

September 7, 2008

Letters to the Editor
The New York Times
620 Eighth Avenue
New York, NY 10018

To the Editor:

The 9/2/08 article, “The Evidence Gap” misstates the evidence by reporting erroneous facts regarding the clinical development and FDA approval of Zetia.

The article states FDA approval was based on “a handful” of clinical trials covering a total of 3900 patients and none took the medicine for more than 12 weeks. In fact, the FDA submission contained over 50 clinical studies and was one of the largest databases ever submitted at that time for a cholesterol lowering drug. The initial approval was based on information on more than 4,700 patients, including 2,106 followed for 6 months or longer and 1,393 followed for 12 months or longer.

The efficacy demonstrated in lowering LDL (bad) cholesterol with Zetia alone or coadministered with a statin was consistent in study after study. The addition of Zetia resulted in significant incremental decreases in LDL cholesterol over that achieved with a statin alone. Zetia was generally well tolerated and demonstrated an excellent safety profile in this large clinical experience – and in the subsequent clinical experience.

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