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February 16, 2011

By Facsimile (without enclosure) and Courier

The Honorable Eric H. Holder, Jr.
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Re: Sodium Thiopental

Dear General Holder:

We write in response to a letter dated January 25, 2011, in which thirteen state attorneys general requested information and other assistance from your office that would facilitate the states' procuring sodium thiopental for use in lethal injection. That letter failed to note that litigation is currently pending alleging that the process by which three states (including Tennessee, a signatory to the letter) were permitted to obtain sodium thiopental violated federal law. We write to apprise you of that litigation and its relevance to the request made by the states, and to suggest that your role as Attorney General may require a course of action opposite from the one urged upon you by the states.

We represent death-row prisoners in California, Arizona, and Tennessee in litigation currently pending in the United States District Court for the District of Columbia against the Food and Drug Administration (FDA) and related defendants. The lawsuit seeks declaratory and injunctive relief, primarily on the ground that FDA violated 21 U.S.C. § 381(a) in allowing sodium thiopental into United States commerce for use in lethal injection. *See Beaty v. FDA*, No. 1:11-cv-00289 (D.D.C. filed Feb. 2, 2011). A copy of our complaint is enclosed.

At the core of our claims is the fact, also unaddressed in the January 25 letter from the states, that sodium thiopental is an illegal product in the United States. It has never been reviewed or approved for use by the FDA. This means that, in statutory terms, it is an unapproved new drug within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 321(p), 355(a). It is also a misbranded and

adulterated drug, the distribution of which constitutes a distinct legal violation. At issue in the litigation is not whether sodium thiopental is legal—we believe that FDA agrees it is not—but rather FDA's decision to permit sodium thiopental to enter the United States despite a clear statutory prohibition against such admission.

We believe that FDA was statutorily required to deny admission into the United States of unapproved sodium thiopental, whether for use in lethal injection or otherwise under 21 U.S.C. § 381(a)(3). The language of that statutory provision is unequivocal on this point. There is no exception for lethal injection or for uses which the FDA believes fall outside its public health mandate. Moreover, despite FDA's claim that lethal injection somehow falls entirely outside its public health mission, it is important to understand that the purpose of sodium thiopental in lethal injections is precisely the same as in all other medical uses: anesthesia.

FDA's decision to permit entry of the unapproved sodium thiopental into the United States notwithstanding the statutory prohibition is, we believe, a clear violation of federal law. For the same reason, the states' letter gives us serious concern. The FDCA includes broad remedial provisions that forbid both a direct violation and the causing of a prohibited act. *See* 21 U.S.C. § 331. These prohibitions are supported by criminal sanctions. Acceding to the attorneys general request would fall within the ambit of, and therefore is prohibited by, these same provisions. To put it bluntly, we believe the attorneys general are urging you to commit an illegal act.

In our view, fulfilling the duties of your office requires precisely the opposite course: ensuring that FDA abides by the clear congressional command of 21 U.S.C. § 381(a). We appreciate, of course, that your department will defend the *Beaty* lawsuit. But we hope you will agree that the prudent and responsible course for you, as the nation's chief law enforcement officer, is to deny the request of the attorneys general for assistance in procuring additional quantities of illegal sodium thiopental and indeed to ensure that no further importation of unapproved sodium thiopental occurs while the matter is under review by the courts. The federal interest in securing our Nation's borders against unapproved medical products easily outweighs the interest of certain states in importing illegal drugs to accelerate lethal injections, particularly given the ready availability of lawful substitutes.[1]

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[1] Ohio recently announced that, rather than violate federal law by importing illegal sodium thiopental, it would switch to an FDA-approved, domestically available alternative. *See, e.g.*, Andrew Welsh-Huggins, *Ohio to Use Assisted-Suicide Drug In Executions*, AOL News (AP), Jan. 25, 2011, www.aolnews.com/2011/01/25/ohio-to-use-surgical-drug-pentobarbital-in-lethal-injections/ (last visited

We therefore respectfully request that you deny the request of the attorneys general in the January 25 letter. If you elect to give the attorneys general the opportunity to discuss the sodium thiopental issue with you or your staff, we further request the opportunity to participate in that discussion or, at a minimum, to receive equal time to explain our views and respond to any questions the Department may have.

Sincerely yours,

Bradford A. Berenson
Coleen Klasmeier
Sidley Austin LLP

DALE A. BAICH /bab

Dale A. Baich
Office of the Federal Public Defender
for the District of Arizona

Enclosure

cc: Gerald C. Kell (without enclosure)
Ralph S. Tyler (without enclosure)
Eric M. Blumberg (without enclosure)

Feb. 15, 2011). Ohio's action belies the claim of the thirteen attorneys general that they will be "unable to perform executions" without sodium thiopental.