### E-Cigarettes and the Future of Tobacco Control

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#### Introduction

Electronic cigarettes (or e-cigarettes) are one of today's most discussed, and controversial, issues in tobacco control, and public health more broadly. However, to best understand e-cigarettes and the effect they may have on the future of tobacco use and control both in the United States and globally, it is important to put them in historical perspective.

It has been 50 years since US Surgeon General Luther L. Terry announced that his Advisory Committee on Smoking and Health had, after nearly 2 years of study, concluded that cigarette smoking was a cause of lung and laryngeal cancer. Furthermore, the committee determined that there was suggestive, if not conclusive, evidence that smoking was a cause of several other cancers, as well as such illnesses as emphysema, cardiovascular disease, and chronic bronchitis.<sup>1</sup>

A half-century later, these conclusions seem obvious to the public at large and, certainly, any clinician. Yet in 1964, they were considered revolutionary and unsettling, to the extent that the press conference at which Dr. Terry announced his committee's findings was held on a Saturday morning to avoid a shock to the stock market.

To commemorate the 50th anniversary of the publication of that first US Surgeon General's Report on Smoking and Health, the US Centers for Disease Control and Prevention issued the 32nd Surgeon General's Report on Smoking and Health in January 2014, entitled *The Health Consequences of Smoking-50 Years of Progress: A Report of the Surgeon General, 2014.*<sup>2</sup> This report, in addition to noting the enormous number of diseases and illnesses now attributable to cigarette smoking, also summarized the progress in tobacco control since 1964:

- While cigarette smoking remains the nation's primary preventable cause of premature death, cigarette smoking has been reduced by more than one-half, with 18% of the US adult population now smoking cigarettes, compared with 43% in 1964<sup>2</sup>; and
- More than 20 million lives have been lost in the United States since 1964 due to smoking, but nearly 10 million

premature deaths have been avoided due to tobacco control measures.<sup>2</sup>

In recognizing these successes, the 2014 Report also noted the need to maintain efforts to reduce tobacco use and therefore introduced a new topic for these reports: the potential for developing a plan for a tobacco "endgame," namely, the elimination of cigarette smoking as a major cause of death and disease in the United States. The idea that the public health community is now in a position to consider how to end cigarette smoking would, of course, have been unthinkable in 1964, but scientific, medical, social, and policy developments in the intervening years have made such an aim an achievable goal.

The 2014 Surgeon General's Report points out that, to reach a smoking "endgame," tobacco control practitioners will need not only to continue and accelerate interventions that they know to be effective (eg, raising prices on cigarettes; expanding protections from secondhand smoke; making tobacco dependence treatment accessible to all smokers who wish to quit; reducing exposure of youth to smoking imagery in the media, especially movies; conducting strong countermarketing media campaigns) but also to seek out and be open to new approaches to ending the use of combustible (ie, burned) cigarettes, which account for the vast majority of all illnesses caused by tobacco use.<sup>3</sup>

Among the newer, additional approaches that the 2014 Report suggests for consideration is whether ending the use of the most harmful tobacco product (ie, combusted tobacco) while decreasing the potential harm from newer, innovative products such as e-cigarettes may be a reasonable goal.<sup>2</sup> This concept of "harm reduction," an approach to risky behavior that prioritizes minimizing the damage rather than eliminating the behavior, has, of course, been used in other areas of public health (eg, providing clean needles to intravenous drug users rather than attempting the more herculean task of ending drug abuse altogether, or encouraging condom use to prevent the spread of the human immunodeficiency virus and acquired immunodeficiency syndrome rather than trying to promote sexual abstinence).<sup>4,5</sup>

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DISCLOSURES: Within the past 5 years (but not the past 36 months), Dr. Glynn has received travel expenses from Pfizer Inc, a manufacturer of a smoking cessation medication (varenicline), to participate on a global tobacco control policy advisory board. Neither e-cigarettes nor specific medications were discussed at the board meetings.

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In tobacco control, however, "harm reduction" has traditionally been viewed as a controversial ideology, often pitting committed public health practitioners against one another, with one side arguing that the only path to eliminating the scourge of cigarette smoking is abstinence from all forms of tobacco, while another side argues that "...it is nonsensical to dismiss a (less harmful) alternative by demanding absolute safety." In practice, of course, the path to reducing and eliminating the dangers of cigarette smoking will weave between these 2 positions.

It is in this context that a relatively new product, the electronic cigarette, has brought the concept of harm reduction to the fore and with it, sharp debates in the public health and tobacco control communities about the future direction of this field and how an "endgame" scenario might play out.

## What Are E-Cigarettes and Why Are They Controversial?

E-cigarettes have been described as the tobacco world's first truly "disruptive technology," defined by the *Harvard Business Review* as "a new technology that unexpectedly displaces an established technology." E-cigarettes are certainly technologically advanced; they are typically battery-operated devices designed to deliver nicotine through a heated solution to their users. Mechanically, most types of e-cigarettes consist of a rechargeable, battery-operated heating element; a replaceable or refillable nicotine-containing cartridge; and an atomizer that uses heat to convert the contents of the cartridge into a nicotine-containing vapor that is then inhaled by the user. Some e-cigarettes can be reused and others are for single use. In addition, some are designed to look very much like a traditional cigarette, while others have unique shapes and profiles that do not conjure a cigarette at all. <sup>8,9</sup>

E-cigarettes were first developed approximately 10 years ago in China, and have been available commercially in the United States for 7 years. There are approximately 250 types of e-cigarettes for sale in the United States and they vary considerably in their ingredients, quality control, and ability to deliver nicotine. Some contain only propylene glycol (used to create the vapor that they emit), water, flavoring agents, and nicotine. Others, however, as tested by the US Food and Drug Administration (FDA), have been found to contain a variety of contaminants, including some that are carcinogenic. <sup>10</sup>

Because they are relatively new, there has not been extensive surveillance of e-cigarette use in the United States to date. A 2013 report from the Centers for Disease Control and Prevention found that any e-cigarette use increased among middle and high school students between 2011 and 2012, from 3.3% to 6.8%, resulting in an estimated 1.78 million youth who have tried e-cigarettes. Current e-cigarette

use (ie, one or more times within the past 30 days) increased for this population of youth from 1.1% to 2.1%. 11

The Centers for Disease Control and Prevention also found that, when examining data from 2010 through 2011, the number of adults who have ever used e-cigarettes increased from 3.3% to 6.2%. In 2011, 21.2% of current smokers had ever tried e-cigarettes, compared with 7.4% of former smokers and 1.3% of never-smokers, suggesting that, at the present, e-cigarette use among adults is largely confined to current and former cigarette smokers. <sup>12</sup> Another study found that the majority of e-cigarette users across 4 countries reported using e-cigarettes to help them quit cigarettes and because they thought they were less harmful than cigarettes. <sup>13</sup>

E-cigarettes have been described by many of their proponents as a possible game-changing product that can end the use of combustible cigarettes once and for all, and by their detractors as the first step on a slippery slope to an expansion of the combusted cigarette-caused epidemic. Of course, as with so many highly celebrated, or reviled, products, their true nature likely lies somewhere in between, with both pros and cons to recommend or discourage their use.

### E-Cigarettes: Arguments For and Against Them

There are social, psychological, medical, and policy reasons that the introduction of e-cigarettes may prove to be a net benefit or net harm for public health. Consider that, among the "pros" favoring e-cigarettes are:

- Their ability to deliver nicotine to the user in a much less harmful way than regular, combusted cigarettes, which contain greater than 7000 other chemicals, including more than 60 carcinogens<sup>8,14</sup>;
- Their absence of secondhand cigarette smoke, meaning they release only a vapor with sharply reduced potential for harm compared with combusted cigarettes<sup>15</sup>;
- Their resemblance to regular cigarettes to cigarette smokers, which provides the tactile and visual sensations (eg, holding them in a certain way, a glowing tip, blowing smoke, etc) that many cigarette smokers have become used to, or even psychologically dependent upon <sup>16</sup>; and
- Their potential for aiding cigarette smokers who wish to quit to do so.<sup>17</sup>

Among the "cons" arguing against e-cigarettes are:

The lack of sufficient scientific data about their safety.
Simply put, e-cigarette users cannot be sure of what they are inhaling, since e-cigarettes have not been subjected to thorough independent testing and, due to their manufacture by many different companies, quality is not always assured in their production;

- Lack of sufficient scientific data about their effectiveness as smoking cessation aids;
- Lack of sufficient scientific data regarding their ability to deliver enough nicotine to satisfy withdrawal effects;
- Lack of sufficient scientific data regarding the potential for e-cigarette use to reverse the decades-long public health effort to "denormalize" combusted cigarette use;
- Lack of sufficient scientific data about the effects of secondhand vapor from e-cigarettes, as well as the desire of most people to avoid being exposed to this vapor in public places such as restaurants, movie theaters, and airplanes, whether proven to be a health hazard or not;
- Lack of sufficient scientific data about whether the use of e-cigarettes encourages smokers who might have otherwise quit to continue smoking and only use e-cigarettes when they are in no-smoking environments (ie, the "dual use" concern); and
- Lack of scientific data about whether youth may use e-cigarettes as an introduction to smoking regular combusted cigarettes.

Therefore, considering these lists of potential benefits and harms, it is easy to see why e-cigarettes are a source of controversy, even among the most sophisticated and informed scientists, clinicians, advocates, and policymakers.

A stark example of this divide occurred recently in reaction to an article regarding e-cigarette vapor and its effect on indoor air quality published by Schober et al in the International Journal of Hygiene and Environmental Health, 18 a widely respected journal. Dr. Stanton Glantz, a professor of medicine at the University of California at San Francisco and an e-cigarette opponent, highlighted the study on his Web site (tobacco.ucsf.edu/blogs/sglantz), with the headline "More Evidence That E-Cigarettes Cause Substantial Air Pollution...and Inflammatory Processes (in Users)." Several days later, Dr. Michael Siegel, a professor of medicine at Boston University and a proponent of e-cigarettes, highlighted the same study on his Web site (tobaccoanalysis. blogspot.com), with the headline "New Study of (E-Cigarette Vapor) Shows No Evidence of a Significant Public Health Hazard." One study, 2 experienced researchers, and 2 sharply divided opinions of the same material.

### Summary of E-Cigarette Positions

In sum, proponents of e-cigarettes, both in the public health community and among e-cigarette manufacturers, emphasize their potential for expanding the tools available for smokers who want to quit, their comforting similarity to regular cigarettes for smokers, the likelihood that they are considerably safer than combusted cigarettes, and their absence of harmful secondhand smoke.

Many of these proponents urge the public health community, the federal government (especially the FDA),

and state and local governments to drop any objections to e-cigarettes, and take actions to promote rather than reduce their use and move them further toward mainstream social and scientific acceptance. Doing so, they argue, could enable e-cigarettes to largely or wholly replace the use of combusted cigarettes, which we know to be harmful, killing nearly one-half their users. E-cigarettes, their proponents argue, while not harmless, certainly do not approach the harm levels of combusted cigarettes and therefore will result in net benefit to public health (ie, less combusted smoking-caused disease and premature death). <sup>19–21</sup>

Opponents of e-cigarettes, however, urge more caution concerning their widespread use and emphasize the considerable lack of scientific knowledge that has accumulated regarding e-cigarettes such as their safety for long-term inhalation, their effectiveness as smoking cessation aids, their appeal to youth, the effects of the e-cigarette industry's marketing strategies, the effects of the mainstream tobacco industry's entry into the e-cigarette marketplace, and the potential for "renormalization" of combusted cigarette use.

They urge the public to remain wary of e-cigarette use; the FDA to take the necessary actions to bring e-cigarettes under their regulatory authority; and e-cigarette manufacturers to open their doors to independent testing, disclosure, and regulatory standards for their products, as well as to provide evidence for any product claims. <sup>22,23</sup>

# Moving From Controversy to Action: The Future of E-Cigarettes

The most immediate action required to address the controversies surrounding e-cigarettes is for the FDA to assert its authority, under the auspices of the 2009 Family Smoking Prevention and Tobacco Control Act, to regulate e-cigarettes. <sup>24</sup> Using this authority, the FDA could, among other actions, require e-cigarette manufacturers to register their products with the FDA, provide a list of their ingredients, establish (or continue) good manufacturing practices, address impure/untested product additions and misbranding issues, and restrict marketing and sales only to those aged 18 years and older.

The FDA's authority over e-cigarettes would be a significant step forward in establishing the safety profile of e-cigarettes and, both through their own and others' research, potentially establish whether they are effective in helping people quit smoking, whether they discourage some smokers from quitting, and whether youth may use them as gateway products to cigarette smoking.

At the same time, as David B. Abrams, PhD, Executive Director of the Schroeder Institute for Tobacco Research and Policy Studies at the American Legacy Foundation, observed in a recent issue of the *Journal of the American Medical Association*:

Overly restrictive policies by either the FDA, the states, or 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 potentially 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.

The answers to those vital questions will need to come from a wide-ranging, independent research agenda, as recently suggested and outlined by a group of international researchers who have themselves been viewed by some to be on both sides of this issue.<sup>25</sup>

During the time the new FDA regulation is being considered and research into e-cigarettes is being conducted, these products will remain controversial: praised by many and looked at with great caution, and even disdain, by many others. Many smokers will use them and say they can help people quit smoking cigarettes, and many others will warn of possible harm from their use, both to individuals and to public health more broadly.

The only solution to bridging this divide, and ultimately improving public health, is, as we have learned from more than 2 centuries of public health advances, to put science to work: obtain solid, independent data and then make decisions and recommendations based on those data. To do otherwise, to develop public health policy on the basis of opinions and anecdotes, will not serve public health well and will, ultimately, undermine both points of view.

Of course, while decisions must be made, we cannot expect that the scientific debate will end at any point soon. As Pulitzer Prize finalist and novelist Barbara Kingsolver observes in her recent novel *Flight Behavior*:

Science as a process is never complete. It is not a foot race with a finish line...people will always be waiting at a particular finish line: journalists with their cameras, impatient crowds eager to call the race, astounded to see the scientists approach, pass the mark, and keep running. It's a common misunderstanding... they conclude there was no race. As long as we won't commit to knowing everything, the presumption is we know nothing.<sup>26</sup>

# Will E-Cigarettes Play a Role in the Tobacco Endgame?

E-cigarettes and other noncombustible nicotine delivery products and devices certainly do have the potential to substantially alter the tobacco control landscape and the way in which smokers stop using combusted cigarettes, as more than 50 million living Americans have already done.

The importance of promoting established, scientifically and medically valid methods of quitting and then developing and determining the usefulness of new ones has been made very clear by the World Bank, which estimates that 180 million premature deaths can be avoided globally if cigarette smoking can be cut by one-half by 2025.<sup>27</sup>

Certainly, many smokers prefer to, and do, stop on their own without assistance, <sup>28</sup> but many others want and need help in doing so. Current methods for quitting, particularly using the 7 FDA-approved cessation medications, have been useful when used as directed, but have not proven revolutionary. <sup>29</sup> E-cigarettes may or may not play a important public health role, hence the need for more research, but until that research produces more data, smokers and their clinicians have been left in a state of uncertainty regarding the use of e-cigarettes as a quitting tool.

In the current absence of a substantial body of clinical research on e-cigarettes, however, clinicians have been strongly advised to recommend that their patients who wish to stop smoking call a quitline, seek counseling, and, when appropriate, use one or more of the 7 FDA-approved cessation medications, advice that is endorsed by such organizations as the American Cancer Society and the International Association for the Study of Lung Cancer. 9,30

There are, however, patients who have tried these treatments and are still unable to quit, and who express an interest in, or are currently using, e-cigarettes as a means of quitting combusted cigarettes. For these patients, some suggest that clinicians consider advising them that, while much is still unknown about e-cigarettes and that they are currently unregulated, they are almost certainly less harmful than combusted cigarettes, at least for short-term use, and it may be better to use them for a short time rather than continue to use combusted cigarettes. <sup>31–33</sup>

E-cigarettes and future nicotine delivery products may indeed have the potential to make an important, and even game-changing, contribution to public health by helping some, or many, smokers stop, especially in the context of, as noted in the 2014 Surgeon General's Report, "...an environment where the appeal, accessibility, promotion, and use of (combusted) cigarettes are being rapidly reduced." Whether they will be a "magic bullet" any more than other smoking cessation tools have been, at least to date, remains unclear and awaits badly needed objective research. However, their safety and effectiveness, as well as their potential to keep some smokers from quitting and possibly encourage young people to start smoking, require both investigation and thoughtful behavior and commentary by those on either side of this issue.

This research and regulation process should move forward as quickly as possible. Delayed regulations, and intrascience disputes based on opinion and not data, can only harm public health. If, at some point in the very near future, the preponderance of objective data show e-cigarettes to be demonstrably unsafe and/or ineffective, we will want to move on to other approaches that can lower the appalling toll from cigarette smoking. Or, in a similarly abbreviated time span, if objective data demonstrate their safety compared with combusted cigarettes and their effectiveness compared with current treatment approaches for tobacco dependence, then smokers can add e-cigarettes to the menu of options they can use to end their combusted cigarette habit and extend their lives.

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