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ONE HUNDRED FOURTEENTH CONGRESS

ELIJAH E. CUMMINGS, MARYLAND
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
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September 30, 2016

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

Dear Ms. Bresch:

When you appeared before the Committee on September 21, 2016, at a hearing on Mylan's price increases for the EpiPen, you repeatedly stated that Mylan makes $100 profit per every EpiPen two-pack that it sells.[1] This week, however, the Committee learned that your testimony omitted key tax assumptions that affect the company's profit per pack. Specifically, neither your testimony, nor the documents Mylan produced to the Committee, clearly disclosed that the company's profit claim was calculated after factoring in the statutory U.S. tax rate—37.5 percent. The *Washington Post* reported:

> Lawmakers were skeptical last week when Mylan chief executive Heather Bresch said that the company made only $100 in profit for a two-pack of EpiPens. During a House hearing, Bresch repeatedly referred to a poster board showing how little of the $608 list price trickled back to the company. The incredulity was warranted: The profits Bresch told Congress about were calculated after factoring in the 37.5 percent U.S. tax rate, according to a filing with the Securities and Exchange Commission first reported by the Wall Street Journal. That tax rate is more than five times the overall tax rate the company actually paid last year and much higher than its actual U.S. tax rate, which tax specialists have pegged at close to zero. Before taxes, the EpiPen profit is actually $160 for a two-pack.[2]

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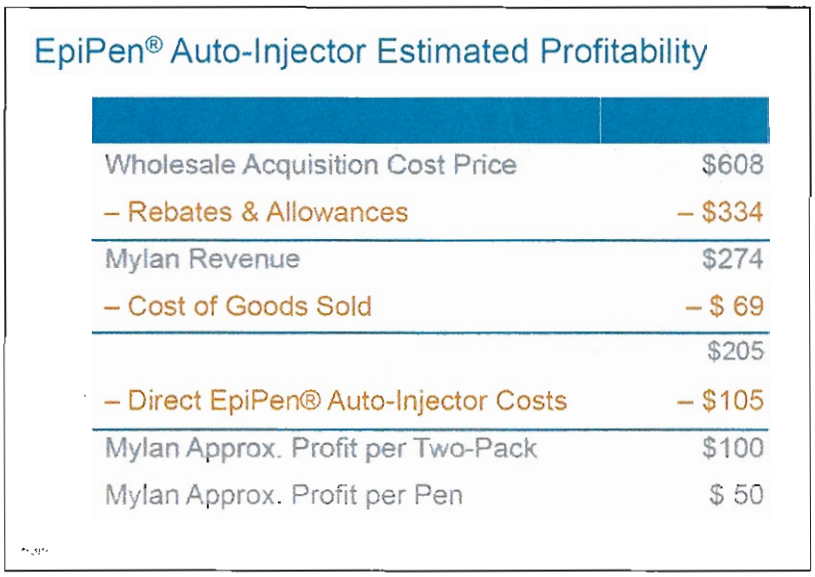
[1] *Reviewing the Rising Price of EpiPens: Hearing before the H. Comm. on Oversight & Gov't Reform*, 114th Cong. (Sept. 21, 2016), *available at* https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/.
[2] Carolyn Y. Johnson, *Mylan's Profits are 60 Percent More Than It Told Congress*, WASH. POST, Sept. 26, 2016.

Mylan claimed an estimated tax impact of $187 million for EpiPens in 2015.[3] That estimate is nearly three times Mylan's company-wide income tax provision that year—$67.7 million—as reported in its annual SEC filing.[4] That figure reflected $93.6 million in *non-U.S.* taxes offset by a U.S. tax *benefit* of $25.9 million.[5]

During your testimony, you frequently referred to a graphic, titled "EpiPen Auto-Injector Estimated Profitability," which identified Rebates & Allowances, Cost of Goods Sold, and Direct EpiPen Auto-Injector Costs as factors that lowered the profitability of the EpiPen.



The graphic made no mention of taxes or the tax assumptions used by Mylan to estimate the $100 profit number. Neither did your written testimony. The only time you mentioned taxes during the hearing was to disclose that Mylan's company-wide effective tax rate is between 15 and 17 percent, as a result of Mylan's decision to move its headquarters overseas.[6]

Failing to disclose tax assumptions that formed the basis for the $100 profit per pack claim, despite opportunities to do so before and during the hearing, raises questions. During the hearing, Chairman Chaffetz noted that Mylan's "dumbed down financials" did not make sense without explanation.[7] Ranking Member Cummings similarly stated, "You know, your numbers don't add up. . . . And it is extremely difficult to believe that you are making only $50 profit when you just increased the price by more than $100 per pen."[8]

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[3] Mylan N.V., *Form 10-K* (Feb. 16, 2016), *available at* http://files.shareholder.com/downloads/ABEA-2LQZGT/2909579967x0xS1623613-16-46/1623613/filing.pdf.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Reviewing the Rising Price of EpiPens: Hearing before the H. Comm. on Oversight & Gov't Reform*, 114th Cong. (Sept. 21, 2016), *available at* https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/.
[8] *Id.*

In response to scrutiny after the hearing, Mylan clarified that the profit figure you presented to the Committee included taxes.[9] In conjunction with Mylan's SEC filing, a Mylan spokesperson stated that "the information provided to Congress has made clear that tax was part of the EpiPen Auto-Injector profitability analysis."[10] Mylan had not directly referenced the tax assumptions for its EpiPen profit estimates, neither in its September 15, 2016, letter to the Committee, nor in the documents that the company produced.

To help us understand the manner by which Mylan prepared and provided information to the Committee and the pricing of the EpiPen, please respond to the following documents and information as soon as possible, but no later than October 7, 2016.

1. All documents, including internal analyses or memoranda, that have been provided to, or prepared for, you or the Mylan Board of Directors, referring or relating to EpiPen sales, profits, costs, manufacturing, distribution, or any other subject that could impact the costs or profitability of the drug-device combination product.

2. All documents referring or relating to your testimony to the Committee, including, but not limited to, any such documents that you relied on to prepare for the September 21, 2016 hearing.

3. All documents and communications referring or relating to Mylan's tax rate, including, but not limited to, those referring or relating to the profitability of the EpiPen.

4. Documents sufficient to show Mylan's actual U.S. tax rate, U.S. taxable income, and the amount of U.S. income tax Mylan paid to the Internal Revenue Service, for each year since 2007.

5. A list of Mylan's profits and expenses relating directly to the sale of EpiPens for each year from 2007 through 2015, including, but not limited to:

    a. profit (including operating and net);
    b. sales;
    c. cost of goods sold;
    d. operating cost;
    e. rebates (including commercial, Medicare Part D, and Medicaid rebates);
    f. discounts;
    g. allowances;
    h. coupons;
    i. patient co-pay;
    j. charge backs;
    k. direct selling expenses;

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[9] Mark Maremont, *Mylan's EpiPen Pretax Profits 60% Percent Higher Than Number Told to Congress*, WALL ST. J., Sept. 26, 2016.
[10] Carolyn Y. Johnson, *Mylan's Profits are 60 Percent More Than It Told Congress*, WASH. POST, Sept. 26, 2016.

l. medical affairs;
m. marketing;
n. research and development;
o. Patient Assistance Programs;
p. EpiPens4Schools program;
q. taxes; and
r. any other expenses or costs.

6. All agreements, contracts, and communications to or from manufacturers, suppliers, distributors, wholesalers, insurers, pharmacy benefit managers, retail pharmacies, and any other partners in the distribution channel for EpiPens, referring or relating to EpiPens.

7. Documents and communications referring or relating to the difference in price between EpiPens sold in the Netherlands and EpiPens sold in the United States.

8. Documents sufficient to define the terms "rebate," "allowances," and "direct EpiPen Auto-Injector Costs" that appeared in the "EpiPen Auto-Injector Estimated Profitability" chart you displayed during the hearing.

9. Documents and communications referring or relating to whether "rebate" and "allowances" (as used in the aforementioned chart) include rebates or discounts provided by Mylan to any state or federal entity under any healthcare program including Medicaid, Medicare, and the Department of Veterans Affairs.

10. Documents sufficient to show whether Mylan accounts for research and development both as an operating cost and as an expense subtracted from profits on a company-wide basis.

11. Documents sufficient to show Mylan's annual charitable contribution deductions for tax years 2007 to 2015.

12. All Profit and Loss statements prepared for Mylan for the last five years.

13. Documents and communications referring or relating to whether Mylan has, or intends to extend, any existing patents or FDA market exclusivity, or file any new patents, for the extended shelf-life formulation of the EpiPen as you described during the hearing.

14. Documents and communications referring or relating to whether the authorized generic version of the EpiPen will be covered by the My EpiPen Savings Card or Mylan's Patient Assistance Program.

15. Documents and communications referring or relating to all rebates, discounts, and any other payments Mylan expects to provide to pharmacy benefit managers, insurers, manufacturers, distributors, wholesalers, suppliers, retail pharmacies, or any other partners in the distribution channel in connection with the authorized generic EpiPen.

16. All documents referring or relating to Mylan's projected annual gross and net sales revenue and profits, from sales of the authorized generic.

17. Documents and communications referring or relating to Mylan's estimate that the net price to Mylan per 2-pack of EpiPens will be $200 after the authorized generic is launched (as the aforementioned chart stated).

18. Documents sufficient to identify all Mylan employees who have worked with the Centers for Medicare & Medicaid Services (CMS) regarding the classification of the EpiPen as a generic drug under the Medicaid Drug Rebate Program, and all CMS employees who have worked with Mylan regarding the classification of the EpiPen under the Medicaid Drug Rebate Program.

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.

The Committee on Oversight and Government 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. Please contact Natalie Turner or Sarah Vance of the Majority Staff or Alexandra Golden with the Minority Staff at (202) 225-5074 with any questions about this request. Thank you for your prompt 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.