

## VIEWPOINT

# Promise and Peril of e-Cigarettes

## Can Disruptive Technology Make Cigarettes Obsolete?

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**Despite extraordinary success**, progress has stalled in reducing premature deaths from tobacco (primarily caused by cigarettes or other combusting tobacco products and not by nicotine per se). The dominance of cigarettes over the past 100 years (the cigarette century) threatens to persist for another century.

Two philosophies have dominated tobacco control: abstinence and harm reduction. Abstinence implies avoiding all tobacco use behavior because there is no safe tobacco or nicotine level. If avoidance is not practical or realistic, harm reduction sets a goal that minimizes the harm caused by the behavior. Tension between reduction and abstinence advocates can be divisive. The rapid rise in the use and popularity of e-cigarettes has substantially increased this tension because of their potential for harm reduction. Although still variable in quality, appeal, and efficient nicotine delivery, e-cigarettes represent an evolving frontier, filled with promise and peril for tobacco control practitioners, policy makers, and regulators.

This Viewpoint examines the promise, from a harm reduction perspective, and the peril, from an abstinence perspective—represented by e-cigarettes and asks the question “Do e-cigarettes represent a breakthrough disruptive technology, able to render the combustion of tobacco obsolete, potentially ending the combustion-related morbidity and mortality that has been characterized by the cigarette century?”

### The Advent of e-Cigarettes

Whether e-cigarettes deliver promise or peril depends on a complex dynamic interplay among the industries marketing e-cigarettes (independent makers and tobacco companies), consumers, regulators, policy makers, practitioners, scientists, and advocates. The public health standard for evaluating e-cigarettes is a critical yardstick because it considers both individual (safety and efficacy) and public health outcomes in terms of the likelihood of harms vs benefits to the population. Although there is insufficient scientific evidence to fully inform the standard, the increasing evidence to date points to an opportunity of a new class of safer, but very appealing, nicotine delivery technologies that could favor the speedy obsolescence of conventional cigarettes.<sup>1-3</sup>

The popularity of e-cigarettes is obvious. e-Cigarette revenues have doubled every year since 2008 and are projected to reach \$2 billion in 2013.<sup>4</sup> Adult use among smokers doubled to 20% from 2010 to 2011; experimental use among teens increased from 1.1% to 2.1% in 2011-2012.<sup>5,6</sup> Even without clear evidence of efficacy, use of e-cigarettes for cessation or harm reduction purposes in England has exceeded nicotine replacement therapy (NRT).<sup>7</sup> The free market suggests there is pent-up inter-

est in products that deliver cleaner nicotine in a safe, appealing mode. Whether this can be translated into a sustained disruptive technology depends on factors including innovation of better products, enhanced labeling and marketing, and appropriate regulation and policy implementation.

### US Food and Drug Administration Regulation

Product regulation is essential to minimize unintended consequences and to appropriately reassure consumers. However, regulations should not be so burdensome as to stifle innovation and independent manufacturers.<sup>3,8-10</sup> A comprehensive nicotine regulatory policy is needed from the US Food and Drug Administration (FDA). Embracing harm reduction, the director of the FDA's Center for Tobacco Products (CTP) proposed a continuum of risk, with combustible products (eg, cigarettes, cigars, and hookahs) posing the most hazard and NRTs posing the least.<sup>9,10</sup> Tobacco control should be based on proportional risk that strongly discourages combusting tobacco and encourages smokers who cannot quit to use safer forms of nicotine including more flexible uses of over-the-counter NRTs.

Assuming appropriate scientific studies are completed (to validate degree of harm reduction, cessation efficacy, craving reduction, and relapse prevention), e-cigarettes could be approved under the Center for Drug Evaluation and Research (CDER) and by CTP to maximize the promise and minimize potential risk of these products, but preferably with premarket requirements that are not overly burdensome for provisional approval by either the CTP or by the CDER. Simultaneously CTP regulation can also be used to make conventional cigarettes less appealing and satisfying using product standards to reduce the nicotine levels in these cigarettes to nonaddictive, non-zero levels, as permitted by law.

A balance between underregulation and overregulation is achieved by flexible and discretionary use of product standard, modified risk, and cessation regulations. Aggressive postmarketing surveillance should be used to detect unintended consequences.<sup>1-3,8-10</sup> Applying overly burdensome, expensive regulatory hurdles to e-cigarettes could stifle innovation and favor the market domination of tobacco companies, which potentially promote dual use of cigarettes and e-cigarettes to minimize losing market share for their primary cigarette products. Independent e-cigarette companies (ie, not subsidiaries of tobacco companies) are more likely to have the goal of eliminating combusted cigarettes.<sup>8</sup>

### Federal and State Tobacco Control Policy and Practice

Other approaches to achieve maximal benefit of e-cigarettes would follow the proportional risk frame-

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work. e-Cigarettes and some noncombustible nicotine delivery products can be used as part of a harm reduction strategy, as a reduce-to-eventually-quit strategy, as a cessation strategy, or to prevent relapse back to smoking.

#### Federal and State Taxation

Taxes should be proportional to harms and should include, for example, health care subsidies and full insurance coverage for long-term NRT (even for a lifetime); no or minimal tax on e-cigarettes or Swedish-type snus, and a doubling or tripling of the current tax on all combustible tobacco products.

#### Indoor Air and Public Restrictions

At present there is little research basis for or against restrictions. Studies of secondhand vapor from e-cigarettes show minimal known harmful exposure compared with conventional cigarettes and reasonable indoor air standards.<sup>8</sup> The potential concern is that e-cigarettes undermine denormalization of smoking. Harm reduction advocates point out that people can readily see these products are not conventional cigarettes and that e-cigarettes are a mechanism to quit smoking rather than prolonging it. Thus, e-cigarettes are a gateway out of smoking and may further denormalize smoking and normalize safer alternatives.<sup>8</sup> The risk of unintended consequences must be monitored. The concern is if most smokers use e-cigarettes as a "bridge" to alleviate craving only when they cannot smoke or to delay cessation, then net population harms might possibly exceed benefits even if some individual users benefit.

#### Practitioners in Health Care and Public Health

Clinicians counseling patients about smoking cessation should first recommend FDA-approved, evidence-based treatments for cessation. However, for smokers who cannot quit, clinicians could point out the reduced harms associated with noncombusted nicotine products. Assuming FDA regulation, exclusive use of noncombusted, nicotine-containing products like e-cigarettes and Swedish snus with low nitrosamines<sup>10</sup> is preferable to any combusted tobacco use (eg, cigarettes, cigars, pipes, and hookahs).

#### The Appeal to Youth

Tobacco products of any kind should not be sold to persons younger than 18 years. Young people should not be targets of marketing for any tobacco products. Products should not be made attractive to

youth. Advertising should not resemble in any way the old approach of tobacco companies (eg, the use of cartoon characters like Joe Camel). Aggressive surveillance and enforcement at every level of tobacco control and at point-of-sale by the FDA is clearly warranted. According to the public health standard, restriction of sales and advertising to minors minimizes the potential harms of potential use by minors, offsetting the net benefits of having minimal restrictions on adults so that e-cigarettes remain attractive, accessible, and appealing to cigarette users to accelerate making conventional cigarettes obsolete.

#### Conclusions

The more appealing e-cigarette innovations become, the more likely they will be a disruptive technology. Although the science is insufficient to reach firm conclusions on some issues, e-cigarettes, with prudent tobacco control regulations, do have the potential to make the combusting of tobacco obsolete. Strong regulatory science research is needed to inform policy. If e-cigarettes represent the new frontier, tobacco control experts must be open to new strategies. Statements based on ideology and insufficient evidence could prevent the use of this opportunity before it becomes established as part of harm reduction strategy. Overly restrictive policies by either the FDA, the states, and tobacco control advocates might support the established tobacco industry, whose rapid entry into the marketplace and history of making potentially misleading claims of harm reduction could promote poly-use of all their tobacco products, and thus perpetuate sales of conventional cigarettes well into the next century rather than speed their obsolescence.

Independent manufacturers of e-cigarettes could compete with tobacco companies and make the cigarette obsolete, just as digital cameras made film obsolete. Use of noncombusted nicotine products is preferable to perpetuating the use of combustible cigarettes and a second cigarette century. The stakes are high, with an estimated 430 000 premature deaths associated with tobacco use per year in the United States and more than 1 billion expected deaths associated primarily with combusted tobacco use worldwide by the next century.<sup>11</sup> The central question is whether e-cigarettes should be aggressively supported by tobacco control in what already appears to be its free market significant rise as a disruptive technology—an extraordinary opportunity to end the cigarette century well before the 100th anniversary of the surgeon general's report on smoking and health in 2064.

#### ARTICLE INFORMATION

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