

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

November 14, 2009

Via Electronic Transmission

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Sebelius and Commissioner Hamburg:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 100 million Americans who receive health care coverage under those programs. In this capacity, I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the Centers for Medicare and Medicaid (CMS) and the Food and Drug Administration (FDA). Specifically I am committed to overseeing the proper administration of these agencies to ensure that taxpayer dollars are appropriately spent on safe and effective drugs and devices.

Back in February 2008, I began an inquiry into Vytorin, a drug made by Schering-Plough and Merck. Vytorin is a pill that combines the statin, simvastatin, with a drug called ezetimibe that decreases absorption of cholesterol by the digestive tract. I initially sent the companies a letter because of reports in the media that they were not releasing the results of a trial called ENHANCE. In response to my concerns, Schering-Plough and Merck explained to me that in 2006 and 2007 they made over \$300 million in Medicare Part D sales for Vytorin. When the trial results for ENHANCE were released, the companies' own press release stated that there is no apparent gain in health benefits from using Vytorin over the much cheaper generic statin, simvastatin.¹

Yesterday, I read reports that the latest trial of Vytorin again found that the drug provides no apparent health benefit over a much cheaper statin.² Accordingly, I would like to understand what actions that the Department of Health and Human Services, CMS, and/or the FDA may be taking in light of this information.

¹ Schering-Plough News Release, "Merck/Schering-Plough Pharmaceuticals Provides Results of EHANCE

² Natasha Singer, "A New Cholesterol Study Puts Focus on Merck Drugs," New York Times, November 12, 2009.

I look forward to hearing from you by no later than December 4, 2009. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Emilia DiSanto or Paul Thacker at (202) 224-4515.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive style with a prominent "C" and "G".

Charles E. Grassley
Ranking Member