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ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5051
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http://oversight.house.gov

June 26, 2019

Mr. Daniel O'Day
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Mr. O'Day:

Thank you for your testimony before the Committee on May 16, 2019, regarding Gilead's practices related to pricing and access to Truvada for pre-exposure prophylaxis (PrEP) therapy. The Committee has additional questions regarding the company's practices following your testimony.

During the hearing, you testified that, "if we had lowered the price of our medicines even a decade ago, we wouldn't be sitting here today with the innovations that are changing the face of HIV/AIDS." You also testified that Gilead's patient access programs and donation of up to 2.4 million vials of Truvada per year to the Centers for Disease Control (CDC) will ensure that "price doesn't get in the way during this period of time of patent exclusivity." Finally, you testified that the amount of Gilead's donation to the CDC "was requested and discussed with the CDC," and that it is a "reasonable assumption" that Gilead would have donated more if the CDC had requested a larger quantity of PrEP.[1]

The Committee is seeking to understand if the company's price increases for Truvada were made with innovations in mind, as well as how the company's patient assistance programs impact its decision-making with regard to price. The Committee is also seeking to understand whether Gilead's donation of Truvada was connected in any way to patents that have been registered in the United States. Gilead has taken the position that the government's patents are not valid. We would like to understand whether these patents played any role in negotiations between the company and the Department of Health and Human Services (HHS) and whether Gilead has otherwise engaged in negotiations with the U.S. government regarding these patents.

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[1] Committee on Oversight and Reform, *Hearing on HIV Prevention Drug: Billions in Corporate Profits After Millions in Taxpayer Investments* (May 16, 2019) (online at https://oversight.house.gov/legislation/hearings/hiv-prevention-drug-billions-in-corporate-profits-after-millions-in-taxpayer).

To assist the Committee with this continuing investigation, please provide the following documents and information by July 26, 2019. Unless otherwise specified, please provide the following information for the period covering January 1, 2012, to the present:

1. All documents and communications, including email communications, with any employee or representative of HHS, CDC, or any other federal agency regarding any donation of Truvada or Descovy by Gilead to the United States;

2. All documents and communications, including email communications, between any employee of Gilead and any employee or representative of HHS, CDC, or any other federal agency regarding any patents related to PrEP registered by the United States;

3. For each year from 2004 through the present, the cost of goods sold (COGS) of Truvada and Descovy, including total COGS and relative cost per 30-tablet vial;

4. For each year from 2004 through the present, the total quantity of Truvada sold or otherwise distributed in the United States for each of the commercial, Medicare, Medicaid, and Department of Veterans Affairs sales channels;

5. All documents and communications, including email communications, regarding each of the following price increases for Truvada, including those reflecting the reasons for each price increase, deliberations regarding whether to increase the price and by how much, and the impact of any change in price on Gilead's earnings:

Date	Previous Average Wholesale Price	New Average Wholesale Price
January 1, 2012	$1,289.70	$1,391.40
January 1, 2013	$1,391.40	$1,467.90
January 1, 2014	$1,467.90	$1,539.90
April 1, 2015	$1,539.90	$1,646.10
January 1, 2016	$1,646.10	$1,759.80
February 1, 2017	$1,759.80	$1,859.40
March 1, 2017	$1,859.40	$1,881.00
January 1, 2018	$1,881.00	$2,010.90
March 16, 2019	$2,010.90	$2,109.48

6. All documents and communications, including email communications, regarding any changes to the price of Truvada in anticipation of or related to the approval by the Food and Drug Administration (FDA) in 2012 of the use of Truvada for PrEP;

7. All documents and communications, including email communications, reflecting any discussion of whether Gilead's patient access programs for Truvada impact the company's ability to raise the list price of Truvada;

8. All analyses related to the impact of Truvada's price on the quantity of Truvada available to be sold or distributed in the United States;

9. All documents and communications, including email communications, to or from John Martin, John Milligan, Robin Washington, Gregg Alton, Laura Hamill, Andrew Dickinson, Brett Pletcher, or any other Gilead executive regarding the impact of Truvada's price on Gilead's earnings; and

10. All documents and communications, including email communications, reflecting deliberations regarding when to apply for FDA approval of any product containing tenofovir alafenamide.

Please do not produce widely-distributed, publicly-available documents in response to these requests. In the event you believe that information responsive to these requests can be located in public documents (such as Securities and Exchange Commission filings), please identify the URL location and page number of the responsive information in a written response.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "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,

Elijah E. Cummings
Chairman

Alexandria Ocasio-Cortez
Member of Congress

Ro Khanna
Member of Congress

Ayanna Pressley
Member of Congress

Enclosure

cc: The Honorable Jim Jordan, Ranking Member

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.