

OFFICE OF LEGAL AFFAIRS

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May 1, 2012

Mr. Domenic J. Veneziano
Director, Division of Import Operations and Policy
Department of Health and Human Services
Food & Drug Administration
12420 Parklawn Drive, Room 3109
Rockville, MD 20857

Dear Mr. Veneziano:

This is subsequent to our conversation on April 17, 2012, and to respond to your letter dated April 6, 2012, requesting that the California Department of Corrections and Rehabilitation (CDCR) contact you to make arrangements for the return to the Food and Drug Administration (FDA) of "any foreign-manufactured thiopental" in the CDCR's possession.

The CDCR has determined that it is unable to acquiesce to the FDA's request. The CDCR is not a defendant in *Cook v. FDA* (formerly *Beatty v. FDA*), and is not under the court's jurisdiction.

The CDCR also believes that the holding in *Cook* was contrary to the United States Supreme Court decision *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). In *Heckler*, the Supreme Court looked at the issue of whether, under the circumstances, a state's execution statute conflicted with federal drug statutes. The Court held that there was a presumption of unreviewability of agency decisions not to undertake enforcement action, and that Congress, under the provisions of the federal FDA Act, gave complete authority to the Secretary of Health and Human Services "to decide how and when" the Act is to be enforced. Accordingly, the CDCR does not believe that state execution statutes and procedures were intended to be part of the drug regulatory design. For that reason, the CDCR urges the FDA to appeal the *Cook* decision and order.

The CDCR is unaware of any laws or imperative that would require it to return the thiopental in its possession. The Drug Control Act and the Pharmacy Practice Act were designed to prevent the illicit sale or distribution of controlled substances and to provide a scheme for drug abuse control. These purposes would not be served or advanced by a strained interpretation making them applicable to a state's execution statutes or protocols. The CDCR is committed to enforcing the laws of the State of California. Given the CDCR's statutory responsibilities, and because the Department believes that the decision in *Cook* is contrary to law, the CDCR must decline to return the thiopental in its possession at this time.

If you have any questions, please call me at (916) 323-6001.

Sincerely,

A handwritten signature in black ink, appearing to read "Ben T. Rice". The signature is fluid and cursive, with a large loop at the end.

BENJAMIN T. RICE
General Counsel
California Department of Corrections and Rehabilitation