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*LLP
**S.C.

January 22, 2014

Pat Holland, SAC
Food and Drug Administration
Office of Criminal Investigation
Kansas City Field Office
HFH-510
5799 Broadmoor St., Suite 600
Mission, KS 66202
Via Hand Delivery

URGENT

Re: Execution of Missouri prisoner Herbert Smulls scheduled for **January 29, 2014**,
using unsafe, expired compounded drugs

Dear Special Agent Holland:

I am one of the attorneys for Herbert Smulls, currently scheduled for execution in Missouri on January 29, 2014. The Missouri Department of Corrections intends to use compounded pentobarbital in the execution, believed to be obtained from an Oklahoma compounding pharmacy. The State of Missouri has sought to protect the identity of the pharmacy as a "state secret" and by asserting the pharmacy is protected as a member of the "execution team" under the Missouri statute, Mo. Rev. Stat. § 546.720. That said, information released under the Missouri Sunshine Law makes it fairly simple, we believe, to determine the identity of the compounding pharmacy. We are able to share that information with you, and have made it available to the Oklahoma Board of Pharmacy which we understand is conducting an active investigation.

Information we have received through litigation in *Zink v. Lombardi* (a lawsuit against Missouri Department of Corrections officials) shows that the compounding pharmacy

supplied on January 14, 2014, syringes filled with compounded pentobarbital to be used to execute Mr. Smulls. The pharmacy directed the Missouri Department of Corrections to store this drug at room temperature, in contravention of USP <797> as well as the pharmacy regulations of the State of Missouri and the State of Oklahoma, including those regulations guarding against the use of drugs beyond their "BUD" (Beyond Use Date). We also understand that the Oklahoma pharmacy is not licensed in Missouri, and is thus prohibited as nonresident pharmacy from delivering drugs into Missouri.

The alleged violations of law that may directly concern your agency are, of course, violations of federal law. We believe that under the newly enacted Drug Quality and Security Act the compounded pentobarbital is a "copy" of an FDA-approved drug and thus constitutes an illegal and unapproved "new drug" under 21 U.S.C. § 355. *See* Pub. L. No 113-54, 127 Stat. 587 (Nov. 27, 2013). Even in the unlikely event the Department's pharmacy were validly registered as a federally regulated "outsourcing facility," its product here is forbidden as "essentially a copy of an approved drug." *Id.* (FDCA, new section 503B(a)(5)).

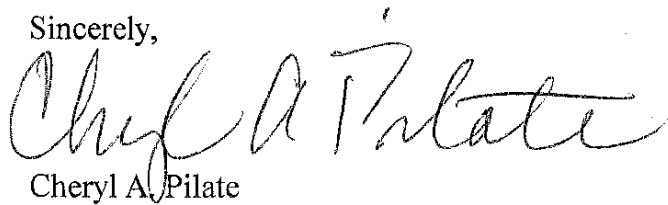
In addition, the Department's actions may further violate the FDCA, because the Department is obtaining, dispensing and administering the prescription-only drug, pentobarbital, without a valid medical prescription, in violation of 21 U.S.C. § 353(b). The "prescription" issued by the Department's anonymous physician is ineffective because he/she has never seen the "patient" and is not writing the prescription in the usual course of medical practice.

The Department of Corrections may also be violating the Controlled Substances Act, as pentobarbital is a Schedule III controlled substance, and may not be dispensed or administered without a prescription from a medical practitioner acting within the usual scope of his or her professional practice. 21 C.F.R. § 1306.04(a).

For your further review, I have enclosed our initial letter to the United States Attorney's Office as well as a lengthy follow-up letter, with attached exhibits from Joseph Luby, an attorney also representing plaintiffs in the *Zink* litigation. I also particularly draw your attention to the several affidavits and sworn declarations, included among the attached exhibits, from Dr. Larry Sasich, an expert pharmacologist who has opined that the improper storage of the compounded pentobarbital at room temperature creates a grave risk that Mr. Smulls will be injected with a degraded, contaminated drug, thus causing excruciating pain to Mr. Smulls during the execution.

We respectfully seek your immediate attention to this matter. I can be reached at either (816) 471-6694 (office) or at (913) 558-6811 (cell). We look forward to hearing from you.

Sincerely,

A handwritten signature in cursive script that reads "Cheryl A. Pilate". The signature is written in black ink and is positioned above the printed name.

Cheryl A. Pilate

Enclosures