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E-Cig Tipping Points vs. FDA Deeming Regulations

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Abstract

E-cigarettes and related vapor products (e-cigs) are here to stay. They have tipped from a fad to a permanent part of the tobacco product scene. They now constitute a ten year old multibillion dollar industry in the United States. More likely than not, they offer personal and public health benefits far exceeding theoretically plausible harms. The current FDA "deeming" regulations threaten to eliminate more than 99% of e-cig products by imposing requirements so costly that few can afford to apply. Federal regulation of all tobacco-related products is needed to best protect the health of the public. Instead, the current regulations protect cigarettes from competition from e-cigs and other low-risk alternatives and threaten to drive dedicated e-cig users back to cigarettes or to hazardous contraband and home-made products. Alternatives to the current regulations are proposed.

Keywords: E-cigarette; Nicotine vapor; Tobacco regulation; FDA; Tobacco harm reduction

Introduction

In 2002, Gladwell introduced the concept of "Tipping Point" into the American lexicon [1]. A "tipping point" is the magic moment when an idea, trend or social behaviour crosses a threshold, tips, and spreads like wildfire, leading to a new and irreversible development.

E-cigarettes and related nicotine vapor products (e-cigs) have already "tipped" in two major ways. The first is popularity. According to the latest Reuter polls, e-cigs are now being used by about 10% of American adults, about 24.5 million people. About 30% of them continue to use them on an on-going basis as a total substitute for cigarettes, with another 62% using them as a partial substitute. Only about 8% of vapers never smoked cigarettes [2]. We now have advocacy groups representing users, manufacturers, vendors, and millions of users. Thus, since their introduction in 2006, e-cigs have become a multi-billion-dollar industry and a permanent part of the American scene [3].

The second tipping point was crossed last year. British authorities came out with the Public Health England report endorsing tobacco harm reduction using e-cig products to reduce tobacco-related illness and death [4]. We now have American, Canadian, and British reports showing that e-cigs are effective in helping smokers cut down and quit [4-8] and doing so without recruiting significant numbers of non-smoking teens to nicotine addiction. This tips e-cigs from a product seen as dangerous and highly addictive to a product that should be seen as having potential public health benefits well in excess of any potential harms; benefits not likely achievable by any other means.

British authorities and other responsible advocates do not claim that e-cigs are risk-free. They do claim that the potential benefits to smokers far outweigh the theoretical risks, and that the risk to non-users is minimal [4-7].

While the crossing of the popularity tipping point is undisputable, American and British authorities differ on whether the public health benefits tipping point has been breached. This difference, in turn, appears to be rooted in how each side has framed the e-cigarette issue. The British carefully considered both potential harms and possible benefits, and concluded that the benefits will likely far outweigh any potential harms. The Americans have limited their consideration to potential harms. Rather than rely on published research by class of product, FDA has challenged the manufacturers to generate new research, making the case for long-term benefit one product at a time. Current FDA regulations require product-specific studies to document that each combination of a device, flavor and strength of nicotine will not recruit non-smoking teens to nicotine addiction and will not deter smokers from quitting.

The result is a regulatory burden so costly that it will eliminate more than 99% of current e-cig manufacturers due to the cost of application. FDA not only recognizes this as the case, but states that one of its goals to be to sharply limit the number of applications they will have to review [9].

Pre-Market Tobacco Product Applications (PMTA's) are required of all tobacco-related products introduced into the market since February 15, 2007. Thus, PMTAs are required of all American e-cig manufacturers. This ignores the fact that e-cigs are now a ten-year-old multi-billion-dollar industry with thousands of manufacturers and millions of users.

FDA estimates the average cost of an e-cig PMTA at about $340,000 [9]. Industry estimates are in the range of $2 million to $5 million per individual application [10]. The FDA estimate does not include all application-related costs. The industry estimates are likely too low because FDA, while specifying the types of data they are requiring, offer no guidance as to the specific standards by which they will judge each element of the application, and no guidance as to what they will accept as evidence of long-term safety, non-recruitment of teen non-smokers and non-discouragement of quitting.

Thus, deeming regulations place a crushing application-related regulatory burden on e-cigs and on any tobacco-related product wishing to claim less risk than cigarettes. FDA regulations place no such burden on the currently marketed cigarettes that recruit 3,000 teens every day and kill an estimated half-million Americans every year [11].

A similar cost burden exists for any product that wishes to claim lower risk than cigarettes, a status referred to as a "Modified Risk Tobacco Product" (MRTP). For this designation, every single stock-keeping-unit (SKU) must separately demonstrate the difference in risk, compared to cigarettes. Even though we know, and FDA readily admits that such differences exist by class of tobacco-related product, the manufacturer is required to duplicate an extensive body of such research for each individual product. While such a requirement may be reasonable for manufacturers to claim lower risk than other products within its class (like a lower risk combustible cigarette), such requirements make no sense when comparing a smokeless or e-cig product to cigarettes.

The result is a set of regulations that protects the most hazardous and most addictive of tobacco products, the cigarette, from competition from an array of far less hazardous and less addictive alternative products. In the case of e-cigs, eliminating almost all of them from the market, as currently planned by FDA, will simply drive many current e-cig users back to cigarettes and drive others to hazardous contraband and home-made products.

Everything we know about the risk posed by tobacco-related products is by class of product. All commonly quoted data for tobacco-related illness and death are from a single class of tobacco product-the cigarette. The smokeless tobacco products available on the American and Scandinavian marketplaces and pharmaceutical nicotine products present substantially less risk [12,13]. Except for American Cancer Society studies on light and low tar cigarettes [14] we have no population-based studies that allege differences in either addiction or risk of potentially fatal tobacco-related illness by chemical or component of the tobacco smoke within a given class of tobacco-related products. By disregarding the studies by class of product, FDA ignores the large and growing body of evidence that e-cigs, as a class, are likely to be far less hazardous and less addictive than cigarettes [5,6,15].

Securing the public health benefits that e-cigs and other relatively low-risk tobacco-related products can offer will require more than amendment of the deeming regulations [16,17]. It will likely require congressional action to amend the Tobacco Control Act [18].

Major amendments needed include the following

1. Eliminate the need for a PMTA by currently marketed e-cig products. The current law specifies February 15, 2007 as the date, after which, products must submit PMTA applications. This date should be changed to the date the amended law comes into effect. This step, like the previously proposed Cole-Bishop Amendment will allow currently marketed e-cig products to stay on the market without having to submit a PMTA [19]. By doing so, it will put them on even footing with legacy cigarette products that need not submit a PMTA.

2. The law should require FDA to define classes of tobacco-related products stratified by risk and addictiveness to guide regulation and enforcement. Initial class definitions might be as follows, with each class having its own regulations, mandated warnings, and allowable communications:

- Cigarettes
- Other Combustible products including hookahs and other products involving combustion of something other than the tobacco.
- Smokeless products
- Vapor/aerosol products
- Other (interim designation, pending definition of other and new classes of product)

3. Full PMTA applications should be required only for proposed new high risk combustible products.

4. Full MRTP applications should be required only for products proposing to claim clinically significant reductions in risk or addictiveness, compared to other products within its class.

5. Requirements for laboratory analyses should be limited to determination of "filth and adulteration" and to parameters epidemiologically demonstrated to predict risk and addictiveness.

6. There are multiple other concerns that should be addressed, that may or may not involve amendment of the regulations or the tobacco control act. These include designation of manufacturer and FDA responsibility for clinical and community studies and post-market surveillance; response to illicit, contraband, and home- made products, and health education as to risk by class of product, and e-cig battery issues.

Unfortunately, lawsuits and the changes in Congress and the presidency this last year raise the specter that the deeming regulations and possibly the entire Tobacco Control Act might be repealed. Repeal without replacement would deprive us of the benefits federal regulation could offer. Effective regulation would enable us to secure the public health benefits e-cigs could offer while eliminating rogue operators, poor quality products, and predatory marketing.

Improved FDA regulation of vape shops and other e-cig manufacturers and vendors could be along the following lines:

1. Regulation of the quality and consistency of e-liquids and e-liquid components could be at the manufacturer or wholesale level. These could be based on the proposed quality standards already published by the American E-Liquid Manufacturing Association at http://www.aemsa.org.

2. Devices and device components could likewise be regulated at the manufacturer or wholesale level. These would cover quality, consistency and performance per label specifications. FDA regulations should cover at least selected battery-related issues.

3. At the vape-shop level, requirements should be imposed as to the quality of products brought into the shop, and, for those who assemble and service devices, and mix their own e-cig fluids, requirements should be in place for hygiene, sanitation and certification of the staff that do the assembly and mixing of products. The entire vape-shop process could be subcontracted to a not-for-profit specifically created for this purpose, under FDA oversight, thus minimizing the burden on FDA staff. The model would be like health facility accreditation.

4. Public health authorities could then work with manufacturers and vendors in counselling and health education efforts to help smokers who are unable or unwilling to quit, switching, and doing so while increasing cigarette quit rates, reducing teen recruitment to nicotine addiction and reducing the risk of exploding e-cigarette batteries.

Billions of dollars and thousands of lives may be hanging in the balance.

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