

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074

MINORITY (202) 225-5051

<http://oversight.house.gov>

August 29, 2016

Ms. Heather Bresch
Chief Executive Officer
Mylan, Inc.
Robert J. Coury Global Center
1000 Mylan Boulevard
Canonsburg, PA 15317

Dear Ms. Bresch:

Americans agree with you that “even one anaphylactic episode without access to epinephrine is one too many.”¹ The EpiPen has saved countless Americans from life-threatening anaphylaxis episodes. Those suffering from allergic reactions depend on the quick-acting, easily-administered EpiPen to deliver a lifesaving dose of epinephrine.

Mylan has a virtual monopoly over the epinephrine auto-injector market. A national dependence on accessibility to EpiPens has been well established since Mylan’s acquisition of the device in 2007. This command of the market has given Mylan the unbridled ability to increase the price of the two-pack EpiPen. While the medicine that actually stops an adverse reaction is remarkably cheap – only a few cents per dose – it is the delivery mechanism that is breaking the bank of many Americans. The price for a pack of two EpiPens has been creeping to over \$600 by way of seventeen price increases over the course of ten years, which represents more than a 400% increase.² Prolonged unaffordability is further exacerbated by the need to replace the device annually due to its short shelf life.

While families and schools are struggling to keep up with your company’s unreasonable price increases, Mylan has profited richly from its pricing strategy. Your company made EpiPen its first billion-dollar product, generating \$1.19 billion in sales revenue for the company’s specialty drug segment in 2014.³ Mylan’s specialty drug business saw similarly strong sales revenue of \$1.2 billion in 2015.⁴

¹ Mylan Inc., “Mylan Applauds New Federal Legislation to Increase Anaphylaxis Preparedness in Schools,” PRNewswire (Nov. 14, 2013).

² *Mylan Faces Scrutiny Over EpiPen Price Increases*, Wall Street Journal (Aug. 24, 2016) (online at www.wsj.com/articles/mylan-faces-scrutiny-over-epipen-price-increases-1472074823).

³ Mylan N.V., *Form 10-K* (Feb. 16, 2016) (online at www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k_20151231xdoc.htm).

⁴ Mylan, N.V., *Form 10-K Amendment No. 1* (Apr. 29, 2016) (online at www.sec.gov/Archives/edgar/data/1623613/000119312516570088/d184592d10ka.htm).

To help us better understand the increasing cost of the EpiPen, please provide the Committee a briefing as soon as possible, but no later than 5:00 p.m. on September 6, 2016. Also, please provide the following documents and information as soon as possible, but no later than 5:00 p.m. on September 12, 2016:

1. Documents and communications referring or relating to the company's gross and net revenues from sales of the EpiPen since its acquisition. This should include, but not be limited to, the total number of EpiPens Mylan sells per year, and the way in which Mylan is compensated for each sale, including private insurance, Medicaid, and on-exchange PPACA plans.
2. Documents and communications referring or relating to the company's expenses from the sales of the epinephrine drug, as well as a breakdown of the specific amounts expended for manufacturing, purchases of active pharmaceutical and other ingredients, marketing and advertising, research and development, and other expenses.
3. Documents sufficient to show the company's profits from the sales of the EpiPen for each year since its acquisition.
4. All letters that have been submitted by Mylan to the federal or state governments referring or relating to the availability or price of the EpiPen. These materials should include, but not be limited to, discussions with any federal officials about EpiPen coverage under the PPACA.
5. Copies of Mylan's quarterly federal and state lobbying disclosure forms from January 1, 2007 to September 8, 2016.
6. Copies of all contracts Mylan has entered into regarding the manufacture and distribution of the EpiPen, and all communications with Meridian Medical Technologies, or any other manufacturer, distributor, or supplier, regarding the price of the EpiPen.
7. Any cost estimates, profit projections, or other analyses relating to the company's current and future sales of the EpiPen.
8. Documents and communications about any assistance programs that exist to help patients access EpiPens, and how these programs have changed since January 1, 2012.
9. Documents and communications referring or relating to the amount of money received by the company from the federal government through reimbursement under federal health care programs, including state programs that receive federal funding.

The Committee on Oversight and Government Reform is the principal oversight Committee of the House of Representatives and may at "any time" investigate "any matter" as set forth in House Rule X.

Ms. Heather Bresch

August 29, 2016

Page 3

When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information about responding to the Committee's request.

If you have any questions about this request, please contact Sarah Vance of the majority staff at (202) 225-5074 or Alexandra Golden of the minority staff at (202) 225-5051. Thank you for your attention to this matter.

Sincerely,



Jason Chaffetz
Chairman



Elijah E. Cummings
Ranking Member

Enclosure

Responding to Committee Document Requests

1. In complying with this request, you are required to 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. You should also produce 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. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.
2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic format should also be organized, identified, and indexed electronically.
5. 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:

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.
6. 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, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. 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.
8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.
9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.
10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.
11. 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.
12. 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) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
13. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
14. 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, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.
15. Unless otherwise specified, the time period covered by this request is from January 1, 2009 to the present.
16. 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.
17. All documents shall be Bates-stamped sequentially and produced sequentially.
18. Two sets of documents 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 2471 of the Rayburn House Office Building.

19. Upon completion of the document production, you should 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 which 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, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other 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, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, 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 which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
4. The terms “person” or “persons” mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.
6. The term “referring or relating,” 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.
7. The term “employee” means agent, borrowed employee, casual employee, consultant, contractor, de facto employee, independent contractor, joint adventurer, loaned employee, part-time employee, permanent employee, provisional employee, subcontractor, or any other type of service provider.