the ethical arguments raised herein. I will conclude with a discussion of how these arguments pertain to the Supreme Court litigation, future attempts to reform lethal injection, and laws governing research with prisoners more broadly.

I. LETHAL INJECTION PROTOCOLS

A. Historical Background

In 1977, Oklahoma pioneered the first lethal injection protocol. n10 The protocol was developed by two state legislators, State Senator Bill Dawson and House Representative Bill Wiseman. n11 These two politicians approached medical societies for help in devising lethal injection protocols, but their requests for assistance were denied. n12 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." n13 [*1104] 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. n14 The lethal chemicals he proposed were an ultra-short-acting barbiturate and a chemical paralytic. n15 Chapman further suggested that the procedure use sodium thiopental as the barbiturate and chloral hydrate as the chemical paralytic. n16 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. n17

Dr. Stanley Deutsch developed a similar protocol that may also have served as a basis for subsequent lethal injection methods. n18 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. n19 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." n20

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. n21 However, it is unclear whether Dr. Deutsch's input influenced Oklahoma's protocol, because Chapman provided the senators with information after the initial passage of the statute. n22 At the time, officials with the Oklahoma Department of Corrections (ODOC) 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. n23 In fact, the drugs that were used by the ODOC varied over time. In May 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-curarine or succinyl-choline chloride or potassium chloride which is an ultrashort-acting barbiturate combination with a chemical paralytic agent." n24 In 1981, Chapman assisted the ODOC once more in creating a lethal injection protocol by adding a third drug to [*1105] what has become known as the lethal injection "cocktail"--potassium chloride. n25 By 2004, the ODOC used sodium thiopental and vecuronium bromide, followed by potassium chloride. n26

B. Current Lethal Injection Protocols

Lethal injection protocols vary somewhat amongst the states. 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. n27 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. n28 The second

chemical is pancuronium bromide, a neuromuscular blocking agent. n29 Pancuronium bromide only serves to paralyze the inmate. n30 The final chemical administered is potassium chloride, which is the agent that typically causes death by inducing cardiac arrest. n31 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 that could occlude the IV line. n32

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. n33 Notably, the method by which anesthesia is used in lethal injection is much less careful and less likely to be effective than the use of anesthesia in clinical practice. The use of anesthesia in lethal injection in the [*1106] United States was not developed with prior testing in clinical trials. n34 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. n35

Importantly, if the anesthesia is ineffectively delivered or wears off so that the inmate regains awareness, the use of the paralytic agent raises serious concerns because it prevents the inmate from indicating that he is aware or reacting to the pain with physical movements. If an inmate is 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. n36

An examination 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." n37 Additionally, the details that were provided often included errors. n38 In 2005, the study's author found that there is no national consensus for conducting lethal injection, and that the responsibility of working out the details of lethal injection protocols is often left to untrained department of corrections personnel. n39

C. Recent Problems with Executions by Lethal Injection

Problems with the administration of lethal injection have also been demonstrated on numerous occasions. Since 1985, at least thirty lethal injections have been prolonged because executioners had difficulty finding suitable veins in which to inject the cocktail of drugs. n40 In 1998, Texas conducted the longest execution on record--the execution lasted for two hours, in part because of the difficulty prison [*1107] officials experienced in trying to insert intravenous lines into the inmate's veins. n41

Several inmates have shown signs of experiencing significant pain after administration of lethal injection. n42 In May 2006, the State of Ohio ran into several difficulties during the execution of Joseph Clark. n43 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. n44 The vein then collapsed, and Mr. Clark had to push himself up and inform the execution team that the procedure was not working. n45 An autopsy revealed that Mr. Clark had nineteen needle puncture marks and signs of paravenous injection of drugs. n46 Misplacing the drugs in this manner would minimize the effectiveness of the anesthesia and make it much more likely that Mr. Clark was aware of the severe pain associated with awareness of the heart-stopping action of the final drug in the sequence. A medical examiner in Michigan who reviewed Mr. Clark's execution called the persons inserting IV catheters "incompetent." n47 All told, Mr. Clark's execution lasted for ninety minutes. n48

Later that year, Angel Diaz's execution in Florida lasted a full thirty-four minutes before the declaration of death. n49 Mr. Diaz continued to move, squint, grimace, and attempt to speak after the first injection was thought to have been administered. n50 An autopsy revealed that the medical personnel inserting the Ns into Mr. Diaz failed to place the Ns inside his veins. n51 The tip of each IV pierced the veins and was placed in the soft tissue of his arms. n52 As a result,

the chemicals were injected directly into the tissue of Mr. Diaz's arms, and he sustained internal chemical blisters of approximately one foot in length. n53 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, including the anesthetic drug, from taking effect as intended. n54 Exacerbating the already [*1108] devastating problem of misplacement of the IVs, the execution team failed to administer the drugs in the correct order. The likely result is that Mr. Diaz felt the excruciating effects of potassium chloride, which causes death by cardiac arrest, before the anesthesia could take effect to block the pain. n55

In hearings in a recent California lethal injection case, the court noted that, based on the heart rates recorded in an execution log, there was a high likelihood in the California execution of Robert Lee Massie on March 27, 2001, that Massie may have been awake when injected with potassium chloride. n56 If this is true, it would indicate that Massie experienced tremendous suffering before his death. n57 The court was forced to look at indicators such as Massie's heart rate to determine whether he was aware of the pain because of the administration of the second drug in the sequence, which causes paralysis. After the administration of a paralytic agent, an inmate like Massie would be unable to communicate or even squirm in a manner that would demonstrate any pain he was experiencing to the observers.

II. HOW LETHAL INJECTION REFORM CONSTITUTES RESEARCH ON PRISONERS

A. Definition of Research

Research "refers to a class of activities designed to develop or contribute to generalizable knowledge." n58 Typically, research involves an activity that tests an intervention or procedure for some purpose, such as ascertaining whether the intervention is safe and effective. In order to demonstrate that the intervention achieves the intended purpose, researchers measure the effects of the intervention or procedure when it is used on people who serve as test subjects. Researchers gather evidence, or data, about how this intervention works in the test subjects, and then seek to use the data to prove that the intervention will achieve the intended purpose if used more generally in the population. Thus, research subjects are exposed to an intervention when there is uncertainty about whether the intervention will achieve its intended purpose, in order to obtain some degree of certainty so the intervention can be used in the future for the benefit of others.

By contrast, medical practice involves "a class of activities designed solely to enhance the well-being of an individual patient or client." n59 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 [*1109] some uncertainty because of individual variation in physiology or behavior, n60 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 borne by research subjects is what raises the most salient ethical issues in research: the potential for exploitation of human, subjects [b]y placing some people at risk of harm for the good of others." n61 The primary reason that research is subject to stringent ethical requirements is "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." n62

B. Overview of Argument

Attempts to reform the practice of lethal injection have involved substantial ill-conceived medical research. State Departments of Corrections have tried to develop procedures for performing lethal injection in a manner that does not constitute cruel and unusual punishment under the Eighth Amendment of the U.S. Constitution. States have modified the drugs used in lethal injection cocktails, the dosages of those drugs, the procedures for people untrained in medicine to administer injections and anesthesia, and the procedures for people who are not medical professionals to determine an

inmate's anesthetic depth. These revisions typically require large amounts of data-gathering both during and after an execution. As states develop lethal injection procedures through modifications and adjustments, test those procedures in an attempt to find a constitutionally sound procedure that can be generalized to future inmates, gather data on the tests of these procedures, and then disseminate the results of their investigations to courts and to the public, they are conducting medical research on prisoners.

In order to explain how states are conducting research on prisoners, it will be necessary to examine specific reform efforts. The next section will examine the extensive and fairly public attempts to reform lethal injection conducted by states such as California and Florida. Another important example is the state of Kentucky, because the Supreme Court has examined the procedures used in Kentucky in order to answer the questions presented in *Baze*. Before proceeding with the application of these arguments to specific state reform efforts, however, it is important to distinguish possible sources of confusion. For the sake of conceptual clarity, the next segment examines possible classifications of lethal injection reform other than medical research. The most common sources of confusion are whether lethal injection reform should be thought of as quality control and not [*1110] research and whether lethal injection is a medical procedure that should be held to medical standards.

C. Some Clarifications

1. Is Lethal Injection Reform Research or Quality Control?

Proponents of lethal injection may argue that lethal injection should be thought of as punishment, and not research. 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 attempts at reform that involve changing dosages and gathering data that lead to the conclusion that departments of corrections are conducting research on prisoners.

Departments of corrections may argue that the attempts at reform are merely quality control designed to improve their procedures; therefore, they would argue that lethal injection reform is not 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." n63 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 should not be treated research. Research is typically defined as "a systematic investigation . . . designed to develop or contribute to generalizable knowledge." n64

This distinction is far from clear, however. Even those who argue for distinctions between quality improvement and research are unable to avoid the conclusion that the two overlap. n65 Both research and quality control involve attempts to determine better ways of determining whether an intervention works. Some research is undertaken at local levels and designed to improve a particular system, such as single-site research that is conducted in only one hospital or clinic. More importantly, both research and quality control activities attempt to find answers beyond what works for an individual patient. Therefore, whether an activity is called research or quality control, it will likely involve exposing individuals to procedures and gathering data in order to develop knowledge beyond that needed [*1111] for the individual participant undergoing the intervention. By exposing an individual to additional risk beyond what is necessary for that individual's situation, research *and* quality control activities pose the possibility of exploitation of individuals for the benefit of others.

Furthermore, it is possible to conduct research on procedures for quality control. Even if departments of corrections are trying to improve their procedures, when they make modifications in drug dosages, develop new procedures, collect evidence on how well these procedures work, and try to prove they have come up with a constitutional system, they may be doing research on how effective their quality control measures are.

For example, some correctional facilities in the country have changed their execution methods for reasons beyond

the interests of the individual prisoner--they have attempted to prove that they have developed best practices of lethal injection to be in line with the Constitution. In significant ways, they have changed the procedures that individual inmates experience. Perhaps if a correctional facility changed one small feature of its execution protocol, such as color-coding the syringes to be used to better ensure that the syringes will be used in the correct order, and then compared the execution outcomes to the data obtained in past executions, such an activity would not be research. However, such minor, relatively risk-free changes that do not require gathering data are not the subject of the argument here. Departments of corrections have changed multiple features of lethal injection protocols and have attempted to design something far removed from standard practice--a procedure that will allow non-medical professionals to mix deadly chemicals, administer injections, and monitor unconsciousness after anesthesia.

Moreover, states have created complex data-gathering systems to prove to courts that they have developed systems that can be generalized to use in all prisoners. As will be discussed further below, the outcomes of these changes are being carefully measured and documented by prison officials in order to determine whether the changes are generalizable to other inmates. The procedures include litigation coordinators and personnel whose jobs involve keeping detailed logs during executions.

To argue that lethal injection reform is merely quality control misses the point and neglects the important reasons that research is regulated and protected. Research is an enterprise that is subject to special protection for very good reason. To the extent that an individual participant is undergoing extra burdens and risks for some greater good, extra protection of that participant and oversight of the research project is necessary. n66 Even if the modifications made by departments of [*1112] corrections have elements of quality control, quality control that involves testing novel procedures and generating data involves *research* activity that is not designed to improve conditions for a particular inmate. Many of the features of lethal injection reform are designed to produce generalizable knowledge for the benefit of others, and therefore cannot be exempt of the requirements placed on research. Finally, as will be shown, the regulations governing research with prisoners do not draw the kinds of controversial and subtle distinctions that separate research from quality control. Instead, they operate to prohibit medical experimentation on prisoners in broad brushstrokes, and therefore encompass the activity involved in lethal injection reform. In at least one instance, a DOC official admitted to conducting research in devising his lethal injection protocol: "[T]he [DOC] will be doing research and determining the state-of-the-art drugs . . . and things change. We understand that the state of the art is changing daily so to say that we are going to use something today when something may be more humane becomes known later [sic] wouldn't make sense for us." n67 Although this DOC official may have been somewhat inartful in his use of the term "research," the fact remains that the relevant statutes prohibit research broadly construed, and it is hardly a stretch to keeping up with the state-of-the-art may require some experimentation on the next prisoner to be executed.

In sum, 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. Even if there are elements of quality control motivating states to make change in their lethal injection protocols, states are nevertheless conducting research on different methods of quality control.

2. Is Lethal Injection Reform a Medical Procedure?

Another objection may be that given that 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. Justice Scalia similarly noted during oral argument of *Baze* that "this is an execution, not surgery." n68 Insisting that lethal injection is not a medical procedure, and is therefore not subject to any medical norms or rules, is flawed. First, with regard to the legal constraints on research, the relevant definitions of research are included in the [*1113] statute. As will be discussed below, these definitions encompass the process of lethal injection reform.

Second, the fact that anesthesia is used in an execution does not change the fact that anesthesia is used in medical

practice for the same reason it is being used in execution--to attempt to prevent pain and suffering. It may well be true that the same safeguards put in place for the use of anesthesia for surgical procedures need not apply here. Nevertheless, lethal injection must pass the test of whether it constitutes cruel and unusual punishment, and the relevant and available evidence for the risks involved comes from the use of anesthesia in other medical contexts, including surgery.

Third, 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 in a process that causes harm. n69 It is true that lethal injection is not intended to cure a disease or limit the suffering it causes. Yet, when a physician administers a medical drug for purposes of euthanasia, the drug does not cease to be medical. Rather, the physician's act is no longer therapeutic. Even if the question is whether lethal injection counts as a therapeutic or non-therapeutic procedure (instead of the distinction between medical and non-medical research present in the relevant statutes), the use of anesthesia to attempt to prevent an inmate from experiencing pain or suffering clearly serves a therapeutic purpose. Thus, at least some elements of lethal injection are not only medical, but are also therapeutic.

Fourth, 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. n70 Justice Alito recognized the importance of such constraints in his concurrence in *Baze*, contending forcefully that "[o]bjections to features of a lethal injection protocol must be considered against the backdrop of the ethics rules of medical professionals and related practical constraints." n71

[*1114] Finally, medical procedures have legitimacy in a way that other instruments that can be used to cause death, such as gas chambers or electric chairs, do not. Some have argued that lethal injection was developed in an attempt to "medicalize" the death penalty in order to make it seem more humane and acceptable to the general public. n72 Departments of corrections are attempting "to have their cake and eat it too" by borrowing legitimacy from the medical profession when it serves the purpose of making executions seem humane, and simultaneously remaining unwilling to be constrained by the medical standards that accompany the use of medical procedures.

III. ANALYSIS OF STATE REFORMS

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." n73 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." n74 In general, the court found that the protocol lacked "reliability and transparency." n75 Judge Fogel also concluded that the system could be fixed, n76 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. n77 The court was particularly troubled by the fact that the changes [*1115] 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. n78

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." n79 The court required the Governor's office to carefully revise the lethal injection procedures and undertake:

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. n80

The court additionally suggested that the State could modify the protocol such that it require the administration of an anesthetic agent alone in sufficiently large doses to cause death. n81

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." n82 The procedure provides "the direction and process for execution by lethal injection," and cites *California Penal Code Section 3604(a)*, which permits the California Department of Corrections (CDC) to specify "the substance or substances to be injected in a lethal quantity sufficient to cause death." n83 The statute does not specify what these substances are, the order in which they should be injected, or the appropriate doses. Presumably, the CDC may change the procedure at any time without legislative amendment. More recently, a Mann 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 [*1116] public comment. n84

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 responsible for many managerial functions. n85 Additionally, the procedure describes a new lethal injection facility that is under construction in the California State Prison at San Quentin. n86 The procedure creates teams of prison officials responsible for security, intravenous access, infusion, and record keeping. n87 It also sets minimal criteria for determining the composition of these teams, such as excluding individuals who have disciplinary infractions on their records from participating in executions. n88 The protocol also mandates lethal injection simulation on a monthly basis. n89 This regular training is designed to identify "[p]otential problems and recommendations for avoidance or resolution." n90

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." n91 In fact, "[e]ach element of the Lethal Injection Protocol will be documented by a member of the Record Keeping Team." n92 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." n93 Logs are to be kept by the teams responsible for security, the intravenous lines, infusion, and the emergency operations center. n94 The associate warden, in the Specialized Housing Division, is charged 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." n95 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 [*1117] considered if the forearm is not an appropriate injection site. n96 The associate warden must schedule "[d]aily training and preparedness exercises on each of the three days prior to the execution," n97 and, in concert with the Lethal Injection Team Leader, must obtain the necessary chemicals. n98 The protocol does not state how many hours before an execution the inmate's last meal will be served. n99

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. n100 A record keeper must observe and document the preparation of the cocktail of drugs. n101 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. n102 Further, a member of the Intravenous Team assesses the inmate's

consciousness throughout the execution inside the execution room. n103 Two intravenous catheters are inserted, one of which is designated as the primary catheter. n104 The chemicals on the primary tray are injected into the inmate through the primary catheter. n105

The process starts with the insertion of syringe number one, which is a sixty cubic centimeter syringe containing 1.5 grams of the short-acting anesthetic, sodium thiopental. n106 A member of the record keeping team then begins a ten-minute count--down. n107 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." n108 If the inmate is unresponsive, then he is deemed to be unconscious. n109 Once this determination is made, another 1.5 grams of sodium thiopental is injected into the inmate. n110 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. n111 If the inmate is determined to be conscious, the injection [*1118] through the primary catheter is discontinued, and the sequence is repeated through the back-up catheter using the materials on the back-up tray. n112 If the member of the intravenous team determines that the inmate is unconscious, the chemicals designed to cause death are administered. n113 First, fifty milligrams of pancuronium bromide are injected to paralyze the inmate. n114 Then another saline flush is administered, and two doses of one hundred milliliters of potassium chloride are administered. n115 Throughout this process, team members are required to document their observations. n116 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. n117 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. n118

California has modified this protocol from its previous protocols--although the same chemicals are used, and in the same sequence, they are used in different amounts. The new protocol requires a larger dose of sodium thiopental than the protocol developed on 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. n119 There is no specification of new evidence or some other reason that led California to make these changes. Instead, as with the other modifications described above, the state appears to be modifying the protocol in light of the increased court scrutiny over whether the method of lethal injection is constitutional.

Significantly, these attempts to modify, 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." n120 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." n121 Unless there is ambiguity, [*1119] courts simply determine the plain meaning of the statutory language. n122 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. n123 The legislators deleted this phrase in 1985, changing their relatively permissive stance on research to a prohibition with only two limited exceptions. n124 Additionally, one limited exception that remained in the law in 1985 was repealed in 1995. n125 Courts presume that a deletion of a statutory provision is meant to effect "a substantial change in the law." n126 In particular, when legislatures delete an exception to a rule, the legislative intent is that the scope of the rule should be read broadly. n127 Therefore, the California legislature's deletion of these exceptions to the prohibition on research with prisoners reflects its intention to make the statute more protective of prisoners and the prohibition on research more absolute.

In 1989, the Legislature further modified the statute to ensure that prisoners were not prevented from accessing beneficial drugs or treatments. n128 The Legislature added Penal Code section 3502.5, under which physicians may provide prisoners with treatment that is only available through research or that is considered an investigational new drug. n129 However, the drug must be in the patient's best medical interest, and the patient's informed consent is necessary. n130 The Legislature amended the statute upon finding that, "state law designed to protect prisoners from inappropriate medical experimentation has had the unintended [*1120] effect of preventing prisoners from having access to drugs or treatments which might be required for good medical care." n131 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. By creating this exception, the Legislature demonstrated their intention to allow research with prisoners when it would benefit an individual prisoner by providing him with medical treatment. This exception does not apply to research done for other purposes, such as gathering data to show that a particular method of execution was constitutional.

Turning to the language used in the statute itself, biomedical research is defined as "research relating to or involving biological, medical, or physical science." n132 Thus, the term "biomedical" broadly encompasses scientific investigation, and specifically refers to medical 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." n133 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." n134 In sum, the plain language of the statute 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. n135

These features of research are present in the reform of lethal injection conducted by the State of California. First, California's lethal injection protocol 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." n136 More specifically, the protocol is an attempt to reform the [*1121] 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 "[t]o ensure direct supervision and managerial oversight of the Lethal Injection process." n137 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 accordance with the law. In other words, the protocol attempts to codify generalizable knowledge about lethal injection that can make the process effective and legal for all inmates who undergo it. Yet the method of reform offers no guarantee of success and relies on untested elements that may or may not work. 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) how the protocol will be modified in response to the various conditions that inmates may have. n138 Moreover, the protocol is subject to annual revisions and requires the gathering of massive amounts of data.

One untested element of California's lethal injection protocol is the administration of euthanasia by people who are not medical professionals. The CDOC has begun using novel protocols that allow untrained individuals, with little or no medical experience, to perform medical procedures in each lethal injection. 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, n139 medical professionals who are willing to assist with

lethal injection have become very difficult to find. n140 Therefore, Judge Fogel noted that non-medical professionals and those who have not received formal medical training may be able to administer lethal injection. Indeed, the revised lethal injection protocols are tailored to non-medical personnel and include instructions for 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.

In contrast to the minimal requirements California places on non-medical professionals monitoring an inmate's consciousness, the American Society of [*1122] Anesthesiologists has rigorous standards for basic anesthetic monitoring. n141 Among these standards, the most fundamental are the requirements that qualified anesthesia personnel must be present and the patient's oxygenation, ventilation, circulation, and temperature must be continually evaluated. n142 The presence of qualified anesthesia personnel is a significant protection for patients undergoing anesthesia because to be qualified requires years of medical training, supervision, observation, and experience. n143 The novel training of non-medical professionals by the CDOC to perform medical procedures in a safe and effective fashion does not appear to be based on evidence and is set to be revised at least annually. Unlike the training of anesthesia personnel, this training does not involve years of knowledge and experience. Devising procedures that can be performed by people without a medical background or considerable experience in observing proper anesthesia administration is complicated, and the CDOC anticipates that it will require a process of trial and error. These procedures may or may not work. For this reason, the CDOC is collecting information to determine how well these procedures work and to figure out what happened when the procedures fail. Under the statutory language, the CDOC is accumulating data "designed to develop or contribute to generalizable knowledge . . . that can be corroborated by accepted scientific observation and inferences." n144 Thus, 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. n145

The experimental administration of drug dosages presents a further problem with California's lethal injection protocol. Contrary to Judge Fogel's recommendation following the extensive evidentiary hearings he held on the matter, n146 the CDOC modified the amounts of drugs in a seemingly ad-hoc fashion. n147 The new protocol does not offer an explanation for why these dosage amounts were chosen, nor does it cite any authority or evidence for this decision. n148

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 intravenously. "[P]hysicians have particular difficulty finding suitable veins among individuals with diabetes, heavily pigmented [*1123] skin, obesity, or extreme muscularity, as well as the very nervous or drug users. One doctor estimates that nearly one quarter of prison inmates' veins may be inaccessible 'because they are deep, flat, covered by fat or damaged by drug use.'" n149 Given these uncertainties, and the fact that it is unclear how the CDOC 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. Thus, the CDOC is aware that problems may arise and therefore plans to revise the protocol at least annually. This means that the first few inmates who will be executed under the protocol will experience these hiccups and deficiencies in the protocol. Thus, these inmates will, essentially, be test subjects who will provide the CDOC with the evidence they need about the deficiencies in the protocol. By using the data generated from these test subjects, departments of corrections intend to determine how to improve the protocol to withstand constitutional scrutiny.

In fact, large amounts of data are to be gathered under the new protocol. Given the long history of problems with executions in general n150 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. n151 These records will [*1124] help determine what new problems arise and how to fix them, thereby enabling the CDOC 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." n152 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 treatments on the same basis that they are made available to patients outside the prison setting." n153 Lethal injection is not made available to patients outside the prison setting even when patients are prepared to give their informed consent; [*1125] voluntary active euthanasia is against the law in California and most other jurisdictions. n154 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 CDOC 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 of excruciating pain. 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." n155 It could be argued that these two sections should be harmonized, and the intent of the Legislature could not have been to prohibit lethal injections. For this argument to be effective, legislative intent would have to be redefined narrowly so as to avoid the outcome of applying to lethal injection, and the more general intent of the legislature to prevent risky biomedical experimentation on prisoners would have to be ignored. 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). It is not that the practice of lethal injection is prohibited by the California Penal Code. Rather, California's experimental attempts to modify its lethal injection protocol are what violate the state's own ban on biomedical research with prisoners.

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." n156 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. n157 The state will execute the first few inmates under the

revised protocol and have them take on risks related to an unknown and novel procedure, anticipating that this procedure may be proven to be effective, or that problems with the procedure will be identified if their executions go badly. And therein lies the very problem that the [*1126] California Penal Code seeks to prevent. Experimenting with dosages of (lethal) drugs on human subjects to determine what the harmful effects might be, such as the experience of excruciating pain, 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.

The process of conducting research involves determining *how* biomedical interventions can be safely administered. In its absence, the CDC 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 was specifically asked to develop findings and conclusions regarding the errors that occurred during Diaz's execution in December 2006, n158 such as the fact that the drugs were not injected into Diaz's veins, and the likely result that Diaz experienced the tremendous suffering associated with being aware during the effects of the drug that caused him to have a heart attack. The commission recently issued a report with findings about the errors in the execution and recommendations about how to improve the process. n159 The Florida commission produced a final report on March 1, 2007, n160 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." n161

The Florida commission recommended that the Florida Department of Corrections (FDOC) consider revising its protocols and specifically that the FDOC, "[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, systematic procedure for ensuring that persons selected to perform these official duties related to carrying [*1127] out lethal injections are suitably qualified." n162 The commission further concluded that the FDOC 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. n163 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. n164 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." n165

These recommendations, designed to improve the lethal injection procedure, require systematic modifications to the method of execution. By recommending that the FDOC explore the use of other chemicals and gather data on the use of the current three-drug combination, the commission is creating an ongoing process of measuring the effects of and experimenting with lethal injection. In turn, this means that the application of the protocol to any given inmate is, in part, a process used to gather information in order to improve future executions.

Following these recommendations, the FDOC issued a new protocol for execution by lethal injection on July 31,

2007. n166 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. n167 In order to ensure compliance with the procedure, extensive records are kept, including checklists that must be followed throughout and signed by the warden after each execution. n168 Two Florida Department of Law Enforcement officers are present at each execution; one sits in a room where the execution takes place and the other officer observes through a window in an adjoining room. n169 They are to keep detailed logs of the procedure, with entries made at a minimum of [*1128] two minute intervals. n170 The same three drug cocktail that is used by other states is required in the Florida protocol. n171 The Secretary of the FDOC is required to review the lethal injection procedure at least every two years, but more frequently if necessary. n172 This review is to take into account medical literature, legal jurisprudence, and protocols and experience from other jurisdictions. n173 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 needed to conduct lethal injection effectively and without the risk of causing excessive or unnecessary pain and suffering. n174

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. n175 Similarly to California law, statutory interpretation requires that the plain language of the statute govern as long as it has a "clear and definite meaning." n176 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 modification by prohibiting "any other health-related experimental procedure." n177

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." n178 Applying this principle, the Florida Supreme Court has [*1129] clarified that two related statutory provisions may still be in harmony so long as the enforcement of one provision does not render the other meaningless. n179 These principles of statutory construction are 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." n180 As the court held in *Knowles v. Beverly Enterprises-Florida, Inc.*, however, the apparent conflict is not a reason to construe either 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 FDOC now must develop new methods designed to avoid the prior problems. These procedures involve medical or pharmaceutical testing because they are modifying an 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 the Florida administrative code.

C. Kentucky

Kentucky's lethal injection protocol has recently been scrutinized by the United States Supreme Court in *Baze*. n181 The attorney general's brief in the case notes that the Kentucky Department of Corrections (KDOC) has modified the dosage of thiopental, and required the presence of phlebotomists and emergency medical technicians (EMTs) in lieu of physicians. n182 Prison officials developed Kentucky's protocol by gathering data from other states, drawing on their own personal experience, and subsequently making numerous modifications to the other protocols they found. n183 One modification of the protocol was prompted by a Kentucky circuit court, which concluded that "the procedure

which attempts to insert an intravenous catheter into the neck through the carotid artery or jugular vein does create a substantial risk of wanton and unnecessary infliction of pain" and was therefore unconstitutional. n184 In preparation for the only execution that has been conducted in the state, the KDOC conducted one hundred practice [*1130] sessions. n185 Several observers were present at the execution, who subsequently testified on how the execution transpired. n186 After hearing this testimony, the Kentucky trial court concluded that the preponderance of the evidence failed to show Kentucky's lethal injection protocol was unconstitutional. n187 In 2004, Kentucky continued to modify its procedures by changing the dose of sodium thiopental from two grams to three grams, this time as a result of the *Baze* litigation. n188

Kentucky has an important safeguard in place that may well serve to minimize the risks involved. Kentucky employs certified phlebotomists and emergency medical technicians who are trained in venipuncture to insert the catheter into the inmate's vein. n189 After the initial insertion of the intravenous line, however, the warden and deputy warden are the only two members of the team who remain with and monitor the inmate, neither of whom have any medical training. The warden visually observes whether the inmate is conscious after receiving the dose of anesthesia. In the one execution conducted by Kentucky, the warden's position allowed him to see the inmate well from the waist down, but not to carefully observe the inmate's face. n190 These measures are in sharp contrast to California's procedures for measuring anesthetic depth by interacting with the inmate and brushing the inmate's eyelashes, and both of these state's procedures fall far short of what an anesthesiologist would undertake in order to determine whether a patient was unconscious, as previously discussed.

Kentucky's lethal injection statute specifies that all prisoners sentenced to death after March 31, 1998 must be executed by lethal injection. n191 Prisoners sentenced before that date were allowed to elect whether they would be executed by electrocution or by lethal injection. n192 The statute does not specify the chemicals to be used in administering a lethal injection. n193 The statute also prohibits physician participation in executions except to declare a prisoner's death. n194

The KDOC has a policy governing research and survey projects that states the following: "Offenders under the jurisdiction of Corrections shall not be required to be the subject of medical, pharmaceutical or experimental behavioral modification research of any type." n195 As with the statutes discussed above, the definitions provided broadly encompass a wide range of activities. Medical experimentation [*1131] refers to "any medical or dental experiments and pharmaceutical studies using consensual offenders as subjects." n196 Research activities are "the application of procedures for solving a problem or testing a hypothesis." n197 Thus, KDOC policy prohibits forcing inmates to be the subject of procedures employed to test whether a medical intervention works or to solve a particular problem.

Kentucky's attempts at lethal injection reform fall under this definition of research. Kentucky modified its lethal injection protocol, tested the procedures it developed in one hundred practice runs, eliminated some procedures in response to court orders, carefully observed the first execution performed under these procedures, modified drug dosages during recent litigation, and presented the data gathered about the execution to establish that its lethal injection protocol meets the constitutional standard prohibiting cruel and unusual punishment. Notably, the KDOC has a policy that does not prohibit research altogether--rather, it only permits research where offenders are allowed to have a choice in the matter. Therefore, offenders sentenced after March 31, 1998, who do not have a choice as to whether they are executed by lethal injection or by electrocution, are unwilling participants in a medical research project that violates KDOC's own policy.

D. Other States

Before the Supreme Court granted certiorari in *Baze*, lethal injection litigation and stays of execution were ongoing in several other states, including Ohio, South Dakota, North Carolina, Tennessee, and Maryland. n198 These states also have laws or policies restricting biomedical research on prisoners, n199 as well as statutory interpretation case law requiring that these laws or policies be interpreted according to their plain meaning. n200 The analysis of whether these states' reform attempts constitute research is similar to the analysis provided above. Therefore, this section will focus on

some unique features of these state reform attempts.

South Dakota law grants considerable discretion to the warden to decide how lethal injection will proceed. On August 29, 2006, the Governor of South Dakota issued a stay of execution for death row inmate Donald Moeller because the [*1132] existing statute governing lethal injection was last updated in 1984 and required a two-drug protocol that used an ultra-short acting barbiturate to anesthetize the inmate and a chemical paralytic agent. n201 Unlike other states, South Dakota's statutes did not require a drug to cause death by stopping the heart. n202 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. n203 The new law states: "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." n204 This allows 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. n205 Without explanation, the law states that the administration of lethal injection "in the manner required by this section may *not* be construed to be the practice of medicine," and also protects pharmacists from liability for prescribing the drugs needed for lethal injection. n206 It is possible that the law is meant to permit the participation of physicians in lethal injection by defining lethal injection as not involving the practice of medicine. However, it is important to note that by allowing the warden such discretion, the law may be subject to considerable modifications whenever the warden so desires.

North Carolina's protocol is unusual in that it uses a bispectral index (BIS) monitor to track an inmate's level of consciousness during the execution procedure. n207 The State's 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 . . . prevent the possibility of the inmate being awake." n208 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 [*1133] picked up by the BIS monitor and misinterpreted as EEG activity." n209 Dr. Dershwitz's earlier statements demonstrate that the use of the BIS monitor is experimental at this stage and may be subject to unknown problems. The warden has the task of tracking the inmate's consciousness through the BIS monitor, not a physician. n210

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. n211 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. n212 Furthermore, the ALJ found that both pancuronium bromide and potassium chloride would result in excruciating pain if administered while an inmate is conscious. n213 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. n214 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 feel pain prior to and at the time of the administration of any pancuronium bromide or potassium chloride." n215 For these reasons, the ALJ ordered that the North Carolina Council of State reconsider its Execution Protocol. n216 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. n217

Also unlike the states previously discussed, North Carolina's policy on research with prisoners adopts the Federal Regulations governing research on prisoners, n218 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." n219 Additionally, the regulations clarify that "[a]ctivities which meet [*1134] 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." n220 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 those risks would require some investigation of this new technique. Furthermore, because this approach will have to be improved in a manner that can be approved by the ALJ, proving that this reform has occurred will require documentation of data that can be generalized to executions with other inmates. North Carolina's restriction on research also 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 (NCDOC) to date. n221 A further requirement is that "the risks involved in the research are equivalent to risks that would be accepted by non-prisoner volunteers." n222 It seems impossible to imagine that non-prisoner 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. n223 Therefore, North Carolina's revision of its lethal injection protocol with respect to the monitoring of a prisoner's anesthetic depth contravenes its own regulations restricting research on prisoners.

Finally, 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). n224 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. n225 This process of developing procedures in an effort to comply with the Constitution is akin to publishing data, which is an important feature of research.

[*1135] IV. ETHICAL CONSIDERATIONS

Over the long history of research in the United States, prisoners in particular were frequently subject to exploitation and abuse. 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. n226 "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 prisoners were not adequately treated for pain." n227 In fact, prior to the early 1970s, "approximately 90% of all pharmaceutical research was conducted on prisoners." n228 Yet, these studies and others, such as the Tuskegee experiment, n229 led the public to become wary of medical experimentation on institutionalized populations. n230 Consequently, the practice of research with prisoners in the United States began to come under increasing scrutiny in the 1960s. n231 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." n232

In addition to the legal concerns discussed at length, reform efforts by states and [*1136] departments of corrections have also raised significant ethical concerns that may be of concern to a public already skeptical of research on prisoners. Reform efforts have neglected at least five major principles of ethical research in their attempts to reform lethal injection. The most prominent framework of the ethical components of research has drawn from the medical ethics literature and domestic and international codes, guidelines, regulations to delineate seven ethical principles for the conduct of research. Of these seven principles, five are clearly relevant to lethal injection reform: (1) social value, (2) scientific validity; (3) fair subject selection; (4) risk minimization; and (5) informed consent. n233

First, states have failed to establish the social value of experimenting with a paralytic drug that runs the risk of preventing an inmate from demonstrating that he is suffering excruciating pain, with the sole purpose to promote his dignity as he dies in front of witnesses. In *Baze*, Kentucky argued that maintaining an appearance of dignity was the sole reason for the second drug in the sequence, a paralytic agent. n234 The three-drug cocktail is being tested for a few different purposes, some of which have legitimate social value. For instance, designing a humane way to conduct state-mandated executions is of legitimate social value. If physicians cannot be involved in executions for ethical and professional reasons, then there is also significant value to determining whether a humane execution can be conducted without physician involvement. Trying to devise a procedure that looks like a peaceful death when it in fact may not be,

however, is not of legitimate social value. In light of the constitutional prohibition on cruel and unusual punishment, creating a cosmetic veneer to conceal an experience of excruciating pain is not a legitimate societal interest; research to accomplish such an end therefore lacks social value.

A further requirement for the ethical conduct of research is that it has scientific value, in that it is methodologically rigorous and can answer an important scientific question. The modifications that individual states have been making to their protocols fail to meet that standard. Reform efforts lack scientific validity because there is no evidentiary basis to suggest that they might improve lethal [*1137] injection for other inmates and they are not being tested in a controlled, rigorous fashion. The gold standard for research is the randomized controlled trial (RCT), in which a novel intervention is tested against a known element so that the effects particular to the trial can be factored out. Yet, there is no control against which the modifications in lethal injection procedures are being tested, and it is not clear that there is a form of lethal injection understood well enough to function as an appropriate comparison. Moreover, gathering systematic data would require methods such as setting a rigid timeframe during which relevant data from executions would be collected, setting criteria for which evidence is relevant, adjusting for variation in subjects that may make them more or less susceptible to the outcome being studied, and using statistical methods to determine the relevant number of test subjects needed to arrive at a definitive answer. n235

The haphazard revision process exhibited by states and prison officials bears almost no resemblance to the rigorous methods used in carefully designed studies. People with no expertise in medicine or medical research are responsible for administering lethal injection procedures and gathering the data on outcomes. States do not measure, account, or control for the many potential complicating factors that may be relevant to outcomes. For instance, inmate-specific issues may complicate the administration of anesthesia in the context of an execution. These issues include 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. n236 Additionally, experimenting with drugs that hide bad outcomes and prevent inmates who are suffering from being provided with medication to alleviate their suffering is deleterious to the process of devising a humane system of lethal injection. In other words, using one drug that hides the effects of the other drugs prevents prison officials from determining how their experiment is going. Lethal injection research lacks rigor for these reasons, which makes it unlikely that death row prisoners serving as research subjects are doing so for any important end. To be clear, although inmates may be executed according to the sentence they received, their participation in *research* to reform lethal injection is largely for naught. Because it is unlikely to generate a constitutional execution method, current lethal injection research lacks scientific value.

Another critical requirement for the ethical conduct of research is fair subject selection. There has been much controversy over whether the racial composition of inmates on death row reflects that of the general population and significant concern [*1138] that minorities are disproportionately represented. n237 Moreover, no consistent standard for lethal injection had been articulated until the decision in *Baze*, and there was a "dysfunctional patchwork of stays and executions" across the country. n238 Some states were modifying and conducting research on their lethal injection protocols, but other states had found execution by lethal injection to be constitutional and therefore allowed executions to proceed. To the extent that death row prisoners are a sample of the population that has been unfairly selected, research conducted on such a skewed population may not meet an important ethical criterion.

Research on lethal injection has also failed to follow the obligation to minimize risks. Prisons have avoided using approaches that are unlikely to cause pain, such as the administration of a single, large dose of an anesthetic. Instead, they have chosen to modify their existing approaches, which require the use of a complex cocktail of three drugs. Because research should be conducted only after risks to subjects have been minimized, research on lethal injection is ethically problematic for this reason as well.

A final requirement for the ethical conduct of research implicated by lethal injection reform is informed consent. Informed consent is one approach to ensuring that research participation is consistent with the subject's exercise of autonomy and that the individual involved in research is respected. Inmates do not, of course, have the right to give

informed consent to being executed--that decision is for a jury to make. Instead, just as prisoners would have a choice to participate in research conducted by the state testing the effectiveness of different approaches to drug delivery in prisoners with mental health issues, inmates should be asked for their consent to participate in research about how they should be killed.

It is unclear how obtaining informed consent to lethal injection research could be achieved. In some states, existing approaches to lethal injection have been ruled unconstitutional and therefore cannot be used. To allow prisoners a choice about whether to participate in lethal injection reform in those states, they must therefore be given a choice between undergoing execution by revised lethal injection procedures and not undergoing execution at all. It is a rare case in which a prisoner will agree to be executed when given the option not to be executed, which makes it difficult to imagine obtaining sufficient numbers of subjects to conduct this kind of research. In addition, one might reasonably question the competence of a prisoner willing to give consent to unknown risks of pain and suffering from participation in research on a medical method of execution.

V. OBJECTION: WHY DOES IT MATTER WHETHER PEOPLE WHO ARE BEING EXECUTED ARE ALSO BEING EXPLOITED?

One objection to this interpretation of state laws prohibiting research on [*1139] prisoners is that if the intent of the prohibition on research with prisoners is to prevent exploitation of prisoners, this is simply irrelevant to the practice of lethal injection. The argument is that the only constraint on lethal injection should be whether it constitutes cruel and unusual punishment under the Constitution, not whether the method of administering lethal injection exploits some prisoners in order to develop a better system of execution that the state can use on others. To put the point forcefully, some may argue that it is simply a waste of time to worry about the potential exploitation of convicted murderers who have already been sentenced to the much more serious penalty of death.

First, it is the attempt to *reform* lethal injection that may well be exploitative of some inmates for the benefit of other people, not the fact that these inmates have been sentenced to death. The institution of a death sentence should not do more work than accomplishing a death sentence--inmates do not relinquish all other rights by being sentenced to death. n239 Requiring inmates to participate in an exploitative research program would violate their legal rights. The first few inmates who receive lethal injections after the protocol is modified will be exploited and exposed to risk as test subjects for novel procedures. The state laws and ethical principles discussed above are designed to protect these very rights, and it is important that the rules and ethical principles regarding research are applicable to everyone. Just as it would not be acceptable to subject inmates to inhumane prison conditions before an execution simply because they are to be put to death, n240 and such actions can hardly be worse than death, it is not acceptable to forego restrictions on research as they apply to inmates on death row. It may even be worse to add such insult to injury by disregarding the standards for the conduct of research and placing burdens of exploitation and exposure to unknown risks of pain and suffering because they are the people whose lives seem to matter the least.

Whether or not proponents of the death penalty are convinced by arguments that require some consideration of the rights of people who are convicted murderers, however, it is also true that research with prisoners and other vulnerable populations has been stained by a history of scandal. Public perception of research may be further strained if it becomes clear that execution by lethal injection has involved a research program on individuals who are compelled to participate and face unknown risks of excruciating pain and suffering.

[*1140] VI. APPLICATION TO *BAZE V. REES*

Although the questions considered in *Baze* are fairly narrow, n241 the arguments herein have special salience in the wake of the Court's decision. The disagreement amongst the Justices on the relevant standard to evaluate lethal injection will make it difficult to predict the long-term effects of this decision. Beginning with the three-Justice plurality opinion, the Court indicates that lethal injection procedures are unconstitutional when they pose a "substantial risk of serious harm." n242 Reform efforts calibrated to a standard of "substantial risk of serious harm" would conflict with the

ethical obligation to minimize research risks. Moreover, this standard would seem to permit some degree of risk in the administration of lethal injection, which means that there may be more failures in lethal injection administration in the future. There is no guarantee that new procedures might be developed and that new problems might be uncovered, and the Court's decision leaves open that possibility. When this happens, states will have to reform their protocols yet again, which may raise the ethical and legal concerns previously discussed.

Justices Thomas and Scalia proposed a very different standard--that "a method of execution violates the Eighth Amendment only if it is deliberately designed to inflict pain." n243 This standard would appear to permit a great deal of experimentation in lethal injection, as long as DOCs conducting the research do not intend to cause pain. The arguments herein have not assumed that DOCs or other state groups intend to experiment on inmates for the purpose of causing harm; it is more likely to be the case that DOCs simply are unaware that the laws and policies governing research with prisoners apply to certain attempts to reform lethal injection. Nevertheless, this standard was persuasive to only two of the justices and seems unlikely to take hold.

Finally, Justices Ginsburg, Souter, and Breyer agree that procedures are unconstitutional when they pose "an untoward, readily avoidable risk of inflicting severe and unnecessary pain." n244 By requiring risks be avoided or minimized, this standard is most in line with the ethical and legal restrictions on research with [*1141] prisoners. Justice Ginsburg would also require a factor analysis considering the degree of risk, magnitude of pain, and availability of alternatives, with the ability to trade-off one factor for another--she indicates that "a strong showing on one [factor] reduces the importance of the others." n245 Justice Ginsburg's dissent does not, however, clarify what an "untoward" risk might mean, and that term seems to allow for more discretion than the other proposed standards permit. The "untoward risk" standard is likely to require the most clarification and interpretation of the three standards discussed in the opinion.

The Court's splintered decision does not make the task facing lower courts much easier, and litigation on these issues is certain to continue. Justice Thomas raises the following questions as likely candidates for future litigation with regard to the plurality's standard: "At what point does a risk become 'substantial'? Which alternative procedures are 'feasible' and 'readily implemented'? What penological justifications are 'legitimate'?" He appropriately concludes that, "we have left the States with nothing resembling a bright-line rule." n246

What is clear, however, is that further, reform efforts are likely to be undertaken by states attempting to respond to the ruling. The plurality opinion expressly states that, "[a] State with a lethal injection protocol substantially similar to the protocol we uphold today would not create a risk that meets this standard." n247 Other states will have to emulate Kentucky's procedures and then prove to their state courts that they have met the constitutional standard. Yet, as Justice Breyer noted in oral argument, the record in the Kentucky case was not well-developed for the purpose of examining the specifics of Kentucky's protocol, its application to inmates and the risks involved (as only one inmate had been executed under the protocol), and the available alternatives. n248 The evidence about alternative protocols and the risks involved with lethal injection are sufficiently underdeveloped in *Baze* that a ruling on the status of Kentucky's protocol cannot definitely answer questions about the risks involved in lethal injection. Kentucky additionally has only had experience in conducting one execution (in stark contrast to states like Texas, which has conducted over 400 executions since 1976), n249 and the State of Kentucky also prohibits physician involvement in executions. n250 Paradoxically, then, a state that has very limited experience in executions by lethal injection and that has prohibited physician involvement in developing their procedures is to serve as the model for states with far more experience in this area and prior physician involvement. Justice Stevens was likely correct in concluding that, "[i]nstead of ending the controversy, I am now convinced that this case will generate debate not [*1142] only about the constitutionality of the three-drug protocol, and specifically about the justification for the use of the paralytic agent, pancuronium bromide, but also about the justification for the death penalty itself." n251

The problems in lethal injection have led to reform attempts partially because of the unseemly and disturbing nature of the botched executions. To the extent that public reaction to lethal injections gone awry will persist, even with a Supreme Court ruling that appears to permit some amount of risk in execution by lethal injection, reform attempts will

continue to occur and litigation and discovery will proceed. Some of these reform attempts may then come into conflict with research laws and research ethics. Thus, states will be conducting practice runs of executions, changing drug amounts, instituting new procedures, and then gathering data about the success of these new procedures to be published and reviewed by courts in their states, thereby conducting research on prisoners.

VII. 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, such as the Eighth Amendment prohibition on cruel and unusual punishment. 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. Some states have lethal gas as a viable method of execution. n252 Other methods of execution have fallen into disfavor, perhaps because of public perception that these methods are inhumane and that medicalization of executions may provide a less painful and more civilized alternative. n253 It is not clear whether the arguments in this Article 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 [*1143] on research with prisoners that are not limited to medicine. n254

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 resulting 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 simply expecting that DOCs will adopt the procedure most recently sanctioned by courts, some national consensus must be reached on lethal injection. As Justice Thomas realized, weighing the risks involved and developing standards for lethal injection will "require courts to resolve medical and scientific controversies that are largely beyond judicial ken." n255 Other commentators have suggested that a nationwide commission should be established to determine what risks and uncertainties are associated with lethal injection. n256 Presumably, such a commission would be charged with examining the existing data, determining what further data are needed, and 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. n257 Furthermore, it might be possible for a protocol that posed no risks of pain, through the use of one large dose of an anesthetic, to meet the ethical criteria for conducting research in the United States. Such a research study might be ethically acceptable if the protocol was tested in a rigorous fashion likely to yield a scientifically valid result, if it did not use a paralytic drug for cosmetic purposes in a manner that undermines its social value, if risks were sufficiently minimized, and if the subjects in the study were fairly selected. It is also conceivable that inmates might agree to participate in such a research program that tried to determine how best to administer [*1144] lethal injection. This is especially true if the alternative would be to conduct lethal injection in its current form, with the attendant risk of excruciating pain and suffering.

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. n258 Additionally troubling is the fact that there may be some level of irreducible risk of pain, suffering, or unintended consequences 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. n259 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. A study of 535 cases of euthanasia performed in the Netherlands, where euthanasia is legal and involves the administration of a large dose of an anesthetic only, demonstrated that technical problems with the practice of euthanasia occurred in five percent of cases and complications occurred in three percent of cases. n260 It is not clear that these problems related to the experience of pain and suffering, however. Because there is no reason to anticipate that it would pose risks of pain and suffering, research on a single, lethal injection of anesthesia may be more acceptable than research on the current protocols, whether conducted in the U.S. or abroad.

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 [*1145] 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.

VIII. 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 the federal regulations governing research with prisoners, and these recommendations may apply even more forcefully to state regulations. n261 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, 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, and now must conduct reform in light of the decision in *Baze*. In fact, the implications for this analysis may be most salient for the Supreme Court's decision in *Baze*. Because the Supreme Court's analysis requires an approach to reform similar to the approaches undertaken by Kentucky, research regulations and policies in many states may prohibit departments of correction from abiding by the Supreme Court decision. The fact that there are three [*1146] different standards for evaluating lethal injection in the Court's decision suggests that more litigation will be necessary to clarify the constitutionality of lethal injection. Ultimately, the successful development of a standard for lethal injection reform must take account of the fact that the approach to reform and the changes it requires cannot involve unethical and unlawful research on prisoners.

APPENDIX 1

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
CALIFORNIA	"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.	"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).
FLORIDA	"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	"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

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
	<p>her/his need for a specific medical procedure that is not generally available." Fla. Admin. Code Ann. R. 4-4402.</p>	<p>RECOMMENDATIONS (Mar. 1, 2007).</p>
KENTUCKY	<p>"Offenders under the jurisdiction of Corrections shall not be required to be the subject of medical, pharmaceutical or experimental behavioral modification research of any type." KENTUCKY DEPT. OF CORRECTIONS, RESEARCH AND SURVEY PROJECTS POLICY No. 5-1 (2005) (on file with author).</p>	<p>The KDOC has modified the dosage of thiopental and required the presence of phlebotomists and emergency medical technicians (EMTs) in lieu of physicians. Prison officials developed Kentucky's protocol by gathering data from other states, drawing on their own personal experience, and subsequently making numerous modifications to the other protocols they found.</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</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. Cooley v. Taft, No. 04-1156</p>

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
	<p>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 description, http://www.drc.state.oh.us/web/hsrrc_review.htm.</p>	<p>(S.D. Ohio Nov. 22, 2006); State v. Rivera, No. 04-CR-065940 (Ct. Com. Pl. July 24, 2007).</p>

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
SOUTH DAKOTA	<p>"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."</p> <p>South Dakota Department of Health, Correctional Health Services Policy P-I-07, "Medical and Other Research" (April 1, 2007)</p>	<p>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.</p> <p>S.D. CODIFIED LAWS § 23A-27A-32 (2007 amendment notes).</p>
NORTH CAROLINA	<p>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;</p>	<p>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</p>

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
	<p>(4) procedures for the selection of within the prison are fair to all prisoners and that prison authorities or other prisoners cannot intervene in the selection.</p> <p>(5). information about the project is written at a level that prisoners can understand.</p> <p>(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."</p> <p>(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.</p>	<p>depth and proceeded with executions. Brown v. Beck, 445 F.3d 752 (4th Cir. 2006).</p>
TENNESSEE	<p>"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</p>	<p>"The plaintiff's pending execution under Tennessee's new lethal injection protocol violates the Eighth Amendment</p>

STATE	REGULATIONS	REFORM OF LETHAL INJECTION
	<p>a specific medical procedure which is not generally available." Tennessee Dept. Correction Policy # 114.02 (June 1, 2004), http://www.state.tn.us/correction/pdf/ researchform.pdf.</p>	<p>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).</p>
MARYLAND	<p>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] § 12.14.04.02.0 (2007).</p>	<p>Executions halted for failure to comply with the Administrative Procedures Act when developing the lethal injection protocol. See <i>Evans v. State</i>, <i>914 A.2d 25</i>, 80-81 (Md. 2006).</p>

Legal Topics:

For related research and practice materials, see the following legal topics:

Constitutional Law Bill of Rights Fundamental Rights Criminal Process Cruel & Unusual Punishment Criminal Law & Procedure Sentencing Capital Punishment Cruel & Unusual Punishment Criminal Law & Procedure Postconviction Proceedings Imprisonment

FOOTNOTES:

n1 *Baze v. Rees*, No. 07-5439, slip op. (U.S. Apr. 16, 2008); *see also* Transcript of Oral Argument, *Baze v. Rees*, No. 07-5439 (Sept. 25, 2007), *available at* http://www.supremecourtus.gov/oral_arguments/argument_transcript/07-5439.pdf.

n2 Prior to the Supreme Court's grant of certiorari in *Baze*, lethal injections were halted in California, Delaware, Florida, Maryland, Missouri, North Carolina, Ohio, Tennessee, Texas, and the federal system. Additionally, the Eighth Circuit lifted stays in Arkansas and Missouri, but reinstated them as a result of *Baze*. *See Death Penalty in Flux*, DEATH PENALTY INFORMATION CENTER, Apr. 10, 2008, <http://www.deathpenaltyinfo.org/article.php?did=2289#exe>.

n3 *See, e.g.*, *Morales v. Tilton*, 465 Supp. 2d 972, 974 (N.D. Cal. 2006) (discussing California's lethal injection system). Additionally, some states, such as Florida, have attempted to reform lethal injection protocols without prior court intervention. *See, e.g.*, GOVERNOR'S COMM'N ON ADMIN. OF LETHAL INJECTION, FINAL REPORT WITH FINDINGS AND RECOMMENDATIONS 9 (2007), *available at* <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Public/MoralesTaylorAmicus/15.pdf>.

n4 *Petition for Writ of Certiorari at Baze v. Rees*, No. 07-5439 (July 11, 2007), 2007 WL 2781088.

n5 *Baze*, No. 07-5439, slip op. at 13 (indicating that alternative procedures should be employed by states when they are "feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain")

n6 *Baze*, No. 07-5439, slip op. at 1 (Thomas, J., concurring).

n7 *See infra* app. 1 (listings states, regulations governing research with prisoners, and cases requiring reform of lethal injection).

n8 Ellyde Roko, *Executioner Identities: Toward Recognizing a Right to Know Who is Hiding Beneath the Hood*, 75 *FORDHAM L. REV.* 2791, 2797 (2007).

n9 *Id.*

n10 Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 *FORDHAM L. REV.* 49, 65 (2007) [hereinafter Denno, *Lethal Injection Quandary*].

n11 *Id.*

n12 *Id.* at 65-66.

n13 *Id.*

n14 *Id.*

n15 Denno, *Lethal Injection Quandary*, *supra* note 10, at 66-67.

n16 *Id.* at 67.

n17 *Id.*

n18 *Id.* at 68.

n19 Deborah W. Denno, *When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocutation and Lethal Injection and What It Says About Us*, 63 *OHIO ST. L.J.* 63, 95-96 (2002) [hereinafter Denno, *Legislatures Delegate Death*].

n20 *Id.* at 97.

n21 Denno, *Lethal Injection Quandary*, *supra* note 10, at 70-71.

n22 *Id* at 72.

n23 *Id.* at 73.

n24 OKLA. DEP'T OF CORR., OKLAHOMA POLICY STATEMENT No. P-090900, PROCEDURES FOR CARRYING OUT THE DEATH SENTENCE (1977) (on file with author).

n25 Denno, *Lethal Injection Quandary*, *supra* note 10, at 74.

n26 OKLA. DEP'T OF CORR., OKLAHOMA POLICY STATEMENT No. P-040301-01, PROCEDURES FOR THE EXECUTION OF INMATES SENTENCED TO DEATH, (2006) (on file with author).

n27 Ty Alper, *Lethal Incompetence: Lethal Injection Litigation is Exposing More Than Torturous Executions*, THE CHAMPION, Sept.-Oct. 2006, at 41 ("All states that employ lethal injection do so by injecting inmates with a series of three powerful drugs."); *see also* Denno, *Lethal Injection Quandary*, *supra* note 8, at 55 (discussing California's use of sodium thiopental, pancuronium bromide and potassium chloride). New Jersey previously required that a two-drug combination be used, but has since abolished executions. *N.J. STAT. ANN.* § 2C:49-2 (repealed 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."); Jeremy W. Peters, *Corzine Signs Bill Ending Executions, Then Commutes Sentences of 8*, N.Y. TIMES, Dec. 18, 2007, at B3 ("New Jersey is now the first state to repeal the death penalty since the United States Supreme Court set the framework for the modern capital punishment system in 1976.").

n28 Denno, *Lethal Injection Quandary*, *supra* note 10, at 55, 78.

n29 *Id.* at 55.

n30 *Id.*

n31 *Id.*

n32 Denno, *Legislatures Delegate Death*, *supra* note 19, at 98.

n33 Mark J. S. Heath et al., *Inadequate Anesthesia in Lethal Injection for Execution*, 366 THE LANCET 1073, 1074 (2005).

n34 . 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 well, *The Needle and the Damage Done*, N.Y. Tams MAGAZINE, Feb. 11, 2007, at 646. 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.

n35 . See American Society of Anesthesiologists, Patient Education Brochure: The Medical Specialty of Anesthesiology, <http://www.asahq.org/patientEducation/specialty.htm> (last visited Mar. 12, 2008) [hereinafter Patient Education Brochure].

n36 . Alper, *supra* note 25, at 41 (emphasis in original).

n37 . Denno, *Lethal Injection Quandary*, *supra* note 10, at 92.

n38 . *Id.*

n39 . *Id.* at 93.

n40 . Michael L. Radelet, *Some Examples of Post-Furman Botched Executions*, DEATH PENALTY INFORMATION CENTER, May 24, 2007, <http://www.deathpenaltyinfo.org/article.php?scid=8&did=478>.

n41 *Id.* (recounting the August 26, 1998 execution of Genaro Ruiz Camacho); see also Denno, *Lethal Injection Quandary*, *supra* note 10, at 18 (noting that as of 2006, Ohio conducted the second longest execution by lethal injection ever recorded--a ninety-minute procedure).

n42 Denno, *Lethal Injection Quandary*, *supra* note 10, at 18 ("Donald Harding's eleven-minute execution and suffocating pain were so disturbing for witnesses that one reporter cried continuously.").

n43 Andrew Welsh-Huggins, *Inmate Sought Injection Alternative During Execution*, CHI. TRIB., May 12, 2006, at C6.

n44 *Id.*

n45 *Id.*

n46 *Woman Sues U.S. Prison Over Son's 86-minute Execution*, AGENCE FRANCE PRESSE, July 3, 2007, available at http://rawstory.com/news/afp/Woman_sues_US_prison_over_son_s_86_07032007.html.

n47 *Id.*

n48 Welsh-Huggins, *supra* note 43, at C6.

n49 Gary Fineout, *Executioners Missed Vein with Lethal Cocktail, Report Says*, MIAMI HERALD, Dec. 15, 2006.

n50 Chris Tisch, *Doctor: Execution flawed at start*, ST. PETE. TIMES, Feb. 13, 2007, at 1B.

n51 *Id.*

n52 *Id.*

n53 *Id.*

n54 *Botched Execution Spurs State Changes*, CHI. TRIB., Aug. 5, 2007, at C10.

n55 Tisch, *supra* note 50, at 1B.

n56 *Morales v. Tilton*, 465 Supp. 2d 972, 980-81 (N.D. Cal. 2006).

n57 *Id.*

n58 ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 3 (2d ed. 1986).

n59 *Id.*

n60 *See id.*

n61 Ezekiel J. Emanuel, et al., *What Makes Clinical Research Ethical?*, 283 *JAMA* 2701, 2701 (2000).

n62 *Id.*

n63 Christine Grady, *Quality Improvement and Ethical Oversight*, 146 *ANNALS INTERNAL MED.* 680, 680 (2007).

n64 *Id.* (citing 45 *C.F.R.* § 46.102(d) (2008)).

n65 *See* J. Lynn et al., *The Ethics of Using Quality Improvement Methods in Health Care*, 146 *ANNALS INTERNAL MED.* 666, 669-70 (2007) (noting that "if a QI activity is designed both to improve local care and to produce broadly generalizable knowledge, it is both QI and research," and further stating that "[i]f that activity has participants who meet the definition of human subjects, it is both QI and human subjects research and the regulations treat it as human subjects research"); Bernard Lo & Michelle Groman, *Oversight of Quality Improvement*, 163 *ARCHIVES INTERNAL MED.* 1481, 1481 (2003) ("[T]he term *quality improvement* is used to refer to a broad range of projects, which vary widely in the potential benefits and risks to participants and which overlap with research.") (emphasis in original).

n66 *See* Grady, *supra* note 63, at 680 ("[G]reat 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.").

n67 *Baze v. Rees*, No. 07-5439, slip op. at 7 (U.S. Apr. 16, 2008) (Stevens, J., concurring in judgment) (quoting Transcript of Public Hearing on Proposed Amendments to the New Jersey Lethal Injection Protocol 36 (Feb. 4, 2005)).

n68 Transcript of Oral Argument, *Baze v. Rees*, *supra* note 1, at 16.

n69 See *AMA Opposes Physician Involvement in Executions*, U.S. NEWSWIRE, Feb. 17 2006, available at <http://www.ama-assn.org/ama/pub/category/16007.html> ("A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution.").

n70 See, e.g., *id.*; AM. NURSES ASS'N COMM. ON ETHICS, ETHICS AND HUMAN RIGHTS POSITION STATEMENTS: NURSES' PARTICIPATION IN CAPITAL PUNISHMENT (1994), available at 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), available at <http://www.asahq.org/news/asanews063006.htm>; NAT'L ASS'N OF EMERGENCY MED. TECHNICIANS, POSITION STATEMENT ON EMT AND PARAMEDIC PARTICIPATION IN CAPITAL PUNISHMENT (2006), available at <http://www.naemt.org/aboutNAEMT/capitalpunishment.htm>.

n71 *Baze*, No. 07-5439, slip op. at 4 (Alito, J., concurring).

n72 See Denno, *Lethal Injection Quandary*, *supra* note 10, at 60.

n73 *Morales v. Tilton*, 465 F. Supp. 2d 972, 972-73 (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. *Morales v. Hickman*, 438 F.3d 926, 931 (9th Cir. 2006). 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. See *AMA Opposes Physician Involvement in Executions*, *supra* note 69 ("The American Medical Association (AMA) is alarmed that Judge Jeremy Fogel has disregarded physicians' ethical obligations when he ordered procedures for physician participation in executions of California inmates by lethal injection.") Because no physicians could be found to participate in the execution after this directive, Morales' execution was effectively stayed indeterminately. The December 15 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.

n74 *Id.* at 980.

n75 *Id.* at 981.

n76 *Id.* at 983-84.

n77 *Id.* at 979.

n78 *Id.*

n79 *Morales v. Tilton*, 465 F. Supp. 2d 972, 979 (N.D. Cal. 2006).

n80 *Id.* at 975 (citing *Morales v. Hickman*, 415 F. Supp. 2d 1037 (N.D. Cal. 2006)).

n81 *Id.* at 983-84.

n82 STATE OF CALIFORNIA, SAN QUENTIN OPERATIONAL PROCEDURE No. 0-770-1: EXECUTION BY LETHAL INJECTION III.A (2007), available at <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/California/Morales/Morales%20Dist%20Ct/2007.05.15%20protocol%20review.pdf> [hereinafter CALIFORNIA PROCEDURES 2007].

n83 *Id.* at I.B.1, V.A.1.a.

n84 Henry Weinstein, *Judge Bars New Plan for Executions: The Jurist Rules that State Broke the Law by not Seeking Public Comment or Independent Review*, L.A. TIMES, Nov. 1, 2007, at B3. Incidentally, Judge Fogel has also stayed the proceedings in *Morales*, pending the outcome of the Supreme Court litigation. *Order Granting Parties' Joint Request to Vacate Case-Management Schedule, Morales v. Tilton*, 465 F. Supp. 2d 972 (N.D. Cal. 2006).

n85 CALIFORNIA PROCEDURES 2007, *supra* note 82, at IV.C.

n86 *Id.* at V.C.1.

n87 *Id.* at V.F.4.

n88 *Id.* at V.F.4.a.5.

n89 *Id.* at V.G.

n90 *Id.* at V.G.4.b.7.

n91 CALIFORNIA PROCEDURES 2007, *supra* note 82, at V.T.5.a.

n92 *Id.* at V.H.2.

n93 *Id.* at V.H.2.e. 1.

n94 *Id.* at V.H.2.

n95 *Id.* at V.R.1.c.3. "Antecubital" refers to the "inner or front surface of the forearm." MERRIAM-WEBSTER MEDICAL DICTIONARY, <http://www2.merriam-webster.com/cgi-bin/mwmednlm?book=Medical&va=antecubital>.

n96 CALIFORNIA PROCEDURES 2007, *supra* note 82, at V.R.1.c.3.

n97 *Id.* at V.R.7.a.2.

n98 *Id.* at V.R.9.c.1.

n99 *Id.*

n100 *Id.* at V.R.11.b.2.

n101 *Id.* at V.R.11.b.3.b.

n102 CALIFORNIA PROCEDURES 2007, *supra* note 82, at V.S.1.e.4.

n103 *Id.* at V.S.1.e.8.

n104 *Id.* at V.S.1.e.3-5.

n105 *Id.* at V.S.1.e.4.

n106 *Id.* at V.S.1.e.4.e.

n107 *Id.* at V.S.1.e.4.d.

n108 CALIFORNIA PROCEDURES 2007, *supra* note 82, at V.S.1.e.4.e.

n109 *Id.*

n110 *Id.*

n111 *Id.*

n112 *Id.*

n113 *Id.*

n114 CALIFORNIA PROCEDURES 2007, *supra* note 82, at V.S.1.e.4.e.

n115 *Id.*

n116 *Id.*

n117 *Id.* at V.S.1.e.4.h.

n118 *Id.* at V.S.1.e.6.a.

n119 Compare CALIFORNIA PROCEDURES 2007, *supra* note 82, at 48, with STATE OF CALIFORNIA, SAN QUENTIN OPERATIONAL PROCEDURE No. 0-770-1: EXECUTION BY LETHAL INJECTION 25 (2006) (requiring the injection of 6.5 gm. sodium thiopental, 40 mg. pancuronium bromide, and 240 m.Eq. potassium chloride). See also STATE OF CALIFORNIA, SAN QUENTIN OPERATIONAL PROCEDURE No. 0-770-1: EXECUTION BY LETHAL INJECTION 26 (2003) (requiring the injection of 5.0 gm. sodium thiopental, 50 mgm. per 50 cc. pancuronium bromide, and 50 ml/Eq potassium chloride).

n120 CAL. PENAL CODE § 3502 (West 2007).

n121 *Roland v. Superior Court*, 124 Cal. App. 4th 154, 162 (2004) (citing *People v. Lawrence*, 25 Cal. 4th 219, 230-31(2000)).

n122 See *id.* ("If the words are unambiguous "we presume the lawmakers meant what they said and the plain meaning of the language governs.") (quoting *Day v. City of Fontana*, 25 Cal. 4th 268, 272 (2001)).

n123 CAL. PENAL CODE § 3502 (1977), amended by 1985 Cal. Legis. Serv. 1553 (West).

n124 CAL. PENAL CODE § 3502 (West 2007).

n125 *Id.*; see also CAL. WELF. & INST. CODE § 1706 (West 2007) (providing exception permitting research on wards of the State with regard to nutritional supplements, such as vitamins).

n126 *People v. Dillon*, 668 P.2d 697, 712 (Cal. 1983) (quoting *People v. Valentine*, 169 P.2d 1, 14 (Cal. 1946)).

n127 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, 315 (Cal. Ct. App. 2d 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").

n128 1989 Cal. Legis. Serv. 1367 (West) (amending CAL. PENAL CODE § 3502).

n129 CAL. PENAL CODE § 3502.5 (West 2007).

n130 *Id.* § 3502.5(a).

n131 1989 Cal. Stat. 979.

n132 CAL. PENAL CODE § 3500(b) (West 2007).

n133 *Id.* § 3500(d).

n134 *Id.* § 3500(e).

n135 Compare CAL. PENAL CODE §§ 3500(b), 3502 (West 2007) (describing and prohibiting biomedical research), with CAL. PENAL CODE §§ 3500(a), 3501, 3505 (West 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." CAL. PENAL CODE § 3500(a) (West 2007).

n136 CALIFORNIA PROCEDURES 2007, *supra* note 83, at I.A.

n137 *Id.* at I.B.

n138 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 III.C. This may be another experimental element of the protocol.

n139 Roko, *supra* note 8, at 2799-2800.

n140 *Id.* at 2800.

n141 *See generally* Am. SOC'Y OF ANESTHESIOLOGISTS, STANDARDS FOR BASIC ANESTHETIC MONITORING 1-3 (2005), available at <http://www.asahq.org/publicationsAndServices/standards/02.pdf>.

n142 *Id.* at 1.

n143 *See generally* Patient Education Brochure, *supra* note 35.

n144 CAL. PENAL CODE § 3500(d) (West 2007).

n145 *See id.* § 3500(b).

n146 *Morales v. Tilton*, 465 F. Supp. 2d 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).

n147 *See* Denno, *Lethal Injection Quandary*, *supra* note 10, at 67.

n148 CALIFORNIA PROCEDURES 2007, *supra* note 82, at V.S.1.e.4.e.

n149 *See* Denno, *Legislatures Delegate Death*, *supra* note 19, at 109-10 (quoting Thomas O. Finks, *Lethal Injection: An Uneasy Alliance of Law and Medicine* 4 J. LEGAL MED. 383, 397 (1983)).

n150 See Radelet, *supra* note 40.

n151 Although the State of California is attempting to keep elements of the new protocols and changes secret, *see, e.g., State Motion for a Protective Order for the Deliberative Process of Producing a New Lethal Injection Protocol, Morales v. Tilton*, 465 F. Supp. 2d 972 (N.D. Cal. 2006), 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. *Id.* at 575-76 ("[T]he First 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, 613 (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.

n152 CAL PENAL CODE § 3502.5(a) (West 2007).

n153 1989 Cal. Stat. 979.

n154 CAL. PENAL CODE § 401 (West 2007) ("Every person who deliberately aids, or advises, or encourages another to commit suicide, is guilty of a felony."); *see also Washington v. Glucksberg*, 521 U.S. 702, 715 (1997) (noting that most Western democracies have a blanket prohibition on active euthanasia and that California has banned assisted suicide since 1874); *Vacco v. Quill*, 521 U.S. 793, 796 (1997) (noting that "[i]n New York, as in most States, it is a crime to aid another to commit or attempt suicide").

n155 CAL. PENAL CODE § 3604 (West 2007).

n156 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).

n157 *Id.* at 447-48.

n158 Tisch, *supra* note 50.

n159 THE GOVERNOR'S COMM'N ON ADMIN. OF LETHAL INJECTION, FINAL REPORT WITH FINDINGS AND RECOMMENDATIONS (2007), available at <http://www.law.berkeley.edu/clinics/dpclinic/LethalinjectionDocuments/Florida/lethalinjectionfinalreport.pdf> [hereinafter GOVERNOR'S FINAL REPORT].

n160 *Id.*

n161 *Id.* at 8.

n162 *Id.* at 9.

n163 *Id.* at 10.

n164 *Id.* at 11.

n165 GOVERNOR'S FINAL REPORT, *supra* note 159, at 13.

n166 FLORIDA DEPARTMENT OF CORRECTIONS, EXECUTION BY LETHAL INJECTION PROCEDURES (2007), available at <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjectionDocuments/Florida/DOC/August%201%202007%20Lethal%20Injection%20Protocol.pdf>.

n167 *Id.* at 4.

n168 *Id.*

n169 *Id.* at 5.

n170 *Id.*

n171 *Id.* at 6-7.

n172 *Id.* at 14.

n173 *Id.*

n174 Lethal injection litigation in Florida circuit courts has suggested that there is a further need for modifications to the Department of Corrections' revised protocol. Order granting temporary stay, *State v. Lightbome*, No. 81-170-CF-A-01 (Fla. Cir. Ct. July 31, 2007); *but see* Order denying defendant's all writs petition to declare Florida's lethal injection procedure unconstitutional, *State v. Lightbome*, No. 81-170-CF-A-01 (Fla. Cir. Ct. Sept. 10, 2007).

n175 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)).

n176 *Holly v. Auld*, 450 So. 2d 217, 219 (Fla. 1984) (quoting *A.R. Douglass, Inc. v. McRainey*, 137 So. 157, 159 (Fla. 1931)).

n177 FLA. ADMIN. CODE ANN. R. 4-4402.

n178 *Knowles v. Beverly Enters.-Fla., Inc.*, 898 So. 2d 1, 8 (Fla. 2004).

n179 *Id.*

n180 *FLA. STAT. § 922.105* (2007).

n181 Transcript of Oral Argument, *Baze v. Rees*, *supra* note 1.

n182 *Brief for Respondents at 12-13, Baze v. Rees, No. 07-5439 (Dec. 3, 2007), 2007 WL 424.4686.*

n183 *Id.* at 4.

n184 *Baze v. Rees, 217 S.W.3d 207, 211 (Ky. 2006).*

n185 Transcript of Oral Argument, *Baze v. Rees*, *supra* note 1, at 29.

n186 *Brief for Respondents, Baze v. Rees, supra* note 182, at 6.

n187 *Brief for Petitioners at 26, Baze v. Rees, No. 07-5439 (Nov. 5, 2007), 2007 WL 3307732.*

n188 *Baze v. Rees, No. 07-5439, slip op. at 5 (U.S. April 16, 2008).*

n189 *Id.* at 6.

n190 *Id.* at 6 (Ginsburg, J., dissenting).

n191 *KY. REV. STAT. ANN. § 431.220* (West 2008).

n192 *Id.* (1)(b).

n193 *Id.*

n194 *Id.* (3).

n195 KENTUCKY DEPT. OF CORRECTIONS, RESEARCH AND SURVEY PROJECTS POLICY No. 5-1 (2005) (on file with author).

n196 *Id.*

n197 *Id.*

n198 See *Evans v. State*, 914 A.2d 25, 80-81 (Md. 2006); *Order Granting John Spirko's Motion to Intervene and Denying Motion for Preliminary Injunction at 1*, *Cooey v. Taft*, No. 04-1156 (S.D. Ohio Nov. 22, 2006), 2007 U.S. Dist. LEXIS 65480; *Order at 3*, *Brown v. Beck*, No. 5:06-3018 (E.D.N.C. Apr. 7, 2006), 2006 U.S. Dist. LEXIS 60084; Monica Davey, *Execution in South Dakota, Delayed a Year by Debate on Method, Is First in Six Decades*, N.Y. TIMES, July 13, 2007; Leslie Schulman, *Tennessee Resumes Lethal Injection Executions after Moratorium Expires*, JURIST, May 9, 2007, available at <http://juristlaw.pitt.edu/paperchase/2007/05/tennessee-resumes-lethal-injection.php>.

n199 See *infra* app. 1.

n200 See, e.g., *Hughes v. Ohio Dep't of Commerce*, 868 N.E.2d 246, 250 (Ohio 2007); *Matter of Sales Tax Refund Applications of Black Hills Power & Light Co.*, 298 N.W.2d 799, 802 (S.D. 1980); *Malloy v. Zoning Bd. of Adjustment*, 573 S.E.2d 760, 762 (N.C. CL App. 2002); *Wells v. Tenn. Bd. of Regents*, 231 S.W.3d 912, 916 (Tenn. 2007); *Carroll v. Konits*, 929 A.2d 19, 34 (Md. 2007).

n201 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>.

n202 S.D. CODIFIED LAWS § 23A-27A-32 (2007). This inconsistency was also challenged by inmate Donald Moeller in a habeas petition. *Moeller v. Weber*, 523 F. Supp.2d 975 (S.D.S.D. 2006).

n203 Davey, *supra* note 198.

n204 *S.D. CODIFIED LAWS § 23A-27A-32* (2007).

n205 *Id.*

n206 *Id.* (emphasis added). Notably, research is expressly not the *practice* of medicine.

n207 *Brown v. Beck*, 445 F.3d 752, 754 (4th Cir. 2006) (Michael, J., dissenting).

n208 See Third Affidavit of Dershwitz, *Brown v. Beck*, No. 5:06-03018, at P 11 (E.D.N.C. Apr. 12, 2006).

n209 Dershwitz Rebuttal report, *Walker v. Johnson*, No. 05-934, at 5 (E.D. Va. Feb. 3, 2006).

n210 *Id.* at 10.

n211 *Id.* at 15.

n212 *Id.* at 12.

n213 *Id.*

n214 *Id.*

n215 *Id.* at 13.

n216 *Id.* at 15.

n217 Order at 5, *N.C. Dep't of Corr. v. N.C. Med. Bd.*, No. 07-CVS-3574 (NE. Sept. 21, 2007). 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.*

n218 See N.C. DEPT OF CORR., CONDUCTING RESEARCH WITHIN THE NORTH CAROLINA DEPARTMENT OF CORRECTION, *available at* <http://www.doc.state.nc.us/rap/ResearchGuidelines.pdf> (Aug. 30, 2007).

n219 45 C.F.R. § 46.102(d) (2007).

n220 *Id.*

n221 *Id.* § 46.102(c), (j).

n222 *Id.* § 46.305(a)(3).

n223 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." *Id.* § 46.305(a)(4). Thus, an equal protection challenge alleging 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.

n224 *Evans v. State*, 914 A.2d 25, 80-81 (Md. 2006).

n225 Jeannie Shawl, *Maryland High Court Rules Lethal Injection Procedures Subject to Public Review*, JURIST, Dec. 19, 2006, *available at* <http://juristlaw.pitt.edu/paperchase/2006/12/maryland-high-court-rules-lethal.php>.

n226 For this example and others see Allen M. Homblum, *They Were Cheap and Available: Prisoners as Research Subjects in Twentieth Century America*, 315 BRIT. MED. J. 1437 (1997), *available at* http://www.bmj.com/cgi/content/full/315/7120/1437?ijkey=b58ac42465f33c5c9a41f9fb3d63ac1662dd6fa0&keytype2=tf_ipsecsha#R33.

n227 Lawrence O. Gostin, *Biomedical Research Involving Prisoners: Ethical values and legal regulation*, 297 JAMA 737, 737 (2007).

n228 *Id.*

n229 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. Amy L. Fairchild & Ronald Bayer, *Uses and Abuses of Tuskegee*, 284 *SCIENCE* 919, 919 (1999).

n230 Hornblum, *supra* note 226, at 1437.

n231 NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECT'S OF BIOMEDICAL & BEHAVIORAL RESEARCH, RESEARCH INVOLVING PRISONERS 3 (1976), *reprinted in* 42 *Fed. Reg.* 3076-77 (1977).

n232 Gostin, *supra* note 227, 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. 45 C.F.R. 46 (2005).

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, and J.M. Clair, *Raising the Ivory Tower: The Production of Knowledge and Distrust of Medicine Among African Americans*, 33 *J. OF MED. ETHICS* 177, 177-80 (2007). Additionally, African-Americans are disproportionately represented on death row. *See generally* U.S. DEPT OF JUSTICE, THE FEDERAL DEATH PENALTY SYSTEM: A STATISTICAL SURVEY (1988-2000) (2000) [hereinafter DEATH PENALTY STATISTICAL SURVEY]. Thus, the fact that departments of corrections 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.

n233 *See generally* Ezekiel J. Emanuel, David Wendler, & Christine Grady, *What Makes Clinical Research Ethical?*, 283 *JAMA* 2701 (2000). The other two principles are independent review and respect for subjects. Although courts may not have expertise in review of human subjects research, they do provide an important check on lethal injection reform efforts. For the purposes of this Article, I have assumed that courts are providing independent review sufficiently carefully to address this principle. With regard to the principle of respect for persons, this principle has been applied to allowing subjects to withdraw from research, protecting privacy through confidentiality, informing subjects of newly discovered risks or benefits, and maintaining subjects' welfare. Permission to withdraw is not an option for inmates who have been convicted of the death penalty, as is protection of their privacy. Informing inmates of risks and benefits overlaps with the category of informed consent, which is discussed in the text. Failure to maintain the welfare of subjects is a clear problem

for lethal injection, but it is a problem for the conduct of lethal injection in general, and not a problem for lethal injection *research* as such. Therefore, I have only discussed five of the seven principles in the text.

n234 Brief for Respondents, *Baze v. Rees*, *supra* note 182, at 50.

n235 John Concato, Nirav Shah, & Ralph L Horwitz, *Randomized Controlled Trials, Observational Studies, and the Hierarchy of Research Designs*, 342 *NEW ENG. J. MED.* 1887, 1890 (2000).

n236 *See generally* Mark J. Heath, et al., *Inadequate Anesthesia in Lethal Injection for Execution*, 366 *LANCET* 1073 (2005).

n237 *See generally* DEATH PENALTY STATISTICAL SURVEY, *supra* note 232; *see also* *Baze v. Rees*, No. 07-5439, slip op. at 16 (Stevens, J., concurring) (citing *McClesky v. Kemp*, 481 U.S. 279 (1987); *Evans v. State*, 396 Md. 256, 323 (2006)) (discussing the risk of discriminatory application of the death penalty).

n238 *Alley v. Little*, 447 F.3d 976 (6th Cir. 2006) (Martin, J., dissenting from denial of a rehearing en banc)

n239 *See* Order granting motion to intervene at *2-3, 5, *Thompson v. Woodford*, No. 79-01630 (N.D. Cal. Apr. 6, 2006), 2006 U.S. Dist. LEXIS 20155 (allowing a death row inmate to challenge a violation of his right to Due Process regarding prisoner classifications).

n240 *See Lancaster v. Tilton*, No. 79-01630, 2008 U.S. Dist. LEXIS 11702, at *10-11 (ND. Cal. Feb. 15, 2008) (noting that prison officials have a duty to "keep[] dangerous men in safe custody under humane conditions" and finding that prison officials had not met their burden to dismiss claims brought by death row inmates regarding "cleaning supplies, shower cleaning, noise, and rodents and vermin" on death row).

n241 Brief for Respondents, *Baze v. Rees*, *supra* note 183, at i. The questions before the Supreme Court were:

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?

n242 *Baze*, No. 07-5439, slip op. at 13.

n243 *Id.* at 1 (Thomas, J., concurring).

n244 *Baze v. Rees*, No. 07-5439, slip op. 11 (U.S. Apr. 16, 2008) (Ginsburg, J., dissenting); *see also id.* at 1 (Breyer, J., concurring in judgment).

n245 *Id.* at 4 (Ginsburg, J., dissenting).

n246 *Id.* at 13 (Thomas, J., concurring).

n247 *Id.* at 22 (majority opinion of Chief Justice Roberts).

n248 Transcript of Oral Argument, *Baze v. Rees*, *supra* note 1, at 51.

n249 DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/statel> (last visited Apr. 16, 2008).

n250 *KY. REV. STAT. ANN. § 431.220(3)* (West 2008).

n251 *Baze v. Rees*, No. 07-5439, slip op. 1 (U.S. Apr. 16, 2008) (Stevens, J., concurring).

n252 *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*, *Gomez v. Fierro*, 519 U.S. 918 (1996).

n253 *See* Michael Madow, *Forbidden Spectacle: Executions, the Public, and the Press in Nineteenth Century*

New York, 43 *BUFF. L. REV.* 461, 486-90 (1995).

n254 See, e.g., *CAL. PENAL CODE* § 3500 (West 2008) (prohibiting research on prisoners relating to "physical science").

n255 *Baze* No. 07-5439, slip op. at 13 (Thomas, J., concurring).

n256 See e.g., Denno, *Lethal Injection Quandary*, *supra* note 10, at 118-20.

n257 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.

n258 See *supra* note 70 and accompanying text.

n259 See, e.g., J. Bruhn, et al., *Depth of Anesthesia Monitoring: What's Available, What's Validated, and What's Next*, 97 *Bur. J. ANESTHESIA* 85, 86 (2006) (noting that incidence of awareness under anesthesia is alarmingly high and ranges from 0.13% to 0.18% in adults); Am. SOC'Y OF ANESTHESIOLOGISTS TASK FORCE ON INTRAOPERATIVE AWARENESS, PRACTICE ADVISORY FOR INTRAOPERATIVE AWARENESS AND BRAIN FUNCTION MONITORING 1 (2005) (reporting an intraoperative awareness rate of 0.1-0.2% in all surgical patients), available at <http://www.asahq.org/publicationsAndServices/AwareAdvisoryFinalOct05.pdf>.

n260 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, 554 tbl.3 (2000).

n261 COMM. ON ETHICAL CONSIDERATIONS FOR REVISIONS TO DHHS REGULATIONS FOR PROTECTION OF PRISONERS INVOLVED IN RESEARCH, ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS (2006).