LEGACY
FOR LONGER HEALTHIER LIVES

E-CIGARETTE POLICY: THE FDA SHOULD PROMPTLY EXERCISE REGULATORY AUTHORITY OVER E-CIGARETTES

Introduction

E-cigarettes[1] are devices that warm a nicotine solution producing an aerosol that is inhaled without the combustion of tobacco. They vary in size, cost, and efficiency of nicotine delivery. The most common are designed to look like cigarettes and mimic the act of smoking. Many e-cigarettes have an indicator light of various colors at their tip. These "cigarette-like" devices are widely available and are either disposable or rechargeable using a cartridge for the nicotine solution. "Personal vaporizers" are larger, are more expensive, have a refillable tank for the nicotine solution (e-juice), and are sold in specialty stores and online. Bottles of e-juice come in a wide variety of flavors and concentrations of nicotine that can be mixed by the user to personal taste. Devices and solutions vary in quality and accuracy of labeling.

Use of e-cigarettes among smokers has doubled, from less than 10% in 2010 to more than 20% in 2011.[2] Sales have doubled every year since 2010 and are projected to reach $2 billion in 2013.[3] Use of e-cigarettes has doubled among middle and high school students from 3.3% in 2011 to 6.8% in 2012.[4] Most of these youth also report using conventional cigarettes. E-cigarettes are gaining attention as they become more widely promoted and used.[5]

In the U.S., more than 43.8 million people smoked cigarettes in 2011,[6] and about half of lifelong smokers will die prematurely from their tobacco use.[7-9] Legacy recognizes that, on an individual level, there is a continuum of risk across tobacco products with combustible products (e.g. cigarettes, cigars, hookah) posing the most danger and Food and Drug Administration (FDA)--approved nicotine replacement therapies (NRTs) posing the least harm.[10,11] Harm reduction is a valuable public health strategy with the potential to reduce, although not eliminate, the preventable death and disease caused by tobacco. E-cigarettes may hold promise in this regard. While they are not without risk, initial scientific evidence suggests that, for the individual smoker, they are likely less harmful than smoking cigarettes, and they likely have significantly lower levels of known tobacco toxicants than combusted tobacco products.[12] In addition, e-cigarettes may help some smokers quit.[13-17] However, the existing evidence is insufficient to support any informed inference on net public health benefits versus harms at this time.

The impact on individual smokers is only part of the story. We must also consider e-cigarettes' impact on public health at a population level. On the one hand, e-cigarettes could have a net public health benefit if they reduce the impact on smokers of the most harmful combustible tobacco products (primarily cigarettes and little cigars) while minimizing the unintended harms to current smokers and to non-users. Smokers of combusted tobacco could benefit from e-cigarettes by switching completely and eliminating their combusted use or by using e-cigarettes as a cessation or relapse prevention aid, eventually leading to stopping use of all tobacco products. On the other hand, if e-cigarettes increase the total number of combusted tobacco smokers by encouraging initiation of use of combusted tobacco products, delaying cessation of combusted tobacco product use, or promoting dual use without eliminating combusted use, then they would not benefit public health.

FDA must promptly exercise its statutory authority to regulate e-cigarettes and begin the process of carefully evaluating and resolving these literally life and death questions consistent with that authority. In addition, the Federal Trade Commission (FTC) should put a stop to the unsupported health claims currently being made about certain e-cigarette products that may mislead the public

The Key Open Questions about E-Cigarettes and Their Health Impact

Smoking Cessation: Despite strong anecdotal claims, there is insufficient scientific evidence that e-cigarettes are effective for cessation.[14-21] Two randomized studies showed e-cigarette use resulted in low cessation rates (4-13%) and differences were not significant compared with NRTs (5.8%) or no-nicotine e-cigarettes. Other studies' results are mixed and have design limitations. Examples of questions that need to be answered through scientific studies include whether e-cigarettes:

- facilitate cessation of smoking by providing an appealing inexpensive nicotine delivery device,
- reduce harm by either complete or partial displacement of cigarette use,
- undermine cessation by displacing use of FDA-approved cessation therapies or encouraging smokers who otherwise might have quit to dual-use both e-cigarettes and cigarettes, or
- undercut efforts to de-normalize tobacco use and encourage cessation through clean indoor air laws, smoke-free workplaces, and related policies.

Youth Smoking Initiation: There is even less information on the impact of e-cigarettes on smoking initiation. The vast majority of smoking initiation occurs among teenagers and young adults.[18] Some e-cigarette marketing campaigns give the appearance of appealing to these audiences, and it is critical to examine whether the availability and marketing of e-cigarettes promotes cigarette smoking experimentation and initiation. Some e-cigarettes resemble cigarettes and are available in flavors including menthol. Evidence indicates that other flavored tobacco products are particularly appealing to youth.[22] In addition, e-cigarettes are marketed in locations, such as malls, convenience stores, and in media, including television and the Internet, that are attractive to youth, possibly facilitating experimentation and/or serving as a gateway to other tobacco products, including cigarettes.[23,24] These are far from idle concerns. The major U.S. cigarette companies marketed to youth and young adults over a period of fifty years, famously describing them as the "replacement smokers" they need to replace their customers who quit or die.[25] With some of these same companies now entering the e-cigarette market, these questions are extremely relevant. Given these concerns, Legacy believes that e-cigarettes should not be sold or marketed to youth. This includes enacting many of the marketing/advertising restrictions currently applicable to cigarettes, including age restrictions on sale, placement of the product in retail outlets, and restricting advertising that is directed towards youth. Regulators should carefully research the issue of whether advertising is re-glamorizing smoking in general, and monitor the impact of promotion on youth uptake of e-cigarettes and combusted tobacco products.

Additional Health Risks: E-cigarettes present a variety of other potential health risks which must also be carefully evaluated even if they are logically assumed to be less harmful to an individual user than combusted tobacco.[26-35] These include, but are not limited to:

- the dangers posed to the public by the distribution of potentially toxic nicotine solutions (including the need for childproof packaging),[36,37]
- the impact of the additives and flavorings used, the risks associated with the presence of heavy metals in some e-cigarette products,[26-35]
- the demonstrated weakness of manufacturing standards for a number of these products that can result in contaminants or amounts of nicotine in solution that are misleading or dangerous,[26-37] and
- the long-term impact of inhaling e-cigarette vapor, which often contains propylene glycol and other potential contaminants and flavorings, for both the individual user and for non-users impacted through second-hand exposure.26-37

Federal Regulatory Authority

Food and Drug Administration: FDA has two avenues available to regulate e-cigarettes.[36,37] Since e-cigarettes contain tobacco-derived nicotine, they are considered to be a "tobacco product" under the 2009 Family Smoking Prevention and Tobacco Control Act. While the Tobacco Control Act did not provide explicit FDA authority over e-cigarettes, it does permit FDA to assert jurisdiction over all tobacco products, including e-cigarettes, via a "deeming" regulation. Once FDA takes such an action, e-cigarettes would be subject to many of the same standards that govern cigarettes and smokeless tobacco, including but not limited to, the requirements regarding assertions of modified risk. The "public health" standard which focuses on the population-based impact of the product, would govern regulation of e-cigarettes as a tobacco product.[38]

Alternatively, a federal court has held that FDA can also regulate e-cigarettes under its authority over drugs and devices if therapeutic claims are made in connection with them – i.e., that they help smokers quit smoking.[36,37] In this event, e-cigarettes would have to be shown to be "safe and effective," just like nicotine replacement products that make therapeutic claims.[38,39] While FDA announced its intent in April 2011 to regulate e-cigarettes under its tobacco authority, it has not yet done so. Nor has it taken regulatory action under its drug and device authority, despite the fact that therapeutic claims are being made in the marketplace. With no FDA action, e-cigarettes currently remain unregulated and the public remains unprotected and ill-informed.

In the long term, we believe FDA should consider the development of a comprehensive nicotine regulation policy that maximizes public health benefits while minimizing the harms of all tobacco products and all tobacco-derived nicotine products.[11] Such a policy would necessarily address the individual and public health harms posed by each product and would most vigorously restrict the marketing of the most harmful products. There is some indication that FDA is pursuing such a vision, and Legacy supports those efforts.

Federal Trade Commission: Some manufacturers or their proxies are marketing e-cigarettes as reduced harm products and/or smoking cessation aids. These claims are appearing in a variety of media outlets, including the Internet, television and radio, and store displays. As previously discussed, there is no reliable scientific evidence to support these claims. We urge FTC to prohibit and take enforcement actions against these deceptive and misleading health claims, just as they have done with deceptive claims made about nutritional supplements and other products.

Conclusion

E-cigarettes may well contain promise as a mechanism to help reduce the devastating death and disease resulting from smoking. While there is growing evidence that e-cigarettes are likely less harmful than cigarettes and may therefore benefit individual smokers, there is insufficient credible scientific evidence to determine their impact on the public health in terms of overall harms versus benefits to the population as outlined in the Tobacco Control Act of 2009. Legacy urges FDA to act immediately to assert its authority over e-cigarettes, begin the process of developing and implementing standards, and establish mechanisms to gather relevant product information from manufacturers and marketers. We also urge FDA to commission rapid and rigorous research to build the evidence base needed to inform the regulatory policies that will protect the public health.

[1] E-Cigarettes or Electronic Cigarettes are not cigarettes at all and are more accurately called Electronic Nicotine Delivery Systems, or ENDS by the World Health Organization. World Health Organization (WHO). Report on the Scientific Basis of Tobacco Product Regulation: Third Report of a WHO Study Group. Geneva, Switzerland: World Health Organization. 2009.
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