



Summary of Testimony of  
Deepak Khanna, Senior Vice President and General Manager,  
Merck/Schering-Plough Pharmaceuticals  
before the Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
United States House of Representatives

May 8, 2008

As early as 1961, scientists identified elevated levels of cholesterol as among the risk factors for coronary heart disease, the leading killer of Americans. Lowering cholesterol – and specifically LDL cholesterol – through diet, exercise, and, if necessary, pharmaceutical treatment is the cornerstone of heart disease prevention.

Approximately 46 million adults in the U.S. have been diagnosed with high cholesterol and might benefit from pharmaceutical treatment. However, just 14.5 million adults are currently being treated with a cholesterol-lowering medication. The result is unnecessary disease and suffering.

Vytorin is a combination of two medicines: Zetia, which limits the absorption of cholesterol from food, and simvastatin, a statin medicine that moderates the body's inherited natural production of cholesterol.

The Vytorin advertising that Merck/Schering-Plough Pharmaceuticals broadcast from September of 2004 until January of this year used an effective approach to educate patients about the importance of lowering cholesterol, the two sources of cholesterol, the importance of diet and the additional LDL lowering that can come from drug therapy when a healthy diet is not enough.

These advertisements only made claims that are supported by research, that were evaluated by the Food and Drug Administration, and that were consistent with our FDA-approved labeling. In developing the advertising campaign, we sought advice from the FDA on the proposed content of our advertisements and revised them in response to those comments.

Merck/Schering-Plough Pharmaceuticals stands behind the benefits of Vytorin in lowering LDL cholesterol. We will continue to responsibly inform patients and prescribers about LDL cholesterol, the importance of diet and exercise, and Vytorin. As we move forward, we will continue to consult with physicians, patients and the FDA to ensure that the information we provide will continue to educate and motivate patients to improve their health.



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Mr. Chairman and members of the committee, I am Deepak Khanna, Senior Vice President and General Manager of Merck/Schering-Plough Pharmaceuticals. Like many Americans, I try to control my cholesterol through diet and exercise. Merck and Schering-Plough formed Merck/Schering-Plough Pharmaceuticals in 2000 to make available important treatment choices for patients who, unlike me, cannot maintain a healthy cholesterol level through diet and exercise alone.

As early as 1961, scientists identified elevated levels of cholesterol as among the risk factors for coronary heart disease, the leading killer of Americans. Lowering cholesterol – and specifically LDL cholesterol – through diet, exercise, and, if necessary, pharmaceutical treatment, is the cornerstone of heart disease prevention.

Mr. Chairman, despite our advances in the understanding of the role of high cholesterol in heart disease and in the development of effective treatments, the toll of heart disease remains too high and the level of understanding and treatment remain too low.

Approximately 46 million adults in the U.S. have been diagnosed with high cholesterol and might benefit from pharmaceutical treatment. However, just 14.5 million adults are currently being treated with a cholesterol-lowering medication. Of those treated, more than 4 million – or nearly one-third – are not attaining the desired



## MERCK / Schering-Plough Pharmaceuticals

cholesterol goals established by the NIH's National Cholesterol Education Program. The result is unnecessary disease and suffering.

It is against this backdrop that Merck/Schering-Plough Pharmaceuticals approached the decision to create and broadcast advertisements for Vytorin, which is a combination of two medicines: Zetia, which limits the absorption of cholesterol from food, and simvastatin, a statin medicine that moderates the body's inherited natural production of cholesterol.

High cholesterol alone has no symptoms. Advertising can be especially helpful in informing people about the need to address this important condition, as well as reminding them to fill their prescriptions and take their medicines as directed by their physician. As we developed our advertising, we learned that the vast majority of people understood the role of diet and exercise in cholesterol control, but did not appreciate the genetic causes. This leads to their disproportionately blaming themselves for a condition that is often inherited.

The advertising that Merck/Schering-Plough Pharmaceuticals broadcast from September of 2004 until January of this year used a unique, memorable, effective approach to educate about the importance of lowering cholesterol, the two sources of cholesterol, the importance of diet and the additional LDL lowering that can come from drug therapy when a healthy diet is not enough.

Our food and family advertisements were entertaining. This approach kept consumers engaged while we delivered a serious educational message. And our consumer research has consistently shown that the information about the two sources of cholesterol is getting through.



We commissioned a Harris survey that found that, prior to our advertising, just 16 percent of people were aware that there were two sources of high cholesterol. In the year following our advertising, we found that a full 54 percent of people now understood this. We also learned that our advertising had helped relieve the guilt people often carry when they are unable to control their high cholesterol with diet and exercise and encouraged them to have discussions with their physicians about additional options for controlling their cholesterol.

In developing the advertising campaign, we sought advice from the Food and Drug Administration on the proposed content of our advertisements and revised our advertisements in response to those comments. These advertisements only made claims that are supported by research, that were evaluated by the FDA, and that were consistent with our FDA-approved labeling.

Merck/Schering-Plough Pharmaceuticals suspended our Vytorin food and family broadcast advertising in January. We took this action in anticipation of the confusion that could be created by our release of the results of the ENHANCE trial.

Mr. Chairman, the ENHANCE trial was a relatively small study of a unique patient population that was genetically predisposed to very high levels of LDL cholesterol. ENHANCE compared the impact of Vytorin versus simvastatin on a surrogate marker for heart disease – reduction in the thickness of carotid arterial wall. While there was no difference on this measurement between the two treatments, Vytorin did demonstrate superior LDL-lowering compared to simvastatin.



Merck/Schering-Plough Pharmaceuticals stands behind the benefits of Vytorin in lowering LDL cholesterol. We will continue to responsibly inform patients and prescribers about LDL cholesterol, the importance of diet and exercise, and Vytorin. As we move forward, we will continue to consult with physicians, patients and the FDA to ensure that the information we provide will continue to educate and motivate patients to improve their health.

I appreciate the opportunity to appear before you and welcome your questions.