

Congress of the United States
Washington, DC 20515

August 13, 2019

Ms. Heather Bresch
Chief Executive Officer
Mylan N.V.
1000 Mylan Boulevard
Cannonsburg, PA 15317

Dear Ms. Bresch:

In 2014, we conducted an investigation into staggering increases in the prices of generic drugs. As part of our investigation, we sent document requests to Mylan and 13 other generic drug companies. Our letter to Mylan requested eight categories of documents regarding price increases for five different pharmaceutical products: Albuterol Sulfate, Benazepril/Hydrochlorothiazide, Divalproex Sodium ER, Doxycycline Hyclate, and Pravastatin Sodium. We noted in our letter that the prices of some of these drugs had risen by as much as 8,281 percent between October 2013 and April 2014.¹ The staggering nature of these price increases seriously impeded patient access to critically needed medications.

Your company never produced any documents in response to our request, despite repeated inquiries and discussions with Mylan's counsel.

On May 10, 2019, Connecticut and 43 other states filed a complaint with troubling allegations of price fixing by Mylan and other drug manufacturers. According to the complaint, investigators have uncovered evidence that manufacturers coordinated to inflate the prices of several drugs that were the subject of our 2014 investigation. Mylan executives allegedly played a central role in this scheme.²

¹ Letter from Ranking Member Elijah E. Cummings, House Committee on Oversight and Government Reform, and Chairman Bernard Sanders, Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor, and Pensions, to Heather Bresch, Chief Executive Officer, Mylan, Inc. (Oct. 2, 2014) (online at www.sanders.senate.gov/download/letter-to-mrs-bresch-ceo-mylan-inc?inline=file).

² *Connecticut et al. v. Teva Pharmaceuticals USA, Inc. et al.* (filed May 10, 2019) (online at portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-UNREDACTED-Teva-Complaint-for-CT-District-Court.pdf); see also *States Allege Generic Drug Executives Deleted Texts, Obstructed Justice In Price Cartel Probe*, Washington Post (May 10, 2019) (online at www.washingtonpost.com/business/economy/states-allege-generic-drug-executives-deleted-texts-obstructed-justice-in-price-cartel-probe/2019/05/10/450c6b30-7355-11e9-9eb4-0828f5389013_story.html); *States Bring Price Fixing Suit Against Generic Drug Makers*, Associated Press (May 11, 2019) (online at www.washingtonpost.com/business/states-bring-price-fixing-suit-against-generic-drug-makers/2019/05/11/414b1524-7421-11e9-9331-30bc5836f48e_story.html).

For example, executives at Mylan reportedly entered into an arrangement with executives at Heritage Pharmaceuticals in which Mylan agreed not to compete for two large Doxycycline Hyclate customers in exchange for granting Heritage an exclusive market for a different product.³

These executives also allegedly coordinated to obstruct our 2014 investigation. Connecticut officials obtained an email sent on October 3, 2014, from outside counsel to Heritage to then-Heritage Pharmaceuticals Chief Executive Officer Jeffrey Glazer discussing how Teva, Mylan, and Heritage planned to coordinate their responses to our requests. Counsel to Heritage wrote that “the consensus at this point is that the responses will be ‘polite f-u’ letters.” The email stated that the companies were planning “to schedule a conference call to coordinate the response and make sure everyone is on the same page.”⁴

Not only did your company’s apparent obstruction undermine our investigation, but it may have caused further harm to patients and health care providers by delaying the discovery of evidence about the companies’ price fixing. Furthermore, obstructing or evading a Congressional investigation, including withholding or concealing information, is a violation of federal law.

We are writing once again to obtain the information requested in 2014. This information is critical to our investigation, and necessary to develop and pursue legislative policies that address anti-competitive behavior in the generic pharmaceutical industry. In addition, we are requesting information regarding Mylan’s apparent efforts to stonewall our investigation to obtain a more detailed understanding of what specific actions Mylan took to impede our efforts, thwart the ability of Congress to enact legislative reform, and jeopardize patients access to generic drugs.

For these reasons, we now renew our October 2, 2014, request to Mylan for documents and communications regarding the prices of Albuterol Sulfate, Benazepril/Hydrochlorothiazide, Divalproex Sodium ER, Doxycycline Hyclate, and Pravastatin Sodium, for the period covering January 1, 2012, through December 31, 2018:

- (1) Total gross revenues from the company’s sales of these drugs;
- (2) The dates, quantities, purchasers, and prices paid for all sales of these drugs;
- (3) Total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;

³ This scheme was also detailed in a related complaint filed by more than 40 states. *See* Plaintiff States’ Consol. Amend. Compl., MDL No. 2724, 2:17-cv-03768 (E.D. Pa. June 15, 2018) (online at www.courtlistener.com/recap/gov.uscourts.paed.533851/gov.uscourts.paed.533851.14.0.pdf).

⁴ Compl., *Connecticut v. Teva Pharmaceuticals USA, Inc.*, No. 3:19-cv-00710, at ¶ 1130.

- (4) Sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;
- (5) A description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the prices of these drugs;
- (6) Any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;
- (7) Prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; and
- (8) The identity of company official(s) responsible for setting the prices of the drugs over the above time period.

In addition, we also request the following documents related to your attempts to coordinate your responses to our investigation:

- (9) All communications relating to our October 2, 2014, request, including but not limited to all communications to, from, between, or among any employees, executives, representatives, or agents of Heritage, Mylan, and/or Teva relating to our request;
- (10) All documents and communications regarding the company's plans for responding to our October 2, 2014, request; and
- (11) Documents sufficient to identify all phone calls between or among any employees, executives, representatives, or agents of Heritage, Mylan, and/or Teva from October 2, 2014, through December 31, 2014.

We request a complete response by August 28, 2019. If you have any questions regarding this request, please contact House Oversight Committee staff at (202) 225-5051 or Senator Sanders' staff at (202) 224-5141.

Sincerely,



Elijah E. Cummings
Chairman
Committee on Oversight and Reform
U.S. House of Representatives



Bernard Sanders
Ranking Member
Committee on the Budget
U.S. Senate

Ms. Heather Bresch
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Enclosure

cc: The Honorable Jim Jordan, Ranking Member
House Committee on Oversight and Reform

The Honorable Mike Enzi, Chairman
Senate Committee on the Budget

Responding to 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 Committees.
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 Committees' 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 Committees 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 Committees 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 Committees' 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 on Oversight and Reform, 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. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.
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.