

April 3, 2013

Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Commissioner Hamburg:

As I travel throughout Kentucky and meet with constituents, I continue to hear concerns about prescription drug abuse. Foremost in the minds of many of my constituents remains the Food and Drug Administration's (FDA) approval of generic versions of extended-release opiates without requiring technologies that reduce the likelihood of misuse and abuse. In particular, law enforcement groups such as the Kentucky Narcotic Officers' Association remain "very fearful that a new wave of overdose deaths and more illegal trafficking of these drugs will occur if the generic formulation is approved."

I was pleased to learn in the response to my initial inquiry that FDA is committed to finding ways to reduce abuse and misuse of prescription opiates and that you have confirmed FDA's authority to regulate specific aspects of this public health epidemic.

While I also recognize that FDA has recently taken additional steps to provide guidance to industry on abuse-deterrent reference drugs, I believe more can be done to prevent an influx of generic opiates from coming to market that fail to incorporate technologies to reduce the likelihood of misuse and abuse.

I would appreciate responses to the following questions to better understand FDA's position regarding this matter.

1. Does FDA believe that the manufacturers of the new formulations of OxyContin and Opana included the necessary data to be considered sufficient under Tiers 1, 2 and/or 3 of the Draft Guidance to Industry on Abuse-Deterrent Opioids in their applications from 2010? Please answer yes or no. If yes, please explain what data was collected and how this decision was made. If no, please explain what information and data FDA used to make its' determination that "the reformulated version of OxyContin is intended to prevent immediate access to the full dose of oxycodone via cutting, chewing or breaking the tablet...[it] reduces the likelihood that this drug will be misused and abused...¹"

¹ FDA. Oxycontin Questions and Answers. April 5, 2010.

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm>

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2. According to a GAO Report, “manufacturers are allowed to make marketing claims based on the product’s abuse-deterrent features as demonstrated in clinical trials. For example, Embeda’s label includes information on the results of clinical trials testing its abuse-deterrent features, but also states that the abuse-deterrent characteristics of the product ‘have not been shown to reduce the abuse liability of Embeda.²’” Does FDA agree with this finding? Please answer yes or no and provide an explanation.
3. Based on the fact that FDA has previously approved reference drugs intended to reduce the misuse and abuse of an opiate, why does FDA now state that they cannot make a decision on a generic formulation unless and until a reference drug is approved as abuse-deterrent?
4. Does FDA have the authority to require that if a reference product was withdrawn from market and reformulated with technologies that reduce the likelihood of misuse and abuse, any generic must also demonstrate similar misuse and abuse prevention technologies before being approved?

I look forward to a prompt response from you based on the immediate impact this issue may have on my constituents. Please do not hesitate to contact my legislative assistant, Jennifer Conklin, if you have any questions or need immediate assistance.

Sincerely,



MITCH McCONNELL
UNITED STATES SENATOR

MM/kec

² GAO. Prescription Pain Reliever Abuse: Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness. December 2011. <http://www.gao.gov/assets/590/587301.pdf>