By hand delivery

July 8, 2016

Mr. Timothy Lockwood
Chief, Regulation and Policy Management Branch
California Department of Corrections and Rehabilitation
P.O. Box 94283-0001
1515 S Street
Sacramento, CA 95811

RE: Substantive Comments Regarding Amendments to Title 15, Article 7.5, Sections 3349, Proposed Lethal Injection Regulations, To Include in Rulemaking File

Dear Mr. Lockwood,

The American Civil Liberties Union of California ("ACLU") has grave substantive concerns about the California Department of Corrections and Rehabilitation's ("CDCR") proposed lethal injection regulations. We request that you include these comments and the attached 63 exhibits (which are provided electronically on a DVD) in the rulemaking file.

CDCR's proposed regulations must be understood in the context of the agency's own history of engaging in secretive efforts to acquire illegal drugs for use in executions and the numerous botched executions that have occurred across the country in recent years. Given this reality, the regulations suffer from numerous defects. *First*, the proposed regulations necessarily entail illegal conduct and, if applied, will necessarily result in multiple violations of federal and state controlled substances laws. *Second,* the proposed regulations create a serious risk of botched executions. *Third*, the proposed regulations do not provide the required transparency; they fail to assure that the public and media have a meaningful ability to witness the process and obtain important information about it. *Fourth*, the proposed regulations adversely affect important individual and collective rights of inmates as well as state employees. *Fifth*, CDCR has failed to conduct an adequate assessment of the fiscal and other costs associated with the implementation of these proposed regulations, including by radically understating the full costs to state and local government associated with resuming executions in California.

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The flaws in the proposed regulations are fundamental and cannot be remedied by amendments that tinker around the edges. In addition, CDCR clearly needs to engage in a meaningful study of its own past mistakes and botched executions in other states, and only then develop proposed regulations that address and prevent foreseeable errors. CDCR should therefore decline to proceed with the proposed action, *see* Gov't Code § 11347, and recommence its process for developing proposed lethal injection regulations, taking into account the fundamental problems described in these comments. If CDCR does not choose to do so, the Office of Administrative Law ("OAL") should disapprove the regulations because they are not consistent with state and federal law.

Table of Contents

Page

Page

Page

Page

I. Interest of Commenting Party

The American Civil Liberties Union is a nationwide, nonprofit, nonpartisan, membership organization dedicated to the defense and promotion of the guarantees of privacy, liberty and other individual rights embodied in the state and federal constitutions and statutes. The American Civil Liberties Union of California consists of the American Civil Liberties Union of Northern California, the American Civil Liberties Union of Southern California, and the American Civil Liberties Union of San Diego and Imperial Counties.

The ACLU is deeply involved in criminal justice reform issues, including the death penalty. It has a long history of working to ensure quality legal representation for those facing a sentence of death, including by providing post-conviction representation to Robert Alton Harris, the first person executed under California's current death penalty statute.

The ACLU has a substantial interest in the proposed regulations. The ACLU is opposed to the death penalty. It is also deeply concerned about the method and means of carrying out executions in California. The American Civil Liberties Union of Northern California has successfully challenged the use of the gas chamber in California as cruel and unusual punishment and the use of a curtain to prevent the media and witnesses from viewing the entire execution process. The American Civil Liberties Union of Northern California also represents Pacific News Service in a challenge still pending in federal court to California's three-drug lethal injection protocol.

The purpose of the Administrative Procedures Act ("APA") is to allow interested members of the public and individuals directly affected by a proposed regulation to provide meaningful feedback to the agency proposing the regulation and to ensure that all regulations actually adopted are in fact necessary, understandable, and the least burdensome possible to the public. The APA serves as the central check on the vast authority of executive agencies to promulgate rules and regulations—an authority that can easily be abused to the detriment of the civil rights and civil liberties of individuals. The APA constrains agency authority by ensuring that the public has a role and a voice in the rulemaking process, by requiring the OAL to ensure that every procedural safeguard in the APA has been followed, and by allowing judicial review of the process and the regulation finally adopted.

Pursuant to the APA, the ACLU submits these substantive comments objecting to the CDCR's Notice of Change to Regulations, Title 15 California Code of Regulations Section 3349, pertaining to lethal injection. In a separate letter, the ACLU presents its procedural concerns about CDCR's process for adopting these regulations.

The ACLU is opposed to the death penalty. But if California is going to resume executions at all, they must be conducted in a humane and transparent manner. These comments are intended to address the proposed regulations' failure to meet those the latter concerns.

II. Background

Since 2010, pharmaceutical companies have increasingly shown reluctance to permit the drugs they manufacture from being used in executions. This reality has meant that states that conduct executions by lethal injection have not been able to procure drugs through ordinary channels. This has resulted in at least three troubling outcomes: First, many departments of corrections across the United States, including California, have undertaken extreme, secretive, and oftentimes illegal measures to obtain drugs and carry out executions. Second, some executions conducted using drugs from secretive, questionable, or even illegal sources have resulted in gruesome botched executions. Third, states have increasingly turned to compounded drugs, which pose significant safety risks.

This recent history is particularly salient to the CDCR's proposed lethal injection regulations. Specifically, the ACLU is deeply concerned that the CDCR has made no effort to learn from the lessons of the past five years regarding drug selection, procurement, handling, and administration and to draft regulations that would prevent foreseeable problems. In addition, given the complicated legal regime surrounding drug procurement, it is very possible that states have unwittingly broken the law in their quest to procure drugs. We are concerned that the proposed regulations do not provide sufficient safeguards to ensure that California does not cross a legal or ethical boundary in its acquisition of drugs. Indeed, California previously imported illegal sodium thiopental and went so far as to resist a federal agency demand that it hand over the illegal drugs. Given this history both in California and other states, any lethal injection regulations must be drafted to ensure that California does not repeat mistakes or continue to flout the law, inadvertently or otherwise. An overview of these events is described below, followed by our specific concerns with the proposed regulations.

A. Drug Acquisition

The FDA-approved manufacturers of all four of the drugs listed in CDCR's proposed regulations—sodium thiopental, pentobarbital, amobarbital, and secobarbital—have either discontinued production of the drug or instituted distribution controls that prohibit use of the drugs for lethal injection. Thus, CDCR will not be able to obtain any of the drugs listed in the proposed regulation from an FDA-approved manufacturer or legitimate distributor of FDA-approved products. When faced with drug shortages in the past, states, including California, have resorted to questionable or illegal conduct to acquire lethal injection drugs.

In May 2010, sodium thiopental, a Schedule III controlled substance commonly used by departments of corrections across the United States in executions, had become unavailable due to production problems with Hospira, the only domestic supplier of the drug. The shortage of sodium thiopental resulted in delays in executions in some states. *See* Exhibit 1 (news coverage related to national drug shortage).

1. States' Questionable and Illegal Conduct to Acquire Lethal Injection Drugs

As the unavailability of thiopental began to impact executions, attorneys, community members, and journalists began to express concerns about whether government officials would violate state or federal law in their efforts to obtain the drug, the efficacy of the drugs in their possession, and what other steps officials might take in order to proceed with executions. *See* Exhibit 2 (news coverage related to the impact of the drug shortage). At the height of this national conversation and concern, California set its first execution date in nearly five years. The execution, scheduled for September 30, 2010, was eventually delayed in part because the state's supply of sodium thiopental expired the very next day, on October 1, and the state was unable to lawfully acquire a new supply. *See* Exhibit 3 (news coverage related to postponement of execution of Albert Brown).

During this period, states including California undertook extraordinary measures to acquire sodium thiopental, including conducting clandestine, international searches for the drug and circumventing federal laws for actual procurement. At least ten states obtained sodium thiopental imported under questionable circumstances. Two states (Nebraska and South Dakota) obtained the drug from India-based Kayem Pharmaceutical, whose owner publicly stated his company was not licensed to import controlled substances into the US. *See* Exhibit 4 (news coverage related to drugs obtained from Kayem Pharmaceutical). Eight states (Alabama, Arizona, Arkansas, California, Georgia, Kentucky, South Carolina, and Tennessee) obtained imported thiopental from Dream Pharma, a distributor in the United Kingdom. Dream Pharma was a, "one-man wholesaler that operated out of the back of a London driving school." *See* Exhibit 5 (Ryan Gabrielson, *Lethal injection drug tied to London wholesaler*, California Watch, January 7, 2011). Kentucky, Tennessee, and Georgia were forced to surrender their supplies to federal authorities because the drug had been unlawfully imported. *See* Exhibit 6 (Katie Zezima, *Two more states turn over drug used in executions*, The New York Times, April 1, 2011).

In addition to searching overseas for lethal injection drugs, state departments of corrections conspired to obtain drugs and even swapped drugs in secret meetings. Records obtained by the ACLU of Northern California through Public Records Act litigation reveal that corrections officials from California and Arizona organized a secret drug swap in which California provided pancuronium bromide in exchange for imported sodium thiopental. *See* Exhibit 7 (CDCR records related to drug swap between California and Arizona). During these inter-state communications, Arizona corrections officials informed their California counterparts that they had imported sodium thiopental from the United Kingdom (DreamPharma) and provided CDCR a roadmap for purchasing its own. California followed Arizona's approach and imported 521 grams of the drug in 2010 from the United Kingdom. *See* Exhibit 8 (news coverage related to California importation of sodium thiopental).

But a federal court subsequently ruled that the Food and Drug Administration ("FDA") should not have permitted the importation because, among other things, the drugs were unapproved and misbranded. *See Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013).

In 2012, the FDA ordered California to turn over the drug, but CDCR refused to comply. As one commentator observed, it was "extraordinary for state law enforcement officials to flout the authority of a federal regulatory agency that's backed by the ruling of a federal court." *See* Exhibit 9 (Bob Egelko, *California refuses to return execution drug to FDA*, SF Gate, May 27, 2012; April 6, 2012 Letter from FDA requesting that CDCR surrender its imported sodium thiopental; May 1, 2012 Letter from CDCR to FDA refusing to do so).

Shortly after CDCR refused to comply with the FDA's request, Governor Brown ordered that the CDCR begin pursuing a one-drug protocol. *See* Exhibit 10 (Howard Mintz, *California abandons defense of three-drug executions*, San Jose Mercury News, July 11, 2013).

In short, domestically-manufactured sodium thiopental is unavailable because the only pharmaceutical company authorized by the FDA to manfacture it discontinued production. And sodium thiopental, as held by the D.C. Circuit, cannot be lawfully imported.

States have continued to use unlawful methods to obtain lethal-injection drugs. In June 2015, Nebraska officials' efforts to import lethal-injection drugs from India were rejected by the FDA. Also in 2015, Arizona and Texas officials also tried to buy unapproved sodium thiopental from a supplier in India that was not registered with the FDA, forcing federal agents to step in and seize the unapproved drugs at the port of entry. *See* Exhibit 11 (news coverage related to 2015 Arizona and Texas drug seizures).

States have also made purchases from extremely questionable sources. Multiple states, for example, have purchased drugs from Chris Harris of Harris Pharma. This India-based vendor has claimed the ability to manufacture sodium thiopental, but the facility it registered with the FDA is incapable of manufacturing drugs and the facility it registered with the Drug Enforcement Administration is an old apartment building which Mr. Harris, who has no pharmaceutical background, vacated after failing to pay his landlord several months' rent. Nebraska is currently seeking a refund from Harris Pharma for drugs the vendor never delivered. Mr. Harris previously sold states lethal injection drugs while employed by Kayem Pharmaceutical, not apprising his own employer that the drugs would be used for executions, and obtaining the drugs from Swiss pharmaceutical company Naari based on the false representation that the drugs would instead be used in Africa. Naari requested the return of Harris-sold drugs and recalled the product from the market because of Mr. Harris' illegal diversion of its product. *See* Exhibit 12 (news coverage related to Chris Harris and Harris Pharma).

In addition, only two companies, Mylan, N.V. and Oak Pharmaceuticals, Inc.,[1] are approved by the FDA to manufacture pentobarbital; both companies have blocked its use in executions. *See* Exhibit 13 (information from FDA website regarding approved manufacturers of pentobarbital and about manufacturers' distribution controls).

[1] Oak is a subsidiary of Akorn, Inc, and acquired the rights to pentobarbital from Lundbeck.

Further, the only FDA-approved manufacturer of amobarbital and secobarbital has also instituted distribution controls blocking the use of these drugs in executions. *See* Exhibit 14 (information from Valeant regarding distribution controls)

2. California Continues to Consider Questionable Sources and Methods for Acquiring Lethal Injection Drugs

Documents recently obtained by the ACLU from a Public Records Act request demonstrate that CDCR continues to consider questionable sources and methods for acquiring lethal injection drugs.

Importing More Foreign Drugs: Although the FDA demanded that CDCR return its supply of illegal, imported sodium thiopental in May 2012, CDCR after that time again considered acquiring foreign lethal injection drugs. For example, CDCR considered information about drug suppliers in India and an online company based in the United Kingdom. *See* Exhibit 15 at PRIV 8679 (September 12, 2012 email identifying sources of pancuronium bromide in India); PRIV 9577 (April 14, 2014 email identifying online United Kingdom company selling nembutal, brand name of pentobarbital).[2] (India and the United Kingdom are the same two countries from which California and other states had previously imported sodium thiopental.) The consultant retained by CDCR to assist in developing these regulations specifically commented in forwarding this information to CDCR "We could do it again," (*id.*) referencing CDCR's prior importation of illegal sodium thiopental.

Violating Distribution Controls: CDCR knew in 2012 that Lundbeck Inc., a Danish pharmaceutical company that is the sole manufacturer of injectable pentobarbital, sold under the brand name Nembutal, had instituted distribution controls barring the drug's use in executions. *See id*. at PRIV 006783. Yet in 2014, CDCR's primary attorney tasked with developing these regulations stated: "We have been able to locate a source and can get pentobarbital (Nembutal)." *See id.* at PRIV 007718. The only way CDCR would be able to purchase Nembutal after Lundbeck's institution of distribution controls would be through a supplier willing to divert the drug illegally. Indeed, CDCR knew that other states that acquired drugs in violation of companies' distribution controls had faced claims that the drug had been illegally diverted and misappropriated. *See id*. at PRIV 013171 (May 2012 email forwarding news article about Nebraska: manufacturer of sodium thiopental acquired by Nebraska notified FDA that it was recalling product "because it was illegally diverted from the company's supply chain"). Nevertheless, CDCR apparently considered purchasing a drug in violation of manufacturer-imposed distribution controls.

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[2] The documents produced at Exhibit 15 are excerpts of documents obtained through litigation in response to the ACLU's August 14, 2015 and September 4, 2015 Public Records Act request. A complete set of the records produced is attached as an exhibit to the ACLU's procedural objections to these regulations, which is being submitted separately.

Alarming Sources: CDCR considered other troubling sources, such as a compounding pharmacy that "specialize[s] in pet prescriptions" and "can flavor the liquids with delicious 'animal' flavors" as well as an online pharmacy that boasts of selling "cheap" pentobarbital without a prescription. *See id*. at PRIV 008556, PRIV 008585. According to the DEA, "Buying controlled substances online without a valid prescription may be punishable by imprisonment under Federal law." *See* Exhibit 16 (DEA Consumer Alert: Report Suspected Unlawful Sales of Pharmaceutical Drugs on the Internet).

Another Secretive State-to-State Acquisition: CDCR previously engaged in a secretive drug swap with Arizona. More recently, CDCR appears to have considered obtaining drugs from Pennsylvania. *See* Exhibit 15 at PRIV 12046 (February 2014 email from CDCR consultant to CDCR attorney forwarding news article noting that Pennsylvania did not have drug shortage and asking "Do you think our new Secretary could ask PA for the drugs?"). Lethal injection drugs are not candy to be casually traded. The drugs in CDCR's protocol are all highly regulated controlled substances and may only be purchased from properly registered, licensed entities.

Evading State Procurement Rules: In 2010, when CDCR previously acquired sodium thiopental, one CDCR official wrote to another: "One important fact I learned is that if shipping or customs fees is itemized on their bill it gets into state bureaucracy we want to avoid. Ask them if they can just include the costs of shipping directly in the bill without itemizing it." *See* Exhibit 17 (Ryan Gabrielson, *State withholds name of lethal drug supplier*, California Watch, December 17, 2010). As media coverage at the time reported, emails such as those "raise questions about whether state corrections officials broke rules in purchasing the anesthetic." ***Id.*** Documents recently obtained through a Public Records Act request show that CDCR's consultant may again be seeking to "avoid state bureaucracy." The consultant specifically asked a potential vendor to "include shipping and any miscellaneous expenses" in the cost of the drugs. *See* Exhibit 15 at PRIV 008516.

CDCR has drawn the wrong lessons from its controversial 2010 acquisition of sodium thiopental. Rather than commiting to a transparent, ethical process, it seems determined to use the knowledge it acquired in 2010 to manipulate invoices, evade state procurement rules, and prevent the public from learning the true costs of lethal injection.

Unrepentant about past mistakes: CDCR claimed in 2014 that "CA is the only state that did everything properly via FDA and DEA for importation and acquisition." *See id.* at PRIV 8461. This is a remarkable—and inaccurate—statement in light of the fact that the FDA informed CDCR in 2012 that its supply of imported sodium thiopental was illegal and should be returned to the federal agency. It is clear that CDCR has been unwilling to learn from its past mistakes because it is refusing to acknowledge them. And the documents discussed above demonstrate that CDCR continues to consider questionable or illegal drug sources and methods of acquisition.

B. Botched Executions

Recent history demonstrates that botched executions are all too likely a possibility—because of problems ranging from difficulties establishing or maintaining intravenous (IV) access to the drugs themselves. The rulemaking file demonstrates that CDCR has made little effort to learn from the mistakes of other states, and the proposed regulations fail to include protocols to prevent such horrific occurrences from happening in California.

On April 29, 2014, Oklahoma executed Clayton D. Lockett using midazolam. Over the course of an hour, the doctor and paramedic stuck Mr. Lockett over 16 times in six locations on his body in their efforts to establish intravenous access. The doctor present at the execution stated that after the lethal injection drugs were administered, Mr. Lockett "raised his head up" and was "kind of jerking it," "started moaning," and "was seizing." The prison warden later testified that the scene was "a bloody mess," and that she "was kind of panicking," and "[t]hinking oh my God. He's coming out of this. It's not working." A victim services advocate with the corrections department stated: "It was like a horror movie…he kept trying to talk." The corrections director actually called off the execution 33 minutes after the first lethal injection drugs were administered, but Mr. Lockett died 10 minutes after that. An investigation into the Lockett execution ultimately concluded that the execution team's failure to establish a viable IV access point "was the single greatest factor that contributed to the difficulty in administering the execution drugs." *See* Exhibit 18 (news coverage related to botched execution of Clayton Lockett).

Problems with establishing intravenous access are not isolated. On September 15, 2009, Ohio attempted to execute Romell Broom but called off the execution after the execution team failed to establish intravenous access through 18 different injection sites over a 95 minute to two-hour period. *See* Exhibit 19 (news coverage related to botched execution of Romell Broom). The Supreme Court of Ohio, in a recent 4-3 decision, concluded that the state could proceed with a second attempt to execute Broom, notwithstanding the prior botched 2009 execution. *See* Exhibit 20 (*Ohio v. Broom*, Slip. Op.). That decision lays out the shocking facts of the 2009 procedure:

> {¶ 3} Broom was transported to the Southern Ohio Correctional Facility ("Lucasville") on September 14, 2009, in anticipation of his execution scheduled for the next day. Upon his arrival at Lucasville, a nurse and a phlebotomist conducted a vein assessment and found that Broom's right-arm vein appeared accessible, but his left-arm vein seemed less so. Prison officials communicated this information to Edwin C. Voorhies Jr., the regional director for the Office of Prisons of the Ohio Department of Rehabilitation and Correction ("ODRC"), and the medical team assured him that this would not present a problem.
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> {¶ 4} At 1:59 p.m. on September 15, the warden finished reading the death warrant to Broom. One minute later, Team Members 9 (a female) and 21 (a male) entered the holding cell to prepare the catheter sites.

{¶ 5} Team Member 9 made three attempts to insert a catheter into Broom's left arm but was unable to access a vein. At the same time, Team Member 21 made three unsuccessful stabs into Broom's right arm. After a short break, Member 9 made two more insertions, the second of which caused Broom to scream aloud from the pain.

{¶ 6} Member 21 managed to insert the IV catheter into a vein, but then he lost the vein and blood began running down Broom's arm. When that occurred, Member 9 rushed out of the room, saying "no" when a security officer asked if she was okay.

{¶ 7} Director Voorhies testified that he could tell there was a problem in the first 10 to 15 minutes. Warden Phillip Kerns saw the team make six or seven attempts on Broom's veins during the same 10–to–15–minute period. According to Kerns, the team members did hit veins, but as soon as they started the saline drip, the vein would bulge, making it unusable.

{¶ 8} About 15 minutes into the process, Kerns and Voorhies saw Member 9 leave the holding cell. Voorhies described her as sweating "profusely" and heard her say that she and Member 21 had both accessed veins, but the veins "blew." Member 17 then entered the holding cell and made "several attempts" to access a vein in Broom's left arm. Simultaneously, Member 21 continued his attempts on Broom's right arm.

{¶ 9} Terry Collins, who was then the director of the ODRC, called a break about 45 minutes into the process to consult with the medical team. The break lasted 20 to 25 minutes. The medical team reported that they were gaining IV access but could not sustain it when they tried to run saline through the line. They expressed "clear concern" about whether they would get usable veins. But because they said that there was a reasonable chance of establishing venous access, the decision was made to continue.

{¶ 10} By this time, Broom was in a great deal of pain from the puncture wounds, which made it difficult for him to move or stretch his arms. The second session commenced with three medical team members—9, 17, and 21—examining Broom's arms and hands for possible injection sites. For the first time, they also began examining areas around and above his elbow as well as his legs. They also reused previous insertion sites, and as they continued inserting catheter needles into already swollen and bruised sites, Broom covered his eyes and began to cry from the pain. Director Voorhies remarked that he had never before seen an inmate cry during the process of venous access.

{¶ 11} After another ten minutes or so, Warden Kerns asked a nurse to contact the Lucasville physician to see if she would assess Broom's veins and offer advice about finding a suitable vein. Broom later stated that he saw "an Asian woman," whom he erroneously identified as "the head nurse," enter the chamber. Someone handed her a needle, and when she inserted it, she struck bone, and Broom screamed from the pain. At the same time, another team member was attempting to access a vein in Broom's right ankle.

> {¶ 12} The Lucasville physician confirmed that she came to Broom's cell, examined his foot, and made one unsuccessful attempt to insert a needle but quickly concluded that the effort would not work. By doing so, she disobeyed the warden's express instructions to observe only and not get involved. The physician examined Broom's foot but could see no other vein.
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> {¶ 13} After the physician departed, the medical team continued trying to establish an IV line for another five to ten minutes. In all, the second session lasted approximately 35 to 40 minutes.
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> {¶ 14} During the second break, the medical team advised that even if they successfully accessed a vein, they were not confident that the site would remain viable throughout the execution process. The governor's office had signaled its willingness to grant a reprieve, and so the decision was made to halt the execution for the day.
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> {¶ 15} Dr. Jonathan Groner examined and photographed Broom three or four days afterward. The photographs show 18 injection sites: one on each bicep, four on his left antecupital (forearm), three on his right antecupital, three on his left wrist, one on the back of his left hand, three on the back of his right hand, and one on each ankle. Prison officials later confirmed that he was stuck at least 18 times.
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> {¶ 16} Dr. Mark Heath met with Broom one week after the event. Dr. Heath observed "considerable bruising" and a lot of "deep and superficial" tissue damage consistent with multiple probing. Dr. Heath also posited that the actual number of catheter insertions was much higher than the number of needle marks, because according to what Broom told him, the medical team would withdraw the catheter partway and then reinsert it at a different angle, a procedure known as "fishing."

See id. at ¶¶ 3-16.

In January 2015, Oklahoma executed Charles Warner under new procedures that involved additional training and a higher dosage of certain drugs. As the injections began, however, he cried out "my body is on fire." Oklahoma later admitted that it used the wrong drug – potassium acetate instead of potassium chloride. *See* Exhibit 21 (news coverage related to botched execution of Charles Warner).

Okalahoma subsequently called off the execution of Richard Glossip, scheduled for September 2015. A doctor overseeing the execution discovered at the last minute that the state had once again obtained the wrong drug, even though it learned months earlier that it had used the wrong drug in the Warner execution. Executions in Oklahoma were placed on hold, pending a grand jury investigation into the drug mix-ups. Several top officials have resigned after testifying before the grand jury. *See* Exhibit 22 (news coverage related to Richard Glossip drug mix-up and grand jury investigation).

The grand jury report found, among other things, that the "Execution Protocols lacked controls to ensure the proper execution drugs were obtained and administered," for example, by failing "to require verification of the execution drugs." *See* Exhibit 23 (In the Matter of the

Multicounty Grand Jury, State of Oklahoma, Interim Report Number 14, May 19, 2016 at 77, 81). The report also found that "[t]he method by which the execution drugs were ordered contributed greatly to the Department's receipt of the wrong execution drugs." The report criticized the "surreptitious" and "questionable" manner in which the drugs were acquired. *See id.* at 88; *see also* Exhibit 24 (news coverage related to Oklahoma Grand Jury Report).

Oklahoma is not the only state that has encountered problems. In January 2014, Ohio executed Dennis McGuire using a two-drug protocol consisting of midazolam and the opioid hydromorphone. The execution took 24 minutes, with McGuire gasping and convulsing for 10 to 13 minutes before he died. *See* Exhibit 25 (news coverage related to botched execution of Dennis McGuire).

In July 2014, Arizona executed Joseph Wood using the same two-drug combination of midazolam and hydromorphone. Officials had to use 15 doses of each of the two drugs, rather than the two doses called for by the state's protocol. The execution took nearly two hours with Wood snorting and gasping for air. One witness counted Wood gasping "about 640 times." *See* Exhibit 26 (news coverage related to botched execution of Joseph Wood).

In March 2015, Georgia, which uses a one-drug protocol consisting of the barbiturate pentobarbital, postponed the execution of Kelly Gissendaner because its supply of the drug, which it obtained from a compounding pharmacy, "appeared cloudy." The quality, sterility, and efficacy of compounded drugs – for use in executions, but also for health care purposes – has come under increased scrutiny in recent years. *See* Exhibit 27 (news coverage of postponed execution of Kelly Gissendaner due to cloudy drugs).

A court in Montana recently ruled that pentobarbital is not a "fast acting barbiturate" and that its use in lethal injection therefore violates state law. *See* Exhibit 28 (news coverage related to Montana court ruling).

The Initial Statement of Reasons of the proposed regulations entirely fails to address the possibility of botched executions. The rulemaking file evinces no effort by CDCR to learn from the mistakes of other states. The only items in the file pertaining to executions in other states are the lethal injection procedures from Georgia, Kentucky, Missouri, North Carolina, Ohio and Oklahoma. The agency's response to a Public Records Act request by the ACLU of Northern California confirms that it has not corresponded with any other state (or federal) agencies regarding lethal injection drugs.[3] *See* Exhibit 29 (August 14, 2015 PRA request issued to the CDCR by the ACLU of Northern California and the CDCR's December 4, 2015 response).

[3] The ACLU of Northern California submitted a Public Records Act request on August 14, 2015. Item 9 requested: "Any correspondence between CDCR and other state and/or federal agencies from May 1, 2013 to the present regarding drugs intended or considered for use in executions." CDCR responded by letter dated December 4, 2015, stating: "CDCR has no responsive documents for the August 14, 2015 PRA request number 9." *See* Exhibit 29.

Although it is unacceptable, it is perhaps not surprising that the proposed regulations do nothing to prevent botched executions in California. Documents obtained from a Public Records Act request troublingly demonstrate that CDCR personnel tasked with overseeing development of these proposed regulations were wholly indifferent to gruesome executions in other states. For example, the CDCR attorney responsible for developing the regulations commented that news coverage of the horrific botched McGuire execution in Ohio, in which the inmate gasped and convulsed before he died, was just "a big hoopla" and "beyond ridiculous." *See* Exhibit 15 at PRIV 8406. She dismissed media reports, insisting that "[w]hat they witnessed was snoring." In addition, the consultant retained by CDCR to assist in developing these regulations forwarded to CDCR a news article of a botched execution in Florida that included graphic photos of chemical burns and extensive "skin slippage" on the inmate's body. Commenting "I do not know where or how they got these pictures!", the consultant apparently harbored deep concerns that the media was able to secure photos, but expressed none about what actually happened to the inmate. The CDCR's response to the news article similarly reflected no concern about what happened in Florida or how to prevent the same tragedy in California. *See id.* at PRIV 6939, 6953.

C. Safety Risks Associated with Compounded Drugs

Drug compounding is "a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." *See* Exhibit 30 (FDA, *Compounding and the FDA: Questions and Answers*). Compounded drugs pose significant risks of contamination, sub-potency, and adulteration. In addition, there is a heightened danger that the compounded drug is simply not the drug it is represented to be. The risks associated with compounded drugs are well documented and incidents involving contaminated compounded drugs have led to federal criminal prosecutions.

The FDA does not verify the safety or effectiveness of compounded drugs, or inspect the facilities in which they are compounded. Compounding pharmacies are subject to much less regulatory oversight than FDA-approved manufacturers. *See* Exhibit 31 (FDA, *The Special Risks of Pharmacy Compounding*, FDA Consumer Health Information, Dec. 2012). "[C]ompounded drugs fail to meet specifications at a considerably higher rate than FDA-approved drugs" and "pose the additional risk of microbial contamination." *Id.* The FDA has alerted consumers to "The Special Risks of Pharmacy Compounding," and warns that compounding is "a practice that is under scrutiny by the Food and Drug Administration (FDA) because of instances in which medications, primarily injectable medications that are intended to be sterile, have endangered public health." *Id.* The FDA has further warned that: "Compounded drugs made using poor quality practices may be sub- or super potent, contaminated, or otherwise adulterated. Additional health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective." *See* Exhibit 30 (FDA, *Compounding and the FDA: Questions and Answers*).

In 2012, more than 750 people in twenty states fell ill after they contracted fungal meningitis from compounded drugs meant to relive pain. Sixty-four people died from the outbreak. The FDA launched an investigation into the New England based compounding pharmacy and found many unsafe practices at the pharmacy that had occurred because, "compounding pharmacies are not subject to the same tight regulations and federal oversight as retail pharmacies." *See* Exhibit 32 (CBS/AP, *Arrests in compounding pharmacy meningitis outbreak*, Dec. 17, 2014 and other news coverage related to meningitis outbreak). Civil litigation resulted in a $210 million settlement. The federal government is also pursuing criminal charges against 14 individuals. *See id.* at Bates 338.

Contaminated drugs from an Alabama compounding pharmacy led to nine deaths and serious infections in other patients in 2011. According to the federal criminal indictment that followed, the pharmacy compounded an amino acid solution and then "kept [it] unrefrigerated, in a room that was not sterile, in a large pot on the floor, sometimes overnight, before it was sterilized and used." Info. at 4, *United States v. Allen*, No. 16-cr-00042-VEH-HGD (N.D. Ala. Jan. 28, 2016), ECF No. 1 (attached as Exhibit 33, indictment and news coverage related to indictment). The solution was found to consist of "a filthy, putrid or decomposed substance, namely *Serratia Marcescens*," and "was prepared, packed, or held under insanitary conditions." *Id.*

Two separate incidents involving contaminated injectable products in 2011 and 2012 also had devastating consequences, with patients suffering partial to complete vision loss. *See* Exhibit 34 (news related to contaminated injectables).

Although the 2012 meningitis outbreak spawned federal legislation in 2013, the current regulatory regime still lacks meaningful oversight. As even the president of one compounding pharmacy has observed, "I don't think this new legislation has a whole lot of teeth. It just adds another level of complexity." *See* Exhibit 35 (Michelle Stephenson, *Compounded Drugs: Understand the Risks*, REVIEW OF OPHTHALMOLOGY, March 5, 2014).

Problems persist even after the passage of the new federal legislation. The FDA has pursued numerous actions in which "purportedly sterile injectable drug products…tested positive for bacterial contamination." *See* Exhibit 36 (FDA, FDA Regulatory Actions Involving Drug Compounding at 17); *see also id.* (FDA News Release, "Federal judge enters consent decree against Downing Labs," January 11, 2016).

While compounding pharmacies are of general concern, those that provide lethal injection drugs to corrections facilities have been mired in controversy as well. A compounding pharmacy that provided lethal injection drugs to Missouri admitted to committing more than a thousand violations of state pharmacy guidelines; FDA inspectors found questionable potency, as well as problematic disinfecting and sterilization practices. *See* Exhibit 37 (Chris McDaniel, "Pharmacy that Mixed Execution Drugs is Being Sold After Admitting Numerous Violations,"

BuzzFeed, April 21, 2016). The pharmacy has been fined and its license placed on probation. *Id.*

The FDA has encountered problems not only with compounding pharmacies but also with the suppliers of the Active Pharmaceutical Ingredient ("API") used to compound drugs. For example, FDA lab testing discovered that a product labeled by the supplier Medisca as "L-citrulline" did not in fact contain *any* L-citrulline. The FDA has also found API imported from China to be "at risk for contamination with particulates" and warned against its use "to compound sterile injectable drugs." *See* Exhibit 38 (information from FDA website).

III. Objections and Recommendations

A. Illegal Distribution and Dispensation of Controlled Substances

The proposed regulations will necessarily entail illegal conduct, in particular, violation of state and federal laws governing the sale and dispensation of controlled substances.

Each of the drugs identified in the proposed regulations is either a Schedule II or Schedule III controlled substance.[4] Federal and state drug laws therefore apply. Several provisions, pertinent here, are summarized below.

First, it is unlawful to dispense a Schedule II or III controlled substance without a prescription. *See* 21 U.S.C. § 841(a)(1) (unlawful to dispense controlled substance, except as authorized); 21 U.S.C. § 829 (prohibiting dispensation of controlled substance without prescription).[5]

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[4] Thiopental is a Schedule III controlled substance. Amobarbital is a Schedule II substance (though "Amobarbital & noncontrolled active ingred." and "Amobarbital suppository dosage form" are Schedule III substances). Pentobarbital is a Schedule II substance (though "Pentobarbital & noncontrolled active ingred." and "Pentobarbital suppository dosage form" are Schedule III substances). Secobarbital is a Schedule II substance (though "Secobarbital & noncontrolled active ingred" and "Secobarbital suppository dosage form" are Schedule III substances). *See* Exhibit 39 (U.S. Dep't of Justice, Drug Enforcement Administration, Office of Diversion Control, List of Controlled Substances).

[5] Title 21 U.S.C. § 829 does not require a prescription if the drug is dispensed directly by a "practitioner" to an ultimate user. State law is similar. Cal. Health & Safety Code § 11158(a); *see* 62 Ops. Cal. Atty. Gen. 65 (1979). The proposed regulations contemplate that the lethal injection chemical will be administered by the Infusion Sub-Team (Proposed § 3349.7(b)(5)), and lack any requirement that the chemical be administered (*i.e.*, dispensed directly) by a practitioner within the meaning of federal or state drug laws. *Compare* Proposed § 3349.2(d)(2) ("Infusion Sub-Team shall have at least one member who is a physician, physician assistant, pharmacist, registered nurse, emergency medical technician, paramedic, *or* medic.") (emphasis added), *with* 21 U.S.C. § 802(21) (defining "practitioner" to mean "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or

Second, prescriptions for controlled substances may only be issued for legitimate medical purposes. 21 C.F.R. § 1306.04(a) ("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."); Cal. Health & Safety Code § 11153 ("A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.").

Third, a prescription for a lethal dose of a chemical serves no legitimate medical purpose. As one federal court has explained, "an execution is not a medical procedure." *Morales v. Tilton*, 465 F. Supp. 2d 972, 983 (N.D. Cal. 2006).[6] State law is also clear. Section 11210 of the Health & Safety Code states that a prescription for a controlled substance is appropriate "when the patient is suffering from a disease, injury, or infirmities attendant upon old age, other than addiction to a controlled substance." It further provides that a prescription for a controlled substance may issue "only when in good faith [the practitioner] believes the disease, ailment, injury, or infirmity requires the treatment" and "only in the quanitity and for the length of time as are reasonably necessary." *Id.* Administration of a controlled substance in a quantity sufficient to kill an individual does not constitute the good faith treatment of a disease, injury, or infirmity attendant upon old age and serves no legitimiate medical purpose. *See also Perzik v. Super. Ct.*, 2 Cal. App. 4th 898, 902 (1991) (construing state statutory scheme governing prescriptions for controlled substances to require "the physician [to use] best efforts and expertise to promote the patient's total health").

Fourth, state and federal prohibitions against dispensing a controlled substance without a valid prescription (defined as one issued for a legitimate medical purpose issued in the usual course of professional practice) apply both to physicians who write prescriptions and pharmacists who fill them. *See, e.g.,* 21 C.F.R. § 1306.04(a) ("An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."); Cal. Health & Safety Code § 11153(a) ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitionier, but a corresponding responsibility rests with the pharmacist who fills the prescription.").

Fifth, it is unlawful to encourage a physician to write an unlawful prescription for a controlled substance. *See* Cal. Health & Safety Code § 11154(b) ("knowingly solicit, direct, induce, aid, or encourage a practitioner authorized to write a prescription to unlawfully prescribe, administer, dispense, or furnish a controlled substance.").

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otherwise permitted…to distribute, dispense, conduct research…or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research"); Cal. Health & Safety Code § 11026 (similar definition).

[6] CDCR cites this decision and in particular the language quoted above in support of the proposed regulations. *See* Text of Proposed Regulations NCR 15-10 at page 14.

Sixth, state and federal law also prohibit the sale of controlled substances except for use pursuant to a valid prescription. *See* 21 U.S.C. § 841(a)(1) (prohibition against distribution of controlled substances, except as authorized); Cal. Health & Safety Code § 11153.5(a) ("No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes").

The proposed regulations call for administration of a lethal injection chemical—all of which are controlled substances—in a quantity CDCR states is lethal. *See, e.g.,* ISOR at 37. As a result, the regulations necessarily entail illegal conduct by: (1) a physician for writing an invalid prescription or dispensing a controlled substance without a prescription, *see, e.g.,* 21 C.F.R. § 1306.04(a); Cal. Health & Safety Code § 11153(a); (2) a pharmacist for filling an invalid prescription or dispensing a controlled substance without a prescription, *see, e.g.,* 21 C.F.R. § 1306.04(a); Cal. Health & Safety Code § 11153(a); (3) a wholesaler or manufacturer for selling a controlled substance for an unauthorized use, *see, e.g.,* 21 U.S.C. § 841(a)(1); Cal. Health & Safety Code § 11153.5(a); and (4) by officials at CDCR for requesting that a physician write an invalid prescription, *see* Cal. Health & Safety Code § 11154(b).

To be sure, the proposed regulations require the warden to "ensure that the lethal injection chemical is obtained from a licensed pharmaceutical facility or distributor." *See* Proposed § 3394.5(f)(1)(D). The ISOR states that such a provision "is necessary to ensure that procurement of the lethal injection chemical shall comply with all state and federal laws regarding controlled substances." ISOR at 25. While the provision may be necessary, it is hardly sufficient to do so, for the reasons discussed above.

Objection: CDCR contends that it is "fulfill[ing] [its] statutory mandate, pursuant to Penal Code section 3604, to establish standards for 'an intravenous injection of a substance or substances in a lethal quantity sufficient to cause death.'" ISOR at 1. But in proposing these regulations, it has selected four chemicals that are all Schedule II or III controlled substances and therefore triggered federal and state controlled substance laws. The regulations, as drafted, necessarily entail multiple violations of federal and state controlled substance laws. The Office of Administrative Law should disapprove the regulations on the ground that they violate the APA's requirement of "consistency" with existing statutes or other provisions of law. *See* Gov't Code § 11349(d) ("'Consistency' means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.").

B. Regulations Create Risk of Botched Executions

As discussed above, documents obtained through a Public Records Act request demonstrate that CDCR harbors a troubling indifference to botched executions. *See supra* at Part II-B. The proposed regulations create a grave and unwarranted risk of botched executions by adopting unnecessary, inhumane procedures, and failing to adopt protocols that would prevent foreseeable problems.

1. Administration of Five Doses Before Halting Execution

The proposed regulations provide for the administration of *five* doses of the lethal injection chemical if death does not result, and before the execution is called off. *See* Proposed §§ 3349.7(c)(9), 3349.7(c)(1), 3349.7(d)(5), 3349.7(d)(6). This is inhumane and inconsistent with CDCR's own insistence that a single dose is lethal.

Under the proposed protocol, an execution involving the administration of *five* doses could last as long as 14 hours and 45 minutes. Even the most conservative calculation (and one that does not include the time needed for actual administration of the drug) would require a procedure that takes at least 2 hours and 25 minutes.[7] The chart below sets forth the steps in the procedure.

Procedure	Minimum Length of Time	Likely Length of Time
Administer Tray A and begin 10-minute countdown (§ 3349.7(c)(3))	10 minutes (for the 10-minute countdown)[A]	150 minutes (for administration of dose)[B]
Administer Tray B and begin 10-minute countdown (§ 3349.7(c)(9))	10 minutes (for the 10-minute countdown)[A]	150 minutes (for administration of dose)[B]
Insert catheter into alternate back-up site (§ 3349.7(d))	5 minutes (estimate)[C]	5 minutes (estimate) [C]
Administer Tray C and begin 10-minute countdown (§ 3349.7(d)(4)&(5))	10 minutes (for the 10-minute countdown)[A]	150 minutes (for administration of dose)[B]
Preparation of 5 syringes for fourth dose & verification of proper preparation (§ 3349.7(d)(5))	5 minutes (estimate)[D]	at least 15 minutes[E]
Administer 1st syringe and "wait for ten minutes" (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes[F]	40 minutes (30 minutes to administer syringe plus 10 minutes waiting time)[B]
Administer 2nd syringe and "wait ten minutes" (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer syringe plus 10 minutes waiting time)[B]
Administer 3rd syringe and wait ten minutes (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer syringe plus 10 minutes waiting time)[B]
Administer 4th syringe and wait ten minutes (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer syringe plus 10 minutes waiting time)[B]
Administer 5th syringe and wait ten minutes (§ 3349.7(d)	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer syringe plus 10 minutes waiting time)[B]
Preparation of 5 syringes for fifth dose & verification of proper preparation (§ 3349.7(d)(5))	5 minutes (estimate)[D]	at least 15 minutes[E]

[7] This calculation unrealistically assumes that each dose, which requires administration of a huge volume—300 cc of the chemical and 60 cc of a saline flush—would not take more than 10 minutes.

Administer 1st syringe and "wait for ten minutes" (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes[F]	40 minutes (30 minutes to administer each syringe with 1.5 gram of drug plus 10 minutes waiting time)[B]
Administer 2nd syringe and "wait ten minutes" (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer each syringe with 1.5 gram of drug plus 10 minutes waiting time)[B]
Administer 3rd syringe and wait ten minutes (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer each syringe with 1.5 gram of drug plus 10 minutes waiting time)[B]
Administer 4th syringe and wait ten minutes (§ 3349.7(d)(5))	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer each syringe with 1.5 gram of drug plus 10 minutes waiting time)[B]
Administer 5th syringe and wait ten minutes (§ 3349.7(d)	Time to administer syringe plus 10 minutes	40 minutes (30 minutes to administer each syringe with 1.5 gram of drug plus 10 minutes waiting time)[B]
Execution stopped if death has not been declared		
TOTAL TIME	**At least 145 minutes**	**At least 885 minutes**

[A]Conservatively assumes administration of dose would not take longer than 10-minute countdown provided for in regulation.

[B]Internal CDCR documents indicate that the infusion time for pentobarbital is "30 minutes for each syringe." *See* Exhibit 15 at PRIV 6670. Each tray consists of 5 syringes of the chemical plus a saline flush. Even if the saline syringe took *no* time to administer, each dose of pentobarbital would require 150 minutes to administer. Similarly, amobarbital would also take 150 minutes for each 7.5 gram dose. According to prescribing information from the manufacturer, the rate for IV injection should not exceed 50 mg per minute. *See* Exhibit 40 (Valeant prescribing information for amytal sodium). This would mean 20 minutes per 1000 mg (=1 gram), or 150 minutes per 7.5 grams. The regulations provide for a ten-minute countdown to begin at the start of each of the first three doses and before the next dose is administered. *See* Proposed § 3349.7(c)(3), (9). But administration will take more than 10 minutes.

[C] The five-minute estimate to establish intravenous access at the back-up alternate location is very conservative. The execution team of Romell Broom failed to establish intravenous access over a 95 minute to two-hour period. *See* Exhibit 19.

[D] Conservatively estimates 1 minute to prepare and verify each syringe.

[E] As described in the expert report of Professor Craig Stevens, preparation of the chemicals is a complex procedure. Preparation of amobarbital, for example, would require preparation of 15 vials for each 7.5 gram dose because the drug is only available in 0.5 gram vials. Conservatively assuming each vial would require only 1 minute to mix, each dose would require at least 15 minutes to prepare.

[F]For the first three doses, the proposed regulations require the "ten minute countdown [to begin] at the start of the infusion of syringe #1." *See* Proposed § 3349.7(c)(3). For the fourth and fifth doses, the proposed regulations require a ten minute waiting period after the administration of each syringe and before the administration of the next syringe. *See* Proposed § 3349.7(d)(5) ("The Warden shall direct the Infusion Sub-Team to administer a syringe containing 1.5 grams of the Lethal Injection Chemical in the alternate backup intravenous line, and wait for ten minutes. If the inmate's death has not been declared by the end of that ten-minute period, the San Quentin

Warden shall direct the Infusion Sub-Team to administer another syringe containing 1.5 grams of Lethal Injection Chemical in the alternate backup intravenous line and wait ten minutes.").

CDCR has clearly stated that it believes a single dose of 7.5 grams to be lethal. In particular, the ISOR states that "Thiopental is a barbiturate that has been vetted by the *Morales* Plaintiffs' expert and it has been determined that a 5-gram dose is lethal." ISOR at 7. CDCR goes on to state that "[a]ll named barbiturates contained in the proposed regulations are equal to, or greater than, Thiopental in strength." *Id.* CDCR therefore selected "a 7.5-gram barbiturate single-chemical dose to address variations in the inmate's Lethal Injection Chemical tolerance, size or weight to ensure that the dose will be lethal even if one or more of these factors exist. Therefore, the 7.5 gram barbiturate option is confirmed lethal." *Id.*

CDCR appears to suggest that back-up doses are necessary "to address variations in the inmate's lethal injection chemical tolerance, size or weight to ensure that the dose will be lethal even if one or more of these factors exist." ISOR at 43. But this is contradicted by CDCR's own assertion that it already accounted for these factors in selecting a 7.5 gram dose, 2.5 grams more than purportedly discussed by the expert in *Morales.* *See* ISOR at 7.

CDCR states that it is necessary to stop the execution if death has not been declared within 10 minutes after administration of the last syringe in the last of the five doses "because the amount of lethal injection chemical in the inmate by that time should have resulted in death. If it did not, it indicates that there may be an issue with delivery of the lethal injection chemical." ISOR at 44. But this reasoning applies after administration of the *first* dose. It also fails to address other problems that may have occurred, such as with drug quality, potency, or sterility.

Documents obtained through a Public Records Act request demonstrate that CDCR itself considered a protocol that involved administration of only three doses, rather than the five in the proposed regulations, if death does not result from each dose. *See* Exhibit 15 at PRIV 0004119-004121 (draft ISOR discussing Trays A through C but not fourth and fifth doses).

If the inmate has not died after administration of the first dose, something has clearly gone very wrong. Administering *five* doses before calling off the execution would unnecessarily and inhumanely prolong a procedure that has clearly been botched.

Objection and recommendation: The proposed regulations provide for an inhumanely long procedure. They should be amended to provide that if death does not result after the administration of a *single* dose of the lethal injection chemical, CDCR should terminate the execution. CDCR fails to acknowledge that it considered an alternative that would have halted an execution after fewer unsuccessful doses. It has failed to explain why five doses, rather than three or one is necessary.

2. Inadequate Safeguards Regarding Intravenous Access

Grisly executions in Oklahoma and Ohio make clear that problems with establishing intravenous access can inflict cruel and inhumane suffering on inmates. The proposed regulations fail to set forth safeguards to prevent such problems in California and indeed, as drafted, will unnecessarily and inhumanely prolong executions, even after they have obviously been botched. The lack of protocols either creates the unacceptable risk of botched executions, or CDCR intends to adhere to a de facto protocol for addressing intravenous access issues, in which case that protocol constitutes an unlawful regulation that should be set forth in duly promulgated regulations.

The proposed regulations provide for a "vein assessment" in which, prior to the execution, the Intravenous Sub-Team identifies "primary, backup, and alternate backup locations" for establishing intravenous access. *See* Proposed § 3349.5(f)(2)(6). The proposed regulation provides that after the inmate is secured in the Lethal Injection Room, the Intravenous Sub-Team is to "[a]ttach the intravenous lines to the catheters and insert two catheters into pre-designated veins," and "[i]nform the San Quentin Warden when the intravenous lines have been successfully established." *See* Proposed § 3349.7(a)(3)&(6). The execution is to proceed "[a]fter the inmate's intravenous lines are successfully established." *See* Proposed § 3349.7(b). If the inmate has not died after the first dose, or "the primary intravenous catheter fails," then the Warden is to direct the discontinuation of the first dose and to recommence the process "using the backup intravenous catheter and the Lethal Injection Chemical on Tray B," (*i.e.*, the second dose). *See* Proposed § 3349.7(c)(5)&(6). If the inmate has not died after the second dose, "or an intravenous site cannot be established or maintained at either the primary or backup site," then the process is to be repeated "using the alternate backup site and Tray C," *i.e*., the third dose. *See* Proposed § 3349.7(c). If the inmate has not died after the third dose, then the Warden is to direct the preparation of a fourth dose, which are to be administered "in the alternate backup intravenous line." *See* Proposed § 3349.7(d)(5). And if the inmate has not died after the fourth dose, then the Warden is to direct the preparation of a fifth dose, which is to be administered "in the alternate backup intravenous line." *Id.* Only after all five doses have been administered and "death has not been declared," do the regulations provide for the Warden to "stop the execution and summon medical assistance." *See* Proposed § 3349.7(d)(6).

The proposed regulations invite alarming and gruesome mistakes and fail to include obvious and important safeguards.

First, the proposed regulations simply assume that intravenous access will be "successfully established," *see* Proposed § 3349.7(b), but do not set forth any protocols governing the establishment of intravenous access to the sites identified in the vein assessment. The proposed regulations do not address what to do if the Intravenous Sub-Team cannot successfully establish access, or "loses" a vein, the vein "bulges," or "blows," as occurred in Ohio with Romell Broom. *See* Exhibit 20 at ¶¶ 6-8. The proposed regulations do not prohibit the Intravenous Sub-Team from "re-us[ing] previous insert sites," or "fishing," i.e., "withdraw[ing] the catheter partway and then reinsert[ing] it at a different angle," as also

occurred in Ohio with Mr. Room. *See id.* at ¶¶ 10 & 16. There is no upper limit on the number of times an inmate can be struck.

Second, the proposed regulations require the suspension of the administration of the chemical during either of the first two doses, if intravenous access cannot be maintained. But they do not require (or appear to authorize) the suspension of the procedure if intravenous access fails during the administration of the third, fourth, or fifth dose. The proposed regulations recognize the importance of discontinuing administration of the drug if the catheter fails, at least for the first and second doses but irrationally fail to require discontinuing administration of the chemical if the catheter fails during any of the subsequent doses. This leaves the gruesome possibility of a seriously botched – and prolonged – procedure.

Third, the proposed regulations provide that if the inmate has not died after the first dose, then the drug is to be administered using the back-up site, and if the inmate has not died after the second dose, then the drug is to be administered through the alternate back-up site. But the proposed regulations also expressly require that the fourth and fifth doses are to be administered through the alternate back-up site. This is irrational and inhumane. The proposed regulations recognize that if each of the first and second doses do not cause death, then the delivery site should be changed. Indeed, CDCR explains that the execution should be suspended after delivery of five doses because "the amount of Lethal Injection Chemical in the inmate by that time should have resulted in death. If it did not, it indicates that there may be an issue with delivery of the Lethal Injection Chemical." ISOR at 44. But by CDCR's own reasoning, if death did not result after the third dose, then "there may be an issue with delivery of the Lethal Injection Chemical," and it is irrational to continue using the *same* site for the fourth and fifth doses. For the reasons discussed above, *see supra* Part III-A-1, it is irrational to proceed with the execution if the inmate has not died after the first dose. That is equally the case after the second, third, and fourth doses. Requiring the execution to proceed using an injection site that has already failed will cause a gruesome, botched, and prolonged procedure.

Fourth, the proposed regulations lack clarity on important issues related to intravenous access. The proposed regulations state that "[t]he alternate backup location may be a vein or a percutaneous portal vein access, if necessary." *See* Proposed § 3349.5(f)(6). The meaning of the term "percutaneous portal vein access" is unclear. The proposed regulations require the insertion of "two catheters into pre-designated veins." *See* Proposed § 3349.7(a)(3). It is unclear if this means inserting *two* catheters into each of the three pre-designated veins for a total of six catheters (the protocols call for the identification of "primary, backup, and alternate backup locations," *see* § Proposed 3349.5(f)(6), or one catheter into each of the pre-designated veins, in which case the proposed regulations leave unclear which of the *three* pre-designated veins the *two* catheters are to be inserted into. Also, the proposed regulations require the Intravenous Sub-Team to inform the warden when "the intravenous lines have been successfully established" but do not provide any definition as to the meaning of "successfully established."

Objection and recommendation: The proposed regulations lack safeguards to prevent gruesome and prolonged executions with respect to establishing and maintaining intravenous access and indeed, as drafted, instead invite prolonged executions even when intravenous access

cannot be established or maintained. The proposed regulations should be amended to provide protocols and create safeguards regarding the establishment and maintenance of intravenous access and address contingenices in the event intravenous access cannot be established or maintained. The proposed regulations should also be amended to eliminate the ambiguities discussed above. CDCR has failed to explain why it is reasonably necessary not to provide protocols and safeguards regarding the establishment and maintenance of intravenous access or why it is reasonably necessary not to address contingenices in the event intravenous access cannot be established or maintained. CDCR has failed to explain why it is reasonably necessary to proceed with the fourth and fifth doses at the alternate back-up site. CDCR has failed to explain why it is reasonably necessary to rely on "percutaneous portal vein access" for the alternate backup location.

3. Use of Amobarbital and Secobarbital Constitutes Illegal Biomedical Research and Inappropriate Human Experimentation

Two of the drugs designated in the proposed regulations—amobarbital and secobarbital, *see* Proposed § 3349.5(f)(1)(C)—are not suitable for use in lethal injection for several reasons, including that they have never been used in an execution before.

Given the high public interest in the death penalty and lethal injection, the media has extensively covered executions by lethal injections and reported on the drugs states have chosen to use. Many such articles are cited and discussed in Part II above. None of the media coverage of which the ACLU is aware has ever identified any execution in which a state used amobarbital or secobarbital. Nor does the rulemaking file contain any document that would indicate that either drug has been used in an execution.

Because these two drugs have not been used in an execution before, the proposed regulations necessarily entail biomedical research on condemned inmates, in violation of state law. Penal Code section 3502 provides: "Biomedical research shall not be conducted on any prisoner in this state."

They also constitute human experimentation, and CDCR lacks a basis for concluding that an execution conducted using either of these drugs can be conducted in a humane manner.

Documents obtained through a Public Records Act request indicate that CDCR had its own questions about amobarbital in particular. Amobarbital appears on a list with three other drugs that CDCR did not ultimately include in the protocol (Butethal, Thiamylal, and Codine) and that CDCR itself described as "questionable." *See* Exhibit 15 at PRIV 001531. The document does not elaborate why CDCR found amobarbital "questionable" and notes that research is "ongoing." The public has a right to understand CDCR's basis for selecting amobarbital and to know that CDCR initially had questions about this drug. If CDCR ultimately satisfied itself that its questions about amobarbital had been put to rest by further research, it should have explained this to the public in the ISOR.

CDCR also knows that these two drugs are simply not suitable for use in lethal injection.

Internal CDCR documents also show that CDCR is aware that secobarbital is only available in pill form, not as a sterile injectable. *See id*. at PRIV 000377, PRIV 006670. But it has failed to offer any explanation of how it will obtain secobarbital in a sterile injectable form. It is also aware that the evidence it reviewed relating to secobarbital involved oral administration of the drug (*see id.* at PRIV 008411), but has not offered any explanation of why the information it reviewed provides a basis, let alone a substantial basis, for concluding that secobarbital is an appropriate choice of drug for *intravenous* administration.

CDCR also knows that amobarbital is packaged in a format that renders it unsuitable for administration according to the protocol contained in these proposed regulations. As made clear from a document CDCR placed in the rulemaking file, the drug is only available in 500 mg vials. *See* Rulemaking File, Volume II, Doc. 52 (Amytal Sodium, Page 1, RxList.com (Aug. 21, 2009) <http://www.rxlist.com/amytal-sodium-drug.htm>). The protocol calls for three doses, with each dose consisting of 7.5 grams, to be mixed in advance of an execution. *See* Proposed § 3349.6(h)(3). Two additional doses must be mixed and administered if prior doses have not caused death, and before an execution will be halted. *See* Proposed § 3349.7(d)(5)-(6). Thus, each execution calls for at least 3 but up to 5 doses to be prepared for each execution. With each vial containing 500 mg (half a gram) of amobarbital, each dose requires 15 vials (0.5 gram x 15 = 7.5 grams). As a result, 45 to 75 vials would have to be mixed for each execution. This is simply too many vials. The manner in which it is packaged renders the drug unsuitable for use in a lethal injection execution.

CDCR knows that packaging is relevant to whether a drug is "amenable to use in an execution." *See id.* at PRIV 13490 (April 11, 2012 email from CDCR attorney Kelly McClease discussing potential source of drug but asking "in what packaging amounts will they be able to access; are they amenable to use in an execution?"). Indeed, in the past, CDCR rejected the possibility of using manufactured pancuronium bromide because the drug was only available in 1 and 2 mg packages. CDCR determined that it was simply "not feasible" to use a manufactured source that was only available in such small packages. *See* Exhibit 41 at AG2772.0001 (March 16, 2012 memo from CDCR General Counsel Benjamin Rice to Secretary Matthew Cate re procurement of pancuronium bromide: where 1 mg packaging would require 50 packages per dose and two doses per execution, CDCR determined it would be "impossible to use [manufactured pancuronium bromide] for the purpose of conducting a lethal injection").[8] CDCR recognized that simply combining the pre-packaged containers raised a number of concerns, including "general issues of contamination." *Id.*

Moreover, amobarbital should not be mixed more than 30 minutes before it is administered. *See supra* Exhibit 40 at (Valeant prescribing information for amytal sodium). But

[8] The documents produced at Exhibit 41 are excerpts of a supplemental production of documents obtained through litigation in response to the ACLU's August 14, 2015 and September 4, 2015 Public Records Act request. A complete set of the records produced is attached as an exhibit to the ACLU's procedural objections to these regulations, which is being submitted separately.

CDCR's proposed protocol calls for the drugs to be prepared *three hours* before the scheduled execution. *See* Proposed § 3349.6(h)(3).

CDCR does not offer any affirmative reasons for including these two drugs in the protocol. It states only that these drugs "are equal to, or greater than, Thiopental in strength." *See* ISOR at 7. Even assuming that is true, which it is not (other commenters such as Professor Craig Stevens explain why that cannot scientifically be supported), it does not explain why these drugs in particular should be designated. There are many drugs that are equal to, or greater than, Thiopental in strength, so that cannot be CDCR's real reason for including these drugs.

Objection and recommendation: The proposed regulations should be amended to eliminate amobarbital and secobarbital as authorized Lethal Injection Chemicals. The drugs are not appropriate for use in lethal injection because, among other reasons, they have never before been used in executions and they are not available in forms that are suitable for administration by lethal injection. Use of these drugs would constitute biomedical research in violation of Penal Code section 3502. The Office of Administrative Law should disapprove the regulations on the ground that they violate the APA's requirement of "consistency" with existing statutes or other provisions of law. *See* Gov't Code § 11349(d). Relatedly, use of the drugs constitute human experimentation. CDCR has not explained why it is necessary to designate amobarbital or secobarbital in the protocol. The proposed regulations should be amended to designate only drugs as to which there is a valid scientific basis for concluding the execution can be conducted humanely.

4. Choice of Sodium Thiopental and Pentobarbital

CDCR has also failed to offer a rational basis for including sodium thiopental and pentobarbital in its protocol. Indeed, based on the information of which CDCR was aware, the choice of sodium thiopental and pentobarbital is not reasonable.

For example, CDCR has known since at least 2012 that the manufacturer of pentobarbital has warned that "it is not safe to use the drug in untested ways, including in lethal injection protocols." *See* Exhibit 15 at PRIV 006783. And it knew at the time it issued the Notice of Change to Regulations that it would have difficulty acquiring sodium thiopental and pentobarbital from an FDA-approved manufacturer, given the distribution controls imposed by pentobarbital's manufacturer (*see id.*) and its own difficulties acquiring sodium thiopental in 2010. *See supra* Part II-A-1; *see also* Exhibit 15 at PRIV 007261 (May 22, 2013 email from CDCR attorney Kelly McClease stating "[redacted] has finally put into writing that they won't have their products used in executions (they expanded the list from Thiopental) and have implemented a restricted distribution system to that end.").[9] CDCR has not offered an

[9] CDCR repeatedly insisted on redacting from public records the name "Hospira," which is the manufacturer of sodium thiopental. *See supra* Part II-A and Exhibit 1. That Hospira

explanation for why it selected two drugs that it knows are unavailable from an FDA-approved manufacturer.

Objection: The proposed regulations should be amended to eliminate sodium thiopental and pentobarbital as authorized Lethal Injection Chemicals. CDCR has not explained why it is necessary to designate sodium thiopental or pentobarbital in the protocol, particularly when neither of these drugs is available from an FDA-approved manufacturer.

5. Designation of Four Drugs in Protocol

The proposed regulations designate 4 drugs, any one of which can be used in an execution. Proposed § 3349.5(f)(1)(C). The reason given for designating multiple drugs is "shifting availability" of the drugs: "CDCR determined it is necessary to provide alternative chemical options to contend with potential issues complicated by the shifting availability of the chemicals." ISOR at 2.

But *none* of the drugs is available in manufactured form. *See supra* Part II-A-1. As a result, CDCR's only option is to compound the drug. But if that is so, unavailability of *manufactured* versions of the drug has no bearing on CDCR's ability to acquire the drug for an execution. As a result, designation of multiple drugs in the protocol serves no purpose other than to keep the public and the inmate guessing about the drug that CDCR intends to use in executions.[10]

Objection and recommenation: The proposed regulation should be amended to include only one drug so that the public and the inmate are on fair notice of, and do not have to guess about, the specific drug CDCR intends to use in executions. CDCR has not adequately explained why it is reasonably necessary to designate multiple drugs.

6. Unbridled Discretion Regarding Selection of Lethal Injection Chemical

The proposed regulations provide the Warden with unbridled discretion to select the chemical to be used in each execution. This either produces wholly arbitrary results—and equal protection violations if inmates are subjected to entirely inconsistent treatment—or CDCR intends to adhere to a de facto protocol to guide the chemical selection process, in which case that protocol constitutes an unlawful underground regulation that should be set forth in duly promulgated regulations.

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manufactured sodium thiopental, discontinued production in the United States, and instituted distribution controls is public knowledge.

[10] Although the Warden will ultimately have to select one chemical "[u]pon CDCR's receipt of the execution warrant," *see* Proposed §§3349.5 & 3349.5(f)(1)(C), this hardly provides sufficient time in advance of a particular execution for an inmate to bring any appropriate legal challenges.

The proposed regulations list four chemicals and state that the chemical to be used in an execution is to be selected "on a case-by-case basis, taking into account changing factors such as the availability of a supply of chemical." *See* Proposed § 3349.5(f)(1)(A) & (C). The ISOR states "CDCR determined that it is necessary to provide alternative chemical options to contend with potential issues complicated by the shifting availability of the chemicals." *See* ISOR at 2. It further states that the provision for "case-by-case" selection "is necessary to ensure that the San Quentin Warden has the discretion required to make a lethal injection chemical selection." ISOR at 25. Although "shifting availability" *may* in theory warrant authorizing more than one chemical in the regulations (although it does not in this case; *see supra* at Part III-B-5), it does not justify granting the Warden unfettered discretion to select the chemical to be used in a particular execution. Indeed, the regulations suggest that availability of the chemical is only one factor for the warden to consider but enumerates no other factors. *See* Proposed § 3349.5(f)(1)(A) ("taking into account changing factors *such as* availability of a supply of chemical"). And CDCR's statement that the provision for "case-by-case" selection is necessary to preserve the Warden's discretion is entirely circular. CDCR essentially states that granting discretion is necessary to preserve discretion, but does not explain why discretion is necessary.

The grant of complete discretion to select between the four chemicals rests on CDCR's assumption that the chemicals are interchangeable. ISOR at 25 ("All named barbiturates contained in the proposed regulations are equal to, or greater than, Thiopental in strength….As a result, CDCR considers the listed chemicals equally effective in carrying out the purpose of these regulations."). But as explained by Professor Craig Stevens in his separately submitted comments, the assertion that the four drugs are equal to or greater than Thiopental in strength is not accurate or supported by the scientific and medical literature; in fact, the drugs are not pharmacologically equivalent.

Moreover, even as to the lone factor that the regulation suggests the warden consider—"availability of a supply of chemical"—the regulations provide no clarity as to the meaning of "availability." Sodium thiopental was literally available in 2011, when California purchased it from DreamPharma, but the FDA subsequently demanded that California hand over the drug because it could not lawfully have been imported. *See supra* Exhibit 9. An unlawfully acquired drug should not be considered "available" within the meaning of the regulations.

The broad discretion and lack of specific detail in the provisions related to drug selection stand in stark contrast with other sections of the proposed regulations, which provide specific detail regarding post-execution procedures. For instance, the proposed regulations provide great detail about precisely when to close windows, in order "to provide clear direction of staff responsibilities post execution." *See* ISOR at 45. CDCR thus acknowledges that the importance of giving "clear direction." But when it comes to such critical decisions, like which drug will be used, the regulations are virtually silent. This has the unacceptable effect of leaving CDCR with unbridled discretion and effectively leaving the public in the dark about how CDCR will implement critical aspects of its lethal injection procedure.

Additionally, the proposed regulations are unclear about *who* actually selects the lethal injection chemical. Form 1801-A suggests that the inmates, when choosing between lethal injection and lethal gas, may also choose which chemical will be used, yet the proposed regulations, at § 3349.5(f)(1), suggest that the warden will select the chemical. These two conflicting provisions in the regulations cause uncertainty about who actually is tasked with selecting the lethal injection chemical.

Given that California has a troubling history of secrecy and acquisition of illegal lethal injection drugs, as detailed above, it is important to curb discretion and to delineate clear protocols and criteria for making these important decisions. Clear protocols are also necessary to prevent the equal protection violations that would result from subjected inmates to wholly inconsistent treatment. And these protocols and criteria must be set forth in regulations, or they would constitute underground regulations. *See generally Morales v. Calif. Dep't of Corr. & Rehab.*, 168 Cal. App. 4th 729 (2008). Both the lack of clarity around who selects the drugs, as well as the unguided discretion to the Warden for critical aspects of the lethal injection protocol are problematic and run the risk of leading the CDCR and the state of California into serious legal and operational problems, as outlined in Section II-A of this comment.

Objection and recommendation: CDCR has not explained why it is reasonably necessary to give the Warden unfettered discretion to select the chemical to be used in a particular execution. If the regulations designate multiple chemicals, they should be amended to include clear and specific guidelines and criteria for the selection of the chemical to be used in a particular execution. The guidelines should specify, in addition to "availability," the other factors that the Warden is to consider in selecting the chemical, and must clearly define "availability." For example, a drug that can only be acquired illegally should not be considered "available." CDCR Form 1801-A should also be amended to reflect the actual protocols outlined in the regulations, and not create any ambiguity. Setting forth clear and specific guidelines for selection of the lethal injection chemical will reduce the risk of subsequent legal and operational problems (like procurement of ineffective drugs or botched executions.) Additionally, removing discretionary decision-making allows for greater transparency, which is necessary to shine the light on any further secretive and/or illegal maneuvers by the state.

7. No Basis for 7.5 Gram Dose

The proposed regulations call for a 7.5 gram dose of the lethal injection chemical. *See* Proposed § 3349.6(h)(3)(A). CDCR's stated basis for this dosage is that the plaintiffs' expert in *Morales* supposedly identified 5 grams as a lethal dose and that CDCR selected a 7.5 gram dose "to address variations in inmate's Lethal Injection Chemical tolerance, size or weight." ISOR at 7. CDCR thus assumes that 5 grams is an appropriate baseline and 2.5 additional grams suffices to address variations across inmates in tolerance, size, or weight. Both of these assumptions are incorrect.

Morales v. Hickman, 415 F. Supp. 2d 1037 (N.D. Cal. 2006), addressed a 3-drug protocol consisting of 5 grams of sodium thiopental, followed by pancuronium bromide, and then potassium chloride. *Id.* at 1039. The purpose of sodium thiopental in that protocol was "to induce unconsciousness." *Id.* The second drug induced paralysis, and the third drug was used to kill the inmate. *Id.* The decision focused on whether sodium thiopental, in the manner and amounts administered, would induce unconsciousness; the decison and testimony in that case did not address the amount of sodium thiopental necessary to kill the inmate, since that function was performed by the third drug in that protocol. *Id.* at 1043-45.

But even assuming the plaintiffs' expert in *Morales* could be characterized as having testified that 5 grams of sodium thiopental is lethal, and even assuming that "[a]ll named barbiturates contained in the proposed regulations are equal to, or greater than, Thiopental in strength," ISOR at 7, CDCR offers no scientific basis to ensure that increasing the dosage by 50% will be effective in producing lethal results in a humane fashion for all inmates. Some drugs, for example, are known to have a "ceiling effect" and experts disagree about the particular point at which that effect occurs for particular drugs. *See, e.g., Glossip v. Gross*, 135 S. Ct. 2726, 2743 (2015) (acknowledging that midazolam has "ceiling effect" above which increase in dosage produces no effect but finding petitioners did not provide probative evidence as to particular point at which midazolam's ceiling effect occurs). The manufacturer of pentobarbital states that "Death commonly occurs after 2 *to 10* grams..." *See* Exhibit 42 at 5 (Nembutal Sodium Solution Product Sheet from Akorn) (emphasis added). Information from the manufacturer thus suggests that less than 10 grams may not be a lethal dose. And elsewhere in the ISOR, CDCR itself states that *15 grams* of the drug—far more than 2.5 grams—are "necessary to address variations in tolerance, size or weight." ISOR at 43 (offering rationale for fourth and fifth back-up doses). Thus, CDCR's own statements are inconsistent as to whether 2.5 grams or 15 grams are necessary to address variations across inmates.

At the same time, CDCR has offered no concrete reason to explain why 7.5 grams is necessary, if the only expert testimony it cites suggests that 5 grams is sufficient. Indeed, CDCR itself previously considered a 6 gram dose. *See* Exhibit 15 at PRIV 3692.

Objection: CDCR has not offered an explanation of why a 7.5 gram dose is appropriate or reasonably necessary. It has considered alternatives to the 7.5 gram dose but failed to identify those alternatives or explain why it rejected them.

8. Same Dose for All For Drugs

The proposed regulations call for the same dose (7.5 grams) to be used for all four of the drugs. *See* Proposed § 3349.6(h)(3)(A). CDCR asserts that "[a]ll named barbiturates contained in the proposed regulations are equal to, or greater than, Thiopental in strength." ISOR at 7. As noted above, the manufacturer of pentobarbital states that "[d]eath commonly occurs after 2 *to 10 grams*…." *See* Exhibit 42 (Nembutal Sodium Solution Product Sheet from Akorn) (emphasis added). Even if CDCR is correct that 5 or 7.5 grams is the appropriate dosage for 7.5 grams, it

has not established that the same dosage is appropriate for the other drugs in the protocol and indeed evidence indicates that a different dosage may be required for the other drugs.

Objection: CDCR has not offered substantial evidence to support its conclusion that the same dose should be used for all four drugs in the protocol. CDCR has not demonstrated that it is reasonbly necessary to use the same dose for all four drugs in the protocol.

9. Administration by 5 Syringes

The proposed regulations call for each 7.5 gram dose of the drug to be administered by 5 60 cc syringes, each containing 1.5 grams. Proposed § 3349.6(h)(3)(A), (C). This would require the administration of a very large volume—300 cc of the drug, followed by 60 cc of the saline flush. The proposed regulations do not address the proposed concentration of the drug. They state that each syringe should contain 1.5 grams but depending on the concentration of the drug, this could take up more or less than 60 cc of fluid. If the proposed concentration would result in a volume less than 60 cc per 1.5 gram of the chemical, then there is no reason to use 5 syringes. Each additional step of the process (for example, preparation of more syringes than is necessary, administering chemical through more syringes than is necessary) introduces the additional possibility of error.

Objection: CDCR has failed to explain why it is reasonably necessary to administer the drugs by five syringes.

10. Failure to Provide Protocols for Critical Issues

The proposed regulations do not establish protocols for critical aspects of the execution process. But specificity in the regulations is necessary to cabin CDCR's discretion and ensure that it will carry out a lawful, humane execution, and to provide transparency about how CDCR will actually implement executions by lethal injection.

CDCR has made clear that the proposed regulations are *not* intended to address a number of essential issues. The "Informative Digest/Policy Statement" contained in the ISOR states that the purpose of the proposed regulations is "to develop a humane and dignified execution that provides safeguards that include a consistent and reliable screening process for Lethal Injection Team members; training, supervision, and oversight of the Lethal Injection Team; preparation and administration of the selected Lethal Injection Chemical; consistent and reliable record-keeping; and use of well-designed facilities in which the Lethal Injection Team performs the designated tasks and the execution takes place." ISOR at 1. By its own admission, CDCR has made no effort to draft regulations that are intended to and that actually ensure a consistent and reliable process for each of the topics discussed below.

By failing to specify protocols in the regulations on critical aspects of the execution process, CDCR will either subject inmates to ad hoc procedures that are arbitrary and capricious and raise equal protection concerns or, to the extent it proposes to adhere to uniform protocols on

these issues, CDCR seeks to evade the APA process and public scrutiny by placing large sections of the protocol in unlawful underground regulations. *See generally Morales v. Calif. Dep't of Corr. & Rehab.*, 168 Cal.App.4th 729 (2008).

a) No Protocols for Acquiring the Lethal Injection Chemical

The proposed regulations do not set forth any protocols for acquiring the lethal injection chemical, after it has been selected for use in a particular execution from the list of the four enumerated in the regulations. Protocols are necessary to ensure transparency so that inmates and the public have fair notice as to the source of the drug and the manner of acquisition. Either the lack of protocols will produce secretive, illegal, and/or unethical behavior, or CDCR intends to adhere to a de facto protocol to guide acquisition, in which case that protocol constitutes an underground regulation that should be set forth in duly promulgated regulations.

The utter silence on the precise protocols for acquiring the lethal injection chemical is unacceptable particularly because of CDCR's past conduct, its refusal to acknowledge its problematic behavior, and its on-going consideration of highly questionable drug sources and methods of acquisition. As discussed above, when CDCR acquired sodium thiopental in 2010, it engaged in a secretive "drug swap" for lethal injection drugs with another state and imported imported sodium thiopental from abroad. The FDA informed CDCR that its drug supply was illegal and demanded that CDCR surrender its supply. The state agency refused to do so. Instead of learning from its mistakes, CDCR continues to consider troubling drug sources and methods of acquisition, including importing foreign drugs, violating manufacturers' distribution controls, purchasing drugs from online sources that sell drugs withour prescriptions, obtaining drugs from other states, and manipulating invoices to avoid state procurement rules. *See supra* at Part II-A.

CDCR acknowledges that availability continues to be an issue. *See* Proposed § 3349.5(f)(1)(A). But it has failed to outline a standard procedure for investigating drug availability and procuring the chemical ultimately selected. An enumeration of permissible methods, along with an express prohibition against use of unenumerated methods, is necessary to ensure CDCR does not again resort to unacceptable methods of acquiring execution drugs. Moreover, the regulation's failure to specify the method of acquisition leaves the public and the inmate completely in the dark about the source of the drug.

To be sure, the proposed regulations require the warden to "ensure that the Lethal Injection Chemical is obtained from a licensed pharmaceutical facility or distributor." Proposed § 3394.5(f)(1)(D). The ISOR states that such a provision "is necessary to ensure that procurement of the Lethal Injection Chemical shall comply with all state and federal laws regarding controlled substances." ISOR at 25. While the provision may be necessary, it is hardly sufficient to do so. The provision uses an indirect requirement that the warden ensure the Chemical is obtained from a licensed facility or distributor, rather than simply requiring that the Chemical be obtained from a licensed facility or distributor. The provision does not specify the

nature of the license (federal or state; licensed for what purpose). Moreover, a detailed and complex legal regime governs the chemicals listed in the protocol, which are all either Schedule II or Schedule III controlled substances. *See supra* note 3. The mere fact that a facility may be licensed for one purpose does not ensure that the drug it sells to CDCR may be used in an execution consistent with all state and federal laws. For example, an entity may be licensed by the California State Board of Pharmacy, *see* Bus. & Prof. Code § 4000 *et seq.*, but it would still violate federal drug laws if that entity imported a Schedule III controlled substance, unless the entity is registered (or exempt from registration), and has filed an import declaration with the DEA. *See* 21 C.F.R. § 1312.11(b); *see also* 21 C.F.R. § 207.40(b) ("No drug may be imported or offered for import into the United States unless it is listed as required in subpart C of this part and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment"). Further, "a separate permit or declaration must be obtained for each consignment of controlled substances to be imported." 21 C.F.R. §1312.11(c). Unlawful importation, distribution, or dispensation of the drug is a criminal offense. *See* 21 U.S.C. §§ 841, 952.

Detailed protocols for vetting sources are also necessary to ensure the state does not acquire compromised products or resort to the questionable sources that CDCR has apparently considered. *See infra* Part II-A-2. Measures need to be instituted to ensure that CDCR does not acquire drugs from compounding pharmacies such as the one that sold lethal injection drugs to Missouri and possibly other states; that pharmacy was fined and had its license placed on probation years later, after state regulators conducted inspections and the pharmacy admitted to more than a thousand violations of state pharmacy laws. *See supra* Exhibit 37. CDCR is aware that secobarbital is available only in pill form. *See* Exhibit 15 at PRIV 000377, PRIV 006670. Yet it has offered no explanation of how it intends to obtain the drug in a sterile injectable form—by crushing up the drug and attempting to dissolve it in solution?

Due Process demands that an inmate have fair notice about the precise source of the drug to be used in an execution, so that he can raise any legal challenges. Particularly given the danger of botched executions, the public also has a right to know exactly what drug the state uses in executions, as well as where and how it obtained the drug.

If history is our guide, when states are not equipped with specific procedures for acquiring drugs and a transparent process for doing so, they engage in secretive and illegal behavior to secure drugs, and purchase drugs from highly questionable sources. The consequence of engaging in this type of behavior has been the violation of federal drug laws and gruesome botched executions, which tarnish the public's perception of the criminal justice system and raise serious questions about the constitutionality of the entire process. The proposed regulations must be amended to specify protocols for drug acquisition to prevent this from happening in California.

Objection and recommendation: The proposed regulations should be amended to specify standard criteria and procedures for drug acquisition, to require vetting of potential drug sources,

and to ensure transparency of the drug source. Further, the proposed regulations should be amended to prohibit acquisition by any method not expressly set forth in the regulations. Protocols are necessary to prevent CDCR's resort to unacceptable, secretive methods, such as its drug swap with Arizona or purchase of illegal imported sodium thiopental. Because the CDCR has acknowledged that drug availability may be difficult and the legality of CDCR's prior acquisition of sodium thiopental has been called into question, and because CDCR continues to consider questionable drug sources and methods of acquisition, a dedicated team should be in place (similar to the Lethal Injection Team) to conduct necessary research, investigation, quality control, legal compliance, and reporting and documentation of the CDCR's acquisition of the lethal injection chemical. CDCR has failed to explain why it is reasonably necessary to leave inmates and the public in the dark about the manner in which it will acquire the chemical.

b) No Protocols for Deciding Whether to Purchase Manufactured or Compounded Drugs

The proposed regulations nowhere address whether CDCR will acquire manufactured or compounded versions of the lethal injection chemical. Either the lack of protocols will produce secretive and arbitrary results—with CDCR subjecting different inmates to wildly different chemicals—or CDCR intends to acquire compounded drugs in all cases but has failed to set this forth in the regulations, in which case CDCR has adopted an unlawful underground regulation.

As drafted, the proposed regulations leave inmates and the public completely in the dark about whether CDCR will acquire manufactured or compounded drugs. Compounded drugs pose radically different safety risks, and inmates as well as the public have a right to know what drug CDCR actually intends to use.

Although the proposed regulations are silent on whether CDCR will acquire manufactured or compounded drugs, all evidence suggests that CDCR intends to compound the chemicals. An internal CDCR document obtained through a Public Records Act request shows that CDCR, when previously faced with a shortage of pancuronium bromide (one of the chemicals in its prior three-drug protocol), proposed compounding the drug. *See* Exhibit 41 at AG2772.0001 (March 16, 2012 memo from CDCR General Counsel Benjamin Rice to Secretary Matthew Cate re procurement of pancuronium bromide).

In addition, CDCR knows that manufactured versions of all of the drugs in the protocol are unavailable or unsuitable for administration by lethal injection.

CDCR knew at the time it issued this notice of proposed change that manufactured sodium thiopental and manufactured pentobarbital are unavailable because of distribution controls imposed by their respective manufacturers. *See* Exhibit 15 at PRIV 006783 (March 30, 2012 email from CDCR attorney Kelly McClease regarding announcement by Lundbeck, manufacturer of pentobarbital, that it was instituting distribution controls), PRIV 007261 (May 22, 2013 email from CDCR attorney Kelly McClease stating "[Hospira] has finally put into

writing that they won't have their products used in executions (they expanded the list from Thiopental) and have implemented a restricted distribution system to that end.").

CDCR also knew at the time it issued this notice of proposed change that manufactured secobarbital is available only in pill form and that manufactured amobarbital is available only in packaging that renders in unsuitable for administration by lethal injection. *See supra* at Part III-B-3. Moreover, the manufacturer of amobarbital and secobarbital has also announced distribution controls rendering these drugs unavailable. *See supra* Part II-A-1 & Exhibit 14.

Because manufactured versions of all of the drugs in the protocol are unavailable, unsuitable for lethal injection, or both, CDCR will have to obtain compounded drugs. CDCR is well aware of this fact, and may indeed have developed concrete plans to obtain compounded drugs. But it has drafted the regulations to obscure this critical information.

Objection and recommendation: The proposed regulations should be amended to make clear whether CDCR will obtain manufactured or compounded drugs. To the extent CDCR intends to obtain compounded drugs, the regulations need to clarify this. CDCR has failed to explain why it is necessary to leave the public and inmates in the dark about whether it will use manufactured or compounded drugs.

c) No Protocols for Requiring Disclosure of Source of Lethal Injection Chemical

As discussed above, the proposed regulations identify four chemicals and grant the Warden unfettered discretion to choose from among them. Proposed § 3349.5(f)(1). But the regulations are entirely silent on the source from which CDCR will procure the chemical. The result will be to keep the public in the dark about the source of the chemical. In the past, CDCR has gone to great lengths to conceal the source of lethal injection chemicals. Indeed, the ACLU has had to sue CDCR to force it to disclose this information. *See ACLU v. CDCR*, 202 Cal. App. 4th 55 (2011). The inmate and the public have a significant interest in knowing the source of the lethal injection chemical to ensure that CDCR obtains execution drugs only from reputable sources. For example, the inmate needs this information to make an informed decision at the time he is given the election beween lethal injection and lethal gas.

CDCR will likely argue that it is necessary to withhold information about the source of the drug for safety concerns. This argument is meritless. In recent Public Records Act litigation, CDCR represented to the Superior Court that it should be permitted to redact the name of a drug source based on safety concerns. It submitted evidence in support of its claim under seal, over the ACLU's objection, so the ACLU never had the opportunity to contest the claim. The Superior Court, lacking the benefit of adversarial briefing, permitted CDCR to withhold the name of the drug source. When CDCR ultimately produced the documents, it was clear that the

drug source it redacted was Hospira, the manufacturer of sodium thiopental.[11] The public is well aware that Hospira is the manufacturer of sodium thiopental and that sodium thiopental has been used in executions, but Hospira has not faced violent or physical attacks, even before it discontinued sodium thiopental production. CDCR's claims for the need for secrecy around its drug source are baseless.

Objection and recommendation: The proposed regulations should be amended to require CDCR to disclose the source of the drug. CDCR has failed to explain why it is reasonably necessary to keep the public and the inmate in the dark about this critical piece of information.

d) No Protocols for Handling Compounded Drugs

As detailed above, compounded drugs pose significant safety risks. *See supra* at Part II-C. The proposed regulations must be amended to include safeguards to mitigate those risks and to ensure that any compounded drug selected and acquired will perform as intended. As currently drafted, the proposed regulations do not contain any protocols for addressing the unique issues and concerns raised by the use of compounded drugs in executions. The lack of protocols either creates the unacceptable risk of botched executions, or CDCR intends to adhere to a de facto protocol for handling compounded drugs, in which case that protocol constitutes an unlawful regulation that should be set forth in duly promulgated regulations.

With respect to compounded drugs, the proposed regulations are notable mostly for their silence. But some of the express language in the proposed regulations also illustrates how CDCR has failed to account for the unique issues raised by compounded drugs. The proposed regulations repeatedly require the lethal injection team to perform critical tasks according to "directions provided by the manufacturer" or "manufacturer's instructions." *See, e.g.,* Proposed § 3349.2(d)(2)(A) (infusion sub-team must be able to follow manufacturer's instructions to prepare lethal injection drugs); § 3349.6(h)(3)(D) (lethal injection chemical "shall be mixed according to the manufacturer's instructions"); § 3349.7(d)(5) (if death is not declared after the administration of three trays, the infusion sub-team is required to prepare additional syringes "according to the manufacturer's instructions"). But if the lethal injection chemical is a compounded drug, it is unclear who the "manufacturer" is and whose "instructions" are therefore to be followed in preparing the drug. This either creates a hopeless ambiguity or leaves execution team members no instructions on preparing compounded drugs.[12]

Equally troubling, the proposed regulations fail to include any specific protocols for addressing compounded drugs. With respect to acquiring the drug, for example, the ISOR states:

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[11] The ACLU is submitting separate comments that raise procedural objections to the proposd regulations and provide more information about the Public Records Act litigation referenced above.

[12] Additionally, the proposed regulations refer to "[p]reparation of Lethal Injection Chemical" by the infusions sub-team, but do not define "preparation." *See, e.g.*, Proposed § 3349.3(h)(3).

"[i]f *for any reason* CDCR is unable to utilize CDCR or other state resources to compound the Lethal Injection Chemical, CDCR is permitted to contract with a private non-state compound pharmacy." ISOR at 10 (emphasis added). Thus, the regulations leave unfettered discretion to determine whether to use a state compounding pharmacy or a private one, and enumerate no criteria for selecting among them. When a compounded drug must be used, experts recommend that an investigation be conducted into the compounding pharmacy to evaluate its overall track record and experience with compounding the particular chemical; the selection should not be based on price. *See supra* Exhibit 35.

Given rampant quality concerns with compounded drugs, it is also essential to provide for rigorous testing to ensure safety and effectiveness.

The proposed regulations' utter failure to address the unique issues raised by compounded drugs will lead to preventable problems, like that faced by the state of Georgia the first time the state attempted to execute Kelly Gissendaner last year. *See supra* Part II-B.

Objection and recommendation: The proposed regulations should be amended to include specific and separate protocols for executions that use a compounded drug, including: special training for the Lethal Injection Team; documentation and record keeping; criteria for vetting and selecting a compounding pharmacy; special testing protocols to ensure potency, quality, and sterility; special testing protocols to ensure that the drug is the drug it is supposed to be; special handling and preparation instructions; and any other separate protocols that are needed to address the unique issues compounded drugs present. CDCR has failed to explain why it is reasonably necessary not to set forth protocols to address compounded drugs.

e) No Protocols for Ensuring Lethal Injection Chemical's Potency, Quality, and Sterility

Efficacy of the drug is the lynchpin of whether the execution can be conducted in a humane manner, and it is therefore essential to implement protocols that ensure the chemical's potency, quality, and sterility before the execution. Either the lack of protocols on this issue creates the unacceptable risk of botched executions, or CDCR intends to adhere to a de facto protocol for ensuring the chemical's potency, quality, and sterility, in which case that protocol constitutes an unlawful regulation that should be set forth in duly promulgated regulations.

If Oklahoma's lethal injection procedure had included specific procedures for testing, the botched execution of Charles Warner – who was executed using *the wrong drug* – may well have been avoided. Outlining a specific protocol to test the chemical will help prevent problems with drug effectiveness by ensuring potency, quality, and sterility. Indeed, the Grand Jury Report in Oklahoma expressly faulted the state's protocol for failing to include verification procedures. *See supra* Exhibit 23.

The proposed regulations, however, do not provide for any testing of the lethal injection chemical for potency, quality, and sterility, let alone enumerate protocols for such testing. Nor do the proposed regulations provide for any testing to verify that the chemical is the correct chemical. Failure to ensure the lethal injection chemical is the correct chemical to begin with, and also prepared and handled properly to ensure potency, quality, and sterility, is tantamount to human experimentation. As such, the CDCR has not provided necessary safeguards to demonstrate that executions performed pursuant to these proposed regulations will be humane and constitutional.

Such protocols are particularly necessary given CDCR's records stating that the Lethal Injection Facility suffers from "overall cleanliness" problems. For example, according to CDCR records produced to the ACLU, a June 2015 inspection of the Lethal Injection Facility found that "overall cleanliness needs to be addressed" and that the floors of critical areas such as the "Prep Room," "Infusion/Control Room" and "Storage Room" were "dusty" or "require[d] cleaning." The report concluded that the "Lethal Injection Facility is in need of cleaning….Facility has accumulated dust and dirt." *See* Exhibit 43 (CDCR response to September 4, 2015 ACLU Public Records Act request and pages 33-32 of responsive documents received).

Given that CDCR currently contemplates use of compounded drugs, it is even more critical that the regulations outline handling and testing procedures. Compounded drugs are not FDA approved and therefore the FDA, the federal regulatory agency tasked with ensuring drug safety, cannot verify the safety or effectiveness of compounded drugs.

Objection and recommendation: The proposed regulations should be amended to include specific procedures for handling and testing the lethal injection chemical to ensure potency, quality, and sterility of the drug and to verify that the drug is the correct drug. This requirement should apply whether or not the drug is compounded or instead manufactured and FDA-approved, although to the extent CDCR permits the use of compounded drugs, then additional testing should be required. CDCR has failed to explain why it is reasonably necessary not to delineate testing procedures.

f) No Protocols Regarding Concentration of Drug

The proposed regulations call for each 7.5 gram dose of the drug to be administered by 5 60 cc syringes, each containing 1.5 grams, but fail to address the concentration of the drug. *See* Proposed § 3349.6(h)(3)(A), (C). Depending on the concentration, 1.5 grams of the drug may occupy more or less volume than 60 cc. As a result, the proposed regulation is very confusing. The Infusion Sub-Team is instructed to mix the drug "according to manufacturer's instructions," Proposed § 3349.6(h)(3)(D), but if mixing 1.5 grams of the drug according to those instructions results in a volume other than 60 cc, it is unclear what the Infusion Sub-Team is supposed to do—leave the syringe partially underfilled (in which case it is unclear why the proposed

regulations call for the use of 5 only partially filled syringes), or use more than 5 syringes or syringes of a different size (which would violate the plain language of the proposed regulations).

Objection and recommendation: The proposed regulations should be amended to address concentrations and account for potentially different recommended concentrations from the manufacturer of each drug. CDCR has not explained why it is reasonably necessary not to delineate procedures addressing concentration.

g) No Protocols Regarding Manner of Administration

The proposed regulations address the amount of the drug to be administered and the number of syringes by which it is to be administered, but do not address the rate at which the drug is infused. *See* Proposed § 3349.6(h)(3). The proposed regulations then state that the lethal injection chemical is to be "administered," Proposed § 3349.7(c), but provide no instructions about *how* it is to be administered.

For example, will the drug be administered manually or with an infusion pump? "In general, an infusion pump is operated by a trained user, who programs the rate and duration of fluid delivery through a built-in software interface. Infusion pumps offer significant advantges over manual administration of fluids, including…the ability to deliver fluids at precisely programmed rates or automated intervals." *See* Exhibit 44 (FDA, "Infusion Pumps"). As the FDA explains, "[i]nfusion pumps provide a high level of control, accuracy, and precision in drug delivery, thereby reducing medication errors….At the same time, infusion pumps have been associated with persistent safety problems that can result in over- or under-infusion, and missed or delayed therapy." *See* Exhibit 45 (FDA, "Infusion Pump Improvement Initiative"). "From 2005 to 2009, FDA received approximately 56,000 reports of adverse events associated with the use of infusion pumps….During this time period, manufacturers conducted 87 infusion pump recalls to address identified safety concerns." *See* Exhibit 44. Some adverse events are caused by user error, while others are due to device design and engineering. *See id*.

The proposed regulations do not address whether the drug will be administered manually or with a pump. CDCR has not indicated whether it even investigated the difference or considered the relevant options regarding method of administration. The regulations should specifically address this issue and CDCR should explain why it is selecting one option over the other. If it selects the option of an infusion pump, it must ensure the Infusion Sub-Team is adequately trained and mechanisms are in place to address safety of the equipment.

Nor do the regulations address infusion rates. Errors in infusion rates can cause infiltration (in which the medication leaks into surrounding tissue rather than entering the blood stream), air embolism (air bubbles entering the vein), or other serious complications. Numerous studies have shown that errors in infusion rates are exceedingly common, even in hospital settings with highly trained staff. *See* Exhibit 46 (information regarding infusion rates). The proposed regulations do not prescribe infusion rates. While they require the Infusion Sub-Team to receive training on "[l]evel and rate of infusion of the Lethal Injection Chemical into the intravenous lines," Proposed § 3349.3(f)(2), there is no information on the nature or content of

the training. Given the frequency of errors in medical settings with qualified staff, additional safeguards are needed.

Objection and recommendation: Errors in the method of administration can cause serious complications. The proposed regulations should be amended to include specific safeguards regarding the method of administration. In particular, the proposed regulations should address whether CDCR intends to administer the drug manually or with a pump, and rates of infusion. CDCR has failed to explain why it is reasonably necessary not to address the method of administration in the proposed regulations.

h) Ambiguity Regarding 10-Minute Countdown

The proposed regulations require the initiation of a ten minute countdown "at the start" of each of the first three doses. *See* Proposed § 3349.7(c)(3), (9). "In the event all six syringes from Tray A have been administered, ten minutes has elapsed and death has not been declared," a member of the Record Keeping Sub-Team is to advise the Team Supervisor, who then informs the Team Administrator and Warden; the Warden then calls for the next dose to be administered. Proposed § 3349.7(c)(9). The same process occurs after the second tray. *See* Proposed § 3349.7(c)(1). And if all six syringes have been administered from the third tray, "ten minutes has elapsed and death has not been declared," then the Warden is to direct preparation of the fourth tray of chemicals. *See* Proposed § 3349.7(d)(5). CDCR states: "The ten minute countdown was selected because if the inmate has not been declared dead within this time, it indicates that delivery of the Lethal Injection Chemical from Tray A via the primary site may have been compromised. This is necessary to identify the need to move to the backup site and utilize Tray B." *See* ISOR at 42.

It is not clear that CDCR has accounted for the time it takes to administer the drug. The ISOR suggests that the inmate should have been declared dead *within* the ten minute countdown. *See* ISOR at 42 ("[I]f the inmate has not been declared dead *within* this time, it indicates that delivery … via the primary site may have been compromised.") (Emphasis added). But as discussed above, each syringe of pentobarbital requires 30 minutes to administer. *See* Exhibit 15 at PRIV 6670. A single dose (5 syringes of the drug) would thus require 150 minutes to administer, plus time for the saline flush. But if the ten minute countdown is initiated at the start of the administration of the first syringe, ten minutes will elapse *long* before the dose has been completely administered.

The protocol is ambiguous, illogical, and confusing. If the execution team is supposed to move to the second dose as soon as the ten minute countdown has elapsed, the result would be to move to the second dose before the first dose (150 minutes) has been fully administered. But if the execution team is not supposed to move to the second dose until the first dose has been fully administered *and* ten minutes have elapsed since the start of the first dose, then the ten minute countdown serves no purpose whatsoever because ten minutes will always elapse before the first dose has been fully administered. The ten minute countdown makes sense only if CDCR believes it can administer an entire dose in less than ten minutes. But it has offered no evidence

to support the conclusion that 360 cc of fluid (6 syringes, 60 cc each) could be administered in this amount of time, and that conclusion is contradicted by information in CDCR's own internal documents, which show that a single syringe of pentobarbital would require 30 minutes. Administering the drug too fast could result in dangerous complications like infiltration and air embolisms.

Objection and recommendation: CDCR has failed to explain why it is reasonably necessary to begin the ten-minute countdown from the start of the first syringe. The proposed regulation is ambiguous and creates confusion about the relationship between the ten minute countdown and the time it takes to administer the lethal injection chemical at recommended infusion rates. The proposed regulation should be amended to address these ambiguities.

C. Failure to Address Lethal Gas Procedures

The Penal Code and proposed regulations allow for the inmate to select his or her method of execution, either lethal gas or lethal injection. Penal Code § 3604(b); Proposed § 3349(b). The proposed regulations, however, outline only a procedure for execution by lethal injection and are silent regarding protocols and procedures for lethal gas. An inmate cannot meaningfully exercise his or her election when presented with the protocols for only one of two methods.

Further, the CDCR has acknowledged that lethal gas procedures must be promulgated under the Administrative Procedures Act. The ACLU issued a Public Records Act Request on November 13, 2015 seeking records related to the CDCR's protocols related to execution by lethal gas, given that this continues to be an option under the proposed regulations. CDCR responded by saying that, "the department currently has no lethal gas operational procedure" and that its previous procedure, "has been rescinded until such time as a regulation can be promulgated under the Administrative Procedures Act." See Exhibit 47 (November 13, 2015 PRA request issued to the CDCR by the ACLU of Northern California and the CDCR's December 7, 2015 response).

Because the proposed regulations enumerate procedures for execution only by lethal injection, they interfere with an inmate's statutory election pursuant to Penal Code Section 3604(b).

In addition, by failing to include procedures for execution by lethal gas, the CDCR has eliminated the public's ability to provide public comment on this key component of the current proposed regulations. Until a procedure for execution by lethal gas is submitted for public comment, we cannot provide the CDCR with our complete or informed comments on the current regulation.

Furthermore, CDCR appears to have considered the alternative of lethal gas. The consultant it retained to assist in developing these regulations provided CDCR with information about nitrogen gas. *See* Exhibit 15 at PRIV 8695.

Objection and recommendation: The proposed regulations should be amended to include protocols for execution by lethal gas. CDCR has failed to explain why it is reasonably necessary to leave inmates and the public in the dark about lethal gas procedures. CDCR has also failed to explain that it considered the alternative of nitrogen gas.

D. Impact on Media Access and the Public's Right to Know

The public and media must have access to information about the execution process. *See Cal. First Amend. Coal. v. Woodord,* 299 F.3d 868, 876 (9th Cir. 2002) ("[T]he public has a First Amendment right to view executions"); *Morales*,, 465 F. Supp. 2d at 973 (N.D. Cal. 2006) ("Few issues in American society have generated as much impassioned debate as the death penalty."). The proposed regulations fail to provide the necessary transparency.

1. Public Viewing of Preparation of Lethal Injection Chemical

The proposed regulations provide for the preparation of the lethal injection chemical to occur out of view of public, media, and inmate witnesses. Section 3349.6(h) provides for preparation of the chemical to occur three hours before the execution, an hour before witnesses are escorted into the viewing room. *See* Proposed § 3349.6(i)(1) (curtain on viewing window opened and witnesses escorted into designated witness rooms two hours prior to execution). The regulations also provide for an "Infusion Control Room" that is separate from the "Lethal Injection Room," in which the drug is administered to the inmate. *See*, *e.g.*, *id.* § 3349.7(a). Therefore, as currently drafted, the proposed regulations do not allow any witnesses to view the preparation of the three trays of the lethal injection chemical prior to the commencement of the execution, *id.* § 3349.6(h)(3), or the preparation of up to two additional trays once the execution has commenced, *id.* § 3349.7(d)(5). Nor do the proposed regulations require a video tape recording of these processes. It is essential for the public to witness the preparation of the chemical, both as a matter of sound public policy and constitutional law. Given the recent and horrific botched executions and drug mix-ups in numerous states, the proposed regulations' confusing directives in the context of compounded drugs to prepare the chemical according to non-existent "manufacturers' instructions," *see supra* Part III-B-10-d, and the uncleanliness of the Lethal Injection Room documented in CDCR's own documents, *see supra* Part III-B-10-e, it is critical that the entire process of preparing the lethal injection chemical is viewed and documented. In addition, "the public enjoys a First Amendment right to view executions from the moment the condemned is escorted into the execution chamber, *including those 'initial procedures' that are inextricably intertwined with the process of putting the condemned inmate to death*." *Cal. First Amend. Coal.*, 299 F.3d at 877 (emphasis added); *see also* Cal. Const., art. I, § 2 (liberty of speech clause). The current protocols call for the chemical to be prepared before the inmate is escorted into the execution chamber. But preparation of the chemical is "inextricably intertwined with the process of putting the condemned inmate to death" and CDCR cannot shield this aspect of the process in secrecy by arbitrarily deciding when and where it should occur.

Objection and recommendation: The proposed regulations should be amended to specify that all witnesses be able to view the preparation of lethal injection chemical—including the preparation of the initial three trays as well as the preparation of any back-up trays. The preparation of the chemical should also be video recorded and preserved in the Master Execution File. CDCR has not explained why it is reasonably necessary to prepare the chemical outside of public view.

2. Selection of Witnesses

The proposed regulations state that selection of witnesses for the execution will be made according to Penal Code section 3605, which provides, "[t]he warden *shall*, at the request of the defendant, permit … any persons, relatives or friends, not to exceed five, to be present at the execution…." (Emphasis added.) CDCR Form 1801-C, however, imposes limitations on the inmate's witnesses that are at odds with the statutory requirements. For instance, Form 1801-C requires the inmate to sign a statement saying "I understand that all requested witnesses must meet all guidelines applied to normal visiting" and that "[a]ll persons not meeting these guidelines will not be approved." But the statute *requires* the warden to "permit *any* persons, relatives or friends," and does not authorize the warden to impose additional guidelines on whether a witness will be approved. Additionally, the form permits the inmate to list five "family and loved ones," implying that if a selected witness is not a "family or loved one," the witness will not be approved. Again, Penal Code section 3605, allows for "*any persons*, relatives, or friends." (Emphasis added.)

In addition, Penal Code section 3605 allows the defendant to select, "ministers of the Gospel" to witness the execution. This statutory provision violates federal and state constitutional prohibitions against the government by giving preference to "ministers of the Gospel," and thus favoring one religion over others. *See, e.g., Epperson v. Arkansas*, 393 U.S. 97, 104 (1968) (Establishment Clause of "First Amendment mandates government neutrality between religion and religion, between religion and nonreligion").

While the proposed regulations broaden this provision by allowing "spiritual advisors," and not merely "ministers of the Gospel," to witness the execution at the request of the inmate, the proposed regulations still violate the federal and state constitutions by establishing a preference for religious or spiritual inmates. *See, e.g., Everson v. Bd. of Educ.*, 330 U.S. 1, 18 (1947) (Establishment Clause of First Amendment "requires the state to be a neutral in its relations with groups of religious believers and non-believers"); *East Bay Asian Local Dev. Corp. v. Cal.*, 24 Cal. 4th 693, 718 (2000) (construing California Constitution's article 1, section 4's prohibition against laws "respecting an establishment of religion" in light of federal Establishment Clause); *Fox v. City of Los Angeles*, 22 Cal. 3d 792, 796 (1978) (in addition to prohibiting establishment of religion, "[t]he California Constitution also guarantees that religion shall be freely exercised and enjoyed 'without discrimination or preference.' Preference thus is forbidden even when there is no discrimination.").

Objection and recommendation: CDCR Form 1801-C currently allows an inmate to select five witnesses but requires them to be "family and loved ones"; two additional witnesses are permitted but they must be "spiritual advisors." These limitations on inmate witnesses should be eliminated. The regulations should expressly authorize inmates to select any seven witnesses they choose and Form 1801-C should clearly so state. CDCR has not explained why it is reasonably necessary to limit the inmate's five witnesses to "family and loved ones" or to limit the inmate's two additional witnesses to "spiritual advisors."

3. Public Witnesses

Penal Code section 3605 provides that the warden "shall … invite …at least 12 reputable citizens, to be selected by the warden." But the proposed regulations enumerate no criteria for the selection of these public witnesses. It is critical that the witnesses reflect an appropriate cross-section of the State. The proposed regulations' silence on this issue suggests that CDCR will either arbitrarily and capriciously use ad hoc procedures or unlawfully implement an underground regulation for selecting these 12 public witnesses.

Objection and recommendation: The proposed regulations should be amended to enumerate criteria for the selection of the 12 public witnesses. CDCR has not explained why it is reasonably necessary to leave the public in the dark about its criteria for selecting these witnesses.

4. Media Witnesses

As currently drafted, the proposed regulations are silent about whether media witnesses will be allowed, how many will be allowed, and how they will be selected; they contain no criteria and guidelines to ensure that the media witnesses will represent a diverse cross-section of the California media community.

On September 22, 2010, Kevin Fagan with the San Francisco Chronicle wrote an article detailing the newly constructed lethal injection facility at San Quentin. In it, Mr. Fagan reports that the new facility's "main observation room for 12 state officials and 17 media witnesses offers four wide, flat windows looking straight into a roomy, open chamber where the lethal injection gurney sits." *See* Exhibit 48 (Kevin Fagan, *San Quentin Gives Glimpse of New Injection Space*, SF Gate, September 22, 2010). This article assumes that the new facility will allow for up to 17 media witnesses to be present at the execution. Yet the proposed regulations fail to address these important witnesses, suggesting that CDCR will either arbitrarily and capriciously use ad hoc procedures or unlawfully implement an underground regulation for selecting media witnesses.

Objection and recommendation: The proposed regulations should be amended expressly to authorize media witnesses. These should be in addition to the 12 public witnesses to be selected by the Warden pursuant to Penal Code section 3605. Specifically, the regulations should outline

the following: 1) how many media witnesses will be allowed to view the execution from the main viewing room, 2) guidelines and criteria for selecting the media witnesses permitted to view the execution from the main viewing room, and 3) guidelines and criteria for allowing additional media witnesses to view the execution from an overflow room. CDCR has not explained why it is reasonably necessary to leave the public in the dark about whether and how many media witnesses will be permitted to view the execution, or its criteria for selecting these witnesses.

5. Pre-Execution Media Access

The proposed regulations do not address media access, either in person or telephonic, in the days and hours prior to an execution. The proposed regulations do, however, provide that the inmate may have access to a "Chaplain or Spiritual Advisor," with the degree of access changing depending on the proximity to the execution. *See, e.g.,* Proposed § 3349.6(g)-(h).

Objection and recommendation: The proposed regulations should be amended to allow members of the media the same access to the inmate as Chaplains or Spiritual Advisors, provided that such access shall be granted only upon the inmate's consent. To the extent pre-execution media access is prohibited, CDCR has not explained why it is reasonably necessary to forbid such access.

6. Viewing Curtain

The proposed regulations state that the viewing curtain shall be opened before the witnesses arrive in the viewing rooms and shall remain open throughout the execution process, until pronouncement of death or if the execution is stayed or stopped for any reason. *See* Proposed §§ 3349.6(i)(1)(A); 3349.7(e). This applies even in the event that the execution procedure does not result in the inmate's death. But if death does not occur after all 5 trays (25 syringes) of the lethal injection chemical have been administered or attempted to be administered, a grave error will clearly have occurred. The ISOR states that closing the curtain in the event the execution is stopped or stayed after administration of the lethal injection chemical has begun is necessary to maintain the inmate's right to medical confidentiality under state and federal law. *See* ISOR at 44. But given the recent botched executions and the importance of transparency about critical aspects of the execution process, the inmate should be allowed to waive privacy and have the curtain and microphone remain open and on for the entirety of the procedure, including usage of all drug trays (including the two back-up trays), after pronouncement of death, termination of execution in the event of a stay, termination of execution in the event of administration of all 5 trays and any efforts after such an execution to provide medical assistance, and post-execution procedures to disconnect intravenous lines and to place the inmate's body into a post-mortem bag.

Recommendation: The proposed regulations should be amended to allow the inmate to waive his or her right to privacy and have the viewing curtain remain open and public access system

remain on for the entirety of the procedure, instead of terminating at the point at which CDCR designates the execution to have terminated. In other words, the inmate should be given the ability to waive privacy and to permit the witnesses to continue viewing steps of the process that follow CDCR's pronouncement of the termination of the execution, including the steps that occur after: pronouncement of death, termination of execution in the event of a stay, termination of execution in the event of administration of all 5 trays and any efforts after such an execution to provide medical assistance, and post-execution procedures to disconnect intravenous lines and to place the inmate's body into a post-mortem bag. The inmate waiver should grant the inmate the choice of specifying the specific point at which she or he wishes the curtain to be closed and public access system to be turned off. The regulations should include a procedure and timeline for notification to the inmate of the right to waive privacy, allow the inmate enough time to make this decision, and ensure that the waiver is included in the Master Execution File.

7. Execution Should be Video Taped

The proposed regulations as currently drafted do not specify whether the entire execution procedure, including preparation of the lethal injection chemical, will be videotaped and if a copy of that recording will be included in the Master Execution File and provided to defense counsel after the execution is complete. It is essential that the entire execution, including preparation of the drugs, be videotaped in order to create a full record of what occurred during the execution procedure. This record is important for many reasons: it can be used to train staff in future executions and it creates a clear account of what occurred at the execution.

According to documents obtained by the ACLU from the CDCR in response to a Public Records Act Request, the Lethal Injection Room is supposed to include equipment (digital camera) that can create a video record of the procedure: An inventory checklist of the "Lethal Injection Facility Security Team Supply Inventory Cabinet #2" lists a "Video Camera (charger/film)." Beginning in June 2015, however, the inventory checklist notes that the video camera is "missing," and thereafter the checklist of July 2015 states "Didn't have" and in subsequent months that the video camera was "Removed." *See* Exhibit 49 (CDCR response to September 4, 2015 ACLU Public Records Act request and a selection of pages from responsive documents received).[13] It is unclear whether CDCR has replaced its "missing" video camera or whether it was intentionally "removed" from the Lethal Injection Room, raising questions about whether CDCR has the capacity or the intent to record the execution process. The proposed regulations should expressly require video recordings and ensure all images and recordings will be preserved in the Master Execution File.

Recommendation: The proposed regulations should be amended to require that the execution procedure be videotaped and the recording be preserved in the Master Execution File. This

[13] The documents attached as Exhibit 36 are excerpts from documents produced by CDCR in response to a September 4, 2015 Public Records Act request.

recording should commence from the mixing of the drugs, and continue through the insertion of the intravenous lines into the inmate, the administration of the drug, and all post-execution procedures. If the mixing of the drugs and post-execution procedures occur in rooms other than the execution chamber, there must be equipment for recording in each of these locations. The video must also record audio, separate and apart from the Public Address system. CDCR Form 2181 should be amended accordingly.

8. Microphone/Public Address System

The proposed regulations fail to specify when the Public Address system will be turned on, and the proposed checklist on CDCR Form 2181 does not identify turning on the Public Address system as a task that the Lethal Injection Team must perform.

Recommendation: The proposed regulations should be amended to specify that the Public Address system must be turned on at the same time the curtains are drawn on viewing windows, and this task should be added to CDCR Form 2181. Inmates should be allowed to waive their right to privacy not only as to the viewing curtain but also the Public Address system. If the inmate chooses to waive privacy as to the Public Address system, it should remain on during the post-execution procedures designated by the inmate. *See supra* Part III-D-6. It is important that the media be allowed to view and hear this process.

9. Time of Execution

The proposed regulations do not address the time at which CDCR will begin administration of the lethal injection chemical. CDCR Form 2178 (Return on Execution Warrant) suggests that the execution will commence sometime after 12:01 a.m., yet this time is not specified anywhere in the actual text of the proposed regulations. The ISOR does not explain why commencing an execution after midnight is necessary, given the burden this creates on the victim family members, the family of the defendant, the media, and the public. Additionally, the CDCR has, in the past, begun executions after midnight. The failure to identify in the proposed egulations a standard time to commence executions, coupled with CDCR's past practice and Form 2178, suggests that CDCR intends to maintain underground regulations regarding the time of executions. Holding executions at this late hour raises practical hurdles to public participation by making it more difficult for witnesses (victim family members, inmate's witnesses, public witnesses, and media witnesses alike) to attend and the public to participate in any protests outside San Quentin.

Objection and recommendation: The regulations should be amended to specify that all executions will begin between the hours of 8 a.m. to 8 p.m. so they are not overly burdensome to media and witnesses and allow the millions of Californians who oppose the death penalty to assert their constitutional right to protest. CDCR has not explained why it is reasonably necessary to leave the public in the dark about the procedures governing the time for conducting executions.

10. Master Execution File

The proposed regulations state that a "Master Execution File" be maintained in the San Quentin Warden's office complex and that this file will serve as the permanent record of all documents related to an execution. The Record Keeping Sub-Team is tasked with assembling all documents for inclusion in the Master Execution File. The proposed regulations outline all documents that must be preserved in the Master Execution File but do not expressly state that it will be provided to the inmate's attorney after the execution is completed, including in the event that the execution does not result in death, nor that portions of the file that do not contain private information about the inmate will be made available to the public under the California Public Records Act (CPRA). Additionally, there are a number of documents that should be include in the Master Execution File that are not referenced by the proposed regulations.

Recommendation: The proposed regulations should be amended as follows:

- A copy of the Master Execution File must be given to the inmate's family/inmate and the inmate's attorney.

- The Master Execution File must be made available to the public under the CPRA, excluding only documents that contain private information about the inmate, designated below by the term "private".

- The regulations should specify that the following documents must also be included in the Master Execution File:

    - All training files of execution team members (the proposed regulations currently include only a copy of the lethal injection training file, Proposed § 3349.3(h)(1), which contains training files in the three days before the execution, but not documentation of all training as outlined in Proposed sections 3349.3(c) through 3349.3(c)(5). Training documentation described in Proposed section 3349.3(h)(2) should thus also be included in the Master Execution File.
    - The record of all individuals approved to enter the Lethal Injection Facility, maintained by the Warden pursuant to Proposed section 3349.4(a). This record should be included in the Master Execution File.
    - Full video (with audio recording) of execution. *See supra* Part III-D-7. (Private as to "post-execution procedures," except to the extent inmate has waived privacy. *See supra* Part III-D-6.)

- Qualifications of alienist panel members.[14]
- Any information regarding the sanity of the inmate, submitted pursuant to Proposed section 3349.5(h)(1). (Private; see recommendation above re CPRA.)
- Any psychiatric information provided to the Alienist panel, pursuant to Proposed section 3349.5(h)(2). (Private; see recommendation above re CPRA.)
- Any documentation submitted in conjunction with Notification by Warden to District Attorney Concerning Sanity of Condemned Inmate (CDCR Form 2174), pursuant to Proposed section 3349.5(h)(3) and Penal Code section 3701.[15] (Private; see recommendation above re CPRA.)
- Any notification by the Warden to the Director – Division of Adult Institutions and the Secretary of CDCR of any notification of the District Attorney concerning the sanity of the condemned inmate, pursuant to Proposed section 3349.5(h)(4).
- Any notification by the Secretary of CDCR to the Governor's Legal Affairs of referrals to the District Attorney's Office pursuant to Penal Code section 3701, which Proposed section 3349.5(h)(5) expressly requires to be "in writing."
- All reports and forms of alienists, including but not limited to all CDCR Forms 2173 (20-Day Pre-Execution Report) and any attached "independent psychiatric report[s], cover letter and summary of examinations, interview and history or other materials, and all CDCR Forms 2175 (7-Day Pre-Execution Report) and any attached cover letter, report, or other materials, pursuant to Proposed section 3349.6(a) & (b).[16] (Private; see recommendation above re CPRA.)
- All summaries of the inmate's conduct and behavior submitted by a Correctional Counselor II-Condemned Unit, to the Director – Division of

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[14] The proposed regulations currently include in the Master Execution File a "Memorandum identifying Alienist Panel," Proposed § 3349.9(e)(7), but it is unclear if this memorandum specifies each alienist's qualifications.

[15] CDCR Form 2174 (Notification By Warden To The District Attorney Concerning Sanity of Condemned Inmate) is already required to be included in the Master Execution File. *See* Proposed § 3349.9(e)(14). The proposed regulations should make express that supporting materials submitted in conjunction with Form 2174 are also to be included in the File. In particular, Form 2174 states that "Enclosed with this memorandum are the following" and lists three items: "Copies of the reports of the three alienists who examined the Inmate/defendant per PC § 3700.5," "A copy of the inmate's psychiatric file," and "Other___."

[16] Forms 2173 (20 Day Pre-Execution Report) and 2175 (7 Day Pre-Execution Report) are already required to be included in the Master Execution File. The proposed regulations should make express that supporting materials submitted in conjunction with these Forms are also to be included in the File.

Adult Institutions and the CDCR Secretary, pursuant to Proposed sections 3349.6(a)(4) & 3349.6(b)(3), or observations of conduct and behavior by the assigned Correctional Counselor I and/or custody staff, pursuant to section 3349.5(g)(2). (Private; see recommendation above re CPRA.)

- Any other writings, reports, or communications pertaining to the alienist review. (Private; see recommendation above re CPRA.)
- All documentation of observations of the inmate after service of the execution warrant, including but not limited to information documented on Form 128-B, pursuant to Proposed section 3349.5(g)(1)(B).[17]
- All test results of lethal injection chemical for potency, quality, and sterility. *See supra* Part III-B-10-e.
- Manufacturer information on drug preparation, handling, storage, and any other issues.
- Inmate privacy waiver regarding viewing curtain and Public Address system. *See supra* Parts III-D-6 through 8.
- The names of lethal injection team members. *See supra* Part III-D-11.
- All records related to research and communications about drug acquisition (even failed attempts).
- The budget estimate of the entire execution and the actual expenditures incurred, including all materials and labor/staffing costs. Note that the budget and the actuals should include all costs associated with procurement of the lethal injection chemical, including but not limited to costs of purchasing the drug, retaining intermediaries to procure or assist in procuring the drug, and internal CDCR staff time to acquire the drug.

11. Identity of Lethal Injection Team Members

The proposed regulations state that the identity of Lethal Injection Team members shall remain confidential. The ISOR states this is necessary to protect Lethal Injection Team members from "potential threats, harassment and retaliation for participating in a lawful activity" (ISOR at 16). The ISOR, however, fails to provide evidence that such threats, harassment, and/or retaliation have occurred in California or in any other state. Given that the CDCR has not provided any actual evidence for why the identities of Lethal Injection Team members must remain confidential, this provision of the regulations is unnecessary and must be removed. The identities of the Lethal Injection Team must be made available to the public and must also be included in the Master Execution File.

[17] The Pre-Execution Logbook is already required to be included in the Master Execution File. *See* Proposed § 3349.9(e)(23). The proposed regulations should make express that any other materials documenting the inmate's behavior after service of the Execution Warrant are also to be included in the File.

Objection and recommendation: The proposed regulations should be amended to make the identities of Lethal Injection Team members public. Proposed section 3349.2(a)(2)(E) should be deleted. CDCR has not demonstrated based on substantial evidence that it is reasonably necessary to keep confidential the identity of Lethal Injection Team members.

E. Individual Rights

The proposed regulations also adversely affect important individual rights, both of inmates as well as state employees.

1. Family Visitation

The proposed regulations provide for the inmate to have access to "Chaplains and Spiritual Advisors." *See, e.g.,* Proposed § 3349.6(d)(6). But they do not address visitation by the inmate's family.

Objection and recommendation: The proposed regulations should be amended to provide the inmate the same access to family in the days and hours leading up to the execution as currently contemplated for Chaplains and Spiritual Advisors. To the extent CDCR intends to forbid access by the inmate's family, CDCR has not explained why it is reasonably necessary to do so. Nor has CDCR explained why it is reasonably necessary to leave the inmate, the inmate's family, and the public in the dark about procedures governing family visitation.

2. Disparate Treatment of Female Inmates, Including Issues with Pregnant Inmates

In general, the proposed regulations fail to address the dignity of female or transgender female persons being executed. The regulations as currently drafted completely fail to outline special considerations and procedures for transgender and female inmates.

Section 3349.5(e)(3) of the proposed regulation is unnecessary and unclear. It states that if there is "good reason to believe" that a female inmate is pregnant, then the provisions outlined in Penal Code sections 3705 and 3706 will come into effect. Specifically, if the inmate is pregnant, the execution will be suspended and carried out when the defendant is no longer pregnant. The ISOR fails to outline why this provision is necessary. Given that inmates on California's death row spend 25-30 years on death row and are not allowed to have any sexual contact with males, it is nearly impossible for a female inmate to find herself pregnant prior to her scheduled execution date. The only way this could occur is if the female inmate had sexual intercourse (consensual or by rape) by a male CDCR personnel or another male official she encountered while at hospital or at court. No matter the cause, we can conclude that the only way a female inmate could find herself pregnant is through gross negligence (or worse) on the part of the CDCR, which this regulation seems to concede could occur. If CDCR expects such a failing to occur, it should make some effort to explain why it should be tolerated and the inclusion of this provision is, in fact, necessary.

In any event, the proposed regulation should not rely on the antiquated, offensive, and unconstitutional statutory provisions laid out in Penal Code Section 3705, which requires "three disinterested physicians, of good standing in their profession, to inquire into the supposed pregnancy, who shall, in the presence of the court, but with closed doors, if requested by the defendant, examine the defendant and hear any evidence that may be produced." Penal Code § 3705. Non-consensual pregnancy testing – and particularly in the highly intrusive manner set forth in the statute – violates female inmates' constitutional right to privacy. *See* U.S. Const. amend. IV; Cal. Const. art. I, § 1; *see also, e.g.*, *Gruenke v. Seip*, 225 F.3d 290, 300 (3d Cir. 2000) ("[A]dministration of a pregnancy test … constitutes a search within the meaning of the Fourth Amendment"); *Ascolese v. Se. Pa. Transp. Auth.*, 902 F. Supp. 533, 550 (E.D. Pa. 1995) (Fourth Amendment recognizes "very strong interest in maintaining the privacy of information related to … pregnancy (or non-pregnancy)"); *Am. Acad. of Pediatrics v. Lungren*, 16 Cal. 4th 307, 336 (1997) ("[T]he state constitutional right of privacy generally guarantees an individual's right to consent to, or refuse to consent to, medical treatment or medication."); *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1269, 1271 (9th Cir. 1998) (unjustified government questions about pregnancy violate article I, section 1 of the California Constitution).

Objection and recommendation: Given the different issues these two condemned inmate populations present from the condemned male inmate population, the proposed regulations must include procedures specifically addressing the unique issues related to the execution of female and transgender inmates. CDCR's failure to enumerate such protocols suggests that it will either arbitrarily and capriciously use ad hoc procedures or unlawfully implement underground regulations for these populations of condemned inmates. CDCR has not explained why it is reasonably necessary to leave the inmate and the public in the dark about the procedures it will follow for female and transgender inmates.

Further, the proposed regulations must outline a specific procedure for how a pregnancy determination will be made, prohibit involuntary pregnancy testing, and enumerate protocols to ensure that any pregnancy testing occurs in a private, dignified manner. Given the antiquated statute, we further recommend that the CDCR ask the legislature to revise this provision to uphold the dignity of female inmates who may be pregnant. CDCR has not explained why it is reasonably necessary to leave the inmate and the public in the dark about how it intends to ascertain if an inmate is pregnant.

3. Establishment and Free Exercise Concerns

a. No End of Life Counseling for Non-Spiritual Individuals

The proposed regulation outlines special in-person and telephonic access to a "Spiritual Advisor" of the inmate's choosing. *See, e.g.*, Proposed sections §§ 3349.6(d)(6), 3349.6(g)(2). The regulation, however, fails to define "Spiritual Advisor" or ensure that inmates who are atheists and are not spiritual, or who wish to have a non-spiritual advisor, will receive equal access to the person of their choice.

As discussed above, the state and federal constitutions prohibit this type of government preference for religion over non-religion. *See, e.g.*, *Everson*, 330 U.S. at 18 (Establishment Clause of First Amendment "requires the state to be a neutral in its relations with groups of religious believers and non-believers"); *East Bay Asian Local Dev.*, 24 Cal. 4th at 718(construing California Constitution's article 1, section 4's prohibition against laws "respecting an establishment of religion" in light of federal Establishment Clause); *Fox*, 22 Cal. 3d at 796 (in addition to prohibiting establishment of religion, "[t]he California Constitution also guarantees that religion shall be freely exercised and enjoyed 'without discrimination or preference.' Preference thus is forbidden even when there is no discrimination").

Objection and recommendation: The regulation should be amended to allow for a non-spiritual advisor or counselor as well. CDCR has failed to explain why it is reasonably necessary to limit the access provided for in these sections to spiritual advisors. The term spiritual advisor is also ambiguous.

b. State Employed Chaplains

The proposed regulations provide for the inmate to have access to "State employed Chaplains." *See, e.g.*, Proposed § 3349.6(d)(6). But CDCR currently has no chaplains at San Quentin to minister to inmates of the following faiths: Shia Islam, Hmong Shamanic tradition, Wotanism, Seventh Day Adventist, Buddhist, Wiccan, Aztec. The state and federal constitutional prohibition against governmental preferences for one religion over another, *see, e.g.*, *Epperson*, 393 U.S. at 104 (Establishment Clause of "First Amendment mandates government neutrality between religion and religion, between religion and nonreligion"), requires that if CDCR provides Chaplains of some faiths, it must provide them for all faiths. Although an inmate may select Spiritual Advisors of their own choosing, *see* Proposed § 3349.6(d)(6)(A), this is not an adequate substitute. The inmate or the Spiritual Advisor may lack the funds to travel to San Quentin and visit the inmate. Inmates of disfavored religions should not be forced to bear costs that CDCR absorbs for inmates of preferred religions.

Recommendation: The regulations should be amended expressly to state that CDCR will provide a Chaplain of the inmate's faith, upon request.

c. Chaplain's "nonspecific report"

CDCR Form 1801-B includes a box that the inmate is to check off that states, "Inmate understands he will be interviewed by a chaplain and a nonspecific report will be filed." The proposed regulations, however, do not mention anywhere that a chaplain will be issuing a nonspecific report, the purpose of this report, and how the report will be used in the execution protocol. Further, the ISOR also does not mention a nonspecific report or any other documentation to be completed by a chaplain or why such a report or documentation is necessary. Communications between the inmate and his counselor, whether a state employed Chaplain or not, should be kept private and not officially documented for the state.

Objection and recommendation: This checkbox on Form 1801-B should be removed and chaplains, spiritual advisors, and/or counselors should not issue any official documentation or reports. The term "nonspecific report" is not defined and ambiguous. CDCR has not explained why it is reasonably necessary for a chaplain to file a "nonspecific report."

d. Accommodations for End of Life Rituals and Counsel

The proposed regulations allow for the inmate to have access to a spiritual advisor who shall "be allowed to perform their spiritual functions at the inmate's cell front." Proposed § 3349.6(d)(6)(A). In-person access to this individual (cell front visitation), however, ceases three hours before the scheduled execution. *Id.* § 3349.6(h)(1)(A). The current regulations do not allow sufficient access to the inmate's chaplain, spiritual advisor, or counselor of choice in the critical moments leading up to the execution. The regulations should accommodate full access to end-of-life counsel.

Objection and recommendation: The proposed regulations should be amended to allow the selected individual to remain with the inmate for the entire process. This includes the ability to have contact visits with the inmate's selected counselor so that the inmate is allowed to sit with the counselor, touch the counselor, walk with the counselor from the holding cell to the execution chamber, and have the counselor present in the execution chamber during the execution. CDCR has not explained why it is reasonably necessary to terminate visitation three hours prior to the execution.

4. Expedited Communications

The proposed regulations acknowledge that prior to the execution, the inmate should have access to enhanced communication, in particular, with attorneys and spiritual advisors. *See, e.g.*, Proposed section 3349.6(d)(5), (6); ISOR at 32 ("There is dedicated staffing to continuously monitor the inmate to respond to any inmate needs including expedited access to the Warden."). But the proposed regulations fail to address whether the inmate is to bear the costs of phone calls made during this period and also fail to address mail, which must be expedited as well. Normal legal mail can take two to ten days to reach the inmate, or to go from the inmate to his counsel. Extra staffing and emergency procedures will need to be put in place to ensure that mail can be sent and received, to provide for similarly "expedited access." The proposed regulations should explicitly state that CDCR will absorb these costs and the fiscal analysis must address them.

Recommendation: The proposed regulations should expressly provide that incoming and outgoing mail will be expedited once the execution warrant has been served and that CDCR will pay for all such mail costs. The proposed regulations should also expressly provide that CDCR will pay for all telephone costs during this period.

F. Employee Rights and Labor Relations Issues

1. Free Speech and Whistleblower Rights

a) Confidentiality of Lethal Injection Team Members' Identities

Proposed section 3349.2(a)(2)(E) provides that the "[n]ames and identities of the Lethal Injection Team members shall remain confidential." The provision is unclear, but suggests that an employee who is a member of the Lethal Injection Team and who *chooses* to publicly identify him or herself and speak out about the execution process could face discipline. As a result, this provision interferes with employees' free speech and whistleblower rights.

The federal and state constitutions give public employees the right to speak out about matters of public concern. *See Pickering v. Bd. of Educ.*, 391 U.S. 563, 568 (1968) (public employees have "First Amendment rights … as citizens to comment on matters of public interest in connection with the operation of the public [agencies] in which they work"); *Fashion Valley Mall, LLC v. NLRB*, 42 Cal.4th 850, 857 (2007) ("[O]ur state Constitution grants broader rights to free expression than does the First Amendment to the United States Constitution"). State law protects their right to blow the whistle about potential wrongdoing. *See* Lab. Code § 1102.5(b) (unlawful to retaliate against employee who discloses information that "the employee has reasonable cause to believe … discloses a violation of state or federal" law).

Lethal Injection Team members will have first-hand information about the execution process, including information about botched executions – unquestionably a matter of public concern – and any potential violations of the law – something that could easily occur given the complex legal regime governing the lethal injection drugs identified in the proposed regulation, all of which are federally controlled substances. *See supra* Part III-A.

Public employees play an important role as watchdogs. They have blown the whistle on government waste and malfeasance and their brave conduct in speaking out has prompted major changes in the way our state does business. Since the California State Auditor ("state auditor") first activated the Whistleblower Hotline in 1993, tips and allegations of improper governmental activities have led to investigations identifying $575.4 million in waste and profound negative social effects. *See* Exhibit 50 (ELAINE HOWLE, CAL. STATE AUDITOR, 2015-1 INVESTIGATIONS OF IMPROPER ACTIVITIES BY STATE AGENCIES AND EMPLOYEE 54 (2015)).

In her most recent report, the state auditor detailed "ten substantial allegations [of improper governmental activities] involving several state departments," and costing state taxpayers "over $4.2 million in wasted funds, improper payments, and misuse of state time." *Id.* at iii. One investigation concluded that CDCR and the California Correctional Health Care Services (CCHCS) had overpaid three employees by $96,245. *Id.* at 23. This followed a 2013 investigation which identified a multi-year, systemic failing in CDCR's and CCHCS's leave accounting policies, which cost the state at least $169,541, and possibly in excess of $400,000.

See Exhibit 51 (ELAINE HOWLE, CAL. STATE AUDITOR, CAL. DEP'T OF CORR. & REHAB. & CAL. CORR. HEALTH CARE SERV. 14 (2013). This 2013 investigation itself followed the state auditors' 2011 report detailing multiple investigations into CDCR, the most serious of which substantiated a complaint alleging that "[CDCR] had continued paying a psychiatrist his full salary even though it had prohibited him from treating patients due to concerns about his competency." *See* Exhibit 52 (ELAINE HOWLE, CAL. STATE AUDITOR, 2010-2 INVESTIGATIONS OF IMPROPER ACTIVITIES BY STATE EMPLOYEES 8, (2011)).

Public employee whistleblowing is not limited to allegations of fiscal waste. Between June 18, 2007 and May 6, 2011, then-Correctional Lieutenant David Wabakken disclosed improper activities, including the negligent supervision of inmates resulting in the temporary escape of one inmate, and allowing contraband into the camp at Pilot Rock Conservation Camp. *Wabakken v. CDCR*, 801 F.3d 1143, 1145 (9th Cir. 2015). Allegedly in retaliation for these disclosures, Wabakken was fired. *Id.* at 1145-46.

Particularly given CDCR's history, it is essential that employees who bravely choose to blow the whistle not face any adverse consequences. But given the mandatory language of the regulation, *see* Proposed § 3349.2(a)(2)(E) (identity of Lethal Injection Team members "shall remain confidential"), a Lethal Injection Team member who voluntarily chooses to reveal his or her identity and speak publicly about the execution process would technically violate the regulation. This raises the spectre that such an employee could face discipline for doing so. *See* Gov't Code § 19572 (e), (o) (insubordination and willful disobedience constitute grounds for discipline). But prohibiting public employees from disclosing to the public information about botched executions or potential violations of the law that occurred during the execution process interfere with their constitutional free speech rights and their statutory whistleblower rights, and is simply bad public policy.

Recommendation: Although the proposed regulations should be amended to eliminate entirely the provision regarding the confidentiality of Lethal Injection Team members' identities, the regulations, at a minimum, should be amended to clarify that Lethal Injection Team members may choose to reveal their identities and speak out about the execution process without fear of discipline or retaliation of any kind.

b) Reports to Licensing Bodies

Proposed section 3349.2(d)(3) provides that "no doctor, nurse, pharmacist, pharmacy, medical, professional or other business entity licensed by a board or department shall be referred to their licensing body by CDCR or any of its employees solely because of participating, assisting, aiding, facilitating or otherwise being involved with an execution or one of the associated, ancillary, auxiliary, supplemental, or supportive related activities as an execution is a legal activity." The provision is unclear, but suggests that any CDCR employee, who learns that a licensed medical professional on the Lethal Injection Team engaged in conduct that potentially violates the norms of that person's profession, could face discipline for reporting such conduct to

the relevant licensing body. As a result, this provision interferes with employees' free speech and whistleblower rights.

As discussed above, public employees enjoy federal and state constitutional free speech rights and statutory whistleblower protections. CDCR employees, especially those who are members of the Lethal Injection Team but potentially other CDCR employees as well, will have first-hand information about the execution process, including information about how lethal injection drugs are prescribed, inventoried, and stored. The lethal injection drugs in the proposed regulations are all controlled substances, and thus trigger detailed legal obligations on licensed medical professionals regarding among other things the prescription, inventorying, and storage of controlled substances. *See, e.g.,* Cal. Health & Safety Code § 11153 (prescriptions for controlled substances "shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice" and "responsibility for the proper prescribing and dispensing of controlled substances" rests with physician and pharmacist); Cal. Bus. & Prof. Code § 4081(a) (physicians and pharmacists to maintain inventory of manufacture, sale, acquisition, receipt, shipment, or disposition of "dangerous drugs" for at least 3 years); *id.* at § 4172 (physicians who dispense controlled substances must store drugs in "secure" area).

While one case has held that physician participation in executions is not "unprofessional conduct" within the meaning of Business and Professions Code § 2234, *Thorburn v. Dep't of Corrections*, 66 Cal. App. 4th 1284, 1292 (1998), that case only involved physicians and only involved the question whether participation in an execution *per se* constituted professional conduct. It did not address any other licensed medical professional and it did not address specific statutory violations relating to the manner in which controlled substances are prescribed, inventoried, or stored that may occur in the course of implementing an execution.

Public employees have a right to report conduct they reasonably believe to violate the law. *See* Cal. Labor Code § 1102.5. Yet the proposed regulation suggests they could face discipline for doing so.

Recommendation: The provision in the proposed regulations stating that neither CDCR nor its employees will report any "doctor, nurse, pharmacist, pharmacy, medical, professional or other business entity licensed by a board or department" for participation in an execution should be eliminated. At a minimum, the regulation should specify that no CDCR employee will suffer any form of retaliation or adverse action for reporting conduct related to an execution to a licensing board or department.

2. Use of Contracted Personnel

The proposed regulations provide that the Lethal Injection Team may consist of "contracted medical personnel." Proposed § 3349.2(a)(2). Participation in an execution is a serious responsibility and should not be entrusted to individuals who are not permanent, full-time

state employees who have been thoroughly vetted. The proposed regulations impose selection criteria on Lethal Injection Team members who are state employees that are more rigorous than the criteria applicable to applicants for the Lethal Injection Team who may be contracted employees. This is illogical.

For example, Proposed section 3349.2(c) sets forth criteria for the selection of Lethal Injection Team members. These mandatory selection criteria include: "Permanent full time CDCR employee or contracted employee." Proposed § 3349.2(c)(1). Thus, there does not appear to be a requirement that contracted employees be permanent full time employees. Contracted employees should not be subjected to more lax criteria than regular state employees. Further, one of the selection criteria is: "No sustained adverse action as reflected in the CDCR Official Personnel File or State Personnel Board records." *Id.* § 3349.2(c)(5). But non-state employees will not have a current CDCR Official Personnel File or State Personnel Board records. Thus, the proposed regulations fail to prohibit the selection of a contracted employee who had a serious history of discipline in private sector employment.

In addition, use of contracted personnel has labor-relations implications. CDCR should not use contracted personnel without bargaining with all affected unions about the decision to use contracted personnel and the effects of that decision on the unions. *Cf. generally Rialto Police Benefit Ass'n v. City of Rialto*, 155 Cal. App. 4th 1295, 1298 (2007) (city's decision to enter into contract for law enforcement services rather than providing services through own police department was subject to meet-and-confer requirement of Meyers-Milias-Brown Act).

Objection and recommendation: CDCR has not explained why it is reasonably necessary to include contracted personnel on the Lethal Injection Team. The provision in the proposed regulations authorizing the use of contracted medical personnel should be removed. At a minimum, the selection criteria should be amended to ensure that requirements are equally rigorous for full-time state employees as for contracted personnel. In particular, Proposed section 3349.2(c)(1) should be revised as follows: "Permanent full time CDCR employee or contracted employee <u>who serves in full-time permanent position</u>." Proposed section 3349.2(c)(5) should be revised as follows: "No sustained adverse action as reflected in the CDCR Official Personnel File or State Personnel Board records<u>, or in the case of contracted personnel, no history of discipline</u>."
In addition, if the provision authorizing the use of contracted medical personnel is not removed, CDCR should first meet and confer with all affected unions and the regulations should be amended to state that prior to each execution, if no willing and available state employees are available, CDCR shall first meet and confer with all affected unions about the particular decision to use contracted personnel.

3. Secondary Trauma Training

The proposed regulations state that the San Quentin Warden shall offer the Team Administrator and the Team Supervisor post trauma counseling, and that the Team Administrator

and Supervisors shall, in turn, offer it to the Lethal Injection Team members. *See* Proposed § 3349.8(k)(1)-(2). Given that the proposed regulations recognize that many individuals across the country who have participated in executions suffer from PTSD, post-trauma counseling should be made available to all persons who participated in the execution and this counseling should be mandatory and conducted by a trained trauma counselor.

Recommendation: The proposed regulations should include ongoing training and counseling opportunities to all staff and contractors who participate in the execution process. The costs of counseling and ongoing secondary trauma training should be reflected in the fiscal estimate.

4. Worker Safety

There has not been an assessment of the physical risk of harm that CDCR workers take on by participating in the executions. There are a number of worker safety issues that may arise with the implementation of these regulations and the CDCR has not provided any worker safety assessment. Specific examples of worker safety issues include: accidental needle sticks, exposure to bloodborne illnesses, and PTSD or other mental health issues that may arise by participation in an execution. Participation in an execution is a unique job duty that will be shared by many different CDCR staff and consultants under the proposed regulations. Given this, it is important that the CDCR do its due diligence to thoroughly assess all worker safety issues that may arise with this unique procedure in order to ensure these regulations will not harm its workers.

Objection and recommendation: The proposed regulations should be amended to include detailed protocols to ensure worker safety. CDCR has not explained why it is reasonably necessary not to address worker safety, or to the extent it intends to follow protocols to adhere to worker safety, it should set forth those protocols in the proposed regulations.

5. Non-Discrimination

The proposed regulations provide that Lethal Injection Team members "shall serve at the will of the Director – Division of Adult Institutions." Proposed § 3349.2(a)(2). The regulations do nothing to ensure that CDCR will comply with state and federal prohibitions against discrimination in selecting, training, providing benefits to, terminating, or retaliating against members of the Lethal Injection Team.

Objection and recommendation: The proposed regulations should be amended to include protocols to ensure that CDCR will comply with all non-discrimination laws in selecting, training, providing benefits to, or terminating Lethal Injection Team members. CDCR has not explained why it is reasonably necessary for the Director-Division of Adult Institutions to have unbridled discretion over the composition of the Lethal Injection Team.

G. Cost Estimate and Fiscal Impact

The APA requires CDCR to undertake several different kinds of economic impact assessments. First, the agency must prepare an estimate "of the cost or savings to any state

agency [and] the cost to any local agency …that is required to be reimbursed…." Cal. Gov't Code § 11346.5(a)(6). Second, the agency must prepare an "economic impact assessment that assesses whether and to what extent [the proposed regulation] will affect," among other things "the benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment." *Id.* § 11346.3(b)(1)(D). Third, the agency must make a determination of the impact on California business enterprises. In particular, the agency must assess whether the regulation will have a significant, statewide adverse economic impact directly affecting businesses. *Id.* §§ 11346.3(a)(3), 11346.5(a)(8). The determination of impact must be supported by evidence. *Id.* § 11346.2(b)(5); *see also id.* § 11346.5(c).

CDCR has failed to conduct an adequate assessment of the fiscal and other costs associated with the implementation of these proposed regulations. In particular, CDCR has failed to account for the $150 million the state stands to save if the death penalty is eliminated and substantially understated the costs of acquiring the lethal injection chemical. In addition, CDCR has failed to account for the ways in which these lethal injection regulations will injure the overall health and welfare of California residents, half of whom oppose the use of their tax dollars to execute people. Further, executions of innocent people seriously injure the overall health and welfare of California residents; CDCR does nothing to prevent this all too likely occurrence.

1. Inadequate Cost Estimate Pursuant to Gov. Code § 11346.5(a)(6)

a. Costs Associated with Resuming Executions, Including Sentencing and Conviction Litigation and Clemency Proceedings

CDCR does not account for the costs associated with implementing these regulations and resuming executions, including but not limited to sentencing and conviction litigation, and clemency proceedings.

In the ISOR, CDCR provides a purported cost estimate "of the Execution Process." ISOR at 8. The ISOR acknowledges that the costs of the execution process include "[c]osts associated with an inmate's conviction and sentencing litigation" but simply fails to discuss these costs because they are "handled by the California Attorney General's Office." *Id*. But according to Department of Finance ("DOF") Regulations, the CDCR is required to make "an estimate of fiscal impact resulting from the 'regulation' on…[a]ny costs…by the issuing state agency and/or *any other state agency*." State Admin Manual § 6604 (emphasis added). Therefore the CDCR's justification for excluding costs associated with the inmate's conviction, sentencing litigation, and appellate litigation does not comport with DOF regulations.

Notably, the rulemaking file contains an op ed published in the *Napa Valley Register* discussing the costs of repealing the death penalty. *See* Rulemaking File, Volume I, Exhibit 47 (O'Reilly op ed). The opinion piece takes the position that death penalty repeal would cost

money and questioned the credibility of various studies, such as a study by the Legislative Analyst's Office, that have said death penalty repeal would, in fact, save the state millions of dollars. The inclusion of this document in the rulemaking file is significant for two reasons. First, it reflects CDCR's acknowledgment that the fiscal implications of death penalty repeal are salient to these proceedings and must be considered. Second, it demonstrates that, notwithstanding this acknowledgment, the agency has failed to consider important and authoritative information regarding the fiscal implications of the death penalty. The *Napa Valley Register* op ed is the *only* document in the rulemaking file addressing the fiscal implications of the death penalty and it takes the position that repealing the death penalty would *cost* the state money. But CDCR has failed to consider the numerous reports and studies from reliable sources such as the state Legislative Analyst's Office that have affirmatively concluded that repeal would result in significant cost *savings*. *See* Exhibit 53 (2011 and 2015 fiscal reports by the Legislative Analyst's Office on ballot measures to repeal the death penalty).

On November 4, 2015, the Legislative Analyst's Office released a fiscal analysis of a proposed initiative to repeal the death penalty in California, which may appear on the November 2016 ballot. The analysis estimates the measure would reduce net state and local costs associated with murder trials, appellate litigation, and prisons by around $150 million dollars annually. According to the report, $50 million of this savings will be incurred by elimination of capital appellate litigation and will be felt by the California Supreme Court, the California Attorney General and state defense agencies. CDCR should have considered this report, the earlier Legislative Analyst's Office report discussed in the *Napa Valley Register* op ed, and other studies discussing cost savings.

In addition, the proposed regulation will cause a resumption of clemency proceedings, which will create costs for the Governor's Office. CDCR has also failed to account for these statewide costs.

The CDCR must revise its fiscal estimate to address all costs associated with implementing these regulations and resuming executions, including but not limited to sentencing and conviction litigation, costs addressed in the Legislative Analyst's Office's studies of the death penalty, and costs associated with clemency proceedings.

b. Local Government Costs

CDCR does not account for the costs associated with implementing these regulations and resuming executions, including but not limited to local government costs.

In the ISOR, CDCR provides a purported cost estimate "of the Execution Process." ISOR at 8. As noted above, it also included in the rulemaking file an article discussing costs associated with repealing the death penalty. Thus, while the agency has acknowledged that costs associated with implementing the death penalty must be considered in these proceedings, it has

failed to address costs to local government, which must be included in its analysis. *See* State Admin Manual § 6604.

The CDCR has failed to include in its fiscal analysis the local government costs discussed in the November 2015 LAO report discussed above (and attached as Exhibit 53). That report outlines a reduction in costs to local government in the tens of millions of dollars on a statewide level if the death penalty were eliminated. Resuming executions would result in additional costs in these amounts. The CDCR has also failed to account for costs incurred to the offices of the district attorneys for participation in clemency proceedings. CDCR must include these costs in its fiscal estimate whether or not they are reimbursable by the state.

c. Williams Execution Was not an "Outlier" that Should Be Excluded

The fiscal assessment cites the execution of Stanley Tookie Williams as an unusually costly execution "due to [Mr.] Williams' status as a founder of the 'Crips' gang." ISOR at 9. CDCR argues that this costly execution is an "outlier" and was therefore not factored into its fiscal assessment because it believe it is an extraordinary example and not reflective of the costs of an average execution in California. ISOR at 9. CDCR offers no evidence to support its contention that the execution was costly *because* of Mr. Williams' status as a founding member of the Crips gang. On the contrary, the execution received worldwide attention because of strong claims that Mr. Williams was innocent and his redemption while on death row. *See* Exhibit 54 (news articles related to execution of Mr. Williams). Also, the execution was the first following an 11-month pause in executions.

Given that California has not conducted an execution in ten years and has limited data (13 executions in in 30 years), it is inappropriate to exclude the costs of the Williams execution. In addition, the CDCR baselessly assumes that future executions will not generate the same publicity as the Williams execution. But factors that led to significant attention on the Williams execution are likely to be present in any future executions in California—such as strong claims of innocence and redemption. In addition, since the execution of Mr. Williams over ten years ago, a number of state and national developments have occurred related to the death penalty and executions. Public opinion has shifted, the public and the media have been made aware of gruesome botched executions, states resorting to extreme measures to obtain lethal injection drugs, and more and more innocent people have been exonerated from death rows. Furthermore, the final vote on Proposition 34 in 2012 shows that half of the electorate in California (5.9 million voters) voted to end executions. *See* Exhibit 55 (Field Poll and other information related to public opinion on the death penalty). Given the sea change in attitudes about the death penalty that have occurred since the execution of Mr. Williams over ten years ago, any future executions in California are likely to generate significant public protest. The costs of the Williams execution are thus very likely to be reflective of or potentially lower than the costs for an average California execution in the future. CDCR's fiscal estimate is therefore inadequate in light of the current political environment regarding executions.

d. Cost of Acquiring Lethal Injection Chemical

The ISOR states that the cost of lethal injection chemical for use in one execution is $4,193. *See* ISOR at 10. CDCR bases this assessment on an estimated 60 grams per execution (37.5 for the execution plus 22.5 grams for training) and a 2010 purchase of Thiopental when the CDCR spent a total of $36,415 on 525 grams of Thiopental amounting to $70/gram. *See* Exhibit 56 (November 4, 2010 invoice to the Neumiller Infirmary Pharmacy at San Quentin State Prison).

While this fiscal assessment takes into account one prior drug purchase from 2010, it does not take into account the current market rate for lethal injection drugs or the likely shift in costs depending on which procurement method the CDCR undertakes (compounding v. manufacturing). Because CDCR only relied on one purchase of thiopental that occurred nearly six years ago, this fiscal assessment is inadequate and needs revision. Even in the ISOR, CDCR itself acknowledges the inadequacy of its estimate. It expressly states that "[b]ecause chemical costs are driven by market factors, it is not possible to know what future costs will be." *See* ISOR at 10. CDCR's own statement that it is "not possible" to make an estimate of chemical costs undermines the reliability of the estimate it provides.

It is, however, entirely possible to make a more accurate estimate. Documents obtained from a Public Records Act request show that CDCR knows the cost is far greater than what it stated in the ISOR. Instead of the $70/gram figure cited in the ISOR, CDCR's own documents demonstrate that the cost may range from $2,218 to $2,500 per gram. *See* Exhibit 15 at PRIV 000377 (May 8, 2014 from CDCR attorney Kelly McClease discussing one potential source that would charge "approximately $500,000 for an initial 200 gram order"); PRIV 007718 (April 16, 2014 from CDCR attorney Kelly McClease discussing source that would charge "list price [of] $1,109 per 500 mg" of pentobarbital). If CDCR purchases 60 grams, lethal injection costs would range from $133,080 to $150,000 per execution. These documents date from 2014, and reflect far more current information than the 2010 purchase of sodium thiopental.

Furthermore, the cost of acquiring the chemical reflects only the amounts needed for the actual execution and training. CDCR has not included the additional amounts that need to be acquired for testing.

In addition, internal CDCR documents also indicate that CDCR would incur "service costs and attorney fees" to purchase any chemicals. *See id.* at PRIV 007718 (April 16, 2014 email from CDCR attorney Kelly McClease discussing potential source of pentobarbital: "In addition [to the cost per 500 mg], there would be fees to cover the source's service costs and attorney fees.").

Thus, CDCR's estimate understates (1) the cost per gram, (2) the number of grams it needs to acquire for each execution, and (3) service costs and attorney fees associated with each purchase.

e. Cost of Testing Lethal Injection Chemical

CDCR bases most of its fiscal estimate on the costs of "previous executions." *See* ISOR at 9. But in the past, CDCR has sent the lethal injection chemical to outside laboratories for testing, at a cost of $1,600, as evidenced by documents obtained through a Public Records Act Request. *See* Exhibit 15 at PRIV 015253. The fiscal estimate needs to reflect (1) increased cost of acquiring additional amounts of the Lethal Injection Chemical for testing,[18] and (2) laboratory costs of testing.

f. Unique Costs Attributable to Compounded Drugs

It is highly likely that CDCR will use compounded drugs. *See supra* Part III-B-10-b. But the fiscal estimate fails to address the unique costs associated with compounded drugs, costs of which CDCR is aware. CDCR previously considered compounding pancuronium bromide (under its prior protocol). A memo from CDCR's general counsel explained that there are "considerably more costs associated with" compounding than purchasing a manufactured drug, and that these "costs include the compounding pharmacy mixing, testing by a third-party laboratory, and submission for FDA review." *See* Exhibit 41 at 2. The fiscal estimate must be revised to address the unique costs associated with compounded drugs.

g. Cost of Equipment

The current cost assessment does not contain any costs for equipment needed to carry out an execution. In documents obtained by the ACLU through a Public Records Act request demonstrate that CDCR maintains various cabinets, storage units and supply inventories with security, medical and record keeping equipment. *See* Exhibit 57 (inventory lists for cabinets 1, 2, and 4).[19] As noted above, the inventory refers to a video camera that has been "removed." *See supra* Part III-D-7 and Exhibit 49. This video camera will have to be replaced. Costs for the items in its inventory have not been accounted for in the current fiscal assessment.

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[18] CDCR estimates that it will purchase 60 grams of the chemical, based on 37.5 grams to carry out the execution plus 22.5 grams for training. *See* ISOR at 10. The 60-gram estimate does not account for additional amounts that would have to be sent to a lab for testing.

[19] The documents attached as Exhibit 44 are excerpts from documents produced by CDCR in response to a September 4, 2015 Public Records Act request.

h. Medical Contracts

The proposed regulations state that the "CDCR may contract with medical personnel to assist with chemical selection," *see* Proposed § 3349.2(a)(2)(D), but failed to account for this cost in the fiscal assessment.

i. Training Costs

The current fiscal assessment does not fully account for training costs. The Lethal Injection Team is comprised of *at least* 12 full-time CDCR employees, Proposed § 3349.2(a)(2), who, when not involved in their ordinary duties, have entirely different jobs within the Department.[20] When they are fulfilling their duties as Lethal Injection Team members, such as the mandatory monthly trainings for a *minimum* of eight hours, *id*. § 3349.3(c)(1), other CDCR staff will have to fill in. CDCR acknowledges the relevance of training costs. *See* ISOR at 11, 12. But it accounts only for training associated with a 12-member Lethal Injection Team that undergoes the *minimum* amount of training. But as discussed further below, *see infra* Part III-G-j, execution teams in the past have been more than twice the size—30 members. Nor does the fiscal estimate address transportation and overtime costs associated with annual training. The ordinary work assignments of Lethal Injection Team members may be at CDCR facilities across the state. *See* Proposed § 3349.2(c)(1) (criteria for selection of Lethal Injection Team members includes "[p]ermanent full time CDCR employee or contracted employee"; criteria do not specify particular CDCR facilities). Lethal Injection Team members may therefore have to travel to attend trainings. The cost of travel (mileage, airfare, hotel, meals) and time associated with travel, including possibly overtime, is not reflected in the fiscal estimate.

j. Staff Time and Ancillary Costs During Execution

The current fiscal assessment does not fully account for staffing costs during an execution, or during pre- and post- execution procedures.

The ISOR estimates that the Lethal Injection Team will have to work four hours of overtime on the day of the execution. *See* ISOR at 11. It further estimates that eight custody staff will provide security for the Lethal Injection facility in the three days preceding the execution, and work four hours of overtime on the day of the execution and that seven additional custody staff will work eight hours to perform various security functions on the day of the execution. *See* ISOR at 11-12. Finally, it provides estimates for "Additional Staff" and "Miscellaneous Ancillary Staff" "based on information from prior executions provided by San Quentin State Prison." *See id.* at 12.

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[20] The proposed regulations also authorize the use of contracted medical personnel, but only if no "qualified state civil service employee … is available and willing to perform the prescribed duties." Proposed § 3349.2(a)(2)(A), (D).

CDCR's estimates related to costs of the Lethal Injection Team are less than *half* what they should be, both with respect to the estimated number of hours and the estimated number of team members.

It is unclear why CDCR has provided staffing costs for the Lethal Injection Team associated with only four hours of overtime, but has excluded the cost of a regular eight-hour shift on the day of the execution. It is also unclear how the four-hour estimate for overtime was derived. CDCR provides no information to substantiate this estimate. Given the many pre- and post-execution procedures set forth in the proposed regulations (such as additional staff to tend to witnesses in the viewing rooms and handle media), it is entirely likely that four hours is a significant underestimate. Indeed, documents obtained from CDCR through a Public Records Act request demonstrate that CDCR incurred double the amount of overtime for the execution team (8, not 4, hours) in prior executions. *See* Exhibit 15 at PRIV009683-00984 (Siripongs execution on November 17, 1997) and PRIV 009698 (Thompson execution on July 14, 1997).

CDCR's estimate related to staffing costs for the Lethal Injection Team is also unjustified because the estimate is based on only 13 team members. *See* ISOR at 11 (estimates 4 members of infusion sub-team; 4 members of intravenous sub-team; 4 members of record-keeping sub-team; and 1 physician). In past executions, however, execution teams have consisted of more than double that number—approximately 30 members, as evidenced by CDCR's own internal fact-finding to develop the cost estimate for these regulations. *See* Exhibit 15 at PRIV 14960 (email from John Curzon discussing his experience with 13 executions at San Quentin). Nor is CDCR's estimate of 13 team members consistent with its own reasoning. It states that it based the cost estimate "on the number of staff required by the proposed regulations." *See* ISOR at 9. But the proposed regulations require a minimum of 12 Lethal Injection Team members. *See* Proposed § 3349.2(a)(2). CDCR estimated 13 members, implicitly acknowledging that it intends to use more than the minimum required by the proposed regulations. As a result, it is more reasonable to base the estimate on the actual numbers of team members in prior executions. The estimate should reflect 30, not 13, members of the Lethal Injection Team.

Additionally, documents obtained from CDCR acknowledge that "CDCR would have additional costs for the coverage for the position that the employee would normally work." *See* Exhibit 15 at PRIV 14939. Yet CDCR's fiscal estimate does not address the cost of covering the work normally done by employees who are working on the execution.

Furthermore, CDCR will very likely have to hire outside contractors for medical personnel on the lethal injection team. The California Correctional Health Care Services, Receiver's Office emailed CDCR on June 3, 2015 to ask whether it would have the opportunity to review these proposed regulations. "The reason I ask is that, given CCHCS' health care mission, there is obviously a concern about CDCR expecting that CCHCS health care providers will have any role in this process. I trust that CDCR will plan to contract with an outside clinician for any clinical services that CDCR might require related to an execution by lethal injection." *See id.* at PRIV 15817. CDCR is thus aware that it will likely have to contract out for medical services, but its fiscal estimate is based on CDCR's salary scale. The fiscal estimate

should reflect the potential need to contract out for these services, which are likely to cost substantially more than CDCR personnel.

CDCR provides no information – other than a reference to unspecified "information from prior executions provided by San Quentin State Prison" (ISOR at 12) – to shed light on the basis for its estimates. It has not put any of this "information from prior executions provided by San Quentin State Prison" in the rulemaking file. Therefore, it has failed to justify its cost estimates with substantial (or indeed any) evidence, and the evidence obtained from CDCR through a Public Records Act request and discussed above calls into question the cost estimate in the ISOR.

k. Lethal Injection Team Selection Panel

The proposed regulations require the Director – Division of Adult Institutions or designee and the Lethal Injection Team Selection Panel (comprised of the Associate Director – Reception Centers, the San Quentin Warden, and the Team Administrator) to recruit and select the Lethal Injection Team. *See* Proposed §§ 3349.1(p), 3349.2(a)(2). The required process includes reviewing applicants' qualifications, screening applicants, and interviewing prospective candidates. *See id.* §§ 3349.2(a)(2)(A), 3349.2(b). The proposed regulations also require annual reviews of Lethal Injection Team members by the Team Administrator. *See id.* § 3349.2(e). All of this requires time, none of which is accounted for in the fiscal analysis.

l. Alienists

The three-person alienist panel is tasked with interviewing and evaluating the inmate to determine sanity 20 and 7 days before a scheduled execution. *See* Proposed §§ 3349.5(d) & (h), 3349.6(a), 3349.6(b). The sanity review entails reviewing documentation, interviewing the inmate, and preparing written evaluations of the inmate. *See id.* §§ 3349.5(h)(1)-(2), 3349.6(a), 3349.6(b). Further, additional security staff may be needed for alienists to conduct interviews. All of this requires time, none of which is accounted for in the fiscal analysis. Indeed, documents obtained from a Public Records Act request demonstrate that CDCR knows that executions will result in costs associated with the alienist review, yet these are not addressed in the ISOR. An internal CDCR document itemizing execution costs states: "Additionally there is a Doctor that is flown up from San Diego to do Mental Health Assessments. This should get captured on the Execution Side of the Cost. We pay their lodging, etc." *See* Exhibit 15 at PRIV 14940.

Further, the proposed regulations authorize "[a]ttorneys [to] submit in writing any current information they believe may have a bearing on evaluating the sanity of an inmate with a scheduled execution date." Proposed § 3349.5(h)(1). The proposed regulations thus contemplate the inmate's retention of a mental health expert, but the fiscal analysis fails to account for this cost.

In short, the fiscal estimate fails to address (1) staff time related to CDCR alienists; (2) travel and out-of-pocket expenses incurred by CDCR alienists; and (3) inmate's mental health experts.

m. Prison Lock Down

Given that the San Quentin community has not experienced an execution in 10 years, it is likely that the prison will need to be locked down. The associated costs are not included in the fiscal analysis.

n. Litigation Costs

The current fiscal analysis of the proposed regulations fails to account for litigation costs that will likely result if the Office of Administrative Law approves a final regulation. *See* ISOR at 2. In the ISOR, the CDCR lays out a "brief history" which outlines 10 years of litigation in which the CDCR has defended their lethal injection regulations in state and federal court. Given this history, the fiscal assessment is inadequate because it fails to address these foreseeable costs.

o. Visiting, Telephone Calls, and Mail

The proposed regulations recognize that expedited forms of inmate communication – legal and non-legal visiting, legal and non-legal telephone calls – are needed. *See, e.g.*, Proposed §§ 3349.6(d)(5) (24-hour access to telephone for attorney contact in five days preceding execution), 3349.6(d)(6) (cell-front visitation with Chaplains and Spiritual Advisors on second or third watch or by telephone at any time); ISOR at 32 ("There is dedicated staffing to continuously monitor the inmate to respond to any inmate needs including expedited access to the Warden."). But such visiting and telephone access requires additional staffing, for example, for coordinating visits, transporting inmates to visiting rooms, escorting visitors, and staffing visiting rooms.[21] The fiscal analysis fails to account for these increased staffing costs.[22] Nor are the costs of the telephone calls – which CDCR should absorb – reflected here. As noted above, *see supra* Part III-E-4, CDCR should also absorb the costs of expedited mail, and these costs should be reflected here as well.

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[21] The proposed regulations provide that Chaplains and Spiritual Advisors may visit the inmate at the cell front. *See* Proposed § 3349.6(d)(6). But this does not preclude such visits from occurring in a visiting room, and it does not address where legal visits are to occur.

[22] The ISOR reflects costs for eight custody staff in the *three* days preceding an execution. *See* ISOR at 11. Given the lack of detail, it is impossible to ascertain whether eight staff would suffice. In any event, staffing costs for three days is clearly not adequate. Pursuant to the proposed regulations, the inmate is to be moved to the Designated Security Housing Area *five* calendar days before the execution, at which point enhanced expedited visiting and telephone access are permitted. *See* Proposed § 3349.6(d)(1), (5), (6).

p. Transportation of Inmate from Other Institutions

CDCR has failed to identify costs associated with transporting inmates to San Quentin prior to a scheduled execution from California Correctional Women's Facility ("CCWF") Corcoran, or some other correctional institution where an inmate may be housed. The associated costs include the transport vehicle, a follow car, staffing for such vehicles, gas, and any other additional security measures.

q. Transportation for Vein Assessment

The proposed regulations contemplate referral of the inmate to the Intravenous Sub-Team for a vein assessment prior to the time the inmate is moved to the Security Housing Area at San Quentin. *See* Proposed §§ 3349.5(f)(6) (San Quentin Warden to refer inmate to Intravenous Sub-Team for vein assessment upon receipt of the execution warrant), 3349.6(d)(1) (male inmate moved 5 days prior to execution); 3349.6(e) (female inmate moved between 72 and 12 hours prior to execution). It is not clear where the members of the Intravenous Sub-Team will ordinarily work. All full time CDCR employees are eligible to apply. *See id,* § 3349.2(c)(1). Thus, to the extent the inmate is housed at San Quentin but some or all of the Intravenous Sub-Team members do not ordinarily work there, either the Intravenous Sub-Team members or the inmate will have to travel. The same is true if the inmate is housed at CCWF, Corcoran, or some other correctional institution. These costs are not reflected in the fiscal analysis.

r. Additional Monitoring Staff

Upon service of the execution warrant, the proposed regulations call for various forms of enhanced monitoring of and contact with the inmate. *See* Proposed §§ 3349.5(g)(1)(A) (checks on inmate at least hourly and documentation of inmate's conduct); 3349.5(g)(1)(C) (Warden of the institution at which the inmate is housed required to visit the inmate's housing unit daily), 3349.5(g) (correctional counselor to maintain daily contact with inmate and document inmate's conduct, and monitoring all non-legal telephone calls). Although the fiscal estimate addresses staffing costs in the three days prior to the execution, *see* ISOR at 11, it does not address the increased staffing costs which the proposed regulations call for much earlier in the process (upon service of the execution warrant).

s. Additional Medical and/or Mental Health Personnel

Scheduling an execution of an inmate is likely to trigger increased needs for mental health or other medical attention. The fiscal estimate fails to account for such increased staffing costs.

t. Spiritual Advisor

As noted above, CDCR should be required, upon an inmate's request, to provide Chaplains of minority faiths not currently reflected in its staff at San Quentin. *See supra* Part III-E-3. The fiscal analysis must address these costs.

u. Female and Transgender Inmates

The proposed regulations contemplate that female inmates will be transported between 72 and 12 hours prior to an execution. *See* Proposed § 3349.6(e)(1). The proposed regulations fail to set forth protocols addressing the unique needs of female and transgender inmates. *See supra* Part III-E-2. It is not clear how various provisions in the proposed regulations would apply to females, if they have not yet even been transported to San Quentin. It is not clear where transgender inmates would be housed. In any event, the fiscal estimate should address the unique costs associated with transporting, housing, monitoring, feeding, and caring for female and transgender inmates prior to an execution.

v. Counseling and Trauma Therapy for CDCR personnel

The proposed regulations offer post trauma counseling for the Lethal Injection Team. *See* Proposed § 3349.8(k)(2). The fiscal estimate does not account for these costs, which may be substantial and on-going. As discussed above, CDCR should also make counseling more widely available to anyone who participated in an execution, not only members of the Lethal Injection Team. *See supra* Part III-F-3. These additional counseling costs must be included in the fiscal estimate as well.

w. Costs of Lethal Injection Consultant

As described in the ACLU's separately submitted procedural comments, CDCR retained a consultant to assist in the development of its lethal injection regulations. *See* ACLU Procedural Comments at Section III-A-2. In response to a Public Records Request by the ACLU for records relating to that consultant, CDCR produced documents revealing that it has entered into two consulting contracts totaling $650,000 from Fiscal Year 2011-12 through 2016-17. *See* Exhibit 63 (May 10, 2016 ACLU Public Records Act request for information related to lethal injection consultant and CDCR's response thereto). In order to implement these regulations, CDCR had to develop them. Costs associated with developing these regulations are necessarily therefore implementation costs. Moreover, it appears that CDCR will use the consultant to provide advice on an on-going basis as CDCR seeks to implement these regulations (after they are adopted). The fiscal estimate fails to identify CDCR's initial and on-going implementation costs associated with its retained consultant.

3. Inadequate Assessment of Impact on Health and Welfare of California Residents pursuant to Government Code § 11346.3(b)(1)(D)

Government Code section 11346.3(b)(1)(D) requires the agency promulgating a regulation to prepare an "economic impact assessment that assesses whether and to what extent [the proposed regulation] will affect," among other things "the benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment." Cal. Gov't Code § 11346.3(b)(1)(D). CDCR has failed to analyze the impact of the proposed regulations on "the health and welfare of California residents." The current assessment in the ISOR is therefore inadequate.

In 2012, 48% of California voters (or roughly 5.97 million residents) voted yes on Proposition 34 to replace the death penalty with life in prison without parole and to end executions. *See* Exhibit 58 (official Proposition 34 election results, California Secretary of State). According to the 2012 Voter Guide, Proposition "34 guarantees we never execute an innocent person by replacing California's broken death penalty with life in prison without possibility of parole. It makes killers work and pay court-ordered restitution to victims. 34 saves wasted tax dollars and directs $100 million to law enforcement to solve rapes and murders." *See* Exhibit 59 (Proposition 34 Quick-Reference Guide). The LAO estimated that passage of Prop 34 would result in state savings up to $100-130 million dollars annually (note that their 2015 analysis of the pending proposed initiative to repeal the death penalty figures annual statewide savings to be $150 million). *See supra* Exhibit 53. Given that a core argument in the 2012 campaign focused on cost savings and re-routing millions of dollars of taxpayer money to improve public safety, 5.97 million people in California have affirmatively said they do not want their tax dollars to be used to resume executions and would rather this money be used to improve public safety, including solving more rape and murder cases. The ISOR fails to account for the will of these voters by failing to include an assessment of the impact of these regulations on the welfare of California residents.

In addition, these regulations have a significant adverse impact on the welfare of innocent Californians, who may be executed if executions are resumed in this State. Since 1973, 156 people have been exonerated from death rows in the United States after they were found innocent. Three individuals came from California. In April 2014, the National Academy of Sciences ("NAS Study") issued a study finding that at least 4.1% of defendants sentenced to death in the United States are innocent. There are currently 745 people on death row in California. Based on the NAS Study, 30 individuals sentenced to death in California could be innocent and at risk of being wrongfully executed if executions resume under this proposed regulation. In addition, for the last 10 years, California counties have sent an average of 17 new individuals to death row, which could potentially add one innocent person to death row every two years. In the current fiscal analysis, the CDCR failed to assess the impact of these regulations on people who may be innocent given these shocking national statistics. *See* Exhibit

60 (Samuel Gross et al., *Rate of false conviction of criminal defendants who are sentenced to death*, PNAS, Vol. 111, No. 20 (2014)).

3. Inadequate Determination of Impact on Business Enterprises pursuant to Government Code § 11346.3(a)(3) & § 11346.5(a)(8)

CDCR states that "The Department has made an initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting business, including the ability to compete with businesses in other states, because the proposed regulations relate strictly to the internal management of state prisons." Notice of Proposed Regulations at 5.

But the statute provides that in making a determination of no adverse impact, "the agency shall provide in the record facts, evidence, documents, testimony or other evidence upon which the agency relies to support its initial determination." Cal. Gov't Code § 11346.5(a)(8). CDCR has offered no "evidence, documents, testimony, or other evidence" to support its determination.

Moreover, the premise on which its determination is based is not true. These proposed regulations do not "relate strictly to the internal management of state prisons."

First, this assertion is foreclosed as a matter of law. The APA does not apply to "[a] regulation that relates only to the internal management of the state agency." Gov't Code § 11340.9(d). The Court of Appeal in *Morales v. Calif. Dep't of Corr. & Rehab.*, 168 Cal. App. 4th 729 (2008), concluded, however, that the APA does apply to lethal injection protocols. CDCR's assertion has thus implicitly been rejected by *Morales.*[23]

Second, implementation of these regulations would entail at a minimum, the acquisition of commercial products from pharmaceutical companies. CDCR clearly contemplates potentially purchasing the drug from a distributor, *see* Proposed § 3349.5(f)(1)(D) ("The San Quentin Warden shall ensure that the lethal injection chemical is obtained from a licensed

[23] CDCR raised the APA's internal management exception in for the first time in its reply brief on appeal. *Id.* at 740-41. Although the court of appeal found the argument waived, CDCR's argument in favor of the exception in that case demonstrates why these proposed regulations do not relate strictly to the internal management of state prisons. In *Morales*, CDCR argued that the protocol at issue regarding selection of the lethal injection team fell under the internal management exception because the "execution-team selection process…merely identifies which prisons employees are eligible to perform one of many state functions that concern inmates." *Id.* at 740-41. Here, by contrast, the proposed regulations expressly contemplate the use of contracted personnel who are not CDCR employees. *See* Proposed § 3349.2(a)(2)(D). In addition, the proposed regulations contemplate the use of "private non-state compound[ing] pharmac[ies]." ISOR at 10. Thus, these proposed regulations fall outside the scope of CDCR's own efforts to justify why they relate to the internal management of the prisons.

pharmaceutical facility or distributor."), or using "a private non-state compound[ing] pharmacy." ISOR at 10. Acquisition of commercial products is not strictly an internal prison management issue.

Third, a number of companies have placed distribution controls on their products in an attempt to block their use in executions. *See* Exhibit 13 and 14; *see also* Exhibit 61 (statements from Akorn, Par, Pfizer, and Sagent). The fact that they have had to take these extraordinary measures—including but not limited to the issuance of press releases, extensive outreach to scores of corrections departments across the country, implementation of controls on their distribution chains—has necessarily required these companies to divert extensive resources from their core business operations. The CDCR has failed to account for the potential impact lethal injection has already had on these businesses, and the potential impact the proposed regulations could have on California based pharmaceutical companies or compounding pharmacies operating in California. Affected pharmaceutical companies, such as Valeant, Pfizer, and Par, have California-based operations. *See* Exhibit 62 (information regarding location of Valeant, Pfizer, and Par operations).

In addition, implementation of the proposed regulations will result in additional state and local costs due to the resumption of clemency proceedings, and the CDCR has not accounted for these costs in the current rulemaking package. In addition to these state and local costs, implementation of the proposed regulations will also have a significant financial impact on private defense counsel appointed to investigate and prepare a clemency petitions. The proposed regulations offer no financial scheme to compensate counsel, and no costs estimated for compensating counsel or any other members of the defense team, including investigators, spiritual advisors, defense mental health experts, or any other needed team members, despite the fact that currently, all condemned inmates save one is indigent. As such, the proposed regulation presents a significant financial burden on panel attorneys qualified to take capital cases.

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III. Conclusion

For the foregoing reasons, the proposed regulations are deeply flawed and should not be adopted absent major revisions. CDCR must undertake a meaningful study of the history of lethal injection drug acquisition by this and other states, as well as botched executions across the country, and draft regulations that would prevent mistakes that are clearly foreseeable – mistakes that the current proposed regulations plainly invite. The proposed regulations must also address the many other flaws identified in these comments. Because the necessary revisions are so radical, CDCR should decline to proceed with the proposed action and begin the rulemaking process anew. *See* Cal. Gov't Code § 11347 (agency may "decide[] not proceed with the proposed action"). If it does not, OAL should disapprove these regulations.

Sincerely,

Linda Lye
Senior Staff Attorney

Ana Zamora
Criminal Justice Policy Director

Enclosure (1 DVD with exhibit list and Exhibits 1 through 63)

Exhibits to ACLU of California Substantive Comments

1. News coverage related to national drug shortage

2. News coverage related to the impact of the drug shortage

3. News coverage related to postponement of execution of Albert Brown

4. News coverage related to drugs obtained from Kayem Pharmaceutical

5. Ryan Gabrielson, *Lethal injection drug tied to London wholesaler*, California Watch, January 7, 2011

6. Katie Zezima, *Two more states turn over drug used in executions*, The New York Times, April 1, 2011

7. CDCR records related to drug swap between California and Arizona

8. Carol Williams, *California Imports drug used in executions, awaits FDA approval*, Los Angeles Times, December 7, 2012

9. Bob Egelko, *California refuses to return execution drug to FDA*, SF Gate, May 27, 2012; April 6, 2012 Letter from FDA to CDCR; May 1, 2012 Letter from CDCR to FDA

10. Howard Mintz, *California abandons defense of three-drug executions*, San Jose Mercury News, July 11, 2013

11. News coverage related to 2015 Arizona and Texas drug seizures

12. News coverage related to Chris Harris and Harris Pharma

13. Information from FDA website and approved manufacturers regarding pentobarbital

14. Information from Valeant regarding distribution controls

15. Excerpts of CDCR May 4, 2016 document production in response to ACLU Public Records Act request

16. DEA Consumer Alert: Report Suspected Unlawful Sales of Pharmaceutical Drugs on the Internet

17. Ryan Gabrielson, *State withholds name of lethal drug supplier*, California Watch, December 17, 2010

18. News coverage related to Clayton Lockett execution

19. News coverage related to Romell Broom execution

20. *Ohio v. Broom*, Slip. Op.

21. News coverage related to Charles Warner execution

22. News coverage related to Richard Glossip drug mix-up and grand jury investigation

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