

FDA Drug Safety

During the last decade the Government Accountability Office, Congress, and the Food and Drug Administration (FDA) have all recognized serious shortcomings with the FDA's foreign drug inspect program. Despite an increase in the volume of imported drug products, resources dedicated to the foreign drug inspection program have declined. Committee staff have traveled to China and India in order to assess what challenges FDA teams face when conducting foreign inspections abroad, including resource constraints and logistics. The Subcommittee on Oversight and Investigations has also held several hearings on the issue of drug safety. The Committee will continue to monitor the safety of prescription drugs sold in this country.

Letters

April 11, 2008

[Letter to Schering-Plough Corporation and Merck and Co., Inc. in regard to the Committee's continuing investigation of the ENHANCE trial](#)

[April 25, 2008 response »](#)

March 31, 2008

[Letter to Johnson & Johnson and Amgen Inc., requesting documents relating to the marketing strategies of a class of drugs known as Erythropoiesis-Stimulating Agents \(ESAs\)](#)

[read the Johnson & Johnson Letter »](#)

[read the Amgen Inc., Letter »](#)

March 28, 2008

[Letter to FDA Commissioner von Eschenbach requesting personnel files of those FDA employees involved in the failed effort to inspect Chinese facilities that supplied bulk heparin to Baxter Laboratories](#)

March 19, 2008

Letter to FDA Commissioner von Eschenbach requesting documents relating to confusion over which Chinese facility supplied bulk heparin

March 12, 2008

Letter to Scientific Protein Laboratories, LLC CEO Strunce requesting information about the company's involvement in the heparin recall

April 2, 2008 response »

March 31, 2008 response »

March 6, 2008

Letter to FDA Commissioner von Eschenbach in regard to a class of drugs known as Erythropoiesis-Stimulating Agents

April 16, 2008 response »

March 5, 2008

Letter to HHS Secretary Leavitt in regard to the Agency's offer to access records related to Dr. von Eschenbach's testimony before the Committee March 22, 2007

Feb. 21, 2008

Letter to Baxter International Inc in regard to Baxter International's manufactured blood-thinning drug Heparin

March 4, 2008 response »

Feb. 21, 2008

Letter to HHS Secretary Leavitt in regard to Baxter International's manufactured blood-thinning drug Heparin

May 15, 2008 FDA response »

April 17, 2008 response »

February 25, 2008 response »

Feb. 21, 2008

Letter to FDA Commissioner von Eschenbach in regard to Baxter International's manufactured blood-thinning drug Heparin

Feb. 15, 2008

Letter to GAO Comptroller General Walker requesting information about the Agency's oversight study of the FDA

Feb. 14, 2008

Letter to FDA Commissioner von Eschenbach in regard to a Chinese facility which produces a drug that has been associated with hundreds of adverse events

March 5, 2008 response »

Feb. 14, 2008

Letter to Office of Management and Budget Director Nussle in regard to findings by the FDA's Science Board as reported in the January 29, 2008 hearing

April 28, 2008 response »

March 18, 2008 response »

Feb. 11, 2008

Letter to FDA Commissioner von Eschenbach requesting further information regarding the ENHANCE trial

March 20, 2008 response »

Feb. 7, 2008

Letter to FDA Commissioner von Eschenbach requesting further information regarding findings by the Science Board

Jan. 24, 2008

Letter to Schering-Plough Corporation and Merck & Co., Inc. in regard to the withholding of clinical data during the ENHANCE trial

Jan. 24, 2008

Letter to American College of Cardiology CEO Lewin in regard to the withholding of clinical data during the ENHANCE trial

February 11, 2008 response »

Jan. 24, 2008

Letter to American Heart Association CEO Wheeler in regard to the withholding of clinical data during the ENHANCE trial

Jan. 22, 2008

Letter to Schering-Plough Corporation and Merck and Co., Inc. in regard to the Committee's ongoing investigation into Vytorin and the ENHANCE trial

Jan. 22, 2008

Letter to Health and Human Services in regard to the Committee's ongoing investigation into Vytorin and the ENHANCE trial

February 11, 2008 response »

Jan. 22, 2008

Letter to FDA Commissioner von Eschenbach in regard to the Committee's ongoing investigation into Vytorin and the ENHANCE trial

Jan. 16, 2008

Letter to GAO Comptroller General Walker requesting more information on a possible third class of "Behind-the-Counter" drugs

January 24, 2008 response »

Jan. 16, 2008

Letter to Schering-Plough Corporation and Merck and Co., Inc. in regard to concerns about misleading statements in Direct-to-Consumer advertisements of prescription drugs

Jan. 16, 2008

Letter to FDA Commissioner von Eschenbach in regard to concerns about misleading statements in Direct-to-Consumer advertisements of prescription drugs

February 1, 2008 response »

Jan. 7, 2008

Letter to CEO and Chairman of the Board Kindler of Pfizer, Inc., in regard to Dr. Robert Jarvik's endorsement of the drug Lipitor

Dec. 13, 2007

Letter to HHS Secretary Leavitt in regard to the recently signed Memorandum of Agreements between China and the United States

Dec. 11, 2007

Letter to Schering-Plough Corporation and Merck & Co., Inc. in regard to withholding of clinical trial data relating to the medical management of hypercholesterolemia

Nov. 26, 2007

Letter to FDA Commissioner von Eschenbach in regard to a report linking use of the the drug Trasyolol with increased risk of renal failure and mortality

February 6, 2008 response »

Oct. 30, 2007

Letter to Housing and Urban Development Inspector General in regard to allegations of misconduct at the FDA

Oct. 12, 2007

Letter to FDA Commissioner von Eschenbach in regard to observations from a Committee staff oversight trip to China and India

Oct. 2, 2007

Letter to FDA Commissioner von Eschenbach in regard to imported prescription drugs and concerns about their ingredients

Oct. 1, 2007

Letter to CDC Director Gerberding in regard to the continued indiscriminate use of animal antibiotics

Dec. 7, 2007 response »

Aug. 20, 2007

Letter to FDA Commissioner von Eschenbach in regard to FDA inspections of drug manufacturing plants in China and India

Aug. 1, 2007

Letter to GAO Comptroller General Walker requesting a GAO report on the FDA's ability to assure the safety of the drug supply

Aug. 16, 2007 response »

July 5, 2007

Letter to FDA Commissioner von Eschenbach in regard to the conduct of FDA officials in the Avandia matter

August 23, 2007 response »

July 2, 2007

Letter to FDA Commissioner von Eschenbach announcing an investigation of FDA inspections of foreign manufacturing facilities

June 15, 2007

Letter to HHS Secretary Leavitt regarding concerns about Erythropoiesis-Stimulating Agents (ESAs) when used at higher than recommended doses

April 17, 2008 response »

January 10, 2008 response »

September 27, 2007 response »

March 28, 2007

Letter to HHS Secretary Leavitt in regard to the accuracy of FDA Commissioner von Eschenbach's testimony at the Committee's March 22, 2007 hearing

[April 11, 2007 response »](#)

[June 7, 2007 response »](#)

March 20, 2007

Letter to Amgen Chairman, CEO, and President Sharer in regard to the increased risk of blood clots and tumor growths for patients taking the drugs trade-named Aranap and Epogen

[April 18, 2007 response »](#)

March 20, 2007

Letter to Johnson & Johnson Chairman and CEO Weldon in regard to the increased risk of blood clots and tumor growths for patients taking the drug trade-named Procrit

[April 18, 2007 response »](#)

[August 10, 2007 response »](#)

March 14, 2007

Letter to David Ross in regard to additional questions for the record from the Feb. 13, 2007 Drug Safety hearing

March 14, 2007

Letter to John Powers in regard to additional questions for the record from the Feb. 13, 2007 Drug Safety hearing

March 14, 2007

Twenty organizations and individuals write open letter to Congress in regard to events at the FDA and the implications on the nation's health

March 9, 2007

Letter to Group Pharmaceutical Activities Chairman Rothwell in regard to the circumstances surrounding the FDA's approval of the Sanofi-Aventis antibiotic Ketek

[June 1, 2007 response »](#)

March 9, 2007

Senator Grassley writes FDA Commissioner von Eschenbach in regard to an FDA employees testifying before Congress

March 6, 2007

Letter from witness, Ann Marie Cisneros in response to questions posed by Ranking Member Barton regarding additional questions for the record from the Feb. 13, 2007 Drug Safety hearing

April 25, 2007

Letter to GAO Director for Public Health and Military Health Care Issues Crosse in regard to additional questions for the record from the March 22, 2007 Drug Safety hearing

response »

April 25, 2007

Letter to University of Washington Professor Psaty in regard to additional questions for the record from the March 22, 2007 Drug Safety hearing

May 1, 2007 response »

April 25, 2007

Letter to the FDA Commissioner von Eschenbach in regard to additional questions for the record from the March 22, 2007 FDA Drug Safety hearing

May 30, 2007 response »

April 24, 2007

Letter to Wake Forest University Professor Furberg in regard to additional questions for the record from the March 22, 2007 FDA Drug Safety hearing

May 7 , 2007 response »

response »

April 24, 2007

Letter to the Critical Path Institute President and CEO Woosley in regard to additional questions for the record from the March 22, 2007 FDA Drug Safety hearing

response »

April 18, 2007

Letter to Commissioner von Eschenbach in regard to the risks associated with antibiotic-treated animals entering the food supply

June 5, 2007 response »

Feb. 27, 2007

Letter to Copernicus Group Chairman and CEO Hill in regard to circumstances surrounding the FDA's approval of the Sanofi-Aventis antibiotic Ketek

Feb. 27, 2007

Letter to PPD CEO Eshelman in regard to circumstances surrounding the FDA's approval of the Sanofi-Aventis antibiotic Ketek

[April 13, 2007 response »](#)

[March 30, 2007 response »](#)

[March 28, 2007 response »](#)

[March 22, 2007 response »](#)

[March 15, 2007 response »](#)

[March 8, 2007 response »](#)

[Feb. 16, 2007](#)

Letter to HHS Secretary Leavitt in regard to the management of drug safety issues specific to the drug Ketek

[July 24, 2007 response »](#)

[July 19, 2007 response »](#)

[May 17, 2007 response »](#)

[April 25, 2007 response »](#)

[April 4, 2007 response »](#)

[March 29, 2007 response »](#)

[March 1, 2007 response »](#)

[Jan. 29, 2007](#)

Letter to FDA Commissioner von Eschenbach in regard to the adequacy of resources devoted to the Office of Generic Drugs

[News Releases](#)

"After Review of ENHANCE Trial Documents, Dingell, Stupak Express 'Serious Concerns'" -- April 15, 2008

"Committee Panel to Hold Hearings on Heparin Failures" -- March 19, 2008

"How Much Will it Cost to Adequately Fund FDA's Core Programs? Energy & Commerce Leaders Release Recommendations of Former Members and Advisors to FDA's Science Advisory Board" -- February 26, 2008

[read the letter to Committee Chairmen »](#)

[read the FDA's Science Board Report »](#)

"Continues Investigation into Celebrity Drug Endorsements" -- February 7, 2008

"Dingell Blasts Bush's Health Care Cuts" -- February 4, 2008

"Dingell, Stupak Comment on FDA Plan for Overseas Inspections" -- January 25, 2008

"Dingell, Stupak Question Merck/Schering-Plough's Sponsorship of American College of Cardiology and American Heart Association" -- January 24, 2008

"Dingell, Stupak Comment on Decision to Pull Vytarin Ads" -- January 23, 2008

"Dingell, Stupak Raise Concerns, Questions on ENHANCE Trial" -- January 16, 2008

"Dingell, Stupak to Continue ENHANCE Trial Investigation" -- January 14, 2008

"Dingell, Stupak Not Satisfied With FDA Response to Committee Requests; Will Consider Other Options to Fulfill Requests" -- May 24, 2007

"Dingell, Stupak Question FDA & Glaxo for Failing to Warn Diabetics of Dangers of Avandia" -- May 21, 2007

"Dingell, Stupak Call on Amgen, Johnson & Johnson to Suspend Direct-to-Consumer Marketing for Anemia Drugs" --
March 21, 2007

Hearing Materials

February 12, 2008

Ketek Clinical Study Fraud: What Did Aventis Know?

(Witness List & Testimony)

Exhibit Binder »

January 29, 2008

Science and Mission at Risk: FDA's Self-Assessment

(Witness List & Testimony)

November 1, 2007

FDA Foreign Drug Inspection Program: A System at Risk
(Witness List & Testimony)

March 22, 2007

The Adequacy of FDA to Assure the Safety of the Drug Supply - Part II (Witness List & Testimony)

Pediatric Exclusivity Labeling Changes »

February 13, 2007
The Adequacy of FDA Efforts to Assure the Safety of the Drug Supply (Witness List & Testimony)

Statements

April 22, 2008

Chairman Stupak at the hearing entitled "FDA's Foreign Drug Inspection Program: Weaknesses Place Americans at Risk"

February 12, 2008

Chairman Dingell at the hearing entitled "Ketek Clinical Study Fraud: What Did Aventis Know"

January 29, 2008

Chairman Dingell at the hearing entitled "Science and Mission at Risk: FDA's Self-Assessment"

March 22, 2007

Chairman Dingell at the hearing entitled "The Adequacy of the FDA Efforts to Assure the Safety of the Drug Supply Part II"

February 13, 2007

Chairman Stupak at the hearing entitled "The Adequacy of FDA Efforts to Assure the Safety of the Drug Supply"

November 1, 2007

Chairman Dingell at the hearing entitled "FDA Foreign Drug Inspection Program: A System At Risk"

Other Documents

- The Science Board Report (Appendix A and Appendix L)
- Action Plan for Import Safety
- HHS/FDA Food Protection Plan - November 2007
- "FDA Foreign Drug Inspection Program: A System At Risk" -- October 30, 2007 Committee Staff Report
- FDA Foreign Inspections -- Power Point by Chairman Stupak
- "Foreign Drugs Get Little Scrutiny by FDA" -- November 1, 2007 AP article
- "FDA's Foreign Inspection Budget Lean" -- November 1, 2007 Washington Post article

- "Chinese Chemicals Flow Unchecked Onto World Drug Market" -- October 31, 2007 New York Times article
- "FDA Publishes Guidance on Communication of Drug Safety Information" -- March 2, 2007 FDA Press Release
- "Ex-FDA Chief: Pharma goal at odds with safety" -- Feb. 22, 2007 Newark Star-Ledger article

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