

**Testimony of Jim Tozzi**

*before*

**FDA Public Workshop:  
Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications**

**August 25, 2011**

I would like to compliment the FDA for convening a workshop on harm reduction.

This compliment is not without hesitation on my part.

I say this because after a lengthy participation in the TPSAC menthol proceeding, I believe that TPSAC's default position on smoking is to not recognize the potential for harm reduction within tobacco products. Instead, the TPSAC's position appears to reflect an absolute commitment to total abstinence no matter how unrealistic or counterproductive that position.

Of course, my initial hesitation might change as a result of FDA's ongoing peer review of the menthol issue.

There are several reasons for my concern:

**1. TPSAC Refusal to Address Health Effects of Counterfeit Cigarettes**

There is a statutory requirement for TPSAC to examine:

*“the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband...”*

Despite the statutory mandate, TPSAC refused to evaluate the adverse health impacts of contraband [the countervailing effects] notwithstanding the overwhelming evidence compiled by agencies throughout the world, including the Centers for Disease Control and Prevention (Pappas, et al. 2007), which clearly demonstrates that the adverse health effects of counterfeit cigarettes are an order of magnitude greater than those of legal cigarettes.

**2. FDA Refusal to Ask TPSAC to Address Health Effects of Counterfeit Cigarettes**

FDA never wrote a “charge” to TPSAC which would have required it to examine the health effects of counterfeit cigarettes, an absence which further heightens my concern regarding the agency's commitment to developing an effective harm reduction strategy.

Thus, FDA and TPSAC have demonstrated little interest in harm reduction during the menthol proceedings. I hope the current proceedings will be more productive with regard to harm reduction.

## The Center for Regulatory Effectiveness

The Institute of Medicine (IOM) examined the potential for harm reduction from modified risk tobacco products in its 2001 report. In that report, the IOM stated two key conclusions relevant to these proceedings:

First, it concluded that harm reduction responses obtainable through reductions in exposure to tobacco substances “are not defined well enough in terms of specific components of smoke to serve as a predictive tool for the effect that a particular product will have on most health outcomes.” At 11.

Second, it considered it advisable for the government to consider whether making the burden of proof of harm reduction too high would have the effect of stifling innovation and reducing the potential for realizing the benefits of harm reduction. At 240.

The agency’s implementation of the statutory provisions could easily run afoul of both these IOM recommendations, especially in view of the vagueness of much of the statutory terminology, such as “substantial,” “significantly,” “minimal,” and “measurable.”

### **Recommendation: The Common Sense Standard for Modified Risk Tobacco Products**

In order to promote advancement of the law’s harm reduction objectives, **CRE recommends that FDA state, as an overarching principle, that the marketing of modifiable risk tobacco products will be permitted when it is reasonably clear that:**

- 1. The new product will not be more harmful than existing products; and**
- 2. There is a reasonable scientific basis indicating the new product has the potential to reduce the risk of adverse health effects from consumption of tobacco products.**

Initial conclusions would, of course, then be subject to ongoing surveillance and analysis.

CRE believe that such a common sense interpretation of the law might also be necessary in order to avoid any successful Constitutional challenges to the FDA’s implementation of the statute. For several decades now, the U.S. Supreme Court has recognized commercial speech in the form of advertising as subject to First Amendment protection.

The government can regulate such speech if the speech is false, misleading, or without a reasonable basis. The burden, however, is generally on the government to show that restrictions on commercial speech are justified. It is very doubtful that the government could impose highly stringent burdens of proof on commercial speech that in effect demand that the speech actually benefits the public in order to be permitted.

In summary, it is up to FDA to make harm reduction work by interpreting the statute’s burden-of-proof provisions in a common sense manner that will not discourage innovation in the introduction of products reasonably likely to reduce tobacco health risks.

Thank you. I would be pleased to address any questions.