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PEER-REVIEWED STUDIES IDENTIFYING PROBLEMS IN THE DESIGN AND IMPLEMENTATION OF LETHAL INJECTION FOR EXECUTION

Teresa A. Zimmers, Ph.D. & Leonidas G. Koniaris, M.D.***

ABSTRACT

Lethal injection was designed and carried out without any research at all. There is no evidence that any literature searches, animal modeling, clinical studies, or investigations of veterinary practice were performed prior to the first lethal injection execution. The paucity of objective information on drug action and mechanism of death in lethal injection belies the assurance of expert testimony in lethal injection litigation. Here we review two peer-reviewed studies on lethal injection for execution in which we present evidence that lethal injection does not affect death through the mechanisms intended, that thiopental may be insufficient to assure anesthesia, and that death might be affected through pancuronium-induced asphyxiation. We conclude that failures in protocol design and implementation indicate that the conventional view of lethal injection as an invariably painless death is flawed.

I. EXECUTION BY LETHAL INJECTION

Lethal injection for execution has largely replaced other modalities for the implementation of the death penalty in the United States. Public repugnance and legal challenges to execution by cya-

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nide gas and electrocution led to the development of lethal injection as an ostensibly more humane method of judicial killing.¹ Lethal injection as the mode of execution has been imposed in 929 of the 1099 executions in the United States from the re-establishment of the death penalty in 1976 to March 8, 2008.² Lethal injection involves the administration of three chemicals into the condemned inmate: thiopental sodium, a barbiturate anesthetic; pancuronium bromide, an agent that causes muscle paralysis including respiratory arrest; and potassium chloride, a depolarizing agent intended to stop cardiac activity. Modifications of the United States' lethal injection protocols have also been adopted world-wide.³

The design of a pharmacologically-based method to impose execution in the United States has generally been attributed to a desire to find a less expensive and more humane method than electrocution.⁴ Some have also contended that the protocol provides the appearance of a quiet, peaceful death, not dissimilar from falling asleep. If lethal injection indeed reliably assured a painless death, the method might comport with some judicial opinions measuring execution methods against "evolving standards of decency that mark the progress of a maturing society," and prohibiting punishments that involve "the unnecessary and wanton infliction of pain," "torture or a lingering death," or which do not accord with "the dignity of man."⁵ Other justices and legal scholars have questioned and even objected to the lethal injection protocol's resemblance to a medical procedure with anesthesia, arguing that such an effort to minimize pain and to cloak execution in the garb of medicine reduces the retribution aspect of execution and confuses the public.⁶

1. See Deborah W. Denno, *When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocution and Lethal Injection and What It Says About Us*, 63 OHIO ST. L.J. 63 (2002); Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 Ford. L. Rev. 49, 105 (2007).

2. DEATH PENALTY INFO. CTR., EXECUTION DATABASE (2008), <http://www.deathpenaltyinfo.org/getexecdata.php>.

3. See AMNESTY INTERNATIONAL, EXECUTION BY LETHAL INJECTION: A QUARTER CENTURY OF STATE KILLING tbl.1 (2007), http://www.amnesty.org/en/library/asset/ACT50/007/2007/en/UTf0Vh4U_1UJ.

4. See Leonard G. Koniaris et al., *Can Lethal Injection For Execution Really Be "Fixed"?*, 369 LANCET 353 (2007).

5. See *Beardslee v. Woodford*, 395 F.3d 1064, 1070 (9th Cir. 2005).

6. See Jonathan I. Groner, *Lethal Injection: A Stain on the Face of Medicine*, 325 BMJ:1026-28 (2002).

Although lethal injection gives the appearance of a medical procedure, no research whatsoever—clinical, veterinary, medical literature search, or other—was ever performed prior to the crafting of the initial Oklahoma legislation or the first lethal injection in Texas.⁷ The designer of the protocol, Jay Chapman, then an Oklahoma medical examiner, was guided by his experiences as a patient.⁸ He intended each of the drugs to be lethal individually and that the combination would provide redundancy. Dr. Stanley Deutsch, then chairman of anesthesiology at an Oklahoma University Medical School arrived at a similar design.⁹ Each proposed the combination of an ultra-short acting barbiturate and a paralytic; potassium chloride was not written into the statute but was added later.

The use of pancuronium bromide in the lethal injection protocol most often results in rapid paralysis of the inmate, rendering him motionless in death. The appearance of restful sleep, however, would mask extreme pain and suffering if the inmate were aware. If the thiopental were inadequate to assure anesthesia, then the inmate would suffer the sensations of paralysis and suffocation induced by the pancuronium and intense burning and cardiac arrest induced by the potassium chloride. Such pain and suffering may well violate the Eighth Amendment prohibition against “cruel and unusual punishment.” This is no mere hypothetical consideration; rather eyewitness testimony, evidence presented in litigation, along with data and interpretation published in scientific journals indicate there are significant problems with lethal injection, both in terms of the methodology by which it is imposed as well as the drug design. This Article discusses peer-reviewed manuscripts in the scientific literature examining the lethal injection protocol.

II. SCIENTIFIC PEER-REVIEW

Peer-review, the process of subjecting an author’s work to criticism and evaluation of other experts in the same field, plays a central role in what research is published. Journal editors screen submitted manuscripts for quality and interest by subjecting them to the criticism and evaluation of other experts in the same field to ensure that manuscripts meet appropriate research, statistical, scholarship, and journal criteria. When manuscripts undergo peer-

7. See Koniaris et al., *supra* note 4, at 352-53.

8. See Jamie Fellner & Sarah Tofte, *So Long as They Die: Lethal Injection in the United States*, HUMAN RIGHTS WATCH, April 2006, at 15.

9. See *id.* at 14.

review, authors receive rigorous, detailed professional critiques from the reviewers either anonymously or openly, and are required to respond to the criticism by performing additional experiments, re-evaluating data, highlighting weaknesses, and/or incorporating other citations or interpretations into manuscript. Editors and reviewers then together decide whether the data in the revised manuscript supports the authors' interpretations and whether the results are of sufficient interest to merit publication. Publication in peer-reviewed journals provides other investigators the necessary information to repeat, reanalyze, and build upon prior data and in that manner grow the knowledge base in the field. In the absence of peer-review, data and claims are viewed skeptically by other scientists and experts, particularly when the data and claims are longstanding and no effort has been made to subject them to peer review.

In lethal injection litigation, federal and state courts have relied extensively upon testimony from paid expert witnesses.¹⁰ Such witnesses typically testify on behalf of the inmate or the jurisdiction. The validity of the testimony rests upon the stated credentials of the witness and the factual content of the testimony is reviewed and checked only by the opposing side and its experts. In contrast to peer-review in the scientific literature, data and claims presented as expert testimony are not subject to unbiased expert review and criticism, and thus otherwise scientifically unsupported conclusions can be used as a basis for judicial opinions. Because the experts testifying on either side have participated in litigation in many states, such illegitimate conclusions and conflicting assertions have been propagated across the United States. In the face of these incompatible expert opinions, justices themselves have looked to the scientific literature, most prominently with Supreme Court Justice Steven Breyer inquiring during oral arguments in *Baze v. Rees*¹¹ about the papers discussed here.¹²

10. See Teresa A. Zimmers & David A. Lubarsky, *Physician Participation in Lethal Injection Executions*, 20 CURRENT OPINION ANAESTHESIOLOGY 147, 147-51 (2007).

11. *Baze v. Rees*, 217 S.W.3d 207 (Ky. 2006), cert. granted, 128 S. Ct. 34 (2007).

12. Transcript of Oral Argument, *Baze v. Rees*, No. 07-5439 (U.S. argued Jan. 7, 2008), available at http://www.oyez.org/cases/2000-2009/2007/2007_07_5439/argument/. At issue in this case is how judges should evaluate claims that the particular combination of drugs used to bring about death in Kentucky lethal injection executions causes suffering that amounts to cruel and unusual punishment, in violation of the Eighth Amendment.

At present, there is a paucity of scientific literature on lethal injection for execution. In extensive reviews of the medical literature, we were unable to find pertinent animal or clinical studies and unlike animal euthanasics, the lethal injection protocol is not approved by the Food and Drug Administration. The lethal injection drugs are administered using doses and methods that are substantially different from current clinical use and no practicing anesthesiologist has practical experience using these drugs in situations similar to executions. The very paucity of scientific information about lethal injection raises questions about its acceptability as a mode of execution and the assurance with which proponents assert its humaneness. We sought to examine all available data pertaining to lethal injection drug delivery and outcomes and submitted our findings for peer-review and publication in two of the world's leading journals in general medicine. Here we summarize those findings.

A. "Inadequate Anesthesia in Lethal Injection for Executions" in *Lancet* 2005

In 2005 our group published an integrated examination of the process of lethal injection.¹³ This article, "Inadequate anesthesia in lethal injection for execution" was published in the second most-cited general medical journal in the world, the *Lancet*. The manuscript underwent a total of three rounds of peer review by multiple experts in several disciplines. Data presented and analyzed in that article were derived from freedom of information requests, open records requests, court testimony, interviews, and the public record. The major findings of the manuscript were: (1) in many jurisdictions the execution personnel received no anesthesia or medical training; (2) drugs were administered remotely; (3) there was no monitoring for depth of anesthesia; (4) there was no review of outcomes; and (5) the protocol design contradicted veterinary practice.¹⁴ The totality of these findings led the authors to the overall conclusion that the process of lethal injection was flawed both in the design of the protocol as well as in its implementation.¹⁵ Despite the superficial resemblance to a medical procedure and use of intravenous tubing and drugs, the lethal injection protocol lacks the defining hallmarks of medical practice, among them a solid

13. See Leonidas G. Koniaris et al., *Inadequate Anaesthesia in Lethal Injection for Execution*, 365 LANCET 1412-14 (2005).

14. See *id.*

15. See *id.* at 1414.

foundation in animal and clinical research and use, expertise of the practitioner, direct monitoring of physiological signs, documentation of monitoring and outcomes, responsibility, review, and oversight by other experts.

Finally, in the absence of documentation of depth of anesthesia, we reported the only available objective measure: serum levels of the anesthetic component, thiopental, measured in blood samples taken after death from inmates executed by lethal injection and documented in autopsy reports from Arizona, South Carolina, North Carolina, and Georgia. We observed that the serum thiopental levels in many instances were much lower than that which would be required for general anesthesia in life. Furthermore, in some executed inmates, trace or undetectable amounts of thiopental were observed. We noted that “extrapolation of antemortem depth of anaesthesia from post-mortem blood thiopental concentrations is admittedly problematic.”¹⁶ Nevertheless, the data clearly did not support a conclusion that inmates invariably received an excess of thiopental. Furthermore, the extraordinary variability of thiopental levels across executions was consistent with the concerns regarding protocol design, credentials, and techniques employed.

B. Letters to the Editor of the *Lancet*

Two letters to the editor critiqued our use of post-mortem thiopental levels as a means to extrapolate adequacy of anesthesia in life.¹⁷ One of these letters was from one of the original reviewers, who retracted his support for its publication.¹⁸ (This was the source of Justice Breyer’s mistaken conclusion that the paper had been repudiated.) All the claims made in the other letter, including claims that data points were “retracted,”¹⁹ that re-plotting of data would reveal a time-dependent decline,²⁰ and that an ongoing study in Oklahoma demonstrated conclusively that thiopental levels declined after death²¹ were refuted definitively in a point-by-

16. *See id.*

17. *See* Jonathan I. Groner, Response, *Inadequate Anaesthesia in Lethal Injection for Execution*, 366 LANCET 1073 (2005); Mark J. Heath et al., Response, *Inadequate Anaesthesia in Lethal Injection for Execution*, 366 LANCET 1073-74 (2005).

18. *See* Groner, *supra* note 17, at 1073.

19. *See* Heath et al., *supra* note 17, at 1073.

20. *See id.* at 1074.

21. *See id.*

point, peer-reviewed response by the original authors.²² Indeed, although additional thiopental data from Oklahoma autopsies of executed inmates failed to show a time-dependent decline, they did confirm that many inmates had thiopental levels below that which would be required for surgical anesthesia in life.

Taken together, the correspondence and the authors' reply illuminated the void of scientific knowledge surrounding the distribution of thiopental in lethal injection and its potential redistribution after death. Simply put, there exists no controlled study examining thiopental post-mortem redistribution. A single case report demonstrated that post-mortem thiopental levels in one patient actually increased from levels in life.²³ In this manner, as well as in its high post-mortem cardiac/peripheral venous drug ratio, thiopental resembles many other drugs that distribute rapidly from blood into tissues during life, then re-distribute from tissues to blood after death.²⁴ This suggests that post-mortem serum thiopental levels might actually *under-estimate* levels in life.²⁵ While the post-mortem serum thiopental levels are an imperfect surrogate for levels in life, the unexpectedly low levels are consistent with other evidence that the anesthetic component may be inadequate, including eyewitness reports of movement and apparent awareness,²⁶ along with evidence presented in the *PLoS Medicine* article as discussed below. In the absence of monitoring and documentation of depth of anesthesia, however, post-mortem thiopental levels remain virtually the only objective available evidence by which to evaluate the protocol.

In summary, the *Lancet* study and the authors' response on lethal injection demonstrated that significant design and implementation issues exist in the lethal injection process. To date, the *Lancet* paper has withstood three years of scrutiny in the scientific literature without having a single claim disproved or even substantively challenged. Moreover, the *Lancet* published several editori-

22. Teresa A. Zimmers et al., *Author's Reply, Inadequate Anaesthesia in Lethal Injection for Execution*, 366 LANCET 1074-76 (2005).

23. See William A. Watson et al., *Blood Pentobarbital Concentrations During Thiopental Therapy*, 20 DRUG INTELLIGENCE & CLINICAL PHARMACY 283-86 (1986).

24. See Derrick J. Pounder, *The Nightmare of Postmortem Drug Changes*, in LEGAL MEDICINE 163-191 (C. H. Wecht ed. 1993); Helen Russo & Francoise Bressolee, *Pharmacodynamics and Pharmacokinetics of Thiopental*, 35 CLINICAL PHARMACOKINETICS 95-132 (1998).

25. See Groner, *supra* note 17, at 1074-76; Heath et al., *supra* note 17, at 1073-74.

26. See Fellner & Tofte, *supra* note 8, at 46; Koniaris et al., *supra* note 13, at 1412-14.

als on lethal injection and subsequently invited these authors to contribute an additional commentary.

**C. “Lethal Injection for Execution: Chemical Asphyxiation?”
in *PloS Medicine* 2007**

Based upon our group’s initial report into the lethal injection process, we hypothesized that current characterization of the pathophysiology of the lethal injection process was inaccurate. Specifically, we noted evidence that even if proper administration were achieved, errors in the lethal injection protocol drug design might result in inadequate anesthesia and severe pain during the process. We sought to evaluate the three-drug protocol for its purported efficacy in producing a rapid death with minimal likelihood of pain and suffering. Our examination concentrated upon lethal injection practice in both North Carolina and California where the most data were available. In 2007, the results were published in the world’s fifth-most-cited general medical journal, *Public Library of Science (PloS) Medicine*.²⁷

We first examined the expert witness testimony that the 2 to 5 grams of thiopental used in execution itself might be lethal, that it reliably induces rapid respiratory arrest, and that properly administered, it should ensure sufficient anesthesia for the duration of the lethal injection protocol.²⁸ Clinical use of injectable anesthetics is typically based upon body weight, not mass quantities as practiced in lethal injection. We calculated actual thiopental doses given to inmates in North Carolina using body weights recorded on autopsy reports. In the forty reports available to us, the median calculated dose of thiopental was 20.3 milligrams (mg) per kilogram (kg) of body weight, ranging from a low of 11.2 mg/kg to a high of 44 mg/kg.²⁹ Assuming that inmates in all jurisdictions weigh approxi-

27. Teresa A. Zimmers et al., *Lethal Injection for Execution: Chemical Asphyxiation?*, 4 PLoS MED. 0646-53 (2007).

28. See Declaration of Dr. Mark Heath ¶¶ 12-42, *Beardlee v. Woodford*, No. C 04-5381 JF, 2005 WL 40073 (N.D. Cal. Jan.7, 2005); Affidavit of Mark Dershwitz, M.D. ¶¶ 9-15, *Perkins v. Beck*, No. 5:04-CT-643-BO, 2004 WL 5003233 (N.D. Cal. Sept. 27, 2004).

29. In North Carolina’s first protocol, inmates were given 3 grams of thiopental, regardless of body weight. In the second version of the protocol, half of the thiopental was given after injection of the other two drugs, when the inmate would be theoretically dead. Thus, the actual amount of thiopental administered was 1.5 grams. In its current protocol, North Carolina administers 3 grams of thiopental, regardless of body weight. Recognizing that patient response to drugs is partially dependent upon the patient’s size, anesthesiologists administer drugs based upon body weight. See Zimmers et al., *supra* note 27. According to the manufacturer, the recommended

mately the same, we calculated that the equivalent dose range in jurisdictions using 2 grams thiopental would be 6.6 to 30 mg/kg, and in California using 5 grams would be 17 to 75 mg/kg. The manufacturer recommends a starting dose of 3 to 6.6 mg/kg thiopental for induction of anesthesia.³⁰ Thus the dose of thiopental used in lethal injections overlaps the clinical range—clearly a dose not designed to be fatal.

The most compelling data that thiopental is not sufficient to cause death was found in execution logs from California. These comprehensive logs which detail drug injection times, heart and respiration rates, as well as time of cessation of heart beat and respiration and flat-lining of the electrocardiogram showed that inmates continued to breathe for 1 to 9 minutes after 5 grams thiopental, indicating that thiopental does not reliably induce respiratory arrest.³¹ The failure of thiopental to cause rapid, predictable death even in gravely ill patients has also been noted by physicians participating in assisted suicides and euthanasia in the Netherlands. In its report, the Netherlands Euthanasics Task Force, concluded “it is not possible to administer so much of [thiopental] that a lethal effect is guaranteed.”³² Furthermore, it is likely that condemned inmates, many of whom were chronic drug and alcohol abusers and who are likely agitated and fearful at execution, would be more resistant to the effects of thiopental than typical surgical patients, much less the terminally ill patients in the Netherlands. Finally, typical clinical veterinary guidelines for large animals such as dogs, sheep, and swine, specify single intravenous injection of 18 to 22 mg/kg thiopental for non-painful procedures lasting only 10 to 15 minutes.³³ Importantly, swine are considered an excellent model of human cardiopulmonary and cardiovascular physiology and are of comparable body and brain size and cerebral

starting amount of thiopental when used for induction of anesthesia prior to the administration of other, longer-acting agents, is 3 to 6.6 milligrams of thiopental per kilogram of total body weight. See ABBOTT LABORATORIES, PENTOTHAL FOR INJECTION, USP (THIOPENTAL SODIUM) 3-4 (1993), available at <http://www.rxlist.com/cgi/generic/thiopental.htm>.

30. See ABBOTT LABORATORIES, *supra* note 29.

31. See Zimmers et al., *supra* note 27.

32. ROYAL DUTCH SOC'Y FOR THE ADVANCEMENT OF PHARMACY, THE HAGUE, ADMINISTRATION AND COMPOUNDING OF EUTHANASIC AGENTS § 2.2.1 (1994).

33. See DENNIS F. KOHN ET AL., ANESTHESIA AND ANALGESIA IN LABORATORY ANIMALS 426 (1997); DONALD C. PLUMB, VETERINARY DRUG HANDBOOK (5th ed. 2005).

blood flow.³⁴ Given the absence of comparable patient data from which to draw comparisons, it is prudent to conclude that when doses in lethal injection are less than or equal to clinical veterinary doses, adequate depth and duration of anesthesia cannot be assured for the duration of the execution.

We next examined the mechanism by which death was effected in the lethal injection process. The conventional wisdom and expert witness testimony typically agree that the mechanism of death is or involves cardiac arrest from potassium chloride. When patients have been accidentally injected with concentrated potassium chloride, they experience near instantaneous cardiac arrest and death.³⁵ In contrast, California data showed that many inmates failed to undergo cardiac arrest for up to eight minutes after injection of potassium chloride, and that several inmates required multiple injections of the drug.³⁶ Furthermore, data from North Carolina, which has used three versions of lethal injection, showed that times to death were not statistically different in executions using potassium chloride versus those that did not.³⁷ If potassium were the agent of death, a shorter time to death should have been noted in executions with potassium chloride. Thus, the available evidence indicates that potassium chloride is not reliably the agent of death in lethal injection.

Finally we inquired, "What is the mechanism of death if neither thiopental nor potassium chloride acts in the manner postulated by the expert witnesses?" We calculated that the dose of pancuronium bromide in lethal injection is some 3 to 11 times the dose used for intubation and would be predicted to induce rapidly a paralysis lasting many hours.³⁸ Thus in cases where thiopental and potassium chloride are insufficient to cause death, death is likely effected by paralysis and asphyxiation. Notably, in cases where catheter misplacement causes administration of the drugs under the skin or into the muscle rather than into the vein, pancuronium bromide asphyxiation is almost certainly the sole

34. See James P. Hannon et al., *Normal Physiological Values for Conscious Pigs Used in Biomedical Research*, 40 *LABORATORY ANIMAL SCI.* 293, 293-98 (1990).

35. See Angela R. Wetherton et al., *Fatal Intravenous Injection of Potassium in Hospitalized Patients*, 24 *AM. J. FORENSIC MED. PATHOLOGY* 128, 128-31 (2003).

36. See Zimmers et al., *supra* note 27.

37. See *id.*

38. See Teva Pharmaceuticals, *Pancuronium Bromide Injection Prescribing Information*, <http://www.tevausa.com/assets/base/products/pi/Pancuronium%20PI%205-2005.pdf> (last visited April 17, 2008).

mechanism of death as neither thiopental nor potassium chloride would reach their target organs and have the desired effect.

The evidence presented in this report indicate that the assumptions underlying the lethal injection protocol that have been propagated in the non-scientific literature and in the courtroom are not supported by the literature, clinical veterinary practice, or the objective data collected in lethal injections in several states. This finding should give pause to those on both sides of the lethal injection debate and should provoke a careful examination of proposals to alter the lethal injection protocol by changing doses or eliminating drugs. If jurisdictions were to move to a thiopental-only protocol, for example, inmates might experience prolonged sleep, but eventually awaken as has been observed in primates and in physician-assisted suicides in the Netherlands.

III. CONCLUSION

Until 2005, most of the scientific debate on lethal injection took place in often sealed testimony by expert witnesses testifying on behalf of adversarial sides in litigation. The nature of the legal system does not permit open, objective scientific inquiry and debate in the manner that is provided by peer-review and publication. Our studies presented here and published in the *Lancet* in 2005 and *PLoS Medicine* in 2007 provide strong evidence that the lethal injection protocol provides a substantial risk of inadequate anesthesia both due to failures of process, as well as problems in the protocol design itself. These studies should be considered by persons on both sides of the lethal injection question, to inform the debate, and to provide quantitative information upon which to base decisions. Moreover, all should take note of the paucity of information which is available and determine just what level of uncertainty and risk is acceptable in this age of modern medicine and high technology.

