ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN



August 13, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Dr. von Eschenbach:

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 decisions made by FDA officials. We are interested in the circumstances surrounding an FDA warning letter to Cordis Corporation regarding their 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 requirements for medical devices set forth in FDA's Quality System Regulation. Despite these numerous violations, however, Cordis was allowed to continue marketing CYPHER stents.

We therefore request all records related to:

- FDA's warning letter dating April 2004 to Richard D. Anderson of Cordis Cardiology, Miami Lakes, Florida;

- All FDA Form 483 reports issued to Cordis in relation to their sites that participate in the production of the CYPHER stent;

- All FDA Establishment Inspection Reports (EIRs) corresponding to Form 483 reports requested above;

- All responses that Cordis supplied as a result of FDA Form 483 reports or EIRs issued to Cordis sites that participate in the production of the CYPHER stent;

- All communications (written, e-mail, notes of telephone calls, notes of meetings) between July 2003 and April 2004, from FDA inspectors involved in the Cordis/CYPHER inspections between September and December 2003;

- All communications (written, e-mail, notes of telephone calls, notes of meetings) between July 2003 and April 2004, from FDA staff in the Puerto Rico, New Jersey, and Florida district offices related to the Cordis/CYPHER inspections; and

- All documents (written, e-mail, notes of telephone calls, notes of meetings) produced by staff from the Center for Devices and Radiological Health or Office of Regulatory Affairs, or Office of the Commissioner related to the Cordis/CYPHER inspections.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter.

In addition, we have directed the staff to interview FDA staff in the New Jersey, Florida, and Puerto Rico district offices and within the Centers for Devices and Radiological Health involved in the CYPHER inspections and subsequent regulatory decisions.

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.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

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.