

Date: February 23, 2009

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 02/19/09 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected inhaled corticosteroids, long acting beta agonists, leukotriene modulators and omalizumab for targeted conditions.

Specific medications under consideration include the following:

Beclomethasone dipropionate

Budesonide

Flunisolide

Fluticasone propionate

Mometasone furoate

Triamcinolone acetonide

Formoterol

Salmeterol

Zafirlukast

Montelukast

Zileuton

Omalizumab

Budesonide/formoterol

Fluticasone/salmeterol

Indications under consideration

Outpatient management of adults and children with persistent asthma including those with exercise induced bronchospasm

The Committee reached the following conclusions unanimously based upon its perception of the bulk of the best available evidence:

The captioned inhaled corticosteroids do not differ significantly in efficacy or toxicity when administered in equivalent doses.

At least one inhaled corticosteroid should be available by nebulizer, at least one by metered dose inhaler and at least one by dry powder inhaler.

Budesonide should be available for pregnant patients.

The captioned long acting beta agonists do not differ significantly in efficacy and toxicity when administered in equivalent doses.

At least one of the captioned leukotriene modulators should be available, but the Committee has concerns about the potential hepatotoxicity of zileuton. Accordingly, if only one leukotriene modulator is selected, then it should not be zileuton.

Omalizumab should be available only with prior authorization at this time.

The captioned combinations of inhaled corticosteroids and long acting beta agonists do not differ significantly in efficacy and toxicity when administered in equivalent doses.

At least one combination product should be available as a dry powder inhaler and at least one by metered dose inhaler.