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February 24, 2011

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

Dear Mr. Attorney General:

I am writing on behalf of Andrew Grant DeYoung, who is currently on death row in Georgia. His petition for a writ of certiorari for habeas relief is pending before the U.S. Supreme Court. If his petition is denied, the Georgia Department of Corrections will schedule him for execution by lethal injection in the near future.

As described more fully below, the Georgia Department of Corrections (GDC) appears to have violated the federal Controlled Substances Act (CSA) by failing to register as an importer of the controlled substance (thiopental) used by the GDC in lethal injections and failing to submit a declaration to the Drug Enforcement Administration (DEA) when GDC imported thiopental last year. The GDC's actions call into question the legality and integrity of the process the department uses to administer lethal injections, including in the planned execution of Mr. DeYoung and the other individuals on Georgia's death row. Given these potential violations of federal law, and the implications they raise with respect to pending executions in Georgia, I respectfully urge you to direct appropriate agencies within your Department to conduct a prompt and thorough investigation of these issues.

Execution by Lethal Injection in Georgia

Lethal injection currently is the only authorized means of execution in Georgia.¹ The state legislature has delegated to the GDC responsibility for developing specific protocols for carrying out lethal injections.² The current GDC protocols call for the administration, in sequence, of three drugs. First, thiopental (sodium pentothal), a Schedule III nonnarcotic controlled substance, is administered to anesthetize the person. Second, the person is paralyzed by the administration of pancurium bromide. Finally, potassium chloride is injected to stop the person's heart from beating. The proper administration of a full dose of thiopental is critical to ensure that the individual does not experience intense pain that would otherwise result from the administration of drugs that paralyze all voluntary muscles and heart functions.

Federal Laws Prohibit the Importation of Controlled Substances by Unregistered Persons

Since 1970, federal law has imposed a comprehensive set of restrictions on the importation, manufacture, and distribution of controlled substances, with stiff criminal, civil and administrative sanctions for violations of such laws.³ In enacting these laws, Congress intended to create a “closed” system to ensure controlled substances used in legitimate medical procedures were not adulterated or counterfeit and to prevent the improper diversion of drugs that were prone to abuse.

The Congress has long recognized the danger involved in the manufacture, distribution, and use of certain psychotropic substances for nonscientific and nonmedical purposes, and has provided strong and effective legislation to control illicit trafficking and to regulate legitimate uses of psychotropic substances in this country.⁴

¹ See Ga. Code Ann. § 17-10-38(a) (2010). While Georgia statutes also authorize execution by the electric chair, the Georgia Supreme Court in 2001 found that use of the electric chair constituted cruel and unusual punishment and struck down the state's use of the method. See *Dawson v. State*, 274 Ga. 327 (Ga. 2001).

² See Ga. Code Ann. § 17-10-44.

³ See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, tit. II, § 101, 84 Stat. 1236, 1242 (1970) (codified at 21 U.S.C. 801 *et seq.*).

⁴ 21 U.S.C. § 801a(1) (Congressional findings and declarations).

A critical component of this system is the strict statutory and regulatory restrictions on the importation of controlled substances. The CSA provides the following prohibition on the import of controlled substances subject to narrow exceptions.

It shall be unlawful to import into the customs territory of the United States from any place outside thereof . . . *any nonnarcotic controlled substance in schedule III* . . . unless such nonnarcotic controlled substance--

- (1) is imported for medical, scientific, or other legitimate uses,
and
- (2) is imported pursuant to such notification, or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe

21 U.S.C. § 952(b) (emphases added); *see also* 21 U.S.C. § 954(2) (“A controlled substance in schedule II, III, or IV may be so imported, transferred or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.”).

Pursuant to the CSA, the Attorney General has promulgated regulations enforced by the DEA requiring that “[n]o person shall import or cause to be imported any non-narcotic controlled substance listed in Schedule III . . . unless and until such person is properly registered under the Act (or exempt from registration) and has filed an import declaration to do so with the Administrator, pursuant to § 1312.18 of this part.” 21 C.F.R. § 1312.11(b)(2011). The CSA also makes it unlawful to “possess, manufacture, distribute, or dispense” controlled substances absent a properly issued registration by the DEA. 21 U.S.C. § 822(a)-(b); *see also* 21 C.F.R. § 1312.11(b).

The Georgia Department of Correction’s Importation of Thiopental in 2010

Based on records provided by GDC in response to a request filed by attorneys for Emmanuel Hammond under Georgia’s Open Records Act,⁵ it appears that on June 24, 2010, Dream Pharma Ltd. (“Dream Pharma”), a pharmaceutical wholesaler/distributor in London, England, shipped one package of twenty-five vials

⁵ The Open Records Act request, and the documents provided by GDC in response thereto (including a cover letter from the GDC’s General Counsel), are attached in Appendix A.

of thiopental sodium for the GDC to a pharmacy somewhere in the United States.⁶ On June 28, 2010, the thiopental arrived in Memphis, Tennessee, where Customs detained it pending review by the FDA.⁷

Dream Pharma appears to be a closely held corporation run by a husband and wife. According to press reports, their only location is rented space at the rear of a driving school.⁸ I have found no evidence (in the GDC-produced documents or otherwise) that the company is registered to export controlled substances. Moreover, the export of thiopental for non-medical purposes has recently been prohibited in the UK.⁹

On July 14, 2010, the Director of Procurement for the GDC sent an email to a recipient, whose name has been redacted, reporting that he had made inquiries with “the POC” as to whether “we could purchase the drug Thiopental directly from distributor [sic].”¹⁰ Later that evening, the Director of Procurement emailed Dream Pharma Ltd. to “inquir[e] if the Department could purchase Thiopental directly from [DreamPharma].”¹¹ The email explained that the GDC “uses the drug for capitol [sic] punishment. We recently purchased the drug through [redacted] and shipment [sic] has not arrived.”¹²

⁶ While the GDC attempted to redact Dream Pharma’s name from the documents that it disclosed, the name is partially readable in the GDC’s email correspondence with Dream Pharma (Appendix A at 0037), is unredacted on the invoice for the shipment (Appendix A at 0051, 0056), and is unredacted on the international wire transfer paying for the purchase of the thiopental (Appendix A at 0053).

⁷ According to documents obtained from the Food and Drug Administration, the shipment was “[r]eleased after Detention” on August 12, 2010. The Georgia Diagnostic and Classification Prison’s inventory log notes the receipt of twenty-five vials of thiopental sodium on August 27, 2010. Appendix A at 0005.

⁸ See, e.g., Steven Swinford, *British Businessman Supplied US Prison With Lethal Injection Drugs*, THE TELEGRAPH, (Jan. 7, 2011, 7:30 AM), <http://www.telegraph.co.uk/news/uknews/8243959/British-businessman-supplied-US-prison-with-lethal-injection-drugs.html>; see also DREAM PHARMA LTD., <http://www.dreampharma.com> (last visited Feb. 24, 2011) (Dream Pharma’s address).

⁹ See Swinford, *supra* note 8.

¹⁰ Appendix A at 0020.

¹¹ Appendix A at 0019, 0041 (email from Director of Procurement to Dream Pharma of Jul. 12, 2010).

¹² *Id.*

An agent of Dream Pharma responded the following morning, stating that he was “more than happy to assist.”¹³ The Director of Procurement sought approval to make the purchase, ultimately receiving authorization within an hour from the Assistant Commissioner, Chief of Staff of the GDC, who admonished: “Yes. Make it happen. Get a good quantity but ensure it has an extended shelf life!”¹⁴

On July 16, 2010, the Director of Procurement emailed Dream Pharma that “GDC would like to make purchase of Thiopental. Request attached on GDC letterhead as requested.”¹⁵ An agent of Dream Pharma responded that same day with confirmation that he had received the GDC’s purchase order and would “order the goods on Monday morning [July 19, 2010] and hopefully . . . will be able to make shipment to you by the end of the week.”¹⁶ Later that day, the agent cautioned the Director of Procurement that “[i]t is your responsibility to get the goods through the US customs. If for some reason the products get’s [sic] held at the customs and was not released, we cannot bring the products back to UK. It would need to be destroyed.”¹⁷

On July 21, 2010, the GDC transferred £183.76 (pounds sterling, the equivalent of \$340.41) to Dream Pharma through an international bank wire. Appendix A at 0052-0053. That same day, Dream Pharma shipped two packages of twenty-five vials of thiopental directly to the Georgia Diagnostic and Classification Prison in Jackson, Georgia – the facility that houses Georgia’s death row.¹⁸ The invoice and label for the shipment identify the contents as “*Pharmaceuticals Not Restricted*.”¹⁹ According to the inventory log maintained by the Georgia Diagnostic and Classification Prison, the prison received these fifty vials of thiopental on July 29, 2010.²⁰

¹³ Appendix A at 0017-18 (email from Dream Pharma to Director of Procurement of July 15, 2010).

¹⁴ Appendix A at 0017 (email from Asst. Commissioner of July 15, 2010).

¹⁵ Appendix A at 0022 (email from Director of Procurement to Dream Pharma of Jul. 16, 2010). The documents disclosed by GDC contain what appear to be several drafts of this request, but, given the extent of the redactions, it is impossible to determine which version accompanied the email.

¹⁶ *Id.* (email from Dream Pharma to Director of Procurement of July 16, 2010).

¹⁷ *Id.*

¹⁸ Appendix A at 0051.

¹⁹ Appendix A at 0051, 0054 (emphasis added).

²⁰ Appendix A at 005.

The GDC's Importation and Possession of Thiopental Appears to Have Violated the Federal Controlled Substances Act

Based on the foregoing, it appears that: (1) the GDC imported thiopental directly from Dream Pharma in July 2010, (2) the GDC was not registered with DEA as an importer of non-narcotic controlled substances when the GDC imported thiopental from Dream Pharma, (3) the GDC did not, in connection with its importation of thiopental from Dream Pharma, provide a declaration of importation to DEA, and (4) GDC was not at the time of importation – and is not today – registered to possess a non-narcotic controlled substance.

The importation of thiopental, absent a valid registration, violated federal law

Based on a variety of documents, it appears that GDC has violated the federal CSA by importing thiopental without proper registration or notification. Specifically, the Federal Defender's Office for the Northern District of Georgia filed a request under the state's Open Records Act for "[a]ny registration by your office . . . with the United States Drug Enforcement Administration (DEA) for the importation of controlled substances, including but not limited to [thiopental], from foreign countries."²¹ The GDC replied that "[t]he Department does not possess documentation responsive to each of [the Federal Defender's Office] requests." The GDC's response also stated that "[t]o the extent that the Department has documentation responsive to your requests, the [redacted] documents are enclosed for your review."²² None of the documents provided pursuant to the request included the registration, application for registration, or evidence of a waiver of or exemption from the registration to import Schedule III controlled substances.

The GDC's failure to declare the importation of thiopental violated federal law

It also appears that the GDC failed to declare its importation of thiopental, as required by 21 U.S.C. § 954(2) ("A controlled substance in schedule II, III, or IV may be so imported, transferred or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General."). The regulations promulgated by the Attorney General require importers of non-narcotic Schedule III controlled substances, such as thiopental, to file an import declaration to the DEA, 21 C.F.R. § 1312.11(b), including the submission of DEA

²¹ The Open Records Act request is attached at Appendix B.

²² The documents produced by the GDC are attached at Appendix C.

Form 235 in quintuplicate no later than fifteen days prior to the proposed date of importation. *See* 21 C.F.R. § 1312.18(b)-(c). None of the documents obtained under Georgia's Open Records Act provides any indication that the GDC properly declared its importation of thiopental.

The GDC appears to lack authority to possess thiopental, in violation of federal law

The GDC has produced a document that appears to be a DEA-issued registration to possess Schedule III *narcotics*.²³ This registration, however, does not appear to authorize the GDC to possess, dispense, or distribute Schedule III *non-narcotic* substances. As noted above, thiopental is a non-narcotic controlled substance. Accordingly, it appears GDC's possession of thiopental may be unlawful under 21 U.S.C. § 822(a) and 21 C.F.R. § 1301.11(9) ("Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26.").

The Department of Justice Should Investigate the GDC's Actions and Take Appropriate Steps if the GDC Has Violated Federal Law

Based on the information summarized above, I respectfully request that you direct the DEA (and/or other appropriate agencies) to conduct a prompt and thorough investigation of these issues. Without the safeguards of the federal closed system created by Congress, illegally imported thiopental may be adulterated, counterfeit, or otherwise ineffective in providing adequate sedation. It is likely that illegally imported or possessed thiopental will be used in the execution of Mr. DeYoung and other individuals on Georgia's death row.

If such an investigation confirms that GDC has violated federal law through its unlawful importation of thiopental from Dream Pharma, the situation presents "an imminent danger to the public health or safety." 21 C.F.R. § 1301.36(e). When such danger exists, the DEA may revoke or suspend the violator's registration to possess controlled substances and require that all controlled substances in the violator's possession are delivered to the DEA. *See* 21 C.F.R. § 1336(e)-(f). The DEA also can direct the GDC to "[d]eliver to the nearest office of the Administration or to authorized agents of the Administration" all of the particular controlled substance or substances affected by the revocation or suspension which are in his/her possession. or "[p]lace all of such substances under seal as described in sections 304(f) or

²³ *See* Appendix A at 0001.

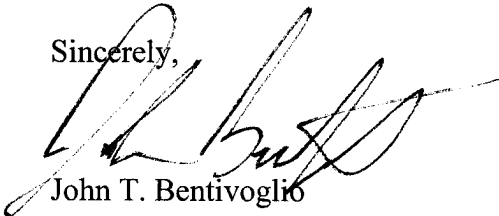
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958(d)(6) of the Act (21 U.S.C. § 824(f) or 958(d)(6))." 21 C.F.R. § 1301.36(f). Both such actions would be appropriate if GDC is in violation of federal law described above.

* * * * *

I appreciate your attention to this matter. If you or a member of your staff have questions or need more information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "John T. Bentivoglio", is written over the typed name below it.

John T. Bentivoglio

cc: Michele Leonhart
Administrator
Drug Enforcement Administration

Carl Humphrey, Warden
Georgia Diagnostic and Classification Prison

Gretchen M. Stork
Federal Defender Program, Inc.