

Date: May 20, 2005

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 05/20/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the inhaled corticosteroids in pediatric outpatients with asthma, adult outpatients with asthma, and adult outpatients with COPD. Specifically considered were beclomethasone, budesonide, flunisolide, fluticasone and triamcinolone.

Dr. Richard Hansen of the EPC addressed the Committee telephonically regarding his organization's views on these agents.

With the understanding that equipotent doses of each drug are used, the Committee reached the following conclusions based upon its perception of the bulk of the best available evidence.

1. None of the five available inhaled steroids is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration for patients in the aforementioned three patient populations.

2. None of the five drugs have been proven more efficacious for patients in the aforementioned three patient populations.

3. None of the five drugs have been associated with fewer adverse events among patients on the basis of sex, race, pregnancy, co-morbidities or concomitant use of other medications.

However, due to considerations regarding potential growth retardation, fluticasone and budesonide should be available for children based upon the available safety data for these two agents.

4. None of the five drugs has been proven more effective in the three subgroups of patients on the basis of sex, race, pregnancy, co-morbidities, or concomitant use of other medications.

5. When prescribing the inhaled corticosteroids, the Committee submits the following considerations:

That budesonide be available by nebulizer

That a dry powder inhalation product be available

That the PDL not be restricted to either triamcinolone or flunisolide without concomitant availability of a more potent agent

That spacers continue to be available.