United States Senate
WASHINGTON, DC 20510

February 12, 2014

Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write to share our appreciation for the U.S. Food and Drug Administration's (FDA) recommendation to reschedule hydrocodone combination products from Schedule III to the more restrictive Schedule II. However, we note that the FDA has also approved a powerful, extended-release pure hydrocodone product. This decision contradicts the FDA's own advisory panel, and could undermine the important measures taken by the FDA, lawmakers, and state attorneys general to curb prescription drug abuse across the country unless accompanied by appropriate safeguards and due consideration for the potential for abuse.

Data from the Centers for Disease Control and Prevention (CDC) show that more than 16,000 Americans die from opioid drug overdoses each year. Further, opioid analgesics, including drugs with hydrocodone, comprise approximately 75 percent of all pharmaceutical overdose deaths.[1] We believe the approval of pure hydrocodone products without methods to prevent abuse, misuse, and diversion, including abuse-deterrent formulations, poses a significant danger to our constituents, as it could worsen the drug abuse epidemic in our country.

The Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) noted in its December 2012 report that "as a hydrocodone single-entity, extended-release product, it is expected that [this drug](if approved and marketed) will be associated with higher levels of abuse than the hydrocodone combination products. These expected higher levels of abuse are based on what has been observed for oxycodone products."[2] Given this clear warning from the FDA's advisory panel, we would like to know what safeguards FDA mandated for the product and we would appreciate answers to the following questions:

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[1] "Opioids drive continued increase in drug overdoses deaths," Centers for Disease Control and Prevention," February 20, 2013, http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html.
[2] FDA Background Material—NDA 202800, Food and Drug Administration: Center for Drug Evaluation and Research, December 7, 2012, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM330683.pdf.

1. What conditions are in place around the production and distribution of this drug, and how were those conditions evaluated to ensure their effectiveness for preventing misuse, abuse, and diversion?

2. How does FDA balance patient needs with regard to access to safe and effective pain medication with the potential for abuse, misuse, and diversion?

3. You have previously confirmed that the FDA has the legal authority under the Federal Food, Drug, and Cosmetic Act to require drugs, including generic versions, to have an abuse-deterrent formulation.[3] How does the FDA plan to use this authority in regards to approving both brand and generic opiates? Please provide examples of the circumstances in which FDA would use this authority.

4. How does FDA plan to monitor the abuse, misuse, and diversion of pure hydrocodone products, including overdose rates, and evaluate and update the conditions put in place to prevent such abuse, misuse, and diversion if necessary? Please include any plans to work with law enforcement and stakeholders on implementing the most effective strategies to prevent abuse, misuse, and diversion, such as the standards for and requirement of abuse deterrent formulations.

We appreciate your response to these questions and look forward to hearing about your systematic approach to balancing the risks and benefits associated with access to innovative pain medication and any associated potential abuse, misuse, and diversion.

Sincerely,

MITCH MCCONNELL
REPUBLICAN LEADER
U.S. SENATE

TOM COBURN, M.D.
U.S. SENATE

LAMAR ALEXANDER
U.S. SENATE

[3] Letter from Commissioner of Food and Drugs, Margaret A. Hamburg, M.D. to Congressman Fred Upton, January 8, 2013, http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/letters/20130108FDAResponse.pdf.