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Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143
MAJORITY (202) 225–5051
MINORITY (202) 225–5074
http://oversight.house.gov

May 16, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

The Committee on Oversight and Reform is investigating the actions of drug companies in raising prescription drug prices in the United States, as well as the effects of these actions on federal and state budgets and on American families. As part of this investigation, we are examining pricing and access issues related to Truvada, a product marketed by Gilead Sciences for pre-exposure prophylaxis (PrEP).

In 2012, Gilead received approval from the Food and Drug Administration to market Truvada for PrEP to prevent new HIV infections. This approval followed a series of federally-funded studies that established that the active ingredients in Truvada could effectively prevent the transmission of HIV. These studies included lab and field research funded by the National Institutes of Health and the Centers for Disease Control and Prevention (CDC). Based on the results of this research, Gilead went on to market Truvada for PrEP in the United States and around the world, generating billions of dollars in revenue.

The CDC registered a total of seven patents related to the use of Truvada for PrEP. Four of these patents were registered in the United States, and the remaining patents were registered in Canada, Australia, and the European Union.[1] The Department of Health and Human Services (HHS) has taken steps to enforce CDC's patents overseas, but it apparently has not done so for patents that CDC registered in the United States. We would like to understand why HHS has taken contrasting approaches enforcing intellectual property rights in the U.S. and abroad.

Separately, on May 9, 2019, HHS announced that it had entered into an arrangement with Gilead through which Gilead would donate up to 2.4 million bottles of Truvada or an equivalent product over the next 11 years.[2] We would like to understand more about HHS's plans to

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[1] U.S. Patent No. 9,937,191 B2 (Apr. 10, 2018); U.S. Patent No. 9,579,333 B2 (Feb. 8, 2017); U.S. Patent No. 9,044,509 B2 (Jun. 2, 2015); U.S. Patent Application No. 15,913,750 (Mar. 6, 2018); European Patent No. PCT/US2007/002926; Canadian Patent No. 2,641,388 (Jun. 19, 2018); Australia Patent No. 2007212583 (filed Feb. 1, 2007).

[2] *Gilead Will Donate Truvada to U.S. for H.I.V. Prevention*, New York Times (May 9, 2019) (online at

distribute this donation and whether it expects to purchase or otherwise obtain additional quantities to cover the rest of the approximately 1.1 million Americans who the CDC recently estimated would benefit from access to the treatment.[3]

To assist the Committee with this investigation, please provide the following information and documents by May 30, 2019:

1. In connection with any patent related to PrEP held by CDC or any other government agency:

    a. all documents related to any analysis related to the validity or value of any patents held by CDC or any other federal agency;

    b. all communications, including emails, between officials at HHS or any of its subsidiary agencies and representatives of Gilead from January 1, 2016, to the present regarding any patents related to PrEP that have been registered by CDC or any other government agency;

    c. all documents related to any steps that HHS, CDC, or any other government agency has taken to enforce patents related to PrEP in Australia, Canada, or the European Union;

    d. documents sufficient to show the total amount of funds that HHS, CDC, or any other government agency has spent on preparing and defending any patents related to PrEP in any country; and

    e. documents sufficient to show the total amount of funds that the U.S. government has collected from enforcement of any patents related to PrEP;

2. In connection with HHS's May 9, 2019, announcement that Gilead will donate PrEP to HHS:

    a. all documents related to any plans for the distribution of donated PrEP, including plans regarding eligibility criteria, distribution channels, and any education, awareness, or other outreach efforts;

    b. all documents related to any plans to provide ancillary services for individuals who receive donated PrEP, including counseling and laboratory testing;

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www.nytimes.com/2019/05/09/health/gilead-truvada-hiv-aids.html).

[3] *HIV Prevention Pill Not Reaching Most Americans Who Could Benefit—Especially People of Color*, National Center for HIV/Aids (Mar. 6, 2018) (online at www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html).

c. all documents related to any plans to purchase or otherwise obtain additional quantities of PrEP to cover additional populations; and

d. all communications, including emails, between officials at HHS or any of its subsidiary agencies and representatives of Gilead from January 1, 2016, to the present regarding Gilead's donation of PrEP to CDC;

3. Documents sufficient to show the total amount of funds that HHS or any of its subsidiary agencies has spent to date on any research related to the safety, efficacy, or mechanism of action in Truvada;

4. Documents sufficient to show the total amount of funds that HHS, CDC, or any other government agency has spent to purchase Truvada or its generic equivalents, including the price per unit; and

5. Documents sufficient to show the total amount of funds that Gilead or any of its employees have donated to the CDC Foundation.

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

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.