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Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

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http://oversight.house.gov

December 15, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10901 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Ostroff:

Generic drugs have historically played an important role in the health care marketplace by offering an alternative to brand drugs at a significantly reduced cost. It is estimated that nearly eighty-six percent of all prescriptions filled in the United States are for generic drugs,[1] with the average cost of generics typically eighty to eighty-five percent lower than their brand drug equivalents.[2] Recent significant price increases for certain generic drugs, however, will make health care more expensive for patients, who will "pay more in copayments and premiums to cover the rising costs of drugs."[3] Industry analysts have cited "declining market competition" as one of the factors driving the recent price increases.[4] This raises questions about the efficiency of the Food and Drug Administration's process for reviewing Abbreviated New Drug Applications (ANDA).

Under the Generic Drug User Fee Amendments of 2012 (GDUFA), the FDA will receive approximately $1.5 billion over five years from industry fees to speed the public's access to safe and effective generic drugs. To help the Committee understand the FDA's process for reviewing generic drug applications, please provide the following documents and information as soon as possible, but no later than 5:00 p.m. on January 5, 2016:

1. Documents referring or relating to the current number of pending ANDAs and the FDA's process for addressing and prioritizing these applications.

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[1] IMS Institute for Healthcare Informatics, *Medicine use and shifting costs of healthcare* (Apr. 2014), *available at* http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last visited Dec. 3, 2015)

[2] FDA website, "Facts About Generic Drugs," *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last visited Dec. 3, 2015).

[3] Priyanka Dayal McCluskey, *As competition wanes, prices for generics skyrockets*, THE BOSTON GLOBE, Nov. 6, 2015.

[4] *Id.*

2. Documents referring or relating to the number of yearly ANDA submissions and yearly ANDA approvals since fiscal year 2012.

3. Documents sufficient to show the median approval time (in months) for the following subsets of ANDAs since fiscal year 2010:

    a. Approvals

    b. Tentative Approvals

    c. Complete Response Letter

    d. Refuse to Receive (RTR)

4. All RTR since fiscal year 2010.

5. All documents and communications referring or relating to any RTR rescind decision since fiscal year 2010.

6. Documents sufficient to show the number of pending ANDAs that have not been assigned target action dates.

7. Documents referring or relating to FDA's communications with ANDA sponsors regarding pending applications, including, but not limited to:

    a. The processes and intervals by which the FDA communicates with ANDA sponsors regarding the review and approval process, the type of information provided to ANDA sponsors, and whether FDA informs ANDA sponsors as to when to expect a filing determination.

    b. Whether the status of inspection and compliance reviews is communicated to ANDA sponsors.

    c. Summarize any feedback that ANDA sponsors have provided to the FDA regarding the need for improved communications.

8. Documents sufficient to show the total number of ANDAs received over the past five years for generic versions of Isuprel, Nitropress, and Daraprim.

9. Documents referring or relating to the total number of approved ANDAs for which there is no generic drug on market since fiscal year 2010.

10. Documents and communications referring or relating to the effect of restrictions on the distribution of brand drugs on the development of generic drugs, including, but not limited to, documents and communications referring or relating to any FDA investigation, FDA's enforcement mechanism to address such conduct, and steps by the FDA to ensure generic drug manufacturers have access to brand drugs for the development of generics.

11. Documents and communications referring or relating to barriers to successful, timely market entry of generic drugs.

12. Documents and communications referring or relating to any legal, regulatory, or logistical impediments to reviewing generic drug applications more quickly, including, but not limited to, additional authorities or modification of existing authorities that might be necessary, obstacles to hiring staff with appropriate technical expertise, and challenges in interacting with overseas manufacturers.

13. Documents sufficient to show user fees collected, spent, and unspent, for each fiscal year since 2012.

14. Documents referring or relating to FDA's spending plan, including, but not limited to, funding for IT projects, strategy for overseas inspections, the process by which the FDA finalizes topics that are funded by the Regulatory Science Initiatives Program, and any metrics for measuring program success.

15. Over the past year, resale prices of priority review vouchers (PRV) have climbed from $67.5 million to $350 million.[5] Skyrocketing PRV resale prices, and the recent acquisition of KaloBios, have raised questions about potential exploitation of the PRV Program by those who may be applying for PRV not to develop new therapies but rather solely to capitalize on the PRV resale market.[6] Please provide all documents and communications referring or relating to any FDA investigation, FDA's enforcement mechanisms to address such conduct, and steps by the FDA to prevent abuses of the PRV 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.

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[5] http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2015/08/priority-review-voucher-updates-valuation-eligibility-reauthorization.html.

[6] Tim Worstall, *Martin Shkreli's KaloBios Proves Why Capitalism Makes Us All So Wonderfully, Stinking, Rich*, Forbes, Dec. 12, 2015, available at http://www.forbes.com/sites/timworstall/2015/12/12/martin-shkrelis-kalobios-proves-why-capitalism-makes-us-all-so-wonderfully-stinking-rich/.

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" set forth in House Rule X.

Please contact Sean Hayes or Chris Hinkle of Chairman Chaffetz's staff at (202) 225-5074 with any questions about this request. Thank you for your attention to this matter.

Sincerely,

Jason Chaffetz
Chairman

John L. Mica
Chairman
Subcommittee on Transportation and Public Assets

Jim Jordan
Chairman
Subcommittee on Health Care, Benefits and Administrative Rules

Cynthia M. Lummis
Chairman
Subcommittee on the Interior

Mark Meadows
Chairman
Subcommittee on Government Operations

Will Hurd
Chairman
Subcommittee on Information Technology

John J. Duncan, Jr.
Member

Scott DesJarlais
Member

Rod Blum
Member

Jody Hice
Member

Earl L. "Buddy" Carter
Member

Glenn Grothman
Member

Gary Palmer
Member

Enclosure

cc: The Honorable Elijah E. Cummings, Ranking Member

The Honorable Matt Cartwright, Ranking Member
Subcommittee on Health Care, Benefits, and Administrative Rules

The Honorable Gerald E. Connolly, Ranking Member
Subcommittee on Government Operations

The Honorable Robin L. Kelly, Ranking Member
Subcommittee on Information Technology

The Honorable Brenda L. Lawrence, Ranking Member
Subcommittee on the Interior

The Honorable Harold Rogers, Chairman
Committee on Appropriations

The Honorable Nita M. Lowey, Ranking Member
Committee on Appropriations

The Honorable Kevin Brady, Chairman
Committee on Ways and Means

The Honorable Sander Levin, Ranking Member
Committee on Ways and Means

The Honorable Fred Upton, Chairman
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce

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.