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Comment in response to Docket No: FDA-2012 – N – 1148

Report to Congress on Regulation of Innovative Tobacco Products with emphasis on e-cigarettes

A Public Health Perspective and Plea for Common Sense

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This comment urges FDA to regulate electronic nicotine delivery systems (ENDS), commonly referred to as "e-cigarettes" as a separate category of tobacco-related nicotine delivery product under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (FDA Tobacco Law).

Section 918 of the FDA Tobacco Law carries the title "Drug Products Used to Treat Tobacco Dependence." Section (b) requires the Secretary, after consultation with multiple parties, to report on "how best to regulate, promote, and encourage the development of innovative products . . . to better achieve . . . (A) total abstinence from tobacco use; (B) reductions in consumption of tobacco; and (C) reductions in harm associated with continued tobacco use."

E-cigarettes represent one such innovative product. E-cigarettes have become extremely popular, with sales more than doubling each of the past five years and an estimated 2.5 million current users of e-cigarettes in the United States.[1]

If properly regulated and promoted, e-cigarettes have the potential to substantially reduce risk of tobacco-attributable illness among current smokers; enhance future total abstinence from tobacco use; and do so in a way that will not increase initiation of tobacco/nicotine use by adolescents and young adults. In this context, e-cigarettes represent but one of a number of products of interest to the FDA Tobacco Law with the potential to satisfy a smoker's urge to smoke while substantially reducing his or her future risk of potentially fatal tobacco-attributable illness.

E-cigarettes deliver nicotine to the user in a manner that mimics conventional cigarettes, and does so without the myriad toxic chemicals that cause the potentially fatal cancer, heart, lung and other diseases so closely associated with cigarettes. By their very nature, they do not fit existing categories of combustible or smokeless tobacco products within the FDA Tobacco Law.

The tobacco-attributable "over 400,000 deaths in the United States each year and approximately 8,600,000 Americans have chronic illnesses" referenced in Section 2. "Findings," (13) of the FDA Tobacco Law are all due to cigarettes.[2]

There is a convincing and basically unchallenged body of scientific studies documenting that smokeless tobacco products in common use in the American and Scandinavian marketplaces since the 1980s pose very little risk of tobacco-attributable illness, and little or no excess risk of mouth cancer when compared with non-users of tobacco products.[3-10] The data suggest a level of risk below 1% of the risk posed by cigarettes.

E-cigarettes are too new to have been included in the epidemiological studies noted above. Given that they deliver the same nicotine as in the smokeless products noted above, and the pharmaceutical nicotine replacement therapy products currently promoted by federal authorities, it seems reasonable to regulate e-cigarettes as an addictive product, but one with little or no excess risk of potentially fatal heart, lung, cancer or other disease.

Opposition to e-cigarettes largely has been based on the theoretical possibility that, if promoted as a relatively low-risk tobacco/nicotine product, e-cigarettes potentially could attract large numbers of teens and other non-users of tobacco products to tobacco/nicotine useor that they could depress tobacco/nicotine quit rates. Experience to date with e-cigarettes shows that these products are almost exclusively purchased by current smokers with the intention to quit or cut down on cigarettes. They attract very few non-smokers.[11]

Some have opposed e-cigarettes based on the fact that some early products were poor in quality and inconsistent in their delivery of nicotine. These are issues that can be addressed readily by FDA manufacturing standards.

Of note is the FDA press conference held of July 22, 2009, in which e-cigarettes were roundly condemned as containing trace carcinogens with one of the 20 analyzed samples showing traces of diethylene glycol. Unfortunately, it was not noted that pharmaceutical nicotine replacement therapy products currently approved under the FDA Drug Law also contain similar trace carcinogens. In February 2010, the American Association of Public Health Physicians submitted two Citizen Petitions to FDA, with more than 300 pages of reference documentation, urging FDA to correct these misimpressions from the July 2009 press conference.[12,13] FDA has never responded.

Tobacco control policy, if it is to succeed in substantially reducing tobacco-attributable illness and death and maintain this public health benefit into the indefinite future, must deal with two conflicting issues. It must reduce the risk to current smokers, including those unable or unwilling to quit. It also must reduce the number of children, teens and young adults initiating tobacco/nicotine use.

These two issues conflict, in that promoting a product as lower in risk has the potential to increase tobacco/nicotine use among non-smokers, and in theory, the potential to reduce quit rates.

Again, experience to date with e-cigarettes cigarettes shows that these products are almost exclusively purchased by current smokers who intend to quit or cut down on cigarettes. They attract very few non-smokers.[11]

Regulation of e-cigarettes should therefore be tailored to address both these issues in the following manner:

1. Quality and consistency of manufacturing of both the e-cigarette device and the e-cigarette fluid to assure that poorly made, inconsistent and unduly contaminated products are eliminated from the marketplace.
2. Nicotine content and nicotine delivery parameters should be designed to meet the needs of current smokers, with emphasis on those who are unable or unwilling to quit.
3. Package and advertisement warnings should be mandated, but limited to the issue of addiction.
4. No sales, marketing or promotion to minors.
5. All sales behind counters consistent with cigarettes
6. A research agenda, possibly in collaboration with CDC, NIH, and the industry, to identify the best ways to reach smokers who are unwilling or unable to quit, while minimizing sales to minors.

Some new thinking, starting with a positive FDA stance on e-cigarettes and other relatively low risk smokeless tobacco products, would be a rational first step toward carrying out the mandate of the FDA Tobacco Law, as articulated in Section 918: " to regulate, promote, and encourage the development of innovative products . . . to better achieve . . . (A) total abstinence from tobacco use; (B) reductions in consumption of tobacco; and (C) reductions in harm associated with continued tobacco use."

Disclosure:

This communication reflects the personal opinion of Joel L. Nitzkin, MD, MPH, FACPM, in his capacity as a public health physician intent on doing what he can to reduce potentially fatal tobacco-attributable illness and maintain these reductions into the long term future. The original research and policy development were done from 2007 through early 2012, when Dr. Nitzkin played a major leadership role on behalf of the Tobacco Control Task Force of the American Association of Public Health Physicians. This work was done on an entirely voluntary basis, with no financial support from government, pharmaceutical or tobacco industries, or any other source. Beginning in 2012, Dr. Nitzkin affiliated with the R Street Institute, a Washington D.C.-based libertarian think tank dedicated to what they refer to as "Free markets. Real solutions." R Street, while independent of government, pharmaceutical and tobacco industries, has taken on tobacco harm reduction as one of their priority issues. This action is based on their perception that both the technically inaccurate warnings mandated on smokeless tobacco products and the hostility shown to the e-cigarette industry by federal authorities represent meddling with free market forces for purposes other than protection of the public's health.

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