

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, Jr., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
DIANA DeGETTE, COLORADO
VICE CHAIRMAN
LOIS CAPPS, CALIFORNIA
MIKE DOYLE, PENNSYLVANIA
JANE HARMAN, CALIFORNIA
TOM ALLEN, MAINE
JAN SCHAKOWSKY, ILLINOIS
HILDA L. SOLIS, CALIFORNIA
CHARLES A. GONZALEZ, TEXAS
JAY INSLEE, WASHINGTON
TAMMY BALDWIN, WISCONSIN
MIKE ROSS, ARKANSAS
DARLENE HOOLEY, OREGON
ANTHONY D. WEINER, NEW YORK
JIM MATHESON, UTAH
G.K. BUTTERFIELD, NORTH CAROLINA
CHARLIE MELANCON, LOUISIANA
JOHN BARROW, GEORGIA
BARON P. HILL, INDIANA

ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER
RALPH M. HALL, TEXAS
J. DENNIS HASTERT, ILLINOIS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
NATHAN DEAL, GEORGIA
ED WHITFIELD, KENTUCKY
BARBARA CUBIN, WYOMING
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
STEVE BUYER, INDIANA
GEORGE RADANOVICH, CALIFORNIA
JOSEPH R. PITTS, PENNSYLVANIA
MARY BONO, CALIFORNIA
GREG WALDEN, OREGON
LEE TERRY, NEBRASKA
MIKE FERGUSON, NEW JERSEY
MIKE ROGERS, MICHIGAN
SUE MYRICK, NORTH CAROLINA
JOHN SULLIVAN, OKLAHOMA
TIM MURPHY, PENNSYLVANIA
MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

August 13, 2007

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

Mr. William Weldon
Chairman of the Board
Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Weldon:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with products regulated under the Food, Drug, and Cosmetic Act and the Public Health Service Act. As part of that inquiry, we have been examining the regulatory activities and enforcement decisions made by FDA officials. We are interested in the circumstances surrounding an FDA warning letter to Cordis Corporation regarding the CYPHER Sirolimus-Eluting Coronary Stent in April 2004.

FDA performed post-approval inspections of Cordis Corporation and its facilities involved in the design, manufacture, and distribution of CYPHER stents in September, October, and December 2003, at Cordis facilities in Miami Lakes, Florida; San German, Puerto Rico; Warren, New Jersey; Roden, Netherlands; Beerse, Belgium; and Latina, Italy. Based on these inspections, FDA inspectors found numerous systemic violations resulting in the adulteration of CYPHER stents, meaning that the methods, facilities, and controls used in the design, manufacturing, packing, storage, or installation of the stents do not conform with Current Good Manufacturing Practice (CGMP) requirements for medical devices set forth in FDA's Quality System (QS) Regulation. Despite these numerous violations, however, Cordis was allowed to continue marketing CYPHER stents.

Mr. William Weldon
Page 2

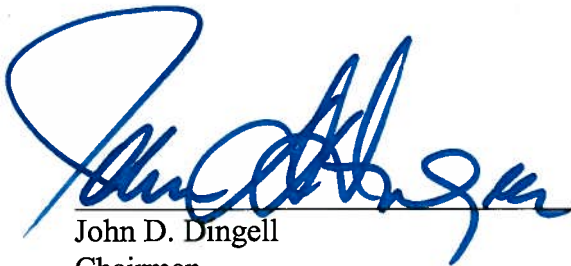
We therefore request all records relating to:

- FDA's warning letter dated April 2004 to Richard D. Anderson of Cordis Cardiology, Miami Lakes, Florida;
- All communications (written, e-mail, notes of telephone calls, notes of meetings) between Johnson & Johnson and FDA related to the Cordis/CYPHER inspections between September 2003 and June 2007;
- All Johnson & Johnson responses supplied to FDA as a result of Form 483 reports or Establishment Inspection Reports issued to Cordis sites that participate in the production of the CYPHER stent; and
- All internal Johnson & Johnson communications related to the Cordis/CYPHER inspections between September 2003 and June 2007.

In addition, we have directed our staff to interview Johnson & Johnson staff involved in the CYPHER inspections and subsequent regulatory decisions.


For the purpose of response to this letter, Johnson & Johnson refers to the parent company and any of its subsidiaries. Please refer to the attachment for definitions of the terms "records" and "relating."

Please provide your response and the requested records and arrange for the initial interviews by the close of business two weeks from the date of this letter. If you have any questions regarding these requests, please contact us, or have your staff contact David Nelson or Paul Jung with the Committee staff at (202) 226-2424.



John D. Dingell
Chairman

Sincerely,



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Mr. William Weldon
Page 3

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

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," or "relate" 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.