

Mr. Timothy Lockwood
Chief, Regulation and Policy Management Branch
California Department of Corrections and Rehabilitation
P.O. Box 94283-0001
Email: LI.Comments@cdcr.ca.gov

August 14, 2017

RE: Comments on California's Proposed Lethal Injection Regulation Amendments described in the Second Notice of Change to Text as Originally Proposed

Dear Mr. Lockwood:

We the undersigned are a group of pharmacists with a combined 178 years' experience teaching and practicing pharmacy.

We are writing to express our grave concerns with the California Department of Corrections and Rehabilitation (CDCR)'s recent changes to its lethal injection regulations. Although as a group we take no position on capital punishment, we are deeply worried that the state of California's proposed procurement of execution drugs will endanger public health, violate the law, and damage the reputation of the pharmacy profession.

We understand that California's recent protocol amendments contemplate the use of compounded lethal injection drugs supplied by an entity such as a compounding pharmacy, licensed pharmacy, or pharmacist, rather than manufactured medicines approved by the United States Food and Drug Administration (FDA).¹ In particular, we understand that the CDCR contemplates using either sodium thiopental or pentobarbital in a single dose lethal injection.

We foresee several issues with this proposal that could have grave implications both for the practice of pharmacy in California and for the lives and health of Californian citizens.

1. Risks to Patients and Public Health

We are aware that manufactured sodium thiopental and manufactured pentobarbital have been unavailable for purchase by correctional facilities for use in executions since 2011.² Due to the unavailability of the manufactured medicines, we understand that several states began to use compounded versions of the pentobarbital in 2012.³ In recent years, the supply of the active ingredient for pentobarbital has run dry, and as a result many states have been unable to procure compounded pentobarbital for executions.

We have researched the key providers of ingredients for medications in the US, and have found that neither sodium thiopental nor pentobarbital active ingredients are available for purchase via these providers. It appears from our research that there are no legitimate supplies of either medicine available to the CDCR. We are deeply concerned that any pharmacist who agrees to compound execution drugs for the CDCR will do so using ingredients procured on the black market, in the process bringing substandard, counterfeit or contaminated products into the US medicine supply chain.

This would not be the first time that we have seen the CDCR procure supplies of domestically unavailable execution drugs through illicit sources that have later ended up in patient healthcare supplies.

In 2011, faced with a nationwide shortage of sodium thiopental -- similar to the situation in which state correctional departments find themselves today -- the CDCR was among a number of states that purchased supplies of unapproved sodium thiopental from a wholesaler that was operating out of the back room of a driving school in England.⁴ These

¹ Specifically, we understand that CDCR has adopted a new subsection 3349.1(i) to provide a definition for the phrase "Lethal Injection Chemical Supplier", a new phrase that has been added to replace the term "manufacturer" in the proposed text. This new definition expands the range of suppliers of lethal injection drugs to include entities other than a manufacturer (i.e., a licensed pharmacy, pharmacist, or compounding pharmacy, or supplier, wholesaler, or distributor).

² In 2011, Hospira—the sole US-based producer of sodium thiopental—announced that it would stop producing the drug in the US, ending the drug's availability in the US market. <https://www.theguardian.com/world/2011/jan/23/lethal-injection-sodium-thiopental-hospira>. Similarly, the sole US-approved manufacturer of pentobarbital Lundbeck that same year put distribution controls in place to bar states from purchasing its medicines for use in executions. <http://www.nytimes.com/2011/02/06/us/06ttdrug.html>.

³ <https://deathpenaltyinfo.org/compounding-pharmacies>

⁴ Severson K, Brown R. Murderer is executed in Georgia after losing stay. NY Times January 25, 2011. (Accessed on June 16, 2017, at <http://www.nytimes.com/2011/01/26/us/26lethal.html>)

drugs – which were not FDA-approved – were used in at least one botched execution and were the subject of a lengthy legal battle brought against the FDA in 2011.⁵ The FDA lost the suit and a federal District Court permanently barred FDA from permitting the entry of these drugs into the United States, noting "By opening up the 'closed' drug system by allowing an unapproved drug -thiopental- into the United States, defendants jeopardize their own system and threaten the public health by creating a risk that thiopental could incorrectly end up in the hands of the general public."⁶

Federal authorities were ultimately forced to seize these illegal imports,⁷ but in the months prior, "substantial quantities" of the sodium thiopental that California intended for use in executions went missing from the CDCR pharmacy.⁸ A CDCR employee responsible for the custody of sodium thiopental was disciplined for smuggling illegal drugs into San Quentin⁹ and the United States District Court for the District of Columbia noted that at least one shipment of foreign thiopental was received by a regular pharmacy servicing patients in Georgia.¹⁰

As this example shows clearly, if an illicit drug supply channel is established for the purpose of procuring medicines for use in executions, there is a high likelihood that the channel will be exploited and unapproved medicines will find their way into the supply chain for patient healthcare.

In recent years, we have seen 1,197 patients killed or seriously harmed by poor-quality compounded medications from questionable suppliers¹¹ – including several incidents directly impacting nearly one hundred patients in the state of California.¹² By encouraging pharmacies to seek out supplies of drugs that are unavailable from approved sellers domestically, the state of California is effectively creating a grey market for the drugs, weakening oversight across the supply chain and potentially paving the way for another tragedy like the 2012 New England Compounding Center meningitis outbreak. As pharmacists dedicated to patient health and safety, we implore you not to do this.

2. Violations of State and Federal Law

It is our position that the compounding of medicines for use in executions is unlawful, and violates a number of state and federal regulations governing the practice of pharmacy.

A bedrock principle of pharmacy practice, as defined in state and federal regulations, is that the pharmacist may not prepare or dispense a drug product without a valid prescription from an authorized prescriber for a legitimate medical purpose. Using compounded controlled substances in executions violates California and federal law, because there will be no valid prescription involved. California law dictates that "no drug product preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug".¹³ The compounding of a drug must instead be "justified by a *specific, documented medical need*" and physicians may prescribe only in the regular practice of their profession and may only be issued for a legitimate medical purpose.¹⁴

⁵ http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/inmates-sue-fda-over-importation-of-death-penalty-drug.html

⁶ https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2011cv0289-23

⁷ <http://www.nytimes.com/2011/03/16/us/16lethal.html>

⁸ *Morales v Tilton* (465 F. Supp. 2d 972 (N.D. Cal. 2006)).

⁹ *Morales v Tilton* (465 F. Supp. 2d 972 (N.D. Cal. 2006)).

¹⁰ *Beaty v. Food & Drug Admin.*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd in part, vacated in part sub nom. Cook v. Food & Drug Admin.*, 733 F.3d 1 (D.C. Cir. 2013). (Accessed on June 16, 2016, on [https://casetext.com/case/beaty-v-food-drug-admin.](https://casetext.com/case/beaty-v-food-drug-admin))

¹¹ http://www.pewtrusts.org/~media/assets/2017/06/compoundingoutbreaks_chartmay17.pdf?la=en

¹² U.S. Food and Drug Administration, "FDA Announces Voluntary Nationwide Recall of All Non-Expired Sterile Drugs From Abrams Royal Compounding Pharmacy," news release, Dec. 21, 2013;

Christina A. Mikosz et al., "Fungal Endophthalmitis Associated With Compounded Products," *Emerging Infectious Diseases* 20, no. 2 (2014): 248–56, doi:10.3201/eid2002.131257;

Department of Veterans Affairs, Office of Inspector General, "Healthcare Inspection: Oversight Review of Ophthalmology Adverse Drug Events, VA Greater Los Angeles Healthcare System, Los Angeles, California," Report No. 12-01515-151 (April 12, 2012), <http://www.va.gov/oig/pubs/VAOIG-12-01515-151.pdf>;

Lisa L. Maragakis et al., "*Sphingomonas paucimobilis* Bloodstream Infections Associated With Contaminated Intravenous Fentanyl," *Emerging Infectious Diseases* 15, no. 1 (2009): 12–18, doi:10.3201/eid1501.081054;

Rebecca Sunenshine et al., "A Multistate Outbreak of *Serratia marcescens* Bloodstream Infection Associated With Contaminated Intravenous Magnesium Sulfate From a Compounding Pharmacy," *Clinical Infectious Diseases*, 45 (2007): 527–33, doi:10.1086/520664; U.S. Food and Drug Administration, "PharMEDium Services, LLC 13-Apr-07 Warning Letter," accessed Aug. 18, 2015;

Rachel Civen et al., "Outbreak of *Serratia marcescens* Infections Following Injection of Betamethasone Compounded at a Community Pharmacy," *Clinical Infectious Diseases* 43 (2006): 831–37, <http://cid.oxfordjournals.org/content/43/7/831.full.pdf+html>

California Board of Pharmacy, "Decision: In the Matter of the Statement of Issues Against Robert Eugene Horwitz," Oct. 15, 2008.

¹³ CCR §1735.2 [emphasis added].

¹⁴ CCR §1735.2 [emphasis added].

These California requirements echo those requirements set forth under the federal Controlled Substances Act's explanation of the "purpose of issue of prescription": "A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an *individual practitioner acting in the usual course of his professional practice*."¹⁵

The only valid prescription under federal and state law is that is issued for a legitimate medical purpose. The taking of a life is not a legitimate medical purpose, and capital punishment is far from the usual course of a practitioner's professional practice. These laws therefore effectively bar any licensed pharmacist from lawfully producing and providing drugs to be used for a lethal injection execution in California.

As pharmacists, we have a vested interest in seeing our fellow pharmacists adhere to the professional standards that our boards and regulatory bodies require of us. Language in state and federal codes governing the practice of pharmacy require the pharmacist to place the safety of the patient as their highest duty, reflecting the Hippocratic Oath – "above all, do no harm."¹⁶ As with every other health profession in the United States, the profession of pharmacy has declared that it is contrary to the ethical and professional commitments of pharmacists to participate in executions. CRDC's execution protocol as amended will necessarily have the result that any pharmacist agreeing to make drugs for executions will not only be violating their obligations under state and federal law, but also their professional oaths as pharmacists.

California's amended lethal injection regulations are not in accordance with minimum requirements for a "valid prescription" in accordance with a "legitimate medical need", and therefore bar any licensed pharmacist from lawfully producing and providing the drugs contemplated in California's execution protocol. In incentivizing pharmacists to violate state and federal statutes, the state of California undermines the rule of law, the legitimacy of pharmacy, and the important protective framework established through these regulations.

3. Risks to the Reputation of Pharmacy

As professional pharmacists who take pride in our profession, the idea that pharmacists would be enlisted to assist with executions is deeply troubling. Not only are we troubled by the clear ethical and legal implications of this practice for the pharmacist and/or pharmacy involved, but we are also deeply concerned about the implications for the majority of pharmacies engaged in legitimate business in California.

The reputation of the pharmaceutical industry has been tarnished by recent high-profile incidents such as the NECC compounding tragedy referenced above. If, in addition to this, an execution in California goes wrong because the compounded medicines used are poor-quality or for some other reason, this will do untold harm to our industry.

We note that all of the FDA-approved manufacturers of execution drugs – including those listed in CDRC's protocol – publicly oppose the misuse of their medicines in executions.¹⁷ This is part of the reason that CDRC and other correctional facilities have turned to compounded medicines rather than using manufactured drugs.¹⁸ Compounders are being portrayed as less ethical, responsible, and concerned with quality than manufacturers. The media has called compounding pharmacists "deadly druggists"¹⁹ and describe states "resorting"²⁰ to compounding pharmacies that are "loosely monitored"²¹, "loosely regulated"²² and which "cannot be trusted to produce safe drugs."²³

As responsible healthcare practitioners, we are distressed and disturbed by this association. We have no desire for pharmacists to be seen by the press and the public as "deadly druggists", and ask CDRC to rethink its plan to implicate our industry in its execution business.

It is the mission of pharmacies across California - including compounding pharmacies - to help their clients meet the highest quality standards and instill confidence in the reputation of the industry. The use of compounded drugs in

¹⁵ 21 C.F.R. § 1306.04(a) [emphases added].

¹⁶ See e.g., California Code of Regulations, Article 3. Scope of Practice and Exemptions 4050.

¹⁷ <https://www.nytimes.com/2016/05/14/us/pfizer-execution-drugs-lethal-injection.html>; <http://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs>

¹⁸ <http://www.nbcnews.com/news/other/specialty-pharmacies-fill-execution-drug-shortage-raising-concerns-f2D11629793>

¹⁹ <http://www.pharmacytimes.com/contributor/daniel-holland-pharmd/2017/04/deadly-druggists-pharmacists-and-the-death-penalty>

²⁰ <http://thelensnola.org/2014/01/15/with-lethal-injection-drugs-hard-to-get-states-turning-to-custom-pharmacies/>

²¹ <http://time.com/2838377/lethal-injection-missouri/>

²² <http://www.nbcnews.com/news/other/specialty-pharmacies-fill-execution-drug-shortage-raising-concerns-f2D11629793>

²³ <http://www.nbcnews.com/news/other/specialty-pharmacies-fill-execution-drug-shortage-raising-concerns-f2D11629793>

executions risks damaging the industry's reputation, both in California and elsewhere in the country, with very real consequences for businesses. It also risks doing serious and irreparable harm to patients in California and beyond.

For the above reasons, we the undersigned strongly oppose implementing the proposed regulations on lethal injection as drafted.

Sincerely,

Dr Philip D. Hansten, PharmD

Professor Emeritus, University of Washington School of Pharmacy
250 Bicentennial Way, #722
Santa Rosa, CA 95403 USA
phansten@gmail.com

Dr Leonard L. Edloe, PharmD

President of the American Pharmacists Association Foundation

See link below for APhA position discouraging pharmacist participation in executions:

<https://www.pharmacist.com/apha-house-delegates-adopts-policy-discouraging-pharmacist-participation-execution>

Dr Randy P. Juhl, PhD

Distinguished Service Professor of Pharmacy Emeritus
The University of Pittsburgh

Dr William E. Fassett, PhD

Professor Emeritus of Pharmacy Law & Ethics
Washington State University
bill@pharmacistlaw.com