

# Summary Remarks

## Risk-Benefit Assessment of Long-Acting Beta-Agonist Bronchodilators in the Treatment of Asthma

Badrul A. Chowdhury, MD, PhD

Director, Division of Pulmonary and Allergy  
Products, Office of New Drugs,

Center for Drug Evaluation and Research,  
US Food and Drug Administration



# Differing Views on Managing LABA Risk

- Unanimous recommendations from OSE
  - Withdraw asthma indication for all LABAs for patients <18 years of age
  - Remove asthma indication and contraindicate use of single ingredient LABAs for all ages
- DPAP's position
  - Products containing LABAs should continue to be marketed
  - Safety risk should be managed through labeling

# Medications for Treating Asthma

- Quick-relief medications
  - Short-acting beta-agonist bronchodilators (SABA). e.g., inhaled albuterol
  - Systemic corticosteroids
- Long-term control medications
  - Cromones
  - Immunomodulators - omalizumab
  - Inhaled corticosteroids (ICSs)
  - Leukotriene modifiers
  - Long-acting beta-agonist bronchodilators (LABAs), e.g., inhaled salmeterol, inhaled formoterol
  - Methylxanthines
  - Systemic corticosteroids

# Medications for Treating Asthma

- Quick-relief medications
  - Short-acting beta-agonist bronchodilators (SABA). e.g., inhaled albuterol
  - Systemic corticosteroids
- Long-term control medications
  - Cromones
  - Immunomodulators - omalizumab
  - Inhaled corticosteroids (ICSs)
  - Leukotriene modifiers
  - Long-acting beta-agonist bronchodilators (LABAs), e.g., inhaled salmeterol, inhaled formoterol
  - Methylxanthines
  - Systemic corticosteroids

# Risk-Benefit Assessment of LABAs

- Risk
  - Serious risk of asthma-related death and asthma exacerbation in a small number of patients
- Benefit
  - Most patients derive symptomatic benefit in the form of improved lung function, reduced nocturnal awakening from asthma symptoms, and decreased use of rescue SABA for asthma exacerbations

## Consequence of Removal of Asthma Indication for LABAs

- Reduce choices for clinicians unable to control patients' asthma on ICS alone
- Increased concern of inappropriate use of LABAs in patient with asthma

## Concluding Remarks

- Risk in a small number of patients, whereas, benefit in most patients
- Accept and manage safety risk
  - Labeling, including Boxed Warning and Medication Guide, to inform patients and health care providers of the risk
  - Labeling to direct use of LABA for appropriate patients

# Concluding Remarks

- Patients 4 years of age and older
  - LABAs should be used in patients not adequately controlled on other asthma-controller medications (e.g., low to medium dose ICSs) or whose disease severity clearly warrants initiation of treatment with two maintenance therapies
  - LABAs should not be used in patients whose asthma can be managed by ICS along with occasional use of inhaled short acting beta2-agonists
- Patients less than 4 years of age
  - LABAs not approved in this age group