PROVINCE OF ONTARIO

CITY OF BURLINGTON

DECLARATION OF LARRY D. SASICH, PharmD MPH FASHP

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this affidavit are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. My experience and qualifications, in part, include: Chairperson of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania, consultant to Public Citizen's Health Research Group, Washington, DC, and I have also served as the Consumer Representative on the Food and Drug Administration's Science Board, an advisory committee to the Commissioner of the Food and Drug Administration. I have also served as a consultant to the Saudi Food and Drug Administration in Riyadh, Saudi Arabia.

3. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology and from The George Washington University and a Doctorate of Pharmacy from University of the Pacific. I have completed a residency in nuclear

pharmacy from the University of New Mexico. I have also been elected a Fellow in the American Society of Health-System Pharmacists (FASHP). I have also authored publications and/or presented analysis on drug safety issues. A complete list of my publications and presentations are listed in my Curriculum Vitae, which is appended to this statement.

4. I have been asked by counsel representing Warren Lee Hill, a death-sentenced Georgia prisoner, to provide opinions on the use and practice of compounding pharmacy in the United States. In particular, I have been asked to comment on the intention of the Georgia Department of Corrections to employ a compounding pharmacist to compound drugs – in this case pentobarbital - intended for use in lethal injection. Counsel for Mr. Hill has asked me to review the processes involved in compounding and assess whether there is a substantial risk of serious harm in using compounded drugs for this purpose.

5. I have reviewed materials provided by the Office of the Georgia Attorney General and Georgia Department of Corrections (DOC) in response to a request by the Georgia Resource Center for information pertaining to the DOC's lethal injection protocol and lethal injection drugs. I am aware that a new Georgia law shields from public scrutiny the identity of the manufacturer of lethal drugs,

any middlemen or supply chain handlers, prescribing or other physicians involved in the execution process, pharmacists, compounding pharmacies, and so on.

I. Pharmacy Compounding Review

6. Pharmacy compounding is a traditional practice of the profession of pharmacy that does not involve the creation of drugs from scratch, using active and inactive ingredients, to meet the individual needs of a patient that cannot be met with an FDA-approved product for medical reasons, according to a legal prescription for an individual patient. This definition reflects essential elements that distinguish traditional pharmacy compounding, for which FDA generally exercises enforcement discretion, from the non-traditional practice, which is regulated if at all only by the states.

7. However, over the past several decades, the traditional, medically-driven, therapeutically essential role of compounding, where federal standards are compromised for critical medical need, has been leveraged by marketing experts to legitimize a substandard drug industry, supported and driven by profiteering chemical distributors and other entities, who provide training and supply active and inactive ingredients, compounding equipment, recipes, and marketing tools for growing compounding businesses. This industry operates in a "grey market," where profits associated with compounding what are essentially copies of FDA-

approved products, produced in non-federally regulated drug manufacturing processes, have trumped industry concerns about the legality of the practice.

8. Non-traditional compounding pharmacy practice is more consistent with drug manufacturing. Under the guise of the traditional practice, pharmacies avoid the costs of drug development and testing to prove their products are pure, potent, safe and effective, and they avoid the substantial costs associated with maintaining compliance with federal manufacturing oversight, while at the same time charging equivalent or even higher prices for their products, where the finely honed marketing term "customized" may impart a designer-quality and perceived added value to the product. Unlike manufacturers, compounding pharmacies are generally not subject to the drug approval process and rigorous checks and regulatory procedures required under federal Good Manufacturing Practices (GMPs). Compounding pharmacies do not adhere to federal labeling regulations that require a summary of risks in all advertising; where all materials and statements must truthfully and fully disclose risks of the product. The circumvention of requirements for truthful disclosure of risk perpetuates public and prescriber misunderstanding regarding the efficacy and safety of drugs mixed in pharmacies. Indeed, it is challenging for compounding pharmacists to define risks

associated with compounding untested and unapproved new drugs without necessary expertise in federal manufacturing oversight.

9. A compounding pharmacist may mistakenly conclude that drugs made according to the enforceable sterile compounding standards issued by the United States Pharmacopeia (USP) Chapter 797 have a high degree of sterility assurance, compared to the federal standard for sterility when, in fact, experts have concluded the opposite: that drugs compounded in accordance with USP Chapter 797 have a low standard of sterility assurance compared to the federal standard. Yet, this very basic risk information is not conveyed to prescribers or patients.

10. Similarly, a pharmacist may have confidence in her ability to accurately measure or weigh individual ingredients and extend this confidence as a quality measure for the finished compound. However, if the pharmacist is starting with an adulterated or counterfeit chemical that would go unrecognized in a pharmacy setting, accurate measurement of chemicals can not remedy an already adulterated or otherwise unsafe product with respect to identify, purity, potency, or harmful contamination. Despite a pharmacist's best efforts, there are parameters beyond their professional control that build risk and uncertainty into all compounded products. This is precisely why FDA approval and oversight is critical for U.S. pharmaceuticals.

11. Compounded drugs do not meet such requirements for purity, potency, efficacy and safety. Existing outside of the gold-standard FDA regulatory framework which ensures the quality, safety and efficacy of manufactured pharmaceutical drugs, compounding pharmacy represents an emerging, substandard drug industry responsible for making large quantities of unregulated, unpredictable and potentially unsafe drugs. Not all pharmacies operate in the non-traditional, unregulated, supplier-driven compounding markets, but there is an increase in those that do.

12. Compounded drugs are not FDA-approved for any purpose. This means that the FDA has not verified their safety or effectiveness or the quality of their manufacture. Counterfeit or substandard ingredients, and/or poor practice on the part of drug compounders, often results in drugs which are contaminated, sub-potent or super-potent, which do not have the strength, quality or purity represented on their labeling or required for the safe and effective treatment of patients. The potential harm associated with the use of such contaminated or sub-potent drugs is extremely high.

13. In Mr. Hill's case, the compounding pharmacist will perform a non-traditional form of compounding, manufacturing what is essentially a copy of an FDA-approved pentobarbital drug product, not pursuant to a learned

intermediary's determination that an FDA-approved product cannot be used for medical reasons, but for the use in Mr. Hill's execution. Because neither the pharmacist nor the prescribing physician is fulfilling the professional role as Mr. Hill's learned intermediary, this non-medically directed compounding is tantamount to drug counterfeiting. The resulting dosage form is experimental and unpredictable in both composition and with respected to intended and unintended, adverse effects.

II. Ingredients Used In Compounding Pharmacy Are Suspect

14. The quality of raw bulk product, or Active Pharmaceutical Ingredients ("APIs"), used in compounding is suspect. Compounding pharmacies have been found to be a primary route of entry for counterfeit bulk drugs, which pose a real or potential health hazard because their manufacturer is often unknown, for which the impurity profile is unknown, and the age, the storage, the manufacturing environment, or the synthesis of the product cannot be determined, creating a situation where no amount of finished product testing can build quality into the product. Further, FDA oversight and monitoring of the flow of counterfeit drugs is substantially lacking.

15. Compounding pharmacists generally do not have the ability to test chemicals for identity, potency, purity and contamination. For example, because

of Georgia's secrecy laws, it is unknown whether, but unlikely that, the pharmacist in this case is capable of conducting testing which could be used to confirm the identity of the chemical, and to identify the presence of harmful contaminants that pose an immediate safety threat if administered intravenously (such intrinsic or extrinsic contaminants can be introduced during chemical manufacture or at any point during the chemical's synthesis; nor is there any available information) again because of Georgia's secrecy laws -- as to whether the pharmacist intends to have either the active and inactive chemical ingredients, or the finished, compounded dosage form tested using robust methods of analysis.

16. The ability to trace the raw API chemicals used in compounding back to the original manufacturers for information on quality, packaging, storage, shipment conditions and chains of custody from a chemical's cradle to grave is incredibly difficult even without the layer of secrecy added by Georgia law. The active ingredients used in the compounding pharmacy may come from the grey market, having been produced in non-FDA-registered, non-FDA inspected facilities. Ambiguous or false marketing statements are frequently used to mislead physicians into authorizing prescriptions for non-FDA-approved prescriptions. The prescribing physician may believe that if ingredients are FDA-approved; they must be safe to use in compounding. However, such a belief would rest on a false

assumption. In fact, the FDA does not approve chemical ingredients: it approves products in their finished dosage forms, with packaging and labeling to support safe use. Chemicals used in compounding are highly suspect, and there is no practical way to verify their quality, constitution or uniformity in limited pharmacy settings.

17. The ingredients often come from plants in China or India, which may or may not be registered with or have records of inspection by the US FDA. In this case, there is no evidence that the pentobarbital sodium selected for use in the non-traditional compounding of what is essentially a copy of an FDA-approved drug has been produced in an FDA-registered and inspected facility. Plants in China have been identified in which pesticides are manufactured using the same equipment as is used to make active ingredients.

18. In this unregulated market, a chemical labeled to represent a certain active ingredient may actually contain another, quite different ingredient. This has been identified historically for chemicals distributed in large quantities to pharmacies throughout the nation for use in compounding.

19. There can be no guarantees that active ingredients purchased from the grey market are safe for use, are not contaminated, or even contain the ingredient listed on the product label. Furthermore, because chemicals may not have been

manufactured in an FDA-registered facility under current GMP standards, there can be no assurance as to the quality variation from lot to lot or container to container. Thus, testing for one lot of a chemical does not prove that a subsequent lot would have the same characteristics as the lot that was tested, and testing would provide only very provisional indication of its suitability for compounding given the unknown disposition of the chemical in the timeframe from testing to pharmacy compounding and use.

20. It is essential to use ingredients manufactured by FDA-registered and inspected manufacturers in order to ensure the quality of the final product. If poor quality ingredients are used, even the best compounding practices will not build quality and suitability into the final product. The compounded drug may be contaminated, super- or sub-potent, making it unpredictable and potentially dangerous in that it may pose a high risk of pain and suffering to the "patient" to whom it was administered.

21. Georgia DOC did not disclose any evidence that the API in this case was manufactured in an FDA-registered facility. There is also no evidence that the API meets U.S. Pharmacopeia standards required for the finished dosage form as there is no way of knowing the current quality of the API in the bottle, after manufacture and initial testing (if performed), and after supply-chain, repackaging

and pharmacy handling. The use of this ingredient that may not have preliminary evidence and additional verification of production in a facility that is registered and inspected by FDA in any compounding process introduces unacceptable risk of harm and is ill advised.

22. Pentobarbital injection compounded from unverified ingredients pose a substantial risk of harm from the ingredients alone: the use of untested, inadequately tested and/or non-validated formulas and compounding methods, environmental controls and container packaging, coupled with lack of instructions for safe use introduces very high burdens of uncertainty and risk of harm. These risks of harm include sub- or super- potency, contamination with dangerous allergens or substances that may cause immediate anaphylactic reactions, contamination with bacteria or fungus, and even the administration of an entirely incorrect chemical or active ingredient.

23. Recently in the wake of a fungal meningitis outbreak due to contaminated injectable steroids manufactured by a Massachusetts compounding pharmacy, the FDA has increased its scrutiny of compounding pharmacies and found widespread safety risks for 30 of 31 pharmacies inspected. Unlike manufacturers, compounding pharmacies do not have to adhere to the rigorous FDA-approved procedures for manufacturing sterile drugs. The U.S. Food and

Drug Administration cannot verify that drugs produced in compounding pharmacies are safe and effective for therapeutic use, and so doctor(s) and compounding pharmacist(s) involved in the prescribing and manufacture of drugs used for non-therapeutic lethal injections should have even less confidence in their purity and potency, and subsequently their intended and unintended effects.

24. Several studies, including a survey conducted by FDA in 2001, have reported a high prevalence of quality problems with various pharmacy-compounded drugs, including sub-potency, super-potency, and contamination. A survey of compounded drug products was conducted by the FDA in 2006 to explore these issues further. The results showed that thirty-three percent of the compounded drugs failed analytical testing using rigorously defensible testing methodology. Further testing by the Missouri Board of Pharmacy, which is the only state which regularly tests compounded drugs, revealed that compounded drugs fail tests for potency and purity on average around twenty-five per cent of the time, an unacceptable failure rate consistent with rates observed by FDA. This is an extremely high failure rate, further supported by recent FDA inspection observations related to absent or limited sampling and testing of compounded drug products that would serve to identify substandard products prior to distribution.

III. Risks of Using Compounded Drugs of Unknown Provenance in Lethal Injections

25. To use drugs from compounding pharmacies in the execution by lethal injection of a prisoner presents a substantial risk that the drugs will not work effectively for the intended process. Compounded pentobarbital may give rise to a completely unanticipated response including, an allergic or anaphylactic reaction to an unidentified adulterant arising from intrinsic contamination of the ingredients or extrinsic contamination during the compounding procedure, or a pulmonary embolism arising from unanticipated drug incompatibilities, or partial or complete lack of effect due to ingredient tampering or controlled drug diversion after analytical testing, circumstances that would be expected to prolonging the anguish of the execution. Highly unpredictable, rapidly evolving and potentially painful and agonizing, not to mention life-threatening, reactions may ensue should the pentobarbital be contaminated by endotoxins or exotoxins. Similarly, should solid particulate matter of any kind contaminate the solution or precipitate out of solution during intravenous injection, there is a substantial risk of pain and suffering upon injection of the solution. Additionally, should the pH (acidity) of the solution be incorrect, Mr. Hill could experience a burning sensation as it is being injected.

26. The use of non-sterile and potentially contaminated active ingredients creates a serious risk of harm, including primary risks of infection and toxic blood reactions from bacterial, fungal and endotoxin contamination. Chemical degradation may be accelerated by the presence of adulterants or growing organisms, and larger than expected moisture content may result in inaccurate weighing. Such initial compounding conditions could result in products that may be sub-potent and fail to attain their expected actions.

27. The dosage form may fail to attain or maintain its ideal pH, increasing the likelihood of a burning sensation upon injection, or that it could form precipitates, or solid particles of drug and other substances, which in the most serious of cases could result in painful pulmonary embolism if administered intravenously. Bacteria and fungus are living organisms that grow and reproduce—their present and metabolic capacity in a solution may alter important quality attributes of the solution, including final pH, with the potential to create instability and/or incompatibility with human blood. In this case, compounding a copy of a non-human formulation, untested in humans and with a higher concentration compared with the FDA-approved human formulation is planned for injection is not safe and presents an unacceptable risk that the injection of the

compounded pentobarbital will, for a variety of possible reasons, cause unnecessary and lingering pain and suffering.

28. There is also a substantial risk that the Georgia DOC will administer a sub-potent dose of pentobarbital, resulting in less than effective CNS depression and an increased potential for a protracted period of only partial response, resulting anxiety and manifestations of known adverse events associated with pentobarbital including symptoms of acute intoxication, life-threatening but not fatal respiratory depression, and/or paradoxical stimulation. The pentobarbital solution will be made of a proportion of water and active ingredient. There does not appear to be any mechanism within Georgia's execution protocol to adjust measurements to account for the hygroscopic (water absorbing) nature of the chemical. In all circumstances, non-adjustment for the hygroscopic nature of a chemical will result in a concentration lower than the intended concentration. The difference will depend on the actual water content of the API. If unaccounted for, this known reduction in potency owing to water content adds to other concerns regarding the purity and potency of the drug as it exists at the time of compounding, its potential for degradation after initial testing, its potential for intentional or unintentional adulteration, its potential for mislabeling, all of which, added together, increase the risk of formulating a sub-potent dosage form. If pentobarbital is administered in a

non-lethal dose, Mr. Hill can experience symptoms of acute but not lethal intoxication including nausea and vomiting, symptoms of life-threatening but not fatal respiratory depression and corollary organ damage, and paradoxical central nervous system excitation.

29. There is also a risk that compounding error could result in a super- or sub- potent injection. The administration of a super-potent drug may result in the patient experiencing suffocation and gasping for breath.

IV. Compounded Pentobarbital In Mr. Hill's Execution

30. In conclusion, compounded drugs have been shown to be unreliable in purity, potency, safety and effectiveness, and have contributed to significant morbidity and mortality threatening U.S. public health and safety. This should be expected due to the abject lack of regulation and oversight of the compounding pharmacy industry. The FDA states categorically that, because of their very nature, the safety and effectiveness of compounded drugs cannot be established. Drugs that are manufactured in developed and even developing countries with federal oversight of drug manufacturing are likely to be of a better quality and uniformity compared to compounded drugs produced without federal oversight in the United States. Here, we have none of the assurances afforded by US FDA or EU oversight, and in this case, the manufacturer of the API (and middlemen) are

undisclosed due to Georgia secrecy laws and possibly unknown to both the prescribing physician and the compounding pharmacist.

31. Compounded drugs exist outside of the FDA regulatory framework and their quality, safety and effectiveness cannot be assured. In fact, they have a much higher probability of being substandard (sub- or super- potent, contaminated or of poor quality). In the context of executions by lethal injection, introducing a further element of unpredictability by using compounded drugs is reckless and dangerous.

32. Starting with poor quality and/or contaminated pentobarbital sodium API, combined with potential errors in compounding and lack of adherence to GMP guideline and sterility standards, is likely to result in substandard, contaminated or super- or sub-potent pentobarbital. There is a serious risk that if such drugs were used in an execution by lethal injection, they would not work in a predictable manner, and could cause serious pain upon injection, considerable mental anguish and anxiety, and thereby put Mr. Hill at substantial risk of serious, unnecessary and substantial harm and mental anguish.

33. I swear under pain and penalty of perjury that the foregoing is true and accurate to the best of my knowledge.

Dated this 15 day of July, 2013.

Larry D. Sasich,
839 Main Street West, #3
North Bay, P1B 2V8 Ontario,
CANADA
[redacted]

CURRICULUM VITAE

Larry D. Sasich, Pharm.D., M.P.H., FASHP
839 Main Street West #3
North Bay, P1B 2V8, Ontario
Canada
[redacted]

EDUCATION

1995 to 1997	Master of Public Health - Epidemiology The George Washington University School of Public Health and Health Services Washington, D.C.
1974 to 1975	Doctor of Pharmacy University of the Pacific College of Pharmacy Stockton, California
1966 to 1970	Bachelor of Science Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho

RESIDENCY

1986 to 1987	Nuclear Pharmacy University of New Mexico College of Pharmacy Albuquerque, New Mexico

PROFESSIONAL LICENSES

1970 to Present	California RPH 27094

PROFESSIONAL EXPERIENCE

April 2013 to date	Consultant, Drug Policy, Drug Safety and Efficacy North Bay, ON Canada
July 2007 to April 2013	Consultant, Saudi Food and Drug Authority 3292 Northern Ring Rd. Al Nafal District Riyadh, Saudi Arabia
November 2009 to 2012	Consultant, Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2007 to 2009	Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2007	Acting Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2005 to 2006	Assistant Professor, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2008	Consultant Centre for Science and the Public Interest – Canada Suite 4550, CTTC Bldg. 1125 Colonel By Drive Ottawa, Ontario K1S 5R1 Canada

PROFESSIONAL EXPERIENCE

2005 to 2007	Consultant Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2005 to 2006	Consultant Canadian Agency for Drugs and Technologies in Health 600-865 Carling Avenue Ottawa, Ontario K1S 5S8 Canada
1995 to 2005	Research Analyst Public Citizen's Health Research Group 1600 20th Street NW Washington, D.C. 20009
1991 to 1995	Drug Information Pharmacist King Faisal Specialist Hospital and Research Centre Riyadh 11211, Saudi Arabia
1993 to 1996	Adjunct Clinical Faculty Welch School of Pharmacy University of Wales Cardiff, Wales
1992 to 1995	Clinical Instructor College of Pharmacy King Saud University Riyadh, Saudi Arabia Graduate and Undergraduate Teaching
1988 to 1990	Clinical Pharmacist St. Helens Hospital and Health Center St. Helens, OR Emanuel Hospital and Health Center Portland, OR
1985 to 1988	Associate Professor of Clinical Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho Promoted and Tenured July 1, 1984

PROFESSIONAL EXPERIENCE

1983 to 1984	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Acting Associate Dean for Student Affairs
1982 to 1983	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director of Professional Practice
1979 to 1982	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director, Idaho Drug Information Service and Regional Poison Control Center
1976 to 1979	Assistant Director of Pharmacy Services USA MEDDAC Berlin, West Germany
1975 to 1976	Staff Pharmacist USA MEDDAC Wuerzburg, West Germany
1970 to 1974	Pharmacist Baneth's Pharmacy Menlo Park, CA

HONORARY SOCIETIES

1982	Rho Chi
1982	Sigma Xi

AWARDS

2000	Distinguished Person of the Year – Pharmacists Planning Services
1995	Fellow American Society of Health-System Pharmacists
1986	Ciba-Geigy Leadership Award
1983	Outstanding Service – Idaho Board of Pharmacy
1982	Phi Delta Chi Faculty Achievement Award

APPOINTMENTS

2009	FDA Science Board Sub Committee on the Center for Food Safety and Applied Nutrition (CFSAN)
2008	FDA Science Board Sub Committee on the review of the National Center for Toxicological Research
2007	Grant Reviewer U.K. Economic and Social Research Council Large Grant proposal: Governance of Pharmaceuticals and Health
2007	Consumer representative, Science Board to the Food and Drug Administration – advisory committee to the FDA Commissioner
2007	Pennsylvania Pharmacists Association Pharmacy Compounding Task Force
2006	Food and Drug Administration Pediatric Advisory Committee November 16, 2006 – substitute consumer representative
2006	Reviewer *PLoS Medicine*
2000	Reviewer for the *Western Journal of Medicine*
2000	Reviewer for the *Journal of the American Medical Association*
1996	Department of Health and Human Services Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Drug Information
1996	Department of Health and Human Services, Food and Drug Administration, Consumer Consortium

APPOINTMENTS

1995	Reviewer for the *Saudi Pharmaceutical Journal*
1993	Reviewer for the *Annals of Saudi Medicine*
1986	Reviewer for *Annals of Pharmacotherapy*
1987	Idaho Delegate to Western Regional Conference on Clinical Pharmacy Practice
1985	Idaho Health Systems Ethics Conference Task Force
1984	American Pharmaceutical Association Committee to prepare accreditation standards for a community pharmacy residency
1982	Assistant Editor DRUGDEX®
1981	USP Dispensing Information Contributors Panel

PUBLICATIONS

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References available on request

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August 4, 2014

MEDICAL REPORT

1. My name is Dr. Kent Diveley. I am a board certified Anesthesiologist in full time clinical practice at Scripps Mercy Hospital, a level one trauma center located in San Diego, California. I have practiced as an Anesthesiologist in San Diego since 1990. At Mercy hospital I've held positions as the Chief of Anesthesia, Chief of Surgery, and Chief of the Medical Staff. Currently I hold the positions of Medical Director of the operating room and Chair of the Credentials Committee. Included is a copy of my curriculum vitae.

2. 80 percent of my work is providing clinical anesthesia care. The other 20 percent is devoted to administrative work. This is the first time I have been asked to provide testimony in a lethal injection case. I am not an academic physician and have not published literature in this area. Personally I've attended more than 20,000 patients undergoing anesthetics for a wide range of procedures and am intimately familiar with the clinical applications of the drugs used for lethal injection in the state of Ohio. It is from my many years of work in rendering patients unconscious and working with these medications that I draw my opinions and conclusions in this case.

3. I am providing my opinions regarding the State of Ohio Department of Rehabilitation and Correction Policy 01-COM-11, effective October 10, 2013 for execution by lethal injection and its application to Dennis B. McGuire, January 16, 2014.

4. In forming my opinions and conclusions, I have reviewed the following documents:

   A. State of Ohio Department of Rehabilitation and Correction execution policy. (effective date October 10, 2013).
   B. Death Certificate, Dennis B. McGuire January 16, 2014
   C. Affidavit of Amber N. McGuire January 24, 2014
   D. Affidavit of Dennis R. McGuire January 24, 2014
   E. Document labeled "Execution Time Line"
   F. Ohio Department of Rehabilitation and Correction After Action Review January 16,2014
   G. Death Warrant
   H. Ohio Department of Rehabilitation and Correction Executive Summary April 28,2014
   I. Package insert for Versed and Dilaudid
   J. Declaration of Dr. David Waisel
   K. Expert Declaration of Dr. Mark Dershiwitz

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MEDICAL REPORT

5. In the Department of Rehabilitation and Correction Standards for Execution it states all execution processes shall be performed in a professional, humane, sensitive, and dignified manner. The question is did the state of Ohio comply with its own policy in the execution of Dennis B. McGuire using the method chosen to carry it out.

6. The State of Ohio used a combination of two drugs given intravenously for the execution. 10 mg. of midazolam and 40 mg. of hydromorphone were administered. These are both drugs which are used frequently in the clinical practice of Anesthesia and thus familiar to any practicing Anesthesiologist.

7. Midazolam is used as a sedative and as an adjunctive drug in general anesthesia. To render an individual unconscious much higher doses would be needed. An Anesthesiologist would not depend on a 10 mg dose of midazolam to provide for total loss of memory, or to produce an unconscious state.

8. Hydromorphone is an older narcotic used to treat pain and or noxious stimuli. In higher doses like the one used in the execution it will cause respiratory depression and eventual death due to a lack of oxygen and metabolic disturbance related to the retention of carbon dioxide. This drug would not be depended on to render a person immediately unconscious.

9. Neither of these drugs combined in the doses used can be depended upon to produce a rapid loss of consciousness and death. It is possible that when this combination of drugs is used for lethal injection there will be a delay of several minutes before the inmate loses consciousness preceding death. Mr. McGuire was noted to be straining against his restraints, struggling to breathe, and making hand gestures. More likely than not these represent conscious voluntary actions by Mr. McGuire. They exemplify true pain and suffering in the several minutes before he lost consciousness. To a degree of medical certainty this was not a humane execution.

10. These drugs do not fulfill the criteria set forth by the state of Ohio. They do not provide for an execution in a professional, humane, sensitive, and dignified manner. Allowing the inmate to suffer for a prolonged period struggling to get free and gasping for air before death certainly is not dignified nor humane.

11. There are other drug combinations that could be used to render the inmate immediately unconscious leading to a dignified and expeditious death. The State of Ohio needs to reconsider the drug combinations they are currently employing.

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August 4, 2014

MEDICAL REPORT

Otherwise other inmates in the future could suffer egregious inhumane deaths like Mr. McGuire.

Respectively submitted,

Kent Diveley, M.D.

Affidavit of Larry D. Sasich

AFFIDAVIT OF LARRY D. SASICH

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this affidavit are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology, from George Washington University, and a Doctorate of Pharmacy from University of the Pacific. I completed my residency in nuclear pharmacy at the University of New Mexico. I have been elected a Fellow in the American Society of Health-System Pharmacists (FASHP), and have authored numerous publications and/or presented analysis on drug safety issues. Among other positions, in 2008 and 2009 I was appointed to the Science Board of the Food and Drug Administration (FDA), and in 2007 served on the Pennsylvania Pharmacists Association Pharmacy Compounding Task Force. My Curriculum Vitae, which is appended to this statement, details my experience and qualifications.

3. Counsel representing Texas death- sentenced prisoners asked me to provide opinions on the use of compounded pentobarbital in executions performed by the Texas Department of Criminal Justice (TDCJ). Specifically, counsel asked me to review the processes involved in compounding, and assess the potential risks resulting from the use of compounded pentobarbital, including that provided by Woodlands Pharmacy, in

an execution scenario. In preparation, I was provided and reviewed the following documents, attached to this Declaration:

a. Execution Protocol of Texas Department of Criminal Justice dated July 2012;

b. Eagle Analytical Services Lab Report dated September 23, 2012

c. Documents sent by Woodlands Compounding Pharmacy to Bobbie Stratton on October 4, 2013, consisting of 15 pages; and

d. FDA 483 issued to Eagle Analytical Services on June 17, 2103.

I was also independently aware of the 483 issued to Professional Compounding Centers of American (PCCA), and the 2006 seizure of 300 vials of misbranded Active Pharmaceutical Ingredients (APIs) intended for sale to compounding pharmacies for use in compounding human drugs.

4. I previously provided a declaration to the lawyers representing Georgia death row inmate Warren Hill that provided an overview of the problems in the compounding industry. However, it was written on short notice, and in the face of the Georgia laws that keep almost all aspects of the execution process and lethal injection drugs a secret. As such, my declaration in that case necessarily lacked some specificity. This affidavit, informed by time and relevant information, provides an overview, but also far more detail.

PHARMACY COMPOUNDING – OVERVIEW

5. Pharmacy compounding is a traditional practice of the profession of pharmacy. There are two types of compounding – traditional and non-traditional. Traditional compounding does not involve the creation of drugs from scratch. Rather, it uses

active and inactive ingredients to meet the individual needs of a patient that cannot be met with an FDA-approved product for medical reasons, according to a legal prescription for an individual patient. For instance, a two- year-old transplant patient may require a medication that is only available in an FDA-approved tablet form. In such a case, a tablet's ingredients may be reformulated into an oral liquid for administration. This medication would be considered to be life-sustaining, and the expected benefits would likely be judged by the patient's learned intermediary (a licensed healthcare professional who holds prescriptive authority) to outweigh risks associated with the use of a non- FDA approved, non-GMP (Good Manufacturing Practices) produced product. With traditional pharmacy compounding, then, the FDA generally exercises enforcement discretion to allow provision of these products to meet the specific needs of patients.

6. Non-traditional compounding involves the use of raw ingredients (API's) to manufacture a copy or substitute for an FDA-approved drug, not for a specific patient with a specific medical need, but for general distribution. It resembles drug manufacturing more than it does the practice of pharmacy. Unlike manufacturers, compounding pharmacies are generally not subject to the drug approval process and rigorous checks and regulatory procedures required under federal GMPs. Because the FDA does not regulate non-traditional compounding, pharmacies practicing non-traditional compounding are not required, under federal law, to demonstrate that their products are pure, potent, safe, or effective, nor are they required to maintain compliance with federal manufacturing guidelines or oversight.

7. Thus, in contrast to the FDA's decision to exercise enforcement discretion with regard to traditional compounding, non-traditional practice is only regulated, if at all, by the states.

8. The FDA may use its resources to enforce provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to compounding in order to ensure (a) the existence of individual medical necessity that cannot be met with FDA-approved products as determined by a licensed prescriber acting as the learned intermediary, and (b) a tacit understanding that FDA-approval, federal GMP, and federal inspection and oversight constitute a basic standard of care for pharmaceuticals in the United States, with a tolerance for circumvention of those standards only in the rarest circumstances of medical necessity. They also avoid the substantial costs associated with maintaining compliance with federal manufacturing oversight. At the same time, they charge equivalent or even higher prices for their products.

9. Over the past several decades, marketing experts have leveraged the traditional, medically-driven, therapeutically essential role of compounding - where federal standards are set aside in instances of critical medical need - to legitimize a substandard drug industry of chemical distributors and other entities, who provide training and supply active and inactive ingredients, compounding equipment, recipes, and marketing tools for a fast-growing (non-traditional) compounding businesses.

10. This industry operates in a "grey market," where non-federally regulated drug manufacturing, marketing, and promotion throughout the United States is

strategically legitimized through consistent messaging around the historical role of drug compounding.

11. Non-traditional compounded drugs, such as the pentobarbital sold by Woodlands Pharmacy to TDCJ, are not FDA-approved for any purpose. This means that the FDA has not verified their safety or effectiveness or the quality of their manufacture. They do not meet federal requirements for purity, potency, efficacy and safety. Existing outside of the FDA regulatory framework which ensures these qualities in manufactured pharmaceutical drugs, compounding pharmacies have evolved into a substandard drug industry responsible for making large quantities of unregulated, unpredictable and potentially unsafe drugs. The FDA's Web site lists numerous examples of serious public health risks associated with the use of pharmacy compounded products at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.

12. Even for the treatment of animals, the American Veterinary Medical Association actively discourages the use of compounded drugs except in cases of veterinary medical necessity. This professional policy was recently underscored after the death of 21 polo ponies from poisoning by compounded drugs. The American Veterinary Medical Association advises that because one cannot assure the quality of bulk APIs, they must not be compounded for use in animals. *See* Katie Thomas, *Polo Ponies were given Incorrect Medication*, NEW YORK TIMES, April 23, 2009, available here:

http://www.nytimes.com/2009/04/24/sports/othersports/24polo.html?_r=0; Katie Thomas, *Deaths of Polo Horses Highlight Practices of Disputed Pharmacies*, NEW YORK TIMES, April 30, 2009, available here: http://www.nytimes.com/2009/05/01/sports/othersports/01polo.html.

13. For these reasons and those detailed below, there is a foreseeable risk that the non-traditional compounded drugs made for use in lethal injections – such as the pentobarbital sold by Woodlands Pharmacy to TDCJ – will be sub-standard in a manner that will cause severe pain upon or shortly after injection. These include the risk that the compounded drug will be sub-potent, expired, contaminated, contain unintended additives, or will contain a substantial level of particulates. The inadequate testing that has been performed of the drugs in TDCJ's possession – both because of its limited nature and because of the laboratories doing the testing – does not address the potentially severe problems that are identified in this declaration.

THE COMPOUNDING PROCESS

14. Drug manufacture is highly technical, requiring strict adherence to current GMP and a rigorous and continuous process of FDA inspection, regulation, supervision and oversight.

15. The manufacture of sterile drugs intended for intravenous administration, such as pentobarbital, is acknowledged by pharmaceutical manufacturers and the FDA alike to be one of the most difficult of all pharmaceutical processes to execute. The preparation of sterile drugs is unavoidably complex, often involving many

steps and manipulations. Each step poses an opportunity for error, including unintended introduction of potentially dangerous cross contaminants, and the possibility of a problematic osmolality or imbalanced pH (acidity or basicity).

16. Unlike manufacturers, compounding pharmacies do not have to adhere to the rigorous FDA-approved procedures for manufacturing sterile drugs. Instead, the less rigorous United States Pharmacopoeia (USP) <797> chapter standards may be applied to compounders. As a result, the potential for product contamination in compounded drugs is far higher than that in manufactured drugs. In some states, compliance with even this lesser standard is not required by Boards of Pharmacy.

QUESTIONABLE INGREDIENTS, INCLUDING ACTIVE PHARMACEUTICAL INGREDIENTS, USED IN COMPOUNDED DRUGS

17. The quality of the raw bulk product, or Active Pharmaceutical Ingredients (APIs), used in compounding is far more suspect than those used in manufactured drugs. A hearing before the U.S. House Energy and Commerce Committee cited compounding pharmacies as a primary route of entry for counterfeit bulk drugs: "Lured by high prices and potential profits in the United States, counterfeit bulks [API's] can get into our prescription drugs in several ways: (1) as imported ingredients to U.S. manufacturers; (2) as imported ingredients to pharmaceutical compounders; and (3) as source ingredients for Internet pharmacies marketing to the U.S. The counterfeiters use sophisticated methods such as preparing false labeling, containers, seals and certificates of analysis, or using a manufacturing process that differs from the filed manufacturing process." *See* Prepared Statement of Honorable Fred Upton before the House Commerce Committee Subcommittee on Oversight and

Investigations Counterfeit Bulk Drugs, June 8, 2000, available here: http://www.fda.gov/ohrms/dockets/dockets/05p0116/05p-0116-cp00001-17-Exhibit-16-vol1.pdf. Former FDA Associate Commissioner Dennis Baker testified that "[counterfeit bulk drugs] pose a real or potential health hazard because their manufacturer is often unknown . . .. The impurity profile is unknown, and the age, the storage, the manufacturing environment, or the synthesis of the product cannot be determined" creating a situation where "no amount of finished product testing can build quality into the product." *Id.*, Statement of Dennis Baker, available here: http://www.hhs.gov/asl/testify/t000608a.html.

18. It is very difficult, if not impossible, to trace the raw API chemicals used in compounding back to the original manufacturer for information on quality, packaging, storage, shipment conditions, and chains of custody – all necessary to ascertain the identity, purity, potency, and efficacy of a medication.

19. I have seen no evidence that the API pentobarbital sodium procured from PCCA by Woodlands Pharmacy to compound the drug sold to TDCJ for use in lethal injections was produced in an FDA-registered and inspected facility. This is not an idle concern. Plants in China have been identified in which pesticides are manufactured using the same equipment used to make APIs bound for human ingestion as part of a compounded-pharmacy product. *See* Statement of Dennis Baker, *supra*. By contrast, API's used in manufactured (FDA regulated) pharmaceuticals must come from a manufacturer that holds a Drug Master File (a confidential, detailed document submitted by API manufacturers to the FDA

containing the chemistry, manufacturing and controls of a drug component) for the chemical, and must be manufactured in an FDA-approved plant. Although PCCA claims that they only buy their API's from FDA registered facilities, this means only that the facility has put their name on file with the FDA – it does not mean that the facility is inspected or approved by the FDA.

20. Ethical chemical manufacturers who adhere to professional Responsible Care principles are more likely to sell directly to FDA-approved manufacturers of finished products, and unlikely to sell chemicals that may be used in grey market drug production operations (non-traditional pharmacy compounding). Accordingly, non-FDA approved chemical manufacturers are more likely to release large quantities of bulk chemicals into the grey market, increasing the likelihood that substandard chemicals will serve as the starting materials for both traditional and non-traditional compounding.

21. In this unregulated market, a chemical labeled to represent a certain active ingredient may actually contain another, quite different ingredient. Practitioners, regulators, and experts have identified this problem as to chemicals distributed in large quantities to pharmacies throughout the nation for use in compounding.

22. There can be no guarantees that APIs purchased from the grey market are safe for use, are not contaminated, or even contain the ingredient listed on the product label. Furthermore, because chemicals may not have been manufactured in an FDA-registered facility under current GMP standards, there can be no assurance as to the quality variation from lot-to-lot or container-to-container.

23. If poor quality ingredients are used, even the best compounding practices will not build quality and suitability into the final product. The compounded drug may be contaminated, super-potent or sub-potent, non-sterile, or at risk of an unusually short shelf life. A pharmacist may have confidence in her ability to accurately measure or weigh individual ingredients and extend this confidence as a quality measure for the finished compound. But if the pharmacist is starting with an adulterated or counterfeit chemical that would go unrecognized in a pharmacy setting (as opposed to a manufacturing facility with the capacity to test the quality of ingredients and overseen by federal regulators), accurate measurement of chemicals cannot remedy an already adulterated or otherwise unsafe product with respect to identity, purity, potency, or harmful contamination. Despite a pharmacist's best efforts, there are parameters beyond her professional control that build risk and uncertainty into all compounded products.

TESTING THE API AND THE FINAL PRODUCT

24. Compounded pentobarbital injection is made from the API, sodium pentobarbital, that is then mixed with other ingredients, in appropriate proportions. Testing of both the API and each step in the production of the final compounded product is important, but an educated understanding of the results – and potentially their inadequacies – is crucial. The quality and adequacy of the analytical lab or labs conducting the testing is also vital.

25. Testing only provides a very provisional indication of an API's suitability for compounding given the unknowns about the chemical's integrity, storage, and

custody in the timeframe from testing to pharmacy compounding and use.

26. Compounding pharmacists generally do not have the ability to test chemicals for identity, potency, purity and contamination. Laboratories, such as Eagle Analytical, are in business to perform such tests for compounding pharmacies and their suppliers.

27. Texas' execution protocol does not include provisions for testing the API or the finished, compounded dosage form of the pentobarbital to be used in executions. The ability of TDCJ's source of pentobarbital to engage a reliable and competent laboratory to conduct testing to confirm the identity of the chemical, or to identify the presence of harmful contaminants that pose an immediate safety threat if administered intravenously, is vital to avoiding the serious hazards inherent to the use of compounded drugs for executions. Neither the testing that has been conducted to date, nor the labs conducting that testing, are adequate to avoid these critical risks.

RISKS SPECIFIC TO EXECUTION BY LETHAL INJECTION IN TEXAS

28. Pentobarbital injection compounded from unverified ingredients poses a substantial risk of harm from the ingredients alone: the use of untested, inadequately tested and/or non-validated formulas and compounding methods, environmental controls and container packaging, coupled with lack of instructions for safe use, introduces very high burdens of uncertainty and risk of harm. These risks include sub- or super- potency, cross contamination with potentially dangerous allergens or other substances that may cause immediate anaphylactic reactions, inappropriate osmolality or pH, and even the administration of an entirely incorrect chemical or active ingredient.

Questionable API's and Substandard Ingredients; Sub and Super Potency

29. As detailed above, the questionable source of API's utilized in and supplied to compounding pharmacies can lead to use of fraudulent or sub-standard primary raw ingredients, leading to a serious risk of a lack of purity, potency, and even identity of the drug itself.

30. There is a substantial risk that the TDCJ will administer a sub-potent dose of pentobarbital, resulting in less than effective depression of the central nervous system. The pentobarbital solution will be made of a proportion of water and active ingredient. There does not appear to be any mechanism within Texas' execution protocol to adjust measurements to account for the hygroscopic (water absorbing) nature of the chemical. In such circumstances, non--adjustment for the hygroscopic nature of a chemical will result in a concentration lower than intended. The difference will depend on the actual water content of the API. If unaccounted for, this known reduction in potency owing to water content adds to other known threats regarding the purity and potency of the drug as it exists at the time of compounding, its potential for degradation after initial testing, its potential for intentional or unintentional adulteration, its potential for mislabeling. Combined, all these threats increase the risk of formulating a sub-potent dosage form. If sub-potent pentobarbital is used -- and thus a non-lethal does is administered - the prisoners will foreseeably experience symptoms of acute but not lethal intoxication including nausea and vomiting, symptoms of life- threatening but not fatal respiratory depression and corollary organ

damage (including brain damage), and paradoxical central nervous system excitation.

31. Foreseeable consequences of the administration of a super-potent drug include suffocation and gasping for breath, before the loss of consciousness.

32. While the PCCA Lab Report reflects analysis of the API presumably used in the compounding of the sodium pentobarbital sold to TDCJ, See Ex. C pp. 5-8, there is no indication who did the analysis, where it was conducted, or the source of the API.

33. The TDCJ has not disclosed evidence that the API used in the pentobarbital in its current possession was manufactured in an FDA-registered facility. There is also no evidence that the API meets U.S. Pharmacopeia standards required for the finished dosage forms. There is no way of knowing the current quality of the API in the bottle, after manufacture and initial testing, and after supply-chain, repackaging and pharmacy handling.

34. Although Eagle Analytical Services conducted potency tests on the compounded product, they ran no other tests, failing to test for sterility, contamination, or particulates. Moreover, Eagle Analytical Services was the recipient of an extremely critical report from the FDA, reflected in the Form 483 attached as Ex. D. That report, the result of an inspection conducted in June 2013, finds significant problems with every significant aspect of Eagle's laboratory, equipment, personnel, and processes. Thus, Observation 1 states in summary: Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that components conform to appropriate standards of identity,

strength, quality and purity." Id. at p. 1. Of the many problems detailed in Observation 1 is finding L: "your firm has failed to Validate the Test Method for any potency assays conducted by your firm. *You have not determined the evaluation of accuracy, sensitivity, specificity, and reproducibility of the test methods used in the analyses of drug products submitted by clients to your firm.*" Id. at p.2 (emphasis added). Controls are not recovered, yet drugs are still passed, and there is no documentation of the deviation. Sterility and Contamination Tracking Logs are not kept, and there are no signatures to indicate any review of such Logs. There is no Quality Control Unit and thus no one "that has responsibility and authority for approving [or] rejecting all procedures, methods, and specifications *related to the identity, strength, quality and purity of drug products submitted to your firm for analysis* . . .." Id. at p. 4 (emphasis added).

35. These are very serious – and very recent - problems that should draw into question any test results obtained by Eagle Analytical. There is no indication that three months later, when Eagle tested the compounded drug sold to TDCJ for use in executions, those problems had been fixed. Given the gravity of the problems identified, there should be substantial concern about the validity of the results of the tests conducted by Eagle on the Pentobarbital sold to TDCJ in September 2013.

<u>The Second Batch of Compounded Pentobarbital is Entirely Untested.</u>

36. Each time the TDCJ obtains a new batch of compounded pentobarbital, the source of the API will be unknown, and the same questions regarding the quality of the API will be implicated. There is no indication whether the Certificate of Analysis of the API

obtained by PCCA was used for both batches of compounded pentobarbital Woodlands sold to TDCJ on September 16 and September 30, 2013. The (questionable) potency testing that was conducted by Eagle took place on September 23 – before the second batch even existed. Thus, there are no documents indicating that any testing has been done of the second batch, or the API used to make it.

Adulteration

37. Adulterated drugs – either those that lack sterility or are contaminated by other substances in the laboratory in which they are made – is a serious risk with compounded drugs. Drugs that are not compounded in accordance with federal standards have a low standard of sterility assurance.

38. Even if a compounding pharmacy starts with a valid API, any number of things can go wrong in the compounding process. Compounding pharmacies, including Woodlands, make a variety of drugs. If the laboratory does not follow strict standards to ensure that cross-contamination does not occur with a potential allergen, then there is a real risk of an anaphylactic reaction with the use of the drug.

39. Thus, while the Eagle Analytical Laboratory Report states that the compounded pentobarbital is 98.8% potent, there is no analysis of any other of the factors that affect the quality or integrity of the drug. Indeed, the Eagle Laboratory Report, Ex. C at 9, lists various Microbiological Tests – none of which were conducted on the compounded pentobarbital sold to TDCJ for use in executions.

40. Eagle Analytical Services provided a "Laboratory Report" which reflects the minimal

information that the compounded pentobarbital – presumably the first batch sold to TDCJ – was 98.8% pure or potent. While this result is within a normal range for potency, it is highly relevant that a laboratory that was cited for numerous deficiencies just four months earlier did the testing. See Ex. A, attached. The deficiencies identified in Eagle Laboratories' practices bring into question the accuracy of the results reflected on the Laboratory Report.

41. Cross contamination is also a serious risk with compounded drugs. Contamination may give rise to a completely unanticipated response including an allergic or anaphylactic reaction to an unidentified adulterant arising from intrinsic contamination of the ingredients or extrinsic contamination during the compounding procedure. Highly unpredictable, rapidly evolving, and potentially painful and agonizing reactions may ensue should the pentobarbital be contaminated by endotoxins.

42. As it is impossible to know all cross contamination possibilities, and what inmate might be allergic to what drug, the risk is unpredictable, yet no less serious, and the possible results severe. The unregulated nature of compounding pharmacies – and the specific inadequacies of the Laboratory that has conducted testing on and been in possession of the drugs in question - renders this risk substantial.

Expired Drugs / Shortened and Untested Shelf Life

43. The questionable nature of the APIs used in compounded drugs, and the unregulated laboratories doing the mixing and testing, combine to render shelf life particularly unpredictable. The presence of adulterants or growing organisms will accelerate

chemical degradation, thus affecting shelf life.

44. The shelf lives of FDA regulated pharmaceuticals are tested to assure that they retain their integrity over specified periods of time. This is far more difficult to do with compounded drugs, and often unnecessary, as in the traditional compounding setting a particular drug is mixed pursuant to a doctor's prescription for an individual patient for immediate use.

45. The drugs sold by Woodlands Pharmacy to TDCJ, however, were not pursuant to a prescription, and are presumably to be used over an unspecified period of time. Woodlands' Logged Formula Worksheets indicate a "beyond use date" of March 15, 2014 for the drugs made on September 16, 2013, and a "beyond use date" of April 1, 2014 for the drugs made on September 30, 2013. See pp. 10; 12 of Ex. C. However, as each batch of compounded drugs is different, these particular batches cannot previously have been tested to determine shelf life. Indeed, the email from Jasper Lovoi of Woodlands Pharmacy to J.D.Willey of PCCA sent on September 18, 2013, states: "please check potency and then check stability at 3 and 6 months." Eagle Analytical Services ran the potency test on September 23, 2013. See Ex. C, p. 9. The Extended Analysis 1 and 2, however, are still pending, as they are the "stability" tests that cannot be run until three and six months. If press accounts are accurate that Woodlands Pharmacy is disenchanted by the nature of their transaction with TDCJ, and unsuccessfully sought to have their drugs returned, it is an open question whether those stability tests have been or will be conducted.

46. While six months is not an unusually long shelf life for a pharmaceutical, potential

contaminants and the unregulated nature of pharmacy compounding puts that assumption into question.

47. Drugs that are expired have lost their potency. Only testing by an independent competent laboratory can determine the extent of the loss.

Imbalances; Particulates

48. In their Logged Formula Worksheet Woodlands Compounding Pharmacy indicates that the pH of the pentobarbital sodium was adjusted with hydrochloric acid. With any compounding-pharmacy there is a substantial likelihood that the pH (acidity or basicity) of the final solution will be incorrect. There is also a possibility that the osmolality of the final product will be out of balance. Either failure increases the likelihood of a painful burning sensation on injection.

49. Non-traditional compounded solutions are also far more likely to contain or form precipitates, or solid particles of drug and other substances. Should solid particulate matter of any kind contaminate the solution or precipitate out of solution during intravenous injection, there is a substantial risk of pain and suffering upon injection of the solution, with the risk of an extremely painful pulmonary embolism in the most serious of cases.

Conclusion

50. When compounded drugs are used in executions, we have none of the assurances afforded by FDA oversight. Because compounded drugs exist outside of the FDA regulatory framework, their quality, purity, potency, safety and effectiveness cannot be assured. In fact, they have a much higher probability of being substandard (sub-

or super- potent, contaminated or of poor quality). In the context of executions by lethal injection, introducing an element of unpredictability by using compounded drugs is a wanton invitation to pain and suffering over and above the statutory objective of the death of the condemned person.

Further, affiant saith naught.

Dated this 2 day of December 2013.

Gary DeSmith

Sworn before me, this 2nd day of December, 2013
In the District of Nipissing, City of North Bay, Ontario.

C. John D'Agostino
D'Agostino & Associates
Barrister & Solicitor
255C Fisher Street, North Bay, ON P1B 2Z...
LSUC No. 33213Q

Curriculum Vitae
of Larry D. Sasich

CURRICULUM VITAE

Larry D. Sasich, Pharm.D., M.P.H., FASHP
839 Main Street West #3
North Bay, P1B 2V8, Ontario
Canada
Cell Phone: 705-491-0609
E-Mail: larry.sasich@gmail.com

EDUCATION

1995 to 1997	Master of Public Health - Epidemiology The George Washington University School of Public Health and Health Services Washington, D.C.
1974 to 1975	Doctor of Pharmacy University of the Pacific College of Pharmacy Stockton, California
1966 to 1970	Bachelor of Science Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho

RESIDENCY

1986 to 1987	Nuclear Pharmacy University of New Mexico College of Pharmacy Albuquerque, New Mexico

PROFESSIONAL LICENSES

1970 to Present	California RPH 27094

PROFESSIONAL EXPERIENCE

April 2013 to date	Consultant, Drug Policy, Drug Safety and Efficacy North Bay, ON Canada
July 2007 to April 2013	Consultant, Saudi Food and Drug Authority 3292 Northern Ring Rd. Al Nafal District Riyadh, Saudi Arabia
November 2009 to 2012	Consultant, Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2007 to 2009	Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2007	Acting Chairman, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2005 to 2006	Assistant Professor, Department of Pharmacy Practice LECOM School of Pharmacy 1858 Grandview Blvd. Erie, PA 16505
2006 to 2008	Consultant Centre for Science and the Public Interest – Canada Suite 4550, CTTC Bldg. 1125 Colonel By Drive Ottawa, Ontario K1S 5R1 Canada

PROFESSIONAL EXPERIENCE

2005 to 2007	Consultant Public Citizen's Health Research Group 1600 20th Street, NW Washington, D.C. 20009
2005 to 2006	Consultant Canadian Agency for Drugs and Technologies in Health 600-865 Carling Avenue Ottawa, Ontario K1S 5S8 Canada
1995 to 2005	Research Analyst Public Citizen's Health Research Group 1600 20th Street NW Washington, D.C. 20009
1991 to 1995	Drug Information Pharmacist King Faisal Specialist Hospital and Research Centre Riyadh 11211, Saudi Arabia
1993 to 1996	Adjunct Clinical Faculty Welch School of Pharmacy University of Wales Cardiff, Wales
1992 to 1995	Clinical Instructor College of Pharmacy King Saud University Riyadh, Saudi Arabia Graduate and Undergraduate Teaching
1988 to 1990	Clinical Pharmacist St. Helens Hospital and Health Center St. Helens, OR Emanuel Hospital and Health Center Portland, OR
1985 to 1988	Associate Professor of Clinical Pharmacy Idaho State University College of Pharmacy Pocatello, Idaho Promoted and Tenured July 1, 1984

PROFESSIONAL EXPERIENCE

1983 to 1984	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Acting Associate Dean for Student Affairs
1982 to 1983	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director of Professional Practice
1979 to 1982	Assistant Professor of Clinical Pharmacy College of Pharmacy Idaho State University Pocatello, Idaho
	Director, Idaho Drug Information Service and Regional Poison Control Center
1976 to 1979	Assistant Director of Pharmacy Services USA MEDDAC Berlin, West Germany
1975 to 1976	Staff Pharmacist USA MEDDAC Wuerzburg, West Germany
1970 to 1974	Pharmacist Baneth's Pharmacy Menlo Park, CA

HONORARY SOCIETIES

1982	Rho Chi
1982	Sigma Xi

AWARDS

2000	Distinguished Person of the Year – Pharmacists Planning Services
1995	Fellow American Society of Health-System Pharmacists
1986	Ciba-Geigy Leadership Award
1983	Outstanding Service – Idaho Board of Pharmacy
1982	Phi Delta Chi Faculty Achievement Award

APPOINTMENTS

2009	FDA Science Board Sub Committee on the Center for Food Safety and Applied Nutrition (CFSAN)
2008	FDA Science Board Sub Committee on the review of the National Center for Toxicological Research
2007	Grant Reviewer U.K. Economic and Social Research Council Large Grant proposal: Governance of Pharmaceuticals and Health
2007	Consumer representative, Science Board to the Food and Drug Administration – advisory committee to the FDA Commissioner
2007	Pennsylvania Pharmacists Association Pharmacy Compounding Task Force
2006	Food and Drug Administration Pediatric Advisory Committee November 16, 2006 – substitute consumer representative
2006	Reviewer *PLoS Medicine*
2000	Reviewer for the *Western Journal of Medicine*
2000	Reviewer for the *Journal of the American Medical Association*
1996	Department of Health and Human Services Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Drug Information
1996	Department of Health and Human Services, Food and Drug Administration, Consumer Consortium

APPOINTMENTS

1995	Reviewer for the *Saudi Pharmaceutical Journal*
1993	Reviewer for the *Annals of Saudi Medicine*
1986	Reviewer for *Annals of Pharmacotherapy*
1987	Idaho Delegate to Western Regional Conference on Clinical Pharmacy Practice
1985	Idaho Health Systems Ethics Conference Task Force
1984	American Pharmaceutical Association Committee to prepare accreditation standards for a community pharmacy residency
1982	Assistant Editor DRUGDEX®
1981	USP Dispensing Information Contributors Panel

PUBLICATIONS

Sasich LD, Abi-Jaoude E. Drug approval packages and briefing documents are already freely available. *BMJ* 2013;347:f4861.

Sasich LD. Rapid Response: Tamiflu: 14 flu seasons and still questions. BMJ 2013. At http://www.bmj.com/content/346/bmj.f547?tab=responses. Accessed January 28, 2013.

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PUBLICATIONS

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Tuttle DA, Sasich LD, Sukkari SR. Improving Access to FDA Reviews and Documents. *Journal of the American Medical Association* 2009; 302: 2204.

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Sasich LD, Barasain MA, Al Kudsi MA. Three country comparison of selected safety information in the prescribing information for rosiglitazone (Avandia). *Saudi Pharmaceutical Journal* 2009; 17: 195-198.

Sukkari SR, Sasich LD. Look in the Looking Glass Not Through It. *American Journal of Pharmaceutical Education* 2009; 73:56-58.

Brown S, Olson P, Sasich LD. My First Drug Information Question – Should My Wife and Baby be Subjects in an Uncontrolled Clinical Trial? *Journal of the American Pharmacists Association* 2008; 48:444-445.

Sukkari SR, Sasich LD, Tuttle DA, Abu-Baker A, Howell H. Development and Evaluation of a Required Patient Safety Course. *American Journal of Pharmaceutical Education* 2008; 73(3)

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Sasich LD, Barasain MA, Al Kudsi MA. The CV Risks of Etoricoxib (Arcoxia). *Annals of Saudi Medicine* 2008; 28:141-142.

Vitry A, Lexchin J Sasich LD, , Dupin-Spriet T, Reed T, Bertele V, Garattini S, Toop L, Hurley E. Provision of information regulatory authorities' websites. *Internal Medicine Journal* 2008 (doi:10.1111/j.445-5994.01588.x).

Sasich LD, Sukkari SR. Unknown risks of pharmacy compounded drugs. *Journal of the American Osteopathic Association* 2008; 108:86 [letter].

Miller J, Olmer J, Sasich LD. Importance and methods for accessing FDA approval packages and briefing documents. *Annals of Pharmacotherapy* 2007; 41:2071-2072.

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Sasich LD. Remembering Jere Goyan. *American Journal of Health-System Pharmacists* 2007; 64:1142 [letter].

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Wolfe S, Lurie P, Sasich LD, Barbehenn E. Information on thiazolidinediones. *Lancet* 2000; 356:254-258 [letter].

Lurie P, Sasich LD. Safety of FDA-approved drugs. *Journal of the American Medical Association* 1999; 282:2297 [letter].

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Sasich LD, Sukkari SR. Bromocriptine: reply to Sandoz. *Saudi Pharmaceutical Journal* 5:197-199; 1997[letter].

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Sasich LD, Sukkari SR. International Drug Information Notes: The lack of safety and efficacy of tramadol (Ultram, Zydol). *Saudi Pharmaceutical Journal* 4:207-209; 1996.

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Julnes T, Sasich LD. Oregon's health rationing act and the policy process. *New England Journal of Human Services* 9:20-26; 1991.

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Dodson RA, Sasich LD. Calcium channel blockers: their actions and indications. *Pharmacy Times* 50:4; 1984.

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Driver PS, Endo RE, Levin A, Hall DH, Sasich LD. Anaphylactic-like reactions to zomepirac. *Drug Intelligence and Clinical Pharmacy* 15:384; 1981.

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Hansten PD, Sasich LD, Biggs RL, Cohen SM. Computerization and drug interaction data for a community pharmacy. *Journal of Clinical Computing.* 3:270; 1975.

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Furberg BD, Furberg CD, Sasich LD. Knowing Your Medications. 2010.

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References available on request

DECLARATION of DAVID B. WAISEL

Appeared before the undersigned authority duly designated to administer oaths, David B. Waisel, M.D. states on oath as follows:

1. My name is David B. Waisel. I am over 18 years of age and am otherwise competent to give this affidavit. No promises or agreements have been made to me in exchange for this statement, and I do not expect any in the future.
2. I am a practicing anesthesiologist at Boston Children's Hospital and an Associate Professor of Anaesthesia, Harvard Medical School. I have been practicing clinical anesthesiology, primarily pediatric anesthesiology, for approximately twenty years. My c.v. is attached.
3. I have been asked by the attorneys representing Edgar Tamayo to provide an expert medical and scientific opinion about scenarios in which the use of compounded pentobarbital in executions could cause severe pain upon injection or shortly thereafter. In preparing this affidavit I reviewed the June 2012 Execution Protocol of the Texas Department of Criminal Justice (TDCJ).
4. Given the well-known problems associated with compounding pharmacies, I only use compounded drugs when there is absolutely no alternative.
5. While sub-par anesthetics or incompetent administration can cause a variety of serious problems, I focus here only upon problems that could

cause serious or severe pain upon or immediately after intravenous injection. These potential problems fall into two basic categories: improper potency and unintended additives. Each category has a number of subcategories.

6. Potency. Potency is the amount of drug required to produce a specific effect. If a solution is assumed to have 10 mg/cc of a drug, but only has 5 mg/cc of a drug, the amount of the drug given which is based on the assumed concentration of 10 mg/cc will not provide the intended effect. If the pentobarbital is not in the assumed concentration, the inmate will receive less than the protocol requires. This smaller dose creates a substantial risk of a prolonged death, including periods of difficulty breathing, which would feel like suffocating to death.

7. Anesthetic solutions, such as compounded pentobarbital, which have expired or gone beyond their 'shelf-life', lose potency. If an expired drug is used, although the concentration may be correct (in that there is 10 mg/cc), the effect of the concentration of the expired drug will be less than the effect of the same concentration of a non-expired drug. This would lead to the same effect upon injection as use of a sub-potent drug: prolonged death with periods of what feels like suffocation.

8. Administration of a sub-potent first dose (through either an incorrect concentration or a sub-potent drug) could lead to a need for a second dose. Because the Director does not have clear instructions about when to administer the second dose (particularly with regard to timing), a delayed

second dose could lead to a longer period of difficulty breathing, leading to substantial pain and suffering.

9. Unintended additives can occur in a variety of forms and ways.

10. Because of inadequate laboratory procedures, the drug may be contaminated by another drug that itself may cause severe pain. For example, it may be mixed with the antibiotic penicillin, present in many pharmaceutical labs. The penicillin family is one of the most prescribed antibiotics; 10% of people report an allergy to penicillin. Allergic individuals who take penicillin may have an anaphylactic reaction, including angioedema, which causes swelling around the face, particularly of the mouth and tongue, and great difficulty breathing. Patients report that a severe anaphylactic reaction is like suffocating to death.

11. Pain on injection may also arise from the chemical composition of a solution, resulting in a direct or indirect irritant effect. Direct pain occurs immediately. Indirect pain occurs 10 – 20 seconds after injection, due to a local chemical reaction. Factors that affect pain on injection from chemical and composition errors include osmolality and acid-base status. Improper compounding, contaminants, and poor quality ingredients can result in incorrect osmolality or acid-base status.

12. Osmolality is the concentration of the solutes (such as sodium and chloride) in the blood. Normal human osmolality is approximately 290 milli-osmoles/liter. Injected drugs that have a non-physiologic osmolality

(that is, an osmolality different than normal human blood) cause significant venous irritation.

13. Acid-base status is assessed by pH. Normal human blood pH is about 7.4. Acid solutions with a pH of less than 4 or alkaline solutions with a pH more than 11 cause extreme pain when injected into veins.

14. Impurities in the lethal injection solution can also be extremely problematic. Improper compounding and testing procedures may leave fine particles undetectable by the naked eye in the solution, or larger particles that would not be detected by an untrained eye. These particles can cause great irritation to the vein, resulting in extraordinary pain.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and abilities.

DAVID B. WAISEL

Date Prepared:	**November 1, 2013**
Name:	**David B. Waisel, M.D.**
Office Address:	**Children's Hospital Boston** **Department of Anesthesiology, Perioperative and Pain Medicine** **300 Longwood Avenue, Bader 3** **Boston, MA 02115**
Home Address:	15 Beechwood Road Wellesley MA 02482
Work Phone:	**617-355-6457**
Work Email:	**David.Waisel@childrens.harvard.edu**
Work FAX:	617-730-9237
Place of Birth:	Harrisburg, Pennsylvania

Education

1987	B.A.	Pre-Medicine	Lehigh University
1989	M.D. Humanities Scholar	Medicine	Medical College of Pennsylvania

Postdoctoral Training

7/1989-6/1990	Intern	Internal Medicine	Wilford Hall Medical Center
7/1990-6/1992	Resident	Anesthesiology	Wilford Hall Medical Center
7/1992-6/1993	Senior Resident	Pediatric Anesthesiology	Children's Hospital Boston/Harvard Medical School
9/1993-5/1994	Fellow	Medical Ethics	Harvard Medical School

Faculty Academic Appointments

7/1992-6/1993	Clinical Fellow	Anaesthesia	Harvard Medical School
7/1993-6/1994	Research Fellow	Anaesthesia	Harvard Medical School
7/1997-6/1999	Clinical Assistant Professor	Anesthesia	F. Edward Hebert School of Medicine, Uniformed Services University of Health Sciences
8/1999-6/2006	Assistant Professor	Anaesthesia	Harvard Medical School
7/2006-	Associate Professor	Anaesthesia	Harvard Medical School

Appointments at Hospitals/Affiliated Institutions

7/1993-6/1994	Assistant in Anesthesia	Department of Anesthesiology, Perioperative and Pain Medicine	Children's Hospital Boston
7/1994-6/1999	Attending	Department of Anesthesia	Wilford Hall Medical Center
1/1995-6/1999	Bioethics Consultant	Office of Medical Ethics	Wilford Hall Medical Center
1/1998-6/1999	Director	Office of Medical Ethics	Wilford Hall Medical Center
9/1999-	Associate Clinical Ethicist	Office of Ethics	Children's Hospital Boston
8/1999-6/2000	Assistant in Anesthesia	Department of Anesthesiology, Perioperative and Pain Medicine	Children's Hospital Boston
7/2000-6/2003	Associate in Anesthesia	Department of Anesthesiology, Perioperative and Pain Medicine	Children's Hospital Boston
7/2003-	Senior Associate in Anesthesia	Department of Anesthesiology, Perioperative and Pain Medicine	Children's Hospital Boston
9/2006-1/2012	Co-Chair, Education Committee	Program for Patient Safety and Quality	Children's Hospital Boston

Other Professional Positions

Major Administrative Leadership Positions

Local

1995-1998	Chief, Pediatric Anesthesiology	Wilford Hall Medical Center
1995-1996	Assistant Chair for Resident Education, Department of Anesthesiology	Wilford Hall Medical Center
1997-1998	Assistant Chair for Research, Department of	Wilford Hall Medical Center

	Anesthesiology	
2000-2011	Chair, Fellow Selection Committee	Children's Hospital Boston
2003-2013	Program Director, Pediatric Anesthesiology Fellowship	Children's Hospital Boston
2006-2012	Chair, Education Committee, Program for Patient Safety and Quality	Children's Hospital Boston

Regional

National and International

2002-204	Councilor	Anesthesia History Association
2004-2008	Treasurer	Anesthesia History Association
2008-2010	Vice President	Anesthesia History Association
2007-2009	President	Pediatric Anesthesiology Program Director's Organization
2009-2011	Immediate Past President	Pediatric Anesthesiology Program Director's Organization
2009-	Board of Trustees	Wood Library-Museum of Anesthesiology
2012-	Treasurer	Wood Library-Museum of Anesthesiology

Committee Service

Local

1994-1999	Bioethics Committee 1994-1997	Wilford Hall Medical Center Chair
1994-1998	Education Committee 1995-1996	Department of Anesthesiology, Wilford Hall Medical Center Chair
1994-1998	Clinical Competence Committee	Department of Anesthesiology, Wilford Hall Medical Center Member
1994-1998	Quality Improvement Committee	Department of Anesthesiology, Wilford Hall Medical Center Member
1997-1999	Institutional Review Board	Wilford Hall Medical Center Member
1998-1999	Patient Care Council	Wilford Hall Medical Center Member
1998-1999	Credentials Committee	Wilford Hall Medical Center Member
1999	Awards Committee 1999	Society of Air Force Clinical Surgeons 46th Annual Meeting Chair
1999-	Ethics Advisory Committee	Children's Hospital Boston

		Member
2001-2012	Graduate Medical Education Committee	Children's Hospital Boston
		Member
2001-2013	Education Committee	Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston
		Member
2002-2003	Leadership Committee for ACGME Competencies	Children's Hospital Boston
		Member
2003	Organizational Ethics Consultation: Hospital Policy for Caring for Jehovah's Witnesses	Children's Hospital Boston
		Member
2003-2013	Clinical Competency Committee	Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston
		Member
2004-2010	Ethics Leadership Group	Harvard Medical School
		Member
2005-2013	Executive Committee	Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston
		Member
2006-2012	Senior Clinical Leadership Quality Council	Children's Hospital Boston
		Member
2007-2013	Information Services Steering Committee	Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston
		Member
2007	Henry K. Beecher Prize in Medical Ethics 2007	Harvard Medical School
		Award Committee Member
2008	Henry K. Beecher Prize in Medical Ethics 2008	Harvard Medical School
		Award Committee Member
2009	Henry K. Beecher Prize in Medical Ethics 2009	Harvard Medical School
		Award Committee Member

Regional

National and International

1995-2010	Committee on Ethics	American Society of Anesthesiologists
2000-2002	Task Force on Ethics	Council of Medical Specialties Society, Representing the American Society of Anesthesiologists
2000-2002	Working Group on Education about Gifts to Physicians	American Medical Association, Representing the American Society of

		Anesthesiologists
2004-2012	Education Committee	Society of Pediatric Anesthesia
2007-	Oral Board Examiner	American Board of Anesthesiology

Professional Societies

1989-	American Society of Anesthesiologists	
	1989-	Member
1992-	Society for Pediatric Anesthesia	
	2004-2012	Education Committee
1995-	Anesthesia History Association	
	2002-2004	Councilor
	2004-2008	Treasurer
	2008	Vice President

Grant Review Activities

Editorial Activities

- Editor, *Bulletin of Anesthesia History* (2012-)
- Ad hoc Reviewer
  - *Anesthesiology*
  - *Journal of Clinical Anesthesia*
  - *Journal of Clinical Ethics*
  - *Bulletin of Anesthesia History*
  - *Annals of Internal Medicine*
  - *Anesthesia and Analgesia*
  - Mayo Clinic Proceedings

Other Editorial Roles

Honors and Prizes

1994	Wood Library-Museum of Anesthesiology Fellowship	Wood Library-Museum of Anesthesiology	Fellowship to provide support to study history at the Wood Library-Museum of Anesthesiology
1994 - 1995	Golden Apple Award	Department of Anesthesiology, Wilford Hall Medical Center	For outstanding teacher of the year
1996 - 1997	Golden Apple Award	Department of Anesthesiology, Wilford Hall Medical Center	For outstanding teacher of the year
2002	David M. Little Prize	Anesthesia History Association	For the best work of anesthesia history published in the previous

			year in English
2004	Honorable Mention for David M. Little Prize	Anesthesia History Association	For the best work of anesthesia history published in the previous year in English
2007	Excellence in Tutoring Award	Harvard Medical School	For excellence in tutoring for Patient – Doctor III
2009	*Anesthesiology Trainees Face Ethical, Practical and Relational Challenges in Obtaining Informed Consent.* Selected by *Anesthesiology* as one of twelve 2009 highlighted article that exemplifies the mission of Anesthesiology	Anesthesiology	Selected by Anesthesiology as one of twelve 2009 highlighted article that exemplifies the mission of Anesthesiology

Report of Local Teaching and Training

Teaching of Students in Courses

2001 – 2007	Hospital Skills Day for rising third year medical students. Instructor/Harvard Medical School	2.5 hours contact time per day for 2 days per year, 2 hours prep time per year
2003 – 2007	IN750M.J Patient – Doctor III Tutor/Harvard Medical School	2.5 hours contact time per week for 24 weeks per year, 2 hours per week prep time

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

2006-	PERCS-Anesthesia	9-15 hours contact per year, 8 hours prep time per year

Clinical Supervisory and Training Responsibilities

1997 – 1999	Surgical and Pediatric ICU Ethics Teaching Rounds	8 hours contact time per month, 2 hours preparation time per month

Laboratory and Other Research Supervisory and Training Responsibilities

Formally Supervised Trainees

1996-1998	Affleck PJ, Waisel DB, Cusick JM, Van Decar T. Recall of risks following labor epidural analgesia. J Clin Anesth 1998;10:111-4.
1996-1998	Scheu KL, Waisel DB. Regional anesthesia equipment checkout recommendations: A case report and discussion. J Clin Anesth 1998;10:502-5.
2003-2004	Elder J, Waisel DB. Case report of the one-armed anesthesiology resident. J Clin Anesth 2004;16:445-8.

Formal Teaching of Peers (e.g., CME and other continuing education courses)

1995 – 1999	ACLS & PALS	4 hours contact time per course, 4-6 courses per year
	ACLS & PALS	Boston, MA
1997	APLS	Lecture, 2 hours contact time
	APLS	Boston, MA
1998	Anesthesia issues for the pediatrician: pain management, conscious sedation, preoperative evaluation, Pediatrics for the Practitioner 35th Annual Teaching Conference, Texa	Lecture, 4 hours contact time
2005-2009	Ethics in health care theories and cases. Harvard Bioethics Course	1 hour contact time per group, 3 groups/year

Local Invited Presentations

1994	The history and future of informed consent. Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston
1998	The physician in pre-World War II Germany - Healer and harbinger of death: Implications for medical ethics today. Maimonides Society of San Antonio
1998	Obligations to the professional community. Frontiers in Pediatrics, The San Antonio Military Pediatric Center
1998	Ethical issues in organ donation. Texas Organ Sharing Alliance
1999	Ethical issues related to anesthetic practice. San Antonio Society of Anesthesiologists
1999	Physician aid-in-dying. San Antonio Society of Psychiatry
1999	Ethics in battlefield medicine. Wilford Hall Medical Center
2000	Stratifying informed consent. Department of Anesthesia, New England Medical Center
2001	Perioperative management of Jehovah's Witnesses. Harvard Consortium on Ethics, Harvard Medical School
2001, 2003	Conference on informed consent in pediatric patients.

	Department of Medicine, Children's Hospital Boston
2002	Ethical issues related to caring for patients with mental retardation.
	Ethics Forum. Massachusetts General Hospital, Boston.
2002	Distribution of scarce resources.
	Harvard Consortium on Ethics, Harvard Medical School
2002	Social capital in the operating room.
	Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston
2003	Difficulties during anesthesia residency.
	Department of Anesthesia, Boston Medical Center
2004	"Being a good citizen in medicine."
	Department of Medicine, Children's Hospital Boston
2004	Pediatric perioperative DNR orders.
	Department of Neurosurgery, Children's Hospital Boston
2005	"Being a good citizen in medicine."
	Department of Medicine, Children's Hospital Boston
2005	Social capital in the operating room.
	Department of Urology, Children's Hospital Boston
2005	Being a jerk affects patient care and efficiency: social capital in the operating room.
	Department of Anesthesia and Critical Care, Beth Israel Deaconess Medical Center
2006	Physician Participation in Capital Punishment.
	Department of Urology, Children's Hospital Boston
2006	Physician Participation in Capital Punishment.
	Department of Surgery, Children's Hospital Boston
2007	Ethics Jeopardy.
	Department of Urology, Children's Hospital Boston
2011	Hearts and Minds.
	Keynote Address, Children's Hospital Boston Academy Retreat

Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses

Regional

2002	Informed refusal.
2004	Perioperative DNR orders.
	Harvard Medical School Anesthesia Review
2006	Ethical Aspects of refusing transfusion therapy in minors.
	Practical Aspects of Pediatric Anesthesia
2010	The development of anesthesiology during World War II.
	Ellison Pierce Symposium
2010	Invited speaker. Grand Round: PERCS. Anesthesia, Critical Care and Pain Medicine,Beth I.
2013	Invited Grand Rounds speaker. Social Capital. Boston Medical Center Anesthesia/Surgery J anesthesiology)

National

1995	The role of the anesthesiologist in physician-assisted death. American Society of Anesthesiologists Annual Meeting
1996	Should the HIV-infected anesthesiologist tell his or her patient? American Society of Anesthesiologists Annual Meeting
1996 - 1999	"Don't Tell My Mom!" Abortion and the minor, confidentiality and production pressure. American Society of Anesthesiologists Annual Meeting
1997	Do business ethics count in anesthesiology? Workshop on Practical Bioethics for the Anesthesiologist. American Society of Anesthesiologists
1997	Can ethics be taught? American Society of Anesthesiologists Annual Meeting
1997	A model curriculum for teaching bioethics. American Society of Anesthesiologists Annual Meeting
1997	Ethical issues in the operating room. Second Annual Practice Management Conference for Anesthesiology Residents and Fellow: Ready for the Real World, Chicago, IL
1997	What bioethics can do for you? Workshop on Practical Bioethics for the Anesthesiologist. American Society of Anesthesiologists
1998	Social capital Department of Anesthesiology, Rush-Presbyterian-St. Luke's Medical Center
1998	Ethical challenges for the practice of anesthesiology. Kentucky Society of Anesthesiologists Spring Meeting
1998	Panel on military anesthesia Society of Air Force Clinical Surgeons 45th Annual Meeting
1998	The importance of modeling. Society of Air Force Clinical Surgeons 45th Annual Meeting
1998	Grand Rounds. The business of anesthesiology is not just business: obligations to the patient and anesthesiology communities. Department of Anesthesiology and Critical Care, Children's Hospitalof Philadelphia, University of Pennsylvania
1998	Ethics in education. Innovation and Challenges in Anesthesiology Education Society for Education in Anesthesia, Fall Meeting
1998	Grand Rounds. Ethics in wartime medicine. Brooke Army Medical Center, Fort Sam Houston
1998	Clinical Forum on Ethics. American Society of Anesthesiologists Annual Meeting
1999	Ethical rules for humanitarian missions. Society of Air Force Clinical Surgeons 46th Annual Meeting
1999	Ethical considerations in pediatric trauma. TraumaCare '99 Symposium International Trauma Anesthesia and Critical Care Society, Chicago
1999	Conflict and communication with patients. American Society of Anesthesiologists Annual Meeting
1999	Perioperative Refusal of Resuscitation. Department of Anesthesiology, University of Texas Health Science Center
2000	Perioperative Refusal of Resuscitation.

	Department of Anesthesiology, Hartford Hospital
2000	Perioperative Refusal of Resuscitation.
	New York Presbyterian Hospital and Weill Medical College at Cornell
2000	DNR in the OR.
	Harvard Medical School Anesthesia Review & Update
2000	Clinical Forum on Ethics.
	American Society of Anesthesiologists Annual Meeting
2000	The business of anesthesiology is not just business.
	Utah Society of Anesthesiologists Winter Meeting
2001	Are we prepared for nuclear war?
	American Society of Anesthesiologists Annual Meeting
2002	The centrality of civility to professionalism.
	American Society of Anesthesiologists Annual Meeting
2003	Role of World War II in the development of anesthesiology as a medical profession.
	Anesthesia History Association 10th Annual Spring Meeting
2003	Clinical Forum on Ethics.
	American Society of Anesthesiologists Annual Meeting
2003	The uncivil and unprofessional physician.
	American Society of Anesthesiologists Annual Meeting
2003	Perioperative DNR orders.
	American Society of Anesthesiologists Annual Meeting
2003	Obstetric anesthesia and analgesia before 1950.
	American Society of Anesthesiologists Annual Meeting
2003	Social capital in the operating room.
	Society of Air Force Clinical Surgeons Annual Meeting, Anesthesia Section
2003	Plenary Session: Lt. Kornfield, World War II physician-anesthetist: why his story matters.
	Anesthesia History Association Spring Meeting
2003	Social Capital
	SAUSHEC Anesthesiology Residency Program, San Antonio
2004	Social Capital
	New York Presbyterian Hospital and Weill Medical College at Cornell
2004	Ethical aspects of refusing transfusion therapy in minors.
	Practical Aspects of Pediatric Anesthesia
2006	Lethal Injection
	American Society of Anesthesiologists Annual Meeting
2006	Social Capital
	Department of Anesthesiology and Pain Medicine, St. Elizabeth's Medical Center
2006	Physician Participation in Capital Punishment
	Department of Anesthesiology and Perioperative Medicine, Mayo Clinic, Rochester
2007	PERCS - Simulation for Informed Consent
	Department of Anesthesia and Critical Care, Massachusetts General Hospital
2007	Clinical Forum on Ethics.
	American Society of Anesthesiologists Annual Meeting
2007	What if Lord Nuffield had not found a Chair of Anesthesia?
	American Society of Anesthesiologists Annual Meeting
2008	Proposal for Format for Pediatric Anesthesiology Department

Department of Anesthesia, University of Iowa

2008 Primer in ethics.
Society of Pediatric Anesthesia 22nd Annual Meeting

2008 John Snow: Pump handles and infectious disease.
American Society of Anesthesiologists Annual Meeting

2008 Putting it all together: A curriculum.
Wood Library -Museum of Anesthesiology Forum on the History of Medicine. American Society of Anesthesiologists Annual Meeting

2008 World War Two: The crucible of "modern" anesthesiology.
Roderick K. Calverley, M.D., Memorial Lecture. Anesthesia History Association Annual Dinner Meeting

2008 Plenary Symposium "The Future of Anesthesia Practice."
Annual Meeting of the Canadian Anesthesiologists' Society, Halifax, Canada

2009 Donation after cardiac death.
ASA Forum on Ethics. American Society of Anesthesiologists Annual Meeting

2009 Oh my G-d, She's pregnant!
SPA/AAP Breakfast Panel

2010 Bedside Medical Ethics during Natural Disasters
Arkansas Children's Hospital, University of Arkansas

2010 Physician Participation in Capital Punishment
Ogden Surgical Medical Society

2010 When is a kid an adult? – Ethics of assent and consent for adolescent regional anesthesia
Panel on Pediatric Anesthesia, American Society of Anesthesiologists Annual Meeting

2010 Ethical dilemmas with health care reform
Panel on Ethics, American Society of Anesthesiologists Annual Meeting

2010 Moderator and participant: Should physicians be permitted to participate in lethal injection
Panel on Professionalism: American Society of Anesthesiologists Annual Meeting
Moderator: The Patrick Sim Forum on the History of Anesthesiology
American Society of Anesthesiologists Annual Meeting

2011 Moderator: The Patrick Sim Forum on the History of Anesthesiology
American Society of Anesthesiologists Annual Meeting

2012 Medical Ethics
Department of Anesthesiology and Perioperative Medicine, University of Missouri School of Medicine

2012 Moderator: The Patrick Sim Forum on the History of Anesthesiology

2013 Moderator: The Patrick Sim Forum on the History of Anesthesiology
American Society of Anesthesiologists Annual Meeting

2013 Keynote speaker. Norman Kornfield and his relevance to modern day military medicine.
Uniformed Services Society of Anesthesiologists Dining Out

International

1999 Physician aid-in-dying.
Austrian International Congress on Anesthesia, Vienna, Austria

2001 5th International Symposium on the History of Anesthesia
Santiago, Spain

2008	Plenary Symposium "The Future of Anesthesia Practice." Annual Meeting of the Canadian Anesthesiologists' Society, Halifax, Canada
2008	World War Two: The crucible of "modern" anesthesiology. Roderick K. Calverley, M.D., Memorial Lecture. Anesthesia History Association Annual Dinner Meeting
20011	Ethics of organ transplantation. 58th Annual Meeting of the Japanese Society of Anesthesiologists
2012	Regional Anesthesia and War 15th WFSA World Congress Anesthesiologists, Buenos Aires, Argentina
2013	ABA Board Certification 8th International Society History of Anesthesia Meeting, Sidney, Australia
2013	Informed Consent DNR in the Operating Room 20th Panhellenic Congress of Anesthesia, Athens, Greece

Report of Clinical Activities and Innovations

Current Licensure and Certification

1993-	Massachusetts Board of Medicine Licensure
1994	Diplomate of the American Board of Anesthesiology
2005	Voluntary Recertification in Anesthesiology (through 12/31/2015)

Report of Scholarship

Publications

Peer reviewed publications in print or other media

1. Truog RD, Waisel DB. Amnesia instead of anesthesia: not always a question of consent. J Clin Ethics 1994;5:153-5.

2. Waisel DB, Fackler JC, Brunner JX, Kohane I. PEFIOS: an expert closed-loop oxygenation algorithm. Medinfo 1995;8Pt2:1132-6.

3. Waisel DB, Truog RD. The cardiopulmonary resuscitation-not-indicated order: futility revisited. Ann Intern Med 1995;122:304-8.

4. Waisel DB, Truog RD. The benefits of the explanation of the risks of anesthesia in the day surgery patient. J Clin Anesth 1995;7:200-4.

5. Liang BA, Truog RD, Waisel DB. What needs to be said? Informed consent in the context of spinal anesthesia. J Clin Anesth 1996;8:525-7.

6. Waisel DB, Truog RD. An introduction to ethics. Anesthesiology 1997;87:411-7.

7. Waisel DB, Truog RD. The end-of-life sequence. Anesthesiology 1997;87:676-86.

8. Waisel DB, Truog RD. Informed consent. Anesthesiology 1997;87:968-78.

9. Waisel DB, Truog RD. How an anesthesiologist can use the ethics consultation service. Anesthesiology 1997;87:1231-8.

10. Medell RJ, Waisel DB, Eskuri SA, Calicott RW. Field block for cranial surgery in World War II. Mil Med 1998;163:80-3.

11. Affleck PJ, Waisel DB, Cusick JM, Van Decar T. Recall of risks following labor epidural analgesia. J Clin Anesth 1998;10:111-4.

12. Scheu KL, Waisel DB. Regional anesthesia equipment checkout recommendations: A case report and discussion. J Clin Anesth 1998;10:502-5.

13. Truog RD, Waisel DB, Burns JP: DNR in the OR: A goal-directed approach. Anesthesiology 1999;90:289-95.

14. Waisel DB. Nonpatient care obligations of anesthesiologists. Anesthesiology 1999;91:1152-8.

15. Waisel DB, Vanscoy SEG, Tice LH, Bulger K, Schmelz J, Perucca P. Activities of an ethics consultation service in a tertiary military medical center. Mil Med 2000;165:528-32.

16. Waisel DB. The hazards of "hanging crepe" or stating overly pessimistic prognoses. J Clin Ethics 2000;11(2):171-4.

17. Waisel DB. The role of World War II and the European Theatre of Operations in the development of anesthesiology as a physician specialty in the USA. Anesthesiology 2001;94:907-14.

18. Truog RD, Waisel DB. Do-not-resuscitate orders: from the ward to the operating room; from procedures to goals. Int Anesthesiol Clin 2001;39(3):53-66.

19. Waisel DB, Burns JP, Johnson JA, Hardart GE, Truog RD. Guidelines for perioperative do-not-resuscitate policies. J Clin Anesth 2002;14:467-73.

20. Waisel DB. Norman's War: Norman B. Kornfield, MD, World War II physician-anesthetist. Anesthesiology 2003;98:995-1003.

21. Elder J, Waisel DB. Case report of the one-armed anesthesiology resident. J Clin Anesth 2004;16:445-8.

22. Waisel DB. Moral permissibility as a guide for decision making about conjoined twins. Anesth Analg 2005;101:41-3.

23. Waisel DB. Developing social capital in the operating room: the use of population-based techniques. Anesthesiology 2005;103:1305-10.

24. Wright L, Waisel DB, Bacon DR. The Anlet: Anesthesiology's response to the needs of the Armed Forces in World War II. Anesthesiology 2006;104:179-82.

25. Waisel DB. Physician participation in capital punishment. Mayo Clin Proc 2007;82:1073-82.

26. Waisel DB, Truog RD. A continuum for using placebo interventions in regional anesthesia and analgesia studies. Clin Pharmacol Ther 2008;84:163-5.

27. Gawande A, Denno DW, Truog RD, Waisel D. Physicians and execution--highlights from a discussion of lethal injection. N Engl J Med 2008;358:448-51.

28. Waisel DB, Lamiani G, Sandroc N, Pascucci R, Truog RD, Meyer EC. Anesthesiology Trainees Face Ethical, Practical and Relational Challenges in Obtaining Informed Consent. Anesthesiology 2009;110:480-6.

29. Waisel DB, Simon R, Truog RD, Baboolal H, Raemer DB. Anesthesiologist Management of Perioperative Do-Not-Resuscitate Orders: A Simulation-Based Experiment. Simulation in Healthcare 2009;4:70-6.

30. Waisel DB. Moral responsibility to attain thorough pediatric drug labeling. Peaediatr Anaesth 2009;19:989-93.

31. Waisel DB. Let the patient drive the informed consent process: ignore legal requirements. Anesth Analg. 2011;113:13-5.

32. Waisel DB. Vulnerable populations in healthcare. Curr Opin Anaesthesiol. 2013 Apr;26(2):186-92.

33. Waisel DB. Thoughts on the Bulletin. Bulletin of Anesthesia History. 2013:31(1):1

Non-peer reviewed scientific or medical publications/materials in print or other media

1. Waisel DB. Should medical professionals participate in executions. The National Association of Defense Lawyers Champion Magazine. June 2010, p 38.

Professional educational materials or reports, in print or other media

- Books/Textbooks for the medical or scientific community

1. Waisel DB. The physician in the arms race. In: Newell JD, Gabrielson IW. *Medicine Looks at the Humanities.* Maryland: United Press of America; 1987. p. 127-9.

2. Waisel DB. Euthanasia. Ethical Issues in Anesthesia, *Advances in Anesthesia.* St. Louis: Mosby-Year Book; 1997. p. 250-3.

3. Waisel DB, Van Norman G. ASA 1997 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1997.

4. Waisel DB. Introduction to ethics. In: Waisel DB, Van Norman G. ASA 1997 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1997.

5. Merrill DG, Waisel DB. Physician-assisted suicide: Con/Pro. American Society of Anesthesiologists Newsletter 1998;62(3):5-8.

6. Waisel DB, Van Norman G. ASA 1998 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1998.

7. Waisel DB, Van Norman D, Fine P. Hospice Care: Living all the days of your life: An interview with Perry Fine, MD. In: Waisel DB, Van Norman G, editors. ASA 1998 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1998.

8. Waisel DB. Perioperative DNR orders: new options, greater flexibility. Amer Society of Anesthesiologists Newsletter, 1999;63(4):5-8.

9. Waisel DB, Jennings JE. Informed consent in anesthesiology. In: Bready LL, Mullins RM, Noorily SH, Smith RB, editors. Decision Making in Anesthesiology, 3rd ed. St. Louis: Mosby-Year Book; 1999. p. 54-5.

10. Jennings JE, Waisel DB. Do-not-resuscitate in the operating room. In: Bready LL, Mullins RM, Noorily SH, Smith RB, editors. Decision-Making in Anesthesiology, 3rd ed. St. Louis: Mosby-Year Book; 1999. p. 56-57.

11. Waisel DB. Perioperative Do-not-resuscitate orders. Current Opinion in Anesthesiology 2000; 13:191-4.

12. Waisel DB, Truog RD, Todres ID. Ethical issues in pediatric anesthesiology. In: Cote CJ, Ryan JF, Todres ID, Goudsouzian NG, editors. A Practice of Anest for Infants and Children, 3rd ed. Philadelphia: W.B. Saunders; 2001. p. 68-78

13. Waisel DB, Truog RD. Informed consent for the patient with an existing DNR order. American Society of Anesthesiologists Newsletter 2001;65(3):13-4.

14. Waisel DB. Getting informed consent: an anesthesiologist's perspective. Inspirations: The Anesthesia Residents' Quarterly 2001;4(1):1-7.

15. Waisel DB. Could the attending be wrong? Inspirations: The Anesthesia Residents' Quarterly, 2001;4(3):12-6.

16. Waisel DB. Ethical issues in pain management and end-of-life care for the AIDS patient. In: Nedeljkovic S. Pain Management of HIV/AIDS Patients. Woburn: Butterworth Heinemann; 2002. p. 175-86.

17. Waisel DB. Ethical and legal issues in pediatric care. In: Yemen TA. Pediatric Anesthesia Handbook. New York: McGraw-Hill; 2002. p. 13-25.

18. Waisel DB, Medical professionalism: is it necessary or too arbitrary? American Society of Anesthesiologists Newsletter 2002;66(7).

19. Waisel DB. Perioperative DNR orders. American Society of Anesthesiologists Newsletter 2002;66(10).

20. Waisel D, Jackson S, Fine P, Should do-not-resuscitate orders be suspended for surgical cases? Curr Opin Anaesthesiol. 2003;16:209-13.

21. Waisel DB, Truog RD. Medical ethics and anaesthesia, In: Healy TEJ, Cohen PJ, editors. Wylie and Churchill-Davidson's A Practice of Anaesthesia, 7th ed. London: Arnold; 2003. p. 1341-52.

22. Van Norman G, Jackson SH, Waisel D. Informed consent: ethical

implications in clinical practice. Curr Opin Anaesthesiol. 2004;17:177-81.

23. Truog RD, Waisel DB, Burns JP. Do-not-resuscitate orders in the surgical setting (editorial). Lancet 2005;365:733-5.

24. Waisel DB, Truog RD. Ethical and legal aspects, In: Miller RD. Anesthesia, 6th ed. Philadelphia: Elsevier Churchill Livingstone; 2005. p. 3175-98.

25. Waisel DB. Ethical and legal considerations in pediatric anesthesia. In: Holzman RS, Mancuso TJ, Polaner DM, eds. A Practical Approach to Pediatric Anesthesia. Philadelphia: Lippincott Williams & Williams; 2008. p. 71-8.

26. Waisel DB, Truog RD, Todres ID. Ethical issues in pediatric anesthesiology. In: Cote CJ, Lerman J, Todres ID, eds. A Practice of Anesthesia for Infants and Children, 4th ed. Philadelphia: W.B. Saunders; 2009. p. 71-88

27. Waisel DB. Ethical issues in critical Care. In: Gabrielli A, Layon AJ, Yu M, editors. Civetta, Taylor, Kirby's Critical Care, 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2009.

28. Clendenin D, Waisel DB. Informed consent and the pediatric patient. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 33-8.

29. Quaine JG, Waisel DB. Ethical use of restraints. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 61-3.

30. McClain CD, Waisel DB. Triage and treatment of wounded during armed conflict. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 275-9.

31. Waisel DB. Physician facilitation of torture and coercive interrogation. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 280-4.

32. Waisel DB. Ethics and conflict of interest in anesthesia practice. In: Longnecker D, Brown DL, Newman MF, Zapol W. Anesthesiology, 2nd ed. 2012. P 45-50,

33. Waisel DB. Editor. Bulletin of Anesthesia History. 2012:30 (1).

34. Waisel DB. Editor. Bulletin of Anesthesia History. 2012:30(2).

35. Waisel DB. Ethical issues in pediatric anesthesiology. In: Cote CJ, et al, eds. /

Anesthesia
for Infants and Children, 5th ed. Philadelphia: W.B. Saunders. 2012. p. 64-76

36. Waisel DB. Ethical Considerations. In: Gregory A, Andropoulos DB. Gregory' Pediatric Anesthesia, Fifth Edition. Oxford: Blackwell Publishing. 2012.

37. Waisel DB. Editor. Bulletin of Anesthesia History. 2013:31(1).

THE CONSTITUTION PROJECT

Safeguarding Liberty, Justice & the Rule of Law

The Constitution Project's Clearinghouse of New Voices for Criminal Justice Reform

STATEMENT FROM CORRECTIONS OFFICIALS REGARDING THE EXECUTION OF CLAYTON LOCKETT

As former correctional officials, we are deeply troubled by the botched execution of Clayton Lockett in Oklahoma last night. Our jobs as officers of the law involved carrying out and enforcing punishment within the confines of state and federal law. What appears to have been a horrific death last night certainly does not seem to have been legal or humane.

Some of the media who witnessed part of the execution appeared to be visibly shaken and disturbed. But the staff whose job it was to administer these drugs and to handle Mr. Lockett's body were surely put through an even more difficult experience. A career in corrections prepares one to see many things, but the terrible memories of witnessing executions remain in one's psyche forever. Correctional officers should not have to prepare to witness the horror of a botched execution such as that endured by Mr. Lockett and we can only imagine the emotional toll of this event on the professionals involved in the procedure.

No individual should be asked to carry out an execution using experimental drugs and dosages or without proper training and medical expertise. We cannot know how last night's events happened without a full independent inquiry, not by the Oklahoma Department of Corrections itself, but by a credible third party whose findings should be made public. And no further executions should be carried out in Oklahoma until Mr. Lockett's death is fully investigated and all the facts are known.

Signatories:

Dr. Allen Ault
Former Commissioner, Georgia, Mississippi, Colorado Departments of Corrections.

Robert Brown, Jr.
Director, Michigan Department of Corrections (1961-1991).

Jane Browning
Executive Director, Compassion Works for All; Former Executive Director, International Community Corrections Association

Paddy Burwell
Director (Public Member), State Bar of Texas (1997-2000); Member, Legal Services to the Poor and Criminal MattersCommittee, State Bar ofTexas (2002-2011), Committee Chair (2010); Member, State Bar of Texas Commission for Lawyer Discipline (2002-2005); Member, Texas Board ofPardons and Paroles (1999-2005); Life Member, Association of Former Texas Rangers.

Terry J. Collins
Director, Ohio Department of Rehabilitation and Correction (2006-2010); Assistant Director, Ohio Department of Rehabilitation and Correction (1977-2006). Correctional consultant utilizing 36 years of

correctional experience.

Kathy Dennehy
Commissioner, Massachusetts Department of Corrections (2004-2007).

Steve J. Martin
Corrections Consultant and Attorney; Special Assistant Attorney General, Texas Attorney General (1985-1986); Executive Assistant to the Director (1984-1985), General Counsel (1983-1985), and Legal Counsel (1981-1983), Texas Department of Corrections, Huntsville, Texas; Federal court monitor, remedial decrees involving staff use of force in prisons and jails in the U.S., (1994-present); Expert, U.S. Department of Justice, Civil Rights Division (1993-2008); Expert, U.S. Department of Homeland Security, Office of Civil Rights and Civil Liberties (2010-present).

Dennis O'Neill
Retired Warden, Florida State Prison.

Rev. Dr. Carroll L. Pickett
Chaplain, Texas State Penitentiary at Hunstville, Texas Department of Corrections (1980-1995).

Chase Riveland
Director, Washington Departments of Corrections (12 years); Director, Colorado Department of Corrections (4 years).

Charles Terrell
Chairman, Texas Department of Criminal Justice (1987-1990); Chairman, Safer Dallas Better Dallas (2006-2012).

Dr. Reginald Wilkinson
Director (Ret.), Ohio Department of Rehabilitation and Correction (DRC), 1991-2006; DRC employee, 1973; President, American Correctional Association; Vice Chair for North America, International Corrections and Prison Association; President, Ohio Correctional and Court Services Association; Founder, Ohio chapter, National Association of Blacks in Criminal Justice.

Jeanne Woodford
Former Warden, San Quentin State Prison, California Department of Corrections and Rehabilitation.

Section 03 – Executions	OP – 001980	Effective Date: 01/15/2013
Execution Procedures	ACA Standards 3-FV-1D-28-1	
David Brent, Director Harrenhal Department of Corrections		

Execution of Offenders Sentenced to Death

The Harrenhal Department of Corrections (HDOC) establishes procedures for planning and carrying out the execution of a person convicted of a capital offense and sentenced to death. These procedures shall be followed as written unless deviation or adjustment is required, as determined by the director of Corrections or their designee (in the event of an absence). This policy outlines the internal procedures and does not create any legally enforceable rights or obligations.

I. Responsibility

The HDOC ensures the execution of a person sentenced to death under state law by a court of competent authority and jurisdiction is carried out in keeping with statute, case law and professional practices.

A. The HDOC shall make every effort in the planning and preparation of an execution to ensure the execution process:

1. Faithfully adheres to constitutional mandates against cruel and unusual punishment, in accordance with the Eighth Amendment to the United States Constitution;

2. Is handled in a manner that minimizes its impact on the safety, security and operational integrity of the facility and the community in which it occurs;

3. Accommodates the public's right to obtain certain information concerning the execution;

4. Reasonably addresses the privacy interests as provided by law;

5. Provides contingency planning to identify and address unforeseen problems;

6. Allows for stays of execution, commutations and other exigencies;

7. Provides opportunity for citizens to exercise their First Amendment Rights to demonstrate for or against capital punishment in a lawful manner; and

8. Ensures there is an appropriate response to unlawful civil disobedience, trespass and other violations of the law by any person attempting to impact the execution or the operation of the facility.

B. The procedures set forth in this policy are to be strictly followed. Any variations of a substantial nature must be approved by the Director as described in this policy. There will be no variations from the following requirements:

1. At least three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions.

2. The drugs required by this policy shall be used.

3. All Execution Team functions shall be performed by appropriately trained and qualified members of the Execution Team.

4. The Director cannot authorize a variation from the three requirements listed immediately above.

II. Procedures

A. General Guidelines

1. All court-ordered executions shall be carried out at the Harrenhal Correctional Facility and will be planned to commence at 10:00 am on the scheduled execution date, subject to developing circumstances

2. Unless otherwise designated by the Director, the prisoner shall remain on Death Row until transferred to the Death House for scheduled execution

3. The Harrenhal Supreme Court shall designate the date of execution. Upon receipt of a scheduled execution date, the Warden of the institution housing the prisoner shall notify the Director and the Warden at HCF.

B. Execution Preparation

1. Notification

The Warden of the institution where the prisoner is housed shall notify the Director of an upcoming scheduled execution date. Notification may also be provided to the supervising Regional Director of HCF, DOC Chief Counsel, DOC Managing Director of Operations, and the Office of Victim Services

2. Execution Drugs

   a. The scheduled execution shall proceed with intravenous administration of midazolam, rocuronium bromide, and potassium chloride, in accordance with the terms of this policy.

   b. The Warden shall determine whether there will be sufficient quantities of the execution drugs available and report those findings to the Director.

   c. The Warden's assessment of what constitutes a sufficient quantity of execution drugs shall include ensuring a sufficient amount for a contingency against contamination or inadvertent loss.

   d. At his discretion, the Warden may direct the Health Care Administrator or the Health Care Administrator's designee to order execution drugs from any licensed pharmacist (including the manufacturer, distributor, or a compounding pharmacy).

   e. All execution drugs delivered to HCF shall be maintained in the infirmary.

3. Assessment of Prisoner

   a. The prisoner's medical condition shall be assessed in order to identify any necessary accommodations or contingencies that may arise from the prisoner's medical condition or history. Any medical condition tor history that may affect the performance of the execution shall be communicated as soon as possible to the Warden of HCF, who shall confer with others as necessary to plan such accommodations or contingencies.

   b. Any concerns for establishing or maintaining IV lines and any concerns or plans for medical accommodations or contingencies shall be communicated to the Execution Team in order that these things may be discussed and addressed in execution trainings.

   c. An appropriate member of the mental health staff shall evaluate the prisoner approximately twenty-one days prior to the execution to evaluate his or her stability and mental health in light of the scheduled execution. Any concerns or contingencies affecting the execution process shall be communicated to the Warden of HCF as soon as possible.

4. Morning of Execution Day

   a. The prisoner shall be permitted to take a shower and dress in the designated clothing the morning of the execution.

   b. A "hands-on" examination of the prisoner's veins shall be made by a Medical Team Member before the IV is established. If any potential problems are identified they shall be discussed between the Medical Team, the Warden and the Director, and potential solutions shall be considered.

   c. A Drug Administrator, in the presence of a second Drug Administrator, shall take possession of the execution drugs from the institution pharmacy storage area, and shall document possession of the drugs by signing form "Order for Execution Medications." The Drug Administrators shall deliver the drugs to the Death House.

   d. The drugs shall be prepared for injection by a Drug Administrator. The preparation of the drugs shall be monitored by a second Drug Administrator who shall independently verify the preparation and dosage of the drugs. The Drug Administrator shall prepare the execution drugs as follows:

      i. Syringe 1: Twenty milligrams (20mg) of midazolam (under whatever name it may be available from a manufacturer, distributor, or compounding pharmacy) shall be obtained or prepared with 5mg/mL concentration. This syringe shall be clearly labeled with the number one (1) and placed in slot one (1) on a stand designated to hold six (6) syringes.

      ii. Syringes 2 and 4: Twenty milliliters (20ml) of sterile saline solution shall be obtained or prepared and drawn into two syringes clearly labeled two (2) and four (4), respectively. These syringes shall be placed in slots two (2) and four (4), respectively, on the designated tray.

      iii. Syringe 3: Fifty milligrams (50mg) of rocurium bromide (under whatever name it may be available from a manufacturer, distributor, or compounding pharmacy) shall be obtained or prepared and drawn into a syringe clearly labeled three (3). This syringe shall be placed in slot three (3) on the designated tray.

      iv. Syringes 5 and 6: One hundred and twenty milliequivalents (120mEq) of potassium chloride (under whatever name it may be available from a manufacturer, distributor, or compounding pharmacy) shall be obtained or

prepared and drawn into two syringes clearly labeled five (5) and six (6), respectively. These syringes shall be placed into slots five (5) and six (6) on the designated tray.

e. The designated member of the Execution Team who has prepared the lethal chemicals will transport them personally, in the presence of one or more additional member of the Team, to the executioner's room. The tray will be placed on the worktop for use by the executioner.

5. Approximately Thirty (30) Minutes Prior to Execution:

a. A designated member of the Execution Team will establish telephone communication with the Governor's office on behalf of the Warden. The phone line will remain open to the Governor's office during the entire execution procedure. The Assistant Warden will use this open line to report the ongoing activities of the execution team and other personnel to the Governor's office.

b. A designated member of the Execution Team will escort the two executioners into the executioner's room, where they will remain until the execution process is complete.

c. The Warden will read the Warrant of Execution to the inmate.

d. Designated members of the Execution Team, supervised by the designated Assistant Warden, will secure the restraining straps.

e. One or more designated members of the Execution Team will attach the leads to two (2) heart monitors to the inmate's chest, ensuring that the monitors are operational both before and after the chest restraints are secured.

f. A designated member of the Execution Team will insert one intravenous (IV) line into each arm at the medial aspect of the antecubital fossa of the inmate and ensure that the saline drip is flowing freely. The team member will designate one IV line as the primary line and clearly identify it with the number "1." The team member will designate the other line as the secondary line and clearly identify it with the number "2." If venous access cannot be achieved in either or both of the arms, access will be secured at other appropriate sites until peripheral venous access is achieved at two separate locations, one identified as the primary injection site and the other as the secondary injection site.

g. One or more designated members of the Execution Team will remove, one at a time, from the pole attached to the gurney, the two (2) saline bags and pass the

bags, along with the extension sets labeled "1" and "2," into the execution room, where the primary or secondary executioner will hang the bags on separate hooks inside the room. The designated team member will ensure that the tubing from the IV insertion points to the bags has not been compromised and that the saline drip is flowing freely.

6. Approximately Fifteen (15) Minutes Prior to Execution

   a. Official witnesses will be secured in the witness room of the execution chamber by two designated Department of Corrections escort staff.

   b. The only persons authorized in the witness room are: twelve (12) official witnesses, including family members of the victim, four (4) alternate official witnesses, one (1) nurse or medical technician, twelve (12) authorized media representatives, one (1) designated staff escort, and one (1) designated security officer.

   c. The execution chamber will be secured. Only designated staff and other authorized persons will be allowed in the chamber.

7. Administration of Execution

   a. The Warden will use the open telephone line to determine from the Governor whether there has been a stay of execution. If the Warden receives a negative response, he or she will return the telephone handset to the designated Assistant Warden to continue reporting the ongoing activities of the Execution Team and other personnel to the Governor's office. The Warden will then proceed with the execution.

   b. One or more designated members of the Execution Team will open the drape to the witness gallery window and turn on the public address (P.A.) system.

   c. The Warden will permit the inmate to make an oral statement, which will be broadcast into the witness gallery over the P.A. system. At the conclusion of the inmate's statement, the Warden will signal that the execution process has begun. A designated member of the execution team will turn off the P.A. system.

   d. In the presence of the secondary executioner and within sight of one or more members of the execution team, the primary executioner will administer the lethal chemicals in the following manner:

i. The executioner will remove from the tray the syringe labeled number one (1), which contains twenty milligrams (20mg) of midazolam in solution, place the blunt cannula into the open port of the IV, and push the entire contents of that syringe into the IV at a rate that meets the injection resistance of the cannula.

ii. The executioner will remove from the tray the syringe labeled number two (2), which contains twenty milliliters (20ml) of saline solution, place the blunt cannula into the open port of the IV, and push the entire contents of that syringe into the IV at a rate that meets the injection resistance of the cannula.

iii. The executioner will remove from the tray the syringe labeled number three (3), which contains fifty milligrams (50mg) of rocurium bromide, place the blunt cannula into the open port of the IV, and push the entire contents of that syringe into the IV port at a rate that meets the injection resistance of the cannula.

iv. The executioner will remove from the tray the syringe labeled number four (4), which contains twenty milliliters (20ml) of saline solution, place the blunt cannula into the open port of the IV, and push the entire contents of that syringe into the IV at a rate that meets the injection resistance of the cannula.

v. The executioner will remove from the tray the syringe labeled number five (5), which contains one hundred and twenty milliequivalents (120mEq) of potassium chloride, place the blunt cannula into the open port of the IV, and push the entire contents of that syringe into the IV port at a rate that meets the injection resistance of the cannula.

vi. The executioner will remove from the tray the syringe labeled number six (6), which contains one hundred and twenty milliequivalents (120mEq) of potassium chloride, place the blunt cannula into the open port of the IV, and push the entire contents of that syringe into the IV port at a rate that meets the injection resistance of the cannula.

e. Throughout the execution process, one or more designated members of the execution team will observe the heart monitors. If the heart monitors reflect a flat line reading during or following the complete administration of the lethal chemicals, the Execution Team physician will examine the inmate to determine whether there is a complete cessation of respiration and heartbeat

f. Once the inmate is pronounced dead by the physician, a designated member of the execution team will record the time of death.

g. The Warden will notify the Governor via the open phone line that the sentence has been carried out and the time of death.

h. A designated member of the execution team will turn on the P.A. system and make the following announcement to the witnesses in the gallery: "The sentence of the State of Harrenhal vs. [inmate name] has been carried out at [time of day]."

i. The designated Department of Corrections escort staff will escort the official witnesses from the witness room of the execution chamber.

Effective January 1, 2014

Har. Code Ann., § 12-122

§ 12-122. Method of infliction of sentence of death; identity of executioners; confidential information

1. The penalty of death shall be inflicted by an intravenous injection of a substance or substances in a lethal quantity sufficient to cause death, under the supervision of the state department of corrections.

2. A defendant who is sentenced to death for an offense committed before June 20, 1993, shall choose either lethal injection or firing squad at least thirty days before the execution date. If the defendant fails to choose either lethal injection or firing squad, the penalty of death shall be inflicted by lethal injection.

3. The identity of executioners and other persons who participate or perform ancillary functions in an execution and any information contained in records that would identify those persons is confidential and is not subject to disclosure pursuant to any other laws.

   (a)(1) As used in this subsection, the term "identifying information" means any records or information that reveals a name, residential or business address, residential or business telephone number, day and month of birth, social security number, or professional qualifications.

   (2) The identifying information of any person or entity who participates in or administers the execution of a death sentence and the identifying information of any person or entity that manufactures, supplies, compounds, or prescribes the drugs, medical supplies, or medical equipment utilized in the execution of a death sentence shall be confidential and shall not be subject to disclosure under any other laws or under judicial process. Such information shall be classified as a confidential state secret.

4. If a person who participates or performs ancillary functions in an execution is licensed by a board, the licensing board shall not suspend or revoke the person's license as a result of the person's participation in an execution

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

Institution/Facility	Institutional Unit	Period Covered
ASPC-Florence	Central Unit	Hour 0800 Date 07/23/2014
Housing Unit/Post/Duty Assignment: Housing Unit 9 Section Leader		Hour 1650 Date 07/23/2014

Staff Member (Last, First M.I. and Title)	Staff Initials	Time Arrived	Time Departed	Staff Member (Last, First M.I. and Title)	Staff Initials	Time Arrived	Time Departed
HU9 Section Leader		0800	1620				
HU9 Recorder		0800	1620				

Time of Day	Occurrence/Action Taken: Events, Activities, Disciplinary Violations, Maintenance Requirements, Safety/Health Hazards, Other Information Received and Action Taken, etc.	Staff Initials
0800	Execution table is prepared at least two hours prior to scheduled time of execution.	
0916	All items are removed from inmate's cell (Linen, property, etc)	
0918	Housing Unit 9 Section Leader advises Director that inmate is ready for search and restraint; requests permission to proceed. Director grants permission to proceed.	
0921	Director receives call from Donna Hallam (Arizona Supreme Court) advising a temporary stay will be issued.	
0922	Director advises the Housing Unit 9 Section Leader to disregard the search and restraint of the inmate.	
0950	Director receives call from the Arizona Supreme Court advising a temporary stay has been issued.	
1003	Director exits Housing Unit 9 to brief witnesses regarding the temporary stay.	
1113	Director advises stay has been lifted.	
1313	Inmate placed in upper restraints by restraint/escort team after strip search.	

Correctional Service Log

1313	Restraint Team Leader notifies Housing Unit 9 Section Leader that inmate is restrained and the team is ready to move the inmate to the injection room.	
1319	Housing Unit 9 Section Leader advises Director all witnesses have arrived at internal staging and requests permission to apply lower restraints to the inmate and move to the injection room.	
1320	Director makes initial call to the Governor's General Counsel to ascertain if there are any reasons to not proceed with the execution. Per Governor's General Counsel, at this time there is no reason to not proceed.	
1321	Director makes initial call to the Attorney General's Office to ascertain if there are any reasons to not proceed with the execution. At this time there is no reason to not proceed.	
1321	The Director informs Housing Unit 9 Section Leader (proceed with movement of inmate to the injection room).	
1321	Housing Unit 9 Section Leader advises Command to begin movement of witnesses to Housing Unit 9 witness room.	
1322	Inmate escorted to Execution Room; one staff in front, two at the inmate's sides, Restraint Team Leader behind. Support staff behind Restraint Team Leader	
1331	Restraint Team Leader advises the Housing Unit 9 Section Leader that inmate is restrained to the table.	
1331	Command advised Housing Unit 9 Section Leader that all witnesses are in place. Housing Unit 9 Section Leader advises Director witnesses are in place.	
1334	Housing Unit 9 Section Leader advises the Director the inmate is secure on the table and ready for the IV procedure. Director grants permission to proceed.	
1335	Monitor turned on in witness room.	
1337	Acting upon the advice of the IV Team Leader, the Director determines the catheter site(s).	
1346	Restraint/Escort Team Leader and Housing Unit 9 Section Leader positioned in Execution Room. Special Ops Team Leader inside the Chemical Room. Inmate is secured to the table with IV flowing, EKG functioning.	

Correctional Service Log

1347	Housing Unit 9 Section Leader advises Director that IV procedure is complete.	
1348	Director makes initial call to the Governor's General Counsel to ascertain if there are any reasons to not proceed with the execution. Per Governor's General Counsel, at this time there is no reason to not proceed.	
1349	Director makes initial call to the Attorney General's office to ascertain if there are any reasons to not proceed with the execution. Per Attorney General's office, at this time there is no reason to not proceed.	
1349	The Director informs Housing Unit 9 Section Leader "we may proceed".	
1349	With permission from the Director and confirmation to proceed, Housing Unit 9 Section Leader opens the curtains.	
1350	Housing Unit 9 Section Leader reads the Execution Order.	
1351	Housing Unit 9 Section Leader asks the inmate if he would like to make a last statement.	
1351	Inmate makes his last statement.	
1357	Housing Unit 9 Section Leader advises witnesses the inmate has been sedated.	
1423	Director orders IV Team to assess sedation and check IV.	
1424	Inmate remains sedated. No issues with IV.	
1441	Director orders IV Team to assess sedation and check IV.	
1442	Inmate remains sedated. No issues with IV.	
1449	Director orders IV Team to assess sedation and check IV.	

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

1450	Inmate remains sedated. No issues with IV.	
1501	Director orders IV Team to assess sedation and check IV.	
1502	Inmate remains sedated. No issues with IV.	
1515	Director makes call to Governor's Office to give update on execution and assessment of inmate.	
1529	Director orders IV Team to assess sedation and check IV.	
1530	Inmate remains sedated. No issues with IV.	
1539	Director orders IV Team to assess sedation and check IV.	
1540	Inmate remains sedated. No issues with IV.	
1542	Director speaks to Jeff Zick in the Attorney General's Office regarding contingency plan and proceeding with execution.	
1549	Director informed of death by Special Ops Team Leader.	
1549	Director advises witnesses that the execution is concluded.	
1549	Housing Unit 9 Section Leader closes the curtains.	
1550	Housing Unit 9 Section Leader notifies command to proceed with removal of witnesses from Delta Staging.	
1553	CIU Investigator examines the body.	

Correctional Service Log

1553	Coroner/Medical Examiner examines the body.	
1602	Housing Unit 9 Section Leader instructs IV Team to cut lines to IV's	
1607	Team enters and removes restraints from the inmate and places inmate on a gurney.	
1608	Restraint/Escort Team assists Coroner in the removal of the inmate's body.	
1609	All Teams perform clean up duties.	
1620	Housing Unit 9 Section Leader gives directives to secure the Execution Facility.	
/	End log.	

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

Institution/Facility	Institutional Unit	Period Covered
ASPC-Florence	Central Unit	Hour 1323 Date 7/23/14.
Housing Unit/Post/Duty Assignment: Lethal Injection Room Log		Hour 1349 Date 7/23/14

Staff Member (Last, First M.I. and Title)	Staff Initials	Time Arrived	Time Departed	Staff Member (Last, First M.I. and Title)	Staff Initials	Time Arrived	Time Departed
HU9 Recorder		1323	1349				

Time of Day	Occurrence/Action Taken: Events, Activities, Disciplinary Violations, Maintenance Requirements, Safety/Health Hazards, Other Information Received and Action Taken, etc.	Staff Initials
1323	Restraint team enters lethal injection room.	
1323	Legs restrained. (maintain good circulation)	
1323	Harness applied.	
1324	Remove left (hard) restraint.	
1324	Apply left (soft) restraint.	
1324	RTL asks inmate if it feels OK; inmate nods.	
1325	Left arm restrained.	
1325	Remove right (hard) restraint.	
1325	RTL advises inmate they are going to apply pulse monitor	
1325	Apply right (soft) restraint.	
1325	Right arm restrained.	
1325	RTL asks inmate if it feels OK; inmate nods	

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

1325	Remove belly chains.	
1326	RTL advises inmate they are going to have to share his upper body	
1329	RTL advises inmate they are going to apply a second blood pressure cuff.	
1329	Restraint Team Leader checks all restraints.	
1329	RTL asks inmate if left restraint feels alright	
1330	Inmate advises RTL that its a little tight but it wont matter in a few minutes. Also states you'll see a scar under there	
1330	RTL advisis inmate they will adjust it.	
1330	Inmate says thank you.	
1330	Inmate is restrained	
1331	RTL advises inmate our IV team is going to come in and do an assessment.	
1333	RTL ask inmate if he feels OK; inmate advises yes but its a little cold in here	

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

1335	IV Team enters lethal injection room, and conducts vein assessment
1335	IVTL advisis inmate they are here to do the IV procedure; and right now they are just going to do an assessment.
1336	IVTL advisis the inmate they'll be right back.
1338	IV Team explains IV procedure to the inmate.
1338	IVTL advisis the inmate they are going to apply a tourniquet
1340	IVTM advisis the inmate he will get this done as quick as he can. Also advisis the inmate hes going to feel a little stick.
1340	IVTM advisis the inmate he is going to remove the tourniquet and blood pressure cuff.
1341	RTM asks SO for primary line
1341	RTM ask SO to check flow
1341	SO advisis RTM flow is good.
1345	IVTM advisis the inmate they are going to do the same thing on this side
1344	RTM asks SO for secondary line
1345	RTM asks SO to check flow
1346	SO advisis RTM flow is good.

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

1347	IV Team exits the lethal injection room.
1347	RTL advises the inmate that over to his right when the curtains open the witnesses will be there
1349	Restraint Team exits the lethal injection room.

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

Institution/Facility	Institutional Unit	Period Covered
ASPC - Florence	Central Unit	Hour 0860 Date 07·23·14
Housing Unit/Post/Duty Assignment: Housing Unit 9, Special Operations		Hour 1718 Date 07·23·14

Staff Member (Last, First M.I. and Title)	Staff Initials	Time Arrived	Time Departed	Staff Member (Last, First M.I. and Title)	Staff Initials	Time Arrived	Time Departed
SOT Leader		0800	1718				
SOT Recorder		0800	1718				

Time of Day	Occurrence/Action Taken: Events, Activities, Disciplinary Violations, Maintenance Requirements, Safety/Health Hazards, Other Information Received and Action Taken, etc.	Staff Initials
0800	Special Operations and IV Teams assembled for execution of inmate:	
✓	Last: **WOOD** First: **JOSEPH R.** ADC#: **086279**	
0804	Audio, visual, and medical equipment inspected. Witness Room AV feed off.	
0818	IV Team Leader checked and verified the flow of each gauge and confirmed there	
✓	are no obstructions in the manifold or lines.	
0819	Commenced the preparation of chemicals and syringes.	
0835	Completed preparing, labeling, and affixing syringes to the manifold.	
0836	Special Operations Team Leader verified that all syringes are properly labeled	
✓	and affixed in the correct location on the manifold.	
1328	EKG leads, Pulse/Oxygen monitor, and blood pressure cuff attached.	
✓	Initial blood pressure: 137 / 84	

Shift Commander's Comments: *(Notes or comments concerning entries above; comments deemed appropriate)*

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

Time of Day	Occurrence/Action Taken: Events, Activities, Disciplinary Violations, Maintenance Requirements, Safety/Health Hazards, Other Information Received and Action taken, etc.	Staff Initials
1340	IV procedure commenced.	
1347	IV procedure completed. Primary IV catheter placed in inmate's Left A/C	
/	Backup IV catheter placed in inmate's Right A/C	
1352	Director instructed Special Ops Team Leader to commence with drug protocol:	
1352	• **Syringe 1A, 60 mL Heparin/Saline**	
1353 22	• **Syringe 2A, 50mg Midazolam and 50mg Hydromorphone**	
1353	• **Syringe 3A, 60 mL Heparin/Saline**	
1354	Drug protocol completed.	
1356	3 minute point: 1356 22. Confirmed 3 minutes have elapsed since	
/	commencing the administration of chemicals.	
1357	IV Team Leader verified the inmate is sedated.	
1408	SEE ADDITIONAL ENTRIES NOTED BELOW	
1549	IV Team Leader pronounced death.	
	Additional entries:	
1408	Syringe 1B 60mL Heparin/Saline	
1409	Syringe 2B 50mg Midazolam and 50mg Hydromorphone	
1409	Syringe 3B 60 mL Heparin/Saline	
1410	Second Drug Protocol Complete.	

Shift Commander's Comments: *(Notes or comments concerning entries above; comments deemed appropriate)*

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8/6/09

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

1413	2C 50mg Midazolam | 50mg Hydromorphone BANK A
1416	3C 60 mL Heparin Saline BANK A
1416	Third Drug Protocol Complete.
1424	Inmate Remains Sedated.
1425	1D 60 mL Heparin Saline BANK A
1426	2D 50 mg Midazolam | 50 mg Hydromorphone BANK A
1427	3D 60 mL Heparin Saline BANK A
1427	4th DRUG Protocol Complete
1433	1E 60 mL Heparin Saline BANK B
1434	2E 50mg Midazolam / 50 mg Hydromorphone. BANK B.
1434	3E 60 mL Heparin Saline BANK B
1434	5th. Drug Protocol Complete.
1442	Inmate Remains SEDATED
1443	1F 60 mL Heparin Saline BANK A
1444	2F 50 mg Midazolam / 50 mg Hydromorphone. BANK A.
1444	3F 60 mL Heparin Saline BANK A
1445	6th Drug Protocol Complete
1450	Inmate Remains Sedated
1452	2G 50 mg Midazolam / 50 mg Hydromorphone BANK B
1452	3G 60 mL Heparin Saline BANK B.
1453	7th Drug Protocol Complete.
1458	2H 50 mg Midazolam / 50 mg Hydromorphone. BANK A
1459	3H 60 mL Heparine Saline BANK A
1459	8th. Drug Protocol Complete.
1502	Inmate Remains Sedated
1502	2I 50 mg. Midazolam / 50 mg Hydromorphone. BANK B

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

1504	3I 60 mL Heparin Saline Bank B
1504	9th Drug Protocol Complete
1507	2J 50 mg Midazolam / 50 mg Hydromorphone. Bank A
1508	3J 60 mL Heparine Saline Bank A
1509	10th Drug Protocol Complete.
1530	Inmate Remains Sedated
1531	2K 50 mg Midazolam / 50 mg. Hydromorphone Bank B
1531	3K 60 mL Heparin Saline Bank B
1532	11th Drug Protocol Complete
1532	2L 50 mg Midazolam / 50 mg. Hydromorphone Bank A
1533	3L 60 mL Heparin Saline Bank A
1533	12th Drug Protocol Complete.
1536	2M 50 mg Midazolam / 50 mg Hydromorphone. Bank B
1537	3M 60 mL Saline Bank B
1537	13th Drug Protocol Complete
1540	Inmate. Remains Sedated
1540	2N 50 mg Midazolam / 50 mg. Hydromorphone. Bank A.
1541	3N 60 mL Saline Bank A
1541	14th Drug Protocol Complete.
1545	2O 50 mg Midazolam / 50 mg Hydromorphone. Bank B
1545	3O 60 mL Saline Bank B
1546	15th Drug Protocol Complete.
1548	Inmate Remains Sedated

8/6/09

ARIZONA DEPARTMENT OF CORRECTIONS

Correctional Service Log

Time of Day	Occurrence/Action Taken: Events, Activities, Disciplinary Violations, Maintenance Requirements, Safety/Health Hazards, Other Information Received and Action taken, etc.	Staff Initials
1549	IV TEAM LEADER PRONOUNCED DEATH	

Shift Commander's Comments: *(Notes or comments concerning entries above; comments deemed appropriate)*

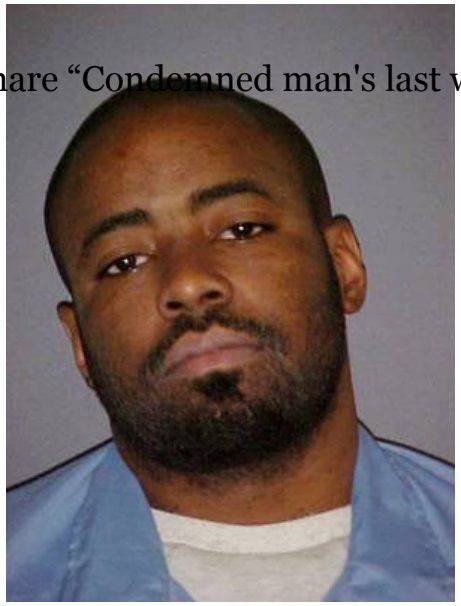
105-6
6/6/09

Condemned man's last words lead to questions about lethal injection 'cocktail' in Oklahoma, U.S.

States across the U.S. began using compounding pharmacies for a drug commonly used in executions after a key supplier stopped providing the drug.

by Graham Lee Brewer (/more/Graham Lee Brewer) (https://plus.google.com/u/0/112932829190486 01?rel=author) *Modified: February 9, 2014 at 10:00 am • Published: February 9, 2014*

The final words of two condemned men have placed Oklahoma at the forefront of the national debate over capital punishment and the constitutionality of the drugs used in lethal injections.



(/gallery/articleid/3932043/1/pictures/2341654)

FILE - This undated file photo provided by the Oklahoma Department of Corrections shows death row inmate Michael Lee Wilson. Wilson, 38, who was convicted of first-degree murder in the death of Richard Yost during a robbery at the convenience store where Yost worked as the night clerk on Feb. 26, 1995, is scheduled to be executed Thursday, Jan. 9, 2014. (AP Photo/Oklahoma Department of Corrections, File)

On Jan. 9, Michael Lee Wilson, 38, was put to death for participating in the 1995 murder of Tulsa store clerk Richard Yost. Shortly [illegible] body, he expressed love to his family and the wo[illegible]ords: “I feel my whole body burning.” Seconds l[illegible]

On Jan. 23, Kenneth Eugene Hogan said h[illegible]as executed for stabbing to death a college st[illegible]

Could the statements by Wilson and Hoga[illegible] cocktail used to carry out executions in Oklahoma and other states, or violate constitutional protection against cruel or unusual punishment?

Wilson's last words were cited in a lawsuit brought against the Missouri Department of Corrections by death row prisoners seeking basic information about the pentobarbital intended for use in their executions.

Pentobarbital is a barbiturate used in the execution process to render the condemned person unconscious. Another drug paralyzes the person and a third stops the heart.

Lundbeck, the Danish company that makes pentobarbital, is no longer distributing it to states that conduct executions, saying this is a “distressing misuse of our product.”

Redacted documents from the Missouri Department of Corrections revealed the state was acquiring pentobarbital from a business in Oklahoma, and the records pointed to three possible pharmacies. The Apothecary Shoppe, a compounding pharmacy with locations in Tulsa and Broken Arrow, was one of the three, and similar documents from the Louisiana Department of Corrections show the shop was also in correspondence with them.

Questions arose about the legality of a pharmacy not licensed in Missouri providing the state with drugs for lethal injection purposes. Cindy Hamilton, chief compliance officer for the Oklahoma State Board of Pharmacy, told The Tulsa World no state laws were violated because officials from Missouri drove to Oklahoma to obtain the drug.

Sarah Lees, spokeswoman for the Apothecary Shoppe, said once the business was sold to its employees it went through the process of reapplying for licensure in surrounding states, including Missouri, Texas, Arkansas and Kansas. She said it is possible the pharmacy also applied for licensure in Louisiana, but she could not confirm that.

Lees also declined to comment on whether or not the business compounds or sells pentobarbital.

Compound drug safety

Compounding pharmacies mix or alter drugs mainly for individual purposes, such as removing a particular ingredient a patient may be allergic to or creating a liquid form of a pill for children.

While compounding pharmacies are required to be licensed by the state in which they practice, they do not have to register with the U.S. Food and Drug Administration, nor do their products have to be approved or tested by the FDA.

“Basically, we don't know A) what the drugs could possibly be contaminated with and B) we don't really know if they're produced at the concentrations and things that we would expect to have from FDA approved drugs,” said Jen Moreno, staff attorney at the UC Berkeley Law Death Penalty Clinic. “That's really the troubling aspect of using compounded drugs, is that you don't really know until you have information what you're actually getting or using.”

information what you're actually getting or using.

In 2012, federal health officials said 64 people died and 686 others were sickened by steroids cleared by Oklahoma City-based Analytical Research Laboratories for a New England compounding pharmacy.

Mysterious process

On Thursday, a colleague of Moreno's, Eighth Amendment Resource Counsel for the UC Berkeley School of Law's Death Penalty Clinic Megan McCracken, filed a lawsuit against the Oklahoma Department of Corrections for not promptly responding to a Jan. 1 open records request asking for, among other things, drug chain of custody documents, correspondences with pharmacies, and any records or documents regarding the manufacturers and distributors of any drugs used for the purpose of execution.

“What we know about Oklahoma is that we really don't know very much,” Moreno said.

“It's probably one of the states where we get the least amounts of information about what they're doing.”

According to Oklahoma statute, “The identity of all persons who participate in or administer the execution process and persons who supply the drugs, medical supplies or medical equipment for the execution shall be confidential and shall not be subject to discovery in any civil or criminal proceedings.”

Death penalty experts like Moreno argue the use of pharmacies that are not federally regulated raises moral and ethical questions about the lethal injection process in America. She said in order to determine that pharmacies used by state corrections departments adhere to quality standards it is important states be as transparent as possible.

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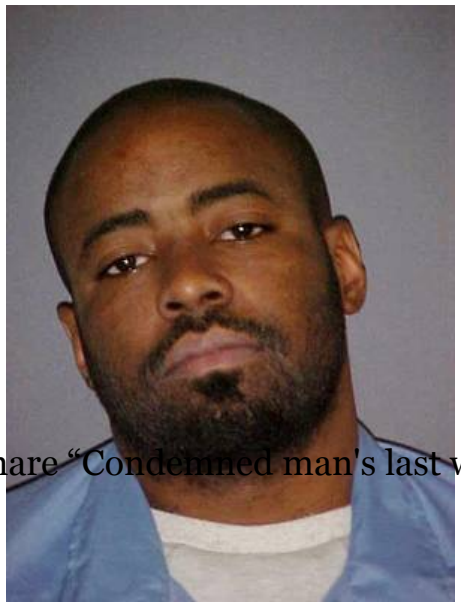
Condemned man's last words lead to questions about lethal injection 'cocktail' in Oklahoma, U.S.

States across the U.S. began using compounding pharmacies for a drug commonly used in executions after a key supplier stopped providing the drug.

by Graham Lee Brewer (/more/Graham Lee Brewer) (https://plus.google.com/u/0/112932829190486 01?rel=author) *Modified: February 9, 2014 at 10:00 am • Published: February 9, 2014*



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FILE - This undated file photo provided by the Oklahoma Department of Corrections shows death row inmate Michael Lee Wilson. Wilson, 38, who was convicted of first-degree murder in the death of Richard Yost during a robbery at the convenience store where Yost worked as the night clerk on Feb. 26, 1995, is scheduled to be executed Thursday, Jan. 9, 2014. (AP Photo/Oklahoma Department of Corrections, File)

“I think that the problems of the drugs that Oklahoma is using is a complete mystery,” said Moreno. “The Oklahoma Department of Corrections has provided no information either to plaintiffs — and I mean plaintiff by inmates — or journalists about where they are getting their drugs, if the drugs are in fact being compounded, and whether or not they're coming from a pharmacy that's reputable, that meets quality standards. And, furthermore, certainly haven't provided any information on the purity or potential contaminants of the drugs that they've received.”

This lack of transparency is typically not applied to other uses of taxpayer dollars, said Executive Director of the Death Penalty Information Center Richard Dieter, a national nonprofit that studies issues concerning capital punishment.

“If they were building a bridge, they'd have to say where the girders are coming from and the bolts and who makes them and how you test them to make sure the bridge will stand up,” said Dieter. “In this case, they're carr etail where they're getting the drugs from and them together and the licensing of these places,

Dieter said not only does the public have a ment's responsibility to protect the interests of pr

“Yeah the company that provides the drug business, but we don't protect against that sort of thing,” said Dieter. “Be open about it and let the public decide. I think that's the concern, that we're hiding from ourselves or we're letting the government hide information that generally we would demand.”

An open records request submitted jointly by *The Oklahoman* and The Tulsa World last month asking for documents pertaining to companies or pharmacies that provide the state with execution drugs, amounts paid and execution protocol have only been partially fulfilled.

On Friday, state Corrections Department spokesman Jerry Massie told *The Oklahoman* while statute specifically says all “persons” who supply execution drugs is confidential information, requests for the names of pharmacies or businesses that provide pentobarbital likely would not be granted.

“Corporations are considered persons under the law,” said Massie.

Crafting alternatives

Oklahoma purchased 20 doses of pentobarbital in the summer of 2012 for $40,000, said Massie. Of those 20, 10 doses remain. It's not clear where Oklahoma got this supply. In 2011, Lundbeck ordered that its pentobarbital no longer be sold for use in executions.

Questions have been raised in other states about the expiration dates of pentobarbital and how the drug is stored. Massie said Oklahoma's doses are already in a usable form and have a shelf life of three years. He said the state Corrections Department's remaining supply is not stored at a state facility.

Oklahoma statute provides that if the lethal injection method of execution is found unconstitutional the state may again use electrocution, which was last used in Oklahoma in the 1966 execution of James French, 29. If electrocution is found unconstitutional, statute allows for the use of firing squad.

Massie said if lethal injection is found unconstitutional or pentobarbital runs out, it is more likely a stay of execution would be granted until an alternative can be acquired, rather than the use of the electric chair.

Last month, the state of Ohio tried a never before used drug combination in the execution of Dennis McGuire. It took McGuire 25 minutes to die in what defense attorney Allen Bohnert called a “failed, agonizing experiment.”

The possibility of again trying new drugs for executions is a troubling and problematic scenario, said Brady Henderson, legal director for the Oklahoma branch of the American Civil Liberties Union.

“Basically, what we're doing is a form of human experimentation, at the end of the day,” said Henderson. “What can happen is executions can start becoming experiments, and what that means is it's much harder to predict whether a particular technique is going to produce something that is cruel and unusual, to use constitutional terms.”

Dieter agrees, again pointing to the necessity for public opinion on how inmates should pay the ultimate price to society.

“If this were another country that was trying new ways of executing people, we would be somewhat shocked. And, if it were in this country in any other context, say taking involuntary patients and trying a drug that had never been used before or any combination and forcibly injecting it into a person,” said Dieter, “I realize it's the death penalty, but it doesn't erase all ethical and constitutional protections.”

“I think instead what's happening is (states are) saying what's available, and when it's available they're using it and not sure exactly what's going to happen, at least the first time.”

The state Corrections Department currently has no backup plan for how to carry out lethal injections if pentobarbital becomes unavailable and a suitable alternative is not found.

“We'll address that when that possibility arises,” said Massie.

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South Dakota carries out execution using contaminated compounded drugs

A prisoner who died this week in a potentially botched lethal injection was killed using drugs from a compounding pharmacy, it has emerged.

Eric Robert was executed in South Dakota on 15 October using a single dose of the barbiturate pentobarbital, which had been made to order by a compounding pharmacy. The status of such pharmacies has been in the spotlight in recent weeks after one was linked to an outbreak of meningitis.

Mr Robert reportedly took 20 minutes to die and opened his eyes during the process, after which they remained open until the end.

A certificate of analysis of the pentobarbital which was used in the execution found that it was contaminated with fungus.

Maya Foa, head of Reprieve's lethal injection project said: "The use of drugs from compounding pharmacies is already risky, as US authorities have themselves stated. But to use contaminated drugs to carry out executions is to invite disaster. Without knowing where the drugs have come from, what their quality is, or even what kind of drugs are being injected, there can be no assurances that the drugs will work – and the prisoner risks dying in agony."

ENDS

Notes to editors

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