11-193

Jackson, Valerie

From: O'Grady, Jordana
Sent: Wednesday, January 05, 2011 8:45 AM
To: Jackson, Valerie
Subject: FW: January 4, 2011 Letter to Margaret A. Hamburg, M.D. re: Sodium Thiopental
Importance: High
Attachments: Untitled.pdf

Jordana O'Grady
Office of the Commissioner
Food and Drug Administration
WO Building 1, Room 2217
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From: Brown, Keisha [mailto:kebrown@sidley.com]
Sent: Tuesday, January 04, 2011 4:06 PM
To: Commissioner FDA; Tyler, Ralph; Blumberg, Eric
Cc: dale_baich@fd.org; Berenson, Bradford; Klasmeier, Coleen
Subject: January 4, 2011 Letter to Margaret A. Hamburg, M.D. re: Sodium Thiopental
Importance: High

Sent on behalf of Coleen Klasmeier.

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Assistant to Coleen Klasmeier,
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communication and (ii) the taxpayer should seek advice based on the taxpayer's particular circumstances from an independent tax advisor.

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FOUNDED 1866

January 4, 2011

By Email and Federal Express

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Sodium Thiopental

Dear Dr. Hamburg:

We write on behalf of clients of the Firm regarding sodium thiopental, a rapid-onset short-acting barbiturate general anesthetic. Sodium thiopental is not generally recognized as safe and effective (GRAS/E), and it is not a "grandfathered" drug. It is, rather, an unapproved new drug, and therefore cannot be introduced, or delivered for introduction, into interstate commerce. 21 U.S.C. § 355(a). Nor can sodium thiopental presented for United States importation lawfully be admitted into domestic commerce. Id. § 381(a). Moreover, because sodium thiopental is unapproved, its safety and efficacy, whether intended for use in anesthesia induction or for other, non-medical purposes, cannot be assured. Indeed, there are ample grounds to suspect the purity and potency of sodium thiopental, based on reports of good manufacturing practice violations affecting at least one important foreign source of the product. Unapproved sodium thiopental has been associated with adverse events including anesthesia awareness (being conscious notwithstanding the administration of an anesthetic) from failure of expected pharmacological activity and tissue necrosis from improper administration technique.

Our clients are incarcerated individuals awaiting administration of sodium thiopental as part of three-drug lethal injection protocols in various States, including California, Arizona, and Tennessee. In October and November, respectively, our co-counsel Dale Baich of the Capital Habeas Unit of the Office of the Federal Public Defender for the District of Arizona sent letters to the Office of the Chief Counsel and to the Los Angeles District Office on behalf of another individual in Arizona, who has since been executed. *See* Enclosure A (Baich letters). The purpose of those letters was to encourage appropriate FDA personnel to investigate and take action to assure that ex-U.S. sources of sodium thiopental were not permitted to enter the country illegally.

We are not aware that any action has been taken in response to Mr. Baich's requests. Indeed, FDA has announced that it lacks the statutory authority to regulate sodium thiopental for this purpose, and certain agency representatives appear to have determined that the drug can be allowed into the United States as an exercise in "enforcement discretion." *See* Enclosure B (notice of FDA action reflecting agency decision to release sodium thiopental to the State of Arizona Corrections Department). We understand that additional sodium thiopental—a much larger quantity than the Arizona shipment—more recently was released upon an FDA determination to allow the drug to proceed into domestic commerce for use in lethal injection procedures in California.

We have been engaged to evaluate potential claims against FDA on behalf of our clients. Based upon our preliminary review, we believe that FDA decisions allowing the importation of sodium thiopental violate the clear terms of the FDCA. The decision whether to allow unapproved new drugs to be imported into the United States is not a matter of enforcement discretion for FDA but has instead been made by Congress itself. It is reflected directly in the text of the FDCA. Where there is no reasonable dispute that a new drug is unapproved, as is the case with sodium thiopental, FDA acts unlawfully if it allows the drug to be imported for any purpose.

In contrast to the situation in *Heckler v. Chaney*, 470 U.S. 821 (1985), which involved a petition that FDA regulate off-label use of approved drugs, here a court would have a statutory standard against which to review the agency's action (*i.e.*, 21 U.S.C. § 381(a)). *See Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 69 n.8 (D.D.C. 2010) (FDA argument that "import decisions are committed to agency discretion" went "much too far" because 21 U.S.C. § 381(a) provided "a meaningful standard" under *Heckler*), *aff'd sub nom. Sottera, Inc. v. FDA*, 2010 U.S. App. LEXIS 24883 (D.C. Cir. Dec. 7, 2010). Further, *Heckler* itself held that review would be available if FDA's decision were based on an erroneous interpretation of the scope of its statutory authority or amounted to a complete abdication of its responsibilities under the FDCA.

In litigation, our requested relief would include a court order directing FDA to forbid illegal U.S. importation of sodium thiopental. In an effort to resolve the status of sodium thiopental without resorting to litigation, we intend to seek a meeting with you and other appropriate representatives of the agency to discuss our conclusions as to the viability of our clients' claims and any potential defenses. We expect that we will be prepared to have that meeting as early as the middle of January.

In the interim, we ask that the agency decline to authorize the release into domestic commerce of any sodium thiopental, whether it is currently awaiting admission into the United States or is presented for such admission at some future time. If additional sodium thiopental were to be allowed into the country before any litigation were commenced, then it could present

a number of challenges for agency personnel if a court were to direct recovery of the drug. We believe that it would be in FDA's interest to seek to preserve the status quo by declining to authorize the release into commerce of any sodium thiopental, at least until the agency has had the opportunity to assess the strength of the legal arguments we are now developing, or perhaps, if we fail to reach agreement on an appropriate way forward, until important questions regarding FDA's responsibilities with respect to the drug can be resolved by the courts.

We expect to contact you within a matter of days to seek a meeting regarding our clients' potential claims. In the meantime, if you have questions, please feel free to contact us. Thank you for your attention to this important matter.

Very truly yours,

Coleen Klasmeier

Bradford A. Berenson/ech

Bradford A. Berenson

Dale A. Baich/ech

Dale A. Baich
Supervisor, Capital Habeas Unit
Office of the Federal Public Defender for the
District of Arizona

Enclosures

cc (w/encls.): Ralph Tyler
Rick Blumberg

A

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit
850 West Adams Street, Suite 201
Phoenix, Arizona 85007

JON M. SANDS
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October 23, 2010

via email ralph.tyler@fda.hhs.gov

Ralph S. Tyler, Chief Counsel
United States Department of Health & Human
Services, Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, Maryland 20993-0002

Dear Mr. Tyler,

I am writing you concerning an urgent matter in the State of Arizona pertaining to potential violations of the Food, Drug, and Cosmetic Act, which may result in immediate harm to an Arizona citizen.

Recently I learned that the Arizona Department of Corrections ("ADOC") may have obtained a quantity of non-FDA-approved sodium thiopental that it intends to use on a human being. The State of Arizona intends to use the non-FDA-approved sodium thiopental as one of the drugs in the planned execution of Jeffrey Landrigan, scheduled to take place at 1:00 p.m. Eastern Daylight Time on Tuesday, October 26. As discussed below, Assistant Attorney General Kent Cattani admitted to the Arizona Supreme Court that the sodium thiopental ADOC obtained for use in Mr. Landrigan's execution is not a Hospira product (which, as you know, is the only FDA-approved manufacturer of thiopental).

I am requesting that you expeditiously investigate whether the State of Arizona and its agencies are in possession of a non-FDA-approved drug, and whether the State intends to use it on a human being.

As you are undoubtedly aware, there is a shortage of sodium thiopental in the United States.[1] Hospira, Inc. ("Hospira") is the only manufacturer of sodium thiopental in the United States, and its product is the only sodium thiopental that the FDA has approved for use in this country. There are no FDA-approved manufacturers of sodium thiopental outside of the United States. Our research has revealed that Hospira manufactured its last lot of sodium thiopental in 2009.

On September 21, 2010, the Arizona Supreme Court scheduled Mr. Landrigan's execution. A few days later, Assistant Attorney General Kent Cattani stated to the press that the ADOC did not have sodium thiopental, and that he was not overly optimistic about securing the drug.[2] Mr. Cattani also stated that the ADOC had been looking not only to other states, but also to other countries, to obtain sodium thiopental.[3] On September 30, the ADOC filed a letter with the Arizona Supreme Court, reporting that it had acquired the drug, but the ADOC did not reveal its source. On October 20, Mr. Cattani admitted to the Arizona Supreme Court that the sodium thiopental the ADOC had obtained was not manufactured by Hospira.

Because we know that Hospira is the only manufacturer of sodium thiopental in the United States, and that its product is the only sodium thiopental approved for use in the United States, Mr. Cattani's admission to the Arizona Supreme Court suggests to us that the thiopental the ADOC obtained was made by a foreign manufacturer.

The FDA controls manufacture and distribution of thiopental in this country. According to Shelly Burgess, a spokesperson at the FDA, the agency "is not aware of any

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[1]See entry for "Pentothal (thiopental) Injection," http://www.fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm.

[2]Paul Davenport, *Ariz. Death Row Inmate to be Executed in October*, the Associated Press, Sept. 23, 2010, http://www.trivalleycentral.com/articles/2010/09/23/casa_grande_dispatch/around_arizona/doc4c9b81d4a0fc9230808604.txt.

[3]Michael Kiefer, *Arizona Obtains Drug Supply for Oct. Execution*, Arizona Republic, Oct. 1, 2010, http://www.azcentral.com/arizonarepublic/local/articles/2010/10/01/20101001deathdrugs1001.html.

firm currently able to supply thiopental to the U.S. . . . A company would need to submit an application to the FDA in order to be considered for approval including approval for overseas manufacturers of a drug for U.S. markets."[4] I have received the name of a local customs broker through an anonymous phone call, which was identified as the source of the sodium thiopental.[5] If this information is accurate, then ADOC's acquisition of sodium thiopental through a customs broker, would appear to be different than the FDA's understanding as expressed through the statement by Ms. Burgess.

We believe that the ADOC may violate federal law if it administers sodium thiopental that has not been approved by the FDA to Mr. Landrigan. We further believe that the ADOC, by acquiring sodium thiopental from a foreign source, directly or indirectly, may have violated the Food, Drug and Cosmetic Act ("FDCA") and the Controlled Substances Act ("CSA").[6]

The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless approval of an application . . . is effective with

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[4]Michael Kiefer, *Judge asks Arizona for execution-drug source*, Arizona Republic, October 22, 2010, http://www.azcentral.com/community/pinal/articles/2010/10/21/20101021arizona-execution-court-blocks-2nd-request.html.

[5]In the event the FDA is interested in pursuing this matter, I will provide you with the name of the local customs broker.

[6]We understand the FDA has no authority to enforce the CSA. However, a referral to the Drug Enforcement Administration may be appropriate.

If a controlled substances is imported into the United States "for medical, scientific or other legitimate uses" (here it was not), the registered importer must file a controlled substance import declaration not later than 15 calendar days prior to importation. 21 C.F.R. 1312.18(a) & (b). The declaration must include the DEA registration number of the importer and import broker, a complete description of the controlled substances, the quantity of controlled substance, DEA registration number of the recipient, date and foreign port of exportation, and the name and address of the consignor in the foreign country of exportation, and any registration or license numbers the consignor may be required to have by if the country of exportation or under U.S. law. 21 C.F.R. 1312.18(c).

respect to each drug."[7] Furthermore, the FDCA requires "foreign establishments" that manufacture drugs imported into the United States to register with the FDA.[8] To date, we have seen no indication that the ADOC applied to import sodium thiopental, or that its source of the drug is registered with the FDA.

It is our position that an execution is not a "legitimate use" that would justify importation of a non-FDA approved form of thiopental. Sodium thiopental is used to anesthetize the prisoner so that he is insensate to the pancuronium bromide and potassium chloride just as it is used in medical procedures, and the execution would be inhumane if it sodium thiopental did not work as planned.

I believe that my concerns, which pertain to matters such as drug misbranding and drug adulteration, fall under the authority of two divisions within the Office of Compliance (OCI): the Division of New Drugs and Labeling Compliance (responsible for, *inter alia*, concerns about misbranding), and the Division of Manufacturing and Product Quality (responsible for, *inter alia*, concerns about adulteration). Accordingly, I ask that you immediately refer this matter to those divisions for an emergency investigation. If those investigations demonstrate that the ADOC intends to use a non-FDA-approved product, I ask that the appropriate personnel consider obtaining a temporary restraining order ("TRO") against—at a minimum—ADOC staff, to enjoin those individuals who intend to administer the non-FDA-approved thiopental to a human being—Jeffrey T. Landrigan. *See* FDA Regulatory Procedures Manual § 6-2-3 ("FDA Recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately."). I also ask that the Office of Compliance take any further action deemed necessary under the Food, Drug, and Cosmetic Act, or any other relevant authority to prevent this and future occurrences of any violations that OCI finds.

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[7] 21 U.S.C. § 355(a).

[8] 21 U.S.C. § 360(i). At the time of registration, the foreign establishment must file with the Secretary a list of all drugs that are being "manufactured, prepared, propagated, compounded, or processed" for commercial distribution. 21 U.S.C. § 360(j)(1). If a foreign establishment lists "new drugs," in its filing, it must also provide "a reference to the authority for the marketing of such drug" and provide a copy of the labeling. 21 U.S.C. § 360(j)(1)(A).

Again, this matter is urgent. I appreciate your expeditious consideration and review of my request. You may reach me by email at dale_baich@fd.org or on my mobile at 602-625-2111 should you need any additional information.

Very truly yours,

Dale A Baich

Dale A. Baich, Supervisor
Capital Habeas Unit

DAB/kls

cc: Jeffrey T. Landrigan

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit
850 West Adams Street, Suite 201
Phoenix, Arizona 85007

JON M. SANDS
Federal Public Defender

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e-mail dale_baich@fd.org

November 17, 2010

via email, original by Federal Express

Thomas Emerick, Assistant Special Agent in Charge
United States Department of Health & Human
Services, Food and Drug Administration
Office of Criminal Investigations
201 Avenida Fabricante, Suite 200
San Clemente, California 92672

Dear Mr. Emerick,

I am writing to report the importation into the United States of non-FDA-approved sodium thiopental for sale and distribution in the state of Arizona. I have information that an Arizona importer obtained the drugs from a distributor in Britain and then sold them to the Arizona Department of Corrections ("ADOC") for use in at least one execution. I am writing to request that your office initiate an investigation into this importation of non-FDA-approved sodium thiopental for sale and distribution.

As you may know, there is a shortage of sodium thiopental in the United States.[1] Hospira, Inc. ("Hospira") is the only manufacturer of sodium thiopental in the United States, and its product is the only sodium thiopental that the FDA has approved for use in this country. There are no FDA-approved manufacturers of sodium thiopental outside of the United States. Our research has revealed that Hospira manufactured its last lot of sodium thiopental in 2009.

[1] *See* entry for "Pentothal (thiopental) Injection," http://www/fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm.

On October 25, Arizona Attorney General Terry Goddard told a reporter that the sodium thiopental the state intended to use during the upcoming execution of Jeffrey Landrigan was imported from Great Britain.[2] State officials previously confirmed that the sodium thiopental the state intended to use in the Landrigan execution was not a Hospira product. Arizona subsequently used this non-FDA-approved drug to anesthetize Mr. Landrigan in his execution on October 26, 2010.

As stated above, my understanding is that foreign-made thiopental is not approved for use on humans in this country. According to Shelly Burgess, a spokesperson at the FDA, the agency "is not aware of any firm currently able to supply thiopental to the U.S. . . . A company would need to submit an application to the FDA in order to be considered for approval including approval for overseas manufacturers of a drug for U.S. markets."[3]

I am willing to assist your investigation in any way that I can, and if you initiate an investigation and find that non-FDA-approved sodium thiopental has been imported illegally into the United States, I ask that you work with federal law enforcement to take all appropriate measures, particularly to prevent future violations of the law.

I appreciate your consideration and review of my request. You may reach me by email at dale_baich@fd.org or at 602-382-2816 should you need any additional information.

Very truly yours,

Dale A. Baich, Supervisor
Capital Habeas Unit

DAB/nar

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[2]Michael Kiefer, U.S. Supreme Court Clears Way for Execution, Arizona Republic, Oct. 26, 2010, http://www.azcentral.com/news/articles/2010/10/25/20101025 arizona-execution-temporary-halt.html

[3]Michael Kiefer, Judge asks Arizona for execution-drug source, Arizona Republic, October 22, 2010, http://www.azcentral.com/community/pinal/articles/2010/10/21/20101021 arizona-execution-court-blocks-2nd-request.html.

B

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1

Notice Number: 1
September 29, 2010

Importer:
Arizona Department Of Correction
1601 W Jefferson St
Phoenix, AZ 85007-3002

Port of Entry: 2805, Phoenix, AZ
Carrier: FEDERAL EXPRESS;
Date Received: September 29, 2010
Arrival Date: September 28, 2010
Filer of Record: [redacted]
Consignee: Arizona State Prison Complex, Florence, AZ 85232

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
001/001	THIOPENTAL SODIUM 500 MG	6 BX	Released 09-29-2010
002/001	PANCURONIUM INJECTION	450 PC	Line Split
002/001A	PANCURONIUM BROMIDE	45 BX	Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE	18 BX	Released 09-29-2010

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry 574-0250322-1. Any status changes are reflected in the Line summary and line detail sections.

[redacted]

U.S. Food & Drug Administration [redacted]@FDA.HHS.GOV
[redacted]

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: DCT