

Opening Remarks

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Purpose

- Benefits and Risks of Prescription Opioid Products for Treatment of Cough in Pediatric Patients
 - Hydrocodone
 - Codeine
- FDA Response to Opioid Abuse
- Focus on Prescription Products

Agenda

- Treatment of Cough- Dr. John Oppenheimer
- FDA Presentations
- Manufacturer Presentations
- Effects on Adolescents - Dr. Sharon Levy
- Open Public Hearing
- Questions to Presenters
- AC Discussion

Questions

1. **Discussion**: Discuss the benefit/risk of the use of prescription codeine and hydrocodone antitussives in pediatric patients.
 - a. What are the benefits and risks for the codeine and hydrocodone products intended for treatment of cough associated with allergy or the common cold? In your deliberations, include the benefits and risks of these products for the patients as well as the wider public health impacts of opioid containing medications.
 - b. Does the benefit risk assessment change for treatment of cough in other specific circumstances?

Questions

- c. Are there important differences in the benefit/risk between hydrocodone and codeine that would affect your recommendations about use in pediatric patients?
- d. Are there differences in the benefit/risk assessment for specific pediatric age groups?
- e. How do the wider public health impacts of opioid containing medications affect your benefit/risk assessment of codeine and hydrocodone products intended for treatment of cough?

Questions

- 2. Voting:** Is the benefit/risk favorable for use of prescription codeine cough suppressants for treatment of cough associated with allergy or the common cold in pediatric patients 12 to < 18 years of age? (**Yes or No**)

Provide the rationale for your vote.

Questions

3. **Voting**: Is the benefit/risk favorable for use of hydrocodone cough suppressants for treatment of cough associated with allergy or the common cold in pediatric patients:
- 6 to < 12 years of age? (**Yes or No**)
 - 12 to < 18 years of age? (**Yes or No**)

Provide the rationale for your vote.

Questions

4. **Voting**: Is the benefit/risk favorable for use of prescription opioid cough suppressants for treatment of cough in pediatric patients?
(Yes or No)

Provide the rationale for your vote.

