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RANKING MINORITY MEMBER

ONE HUNDRED ELEVENTH CONGRESS

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) 225–5051
Minority (202) 225–5074

June 11, 2010

Mr. Jeffrey Kindler
Chief Executive Officer
and Chairman of the Board
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Kindler:

The Committee on Oversight and Government Reform is the principal oversight committee in the U.S. House of Representatives, with jurisdiction over "any matter." Under Rules X and XI of the Rules of the House of Representatives, the Committee is investigating reports that Wyeth Pharmaceuticals, Inc., which was acquired by Pfizer in October 2009, marketed the prescription drug Rapamune for purposes that were not approved by the Food and Drug Administration (FDA). In addition, the Committee is investigating the allegation that certain Wyeth promotional activities involving Rapamune targeted African-American patients and may have placed them at far greater risk of harm.

As you know, Rapamune is approved by the FDA for use as a drug to prevent the immune systems of kidney transplant patients from rejecting their new organs. It is subject to specific instructions regarding when, how, and to whom the drug should be administered.[1] However, it has been alleged that Wyeth aggressively encouraged the use of Rapamune to prevent organ rejection following heart, lung, liver, pancreas, and islet cell transplants, without FDA approval.

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[1] *See* "Rapamune (Sirolimus) Oral Solution and Tablets: Full Prescribing Information," Wyeth.com, Wyeth Inc., Initial U.S. Approval 1999, *available at* http://www.wyeth.com/content/showlabeling.asp?id=139 (last accessed May 26, 2010); *see also* Rapamune: Label and Approval History, U.S. Food and Drug Administration *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (last accessed May 26, 2010).

It has also been alleged that unapproved dosing regimens for Rapamune were promoted by Wyeth. According to former Wyeth employees, Wyeth allegedly encouraged physicians to switch patients from other medications and begin treatment with Rapamune at a later stage following a transplant than is approved by the FDA. Similarly, despite the FDA's concerns and specific instructions regarding the drug's use in kidney transplant patients at a high risk of organ rejection, such as African-Americans, the former employees claim that Wyeth may have targeted that population for the marketing of unapproved uses for Rapamune.

These are very serious allegations. Because of the seriousness of these issues, the Committee is investigating this matter further. To assist in our investigation, please provide the following information and records:

1. Have Pfizer or Wyeth, or any of their employees or agents, engaged in off-label marketing or promotion of Rapamune? If so, please explain in detail.

2. Have Pfizer or Wyeth, or any of their employees or agents encouraged off-label use of Rapamune? If so, please explain in detail.

3. Since January 1, 2000, did Wyeth target certain medical facilities for increased Rapamune sales? If so, please identify all such facilities and the dates they were targeted.

4. Since January 1, 2000, did Wyeth target certain medical facilities for Rapamune conversion, meaning switching patients from their existing transplant drugs to Rapamune? If so, please list all such medical facilities and the dates they were targeted for conversion.

5. Please provide copies of all written materials Pfizer and Wyeth have provided to healthcare providers regarding the safety or effectiveness of Rapamune when used for any purpose, or in any patient populations, other than that which has been explicitly approved by the FDA.

6. Please provide copies of all written material Pfizer and Wyeth have provided to healthcare providers that encourage conversion of transplant patients to Rapamune.

7. Please provide copies of all records pertaining to Pfizer or Wyeth arranging for physicians or other personnel to present to healthcare providers information on converting African-American patients to Rapamune.

8. Please provide copies of all records pertaining to complaints Pfizer or Wyeth have received from healthcare providers about Rapamune conversions.

9. Please provide copies of all records pertaining to reports Pfizer or Wyeth may have received from the Mayo Clinic regarding side effects from using Rapamune.

10. Have Pfizer or Wyeth ever offered incentives to health care providers related to the use of Rapamune? If so, please provide a detailed explanation, including a list of all such incentives, to whom they were offered, and the dates.

11. Please provide copies of any assessment of patient outcomes resulting from Pfizer's or Wyeth's encouragement of Rapamune use for any purpose other than that which has been explicitly approved by the FDA.

12. Please provide copies of all correspondence between Wyeth and Einstein Medical Center (Philadelphia) and SUNY Downstate Medical Center (Brooklyn) regarding Rapamune.

13. Have Pfizer or Wyeth been named as defendants in any criminal investigations or proceedings relating to Rapamune? If so, please provide a summary of the nature of all such investigations and proceedings, including the issues involved and the date, location, and disposition of the investigation or proceeding.

Please deliver the requested information and records to the Committee on Oversight and Government Reform, room 2157 Rayburn House Office Building, no later than 4:00 p.m. on Monday, June 28, 2010. To facilitate delivery and review, we prefer that the records be delivered in digital form. Please note that the terms "records" and "relating to" are defined in the attachment to this letter.

Should you have any questions regarding this request, please contact Jason Powell or Ryshelle McCadney of the Committee staff at (202) 225-5051.

Sincerely,

Edolphus Towns
Chairman

Attachment

cc: The Honorable Darrell Issa, Ranking Minority Member
Committee on Oversight and Government Reform

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.