



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 21, 2013

James McPherson
Executive Director, National Association of Attorneys General
2030 M Street, NW
Eighth Floor
Washington, DC 20036

Dear Mr. McPherson:

Thank you for the letter from the National Association of Attorneys General, signed by 48 members, expressing concern about the abuse of opioids. FDA shares these concerns and has taken several actions to address abuse and misuse of opioid analgesics, including:

- On July 9, 2012, FDA approved Risk Evaluation and Mitigation Strategies for long-acting (LA) and extended-release (ER) prescription opioids requiring sponsors of these products to make training available on proper prescribing practices and to distribute educational materials to prescribers and patients on the safe use of these medications. Additional information about this can be found on the FDA website at:
<http://www.fda.gov/Drugs/DrugSafety/%20InformationbyDrugClass/ucm309742.htm>.
- When the applicable statutory and regulatory requirements are satisfied, FDA grants "Fast Track" and "Priority Review" status to applications for potentially abuse-deterrent formulations of prescription opioid products to both encourage the development and speed the approval process of such products.
- On January 9, 2013, as required by Section 1122 of the Food and Drug Administration Safety and Innovation Act (FDASIA, Public Law 112-144), FDA issued a draft guidance for industry on the development and evaluation of abuse-deterrent opioids. A copy of the draft guidance is available on FDA's website at:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf>.

I am unable to comment on what further actions the agency will take with respect to approval or withdrawal of opioids that are not formulated to deter abuse if that same opioid is already available in a proven abuse-deterrent formulation. However, I can assure you that we are actively evaluating our policies regarding the safety of all prescription opioids, including opioids with and without potentially abuse-deterrent properties, and we appreciate your input.

Thank you for contacting me concerning this important issue. Please contact me if you have further thoughts or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Margaret A. Hamburg". The signature is fluid and cursive, with the first name "Margaret" being more prominent.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs