

Date: April 20, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 04/20/06 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, mometasone, and triamcinolone.

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 six 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 six drugs have been proven more effective for patients in the aforementioned three patient populations.
3. Although data are limited, at least one of the following inhaled corticosteroids should be available adults with COPD: beclomethasone, budesonide, fluticasone, and triamcinolone.
4. None of the six inhaled corticosteroids have been associated with fewer adverse events on the basis of sex, race, pregnancy, co-morbidities or concomitant use of other medications.
5. Due to considerations regarding potential growth retardation budesonide should be available for children.
6. None of the six drugs has been proven more effective on the basis of sex, race, pregnancy, comorbidities, or concomitant use of other medications.

7. At least one of the following delivery systems should be available given the varying capabilities of patients: dry powder inhaler, metered dose inhaler and nebulizer.

8. Triamcinolone should not be the sole agent available due to its relatively low potency.

Henry F. Simmons, Jr.
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