

## Investigative Assignment: “At the Crossroads for Cholesterol Drugs”

### *Specifics:*

This assignment may be utilized in lieu of attendance at one on-campus session for the course. It is comprised of a written piece only; i.e., no formal assigned readings that you will be quizzed on. Your document should be 2-3 pages (single-spaced, 12 pt font with 1 inch margins). Put only your ID. **Please do not include the assignment instructions given below in your submission.**

**Must be submitted online (in Turnitin) by:** Tuesday, December 15<sup>th</sup> at midnight  
**Peer grading (in Turnitin) must be completed by:** Friday, December 18<sup>th</sup> at midnight

Earlier this week, controversial results from the latest research study investigating lowering of patient cholesterol with potentially significant implications for multibillion-dollar cholesterol medications already on the market were discussed at the annual meeting of the American Heart Association, and subsequently publicized in mainstream newspapers (see USA Today article titled “[Small heart study makes a big impact](#)”) and on the evening news (see clip from CBS Evening News titled “[Zytarin, Zetia put to the test](#)”).

In response to the announcement, the *New York Times* reports that Senator Grassley from Iowa (who sits on the Senate Finance Committee which has jurisdiction over Medicare and its drug spending) wrote to the Department of Health and Human Services, asking its director what action she intended to take in light of the study results. Senator Grassley indicated that in 2006 and 2007 alone, the drug makers made more than \$300 million through Medicare Part D in sales of Vytorin.

**On the heels of this fanfare, imagine that a patient comes to your office with printed newspaper article in hand and asks you whether they should continue taking their current medication (if you do not envision yourself in primary care, imagine that a relative asks you at Thanksgiving about whether they should switch their medication based on what they saw on TV). Before responding with your medical opinion, you conduct research in order to better inform your answer.**

### For this assignment:

Read the news release in *USA Today* and watch the video clip from CBS News. Using those pieces as a launching point, investigate the validity of the claims being made to the American public. In order to accomplish this, you may wish to review the primary source material that is referenced in these articles, including the new “HALTS” trial from the *New England Journal of Medicine* along with its two accompanying expert commentaries as well as the previously published “ENHANCE” and “SEAS” studies also alluded to in the stories. Another angle to a well-informed opinion might include reading the response by the pharmaceutical companies intended to sway consumers in favor of the efficacy of their products.

Once you have completed your “investigative research”, draft a **two-part response**, **firstly** to your patient/relative, putting the results into context and advising them on a course of action. **Secondly**, frame a scholarly response to Dr. Shanley and Dr. Epling in which you discuss the relevant studies (their design, limitations, outcomes and the validity issues raised by these and how the authors address them). Comment on how these studies are accurately or inaccurately being represented in the news media. Finally, discuss current ideas about the cholesterol-lowering mechanism(s) of niacin and summarize research that either supports these mechanistic hypotheses or that makes them doubtful.

*(AAMC Objectives: Knowledge of the relevant background concepts in the basic sciences; Knowledge of what is established and what the question is with respect to the clinical issue being addressed; Ability to translate the findings of the study and the state of knowledge in the field into lay language appropriate for communication with patients; Ability to critically assess the information presented in terms of the conclusions drawn by the authors; Awareness of the ethical issues raised by the investigation (e.g., conflicts of interest); Attitudes of curiosity, skepticism, humility in the face of the unknown and intent to pursue a career of lifelong diligent questioning and learning)*

