ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

December 17, 2004

Dr. Hank A. McKinnell
Chairman & Chief Executive Officer
Pfizer Inc.
235 East 42nd Street
New York City, NY 10017

Dear Dr. McKinnell:

As part of its continuing oversight of the public health and the safety of prescription drugs, the Committee is examining potential cardiovascular safety issues surrounding COX-2 inhibitor drugs, such as Vioxx, Celebrex, and Bextra. As you know, Merck & Co., Inc. ("Merck") recently withdrew its COX-2 inhibitor drug rofecoxib, known commercially as Vioxx, from the market due to an increased risk profile associated with cardiovascular safety. As part of our investigation to date, we requested documents from the Food & Drug Administration ("FDA") relating to cardiovascular safety concerns associated with Celebrex and Bextra, two Cox-2 inhibitor drugs manufactured and marketed by Pfizer, Inc. ("Pfizer"), in addition to Vioxx. We have learned today that Pfizer Inc. ("Pfizer") announced prior to the stock market opening that it received results last night from a U.S. National Cancer Institute ("NCI") study that showed patients taking Celebrex had a 2.5 fold increase in their risk of a serious cardiovascular adverse event compared to those patients taking a placebo.

According to Pfizer's press release issued today, the Data Safety Monitoring Board ("DSMB") for two on-going long-term studies in Celebrex, reported to Pfizer last night that one of the studies showed a 2.5 fold increase in serious cardiovascular adverse events and that the sponsor of the study, NCI, suspended the dosing of the drug in the study. Pfizer further reported in its press release that the other long-term study, monitored by the same independent safety board as the NCI study, found no increased cardiovascular risk between the drug and placebo. According to the press release, the DSMB had previously reviewed the then-available data on cardiovascular adverse events in September and October and determined to continue the studies. We are seeking information to understand how the cardiovascular data from the NCI-sponsored trial dramatically shifted after the DSMB October review, as well as to gain a full

understanding about the known cardiovascular risks associated with Celebrex since it first came on the market in 1998.

In addition, we are concerned about public representations made by the company touting the safety of Celebrex during the Fall of 2004, when the cardiovascular data in these two long-term Celebrex trials was being analyzed. For example, on November 4, 2004, the company issued a press release entitled "Pfizer Affirms Celebrex Safety," in which the company responds to a Canadian newspaper article that reported on voluntary spontaneous reports of cardiovascular adverse events in people taking Celebrex. We are interested in learning what information the company had regarding the NCI-sponsored study cardiovascular data at that time. Further, in November, Pfizer announced a labeling change to its other marketed Cox-2 inhibitor, known commercially as Bextra, which warned about potential cardiovascular risks. Given these events happening within a month or so before the announcement today that call into question the cardiovascular safety profile of Celebrex, we are interested in learning when and why the company chose to have a DSMB monitoring cardiovascular adverse events in Celebrex trials.

In light of the Committee's jurisdiction over public health matters, we are requesting that, pursuant to Rules X and XI of the U.S. House of Representatives, you provide the Committee with the information requested below by Tuesday, January 4, 2005:

1. All records relating to cardiovascular adverse events associated with Celebrex including, but not limited to, the preliminary reports from the NCI-sponsored study, the PreSAP study, and the long-term Alzheimer patient study currently underway.

2. All records relating to cardiovascular adverse events associated with Bextra, including but not limited to, any study reports or internal memorandum that discuss cardiovascular safety issues associated with the drug or its class.

3. All records relating to any Data Safety and Monitoring Board of a Pfizer-sponsored study on Celebrex or Bextra that considered cardiovascular adverse events including, but not limited to, meeting minutes, internal correspondence between or among Data Safety and Monitoring Board members and Pfizer employees, telephone conference call memos, and meeting notes.

4. A listing of all Celebrex or Bextra trials in which there was a Data Safety Monitoring Board that reviewed cardiovascular events.

5. For each Celebrex or Bextra trial sponsored by Pfizer in which there was a Data Safety and Monitoring Board, provide the names of the members of

the Board, their most recent employment information and the dates upon which they served on the Board.

6. All communications between the FDA and Pfizer relating to possible increases in cardiovascular adverse events associated with Celebrex or Bextra, including but not limited to, any proposed or actual labeling changes.

7. All communications between current or former Pfizer employees relating to concerns about cardiovascular safety of Celebrex, Bextra, or Cox-2 inhibitors generally.

8. All records relating to the November 2004 labeling change to Bextra and the associated increase in cardiovascular adverse events.

9. All corporate minutes relating to any adverse events associated with Celebrex, Bextra or Cox-2 inhibitors generally.

10. A listing of all studies of Celebrex and Bextra performed, or in some manner sponsored, by Pfizer and the dates the study was started and completed.

11. For each study listed in Question 10, state whether the study was published in a peer-reviewed medical journal and, if so, provide the name of the journal and the publication date.

12. From the time Celebrex was first approved for use in the United States to the present, provide all data about monthly and annual Celebrex prescription and usage rates in the United States, in the aggregate and for all subcategories (e.g., states, major metropolitan areas, types of prescribers).

13. Provide the same information requested in Question 12 for Bextra.

14. From the time Celebrex was first approved for use in the United States to the present, state the annual revenue generated from Celebrex sales in the United States.

15. From the time Bextra was first approved for use in the United States to the present, state the annual revenue generated from Bextra sales in the United States.

In addition, we are requesting a briefing to take place as soon as possible to discuss the recent developments with respect to Celebrex and Bextra. Please note that, for purposes of responding to this request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. In order to set up a briefing

on this matter and for any questions you may have, please contact Kelli Andrews, Majority Committee Counsel, at (202) 226-2424 or David Nelson, Minority Investigator, at (202) 226-3400.

Sincerely,

Joe Barton
Chairman

John D. Dingell
Ranking Member

cc: The Honorable Greg Walden, Vice Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

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.