United States Congress
WASHINGTON, D.C.

March 5, 2013

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

Dear Commissioner Hamburg,

We appreciate your January 8, 2013, correspondence confirming the Food and Drug Administration's (FDA) legal authority to require that generic versions of abuse-deterrent formulations of prescription opioid products have abuse-deterrent properties similar to the innovator product. We also applaud the FDA's timely release on January 9, 2013, of a draft guidance document on the testing and labeling of abuse-deterrent opioid products.

However, despite these positive steps, we continue to be concerned about the lack of a clear statement from FDA regarding the agency's intention to prevent the marketing of non-abuse-deterrent generic versions of innovator products that have been withdrawn from the market and replaced with abuse-deterrent formulations. We believe such marketing could present a threat to the public health as it could worsen the prescription drug abuse epidemic already threatening our country. Sadly, Canada's experience serves as a cautionary tale. Canadian authorities now permit the marketing of non-abuse-deterrent generic versions of the original OxyContin formulation, and not surprisingly, the U.S. Office of National Drug Control Policy Director Gil Kerlikowske recently announced the first seizure of non-abuse-deterrent Canadian product discovered in the U.S. The illicit spread of certain drugs prone to abuse is both predictable and preventable.

To help prevent the illicit spread in the U.S. of certain drugs particularly vulnerable to abuse, is FDA prepared, under its existing authority, to prevent the marketing of non-abuse-deterrent versions of innovator products that have been withdrawn from the market and replaced with abuse-deterrent formulations?

FDA also has not published guidance on the testing requirements by which a manufacturer of a generic opioid drug product may demonstrate that its product has abuse-deterrence properties similar to those of the innovator product. We believe that such guidance is critical to enabling generic manufacturers to design abuse-deterrent products and allowing public input into the level of assurance that generic manufacturers should have to provide on comparability. To help us better understand the FDA's thinking in this regard, please respond to the following questions:

- What advice has FDA provided to date to Abbreviated New Drug Application (ANDA) applicants regarding the type and extent of data which will be required to establish that a generic product has comparable abuse-deterrent features to an abuse-deterrent innovator product?

- What are FDA's criteria for deciding whether to provide public advice on a specific category of testing requirements applicable to a large number of products both pending and in development?

- Are offices within FDA which are developing policies on abuse-deterrent formulations coordinating with each other so those policies are consistently understood and applied, particularly when it comes to the question of how generic products could demonstrate that they have abuse-deterrent features comparable to the innovator?

We appreciate the FDA has many factors to balance when considering any action and the need to consider how any action in this area could impact future abuse-deterrent innovations and the underlying definition for drug approvals. However, we believe that patient safety concerns merit careful, targeted action on this issue.

To help us better understand the FDA's thinking on the issues raised in this letter, we request a briefing with appropriate Agency staff to occur no later than March 19, 2013. Prior to this briefing, please respond to the aforementioned questions.

Thank you in advance for your prompt consideration of these issues. We look forward to your expeditious reply.

Sincerely,

Fred Upton
Chairman
House Committee on Energy and Commerce

Tom Coburn
Member
U.S. Senate

cc: The Honorable Henry A. Waxman, Ranking Member
House Committee on Energy and Commerce