

IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE

FILED
AUG 03 2018
Clerk of the Appellate Courts
Rec'd By _____

STATE OF TENNESSEE,)
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v.)
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BILLY RAY IRICK)

CAPITAL CASE
No. M1987-00131-SC-DPE-DD

EXECUTION: August 9, 2018

MOTION FOR LEAVE TO FILE BRIEF
AS *AMICI CURIAE*

Pursuant to Tennessee Rule of Appellate Procedure 31, Rosanna Bennington, Frances Farmer Hayes, Nancy Riley-Dargan, Leah Heyman, and Vicki Scott (collectively, “*Amici*”), by and through their undersigned counsel, respectfully move this Court for leave to file the accompanying brief as *Amici Curiae* in support of Billy Ray Irick’s motion to this Court to vacate execution date.

I. IDENTIFICATION OF AMICI

Amici are five survivors and family members of victims of contaminated compounded drugs. *Amici*, their families, and others have suffered serious harms from contaminated compounded drugs produced by the New England Compounding Center (NECC), which resulted in a catastrophic meningitis outbreak that sickened over 750 individuals and killed at least 60.

II. INTEREST OF THE APPLICANTS

Amici take no position with respect to capital punishment in the United States. However,

they are concerned by the lack of transparency surrounding Tennessee's efforts to bring compounded drugs into the state, and are troubled by the lack of state oversight of the pharmacy supplying compounded drugs to the state for use in lethal injections.


Amici are gravely concerned that by tasking a secret unlicensed and unregulated, out-of-state compounding pharmacy with compounding drugs, Tennessee officials are undermining the regulations that govern the supply chain for medicines, putting the general public at risk of receiving unsafe drugs that make their way into the public stream of commerce.

Amici are calling for a full and transparent investigation to be conducted into Tennessee's lethal injection procurement practices to ensure that they do not provoke another devastating public health crisis in the State.

III. APPLICANTS' BRIEF WILL ASSIST THE COURT

Amici's arguments will assist the Court in deciding the issues of this motion. *Amici* have a unique perspective on the consequences and harms that can arise from a lack of oversight of pharmacies supplying compounded drugs. The proposed *amici curiae* brief will provide the Court with a perspective as to the reasons why it should grant Mr. Irick's motion to stay his execution to ensure the State does not undermine or breach the law in its quest for lethal injection drugs, putting patients and the public at risk.

Respectfully submitted,



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EXHIBIT A

**IN THE SUPREME COURT OF TENNESSEE
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STATE OF TENNESSEE,

v.

BILLY RAY IRICK

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**CAPITAL CASE
No. M1987-00131-SC-DPE-DD**

EXECUTION: August 9, 2018

**BRIEF OF *AMICUS CURIAE* SURVIVORS AND FAMILY MEMBERS OF VICTIMS OF
CONTAMINATED DRUGS**

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IDENTIFICATION AND INTEREST OF *AMICI CURIAE*

Amici curiae are Rosanna Bennington, Frances Farmer Hayes, Nancy Riley-Dargan, Leah Heyman, and Vicki Scott, five survivors and family members of victims of contaminated compounded drugs.

Amici, their families, and others have suffered serious harms from contaminated compounded drugs produced by the New England Compounding Center (NECC), which resulted in a catastrophic meningitis outbreak that sickened over 750 individuals and killed at least 60.

Amici take no position with respect to capital punishment in the United States. However, they are concerned by the lack of transparency surrounding Tennessee's efforts to bring compounded drugs into the state, and are troubled by the lack of state oversight of the pharmacy supplying compounded drugs to the state for use in lethal injections.

Amici are gravely concerned that by tasking a secret unlicensed and unregulated, out-of-state compounding pharmacy with compounding drugs, Tennessee officials are undermining the regulations that govern the supply chain for medicines, putting the general public at risk of receiving unsafe drugs that make their way into the public stream of commerce.

Amici are calling for a full and transparent investigation to be conducted into Tennessee's lethal injection procurement practices to ensure that they do not provoke another devastating public health crisis in the State.

SUMMARY OF ARGUMENT

In their efforts to procure compounded drugs for use in executions, Tennessee officials risk creating another public health crisis from unsafe medications.

Tennessee officials have turned to an unlicensed, out-of-state compounding pharmacy with a questionable history to supply its drugs for the scheduled execution of Billy Ray Irick.

The identity of this pharmacy is unknown – preventing state and federal regulatory authorities from exercising effective oversight and ensuring that this pharmacy is complying with the laws and regulations that protect public health and the safety of medicines.

Regardless of the intended purpose of the drugs they make, allowing pharmacies to operate without oversight is profoundly dangerous, and has resulted in patient injury and death. Experts have repeatedly warned that states’ secret procurement of compounded execution drugs risks creating a public health crisis. Other states that have obtained compounded drugs for lethal injections have used pharmacies that were in breach of the laws and regulations governing the safe manufacture and distribution of medicines.

When pharmacies are permitted to undermine drug safety laws and operate without regulatory scrutiny, the harms are grave. *Amici* have seen witnessed these harms firsthand, having suffered the effects of contaminated drugs or having lost a loved one to compounded drugs.

This case presents the Court with the opportunity to consider these risks and make clear that Tennessee may not undermine or breach the law in its quest for lethal injection drugs, putting patients and the public at risk.

ARGUMENT

I. TENNESSEE HAS BEEN BADLY IMPACTED BY THE NEW ENGLAND COMPOUNDING CENTER CRISIS

In 2012, a deadly outbreak of fungal meningitis swept across Tennessee and the country at large, caused by contaminated injections that had been compounded by the New England Compounding Center (NECC).

More than 60 people died of fungal infections caused by injectable products made at

NECC, and more than 750 people became seriously ill.¹ Tennessee was hit particularly hard, suffering the second highest number of fungal meningitis cases in the nation, with 153 reported cases that resulted in 16 people's deaths. Many of the patients who were sickened still struggle with chronic and sometimes disabling health problems today.²

These harms were so extensive because the NECC was permitted to operate in violation of safety laws and regulations, with little regulatory oversight. Even prior to producing and shipping the contaminated steroid at the center of the meningitis crisis, the NECC was in violation of several state and federal laws and had a history of such violations.³ The Massachusetts Department of Public Health reported that the NECC was violating the requirements of its state license,⁴ and that it had misled state authorities about the scale of its operations in an effort to evade scrutiny.⁵

A matter that originally developed out of Massachusetts turned into a tragedy for Tennessee because the NECC was permitted to ship its contaminated drugs across state lines. In Tennessee, one clinic received 2,000 vials of potentially contaminated steroid supplies - more than any facility in the nation.⁶

¹ *Multistate Outbreak of Fungal Meningitis and Other Infections*, CENTER FOR DISEASE CONTROL AND PREVENTION (Oct. 30, 2015), <https://www.cdc.gov/hai/outbreaks/meningitis.html>.

² *A Q&A With a Survivor of Contaminated Compounded Drugs*, THE PEW CHARITABLE TRUSTS (Nov. 27, 2017), <http://www.pewtrusts.org/en/research-and-analysis/articles/2017/11/a-q-and-a-with-a-survivor-of-contaminated-compounded-drugs>.

³ Besu F Teshome et al., *How Gaps in Regulation of Compounding Pharmacy Set the Stage For a Multistate Fungal Meningitis Outbreak*, 54(4) J. Am. Pharmacists Ass'n 441-445 (2014), available at <https://www.sciencedirect.com/science/article/pii/S154431911530220X>.

⁴ Michael Smith, *Meningitis Outbreak: Pharmacy Violated License*, ABC NEWS (Oct. 12, 2012), <https://abcnews.go.com/Health/fungal-meningitis-prompts-fear-steroid-injection-patients/story?id=17447007>.

⁵ Richard Knox, *Meningitis Outbreak Puts Doctors, Regulators In New Territory*, NPR (Oct. 11, 2012), <https://www.npr.org/sections/health-shots/2012/10/12/162744871/meningitis-outbreak-puts-doctors-regulators-in-new-territory>.

⁶ Tim McLaughlin & Bill Bekrot, *Meningitis Toll Rises; Pharmacy Owners Sued*, REUTERS (Oct.

Compounded medications pose a higher level of risk to patients than FDA-approved drugs because they have not been tested for safety and efficacy, have not gone through an approval process, and are typically not made under the same quality standards as approved products.⁷ While the NECC outbreak is an example of one of the largest-scale incidents of harm to patients from compounded drugs, there have been many other cases of serious illness, injury, and death associated with compounded drugs.⁸

Since 2001, there have been a reported 1,416 adverse events, including 115 deaths, associated with compounded medications.⁹ And because many such events may go unreported, this number is likely to be an underestimation. The FDA has conducted inspections of hundreds of compounding pharmacies, and have uncovered troubling conditions in the vast majority of such inspections, including finding “dead insects in compounding areas designated for sterile processing, visible mold on ceiling tiles in compounding rooms, and dog beds and dog hairs in close proximity to compounding areas.”¹⁰

To safeguard against the risks posed by under-regulated pharmacies and compounded drugs, the Tennessee Board of Pharmacy in 2013 adopted more extensive and updated

19, 2012, 11:00 AM), <https://www.reuters.com/article/us-usa-health-meningitis-idUSBRE89I0UB20121019>.

⁷ U.S. FOOD & DRUG ADMINISTRATION, *Compounding & the FDA: Questions & Answers*, <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm339764.htm> (last visited Aug. 2, 2018).

⁸ *U.S. Illnesses and Deaths Associated With Compounded Medications or Repackaged Medications 2001-Present*, THE PEW CHARITABLE TRUSTS (Oct. 14, 2014), <http://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2014/us-illnesses-and-deaths-associated-with-compounded-medications>.

⁹ *Id.*

¹⁰ Janet Woodcock & Julie Dohm, *Toward Better-Quality Compounded Drugs — An Update from the FDA*, 377 N. Engl. J. Med. 2509–2512 (2017), available at <https://www.nejm.org/doi/full/10.1056/NEJMp1712905>.

emergency rules which required compliance with federal guidelines (USP 797).¹¹ Congress also passed the Drug Quality and Security Act in 2013 to clarify and enhance the public health protections applicable to compounded drug products, and to help prevent a recurrence of tragedies like the 2012 fungal meningitis outbreak.

Together, these laws and regulations govern the practice of pharmacy and medicine, and exist to protect public health and the safety of medicines. They work to prevent contaminated medicines from crossing the state's borders and to ensure that unlicensed pharmacies do not operate in the state and put patients at risk.

II. TENNESSEE HAS SOLICITED COMPOUNDED DRUGS FOR USE IN EXECUTIONS FROM AN UNLICENSED, OUT-OF-STATE PHARMACY

On June 21, 2018, the state of Tennessee announced that it would adopt a new execution protocol using compounded Midazolam and Potassium Chloride prepared by a compounding pharmacy.

Not much is known about the identity of the compounding pharmacy due to a 'secrecy law' passed by the state, but what is known is troubling:

Like the NECC, the pharmacy supplying drugs to Tennessee is located out-of-state. In fact, it is unlicensed to practice or dispense drugs in the state of Tennessee and is providing drugs for use in executions unlawfully.¹² The pharmacy does not have approval to compound drugs for Tennessee, and only received approval to compound drugs in its home state last month, on June

¹¹ Martha Kessler & Adrienne Appel, *States Adopt Variety of Oversight Strategies in Wake of NECC Disaster*, BLOOMBERG BNA (MAR. 20, 2014), <https://www.bna.com/states-adopt-variety-n17179888981/>.

¹² See Mot. To Vacate Execution Date at 4, *State of Tennessee v. Billy Ray Irick*, No. M1987-00131-SC-DPE-DD.

26, 2018.¹³ And like the pharmacists at NECC, the pharmacist supplying these drugs in Tennessee has a history of disciplinary infractions in their home state.¹⁴

Further information about the pharmacy and pharmacist in question is unknown, and the state has invoked a secrecy law to justify its refusal to provide further information. This law, enacted in 2014, makes secret information relating to any person or entity “involved in the procurement or provision of chemicals, equipment, supplies, and other items for use in carrying out a sentence of death.”¹⁵

In the wake of the NECC crisis, it is shocking that Tennessee would solicit an unlicensed pharmacy with a questionable history to transport drug supplies into the state. And it is deeply worrying that the identity of the pharmacy is unknown, permitting this pharmacy to continue to operate unlawfully without drawing the attention of state or federal regulatory authorities. As the sections below outline, these practices risk creating serious harms for citizens in Tennessee.

III. TENNESSEE’S SECRET SOLICITATION OF EXECUTION DRUGS POSES GRAVE RISKS TO PATIENTS AND THE PUBLIC

In turning to compounded execution drugs, Tennessee officials have invited an unlicensed, out-of-state pharmacy to operate in the state without oversight.

Pharmacies that operate without oversight have caused serious injury and death to patients in Tennessee and across the nation. Experts have warned that allowing unregulated pharmacies to supply compounded execution drugs risks creating a public health crisis.

These risks are not merely speculative: those pharmacies that have supplied execution drugs to other states have operated outside the law and caused harms to patients.

¹³ *Id.* at 4.

¹⁴ *Id.* at 4.

¹⁵ Tenn. Code Ann. § 10-7-594(h)(1)-(2).

A. PHARMACIES NOT SUBJECT TO OVERSIGHT HAVE CAUSED SERIOUS HARM TO PATIENTS IN TENNESSEE AND THE NATION

Drugs from unlicensed sources pose serious public safety risks. Without oversight, the concentration, strength, and effectiveness of these drugs cannot be guaranteed. They may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions as required by state law and regulations.¹⁶

Given these safety risks, it is little surprise that unlicensed pharmacies that have operated outside of law have supplied drugs that have caused injuries to patients across the nation.

Earlier this year, for example, a man in Texas was sentenced to 15 years in federal prison for distributing prescription drugs in Nashville that been purchased from unlicensed suppliers. Pharmacies in Tennessee reported that these drugs contained the wrong medicine, the wrong dosage information, foreign objects, and in one case a bottle was filled with breath fresheners.¹⁷

¹⁶ *Learn More About FDA Warnings to Doctors About Fake Cancer Drugs*, THE PARTNERSHIP FOR SAFE MEDICINES (May 2, 2012), <https://www.safemedicines.org/2012/05/50-more-us-doctors-warned-about-fake-cancer-drugs-433.html>; THE AMERICAN PHARMACISTS ASSOCIATION AND THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, *Letter to Members of Congress Re: Importation of Non-FDA Approved Prescription Drugs* (May 9, 2017), https://portal.pharmacist.com/sites/default/files/files/APhA-NACDS%20Joint%20Comments%20on%20Importation%20May_09_%202017.pdf; U.S. FOOD & DRUG ADMINISTRATION, *From our perspective: The U.S. drug supply chain and patient safety*, <https://www.fda.gov/Drugs/NewsEvents/ucm446918.htm> (last visited Aug. 2, 2018) ; DEP'T HEALTH & HUMAN SERVICES, *Letter to Doctors about the Risks of Purchasing Unapproved Drugs from Distributors Owned and Operated by Canada Drugs* (Apr. 5, 2012), <https://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM440570.pdf>, available at U.S. FOOD AND DRUG ADMINISTRATION, *Historical Information: FDA Issues Letters to Doctors Who May Have Purchased Counterfeit or Unapproved Prescription Drugs, 2012-2014*, <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm519702.htm> (last visited Aug. 2, 2018).

¹⁷ Eric Palmer, *Head of Cumberland Distribution Gets 15-Year Sentence For Drug Diversion Scam*, FIERCEPHARMA (Jul. 25, 2018 10:20 AM), <https://www.fiercepharma.com/manufacturing/head-cumberland-distribution-gets-15-year-sentence-for-drug-diversion-scam>.

The risks posed by under-regulated compounding pharmacies are increased when such pharmacies supply medications across state lines. Because states are primarily responsible for the oversight of compounding pharmacies, the safety requirements for pharmacies can vary significantly by state. Poor-quality drugs can reach a state when an out-of-state pharmacy held to lower quality or regulation standards supplies drugs to a state with more rigorous protections in place.

Unlike many other states, Tennessee's requirements for compounding licensure are robust. Prior to initial licensure in Tennessee as a compounding pharmacy, a pharmacy located outside of the state must undergo an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located.¹⁸ Pharmacies engaged in compounding must comply with relevant United States Pharmacopeia (USP) guidelines and must make reports to the Board of Pharmacy on a quarterly basis.¹⁹

The Tennessee Board of Pharmacy will also determine the competency of pharmacists applying for licensure. The Board will check to ensure that the pharmacist in charge holds a valid and current license to practice pharmacy in Tennessee,²⁰ assess whether the pharmacist or pharmacy has ever been disciplined by any licensing agency,²¹ and even determine that the pharmacist is residing in the country legally.²²

Other states do not take the same precautions when licensing pharmacists or pharmacies. Unlike Tennessee, states that share a border with Tennessee such as Alabama, Arkansas, and

¹⁸ Tenn. Code Ann. § 63-10-216.

¹⁹ *Id.*

²⁰ DEP'T OF HEALTH, INSTRUCTIONS FOR TENNESSEE PHARMACY LICENSE (2017), <https://www.tn.gov/content/dam/tn/health/healthprofboards/Pharmacy02-2017.pdf>.

²¹ *Id.*

²² DEP'T OF HEALTH, DECLARATION OF CITIZENSHIP MUST ACCOMPANY ALL APPLICATIONS FOR INITIAL LICENSURE OR REINSTATEMENT OF LICENSURE (2017), <https://www.tn.gov/content/dam/tn/health/healthprofboards/PH-41833.pdf>.

Missouri do not require that pharmacies engaged in compounding comply with relevant USP guidelines developed to prevent contaminated medicines from reaching patients.²³ And while Tennessee will conduct routine inspections of pharmacies at least once a year, Georgia, Utah, Illinois, and Michigan conduct inspections with no specific frequency.²⁴

In seeking drugs for use in executions, Tennessee officials have solicited an out-of-state pharmacy without a license to supply drugs across state lines. In so doing, the state of Tennessee risks inviting poor-quality, contaminated drugs into the state. For the reasons set forth below, these actions are not confined to the execution chamber: they increase the risk that dangerous drugs reach patients and the wider public.

B. EXPERTS HAVE WARNED THAT THE SECRET PROCUREMENT OF COMPOUNDED EXECUTION DRUGS RISKS CREATING A PUBLIC HEALTH CRISIS

Experts have repeatedly warned that states' secret procurement of compounded execution drugs risks creating a public health crisis. Innocent lives are put at risk when compounding pharmacies are permitted to make execution drugs without oversight or scrutiny.

The Journal of the American Pharmacists Association (JAPhA) recently published a paper warning that death penalty states could cause a public health emergency through their efforts to source compounded lethal injection drugs. This report was authored by Dr. Prashant Yadav, a globally recognized expert in healthcare supply chains from Harvard Medical School, Dr. Rebecca Weintraub, Assistant Professor of Medicine and of Global Health and Social Medicine at Harvard Medical School, and Dr. Andy Stergachis, Editor in Chief of JAPhA and

²³ *State Oversight of Drug Compounding*, THE PEW CHARITABLE TRUSTS (Feb. 2018), http://www.pewtrusts.org/-/media/assets/2018/02/drug_safety_assesment_web.pdf.

²⁴ *Id.*

expert consultant to the Food and Drug Administration.

The report notes that ordinarily, compounding pharmacies would be regulated by state boards of pharmacies, who work to ensure that pharmacies abide by state laws intended to keep patients safe. But in the execution drug context, pharmacies and the middlemen they work with are invisible, hidden from sight by secrecy laws and sometimes explicitly exempted from regulation that otherwise apply to all pharmacies operating in the state.²⁵ This prevents the responsible authorities from performing their crucial roles in ensuring quality standards of medicines.²⁶

The scholars explain that the increasing use of compounded medicines in executions results in “a greater risk that non-pharmaceutical grade, substandard or contaminated product will enter the US market,”²⁷ creating a “regulatory vacuum for execution drugs,” which risk “allowing poor-quality medicines to infiltrate the market, putting the public, as well as prisoners, at risk.”²⁸

Compounding pharmacies have repeatedly been found to produce medicines of questionable quality. In one example in Georgia, an execution had to be stopped at the last minute because the drugs made by the secret pharmacy due to be used that night were found to be “cloudy” with white solid material floating in the pale yellow liquid.²⁹

The report notes that there have been several documented instances where drugs have

²⁵ Prashant Yadav et al., *When Government Agencies Turn to Unregulated Drug Sources—Implications For the Drug Supply Chain & Public Health Are Grave*, J. Am. Pharmacists Ass’n (forthcoming 2018), available at [https://www.japha.org/article/S1544-3191\(18\)30336-4/pdf](https://www.japha.org/article/S1544-3191(18)30336-4/pdf).

²⁶ *Id.* at 4.

²⁷ *Id.* at 5.

²⁸ *Id.* at 4.

²⁹ Alan Blinder, *Georgia Postpones 2 Executions, Citing ‘Cloudy’ Drug*, N.Y. TIMES (Mar. 3, 2015), https://www.nytimes.com/2015/03/04/us/execution-of-georgia-woman-is-postponed-indefinitely.html?_r=0.

been directly diverted from prison supply rooms to hospitals for patients – including one case where substantial quantities of the execution drug sodium thiopental went missing from a prison in California, and it was later revealed that the person responsible for maintaining custody of the drug there was an illicit drug smuggler.³⁰

Finally, the report warns that these practices create supply channels that allow other unregulated contaminated drugs to reach patients, since suppliers have every incentive to maximize profits by increasing the quantity and range of drugs that move through a supply channel. The authors conclude, “[n]o matter where one stands on capital punishment, in executing prisoners we cannot afford to jeopardize our medicines supply chain and put innocent lives at risk.”³¹

In a recent *amicus curiae* brief before the US Supreme Court, a group of 18 pharmacy, medicine, and health policy experts – including a former FDA Commissioner and Deputy Commissioner – made similar warnings, noting that states’ secret procurement of execution drugs “could lead to a public health crisis.”³²

These experts note that drug makers’ restrictions on the sale of their drugs for capital punishment mean a small minority of states are now obtaining drugs through “overseas sellers, unlicensed middlemen, and secret compounding pharmacies...undermin(ing) federal laws that protect the public health.”³³

³⁰ Yadav et al., *supra* note 25, at 6.

³¹ *Id.* at 6.

³² Brief of Pharmacy, Medicine and Health Policy Experts as Amicus Curiae in Support of Petitioner at 2, *Bucklew v. Precythe*, No. 17-8151 (filed Jul. 23, 2018).

³³ *Id.* at 4.

The brief goes on to explain that the public health risks created by these practices are “not merely theoretical,” warning that “drugs obtained by States ostensibly for lethal injection have been diverted from that use and have reached the patient population”.³⁴

The brief points to the tangible harm that these practices have caused patients, who have “been exposed to substandard drugs compounded at pharmacies operating under the cover of ‘execution secrecy’ laws that effectively place the compounders beyond the scope of regulation by federal and state authorities.”³⁵

As these scholars and experts have warned, the sourcing of execution drugs is not an isolated event that can simply be cordoned off from the wider patient population. Allowing pharmacies to operate in secrecy and without oversight has an influence that extends beyond the execution chamber, impacting patients and the wider public.

Regardless of the intended purpose of the drugs it makes, no pharmacy should be given free rein to operate outside the regulatory regime that exists to protect patients. This is doubly true for unlicensed pharmacies and for pharmacists with a history of disciplinary infractions.

C. UNREGULATED PHARMACIES THAT HAVE SUPPLIED COMPOUNDED EXECUTION DRUGS ILLECTLY HAVE CAUSED HARMS TO PATIENTS AND THE WIDER PUBLIC

These risks are not speculative. Many states have struggled to find FDA-approved drugs for use in lethal injection executions as legitimate sellers have refused to provide them,³⁶ and have turned instead to compounding pharmacies or unlicensed foreign suppliers. These suppliers

³⁴ *Id.* at 4.

³⁵ *Id.* at 5.

³⁶ Lincoln Caplan, *The End of the Open Market for Lethal-Injection Drugs*, THE NEW YORKER (May 21, 2016), <https://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs>

have repeatedly been found to be in violation of both state and federal regulations governing the safe manufacture and distribution of medicine and have caused harms to patients.

Many states have struggled to find compounders willing to assist with making execution drugs.³⁷ The American Pharmacists Association (APhA) and the International Academy for Compounding Pharmacists (IACP) discourage pharmacists from compounding medicines for use in or otherwise assisting with executions.³⁸

Where states have managed to identify outlier compounding pharmacies willing to make execution drugs, these pharmacies have turned out to have numerous licensing violations and in some cases supplied medicines that have injured patients.

For example, a compounding pharmacy operating out of Oklahoma called the Apothecary Shoppe offered to supply execution drugs to at least three states. It later came to light that the

³⁷ See e.g., Tim Lockette, *Drug Company's Withdrawal Limits Death Penalty Options in Alabama*, THE ANNISTON STAR (May 16, 2016), http://www.annistonstar.com/news/state/drug-company-s-withdrawal-limits-death-penalty-options-in-alabama/article_44ce96e4-1beb-11e6-8f54-9b82f529ead9.html (where in court records filed in December, Alabama state officials said they asked every compounding pharmacist in the state to make pentobarbital — once the state's primary execution drug — and every pharmacist turned them down); *Oklahoma Faces Lethal Drug Shortage As Death Row Inmates Seek Further Delay*, THE GUARDIAN (Mar. 17, 2014), <http://www.theguardian.com/world/2014/mar/17/oklahoma-execution-drug-shortage-death-row-inmates> (where the Oklahoma Department of Corrections said it had made a "Herculean effort" to obtain compounded pentobarbital and vecuronium bromide for the lethal injections, but still lacked a supply of either drug); see also German Lopez, *9 Reasons The Death Penalty is on the Decline in America*, VOX (Jun. 29, 2015 10:30 AM), <https://www.vox.com/cards/death-penalty-capital-punishment/death-penalty-compounding-pharmacies>; Tracy Connor, *Pharmacy Groups Balk at Supplying Lethal Injection Drugs*, NBC NEWS (Mar. 31, 2015 2:56 PM), <https://www.nbcnews.com/news/us-news/pharmacy-groups-balk-supplying-lethal-injection-drugs-n332656>.

³⁸ Am. Pharmacists Ass'n, *APhA House of Delegates Adopts Policy Discouraging Pharmacist Participation in Execution* (Mar. 30, 2015), <https://www.pharmacist.com/press-release/apha-house-delegates-adopts-policy-discouraging-pharmacist-participation-execution>; International Society of Compounding Pharmacists, *IACP Adopts Position on Compounding of Lethal Injection Drugs* (Mar. 24, 2015), <https://deathpenaltyinfo.org/documents/IACPPressRelease.pdf>.

pharmacy had committed 1,892 violations of state pharmacy guidelines.³⁹ The Oklahoma pharmacy is thought to have provided or offered medicines for executions in Missouri, Louisiana, and Georgia, despite the fact that it was unlicensed to dispense or distribute controlled substances in any of those states.⁴⁰

The Oklahoma pharmacy had been operating in secret, relying on state laws that granted anonymity and exemption from state regulation, and provided execution drugs to Departments of Corrections for many months before its identity – and its numerous violations – were revealed. After the pharmacy was identified publically, inspectors from the FDA and Oklahoma Board of Pharmacy launched an investigation into the pharmacy and put the licenses of the pharmacy and head pharmacist on probation.⁴¹

Foundation Care, another compounding pharmacy that supplied drugs for executions in Missouri, contributed to the death of at least one patient who contracted pneumonia after receiving Foundation Care medicines.⁴²

When FDA agents arrived to conduct an inspection of Foundation Care’s facilities in 2013, the pharmacy’s CEO attempted to prevent them from entering. Upon gaining access to the premises, the FDA agents found “multiple examples” of inadequate procedures that “could lead to contamination of drugs, potentially putting patients at risk.”⁴³

³⁹ Chris McDaniel, *Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations*, BUZZFEED NEWS (Apr. 21, 2016 10:45 PM), https://www.buzzfeed.com/chrismdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc?utm_term=.kcopbMDX4#.ycDLE46a1.

⁴⁰ Ed Pilkington, *Tulsa Pharmacy Faces Questions Over Lethal Drug to be Used in Execution*, THE GUARDIAN (Jan. 28, 2014, 5:53 PM), <https://www.theguardian.com/world/2014/jan/28/tulsa-compounding-pharmacy-lethal-injection-execution>.

⁴¹ McDaniel, *supra* note 39.

⁴² *Id.*

⁴³ Chris McDaniel, *The Secretive Company Behind Missouri’s Lethal Injections*, BUZZFEED

Foundation Care was repeatedly found to engage in hazardous pharmaceutical procedures and its cofounder has been accused of regularly ordering prescription medications for himself without a doctor's prescription (a crime that carries imprisonment up to a year), as well as violating state or federal regulations by reselling drugs returned by patients and purposefully omitting the names of ingredients in drugs it prepared.⁴⁴

In spite of these violations, Foundation Care was able to continue its practice, operating outside of the law and providing execution drugs to Missouri Department of Corrections for a number of years due to the state's secrecy statute. These practices exposed patients and the broader public to serious risks.

Many states that have struggled to find drugs for use in lethal injection executions has also turned to foreign suppliers.

When Tennessee was unable to procure drugs from legitimate sellers in the past, state officials turned to a pharmacy operating out of the back room of a driving school in London.⁴⁵ Those drugs were not approved and some found their way into the supply stream for patients.⁴⁶

Oklahoma officials recently said that there is no way for them to obtain lethal injection drugs legally, and that they would have to resort to "seedy individuals" who had access to the drugs "on the backstreets of the Indian subcontinent" if they were to acquire them.

Midazolam and Potassium Chloride are no longer available for sale to the Tennessee Department of Correction through authorized sellers, and there is no information on where the

NEWS (Feb. 20, 2018 5:55 AM), https://www.buzzfeed.com/chrisgcdaniel/missouri-executed-17-men-with-drugs-from-a-high-risk?utm_term=.sukodN1P#.hq3n9YRL.

⁴⁴ *Id.*

⁴⁵ Ariane de Vogue, *States Depend on Unapproved Foreign Drugs for Executions*, ABC NEWS (Feb. 8, 2011), <https://abcnews.go.com/Politics/death-row-lethal-injections-depending-unapproved-foreign-drugs/story?id=12861373>.

⁴⁶ Yadav et al., *supra* note 25, at 6.

out-of-state pharmacy will be procuring its drugs.⁴⁷

Amici are concerned that the out-of-state pharmacy supplying execution drugs in Tennessee may have turned to foreign suppliers because domestic manufacturers will not supply these drugs for executions. As a result, contaminated, counterfeit or adulterated ingredients could be brought into the state of Tennessee and cause further harms to patients and the public.

IV. *AMICI* HAVE SEEN FIRSTHAND THE HARMS DONE BY COMPOUNDED DRUGS DISTRIBUTED FROM UNDER-REGULATED OUT-OF-STATE PHARMACIES

Amici have each witnessed firsthand the harms that compounded drugs, produced by pharmacy permitted to operate in violation of safety laws and regulations, and with little regulatory oversight, pose to the public.

Rosanna Bennington received an injection of contaminated drugs in 2012, from a clinic in Maple Grove, Minnesota. Within a week, she became so ill that she could not work, suffering from severe headache, nausea, sweating and light sensitivity. Initially, a local clinic sent her home with a flu diagnosis, and a hospital emergency room came to the same conclusion. She then received a call from the clinic that had originally administered her with the injection and eventually was prescribed an anti-fungal drug with serious side effects. Since 2012, she has suffered from a host of harms including memory loss, loss of motor skills, speech problems, and balance issues.

Frances Farmer Hayes became ill after receiving contaminated compounded drugs in 2012. Six years on, she continues to suffer from severe recurring pain.

Nancy Riley-Dargan was infected by contaminated NECC drugs in early 2012. Nancy

⁴⁷ Dave Boucher, *Tennessee Must Rely On 'Black Market Drugs' For Executions, Attorney Says*, THE TENNESSEAN (June 13, 2018), <https://www.tennessean.com/story/news/local/davidson/2018/06/13/lethal-injection-tennessee-must-rely-black-market-drugs-executions-attorney-says/695846002/>.

did not immediately feel the symptoms of the contaminated drugs, but began to experience symptoms during a business trip that had to be cut short when her pain began to prevent her from walking. After her diagnosis, Nancy was placed on a series of anti-fungal medications with severe side-effects, including vomiting, fevers, hives, swollen hands and feet and exhaustion. At the worst moments, she hallucinated conversations with her daughter, who died in 1979. She has described this experience as “nearly as bad as death itself.”

While life has improved for Nancy, she still suffers. She cannot receive a needed hip replacement because there are pockets of fungal meningitis on her bones. She and her husband were forced to use all of their savings and retirement in order to pay for her treatments.⁴⁸

Leah Heyman is a physician, who suffers from Complex Regional Pain Syndrome, a chronic pain condition. She received Epidural Steroid Injections (ESI) after a car crash. The ESIs she received were contaminated, and produced by the NECC. She was severely sick within one week of receiving the injection. Leah has had meningitis eight times since her first injection. Because her brain was so compromised, she is predisposed to having meningitis symptoms for life.

Vicki G. Scott became gravely ill after receiving an injection contaminated with fungal matter. In 2012, a spinal tap tested positive for fungal meningitis, but her doctor missed the diagnosis and it took her nearly four years to finally get a confirmed diagnosis. Because she did not receive a diagnosis for so long, she was not originally listed on the Center for Disease Control’s list of approved recipients of victim funds. Following her diagnosis, Vicki has struggled to find a doctor who can help her, and was dropped by a primary care physician

⁴⁸ Heather Unruh, *Fungal Meningitis Survivors, Widows Speak Out One Year After Outbreak*, WCVB (Oct. 2, 2013 12:41 PM), <http://www.wcvb.com/article/fungal-meningitis-survivors-widows-speak-out-one-year-after-outbreak/8189059>.

because they had no experience with meningitis.

V. CONCLUSION

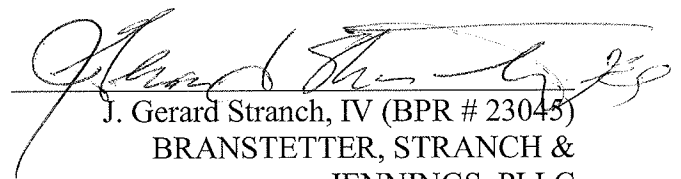
One of the most tragic aspects of the NECC disaster is that it was preventable. Just months before the deadly outbreak, the head of the NECC warned his supervising pharmacist that practices at their company were "a disaster waiting to happen. People can die."⁴⁹

Today, public health experts are making a similar warning. Innocent lives are put at risk when compounding pharmacies are permitted to make execution drugs without oversight or scrutiny.

The state of Tennessee has an obligation to prevent this kind of tragedy from repeating, and to ensure that the state and federal laws established to protect public health are enforced.

Amici respectfully request that the scheduled execution of Billy Ray Irick is halted until a full and transparent investigation has been conducted into its lethal injection drug procurement practices. The State must assure citizens of Tennessee that it will not undermine or breach the law in its quest for lethal injection drugs, putting patients and the public at risk.

Respectfully submitted,



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⁴⁹ Walter F. Roche, *Drug Firm Exec: Compounding Firm Practices Were "Disaster Waiting to Happen" Before Meningitis Outbreak*, TENNESSEAN (Oct. 2, 2017 11:31 PM), <https://tennessean.com/story/news/2017/10/02/meningitis-trial-new-england-compounding-center/725638001/>.

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Frances Farmer Hayes

Nancy Riley-Dargan

Leah Heyman

Vicki Scott

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of August, 2018, a true and exact copy of the foregoing Application of Leave to File Brief of Amici Curiae has been served upon counsel for the parties of interest herein by mailing to said counsel to their offices via United States mail, postage prepaid.

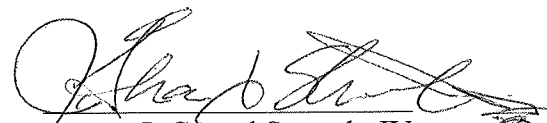
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