State of California

Department of Corrections and Rehabilitation

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Memorandum

Date: March 16, 2012

To: Matthew Cate
Secretary

Via: Benjamin T. Rice
General Counsel
Office of Legal Affairs

Subject: **PROCUREMENT OF PANCURONIUM BROMIDE**
Matter ID No. 2006-000356
Lethal Injection

ISSUE

Pursuant to the California Penal Code, section 3600 et seq., the California Department of Corrections and Rehabilitation (CDCR) is charged with carrying out a sentence of death on behalf of the State of California. Existing law provides that a person sentenced to death shall have the opportunity to elect to have the punishment imposed by lethal gas or by an intravenous injection of a substance or substances in a lethal quantity sufficient to cause death, by standards established under the direction of the Department of Corrections. While the statute leaves the choice of substance or substances entirely up to the CDCR's judgment, the California Code of Regulations, title 15, section 3349.4.3(b)(2) specifically identifies three chemicals in express quantities to be utilized in combination to perform a lethal injection. One of these is Pancuronium Bromide. In addition, the Lethal Injection Team is required to practice with the execution chemicals in order to remain in compliance with the regulations. (Cal. Code Regs., tit 15, § 3349.1.4(c)(4)(A).)

CDCR's supply of Pancuronium Bromide recently expired. While it appears that a supply of Pancuronium Bromide may be available sometime in the future, it may not be available in packaging that allows use in an execution. Sale or trade appears inadequate to secure a viable supply. Therefore, I recommend procuring the raw ingredients and contracting with a compounding pharmacy to ensure that a stock of Pancuronium Bromide is available.

AVAILABLE SUPPLIES

At this time, the Food and Drug Administration website lists Pancuronium Bromide as backordered until March 2012 due to recall for contamination. However, four drug companies have discontinued making the drug. In addition, an exhaustive search has been conducted by the Department's expert. If the backorder issue resolves, an available supply of Pancuronium Bromide may surface that currently is not apparent. It is more likely that available amounts will remain extremely limited and packaging will remain un-amenable to the State's needs. Of the companies still known to make Pancuronium Bromide, the only sources located and currently produced are prepackaged as premeasured 1 or 2 milligram syringes. It takes 50 mg of Pancuronium Bromide for each tray and two trays per lethal injection execution. The 1 mg syringe packaging is not feasible because it would require 50 syringes per tray and two trays

per execution. The 2 mg packaging provides no answer, either. The syringe contents may not be transferred to a different delivery because of regulation requirements to adhere to the drug companies' packaging instructions. As a result, the substantial difference in amounts and regulation requirements to adhere to drug company packaging instructions, as well as general issues of contamination and the likelihood of a legal challenge, preclude transfer to a different delivery system. Consequently, the prepackaged syringes make these impossible to use for the purpose of conducting a lethal injection.

SALE OR TRADE

One option considered is either sale or trade of Thiopental with other states in exchange for a supply of Pancuronium Bromide. However, sister states have similar shortage issues with Pancuronium Bromide. In addition, only five percent (5%) of the Department's Thiopental supply may be sold or traded annually. Interstate trade triggers oversight by the FDA. Previously, the FDA detained California's imported Thiopental before finally releasing it subject to their indication that they "…do[] not review or approve products for the purpose of lethal injection". (FDA letter January 7, 2011.) Other than California, every state that imported Thiopental and transported to another state has had their supply of Thiopental seized by the DEA. California properly imported under DEA requirements, but interstate trade could trigger further challenges by the DEA or FDA. Thus, this option is not believed a reasonable alternative to resolve the issue.

OTHER OPTIONS

The Department has been able to locate a supply of the raw ingredients. A licensed compounding pharmacy can be contracted to mix the Pancuronium Bromide. Once mixed, the chemical must be submitted for testing to an independent lab. Testing results must then be submitted to the FDA for assessment against the U.S. requirements for Pancuronium Bromide to verify that it meets U.S. standards. Once the FDA signs off, the pharmacy may only issue the resulting Pancuronium Bromide with a 180-day expiration from the date of the FDA signoff. The mixing, testing, and FDA approval process takes approximately 14 days, provided that there are no delays. Because costs include the compounding pharmacy mixing, testing by a third-party laboratory, and submission for FDA review, there are considerably more costs associated with this avenue. However, the base products if purchased today would have a shelf life expiration of approximately two years and may be mixed upon request.

FURTHER CONSIDERATIONS

The Department's supply of Thiopental expires in 2014. At that time, it will be necessary to locate a fresh supply. Europe has recently implemented a ban on export to correctional institutions for use in executions. Therefore, it is impossible to look to the prior source to procure additional chemicals in the future. However, the department has possibly located a new source in China which has no prohibition to export to correctional institutions. The department would need to explore this possible option before any concrete conclusion can be drawn as to whether this avenue is available to obtain additional supplies once the current stock expires.

The department might consider using a generic form of thiopental (industry trade mark name, Pentothal, a brand of Thiopental Sodium). There are a number of possible generics for this chemical. The department would have to explore whether these generics have the same potency and could be used in an execution as alternatives. It is unclear whether the regulation would have to be modified to permit the use of a generic version of thiopental and therefore trigger the Administrative Procedures Act (APA).

If the department is unable to locate an alternate source for thiopental or find available generics which are compatible with use in an execution, another option would be to modify the regulations and expand the named chemical options. A number of substitute anesthetics or barbiturates could be considered. More than one option could be listed on the regulation and discretion given to the department to choose which chemical would be used. Modification of the regulation would trigger the APA and require the department to promulgate any change in compliance with the statute, requiring a public hearing and comment period before the amendment could be adopted. In addition, a regulation permitting the department discretion to choose which chemical to use presents a possible constitutional challenge. The federal Ninth Circuit Court of Appeal recently considered a Fourteenth Amendment Equal Protection Clause challenge to Arizona's protocol. The protocol granted the Director discretion regarding the manner in which an execution would be carried out; i.e., in part, the discretion to choose either a three- or one-drug method, using either sodium pentothal or pentobarbital. While the court upheld the Arizona protocol's discretion component, it said,

> That is not to say that there could not be exercises of discretion that do burden the right to be free of cruel and unusual punishment. The contrast with the litigation surrounding Ohio's lethal injection protocol, invoked by [plaintiff's] in support of their fundamental rights Equal Protection argument, is instructive. In those cases, plaintiffs were able to show an actual pattern of treating prisoners differently in ways that did affect the *risk* of pain to which they would be subjected, and therefore, the *risk* of being subjected to cruel and unusual punishment.

CONCLUSION

At this time, no guaranteed supply of Pancuronium Bromide has been located. While the FDA website suggests that the severe shortage of this chemical are due to contamination, inquiries by the Department's contracted expert have suggested that the pharmaceutical companies which have previously made this substance are actively phasing it out and those supplies which may remain will be packaged in a manner as to be incompatible with use in an execution. Because the only reliable means by which the department can assure a supply at this time is to procure the raw materials, I recommend purchasing the ingredients and contracting with a compounding pharmacy to, upon request, mix the chemical, have it independently tested, and submit it for FDA approval.

If you have any questions relating to this matter, please do not hesitate to contact me at (916) 323-5448.

KELLY L. McCLEASE
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Attachment: FDA letter