

Date: January 15, 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 01/15/09 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected beta agonists, anticholinergic agents and combinations for targeted conditions.

### **Agents**

#### Short- acting Inhaled beta2 agonists [SABAs]

Albuterol (Ventolin, Proventil)

Levalbuterol (Xopenex)

Pirbuterol (Exirel, Maxair)

Metaproterenol (Alupent)

#### Anticholinergics

Ipratropium bromide (Atrovent)

#### Combinations

Ipratropium bromide with albuterol (Combivent)

### **Indications**

Adults and children with asthma or exercise induced bronchospasm

### **Discussion**

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

### **Safety Adverse Events**

1. The available agents do not differ significantly in terms of either safety or adverse event profiles in children or adults.

### **Efficacy/Effectiveness**

2. Albuterol should be available for adults and children.

### **Demographics**

3. Ipratropium should be available as a sole agent for children and adults with unstable upper airway diseases.

4. For adult patients with asthma and with chronic obstructive pulmonary disease [emphysema, chronic bronchitis] both ipratropium bromide and albuterol should be available.

5. Ipratropium should be available for use in combination with albuterol for adults and children.

6. Levalbuterol should be available for patients with demonstrated, clinically significant, adverse reactions to albuterol and for those who are potentially at increased risk for cardiovascular side effects of albuterol. Examples of the latter category include those with congenital heart disease and arrhythmias.