

United States Senate

WASHINGTON, DC 20510

March 25, 2014

The Honorable Rona Ambrose, Minister
Health Canada
70 Columbine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Dear Minister Ambrose,

As you know, prescription drug abuse, misuse, and diversion is a significant public health challenge facing both the United States and Canada. Drug overdose death rates have increased over three-fold since 1990, and much of that growth occurred in the last decade.¹ A major component of this challenge is the prevalence of opioids. Formulations of opioid drugs without abuse deterrent characteristics are generally susceptible to manipulation, enabling users to abuse opioids in dangerous ways. At the same time, millions of patients suffer from chronic and acute pain, and these drugs can provide needed relief. Abuse-deterrent technology offers a significant way forward to prevent the abuse of these powerful drugs while preserving access for those patients who need them. The benefit of abuse deterrent formulations of opioid drugs is clearly significant for both our nations.

We are aware Health Canada is exploring how to address the future of opioid drugs, including generic non-abuse deterrent formulations. The U.S. Food and Drug Administration (FDA) is also actively developing policies that will have an important impact on how opioids are considered in the future. For example, last year, FDA released draft guidance outlining how abuse deterrent properties will be evaluated for sponsors seeking approval of abuse-deterrent formulations of opioid drugs. Further clarity with respect to generic manufacturers using abuse-deterrent properties is also expected to be forthcoming.

As our nations face similar challenges with respect to prescription drug abuse, it is our hope that Health Canada and the FDA will appropriately collaborate and coordinate their respective regulatory approaches to this issue. The U.S. Office of National Drug Control Policy (ONDCP) has expressed a strong interest in working with Canada to ensure complementary policies. The importance of such coordination is underscored by the proximity of our nations whereby drugs can easily cross the border, either legally or illegally, including non-abuse deterrent formulations of opioid drugs. Partnership between Health Canada and FDA has the strong potential to result in a coordinated response to prescription drug abuse and improve the public health in both nations, while also ensuring American and Canadian patients have the access to the medications they need.

¹ "Policy Impact: Prescription Painkiller Overdoses," Centers for Disease Control and Prevention, November 2011.

Thank you in advance for your attention to this important matter.

Sincerely,



Tom A. Coburn, M.D.
U.S. Senate



Richard Burr
U.S. Senate

CC: The Honorable Rob Merrifield