

After Review of ENHANCE Trial Documents, Dingell, Stupak Express "Serious Concerns"

Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Rep. Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, today wrote to the CEOs of Schering-Plough Corporation and Merck & Co, Inc., requesting additional information about the ENHANCE study trial.

NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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After Review of ENHANCE Trial Documents, Dingell, Stupak Express "Serious Concerns";
Merck, Schering-Plough Documents Raise New Questions

Washington, D.C. — Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Rep. Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, today wrote to the CEOs of Schering-Plough Corporation and Merck & Co, Inc., requesting additional information about the ENHANCE study trial. This latest information request follows a review of documents related to conduct and reporting of the study.

"We continue to have serious concerns about the handling of the ENHANCE trial and the release of its results," said Dingell. "Our investigation has uncovered some unusual circumstances which has raised new questions for Merck and Schering-Plough about why the companies waited so long to release the study results."

The ENHANCE study compared the brand-name drug Vytorin to the generic drug simvastatin, both of which are used to treat patients with high-cholesterol. The study results show that Vytorin, which is a combination of Zetia and the generic

simvastatin, resulted in no significant difference when compared to simvastatin alone. The Committee on Energy and Commerce began an investigation into the ENHANCE trial on December 11, 2007. The investigation was launched following concerns that, although the ENHANCE trial ended in April 2006, the data was not released until January 14, 2008.

“Our investigation is far from over,” said Stupak. “We began looking into the ENHANCE trial because of concerns raised about the delay in the release of the results. Our questions have led to more questions that still need to be answered. We will continue to explore Merck and Schering-Plough’s conduct of the ENHANCE trial and what happened in the 20 months between when the trial ended and when the results were released.”

Additional information regarding the Committee’s ENHANCE/drug safety investigation

[Read the letter »](#)

[Attachments »](#)

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Prepared by the Committee on Energy and Commerce

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