FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 17-18, 2018

DRAFT QUESTIONS

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1. **DISCUSS:** Naloxone is currently available through individual prescriptions for patients from their healthcare providers (e.g., pain clinics and opioid treatment programs) and without individual prescriptions through community-based programs offering overdose education and naloxone distribution and by direct access from pharmacies under programs such as statewide naloxone standing orders or collaborative practice agreements. Discuss the comparative and collective effectiveness of these programs with regard to prevention of overdose death and their ability to get naloxone where it is most needed in communities to save lives.

2. **DISCUSS:** Discuss potential burdens and barriers associated with co-prescribing naloxone concurrently with opioid prescriptions for all or some patients or with targeted prescribing for individuals considered at high risk for overdose. Discuss how these burdens or barriers may affect implementation of co-prescription or targeted prescribing and what steps could be taken to mitigate these impacts.

3. **DISCUSS:** Because of the significant costs for patients and the health care system associated with increasing naloxone availability, prioritization of strategies will likely be needed. Discuss, in terms of available data on effectiveness and costs, which, if any, of the following approaches may be beneficial for public health:

    a. Relying on alternate approaches for increasing naloxone availability (e.g., community-based distribution programs, statewide standing orders)

    b. Limiting co-prescribing or targeted prescribing to certain populations that may potentially benefit the most from having naloxone available (i.e., those at highest risk for overdose or death due to overdose). If so, identify those populations, along with the evidence supporting this benefit.

4. **DISCUSS:** Discuss any potential unintended consequences that should be considered if naloxone is co-prescribed to all or some patients prescribed opioids, and what steps can be taken to mitigate them.

5. **VOTE:** Would labeling language that recommends co-prescription of naloxone for all or some patients prescribed opioids, or more targeted prescribing for patients otherwise at high risk for death from opioid overdose be an effective method for expanding access to naloxone and improving public health?

    a. If so, which populations do you believe should be included in such labeling?