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March 11, 2013

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

Dear Dr. Hamburg:

Relief from pain is important to millions of individuals who suffer from chronic illness, and prescription drugs such as opioids have proven useful. However, the abuse of prescription drugs is a significant danger and has reached epidemic levels in many of our states.

Against this background, the development of tamper-resistant drugs provides an opportunity. Adding new physical and chemical features to prescription opioids to deter abuse could reduce misuse of these drugs and the sometimes deadly consequences. These products can be part of a comprehensive approach which should include prevention, interdiction, prosecution and substance-abuse treatment.

In our states, nonmedical users are shifting away from the new tamper-resistant formulations to non-tamper-resistant formulations of other opioids as well as to illegal drugs. There is great concern in our law enforcement community that many non-tamper-resistant products are available for abuse when only a few products have been formulated with tamper-resistant features.

As a specific example, we are concerned with the possibility that generic versions of extended-release opioid prescription drugs and other non-tamper-resistant products may reach the market. We applaud the FDA for expeditiously proposing guidelines establishing clear standards for manufacturers who develop and market tamper- and abuse-resistant opioid products while considering incentives for undertaking the research and development necessary to bring such products to market. Most importantly, we encourage the FDA to assure that generic versions of such products are designed with similar features.

Sincerely,

Luther Strange

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