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February 2, 2011

**CONTACT**

NATIONAL NEWS MEDIA:

Bradford A. Berenson, Partner, 202.736.8971

bberenson@sidley.com

STATE AND LOCAL NEWS MEDIA:

Janet Zagorin, Director of Practice Development, 212.839.8797

jzagorin@sidley.com

# *Lawsuit Filed Against FDA To Prohibit The Importation And Use Of Unapproved Sodium Thiopental In Lethal Injections*

Washington, D.C. – Today, on behalf of six death-row prisoners from California, Arizona, and Tennessee, Sidley Austin LLP filed suit against the Food and Drug Administration (FDA) seeking to prohibit FDA from allowing the importation or use of unapproved sodium thiopental. During the past year, FDA has knowingly permitted unapproved sodium thiopental to be imported by state corrections agencies for use in executions by lethal injection. According to Bradford A. Berenson, a partner in the firm's Washington, D.C. office, "The law requires FDA to ensure that only safe, effective drugs are brought into the United States. When the agency allowed states to import unapproved sodium thiopental, it abdicated its responsibilities and violated federal law."

The Complaint alleges that FDA is required to deny admission to any drug that is unapproved, misbranded, or adulterated. Sodium thiopental recently imported by various states for use in lethal injections is all three. Because sodium thiopental has not been approved by FDA—meaning that FDA has made no determination of its safety, effectiveness, purity, potency, or any other characteristic—it cannot legally be imported into the United States. Plaintiffs allege that FDA has violated U.S. federal law and acted in a manner inconsistent with its own prior policies and practices by allowing importation of the unapproved drug.

Berenson noted that the lawsuit is "not about halting executions but rather about ensuring that illegal drugs are not used in carrying out otherwise lawful sentences." Because unapproved sodium thiopental has not been shown to work as intended, using it in executions creates unacceptable risks that prisoners will not be properly anesthetized before the other drugs used in lethal injection protocols stop the prisoners' breathing and induce cardiac arrest. "Whatever one's views may be on the death penalty, no reasonable person is in favor of botched or inhumane executions," Berenson said.

"Ineffective anesthesia that subjects condemned prisoners to needless, and indeed unconstitutional, suffering serves no one's interests, least of all the states'."

FDA's decision to allow the importation of unapproved sodium thiopental is unprecedented. The clear command of the federal Food, Drug, and Cosmetic Act (FDCA) is that no unapproved drug may be imported. For that reason, FDA has consistently maintained that no one—including state governments—may lawfully import unapproved drugs for commercial use. In fact, in other contexts, FDA has repeatedly sent letters to state and local governments, denied permission requests, and taken law enforcement measures against states and firms seeking to import unapproved drugs.

Today's lawsuit asks the federal district court in Washington, D.C. to declare that FDA has violated the law, enjoin it from allowing any further shipments of unapproved sodium thiopental into the United States, and take reasonable steps to recover and destroy the unlawful, unapproved product previously admitted for use by the states. According to Coleen Klasmeier, a partner in Sidley's Washington D.C. office and head of the firm's Food, Drug and Medical Device Regulatory practice, "Assuring drug safety and efficacy is the bedrock of FDA's public health mission. We are asking FDA only to fulfill its duty to secure the border against the unlawful importation of potentially substandard and dangerous unapproved drugs."

Records obtained through requests under various open records laws show that large amounts of unapproved sodium thiopental have been imported into the U.S. by at least five states with the knowledge and acquiescence of FDA. The records suggest that the imported drug was manufactured in Austria and sold by a broker sharing space with a driving school in London to state officials in Arizona, Arkansas, California, Georgia, and Tennessee. Nebraska recently announced that it obtained the drug from India.

Sodium thiopental for injection has never been approved for use by FDA, and there are currently no domestic producers of the drug. There are, however, adequate FDA-approved alternatives available for use in lethal injections.