

Date: March 20, 2008

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 03/20/08 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of atorvastatin, fluvastatin, pravastatin, rosuvastatin, simvastatin and lovastatin. It also considered fixed dose combination products including Advicor, Simcor and Vytorin. Ms. Carson through a recording and Dr. McDonough by telephone conference addressed the Committee telephonically regarding the EPC's views on the individual statins and combination drugs respectively and responded to questions.

The voting members of the Committee made the following formal recommendations based upon their perception of the bulk of the best available evidence with the understanding that comparable doses of each drug are used.

1. None of the six drugs differ significantly in either the incidence or the nature of clinically evident complications in patients of a particular sex, age or race when appropriately dosed.
2. None of the six drugs have been proven more efficacious for patients of a particular sex, age or race.
3. Atorvastatin, simvastatin, pravastatin, fluvastatin and lovastatin all improve some primary health outcomes. However, lovastatin lacks data on intermediate outcomes.
4. Atorvastatin, simvastatin, pravastatin and rosuvastatin are all effective in reducing LDL cholesterol in patients with moderate elevations. Furthermore, all have both primary and intermediate outcome data except rosuvastatin which lacks primary outcome data. At least two of these agents with primary outcome data should be available. [The Committee defines the relative elevations requiring reduction as follows: low < 35%, moderate 35 to 50%, and high > 50%.]
5. Either rosuvastatin or atorvastatin should be available for patients requiring greater than 50% reduction.
6. Atorvastatin, simvastatin, pravastatin and rosuvastatin all increase HDL-c. Of these all have primary outcome data except rosuvastatin.

7. The Committee also offers the following comment: It is not possible to make generic recommendations for individuals having certain co-morbidities, taking potentially interacting drugs or experiencing refractory hyperlipidemias. However, pravastatin is a good potential choice for patients taking cytochrome P450 inhibitors and should be available to such patients. Various other cases will quite possibly need to be addressed in the prior authorization process.

8. The Committee voted to table discussion of the three combination drugs Vytorin, Simcor and Advicor pending receipt of additional information about primary and intermediate outcomes.