

October 9, 2015

Via email ([Domenic.veneziano@fda.hhs.gov](mailto:Domenic.veneziano@fda.hhs.gov))

CAPT Domenic J. Veneziano  
Director, Division of Import Operation  
United States Public Health Service  
Food and Drug Administration  
Department of Health and Human Services  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Re: Importation of sodium thiopental

Dear Captain Veneziano:

Your June 26, 2015 letter to Director of the Ohio Department of Rehabilitation and Correction (ODRC), Gary Mohr, referenced some unspecified information you had received about Ohio's "inten[t] to obtain bulk and finished dosage forms of sodium thiopental." Based on this information, you referenced two federal court decisions, *Beatty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012) and *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013), and sought to "remind [Ohio] of the applicable legal framework" for importation of sodium thiopental. Contrary to the implication in your letter that the importation of sodium thiopental is currently prohibited, there is a legal framework for a state, if it so chooses, to import sodium thiopental in accordance with both the federal Food, Drug, and Cosmetic Act (FDCA) and the June 2012 Court Order issued by Judge Leon in *Beatty*. Further, please be advised that if at some point in the future the State of Ohio should choose to pursue the importation of sodium thiopental or any other drug that may be used to carry out a sentence of lethal injection, Ohio has no intention of breaking any federal laws or violating any court orders in an attempt to procure the legal drugs necessary to carry out constitutionally approved and court-ordered death sentences.

The death penalty, though much debated and litigated over the years, has routinely been held by United States Supreme Court to be constitutional. Moreover, while the preferred methods of execution have changed, the United States Supreme Court has never invalidated a State's chosen procedure. *Glossip v. Gross*, 576 U.S. (2015), No. 14-7955 (June 29, 2015), slip at 3. Lethal injection, the method required by Ohio law, has specifically been found to be

constitutional on two separate occasions. *Baze v. Rees*, 553 U.S. 35 (2008) and *Glossip, supra*. Given these realities, the Supreme Court recently explained, “that because it is settled that capital punishment is constitutional, [i]t necessarily follows that there must be a [constitutional] means of carrying it out.” *Glossip*, slip at 4, quoting *Baze* at 47.

In fact, when Ohio has been able to procure the drugs necessary to carry out its constitutionally approved method of capital punishment via lethal injection, it has a history of doing so humanely and efficiently. Since capital punishment was reinstated in Ohio in 1994, Ohio has successfully and humanely utilized both three-drug and single drug protocols in carrying out 52 executions. Moreover, when sodium thiopental and pentobarbital were broadly available and utilized as part of either a three drug or single drug protocol, Ohio was widely considered a responsible steward in the implementation of its capital punishment regime. Since 2009, however, it has become increasingly difficult for Ohio and many other states to secure the drugs required for these protocols. Specifically, the original manufacturer of sodium thiopental has stopped production of the drug, while the manufacturers and suppliers of pentobarbital have contractually prohibited its sale to corrections departments, like ODRC. As some of the Justices noted in *Glossip*, the severely restricted availability of these drugs is largely the result of political pressure placed upon pharmaceutical companies by anti-death penalty advocates. *See generally Glossip*, slip at 4-6.

As domestic supplies of sodium thiopental and pentobarbital have become unavailable, states with capital punishment have sought other lawful means to carry out executions. This has included production of these drugs by compounding pharmacies, the examination of execution methods other than lethal injection, and in some cases importation of drugs from foreign manufacturers. It is this final option that led death penalty opponents to sue the FDA, which ultimately led to the court decisions in *Beatty* and *Cook*.<sup>1</sup> While Ohio recognizes that the opinions in these cases have not been overruled, it is ODRC’s position that the FDA’s apparent belief that those two decisions completely prohibit the importation of sodium thiopental grossly overstates what the courts’ actual rulings were in those two decisions.

The underlying facts in the case that led to Judge Leon’s March and June 2012 Orders were these – the three states involved in *Beatty* and *Cook* attempted to import sodium thiopental from an overseas source that was **not** registered with the FDA. Because the drug source lacked proper FDA registration, the Court held that the FDA was required to stop and examine the

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<sup>1</sup> As you must be aware, prior to the decisions in *Beatty* and *Cook*, it was the FDA’s position that state correctional departments could lawfully import lethal injections drugs from overseas sources.

shipment to determine if any of the conditions outlined in 21 U.S.C. § 381(a) existed. In other words, once this statutorily mandated inspection requirement was triggered, the FDA was required to inspect the imported drugs for potential violations of the FDCA. If the FDA found any such violations existed, it was bound to refuse the drug's admission. *Cook*, 733 F.3d. at 10. In affirming the district court, *Cook* upheld the preliminary injunction entered by the *Beaty* court against the FDA.

A key fact in this litigation was the argument put forth by the FDA that it had the enforcement discretion to release drugs imported from non-FDA registered foreign manufacturers for use in lethal injections<sup>2</sup>. As ORDC understands the courts' decisions and injunction, the FDA is statutorily required to inspect any drug shipments imported from non-FDA registered foreign sources. If it is determined that such drugs are misbranded or otherwise do not conform to the FDCA or the FDA's applicable regulations, then the importation is prohibited and the drugs must be refused admission into the United States. In other words, the FDA was found not to have enforcement discretion when a drug is imported from a non-FDA registered foreign source.

Given the specific facts and parameters of those decisions, it is clear that importation of sodium thiopental is not completely prohibited by Judge Leon's 2012 Orders. That is, importation of sodium thiopental is not prohibited provided that:

- 1) The source of the sodium thiopental is an FDA-registered source, subject to FDA regulation and inspection;
- 2) The FDA-registered source of the sodium thiopental must have submitted sodium thiopental on its list of drugs in commercial distribution to the United States with the FDA;
- 3) The sodium thiopental is not misbranded;
- 4) The sodium thiopental is not adulterated; and
- 5) The FDA examines the shipment to determine if any of the conditions outlined in 21 U.S.C. 381(a) exist.

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<sup>2</sup> As noted in *Beaty*, the FDA justified its "enforcement discretion" position by indicating that the use of drugs for "state authorized lethal injection clearly [fell] outside [its] explicit public health role." *Beaty*, 853 F.Supp.2d at 35.

Thus, we believe that if a state were to attempt to import sodium thiopental under these five conditions, then the specific terms of the *Beatty* injunction would not apply. In other words, the FDA would not be permanently enjoined from permitting that shipment into the United States, and that it would be lawful and permissible for a state to proceed with such lawful importation.

The responsibility to carry out lawful and humane executions when called upon by the courts to do so is enormous, and it is a responsibility that ODRC does not take lightly. To that end, ODRC has no intention of attempting to procure drugs for lethal injection in a manner that would violate a proper interpretation of the FDCA. And, as the federal agency tasked with enforcing the FDCA and subject to the Court Order in *Beatty*, we would be happy to begin a dialog with the FDA as to how best achieve this goal.

If you have any questions of ODRC or require any additional information, please do not hesitate to contact me.

Sincerely,



Stephen C. Gray  
Chief Counsel and Managing Director of Risk Management

cc: Gary C. Mohr, Director, Ohio Department of Rehabilitation & Correction