

Center for Regulatory Effectiveness

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MEMORANDUM

To: Risk Communication Advisory Committee (RCAC)

Through: Luis G. Bravo, Risk Communication Staff
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From: Jim Tozzi

Date: August 8, 2013

Subject: CRE Comments for the August 16, 2013 RCAC Meeting

The Center for Regulatory Effectiveness¹ (CRE) thanks the RCAC for recognizing the public health risks from counterfeit consumer products. CRE has a long record of supporting vigorous FDA action against counterfeit products. For example, CRE's 2003 comments to the FDA's Anti-Counterfeit Drug Initiative are available here, <http://www.fda.gov/ohrms/dockets/dailys/03/Nov03/110603/03n-0361-c000021-vol3.pdf>.

The *Federal Register* notice for the August 16 meeting [78 FR 42087-8] states,

- *“On August 16, 2013, the Committee will discuss how FDA can communicate more effectively with health care professionals and other stakeholders about the public health risks posed by counterfeit and unapproved drugs, in addition to safe purchasing practices, and how FDA can evaluate that communication and its impact.”*

It is fortuitous that the RCAC is holding this meeting on the public health risks from counterfeit versions of FDA-regulated products on the day after the RSAC and the TPSAC hold a joint meeting “to assess the impact of HPHC information on consumer perceptions and comprehension, and how to effectively communicate information about the HPHCs of tobacco products to the general public.”²

CRE expects that the joint meeting will sensitize the RCAC to public health hazards from counterfeit tobacco products that contain tremendously elevated levels of hazardous constituents including lead, cadmium, thallium, CO and nicotine. For discussions in the peer reviewed literature regarding measurement and analysis of the very high levels of various HPHCs in counterfeit tobacco products, CRE directs the Committee's attention to the following documents which are included by reference as an integral component of these comments:

¹ For information about CRE, please see http://www.thecre.com/oira/?page_id=8. For information about my background and qualifications, please see http://www.thecre.com/emerging/Jim_Tozzi_Bio.html.

² <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm358165.htm>.

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- CRE, *The Health Effects of Contraband Cigarettes*, a document which provides citations to and excerpts from peer reviewed studies in the literature regarding the elevated public health risks from counterfeit cigarettes, available at <http://www.thecre.com/tpsac/wp-content/uploads/2011/02/Health-Effects-of-Contraband..pdf>; and
- CRE, *The Countervailing Effects of Counterfeit Cigarettes*, a study which provides data from the literature regarding the level of public health risks specific to counterfeit tobacco, available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM263564.pdf>.

In particular, we call the RCAC's attention to one of the studies discussed in both documents,

- *Source and Health Implications of High Toxic Metal Concentrations in Illicit Tobacco Products* by W. Edryd Stephens, Angus Calder, and Jason Newton, Environmental Science & Technology Vol. 39, No. 2, 2005, pp. 479-488.

Stephens, et al concluded their study with the following statement which highlights why the public health risks from counterfeit tobacco are an issue the RCAC needs to explicitly address:

Further Implications. *The purchase of counterfeit cigarettes is often regarded as a victimless crime, with evasion of tax being the only misdemeanor. As well as loss of considerable government revenue, there are important social implications. Organized criminal gangs manage the manufacture and distribution of counterfeits, and increasing resources are having to be diverted to combating this activity. The main purchasers of counterfeit cigarettes are dominantly those on low incomes, either young people who then become addicted to smoking or the socially disadvantaged for whom so many other factors impact negatively on their state of health that the addition of another factor is potentially very serious. The extent of the U.K. market share now claimed by counterfeits means that an issue once considered marginal is rapidly becoming a major problem. The health risks described above as well as social implications means that **early awareness of these issues is important if remedial action is to have significant impact.***

The size and scope of the counterfeit cigarette problem in the US is extensively discussed in CRE's Monograph, *An Inquiry into the Nature, Causes and Impacts of Contraband Cigarettes* available at <http://www.thecre.com/ccsf/wp-content/uploads/2011/06/AnInquiryIntoContrabandCigarettes.pdf>.

For a sample of the current data on the problem of counterfeit cigarettes in the US, the Committee should consider and evaluate a June 14, 2013 Justice Department Press Release from the US Attorney's Office/ Western District of Washington, concerning a defendant who pleaded guilty early this year "to trafficking in counterfeit cigarettes." <http://www.justice.gov/usao/waw/press/2013/June/bui.html>.

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To focus the RCAC's attention on the gravity of the elevated health risks from counterfeit cigarettes that need to be communicated to the public, I emphasize the DOJ Press Release's subheading, in bold, italics and large type in the original:

Defendant Illegally Imported and Sold Vietnamese Cigarettes – Frequently Sold to Juveniles

- CRE advises the RCAC to recommend that FDA initiate a risk communications program specific to counterfeit tobacco products.