No. 13-892

In the Supreme Court of the United States

CHRISTOPHER SEPULVADO,

Petitioner,

v.

BOBBY JINDAL, *ET AL.*,

Respondents.

CAPITAL CASE, DATE OF EXECUTION 2/5/14

On Petition for a Writ of Certiorari to the United States Fifth Circuit Court of Appeals

MOTION FOR WAIVER OF TIME AND LEAVE TO FILE BRIEF AND BRIEF OF ALLEN S. KELLER, M.D., KATHERINE PORTERFIELD, PH.D. AND SCOTT A. ALLEN, M.D., FACP AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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MOTION FOR WAIVER OF TIME AND LEAVE TO FILE BRIEF OF *AMICI CURIAE* ON BEHALF OF ALLEN S. KELLER, M.D., KATHERINE PORTERFIELD, PH.D. AND SCOTT A. ALLEN, M.D., FACP

Pursuant to Rule 37.2(a) and (b) of the rules of this Court, *Amici* physicians respectfully move this Court for a waiver of the 10-day notice requirement and for leave to file the accompanying *amicus curiae* brief in support of the petition for a writ of *certiorari*. Counsel for petitioner has provided *Amici* a waiver of time and has consented to the filing of this brief; counsel for respondent has refused to waive time and has opposed its filing.

Petitioner's execution date is set for February 5, 2014 and the Petition for Writ of Certiorari was filed timely on January 27, 2014. There is insufficient time between the opportunity to file this *amicus* brief and the execution date to allow the 10 days to pass, making a waiver essential. If this Court grants certiorari, this *amicus* brief is timely filed.

Allen S. Keller, M.D. is the Director of the Bellevue/NYU Program for Survivors of Torture. Dr. Keller is also Associate Professor of Medicine at New York University School of Medicine, Director, NYU School of Medicine Center for Health and Human Rights, and Director, Master Scholars Humanism and Medicine Program.

Scott A. Allen, M.D. is a Clinical Professor of Medicine and Associate Dean of Academic Affairs at the University of California, Riverside School of Medicine. He is also the Co-Founder and Co-Director of the Center for Prisoner Health and

Human Rights at Brown University and the former Rhode Island State Prison Medical Director.

Katherine Porterfield, Ph.D. is a psychologist at the Bellevue/NYU Program for Survivors of Torture and has extensive experience working with children, adolescents and adults who are survivors of torture and other trauma.

Dr. Allen and Dr. Keller are also experts for Physicians for Human Rights, an independent organization founded in 1986 on the principle that health professionals, with their specialized skills, ethical duties, and credible voices, are uniquely positioned to stop human rights violations. The expertise of PHR is sought by local human rights organizations, governments, the United Nations, international courts, and regional groups like the African Union and the European Union.[1]

Amici Curiae have special expertise in the question of the scientific and ethical issues governing the use of experimental techniques on prisoners. Petitioner Christopher Sepulvado faces execution with the use of drugs that may not have been scientifically tested for this purpose. Because of the cloak of secrecy that the State of Louisiana has extended over its lethal injection protocol, there can be no assurance that Louisiana is not violating the legal and ethical injunctions prohibiting human experimentation.

Accordingly, counsel respectfully asks that this Court grant *Amici* a waiver of the 10-day notice rule and leave to to file the attached brief.

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[1] PHR shared the Nobel Peace Prize in 1997.

Respectfully Submitted,

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INTEREST OF THE *AMICI CURIAE*[1]

Amici Curiae are physicians and health care professionals who have dedicated our careers to the protection of human rights.

Allen S. Keller, M.D. is the Director of the Bellevue/NYU Program for Survivors of Torture. Dr. Keller is also Associate Professor of Medicine at New York University School of Medicine, Director of the NYU School of Medicine Center for Health and Human Rights, and Director of the Master Scholars Humanism and Medicine Program.

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[1] Pursuant to Rule 37.3, a letter of consent from petitioner to the filing of this brief has been lodged with the Clerk of the Court. As a result of respondent's refusal to grant consent to the filing of this brief, a motion for leave to file this amicus is attached to this brief. Pursuant to Rule 37.6, counsel for *amici curiae* state that no counsel for a party authored this brief in whole or in part, and no person other than *Amicus* or their counsel made a monetary contribution to this brief.

Dr. Allen and Dr. Keller are also experts for Physicians for Human Rights, an independent organization founded in 1986 on the principle that health professionals, with their specialized skills, ethical duties, and credible voices, are uniquely positioned to stop human rights violations. The expertise of PHR is sought by local human rights organizations, governments, the United Nations, international courts, and regional groups like the African Union and the European Union.[2]

Amici Curiae have special expertise in the question of the scientific and ethical issues governing the use of experimental techniques on prisoners.

As physicians and health care professionals, we use our skills to relieve pain and suffering and to preserve life when there is a hope of doing so. We adhere to the American Medical Association's (AMA's) ethical guideline E-2.06, adopted in 2000, which prohibits physician participation in executions.

As physicians and health care professionals, we also have a specialized knowledge of principles and practices in the medical and scientific communities that are designed to protect the rights of patients and prevent non-professional actors from engaging in medical interventions for non-medical purposes. Prisoners are particularly vulnerable to human rights abuses; it is therefore unethical, under our professional standards, to ever conduct harmful treatment of prisoners, whether performed by a licensed professional or not.

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[2] PHR shared the Nobel Peace Prize in 1997.

SUMMARY OF ARGUMENT

The United States Fifth Circuit Court of Appeals wrongly held that Due Process tolerates state-sanctioned killing without adversarial scrutiny of the state's execution protocol. *Sepulvado v. Jindal et al.*, 729 F.3d 413, 420 (5th Cir. 2013). In doing so it declared that even though a "state's secrecy [perhaps] masks a substantial risk of serious harm," secrecy does not in itself *create* a substantial risk of serious harm. *Id.* (quotations omitted).

This reasoning runs afoul of long-established and institutionalized principles governing the use of pharmaceutical agents and medical procedures on humans adhered to by scientific and medical communities. The use of novel protocols, procedures and/or pharmaceutical interventions—without peer review, scientific scrutiny, and the involvement of duly-certified and trained professionals—will inevitably lead to violations of human rights that are intolerable under the Eighth Amendment to the United States Constitution.

STATEMENT OF *AMICI CURIAE*

LETHAL INJECTION AS A METHOD OF EXECUTION HAS COME FULL CIRCLE FROM THE ORIGINAL CREATION OF A DRUG PROTOCOL BASED ON SHEER SPECULATION, THROUGH A PERIOD OF PROTOCOL DEVELOPMENT BASED ON STATES' EXPERIENCES WITH A SETTLED GROUP OF THREE DRUGS, TO THE PRESENT-DAY REVIVAL OF HUMAN EXPERIMENTATION UNINFORMED BY SCIENCE AND WITHOUT EXTERNAL REVIEW.

A. When human-subject experimentation goes unregulated, patients are subjected to human rights violations, contrary to the long-held international and domestic codes of conduct which have evolved to protect patients.

> The essence of the extensive ethical and legal protections for human subjects is that the subjects, especially vulnerable populations such as prisoners, must be treated with the dignity befitting human beings and not simply as experimental guinea pigs.[3]

The application of medical and scientific research to lethal injection experimentation is an

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[3] Physicians for Human Rights: *Experiments in Torture* (June 2010), at 6, *available at* https://s3.amazonaws.com/PHR_Reports/Experiments_in_Torture.pdf.

imperfect one: those tasked with carrying out executions are not in any way qualified as members of the medical or scientific professions, and the medical Code of Ethics is quite clear that a physician "should not be a participant in legally authorized execution."[4] Yet ethical principles and laws governing medical and scientific experimentation using human beings should inform practices and procedures involved in lethal injection. The means of death in this event is a medical-in-nature procedure, carried out by non-medical personnel, and uninformed by science. In this context, the ethical principles and laws otherwise governing human-subject experimentation are part and parcel of our society's evolving standards of decency which are enforced by the Eighth Amendment's protection of individuals against cruel and unusual punishment.

Research involving human beings is defined by federal regulations as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[5] A human subject is a "living individual" about whom a research investigator … obtains data …through intervention or interaction with the individual …."[6] These definitions represent the crystallization of what we have learned since World War II about protecting the human rights of individuals.

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[4] American Medical Association Code of Ethics, Opinion 2.06 (2000).

[5] 45 C.F.R. § 46.102(d) (2013).

[6] *Id*.

A shocked world learned of unconscionable human experimentation exposed at the Nuremberg Trials following World War II. The first attempt to establish international human rights protections for human experimentation ensued: the Nuremberg Code. Significantly, the Nuremberg Code mandated that:

- Experiments not be random and unnecessary in nature;
- Experiments be conducted by qualified, highly skilled researchers;
- Human experimentation be designed and based on the results of animal experimentation;
- Experiments be conducted so as to avoid unnecessary physical and mental suffering and injury; and
- Experiments be terminated when unnecessary physical and mental suffering begins to occur.[7]

Since 1947, international standards for human subject experimentation have evolved, through the establishment of the World Medical Association in

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[7] Evelyne Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW. ENG. J. MED.:1436-1440.(1997) Other provisions of the Nuremberg Code address the need to have highly qualified and skilled scientists conducting experimentation and prohibit experimentation where it may result in injury, disability or death. *Id.* Those provisions are, for obvious reasons, inapplicable to lethal injection.

1947, to the Declaration of Helsinki in 1964 and subsequent amendments.[8]

These core principles remain the same and have made their way into our domestic law by means of the Code of Federal Regulations.

45 C.F.R. § 46 governs "all research involving human subjects" conducted or supported by federal departments and agencies.[9] While obviously inapplicable to execution by lethal injection, Section 46 clearly adopts the human rights provisions protecting human subjects first enunciated in the Nuremberg Code:

First, "risks to subjects" must be minimized by using procedures "consistent with sound research design and which do not unnecessarily expose subjects to risk" and if appropriate, "by using procedures already being performed on the subjects."[10]

Second, informed consent must be obtained from those participating in human subject research or their legally authorized representative.[11]

Moreover, certain populations are vulnerable and require heightened protection. Prisoners are

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[8] Kevin M. King, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L LAW 163, 166 (1998).

[9] 45 C.F.R. § 46.101(a) (2013).

[10] 45 C.F.R. § 46.111(a)(1) (2013).

[11] 45 C.F.R. § 46.111(a)(4) (2013).

included in the definition of "vulnerable populations,"[12] which require heightened protection:

- Research involving prisoners must present "minimal risk" and "no more than inconvenience" to participants.[13]

- Any research that particularly affects prisoners as a class must be reviewed by experts in penology, medicine, and ethics and notice of the proposed human subject research must be published in the Federal Register.[14]

These are the ethical, humanitarian and legal principles that govern the medical profession. Human experimentation in the medical profession would be wholly unethical, illegal, and inhumane if the goal was to kill an individual. In this respect, these principles cannot be extended with full force to the practice of lethal injection where the goal is death. .

Nonetheless, the practice of using untested, secret pharmaceutical products in the process of execution cannot be wholly divorced from the basic ethical guidelines that control the use of these products in the practice of medicine and the healing arts. Experimentation is curtailed and closely monitored in the practice of medicine precisely because of its potential to inflict needless pain and suffering upon patients. These medical principles

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[12] 45 C.F.R. § 46.111(a)(7) (2013).

[13] 45 C.F.R. § 46.306(a)(2)(i) (2013).

[14] 45 C.F.R. § 46.306(a)(2)(iii) (2013).

should inform the Eighth Amendment standard prohibiting cruel and unusual punishment.

B. Experiments with lethal injection would constitute unethical human experimentation in the medical field, and violate the Constitutional prohibition against cruel and unusual punishment.

States have pursued knowledge of how best to kill condemned prisoners by asking other states what they have done.[15] Information concerning the development of protocols is now available, but was unavailable in the early days of lethal injection due to secrecy. What we now know demonstrates that the proverbial Emperor's fashion is non-existent. Lethal injection protocols originated in ignorance, based on guesswork, convenience, and disregard for the suffering of those who were the subjects of the poorly-constructed experiment.

Oklahoma was the leader in the lethal injection experiment, and looked to its medical examiner, Dr. Jay Chapman, for a recommendation of drugs and a protocol. Chapman "had no experience in this sort of thing." "I didn't do any research. I just knew from having been placed under anesthesia myself, what we needed."[16] The end result was enactment of a lethal injection statute that specified use of an "ultra-short-acting barbiturate in combination with a

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[15] Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 OHIO ST. L.J. 49, 78-79 (2007).

[16] Human Rights Watch: *So Long As They Die* (April 2006), at 4 (quotes from interview of Jay Chapman), *available at* http://www.hrw.org/node/11414/section/4.

chemical paralytic."[17] For reasons unknown even to himself, Chapman later added a third drug to the lethal injection protocol: potassium chloride.[18]

In 1982, Texas became the first state to execute a man using lethal injection.[19] The Texas Legislature delegated responsibility for developing the protocol of drugs and their administration to the state corrections agency.[20] In turn, corrections officials came up with a system of doing "whatever worked at the time."[21] Texas used what became a standard three-drug cocktail of sodium thiopental, pancuroniam bromide, and potassium chloride. Dosages and timing of the drugs were less important than the end result. "The only thing that mattered was that the guy ended up dead."[22] Indeed, the Texas prison pharmacy director once explained that Texas uses a higher dosage of sodium thiopental than other states because its vials come in that size,

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[17] Denno (2007), at 66-67.

[18] *So Long As They Die*, at 4. When asked why he added a third drug to the protocol, Chapman responded, "Why not?" He did not research potassium chloride because it was common knowledge amongst doctors that "potassium chloride is lethal." *Id.*

[19] Denno (2007), at 79.

[20] Tex. Code Crim. Pro. Ann. art. 43.14 (West 1978).

[21] *So Long As They Die*, at 4 (quoting Testimony of Annette Viator, Special Hearing, *Cain v. Code*, No. 138,860-A, First Judicial District Court of Louisiana, March 18, 2003, Vol. II, p. 32). Annette Viator had served as Chief Counsel to the Louisiana Department of Public Safety and Corrections, and testified to her conversations with the Texas warden responsible for executions in 1990.

[22] *Id.*

and doing the paperwork explaining why a full vial is not used is too time-consuming.[23]

These ill-informed, haphazard decisions about lethal injection procedures went on to form the basis of lethal injection protocols across the country.[24] Ultimately they also led to at least 31 botched executions by lethal injection between 1982 and 2001[25] and at least 7 additional ones since then, using the three-drug protocol.[26] At least 13 of the executions have involved retained consciousness, struggling against restraints, gasping for air or gurgling, and/or statements describing pain as the execution is occurring.[27] At least 25 of the executions have involved prolonged efforts to find suitable veins through which to administer the

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[23] *Id.* (quoting Testimony of Donald Courts, Special Hearing, *Cain v. Code*, No. 138,860-A, First Judicial District Court of Louisiana, March 18, 2003, Vol. II, p. 58-59).

[24] Denno (2007), at 78-79.

[25] 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, 139-41 (2002) (listing by inmate name and date witness observations of lethal injections gone awry).

[26] Michael L. Radelet, *Examples of Post-Furman Botched Executions, available at* http://www.deathpenaltyinfo.org/some-examples-post-furman-botched-executions.

[27] Denno (2002), at 139-41 (Charles Brooks, Texas, 1982; James Autry, Texas, 1984; Thomas Barefoot, Texas, 1984; Stephen McCoy, Texas, 1989;Charles Walker, Illinois, 1990; Robyn Parks, Oklahoma, 1992; Justin May, Texas, 1992; John Gacy, Illinois, 1994; Luis Mata, Arizona, 1996; Scott Carpenter, Oklahoma, 1997; Bert Hunter, Missouri, 2000); *Examples of Post-Furman Botched Executions* (Joseph Clark, Ohio, 2006; Angel Diaz, Florida, 2006).

drugs.[28] At least two of the executions have required re-administering drugs a second time after a first failed attempt.[29] And in one case, the execution attempt completely failed, and the condemned man was returned to death row, where he remains to this day.[30]

The process of implementing lethal injection as a method of execution has relied on using human guinea pigs. It has consisted of ill-informed choices with no knowledge of the human suffering that would result from those choices and no effort to deduce it.

Dr. Chapman, the original architect of the lethal injection protocol that has been followed for over 30

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[28] Denno (2002), at 139-41 (Stephen Morin, Texas, 1985; Randy Woolls, Texas, 1986; Elliot Johnson, Texas, 1987; Raymond Landry, Texas, 1988; George Mercer, Missouri, 1990; George Gilmore, Missouri, 1990; Charles Coleman, Oklahoma, 1990; Rickey Rector, Arkansas, 1992; Billy White, Texas, 1992; Emmitt Foster, Missouri, 1995; Ronald Allridge, Texas, 1995; Richard Townes, Virginia, 1996; Tommie Smith, Indiana, 1996; Michael Elkins, South Carolina, 1997; Genaro Camacho, Texas, 1998; Roderick Abeyta, Nevada, 1998; Bennie Demps, Florida, 2000; Joseph High, Georgia, 2001); *Examples of Post-Furman Botched Executions* (Joseph Clark, Ohio, 2006; Angel Diaz, Florida, 2006; Christopher Newton, Ohio, 2007; John Hightower, Georgia, 2007; Curtis Osborne, Georgia, 2008; Romell Broom, Ohio, 2009; Brandon Rhode, Georgia, 2010).

[29] Denno (2002), at 139-41 (Joseph Cannon, Texas, 1998, needle popped out after first injection and second injection administered); *Examples of Post-Furman Botched Executions* (Joseph Clark, Ohio, 2006, vein collapsed after injection began and second injection administered).

[30] *Examples of Post-Furman Botched Executions* (Romell Broom, Ohio, 2009, executioners unable to locate suitable vein for two hours so execution halted by Governor).

years, based the design on pure speculation. To this day, completely unqualified non-medical prison personnel determine the specifics of the protocols and carry them out.

Paradoxically, states have chosen a method of execution that requires medical training to design and implement consistent with Eighth Amendment requirements, while physicians are ethically excluded from participation in this process.[31] As a result, the highly-vulnerable men and women on death row have, one by one, been subjected to random experimentation. Even in non-medical communities, this violation of human and constitutional rights should not be tolerated.

C. The recent unavailability of drugs previously used in lethal injection has triggered a new chapter in lethal injection experimentation that should be halted.

Less than two weeks ago, on January 16, 2014, the State of Ohio executed Dennis McGuire. The State used drugs never before used in an execution. Over the 25 minutes from the time drugs were started to the time Mr. McGuire was declared dead, witnesses observed "movement and gasping, snorting and choking sounds."[32] Prior to the

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[31] Under Eighth Amendment jurisprudence, the lethal injection procedure must not pose "a substantial risk of serious harm," which, when death is the anticipated result, is understood as a substantial risk of serious pain. *Baze v. Rees*, 553 U.S. 35, 52 (2008).

[32] Erica Goode, *After Prolonged Execution in Ohio, Questions Over 'Cruel and Unusual.'* N.Y. TIMES, Jan. 17, 2014, *available at* http://www.nytimes.com/2014/01/18/us/prolonged-execution-

execution, Mr. McGuire's lawyers argued that the drugs Ohio had chosen would cause "air hunger" which would leave Mr. McGuire struggling for breath.[33] A State expert responded that he did not know how long it would take for Mr. McGuire to stop breathing. "'There is no science to guide me on exactly how long this is going to take.'"[34]

The need to return anew to lethal injection experimentation has arisen from the very paradox that prompts *Amici* to submit this brief: it is unethical for anyone in the medical profession to be involved in this inherently medical procedure. Pharmaceutical companies are now eschewing any involvement in using therapeutic drugs they manufacture for the purpose of killing human beings.

In August 2009, Hospira, the sole United States producer of sodium thiopental, temporarily ceased production of the drug.[35] A nation-wide shortage of

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prompts-debate-over-death-penalty-methods.html?ref=ericagoode&_r=1.

[33] Associated Press, *Records Show Execution Was Longest for Ohio*, Jan. 17, 2014, *available at* http://cherokeetribune.com/view/full_story/24408513/article-AP-Records-show-execution-was-longest-for-Ohio.

[34] Max Ehrenfreund, *Dennis McGuire Executed in Ohio with New Combination of Lethal Drugs*, WASH. POST, Jan. 16, 2014

[35] Nathan Koppel, *Drug Halt Hinders Executions in the U.S.*, WALL ST. J., Jan. 22, 2011, *available at* http://online.wsj.com/article/SB10001424052748704754304576095980790129692.html.

sodium thiopental resulted.[36] In January 2011, Hospira announced it would no longer produce the drug.[37] The last batch of Hospira sodium thiopental expired on March 1, 2011.

Many states sought to obtain sodium thiopental illegally from abroad,[38] even though there were no FDA-registered or FDA-approved foreign sources of sodium thiopental. The Drug Enforcement Administration (DEA) seized illegally-obtained sodium thiopental from corrections officials in Alabama, South Carolina, Tennessee, Kentucky and Georgia. The DEA also instructed one state, Arizona, not to use illegally-obtained sodium thiopental in an execution which was to occur the following day. Subsequently, in November 2011, the United Kingdom barred exports of sodium thiopental to the United States, and an Indian manufacturer announced that it would no longer provide the drug for use in executions in 2012.[39]

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[36] Erik Eckholm and Katie Zezima, *Lethal Injection Drug Shortage May Delay Executions*, N.Y. TIMES, Jan. 21, 2011, *available at*:
http://www.nytimes.com/2011/01/22/us/22lethal.html.

[37] *Id*.

[38] Arkansas, Arizona, California, Georgia, Tennessee and South Carolina imported sodium thiopental from United Kingdom-based Dream Pharma, and Tennessee later sold or transferred part of its shipment to Alabama and Kentucky. Dream Pharma was not registered with the FDA to import sodium thiopental. Nebraska and South Dakota imported sodium thiopental from an Indian manufacturer, Kayem. Kayem also was not registered with the FDA to import sodium thiopental.

[39] Dominic Casciani, *US Lethal Injection Drug Faces UK Export Restrictions*, BBC NEWS, Nov. 29, 2010, *available at* http://www.bbc.co.uk/news/uk-11865881; Greg Bluestein, *Firm*

As sodium thiopental became unavailable to states for use in executions, they cast about for another drug and settled on pentobarbital.[40] A Danish company, Lundbeck, was the sole producer of pentobarbital in the United States, and subsequently, in July 2011, instituted a system whereby pentobarbital would not be sold to United States prisons conducting executions.[41] Recently, in the mid to latter part of 2013, prison supplies of pentobarbital, acquired before Lundbeck banned its sale to prisons, began expiring.[42]

Lethal injection experimentation with the drugs used in executions began again in earnest with pentobarbital, and condemned men suffered during

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in India halts sales of execution drug to US, Associated Press, Apr. 7, 2011, *available at* http://www.kitsapsun.com/news/2011/apr/07/firm-in-india-halts-sales-of-execution-drug-to/?print=1.

[40] Karin Buhmann, *Damned If You Do, Damned If You Don't? The Lundbeck Case of Pentobarbital, the Guiding Principles on Business and Human Rights, and Competing Human Rights Responsibilities*, 40 J. L. LAW & ETHICS 206, 207 (2012).

[41] David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, N.Y. TIMES, Jul. 1, 2011, *available at*: http://www.nytimes.com/2011/07/02/world/europe/02execute.html?_r=0.

[42] Michael Graczyk, *Texas Execution Drug Shortage: State Running Out of Pentobarbital*, HUFFINGTON POST, Aug. 1, 2013, *available at*: http://www.huffingtonpost.com/2013/08/01/texas-execution-drug-shortage-running-out_n_3690893.html; Manny Fernandez, *Executions Stall as States Seek Different Drugs*, N.Y. TIMES, A1, Nov. 9, 2013, *available at*: http://www.nytimes.com/2013/11/09/us/executions-stall-as-states-seek-different-drugs.html?_r=1&adxnnl=1&rref=us&hpw=&pagewanted=1&adxnnlx=1384275891-cgRgUIx4UUpS77T8UwIKXA

their final moments.[43] On June 16, 2011, Alabama executed Eddie Powell using pentobarbital for the first time. The Birmingham News reported: "After a moment his eyes opened again and he raised his head and neck off the gurney. Seemingly confused and startled, he jerked his head to one side and began breathing heavily, his chest rose and contracted."[44]

On June 24, 2011, Georgia used pentobarbital for the first time, to execute Roy Willard Blankenship. The Associated Press reported: "Blankenship jerked his head several times, mumbled inaudibly and appeared to gasp for breath for several minutes after he was pumped with pentobarbital on Thursday in Georgia's death chamber."[45]

In the most recent chapter of the scramble for drugs, states that no longer have pentobarbital are turning to compounding pharmacies for the drug. The compounding pharmacies are not regulated by the FDA, and the generic drugs mixed by them do

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[43] The first execution involving the use of pentobarbital instead of sodium thiopental in the three-drug cocktail occurred on December16, 2010 in Oklahoma. In March 2011, Ohio was the first state to execute a man using pentobarbital as the only drug.

[44] Matthew Busch, *Powell Says He's Sorry Before Death By Lethal Injection At Alabama's Holman Prison*, BIRMINGHAM NEWS, June 16, 2011, *available at*: http://blog.al.com/spotnews/2011/06/powell_says_hes_sorry_before_d.html.

[45] Associated Press, *Georgia Inmate's Thrashing During Execution Raises New Questions About Death Row Drug*, July 28, 2011.

not necessarily have the same properties as manufactured pentobarbital.[46]

Eric Robert became the first man known to be executed with compounded pentobarbital, on October 15, 2012 in South Dakota. During the execution his eyes remained open and he cleared his throat and gasped for air.[47]

Earlier this month, on January 9, 2014, Oklahoma executed Michael Lee Wilson using compounded pentobarbital from an Oklahoma pharmacy. His last words were: "I feel my whole body burning."[48]

Then came the execution of Dennis McGuire in Ohio. Having run out of its supply of pentobarbital, Ohio came up with an entirely new, completely experimental drug protocol for lethal injections. On January 16, 2014, Ohio used a combination of midazolam and hydromorphone to execute Dennis McGuire, with results that made national news and editorials across the country. According to one

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[46] *See infra*, Section D.

[47] Dave Kolpack and Kristi Eaton, *Eric Robert Execution*, HUFFINGTON POST, Oct. 15, 2012, *available at:* http://www.huffingtonpost.com/2012/10/16/eric-robert-execution_n_1969640.html.

[48] Associated Press, *"I Feel My Whole Body Burning": Last Words of Man Executed by Lethal Injection in Oklahoma*, Jan. 10, 2013, *available at* http://www.dailymail.co.uk/news/article-2536976/I-feel-body-burning-Man-executed-lethal-injection-Oklahoma-beating-convenience-store-worker-death-1995.html?utm_source=Press+mailing+list&utm_campaign=d80580001c-2014_01_10_botched_execution&utm_medium=email&utm_term=0_022da08134-d80580001c-285915586.

witness, Mr. McGuire "struggled, made guttural noises, gasped for air and choked for about 10 minutes before succumbing to a new, two-drug execution method."[49]

Mr. McGuire's execution epitomizes inhumane lethal injection experimentation. Drugs were administered without a clear idea of what would happen or how long it would take. Likely, based on the experiment, Ohio will revisit its drug choice. And the experimentation will continue, unless courts act to stop it.

D. In the absence of transparency, the use of drugs obtained from compounding pharmacies presents a substantial risk of serious harm and suffering.

Amici have been informed that there is a strong likelihood that the State of Louisiana intends to use compounded pentobarbital in Mr. Sepulvado's upcoming execution. In and of itself, the use of a drug unregulated by the Food and Drug Administration (FDA) involves lethal injection experimentation and would pose a substantial risk of harm.

Compounding pharmacies are regulated by the state in which they do business—the FDA does not

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[49] Andrew Cohen, *The Secrecy Behind the Drugs Used to Carry Out the Death Penalty*, THE ATLANTIC, Jan. 26, 2014, *available at* http://www.theatlantic.com/national/archive/2014/01/the-secrecy-behind-the-drugs-used-to-carry-out-the-death-penalty/283348.

approve any drugs produced by them.[50] The FDA has promulgated numerous information bulletins addressing the dangers of compounded drugs. It has warned consumers that "medications, primarily injectable medications that are intended to be sterile, have endangered public health."[51] Injectable compounded medications have been more closely scrutinized recently due to an outbreak of fungal infections linked to steroid injections produced by the New England Compounding Center.[52] A total of 751 infections were reported across the country with 64 deaths resulting.[53] Following the outbreak, FDA inspections of 30 compounding pharmacies producing "high-risk sterile products" found potentially dangerous safety issues in all 30.[54]

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[50] U.S. Food And Drug Administration**,** *Pharmacy Compounding and the FDA: Questions and Answers***,** FDA.GOV (Mar. 1, 2013), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.

[51] U.S. Food and Drug Administration, *The Special Risks of Pharmacy Compounding,* FDA.GOV (Dec. 7, 2013), *available at* http://www.fda.gov/forconsumers/consumerupdates/ucm107836.htm.

[52] Centers for Disease Control and Prevention, Healthcare-Associated Infections, *Multistate Outbreak of Fungal Meningitis and Other Infections*, CDC.GOV (Oct. 23, 2013), *available at* http://cdc.gov/hai/outbreaks/meningitis.html.

[53] *Id*.

[54] Lena H. Sun, *FDA finds widespread safety issues at compounding pharmacies*, WASH. POST, Apr. 11, 2013, *available at* http://www.washingtonpost.com/national/health-science/fda-finds-widespread-safety-issues-at-compounding-pharmacies/2013/04/11/5321e17a-a20d-11e2-be47-b44febada3a8_story.html; *see also* U.S. Food and Drug Administration, *Summary: 2013 Pharmacy Inspection*

In general, compounding pharmacies exist to provide individualized prescriptions for drugs that are not available in a form approved by the FDA. Congress has recognized the danger of compounded drugs that mimic those available in FDA-approved form.[55] Such "knock-off" drugs have not been comprehensively tested for efficacy and safety.[56]

The effect of this new legislation is to amend the Food, Drug and Cosmetic Act so as to allow increased regulation of compounding pharmacies which make drugs which are "copies" of drugs available in an FDA-approved form. The same legislation requires that compounding pharmacies only sell compounded drugs pursuant to a physician prescription for an individual. This would seem to prohibit prison pharmacies from obtaining batches of drugs for non-specified individuals.[57] But in any event, the new legislation demonstrates the extreme danger posed by the attempted duplication of FDA-approved drugs by compounding pharmacies.

Assignment, *last updated* Jan. 9, 2014, *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm.

[55] Pub.L.No. 113-54, 127 Stat. 587 (November 27, 2013) §102.

[56] Sarah Sellers and Wulf H. Utian, *Pharmacy Compounding Primer for Physicians, Prescriber Beware*, DRUGS 72(16), 2043-50 (DEC. 2012), *available at*, http://ncbi.nlm.nih.gov/pmc/articles/PMC3695671/#!po=2.94118 ("extemporaneous formulations generally lack studies to document stability, bioavailability, pharmacokinetics, efficacy and safety").

[57] Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEORGETOWN L. J. (forthcoming 2014), *available at* http://www.ssrn.com/abstract=2328407, at 44-45.

The use of compounded pentobarbital, or other compounded drugs, adds an additional dimension to lethal injection experimentation. Because compounded drugs are not tested for uniformity, even batches obtained from the same compounding pharmacy at different times for different executions may have different effects: "[c]ompounded drugs made using poor quality practices may be sub- or super-potent, contaminated, or otherwise adulterated."[58]

In particular, without transparency with respect to the identity and location of the compounding pharmacy and the specific drugs and compounds used by that pharmacy in the creation of a lethal injection drug series, it is impossible for the public or the condemned prisoner to know whether the state's vendor is in violation of Pub.L.No. 113-54, 127 Stat. 587 (November 27, 2013) §102.

In the absence of any analysis of the compounded drugs, it is impossible to insure their quality in advance of testing them out on the condemned prisoner. The inherent risks associated with compounded pentobarbital render its use for executions unconstitutional under the Eighth Amendment.

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[58] U.S. Food And Drug Administration, *Pharmacy Compounding and the FDA: Questions and Answers*, FDA.GOV (Mar. 1, 2013), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.

E. Secrecy surrounding lethal injection protocols only increases the substantial risk of serious harm that results from ill-informed lethal injection experimentation.

Since the adoption of the Nuremberg Code, the world has recognized that conducting experiments on human beings is unacceptable when those experiments involve needless suffering and do not benefit the individual involved.

Significantly, the Nazis' practice of human experimentation was hidden from the community of nations until the victory of the Allies in World War II. Implicit in the Nuremberg Code is the necessity of transparency in medical/pharmaceutical practices to prevent a repetition of coerced human experimentation.

Death by lethal injection affects perhaps the most vulnerable of the vulnerable population of prisoners—those on death row. The men and women sentenced to death in this country are the objects of society's most extreme and irrevocable retribution—death. Yet they are also human beings with human rights.

All that stands between what is deemed a constitutionally acceptable means of retribution, versus an unconstitutional risk of serious pain at the hands of the executioner, are the courts. While this Court has recognized that courts are ill-equipped to determine what does and does not constitute needless suffering,[59] abdicating that determination to a patchwork of non-medical lay persons is

[59] *Baze*, 553 U.S. at 51.

exponentially more alarming, and inconsistent with the Eighth Amendment.

What appeared to be the solution to the problem of botched executions involving the use of lethal gas and electrocution has failed. Lethal injection involves the use of prescription drugs and their injection into the human body, without physician oversight or participation. On the most practical level, it is impossible to understand how the drugs are legally obtained, prescribed and administered without physician involvement. Perhaps particularly because of the non-involvement of physicians, the selection and administration of lethal drugs must be subject to scrutiny beyond the walls of departments of corrections.

History repeatedly demonstrates that cruel and unusual punishment will occur unless execution protocols are subject to open, informed scrutiny by the individual who will be executed, at a minimum, and by the society in whose name the execution is performed.

Taken to its logical conclusion, the Fifth Circuit Court of Appeals' decision allows the Louisiana corrections department to secretly change its protocol, throw gasoline on Mr. Sepulvado, and set him on fire. Such a horrific constitutional and human rights violation would be over before it could be contested. That is unacceptable in a civilized society.

CONCLUSION

For the foregoing reasons, *Amici* respectfully suggest that the petition for a writ of *certiorari* be granted.

Respectfully submitted,

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