Congress of the United States

Washington, D.C. 20515

December 21, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

We write regarding the imminent release of non-tamper-resistant versions of extended-release opioids and the impact of this release on our nation's struggle against prescription drug abuse. During the past month, we have heard from a number of concerned citizens, including parents, law enforcement officials, health care providers, state and local officials, and our colleagues in Congress, about the impending release of the non-tamper-resistant versions of these opioids. According to these concerned citizens, the release of the non-tamper-resistant versions will deal a significant setback to our nation's ongoing struggle to stop prescription drug abuse. To help us understand how your Department could address this situation, we ask you to answer the following questions:

1. Assuming the Food and Drug Administration (FDA or Agency) was convinced that the innovator product was tamper resistant, what authority does the Agency have to prevent the marketing of these non-tamper-resistant generic versions, or remove them from market, should they jeopardize the public health?

2. Section 505(e) of the Federal Food, Drug and Cosmetic Act provides that the Secretary may suspend the approval of an application if she finds an "imminent hazard to the public health." Please provide us examples of how this authority has been utilized. If FDA concluded that an innovator product was tamper resistant but the generic versions were not, are there any circumstances under which this imminent hazard authority could be applied to the situation?

3. Pursuant to section 1122 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), FDA must promulgate guidance on the development of abuse-deterrent products by January 9, 2013. Please provide an update on the status of this guidance, whether FDA will comply with the statutory mandate and how this guidance will address the evidentiary standard to show tamper resistance and the release of these non-tamper-resistant opioids if FDA found that the innovator product was tamper resistant.

We look forward to your expeditious reply.

Sincerely,

Fred Upton
Chairman
House Energy and Commerce Committee

Tom Coburn
Member
U.S. Senate

cc: The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration