Abuse-deterrent formulations: transitioning the pharmaceutical market to improve public health and safety—reply

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In an article published in this journal, my colleagues and I wrote that “Waiting for the ‘perfect’ technology before a grand transition to abuse-deterrent medications leads to inaction” [Simon *et al.* 2015]. Abuse-deterrent formulations (ADFs) have already proven successful at reducing opioid-related overdose incidents, according to a recent study published in *J. Internal Medicine* and conducted by Boston University School of Medicine and Boston Medical Center.

Reformulated oxycodone received labeling by the Food and Drug Administration indicating that it is resistant to crushing and dissolving [FDA, 2013a]. The product’s manufacturer voluntarily took the non-reformulated product, notoriously subject to diversion, misuse, and abuse, off the market in 2013 [FDA, 2013a].

“The weight of evidence to date suggests that abuse of [reformulated oxycodone] decreased after the formulation change,” said lead researcher Dr Marc Larochelle of Boston University School of Medicine and Boston Medical Center to Reuters Health [Larochelle *et al.* 2015].

Health insurance claims records with data on prescriptions and hospitalizations for more than 30 million adults covered by UnitedHealthCare from 2003 to 2012 showed that extended-release oxycodone prescriptions and overdoses both decreased by approximately 20% after the product was reformulated [Larochelle *et al.* 2015].

Dr Xiulu Ruan and Dr Alan David Kaye of the Louisiana State University Health Science Center accurately suggest in their letter that individuals who abuse opioids are shifting to non-reformulated opioids and heroin. They go too far in suggesting that the shift in substances of abuse

diminishes the need to reformulate commonly abused controlled substances.

In our article and in the *National Prescription Drug Abuse Prevention Strategy*, our organization notes that ADFs are only one part of a comprehensive strategy toward reducing prescription drug abuse [Barthwell *et al.* 2013]. Similarly, Gil, stated that “While there are no silver bullet solutions to this public health and safety challenge, abuse-deterrent formulations of powerful prescription opioids can make a difference in addressing this epidemic” [FDA, 2013b]. Larochelle and colleagues echoed our view in stating, “Abuse-deterrent formulations can represent only a portion of a comprehensive strategy to tackle the opioid epidemic we are facing” [Larochelle *et al.* 2015].

Policy makers, public health and safety officials, and other stakeholders must work together to optimize prescription drug monitoring programs, implement safer prescribing standards for health care providers, and expand access to therapeutic testing for substance use disorders, drug court programs, and addiction treatment services.

My colleagues and I agree with Ruan and Kaye in their closing statement that “...the introduction of ADF opioids has resulted in significantly reduced abuse of those specific ADF opioids after they have fully replaced their original reformulations”.

It follows, as my colleagues and I point out in our article [Simon *et al.* 2015] and Larochelle and colleagues’ research confirmed [Larochelle *et al.* 2015], that a full market transition of extended-release and immediate-release opioids and other commonly abused controlled substances can be expected to reduce abuse of all such products.

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