



March 24, 2010

The Honorable Hal Rogers
United States Representative
2406 Rayburn House Office Building
Washington, DC 20515

The Honorable Mary Bono Mack
United States Representative
104 Cannon House Office Building
Washington, DC 20515

Via E-mail

RE: Labeling of Medications Introducing Some Limits or Impediments to Abuse

Dear Congressman Rogers and Congresswoman Bono Mack:

The Center for Lawful Access and Abuse Deterrence (CLAAD) once again thanks you for your leadership in preventing and treating prescription drug abuse. We continue to look primarily to you as we identify ways the federal government can help families, health care providers, state governments, and pharmaceutical companies address this public health problem. Today we are asking for your help in drawing the Food and Drug Administration (FDA)'s attention to an important step it can take to help prevent prescription drug abuse while preserving patient access to medications.

The FDA's Center for Drug Evaluation and Research (CDER) recently published Draft Guidance for Industry on the Assessment of Abuse Potential of Drugs. In this document, the CDER shared its perspective on the role that pain relievers formulated to be less susceptible to certain forms of tampering (commonly known as "abuse-deterrent formulations") can play in preventing intentional abuse. CDER stated, and CLAAD agrees, that "the concept of *abuse deterrence* is viewed as the introduction of some limits or impediments to abuse, as opposed to the outright elimination of abuse" (334-35). As we explained in our *2009 National Prescription Drug Abuse Prevention Strategy*, CLAAD supports pharmaceutical industry efforts to develop and commercialize safer medications.

The ability of pharmaceutical companies to communicate to health care professionals the unique characteristics of newly commercialized medications is essential to the medications' market adoption. Without the right to present new formulations' innovative features and the significance thereof, pharmaceutical companies have minimal means of informing health care providers of the new pharmaceutical options available to them. Prescribers and patients are then likely to continue utilizing traditional formulations.

When a medication introducing some limits or impediments to abuse is not adequately adopted in the market, its sponsor cannot collect the valuable post-marketing epidemiologic data necessary for the product to be labeled "abuse deterrent," and the vicious cycle of inadequate market adoption continues. Poor acceptance of a new, safer medication could discourage the future development and commercialization of other products designed to be less susceptible to certain forms of abuse. This quandary is especially troublesome given the urgent public health need to intervene in the widespread intentional abuse of opioid pain relievers.

To facilitate the education of practitioners on the novel formulations available to them, CLAAD has asked the FDA to implement an interim labeling convention for medications introducing some limits or impediments to abuse. An interim labeling regime should be based on evidence from laboratory studies and human abuse potential studies such as those described in CDER's Draft Guidance (340-50; 511-519). Labeling as simple as "formulated to be less susceptible to certain forms of tampering for purposes of abuse" with further information describing the need for post-marketing data to support a full claim of abuse deterrence, would enable manufacturers to educate prescribers on the novel features of a medication, and facilitate market adoption sufficient to permit the collection of epidemiological data necessary for final labeling.

CLAAD agrees with CDER that the labeling of a medication plays an important role in "minimizing the actual abuse, misuse, and diversion that may result" from the medication's availability (755-776). Labeling plays an equally important role in optimizing prescriber selection of a medication based on its unique risk-benefit profile. CLAAD respectfully requests that you express to the FDA your support for a practical interim labeling regime for medications introducing some limits or impediments to abuse.

Sincerely,



Michael C. Barnes
For CLAAD

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