CAROLYN B. MALONEY
CHAIRWOMAN

ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143
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http://oversight.house.gov

July 14, 2020

Dr. Thomas C. Kupiec
Chief Executive Officer
ARL Bio Pharma
840 Research Parkway, Ste. 546
Oklahoma City, OK 73104

Dear Dr. Kupiec:

The Subcommittee on Civil Rights and Civil Liberties is investigating the decision by the Department of Justice (DOJ) to resume federal executions using a lethal injection drug called pentobarbital. Our investigation and public reporting indicate that ARL Bio Pharma may have information relevant to the acquisition and use of this drug by DOJ.[1]

On July 25, 2019, DOJ announced that it would resume executions for federal inmates with death penalty convictions and that it would use pentobarbital instead of the three-drug cocktail used previously. This closely mirrors the lethal injection protocols of several states, including Georgia, Missouri, and Texas.[2]

We are deeply concerned about the use of pentobarbital in executions. Due to a lack of supply of the drug in the United States, the few states that use it for lethal injections have resorted to purchasing it from compounding pharmacies. Products of compounding pharmacies are typically not subject to the same rigorous approval process as those of other manufacturers, leading to many reported problems with the efficacy and potency of the pentobarbital they may sell. There have been several reports of inmates injected with the chemical saying before they died that they could feel themselves "burning."[3]

DOJ and the federal Bureau of Prisons (BOP) have refused to disclose to the Subcommittee how and from whom they will acquire this chemical or who tests it for them, but

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[1] *Special Report: How the Trump Administration Secured a Secret Supply of Execution Drugs*, Reuters (July 10, 2020) (online at www.reuters.com/article/us-usa-executions-specialreport/special-report-how-the-trump-administration-secured-a-secret-supply-of-execution-drugs-idUSKBN24B1E4).

[2] Department of Justice, *Federal Government to Resume Capital Punishment After Nearly Two Decade Lapse* (July 25, 2019) (online at www.justice.gov/opa/pr/federal-government-resume-capital-punishment-after-nearly-two-decade-lapse).

[3] *Lethal Injection Drugs' Efficacy and Availability for Federal Executions*, NPR (July 26, 2019) (online at www.npr.org/2019/07/26/745722219/lethal-injection-drugs-efficacy-and-availability-for-federal-executions).

DOJ has filed redacted testing reports indicating that your company has assisted DOJ in securing and/or testing pentobarbital for death penalty executions.

For these reasons, we request that you answer the following questions for the period of January 1, 2017, to the present, and references to "government entity" should be construed to mean federal or state governments:

1. What services or products has your company provided to any government entity or contractor acting on behalf of a government entity regarding the use of pentobarbital?

2. Has your company sold or compounded pentobarbital for any government entity or contractor acting on behalf of a government entity, and if so, how much pentobarbital has it sold, to which clients, when, and for how much?

3. Has your company conducted any tests on pentobarbital for any government entity or contractor acting on behalf of a government entity, and if so, for which clients, when, and for how much?

4. Has your company communicated with any compounding pharmacy or dosage manufacturer regarding the use or sale of pentobarbital, and if so, which pharmacies or manufacturers?

5. Does your company have any knowledge of compounding pharmacies or dosage manufacturers that have been in communication with or sold pentobarbital to any government entity or contractor acting on behalf of a government entity, and if so, which pharmacy or manufacturer?

6. When did your company become aware that it was testing or providing pentobarbital for use in human lethal injections?

7. Does your company have any internal guidance referring or relating to the sale of pentobarbital for use in executions, and if so, when was it instituted and how does it ensure compliance with that guidance?

In addition, we request that you provide, all documents for the period from January 1, 2017, to the present referring or relating to:

1. The sale or potential sale of pentobarbital to any government entity or contractor acting on behalf of a government agency, including but not limited to purchase orders, invoices, and task orders;

2. The testing of pentobarbital for use in lethal injections;

3. The client whose Certificates of Analysis are included in the attached document; and

4. The potential sourcing of pentobarbital from compounding pharmacies or other manufacturing companies.

Please provide the requested information by Tuesday, July 28, 2020. The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" and "any time" under House Rule X.

An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Committee staff at (202)-225-5051.

Sincerely,

Jamie Raskin
Chairman
Subcommittee on Civil Rights and Civil Liberties

Ayanna Pressley
Member
Subcommittee on Civil Rights and Civil Liberties

Enclosure

cc: The Honorable Chip Roy, Ranking Member
Subcommittee on Civil Rights and Civil Liberties

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.

[redacted]

Certificate Of Analysis

CLIENT: [redacted]

[redacted] [redacted]

LOT #: [redacted]

DESCRIPTION: Pentobarbital Sodium

DATE RECEIVED: 10/26/2018

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: One amber container w/ 1g of powder in a clear bag

Test	Test Method	Limits	Results	Date Tested
Identification B (HPLC - Retention Time)	USP 41	Conforms to USP Specifications	Conforms	11/06/2018
Loss on Drying <731>	USP 41	NMT 3.5%	1.6%	11/06/2018
Related Compounds (HPLC) <621>	USP 41	see**Note	Fail	11/06/2018
Assay (HPLC) <621>	USP 41	98.0% - 102.0%	99.6%	11/06/2018

Assay: on the dried basis.

**Note: USP 41, Pentobarbital Sodium, Related compounds Results: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid = 0.005%, limit: NMT 0.2%; 5-Ethyl-5-(1-ethyl-propyl)barbituric acid = 0.259%, limit: 0.1%; 5-Ethyl-5-(1,3-dimethylbutyl)barbituric acid = not detected, limit: NMT 0.3%. NMT 0.1% of unknown impurity; unknown impurity = 0.028%, unknown impurity = 0.003%, unknown impurity = 0.006%. Total impurities = 0.3%, limit: NMT 0.5%.

[redacted]

11/19/2018

Date Reported

Results reported above relate only to the sample that was tested.

[redacted]

[redacted]

Certificate of Analysis

Client: Bureau of Prisons [redacted]

[redacted] **Product ID:** N/A
Lot Number: [redacted]
Description: Pentobarbital Sodium powder – 1 g

Test	Results	Limits	Test Method	Date Tested
Identification B (HPLC – Retention Time)	Conforms	Conforms to USP Specifications	USP 41	11/06/2018
Loss on Drying <731>	1.6%	NMT 3.5%	USP 41	11/06/2018
Related Compounds (HPLC) <621>	Fail	See Below	USP 41	11/06/2018
6-Imino-5-ethyl-5-(1methyl-butyl)barbituric acid	0.005%	NMT 0.2%		
5-Ethyl-5-(1-ethylpropyl)barbituric acid	0.259%	0.1%		
5-Ethyl-5-(1,3dimethylbutyl)barbituric acid	Not Detected	NMT 0.3%		
Unknown Impurities	0.028% 0.003% 0.006%	NMT 0.1%		
Total Impurities	0.3%	NMT 0.5%		
Assay (HPLC) <621>	99.6%	98.0% - 102.0%	USP 41	11/06/2018

Respectfully,

[redacted]

12/06/2018
Date Reported

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium Powder

Test / Specification	Results	Test Method	Date Tested
Completeness of Solution Conforms / does not conform	Conforms	USP <41>	02/21/2019
pH <791> 9.8 – 11.0	10.3	USP <41>	02/21/2019
Loss on Drying <731> NMT 3.5%	1.0%	USP <41>	02/21/2019
Related Compounds (HPLC) <621> See ** note	Pass	USP <41>	02/21/2019
Assay (HPLC) <621> 97.0% - 102.0%	101.2%	USP <41>	02/21/2019

**Note: USP 41, Pentobarbital Sodium, related compounds results: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid = not detected, limit: NMT 0.2%; 5-ethyl-5-(1-ethyl-propyl)barbituric acid = not detected, limit: 0.1%; 5-ethyl-5-(1,3-dimethylbutyl) barbituric acid = 0.005%, limit: NMT 0.3%. NMT 0.1% of unknown impurity; unknown impurity = 0.009%, unknown impurity = 0.02%, unknown impurity = 0.004%. Total impurities = 0.04%, limit: NMT 0.5%.

Respectfully,

[redacted]

[redacted]

Certificate Of Analysis

CLIENT: [redacted]

[redacted] **#:** [redacted]

LOT #: [redacted]

DESCRIPTION: Pentobarbital Sodium

DATE RECEIVED: 02/08/2019

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: One amber container w/ 3.14g of powder in a clear bag

Test	Test Method	Limits	Results	Date Tested
Completeness of Solution	USP 41	Conforms to USP Specifications	Conforms	02/21/2019
pH <791>	USP 41	9.8 - 11.0	10.3	02/21/2019
Loss on Drying <731>	USP 41	NMT 3.5%	1.0%	02/21/2019
Related Compounds (HPLC) <621>	USP 41	See *Note	Pass	02/21/2019
Assay (HPLC) <621>	USP 41	97.0% - 102.0%	101.2%	02/21/2019

Assay: On dried basis.

*Note: Per USP 41, Pentobarbital Sodium Related Compounds Limits: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid NMT 0.2%, 5-ethyl-5-(1-ethyl-propyl)barbituric acid NMT 0.1%, 5-ethyl-5-(1,3-dimethylbutyl)barbituric acid NMT 0.3%, Unknown Impurities NMT 0.1%, Total Impurities NMT 0.5%. Results: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid (RRT~0.39) = Not Detected, Unknown Impurity (RRT=0.64) = 0.009%, Unknown Impurity (RRT=0.73) = 0.02%, 5-ethyl-5-(1-ethyl-propyl)barbituric acid (RRT~0.93) = Not Detected, Unknown Impurity (RRT=1.40) = 0.004%, 5-ethyl-5-(1,3-dimethylbutyl)barbituric acid (RRT=1.47) = 0.005%,, Total Impurities=0.04%.

[redacted]

02/22/2019

Date Reported

Results reported above relate only to the sample that was tested.

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted] **Product ID:** [redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV

Test / Specification	Results	Test Method	Date Tested
Sterility Sterile / Not Sterile	Sterile	USP <71>	05/16/2019
Particulate Matter ≥ 10 µm: ≤ 6000/container ≥ 25 µm: ≤ 600/container	≥ 10 µm: 343.3/container ≥ 25 µm: 6.7/container	USP <788>	05/17/2019
Potency/Purity 92 – 108%	93.1%	HPLC	05/21/2019
Bacterial Endotoxin NMT 40 EU/mL	< 0.10 EU/mL	USP <85>	06/03/2019

Respectfully,

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV – Room Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	95.5%	HPLC	07/01/2019
pH Trend	10.00	USP <791>	07/08/2019

Respectfully,

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV – Elevated Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	90.8%	HPLC	07/10/2019
pH Trend	9.91	USP <791>	07/03/2019

Respectfully,

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

[redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV - Room Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	94.6%	HPLC	08/21/2019
pH Trend	10.03	USP <791>	08/13/2019

Respectfully,

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV – Elevated Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	92.2%	HPLC	08/21/2019
pH Trend	10.12	USP <791>	08/14/2019

Respectfully,

[redacted]