

# ACSH Testimony to the FDA on Tobacco Harm Reduction

*By ACSH Staff — March 19, 2015*

American Council on Science and Health Senior Director of Medicine and Public Health Dr. Gil Ross testified before the US Food and Drug Administration to urge them to promote the benefits of electronic cigarettes (e-cigarettes) as a method of Tobacco Harm Reduction (THR) in helping smokers quit, and reconsider regulations proposed by the FDA which would consider them tobacco products and make them less accessible, less affordable and therefore less attractive to adult consumers who are choosing to use e-cigarettes as a safer alternative to smoking.

The rest of his statement to the FDA is below:

These proposed regulations on e-cigarettes should be commensurate with health risk and because e-cigarettes are far less harmful than combustible tobacco products, the regulations should take that into account. Although we do agree that sensible e-cig regulatory measures, such as enforceable age limits on sales and marketing, good manufacturing standards, accurate labeling and childproof packaging, are surely in order, the requirement for manufacturers to obtain pre-market approval via a new tobacco product application will limit the availability of e-cigarettes to addicted smokers trying to quit.

The FDA itself estimates that these applications will require thousands of man-hours of data collection and hundreds of thousands (or millions) of dollars or more, a burden few current e-cigarette companies will be able to bear. Yet, the older, less reliable products entering the market before February 15, 2007 will be grandfathered in under the Family Smoking Prevention and Tobacco Control Act. And still, this applies to only about one percent of all e-cigarettes and vapor products.

The reality is that the only e-cigarette marketers with the wherewithal to comply with the deeming regulations would be Big Tobacco.

Our own published research on tobacco harm reduction published in a peer-reviewed academic journal, as well as many other studies and epidemiological data, support our assertion that the methodologies comprising THR have significant potential benefits in terms of reducing the tragic toll of cigarette smoking by supplying addicted smokers with the substance they crave nicotine but at a much reduced cost in terms of adverse health effects. The currently approved cessation methods fail far too often and the reduction in the adult smoking rate has plateaued recently at 18 percent.

We urge you to rely on the readily available scientific and empirical evidence to recommend policies promoting THR and e-cigarettes, which is that e-cigarettes:

- are far less hazardous than cigarettes
- regular use is confined almost exclusively to smokers and former smokers who quit by switching to e-cigs
- have helped several million smokers quit and/or sharply reduce cigarette consumption

*The most important piece of supporting evidence for the use of e-cigarettes to help smokers quit is this: **smokers smoke for the nicotine, but they die from the smoke.***

Furthermore, studies have indicated that levels of the contaminants that e-cigarette users are exposed to are far below any levels that would pose a health risk. And, the exhaled vapor poses no risk to bystanders.

If onerous, needless regulations such as those recently proposed by the FDA are enacted presenting obstacles for desperate smokers trying to quit electronic cigarettes will become black market items or sold almost exclusively by Big Tobacco companies, eager to snap up the currently vibrant small businesses in the e-cigarette stream of commerce.

The recently released federal survey of youth drug, alcohol and tobacco use Monitoring the Future found that youth smoking rates have continued their decline to historically low levels. Clearly the increased availability of e-cigs is not promoting an epidemic of smoking, nor serving as a gateway.

Making e-cigs inaccessible to desperate smokers by these needless measures will send smokers this message: *Keep on smoking.* While no tobacco product is free of health risks, e-cigarette and vapor products are a noncombustible alternative to traditional cigarettes. The likely outcome, should these regulations be passed, is a severe reduction in consumer (smoker) choice, and thus fewer quitting and more preventable deaths we already have almost one-half million smoking-related deaths each year (as opposed to zero from e-cigarettes).

The World Health Organization predicts **one-billion** prematurely dead from cigarettes this century if current trends continue. That must not be allowed to happen. While some opponents of e-cigarettes warn: We just don't know what might happen with e-cigarettes, we at The American Council on Science and Health respond, We surely do know what will happen with the real ones: e-cigarettes present the best hope for averting this catastrophe if stringent regulations are avoided.

Thank you.

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