From:	Fedorchak, Carol
To:	"blengland@fdaimports.com"; "contact@benjaminlengland.com"
Cc:	Stearn, Douglas
Subject:	sodium thiopental
Date:	Friday, June 19, 2015 6:06:00 PM
Attachments:	Thiopental-dismisscount1_order.pdf Thiopental-order1.pdf ABC NewsThiopental-Press-Article May2015.pdf Letter to Ben England sodium thiopental.pdf

Mr. England,

Please note the attached letter from Douglas Stearn, Director of Enforcement and Import Operations, regarding the regulatory status of sodium thiopental.

Carol Fedorchak / Special Assistant, Office of Enforcement and Import Operations / Office of Regulatory Affairs / FDA / ☎ 240-402-2545

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Mr. Ben England
810 Landmark Drive, Suite 126
Glen Burnie, MD 21061

JUN 19 2015

Re: Regulatory status of sodium thiopental

Dear Mr. England,

It has come to our attention that your firm, which specializes in facilitating the importation of FDA-regulated commodities, has inquired about the status of sodium thiopental. I am writing to inform you of our position on the regulatory status of this product.

Media reported that the state of Nebraska has recently purchased sodium thiopental for use by the Nebraska Department of Correctional Services. On April 10, 2012, and on May 28, 2015, FDA notified the Nebraska Department of Correctional Services of the U.S. District Court for the District of Columbia decision in *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd in part, rev'd in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). The District Court's June 2012 Order, which modified the Court's March 2012 Order, permanently enjoined FDA from permitting the entry of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved new drug in violation of 21 U.S.C. § 355. Please note that there is no FDA approved application for sodium thiopental, and it is illegal to import an unapproved new drug into the United States.

A recent ABC News article indicated that Nebraska Governor, Pete Ricketts, has recently purchased sodium thiopental.

With this letter, I would like to advise you of the applicable legal framework and that any shipment would not be allowed into U.S. commerce.

If you have any questions, I can be reached at (301) 796-3668 or by e-mail at Douglas.Stearn@fda.hhs.gov.

Respectfully,

Douglas W. Stearn -S

Digitally signed by Douglas W. Stearn -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000351437, cn=Douglas W. Stearn -S
Date: 2015.06.19 17:19:43 -04'00'

Douglas Stearn
Director, Office of Enforcement and Import Operations
Office of Regulatory Affairs

Enclosure: Order, *Beaty v. FDA*, No. 1:11-cv-00289 (RJL) (D.D.C. Mar 27, 2012)
Order, *Beaty v. FDA*, No. 1:11-cv-00289 (RJL) (D.D.C. June 22, 2012)
ABC news article dated 5/14/2015

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DONALD EDWARD BEATY, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Case No. 11-289 (RJL)**
	)	
FOOD AND DRUG ADMINISTRATION,	)	
	)	
and	)	
	)	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
	)	
and	)	
	)	
KATHLEEN SEBELIUS, in her official capacity as Secretary of the U.S. Department of Health and Human Services,	)	
	)	
and	)	
	)	
MARGARET A. HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs,	)	
	)	
Defendants.	)	

ORDER
(March 27, 2012)

For the reasons set forth in the Memorandum Opinion entered this 27th day of March, 2012, it is hereby

ORDERED that plaintiffs' Motion for Summary Judgment and Declaratory Relief on Counts I and III [#12] is **GRANTED**; and it is further

ORDERED that the defendants' Motion to Dismiss and/or for Summary Judgment [#13] is **DENIED**; and it is further

DECLARED, pursuant to 28 U.S.C. § 2201(a), that

1. the foreign manufactured thiopental (or "thiopental") imported by the importing States (e.g. Arizona, California, South Carolina, Georgia, and Tennessee) is a misbranded drug and an unapproved new drug within the meaning of the FDCA; and

2. as such, this thiopental cannot lawfully be introduced or delivered for introduction into interstate commerce or lawfully be imported into the United States; and

3. defendants' recent actions allowing such thiopental to enter the United States were each contrary to law, arbitrary, capricious, and an abuse of discretion under the APA; and, in particular,

4. defendants' January 4, 2011 announcement that they will allow future shipments of such thiopental to enter the United States is contrary to law, arbitrary, capricious, and an abuse of discretion under the APA; accordingly

IT IS HEREBY ORDERED that the FDA:

1. immediately notify any and all state correctional departments which it has reason to believe are still in possession of any foreign manufactured thiopental that the use of such drug is prohibited by law and that, that thiopental must be returned immediately to the FDA; and

2. be permanently enjoined from permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental into interstate commerce; and

IT IS FURTHER ORDERED that the parties are hereby directed to meet and confer to determine whether further litigation is necessary, or proper, with respect to the remaining count in this Complaint.

SO ORDERED.

RICHARD J. LEON
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Donald Edward BEATY, Daniel Wayne COOK, Eric J. KING, Brett Patrick PENSINGER, and Stephen Michael WEST, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Kathleen SEBELIUS, and Margaret A. HAMBURG, M.D., Defendants.	**Civil Action No. 1:11-cv-00289 (RJL)** **ECF Case**

ORDER

Upon consideration of the Unopposed Motion to Dismiss Count II, Enter Final Judgment, and Make Certain Modifications to the Court's Injunction filed by Plaintiffs in the above-captioned matter, it is this 22 day of June, 2012,

ORDERED, that the Motion is GRANTED, and it is further,

ORDERED, pursuant to Federal Rule of Civil Procedure 41(a)(2) that Count II of Plaintiffs' First Amended Complaint is dismissed without prejudice; and it is further,

ORDERED, that the sentence of the Order dated March 27, 2012 (Dkt. No. 24), stating that FDA is "permanently enjoined from permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental into interstate commerce" is hereby modified to read, "permanently enjoined from permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental that appears to be misbranded or in violation of 21 U.S.C. §§ 355," and it is further,

ORDERED, pursuant to Federal Rule of Civil Procedure 54(b) that the Clerk shall enter final judgment disposing of this action in its entirety.

Hon. Richard J. Leon
United States District Court Judge

Governor says Nebraska has ordered new death penalty drugs

By GRANT SCHULTE

May. 14, 2015 10:25 PM EDT

LINCOLN, Neb. (AP) — Nebraska's Republican governor is taking new steps to resume executions in a state that hasn't imposed the death penalty since 1997, as lawmakers look seriously at abolishing capital punishment.

Gov. Pete Ricketts said Thursday evening that state officials have bought all three drugs required to carry out executions. Nebraska lost its ability to execute prisoners when its supply of sodium thiopental, a required lethal injection drug, expired in December 2013.

The announcement comes one day before lawmakers are scheduled to debate a death penalty repeal measure that has gained more support than usual. The bill won first-round approval with a veto-proof majority in April, but two more votes are required before it goes to Ricketts, a death-penalty supporter.

Some opponents have argued that Nebraska should abolish capital punishment because it has only wasted money and created a false promise for victims' families. The state hasn't executed anyone since 1997, and some prisoners have been on death row for decades.

Nebraska has only carried out four executions since 1973, partly because of repeated legal challenges.

Ricketts and his corrections director, Scott Frakes, said the state now possesses one of the three lethal injection drugs that state law requires for executions and will receive the other two in the near future. Nebraska Attorney General Doug Peterson has said three of Nebraska's 11 death-row inmates have exhausted all of their appeals.

"The functionality of the death penalty in Nebraska has been a management issue that I have promised to resolve," Ricketts said.

Ricketts said the department has already obtained potassium chloride, a drug that stops the heart, and has bought the other two drugs — sodium thiopental and pancuronium bromide — from a distributor in West Bengal, India. Sodium thiopental serves as an anesthetic, and pancuronium bromide is a muscle relaxant that induces paralysis.

Ricketts spokesman Taylor Gage said the state ordered the drugs over the past few weeks from HarrisPharma, a distributor that has sold to state officials before. The last purchase was made this week.

Defense attorneys for Nebraska's death-row inmates have raised legal questions about the company before. One lawyer argued that Chris Harris, the company's owner, sold drugs that were only meant to be used as testing samples, and was not authorized to do so.

Because he was not allowed do so, the defense attorney argued that the drug was stolen property and Nebraska shouldn't be allowed to use it in executions.

Nebraska Solicitor General Jim Smith, who handled previous death penalty cases, said those arguments were later rejected. The Nebraska Supreme Court ruled that the argument wasn't a valid challenge in a death penalty case under state law.