

February 27, 2014

Public Health Committee  
Room 3000, Legislative Office Building  
Hartford, CT 06106  
[PHC.Testimony@cga.ct.gov](mailto:PHC.Testimony@cga.ct.gov)

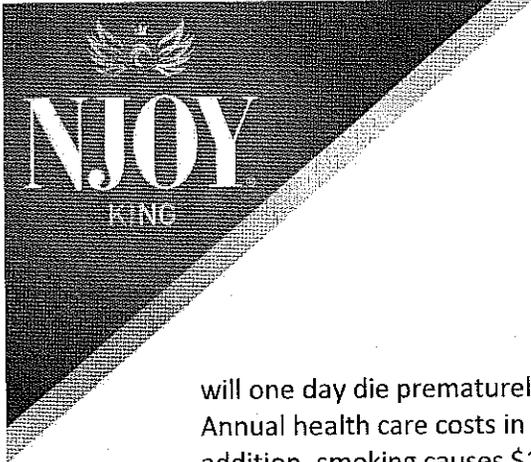
Re: HB-5286 / Electronic Cigarettes

I write on behalf of NJOY Inc. ("NJOY"), the leading independent (i.e., not affiliated with Big Tobacco) electronic cigarette company in the United States. NJOY appreciates the opportunity to provide comments on the above-referenced legislation. For the reasons set forth below, we urge its prompt rejection.

First, a brief word about NJOY. Under its prior corporate name Sottera, it was the sole plaintiff in the landmark legal action (*Sottera v. FDA*) that established the legal framework for the electronic cigarette industry. It was that case, and the legal theory presented by NJOY there, which led FDA to announce its intention to regulate electronic cigarettes under the 2009 Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). NJOY has strongly endorsed such action by FDA.

NJOY is wholly independent of the tobacco industry. It does not manufacture or sell combustion tobacco products of any kind. In fact, NJOY proudly declares that its corporate mission is to obsolete the combustible tobacco cigarette obsolete – and the unparalleled death and disease it has visited on its users. The role that electronic cigarettes can play in obsoleting tobacco cigarettes and addressing the tobacco epidemic is now being publicly discussed by established scholars. See, e.g., David Abrams, "Promise and Peril of e-Cigarettes Can Disruptive Technology Make Cigarettes Obsolete?" *Journal of the American Medical Association*, Vol. 311:2, 135-136 (2014); Sally Satel, "How e-cigarettes could save lives," *The Washington Post*, February 14, 2014.

No doubt you are familiar with many of these statistics, but I believe they bear remembering and repeating. The adult smoking rate in Connecticut is 17.1%. Approximately 4,700 Connecticut adults die each year from tobacco-related illness (nationally the number is above 430,000) – and 76,000 Connecticut children living today



will one day die prematurely of tobacco-related illness if present trends continue. Annual health care costs in Connecticut directly caused by smoking are \$2.03 billion. In addition, smoking causes \$1.03 billion in productivity losses each year in this state. (The above data is available at [www.tobaccofreekids.org](http://www.tobaccofreekids.org).)

We believe that providing smokers who are either unable or unwilling to quit with a tobacco-free, combustion-free alternative is absolutely critical to achieving our shared goal of a tobacco-free world. We respectfully submit that HB-5286, though well-intentioned, would represent a giant step backward in efforts to achieve this goal, and would powerfully disserve Connecticut smokers who are looking for a way out of tobacco smoking and its attendant harms. In this regard, the labeling requirements proposed therein are extensive and would not be satisfied by any electronic cigarette product on the market, manufactured by any current company. The adoption of the statute would either lead to the wholesale departure of electronic cigarettes from the State – leaving smokers who are unable or unwilling to quit with the sole alternative of continued consumption of a toxic product from Big Tobacco – or would surrender the state to electronic cigarettes manufactured by Big Tobacco, since these are the only companies with the resources to separately manufacture Connecticut-specific packaging. Neither goal comports with the interests of public health. It is difficult to imagine that it was intended through this statute to promote the interests of Big Tobacco, yet this is precisely what it would do.

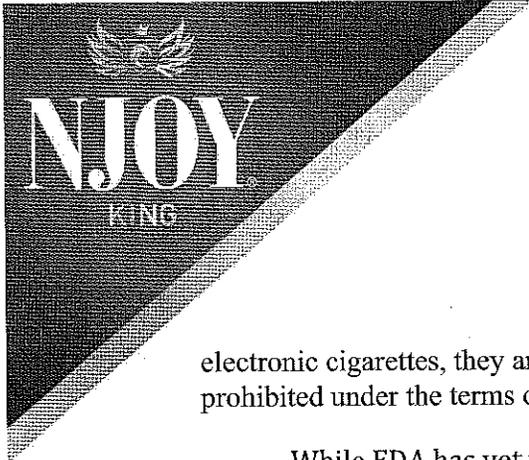
### **HB-5286 Will Be Preempted Under Federal Law**

The 2009 Tobacco Control Act provides the FDA with broad authority to regulate the labeling and advertising of products regulated thereunder. This authority essentially extends to any action permitted by the First Amendment.<sup>1</sup> Further, acknowledging the importance of consistent, uniform regulation, Congress expressly prohibited States from “establish[ing]” or “continu[ing] in effect” any requirement for a regulated product that is different from, or in addition to, a requirement under the Tobacco Control Act with respect to product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.<sup>2</sup> As the House Bill’s provisions seek to impose requirements on the labeling and packaging of

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<sup>1</sup> The Tobacco Control Act states that FDA may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to the full extent permitted under the first amendment to the Constitution. 21 U.S.C. § 387f(d)(1).

<sup>2</sup> 21 U.S.C. § 387p(a)(2).



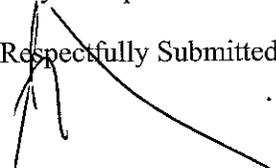
electronic cigarettes, they are subject to this preemption provision and would be prohibited under the terms of the Tobacco Control Act.

While FDA has yet to formally assert jurisdiction over electronic cigarettes under the Tobacco Control Act, it is clear that FDA regulation of this product category is imminent. Indeed, FDA sent a proposed Notice of Proposed Rulemaking ("NPRM") to the Office of Management and Budget's ("OMB's") Office of Information and Regulatory Affairs ("OIRA") for review in the fall of 2013, which is the last step before publication.<sup>3</sup> The projected publication date is listed on FDA's website as December 31, 2013, which confirms that the publication has already been delayed and should be released in the near future.<sup>4</sup>

In light of the public health interests discussed above, the imminent change to the regulatory landscape governing the marketing and distribution of electronic cigarettes across Connecticut and the other states, the likelihood that the ostensible safety concerns giving rise to the Health Bill will be addressed by the governmental authority best equipped to do so (the FDA), and the express preemption provision set forth by Congress in the Tobacco Control Act, NJOY urges the rejection of HB-5286.

We thank you for your consideration of this important matter. Please do not hesitate to contact me at (480)-397-2294 should you require additional information.

Respectfully Submitted,

  
Jeffrey Weiss  
General Counsel  
NJOY, Inc.

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<sup>3</sup> FDA, *Unified Agenda-Track*, <http://www.fda.gov/AboutFDA/Transparency/track/ucm351742.htm> (last visited 2/26/14). The period for OIRA review of a proposed regulation is generally limited to 90 days, Executive Order 12866, unless extended.

<sup>4</sup> *Id.*

# The Washington Post

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## How e-cigarettes could save lives

By Sally Satel, Published: February 14

Sally Satel is a resident scholar at the American Enterprise Institute and a psychiatrist specializing in addiction. She has served as an expert witness in tobacco litigation.

Should electronic cigarettes be regulated like tobacco products, emblazoned with warnings and subject to tight marketing restrictions? Those are among the questions before the Food and Drug Administration as it decides in the coming weeks how to handle the battery-powered cigarette mimics that have become a \$1.5 billion business in the United States.

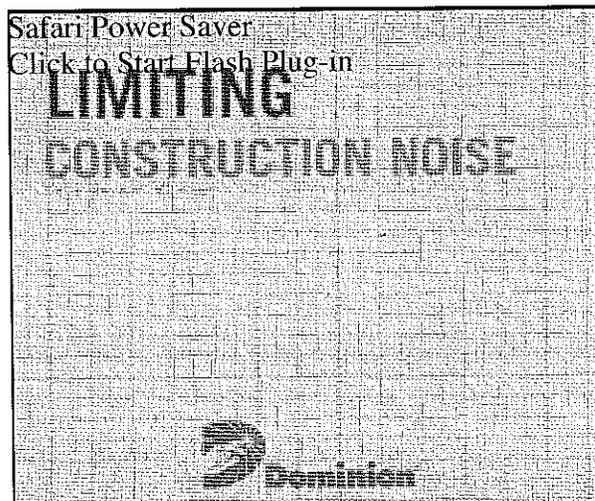
Groups promoting intensive regulation include the [American Lung Association](#) and the Campaign for Tobacco-Free Kids. They worry that the health risks haven't been fully established and that e-cigarettes will make smoking commonplace again, especially among teens. They are quick to push back in response to anything that might make e-cigarettes more attractive, such as the [NJOY King ad](#) that aired during the Super Bowl or when actors [Leonardo DiCaprio](#) and [Julia Louis-Dreyfus](#) were shown "vaping" at the Golden Globes.

A [surgeon general's report](#) released last month, on the [50th anniversary](#) of the office's first warning about the dangers of smoking, had little to say about e-cigarettes. Its suggestions for further reducing tobacco use were familiar, including: increase taxes on cigarettes, prohibit indoor smoking, launch media campaigns and reduce the nicotine content of cigarettes.

E-cigarettes, however, could be what we need to knock the U.S. smoking rate from a stubborn 18 percent to the government's goal of 12 percent by 2020. We should not only tolerate them but encourage their use.

Although critics stress the need for more research, we can say with high confidence that e-cigarettes are far safer than smoking. No tobacco leaves are combusted, so they don't release the tars and gases that lead to cancer and other smoking-related diseases. Instead, a heating element converts a liquid solution into an aerosol that users exhale as a white plume.

The solution comes in [varying concentrations of nicotine](#) — from high (36 mg per milliliter of liquid) to zero — to help people wean themselves off cigarettes, as well as e-cigarettes, and the addictive stimulant in them.



But even if people continue using electronic cigarettes with some nicotine, regular exposure has generally benign effects in healthy people, and the FDA has approved the extended use of nicotine gums, patches and lozenges.

The other main ingredients in e-cigarettes are propylene glycol and glycerin. These are generally regarded as harmless — they're found in toothpaste, hand sanitizer, asthma inhalers, and many other FDA-approved foods, cosmetics and pharmaceuticals. There are also traces of nitrosamines, known carcinogens, but they are present at levels comparable to the patch and at far lower concentrations than in regular cigarettes — 500- to 1,400-fold lower. Cadmium, lead and nickel may be there, too, but in amounts and forms considered nontoxic.

“Few, if any, chemicals at levels detected in electronic cigarettes raise serious health concerns,” a 2011 [study in the Journal of Health Policy](#) determined. “A preponderance of the available evidence shows [e-cigarettes] to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products.”

The potential for e-cigarettes to help people quit smoking is encouraging. Yet so far there has been little research on their effectiveness. A [study published in the Lancet](#) in November concluded that e-cigarettes, with or without nicotine, were as effective as nicotine patches for helping smokers quit. Granted, patches have had a disappointing record in helping people stay off cigarettes for more than a few months. But there are reasons to think that e-cigarettes would be even more effective outside the laboratory.

Participants in the Lancet study were randomly assigned to nicotine e-cigarettes, patches or placebo e-cigarettes. In the real world, of course, people get to choose. And e-cigarettes have several advantages over patches and gums. For one, they provide a quicker fix, because the pulmonary route is the fastest practical way to deliver nicotine to the brain. They also offer visual, tactile and gestural similarities to traditional cigarettes.

Reporter Megan McArdle tested the comparison for a [Bloomberg Businessweek article](#) this month: “After I’d put it together, I had something surprisingly close to one of the cigarettes I used to smoke. The mentholated tobacco flavor rolled sinuously over my tongue, hit the back of my throat in an unctuously familiar cloud, and rushed through my capillaries, buzzing along my dormant nicotine receptors. The only thing missing was the unpleasant clawing feeling in my chest as my lungs begged me not to pollute them with tar and soot.”

This is where anti-smoking advocates get worried about e-cigarettes being too attractive and encouraging people — especially young people — to become addicted to nicotine and, in some cases, to progress to smoking. The [Centers for Disease Control and Prevention stoked concerns](#) with data released in September showing that 1.78 million middle and high school students had tried e-cigarettes and that one in five middle school students who reported trying them said they hadn’t tried traditional cigarettes. “This raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes,” the CDC concluded.

According to that same CDC study, however, an extremely small percentage of teenagers use e-cigarettes regularly — only 2.8 percent of high school students reported using one in the previous 30 days in 2012. And while that number is rising — it was 1.5 percent in 2011 — teenage cigarette smoking rates are at record lows. That might suggest that increased exposure to e-cigarettes isn’t encouraging more people to smoke. But the numbers are so small that it’s too early to make definitive claims about the relationship between teen vaping and smoking.

Yes, we still need research on the long-term health and behavioral impacts of e-cigarettes. Brad Rodu, a pathologist at the University of Louisville, offers an apt analogy between electronic cigarettes and cellphones. When cellphones became popular in the late '90s, there were no data on their long-term safety. As it turns out, the risk of a brain tumor with prolonged cellphone use is not zero, but it is very small and of uncertain health significance.

In the case of e-cigarettes, Rodu says that “at least a decade of continued use by thousands of users would need to transpire before confident assessments could be conducted.” Were the FDA to ban e-cigarette marketing until then, the promise of vaping would be put on hold. Meanwhile, millions of smokers who might otherwise switch would keep buying tobacco products. “We can’t say that decades of e-cigarette use will be perfectly safe,” Rodu told me, “but for cigarette users, we are sure that smoke is thousands of times worse.”

The FDA should call for reliable, informative labeling and safe manufacturing standards for e-cigarettes. It should also allay concerns about potential gateway use and youth addiction to nicotine by banning the marketing and sale of e-cigarettes to minors. It should not be heavyhanded in restricting marketing and sales to adults.

Instead, promoting electronic cigarettes to smokers should be a public health priority. Given that the direct medical costs of smoking are estimated to be more than \$130 billion per year, along with \$150 billion annually in productivity losses from premature deaths, getting more smokers to switch would result in significant cost savings — as well as almost half a million lives saved each year.

We should make e-cigarettes accessible to smokers by eschewing hefty taxes, if we tax them at all, and offering free samples and starter kits. Those kits, which contain a battery, a charger and nicotine-liquid cartridges, typically run between \$30 and \$90. To reduce the hurdle to initiation, any payer of smoking-related costs — health insurers, Veterans Affairs medical centers, companies that offer smoking-cessation programs for their employees, Medicare, Medicaid — should make the starter kits available gratis. Users should have to pay for their own replacement cartridges, but those are much cheaper than cigarette packs.

Also, we should allow and welcome public vaping in adult environments such as bars, restaurants and workplaces. Vapers would serve as visual prompts for smokers to ask about vaping and, ideally, ditch traditional cigarettes and take up electronic ones instead.

It may be hard for anti-smoking activists to feel at ease with e-cigarettes in light of their view that traditional cigarette makers have long downplayed the health dangers of their product. This perception has generated distrust of anything remotely resembling the act of smoking. It doesn't help that major tobacco companies are now investing in e-cigarettes.

But if we embrace electronic cigarettes as a way for smokers to either kick their nicotine addictions or, at least, obtain nicotine in a safer way, they could help instigate the wave of smoking cessation that anti-smoking activists — and all of us — are hoping for.

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## Promise and Peril of e-Cigarettes Can Disruptive Technology Make Cigarettes Obsolete?

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Author Reading at  
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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

**Conflict of Interest Disclosures:** The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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