



Free markets. Real solutions.

R STREET POLICY STUDY NO. 25
June 2014

E-CIGARETTE PRIMER FOR STATE AND LOCAL LAWMAKERS

Dr. Joel L. Nitzkin

ABSTRACT

CIGARETTES KILL AN estimated 480,000 Americans each year. An estimated 46 million Americans smoke cigarettes, the most hazardous and most addictive of tobacco products. Despite our best efforts, these numbers have been consistent, year to year, for more than a decade. Switching from cigarettes to a smokeless tobacco product or an e-cigarette can reduce a smoker's risk of potentially fatal tobacco-attributable cancer, heart and lung disease by 98 percent or better. This approach is called "tobacco harm reduction" (THR). Adding a THR component to current tobacco-control programming is the only policy option likely to substantially reduce tobacco-attributable illness and death in the United States over the next 20 years. The e-cigarette family of products offers the most promising set of harm reduction methods because of their relative safety compared to cigarettes, their efficacy in helping smokers cut down or quit and their unattractiveness to teens and other non-smokers. They also promise to be less addictive than cigarettes and easier to quit.

This primer provides evidence in favor of e-cigarettes as a THR modality and a review of the arguments against

CONTENTS	
Abstract	1
Introduction	1
The problem	1
E-cigarettes	2
Tobacco Harm Reduction (THR)	2
Objections to e-cigarettes	3
Evidence in favor of THR and e-cigarettes	3
Ineffectiveness of smoking cessation therapy	3
Safety of nicotine replacement therapy medications	3
Safety of e-cigarettes	3
Efficacy of e-cigarettes	4
Non-attractiveness to teens and non-smoking adults	4
Step-down in risk	5
Cigarettes	5
Environmental tobacco smoke	5
Smokeless tobacco in the United States	5
E-cigarettes	5
Environmental e-cigarette vapor	6
Step-down in addictiveness	6
Statistical projections of benefits of THR and e-cigarettes	7
Objections to THR and e-cigarettes	7
Goal of "tobacco-free" society	7
Fear of recruitment of teens and other non-smokers	7
The hidden influence of the pharmaceutical industry	8
Enforcement of no-smoking restrictions	9
Lies and half-truths	9
Other pertinent Issues	10
FDA regulation	11
Mental health patients	11
Smokeless tobacco warnings	11
Contraband	12
Flavored e-cigarettes	12
Age of Initiation in adult smokers	12
What are state and local governments to do?	12
What should state and local governments not do?	13
Conclusion	13
About the author	13

them. Many in tobacco control oppose any consideration of e-cigarettes because of their dislike of the "tobacco industry"; because they fear that THR will attract large numbers of teens to nicotine addiction; because the case in favor of e-cigarettes has not been proven to their satisfaction; and possibly because of likely harm to the major pharmaceutical firms that now support much tobacco-control research and programming. This primer closes with recommendations for actions state and local lawmakers should and should not consider with respect to THR and e-cigarettes.

INTRODUCTION

The problem: There are about 46 million cigarette smokers in the United States and about 480,000 U.S. deaths annually attributable to cigarette smoking. Despite our best efforts, these numbers have been essentially stable since 2004.^{1,2} As

1. Boris Lushniak, "The health consequences of smoking - 50 years of progress," Office of the U.S. Surgeon General, 2014. <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>

2. CDC Fact Sheet, "Tobacco-Related Mortality," Centers for Disease Control and Prevention, Feb. 6, 2014. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/

will be shown in this primer, adding a THR component to current tobacco-control programming offers the only feasible option likely to substantially reduce the number of smokers and deaths over the next 20 years.

A major part of the problem is the remarkable ineffectiveness of current smoking-cessation therapies. The currently favored “evidence-based” pharmaceuticals fail about 90 percent of smokers who try them, even under the best study conditions.³ Research reported these past few years shows no population-level public health impact from decades of pharmaceutical smoking cessation therapy.⁴ Some people benefit for a short time, but most relapse within a year or two. Most who successfully quit, and stay quit, do so without medication or medical assistance.

E-cigarettes: E-cigarettes are battery-operated devices that enable the user to inhale nicotine without the heavy concentration of deadly toxins in cigarette smoke. Some look like cigarettes. Others are more elaborate devices. All emulate the feel of smoking a cigarette. E-cigarette fluid consists of purified nicotine, propylene glycol (used in theatrical fog and some asthma inhalers), vegetable glycerin, flavoring and distilled water. No nicotine-delivery product can be considered totally risk free. E-cigarettes present a risk of potentially serious illness similar to the risk posed by pharmaceutical nicotine-replacement therapy gum, patches, lozenges and inhalers. This is a level of risk estimated to be well under 2 percent the risk posed by cigarettes.^{5 6 7}

In the absence of FDA regulation, the e-cigarette industry has developed an extensive set of voluntary standards to assure the quality and consistency of the product and freedom from contamination.⁸ Sensible FDA regulation will be needed if e-cigarette makers and vendors are to present the level of risk posed by these products honestly and if we are to prohibit the kinds of advertising that attracted large num-

bers of teens to tobacco use decades ago. As will be discussed later in this narrative, the recently proposed “deeming” regulations do not meet this standard. As proposed, they seem intended to remove most e-cigarette products from the market and give those that remain to the “big tobacco” cigarette companies.

Tobacco harm reduction: Tobacco harm reduction (THR) is envisioned as an educational initiative under which smokers are advised they can lower their risk of a potentially fatal illness by 98 percent or better by switching to one of a number of relatively low-risk nicotine-delivery products, including but not limited to e-cigarettes.⁹ The evidence is partly based on long-term epidemiological studies of the use of *snus* in Sweden¹⁰ and on use of smokeless tobacco in the United States since the 1980s.^{11 12 13} Since e-cigarettes are basically a nicotine-only product with only the smallest traces of the carcinogens and other toxins found in smokeless tobacco products, e-cigarettes almost certainly carry even less risk. The remainder of the evidence is based on the safety record of pharmaceutical nicotine-replacement therapy products. These products (gum, patches, lozenges and inhalers) have been on the American market since the 1980s and recently were approved for unlimited use as to dose and duration.¹⁴

THR differs from smoking-cessation medical therapy in that “therapy” implies a short-term (usually 12-week) course of medication, while THR implies use of the substitute product as long as the user feels the need for the product in question.

Tobacco harm reduction can be done in one of three ways. The first is switching to one of the smokeless tobacco products currently available on the American market – chewing tobacco, snuff, snus or one of the dissolvables (sticks, strips or orbs). The second is use of one of the pharmaceutical nicotine replacement products (gum, patches, lozenges or inhalers) on a long-term basis, in a harm-reduction mode. The third is to switch to e-cigarettes. Given the current interest in e-cigarettes, this paper will concentrate on the third of these three options.

Harm reduction is not harm elimination. All nicotine-delivery products present a risk of potential illness greater than would be considered acceptable in other consumer products. It is only in comparison to the extreme risk presented by

health_effects/tobacco_related_mortality/index.htm

3. David Moore, et al., “Effectiveness and Safety of Nicotine Replacement Therapy Assisted Reduction to Stop Smoking: Systematic Review and Meta-Analysis,” *British Medical Journal*, Jan. 14, 2009. http://www.bmj.com/cgi/content/full/338/apr02_3/b1024 (Accessed Sept. 24, 2009).

4. Shu-Hong Zhu, et al., “Interventions to increase smoking cessation at the population level: How much progress has been made in the last two decades,” *Tobacco Control*, 2012. <http://tobaccocontrol.bmj.com/content/21/2/110>

5. Brad Rodu, “The Scientific Foundation for Tobacco Harm Reduction, 2006-2011,” *Harm Reduction Journal*, 8:19, July 29, 2011. <http://www.harmreductionjournal.com/content/8/1/19>

6. Carl V. Phillips, et al., “Calculating the comparative mortality risk from smokeless tobacco vs. smoking,” *American Journal of Epidemiology*, 2006.

7. Peter N. Lee, “Epidemiologic evidence relating snus to health – an updated review based on recent publications,” *Harm Reduction Journal*, 10:36, December 2013. <http://www.harmreductionjournal.com/content/pdf/1477-7517-10-36.pdf>

8. American E-Liquid Manufacturing Standards Association, “Creating responsible and sustainable practices and process for the safe manufacturing of ‘e-liquids’ used in electronic cigarettes,” Version 1.8, Jan. 11, 2014. http://www.aemsa.org/wp-content/uploads/2014/02/AEMSA-Standards_Version-1-8.pdf (Accessed May 27, 2014).

9. Rodu, July 29, 2011.

10. Lee, December 2013.

11. Rodu, July 29, 2011.

12. Lee, December 2013.

13. Phillips, et al., 2006.

14. Food and Drug Administration, “Modifications to Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use,” April 1, 2013. http://www.ofr.gov/OFRUpload/OFRData/2013-07528_PI.pdf (Accessed April 2, 2013).

cigarettes that these products can be considered relatively “safe.” It is best never to start use of any nicotine-delivery product. The second best option is to quit entirely. THR is an option for smokers who do not want to quit, or have tried to quit but have been unable to do so. The benefit is to smokers who are unable or unwilling to quit smoking. The theoretical harms of THR relate to whether a THR initiative would reduce quit rates or attract large numbers of teens or other non-smokers to nicotine and cigarette use.

Evidence gathered to date shows e-cigarettes are unlikely to lure large numbers of teens and other non-smokers to continuing use of e-cigarettes, and even less likely to serve as a “gateway” to cigarettes.^{15 16 17 18 19 20}

Objections to e-cigarettes: Objections to e-cigarettes are largely based on the stated goal of the tobacco-control community for a “tobacco-free society,” a goal seen as ruling out any use of non-pharmaceutical tobacco products in the context of any public health initiative. Other objections are based on dislike of the “tobacco industry”; fear that a THR initiative would attract large numbers of non-smoking teens to tobacco use; a perceived lack of “proof” of efficacy and safety; and possibly, concern that the pharmaceutical sponsors of much of tobacco-control programming and research might be adversely affected by a THR initiative.

EVIDENCE IN FAVOR OF THR AND E-CIGARETTES

NICOTINE ADDICTS, BUT it is the products of combustion that kill smokers and bystanders alike.²¹

Ineffectiveness of smoking-cessation therapy: The remarkable ineffectiveness of currently favored pharmaceutical-based smoking cessation therapy creates the need for a THR initiative.

15. Centers for Disease Control & Prevention, “National Youth Tobacco Survey 2012,” 2013. http://www.cdc.gov/tobacco/data_statistics/surveys/nyts (Accessed Jan. 17, 2014).

16. Action on Smoking and Health-United Kingdom, “ASH fact sheet on the use of e-cigarettes in Great Britain among adults and young people,” May 2013. http://www.ash.org.uk/files/documents/ASH_891.pdf

17. Michael Siegel, “CDC Director and Prominent Anti-Smoking Researcher Appear to Be Fabricating Scientific Evidence to Oppose Electronic Cigarettes,” *The Rest of the Story*, Sept. 30, 2013. <http://tobaccoanalysis.blogspot.com/2013/09/cdc-director-and-prominent-anti-smoking.html>. (Accessed Nov. 30, 2013).

18. Michael Siegel, “Electronic Cigarette Experimentation Increases Among Youth, but Use Among Non-Smokers Remains Low and Regular Use Rates Are Still Unknown,” *The Rest of the Story*, Sept. 9, 2013. <http://tobaccoanalysis.blogspot.com/2013/09/electronic-cigarette-experimentation.html> (Accessed Nov. 30, 2013).

19. ASH-UK, May 2013.

20. Michael Siegel, “If Electronic Cigarettes Are a Gateway to Smoking, Then Why Were Youth Smoking Rates at an All-Time Low in 2013,” *The Rest of the Story*, Jan. 7, 2014. <http://tobaccoanalysis.blogspot.com/2014/01/if-electronic-cigarettes-are-gateway-to.html> (Accessed Jan. 7, 2014).

21. Lushniak, 2014.

The current “standard of care” for smoking cessation involves use of one of a number of smoking-cessation medications. These include nicotine replacement therapy (NRT) products (nicotine gum, lozenges, patches and inhalers), varenicline (Chantix) and bupropion (Zyban).

The major problem with these products is that they fail about 90 percent of the smokers who use them, even under the best study circumstances.²² It is largely because of this failure rate that a THR element needs to be added to tobacco-control programming, so that large numbers of smokers who are unable or unwilling to quit using pharmaceutical products can eliminate almost all exposure to the many toxins in cigarette smoke by switching to e-cigarettes.^{23 24}

The flaws in the current “evidence-based” promotion of these drugs are fairly obvious. Their promotion is based on studies showing a statistically significant increase in quit rates, with cases quitting at double to triple the quit rate of controls. The problem is that the increase is from a baseline of about 3 percent to heightened quit rates of about 6 percent to 9 percent, failing more than 90 percent of the smokers who use them.²⁵ They do not satisfy the urge to smoke in the majority of smokers. The dose is too low, the duration of treatment is too short and there is no built-in provision for self-reinforcement when the urge to smoke returns.

As a result, despite decades of use, these smoking-cessation medications have had no discernable impact on prevalence of smoking in the United States.²⁶

Safety of nicotine-replacement medications: While ineffective, NRT products have an excellent safety record. Long-term use of NRT products is perceived to pose no risk of tobacco-attributable illness and death, despite the presence of many of the same trace contaminants that exist in e-cigarettes.²⁷ They are approved by FDA for over-the-counter sale without restriction as to dose, duration²⁸ or enforcement of age restrictions. Because NRTs are considered drugs, not tobacco products, no federal agency tracks teen use of

22. Moore, et al., Jan. 14, 2009.

23. T.R. McAuley, et al, “Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality,” *Inhalation Toxicology*, October 2012, <http://www.ncbi.nlm.nih.gov/pubmed/23033998>

24. Igor Burstyn, “Peering Through the Mist: What Does the Chemistry of Contaminants in Electronic Cigarettes Tell Us About Health Risks?,” technical report, July-August 2013. <http://publichealth.drexel.edu/SiteData/docs/ms08/f90349264250e603/ms08.pdf>

25. Moore, et al., Jan. 14, 2009

26. Zhu, et al, 2012

27. Zachary Cahn and Michael Siegel, “Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes,” *Journal of Public Health Policy*, Dec. 9, 2010. <http://www.palgrave-journals.com/jphp/journal/v32/n1/abs/jphp201041a.html>

28. FDA, April 1, 2013.

these products in any of their tobacco-related surveillance systems. Thus, while these are the nicotine products most accessible to children and teens, we have no idea whether they are abused by teens or serve as a gateway to smoking.

If e-cigarettes are to be used to reduce illness and death among current smokers, and do so without recruiting teens and other non-smokers to tobacco/nicotine use, three sets of issues must be considered.

Safety of e-cigarettes: The first issue is e-cigarettes' relative safety compared to traditional cigarettes. That e-cigarettes are safer appears certain, based on experience over the past three decades with both NRT products and the smokeless tobacco products available on the American market since the 1980s. While questions remain about the risk posed by consistent and high-dose inhalation of propylene glycol, vegetable glycerin and flavorings, it appears exceedingly unlikely that any such risk would ever come close to the risk posed by cigarettes.

Efficacy of e-cigarettes: The second issue is the efficacy of e-cigarettes in getting smokers to cut down or quit. Here, the various lines of evidence show e-cigarettes range from slightly better than the pharmaceutical options²⁹ to substantially better.^{30 31} There have been no reports of e-cigarettes being inferior in efficacy to the pharmaceutical options, and no reports show any benefit of the pharmaceutical options to smokers who aren't interested in quitting.

Non-attractiveness to teens and non-smoking adults: The third issue, and the most contentious, is the attractiveness of e-cigarettes to teens and other non-smokers. Opponents cite the use of symbolic and psychological themes in e-cigarette marketing and the presence of fruit and candy flavors as evidence that these products must be attracting teen non-smokers to nicotine addiction. Experience to date, however, has shown that while many non-smoking teens may experiment with e-cigarettes, very few continue their use and that it is extremely rare for a previously non-smoking teen to transi-

tion from e-cigarettes to tobacco cigarettes.^{32 33 34 35 36 37}

Two recently published studies conducted by public health non-profits – one in the United States and the other in the United Kingdom – show that teens are very aware of e-cigarettes, but researchers were unable to find even a single non-smoking teen who had taken them up. One study published online in the *Journal of Environmental and Public Health* and co-authored by Dr. Jonathan Winickoff, chairman of the American Academy of Pediatrics' Tobacco Consortium, was able to find only six nonsmokers who had ever used e-cigarettes in a national survey of 3,240 adults, including 1,802 non-smokers.³⁸

A second study from Action on Smoking and Health (ASH-UK) also contradicts the allegation that e-cigarettes appeal to nonsmokers, especially youth. ASH-UK was unable to find a single nonsmoker in Great Britain – either youth or adult – who regularly uses e-cigarettes.³⁹ The group's study was based on a survey of 12,171 adults and 2,178 children ages 11 to 18 in February and March 2013.

The ASH-UK study found awareness of electronic cigarettes was 67 percent among those between the ages of 11 and 18 and 83 percent among those between the ages of 16 and 18. Nevertheless, it found that, among young people who had never smoked, "0 percent report continued e-cigarette use and 0 percent expect to try an e-cigarette soon." The study also found that, among adults who had never smoked, none reported current electronic cigarette use.⁴⁰

In early September 2013, the CDC published a study showing that e-cigarette use among middle and high school students had doubled from 2011 to 2012.⁴¹ In response to these data, CDC Director Dr. Thomas Frieden proclaimed:

"The increased use of e-cigarettes by teens is deeply troubling...Many teens who start with e-cigarettes

29. Christopher Bullen, et al., "Electronic cigarettes for smoking cessation: A randomised controlled trial," *The Lancet*, 382:1629-37, Nov. 16, 2013. <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2961842-5/abstract>

30. Jamie Brown, et al., "Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study," *Addiction*, May 2014. <http://onlinelibrary.wiley.com/doi/10.1111/add.12623/abstract>

31. Michael Siegel, "New Population-Based Study Reports That e-Cigarettes Outperform NRT for Self-Assisted Smoking Cessation Among Smokers Who Choose These Approaches," May 21, 2014. <http://tobaccoanalysis.blogspot.com/2014/05/new-population-based-study-reports-that.html> (Accessed May 21, 2014).

32. CDC, 2013.

33. ASH-UK, May 2013.

34. Siegel, Sept. 30, 2013.

35. Siegel, Sept. 9, 2013.

36. ASH-UK, May 2013.

37. Siegel, Jan. 7, 2014.

38. Robert McMillen, Jeomi Maduka and Jonathan Winickoff, "Use of emerging tobacco products in the United States," *Journal of Environmental Public Health*, March 1, 2012. <http://www.hindawi.com/journals/jep/h/2012/989474/>

39. ASH-UK, May 2013.

40. Ibid.

41. Centers for Disease Control & Prevention, "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students -- United States, 2011-2012," *Morbidity and Mortality Weekly Report*, Sept. 6, 2013. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>

may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes.”

A careful reading of the CDC study and a review of the data leads to a very different conclusion. The approximate doubling in use of e-cigarettes by teens is exactly the same increase shown in overall e-cigarette sales. Other data in the CDC report show the vast majority of such use was by teen smokers, not teen non-smokers. No CDC data was presented on daily use of either cigarettes or e-cigarettes. The fact that the increase in use by teens was no greater than the increase in use by adults suggests that, if any teens are becoming addicted to nicotine through e-cigarettes, that number is exceedingly small. No data was presented suggesting that teens starting with e-cigarettes had transitioned to tobacco cigarettes. Thus, the CDC data are fully consistent with the results of the other two recent surveys, referenced above.

These surveys show that e-cigarettes attract almost no non-smokers to continuing e-cigarette use. This, in turn, suggests it should be possible to endorse these products to smokers without fear that large numbers of teen and other non-smokers will be attracted by a THR initiative promoting e-cigarettes for smoking reduction and cessation.

Step-down in risk: As one steps down from cigarettes to smokeless tobacco products and finally to nicotine-only products, one also steps down to less-addictive products. One recent study showed that, with increasing duration of use, dual users of cigarettes and e-cigarettes moved to fewer cigarettes per day and decreasing strength of nicotine in their e-cigarettes.^{42 43}

Cigarettes: Tobacco cigarettes are the most hazardous and addictive tobacco product and the product most attractive to teens. There was no pandemic of tobacco-related addiction, illness and death until the advent of machine-made cigarettes.

For most of the past half-century, cigarettes have been so dominant in the United States that anti-smoking advocates came to use the terms “cigarette” and “tobacco” as if they were synonymous. Working from the seemingly reasonable (but demonstrably untrue) premise that all tobacco products were equally hazardous, and that tobacco companies were evil, many anti-smoking advocates have worked to block introduction of any new tobacco product on grounds this would protect public health. This philosophical orientation

is clearly reflected in the text of the FDA tobacco law.⁴⁴

Environmental tobacco smoke: Tobacco smoke is a witch’s brew of toxic chemical substances from the incomplete combustion of tobacco. The main component is carbon monoxide, but it also includes other gasses and tarry particulate residue, which contain most of the nicotine and the worst of the carcinogens.⁴⁵

About 85 percent of environmental tobacco smoke (ETS), commonly called “second-hand smoke,” is what curls off the end of a cigarette when no one is puffing on it. Solid particles make up about 10 percent of the smoke, including the tar and most of the nicotine. “Mainstream” smoke exhaled by the smoker includes only what is left after much of what was inhaled has been absorbed by the smoker.

ETS increases the risk of lung cancer and other cancers; the risk of heart and lung disease; the risk of low-birth weight; and is suspected of increasing the risk of birth defects. The CDC estimates that approximately 49,000 non-smokers die in the United States from exposure to ETS.⁴⁶ In addition, ETS is known to irritate the eyes, throat and respiratory mucous membranes.⁴⁷

Smokeless tobacco in the United States: The smokeless tobacco products that have been on the U.S. market since the 1980s are estimated to pose less than 2 percent of the risk of potentially fatal illness as that posed by cigarettes.⁴⁸

E-cigarettes are one of a number of smoke-free tobacco/nicotine alternatives to cigarettes that can reduce the risk of tobacco-attributable illness and death, while satisfying the smoker’s urge for nicotine. These also include chewing tobacco; snus and other snuff products; and dissolvables (sticks, strips and orbs). Options also include use of NRT products such as patches, gum, lozenges and inhalers on a long-term basis in a harm-reduction mode.

E-cigarettes: E-cigarette devices are currently the most promising THR option. These metal or plastic tubes use a battery, heating element and small amount of nicotine-containing fluid to give smokers nicotine without the high concentration of thousands of other toxic chemicals that exist in cigarette smoke. E-cigarettes also emulate the

42. William V. Lechner, et al., “Effects of duration of electronic cigarette use,” *Nicotine & Tobacco Research*, May 2014. <http://ntr.oxfordjournals.org/content/early/2014/05/13/ntr.ntu061.abstract>

43. Michael Siegel, “New Study of Trajectory of e-Cigarette Use Suggests a Pattern of Decreasing Cigarette and Nicotine Addiction,” *The Rest of The Story*, May 22, 2014. <http://tobaccoanalysis.blogspot.com/2014/05/new-study-of-trajectory-of-e-cigarette.html> (Accessed May 22, 2014).

44. 111th U.S. Congress, “Family Smoking Prevention and Tobacco Control Act. Public Law 111-31,” text of legislation, June 22, 2009. (Accessed September 2010).

45. Terry Martin, “Environmental Tobacco Smoke,” About.com, March 29, 2013. <http://quitsmoking.about.com/cs/secondhandsmoke/g/ETS.htm>

46. CDC Fact Sheet, Feb. 6, 2014.

47. Air Resources Board Fact Sheet, “Environmental Tobacco Smoke: A Toxic Air Contaminant,” California Environmental Protection Agency, Oct. 18, 2006. <http://www.arb.ca.gov/toxics/ets/factsheetets.pdf>

48. Rodu, July 29, 2011.

cigarette-handling ritual and the feel of cigarette smoke in the mouth and throat.

E-cigarettes are unique in the U.S. market in that they are the only smoke-free tobacco products that do not carry mandated warnings about cancer or other diseases. They are also unique in terms of their skyrocketing sales. Bonnie Herzog, Wells Fargo's managing director for beverage, tobacco and convenience store research, predicted in January 2013 that "consumption of e-cigs may overtake traditional cigarettes in the next decade."⁴⁹ At that time, e-cigarette sales were projected at \$1 billion for 2013. In mid-September, Herzog upped her projection to "around \$2 billion by the end of the year and up to \$10 billion by 2017," adding that she expects electronic products would overtake tobacco cigarettes within the next decade.⁵⁰

Environmental e-cigarette vapor: E-cigarette vapor, as exhaled by the e-cigarette user, poses no significant risk to bystanders.⁵¹ E-cigarettes have no products of combustion. Nothing curls off the end of an e-cigarette when no one is puffing on it. The mainstream vapor exhaled by the user includes only the tiniest traces of chemical contaminants.

E-cigarette vapor inhaled by users consists mainly of water, propylene glycol and glycerin, with small amounts of nicotine and flavoring. There is no carbon monoxide, no tar and no products of combustion. There is no side-stream smoke or vapor. Propylene glycol and glycerin are generally recognized as safe. Propylene glycol has been used as the propellant in asthma inhalers and is the main ingredient in theatrical fog.

A number of studies have been published dealing with the concentration of organic chemicals in exhaled e-cigarette vapor. These studies show that when an e-cigarette user exhales into a glass tube or similar container, trace quantities of a variety of organic chemicals can be detected. However, when the tests are conducted for a half-hour or more in an eight-cubic-meter test chamber or similar room, e-cigarette use does not measurably increase the trace quantities of these chemical substances above background levels, while

cigarettes cause dramatic rapid increases.^{52 53 54} Perhaps the most interesting finding in these studies is that even non-smokers routinely exhale trace amounts of acetone, ethane, pentane, isoprene and other endogenous volatile organic compounds.^{55 56 57 58}

An October 2012 study published in *Inhalation Toxicology* found that, for all byproducts measured, e-cigarettes produced very small exposures relative to tobacco cigarettes, indicating no apparent risk to human health from e-cigarette emissions.⁵⁹ Further research presented to Europe's Society for Research on Nicotine and Tobacco compared total organic carbons in a test chamber five hours after smoking and after "vaping." It found no detectable levels of acrolein, toluene, xylene and polycyclic aromatic hydrocarbons (PAH) in the e-cigarette vapor chamber compared to high levels in the cigarette chamber.⁶⁰

In tests comparing the effects of e-cigarette vapor to cigarette smoke on cultures of myocardial cells, the vapor had minimal impact, while the smoke killed almost all of the cells.⁶¹

If the nicotine and trace carcinogens in e-cigarette vapor presented any significant hazard to bystanders, those advocating for banning e-cigarette use in no-smoking areas could have and should have included pharmaceutical nicotine inhalers in their proposed bans. The fact that they have not suggests a perception that no such hazard exists.

Step-down in addictiveness: E-cigarettes and other lower-risk products are less addictive than cigarettes. In a well-

49. Josh Sanburn, "Can Electronic Cigarettes Challenge Big Tobacco?" *Time*, Jan. 8, 2013. <http://business.time.com/2013/01/08/can-electronic-cigarettes-challenge-big-tobacco/>

50. Vranks, "Analyst Confirms Projection That e-Cigarettes Will Overtake Traditional Cigarettes in the Next Decade," VaporRanks.com, Sept. 16, 2013. <http://vaporranks.com/analyst-confirms-projection-that-e-cigarettes-will-overtake-traditional-cigarettes-in-the-next-decade/#sthash.tYRn3D5q.dpuf>

51. Burstyn, July-August 2013.

52. Giorgio Romagna, et al., "Characterization of chemicals released to the environment by electronic cigarettes use," ClearStream-AIR project, 14th Annual Meeting of the Society for Research on Nicotine and Tobacco, Helsinki, Finland, Sept. 1, 2012. http://clearstream.flavourart.it/site/wp-content/uploads/2012/09/CSA_ItaEng.pdf

53. Tobias Schripp, et al., "Does e-cigarette consumption cause passive vaping?," *Indoor Air* February 2013. <http://www.ncbi.nlm.nih.gov/pubmed/22672560>

54. Jan Czogala, et al., "Secondhand exposure to vapors from electronic cigarettes," *Nicotine & Tobacco Research*, Nov. 10, 2013. <http://ntr.oxfordjournals.org/content/early/2013/12/10/ntr.ntt203.short>

55. M.A. Larstad, et al., "Determination of ethane, pentane and isoprene in exhaled air -- effects of breath-holding, flow rate and purified air," *Acta Physiologica*, Oxford, England, January 2007. <http://www.ncbi.nlm.nih.gov/pubmed/17280560>

56. David Smith, et al., "Isoprene Levels in the Exhaled Breath of 200 Healthy Pupils Within the Age Range 7-18 Years Studied Using SIFT-MS," *Journal of Breath Research*, 2010. <http://iopscience.iop.org/1752-7163/4/1/017101>

57. Julian King, et al., "Physiological modeling of isoprene dynamics in exhaled breath," *Journal of Theoretical Biology*, December 2010. <http://arxiv.org/abs/1010.2145>

58. Julian King, et al., "Measurement of Endogenous Acetone and Isoprene in Exhaled Breath During Sleep," *Physiological Measurement*, March 2012. <http://www.ncbi.nlm.nih.gov/pubmed/22370046>

59. McAuley, et al, October 2012.

60. Romagna, et al., Sept. 1, 2012.

61. Konstantinos Farsalinos, "Research on safety of electronic cigarettes," 98th Annual Meeting of the Tobacco Merchants Association, Williamsburg, Va., May 15, 2013.

referenced essay published online in December 2013,⁶² Karl Fagerstrom makes a very strong case for a “continuum of dependence” in which cigarettes foster the strongest dependence and NRT products the least, with smokeless products and e-cigarettes in-between. Among the elements affecting the strength of dependence are the other chemical substances in cigarette smoke, habituation to the cigarette-handling ritual and social and psychological factors. In other words, when a smoker switches to a lower risk product, not only does he or she dramatically reduce future risk of potentially fatal tobacco-attributable illness, he or she also is switching to a product that will be easier to quit than cigarettes. This also means that if and when a teen or other non-smoker experiments with an e-cigarette, he or she is unlikely to continue use or become addicted to it. As another variant of this theme, Lechner et al, in a study of the trajectory of dual use of cigarettes and e-cigarettes, showed decreasing use of cigarettes and decreasing strength of e-cigarettes over time.^{63 64}

Statistical projections of benefits of THR and e-cigarettes: As previously noted, the recent Surgeon General’s report⁶⁵ upped annual estimates of tobacco-attributable deaths in the United States from 443,000 to 480,000 per year, due to new research showing yet more diseases are attributable to cigarette smoking. As previously noted, all of these deaths are due to a single tobacco product – the combustible cigarette.⁶⁶ Deaths from all other tobacco products are so low in number and so hard to distinguish from background levels that they are not tracked by federal agencies.

If the number of smokers and fatalities remains flat, as appears likely, an estimated 9.6 million Americans will die of cigarette-related illness over the next 20 years. Given the 15- to 20-year delay after initiation of cigarette use before the onset of potentially fatal cancer, heart, lung and other disease, most of those 9.6 million deaths will be smokers currently over 35 years old. This means that further reductions in teen initiation of tobacco use would not have a measurable impact on fatality rates until 25 to 30 years from now.

In Chapter 13 of the recent Surgeon General’s report, dealing with tobacco use among youth and young adults, researchers recognized that the rate of quitting has increased in recent years, that cigarette consumption has decreased and that such decreases may be due to “increase in use of other tobacco products.”⁶⁷ A new CDC report, also issued this

January,³⁷ notes the greatest recent decrease in cigarette smoking prevalence was in the 18-to-24 year-old cohort, adding that this decrease “might be attributable, in part, to use of other tobacco products.”⁶⁸ Product sales data and huge numbers of anecdotal reports by e-cigarette users strongly suggest that the “other tobacco products” are likely to have been e-cigarettes.

According to my (JLN) calculations,⁶⁹ a modestly successful THR initiative likely would save the lives of 1.5 to 4.8 million of the 9.6 million Americans projected to die of a cigarette-attributable illness over the next 20 years. In the twentieth year, the number of smokers and smoking-related fatalities would be down 30 percent to 80 percent from current estimates. The exact numbers would depend on the rate of switching to e-cigarettes and other relatively low-risk products.

It seems exceedingly unlikely that any other tobacco policy option or sets of interventions could secure public health benefits of this magnitude. THR involves no new costs to taxpayers, no drugs to buy and only trivial additional health education programming. It would be in addition to, not instead of current tobacco-control programming. We would still prohibit sales to minors, prohibit smoking in no-smoking areas, impose excise taxes and take other reasonable steps to control tobacco.

OBJECTIONS TO E-CIGARETTES

Goal of “tobacco-free” society: Many within the tobacco-control community refuse to consider use of any non-pharmaceutical tobacco or nicotine delivery product in the context of any public health initiative, regardless of the evidence. They fear and distrust the “tobacco industry.” For decades, tobacco-control advocates have considered the terms “smoking” and “tobacco use” as if they were synonymous. Their stated goal has been “a tobacco-free society,” even though almost all the deaths and almost all the addiction has been from a single tobacco product – cigarettes.

Fear of recruitment of teens and other non-smokers: Rejection of THR is also based on the dubious and largely disproven premise that telling the general public that some tobacco and nicotine products are less risky than cigarettes will result in large numbers of teens becoming addicted to nicotine, then transitioning to cigarettes. This fear has been magnified by purposeful misrepresentation of surveillance data from the U.S. Centers for Disease Control & Prevention (CDC).

62. Karl Fagerstrom, “Dependence on Tobacco and Nicotine,” *Nicotine Science and Policy*, Dec. 14, 2013. <http://nicotinepolicy.net/karl-fagerstrom/520-dependence-on-tobacco-and-nicotine>

63. Lechner, et al., May 2014.

64. Siegel, May 22, 2014.

65. Lushniak, 2014.

66. Ibid.

67. Lushniak, 2014.

68. Israel T. Agaku, Brian A. King and Shanta R. Dube, “Current Cigarette Smoking Among Adults - United States, 2005-2012,” *Morbidity and Mortality Weekly Report* 2014, Jan. 17, 2014. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6302a2.htm>

69. Joel Nitzkin, “Tobacco Harm Reduction: 20-year projections of smoking prevalence and smoking-related deaths in USA,” Available on request from jlj@jlj-md.com, 2010.

The CDC survey data^{70 71 72} and studies from Dr. Stanton Glantz and his team at the University of California at San Francisco^{73 74} are cross-sectional surveys. They have been presented as if they were studies with follow-up, falsely claiming that e-cigarettes caused heavier smoking and recruitment of teens to continuing use of e-cigarettes.

The surveys asked if kids had ever tried e-cigarettes, or if they had done so in the last 30 days. The questionnaires failed to discriminate between one-time experimentation and continuing use. This left the results open to multiple interpretations. Nothing in the CDC and Glantz survey data even suggests that e-cigarette use would likely lead to cigarette use.

The full set of CDC survey data actually shows a continuing downward trend in teen cigarette use over the two-year period. As e-cigarette use went up, cigarette and total tobacco use went down. When properly interpreted, the data provide strong evidence that e-cigarettes are not attractive to non-smoking teens and that e-cigarettes help lead smoking teens away from cigarettes.⁷⁵

The CDC survey data are consistent with two other recent and previously referenced studies. These show that the vast majority of e-cigarettes were used by smokers to cut down on cigarette use and that the few used by non-smoking teens and adult non-smokers were experimentation, not continuing use.

As previously noted, there were two other recent surveys. One was conducted in the United States⁷⁶, the other in the United Kingdom.⁷⁷ The American study, of adults only, could only find six of 1,802 non-smokers who had ever used e-cigarettes. The British study, of 12,171 adults and 2,178 teens, could not find a single non-smoker who regularly uses e-cigarettes.

70. Lloyd Johnston, et al., "Teen Smoking Continues to Decline in 2013," *Monitoring the Future*, Dec. 18, 2013. <http://www.monitoringthefuture.org/data/13data.html#2013data-cigs>

71. CDC, 2013.

72. Mike Mitka, "CDC: Use of emerging tobacco products increasing among US youths," *Journal of the American Medical Association*, Jan. 8, 2013. <http://jama.jamanetwork.com/article.aspx?articleid=1812957>

73. Lauren M. Dutra and Stanton A. Glantz, "Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents: A Cross-sectional Study," *JAMA Pediatrics*, March 6, 2014. <http://archpedi.jamanetwork.com/article.aspx?articleid=1840772>

74. Carl V. Phillips, "Stanton Glantz is such a liar that even the ACS balks: his latest cig gateway 'study,'" *Anti-THR Lies and Related Topics*, March 7, 2014. <http://anti-thrlied.com/2014/03/07/stanton-glantz-is-such-a-liar-that-even-the-acsbalks/>

75. Centers for Disease Control & Prevention, "E-Cigarette Use More Than Doubles Among U.S. Middle and High School Students from 2011-2012," press release, Sept. 5, 2013. <http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html>

76. McMillen, Maduka and Winickoff, March 1, 2012.

77. ASH-UK, May 2013.

The hidden influence of the pharmaceutical industry: THR threatens two of the nation's most powerful political interests – the tobacco and pharmaceutical industries. One thing these two lobbies agree on is their desire to eliminate competition from attractive and less hazardous nicotine delivery products. This can be easily seen in the text of the 2009 FDA tobacco law.⁷⁸ The law grandfathers the most hazardous tobacco product – combustible cigarettes – while erecting nearly impossible barriers to the introduction of new, less hazardous and less addictive products.^{79 80}

The pharmaceutical companies that make NRT and other smoking cessation drugs are major supporters of tobacco-control research and programming, such as that conducted by the Centers for Disease Control; the Heart, Lung and Cancer Associations; the Campaign for Tobacco Free Kids; the American Medical Association; and major academic centers.^{81 82 83 84 85 86} Some of the opposition to e-cigarettes by these agencies may be based on a reluctance to adopt policy potentially damaging to their pharmaceutical industry sponsors.

If there was any doubt as to the attitude of the pharmaceutical companies, their actions behind the scenes suggest they are doing everything within their power to eliminate competition from e-cigarettes.^{87 88}

78. 111th U.S. Congress, "Family Smoking Prevention and Tobacco Control Act."

79. Ibid.

80. Consumer Advocates for Smoke-free Alternatives Association, "Second Call to Action for FDA Proposed Regulations - Consumer Comment on Paperwork Reduction Act," *CASAA Blog*, May 21, 2014. <http://blog.casaa.org/2014/05/second-call-to-action-for-fda-proposed.html> (Accessed May 27, 2014).

81. Michael Siegel, "Financial Ties Between Head of Smoking Cessation Guideline Panels and Big Pharma Run Deep," *The Rest of The Story*, Jan. 25, 2007. <http://tobaccoanalysis.blogspot.com/2007/01/financial-ties-between-head-of-smoking.html> (Accessed Dec. 26, 2013).

82. Michael Siegel, "National Tobacco Control Conference Sacrifices Scientific and Moral Integrity for Money," *The Rest of The Story*, Oct. 29, 2007. <http://tobaccoanalysis.blogspot.com/2007/10/national-tobacco-control-conference.html> (Accessed Dec. 26, 2013).

83. Michael Siegel, "NIH Expert Panel Recommends Smoking Cessation Pharmaceuticals for Every Smoking Patient: Panel Chair and 8 Members Have Financial Ties to Big Pharma," *The Rest of The Story*, May 8, 2008. <http://tobaccoanalysis.blogspot.com/2008/05/nih-expert-panel-recommends-smoking.html> (Accessed Dec. 26, 2013).

84. Michael Siegel, "CDC Partnership with Pfizer Puts Question Mark on Its Scientific Objectivity," *The Rest of The Story*, Dec. 5, 2011. <http://tobaccoanalysis.blogspot.com/2011/12/cdc-partnership-with-pfizer-puts.html> (Accessed Dec. 26, 2013).

85. Michael Siegel, "UCSD Researchers Call Attention to Differences Between Science and Policy on National Smoking Cessation Strategy," *The Rest of The Story*, May 1, 2012. <http://tobaccoanalysis.blogspot.com/2012/05/ucsd-researchers-call-attention-to.html> (Accessed Dec. 26, 2013).

86. Michael Siegel, "Why is the CDC Taking Research Funding from a Pharmaceutical Company," *The Rest of The Story*, Aug. 12, 2013. <http://tobaccoanalysis.blogspot.com/2013/08/why-is-cdc-taking-research-funding-from.html> (Accessed Dec. 26, 2013).

87. Joel L. Nitzkin, "Tobacco Harm Reduction: 20-year projections of smoking prevalence and smoking-related deaths in USA," Available on request from jl@jln-md.com, 2010.

88. Timothy P. Carney, "Big Pharma, not tobacco companies, wages war on electronic

Enforcement of no-smoking restrictions: Some have claimed, particularly in the context of proposed bans of e-cigarettes in no-smoking areas, that bystanders and those entrusted to enforce smoking bans may have difficulty telling e-cigarettes from conventional cigarettes. Despite assertions to the contrary, it is very easy for any bystander to tell the difference between a conventional tobacco cigarette and an e-cigarette. The newer “mod” and “tank” devices do not even resemble cigarettes. While we have no data on this issue, it seems unlikely that use of these devices in no-smoking areas would induce smokers to light up.

Lies and half-truths: After decades of fighting outright lies and other misleading statements by the major cigarette companies, the tobacco-control movement is now the party deceiving the public through unfounded speculation and outright lies as to the risk posed by e-cigarettes and their addictiveness to teen non-smokers.^{89 90 91 92 93 94 95}

Other objections to e-cigarettes by public health advocates are based on the false premise that we do not know what chemicals e-cigarettes contain. Due to the relative simplicity of e-cigarette vapor and the complexity of tobacco smoke, we actually know more about e-cigarette liquid and vapor than we do about the chemical make-up of cigarette smoke.

Finally, some objections to e-cigarettes continue to stem from misrepresentations made at a July 22, 2009 FDA press conference, in which e-cigarettes were roundly condemned on the basis that e-cigarette fluid contains trace carcinogens and that one of the 20 samples tested showed a trace amount of diethylene glycol – the main ingredient in automobile anti-freeze.

cigarettes.” *Washington Examiner*, Nov. 19, 2013. <http://washingtonexaminer.com/big-pharma-not-tobacco-companies-wages-war-on-electronic-cigarettes/article/2539441>

89. Siegel, Sept. 30, 2013.

90. Michael Siegel, “Anti-Smoking Researcher Misleads Public with Invalid Comparison of E-Cigs and Nicotine Inhaler: Correct Analysis Shows That Nicotine Inhalers Have Higher Amounts of Six Carcinogens,” *The Rest of the Story*, July 25, 2013. www.tobaccoanalysis.blogspot.com/2013/07/anti-smoking-researcher-misleads-public.html

91. Michael Siegel, “CDC Director Apparently Fabricating More ‘Scientific Evidence’ to Demonize Electronic Cigarettes,” *The Rest of the Story*, May 12, 2014. <http://tobaccoanalysis.blogspot.com/2014/05/cdc-director-apparently-fabricating.html> (Accessed May 12, 2014).

92. Michael Siegel, “Glantz Review Article is Little More Than an Unscientific Hatchet Job on e-Cigarettes,” *The Rest of the Story*, May 14, 2014. <http://tobaccoanalysis.blogspot.com/2014/05/glantz-review-article-is-little-more.html> (Accessed May 14, 2014).

93. Michael Siegel, “Tobacco Control Practitioner Tells Public That Cigarettes May Have Fewer Carcinogens and Chemicals Than Electronic Cigarettes,” *The Rest of the Story*, Oct. 22, 2013. <http://tobaccoanalysis.blogspot.com/2013/10/tobacco-control-practitioner-tells.html> (Accessed October 22, 2013).

94. Michael Siegel, “Another Tobacco Control Practitioner Tells Public That Smoking May Be No More Harmful Than Vaping,” *The Rest of the Story*, March 24, 2014. <http://tobaccoanalysis.blogspot.com/2014/03/another-tobacco-control-practitioner.html> (Accessed March 24, 2014).

95. Michael Siegel, “UC Researcher: Vaping May Be More Hazardous Than Smoking,” *The Rest of the Story*, March 13, 2014. <http://tobaccoanalysis.blogspot.com/2014/03/uc-researcher-vaping-may-be-more.html> (Accessed March 13, 2014).

In that one sample, the amount of diethylene glycol was so small that one would have to consume the e-cigarette equivalent of about 1,500 cigarettes in a single day to reach the minimal toxic dose of this liver toxin. With the exception of that sample, e-cigarette fluids showed about the same trace carcinogens in about the same concentrations as NRT products approved by the FDA.

Over the past four years, public health advocates have embellished, exaggerated and distorted statements from the July 2009 press conference to suggest that e-cigarettes might be even more harmful than cigarettes. It simply is not so. For its part, the FDA is more careful not to compare the hazard posed by e-cigarette vapor to the hazard posed by cigarette smoke. Even though there have been no further reports of diethylene glycol in any e-cigarette samples, tobacco-control advocates continue to reference this one trace finding again and again.

From the 1960s through the 1990s, cigarette companies knowingly issued false statements to the public about the risks posed by their products. Over the past decade, it has been the tobacco-control community that has misled the American public, with wrong or misleading warnings on packages of smokeless tobacco products, with claims that certain studies show e-cigarettes attract non-smoking teens and with claims that e-cigarettes may be as hazardous as, or more hazardous than, tobacco cigarettes. Even worse have been actions by the FDA that prevent e-cigarette manufacturers and vendors from telling the truth about the difference in risk between cigarettes and e-cigarettes.

Some remarks by public health authorities demeaning e-cigarettes have shown total disregard of well-established scientific findings. Examples include two quotes from authority figures in a Sept. 19, 2013 article published by *WebMD*.⁹⁶ In the piece, Norman Edelman, chief medical officer of the American Lung Association said:

“They are nicotine delivery devices intended to be used like a cigarette. What happens to someone who stops inhaling the tars of cigarettes and inhales only the nicotine? We don’t know. There is at least the potential for harm.”

This quote suggests total ignorance of the experience with FDA-approved pharmaceutical nicotine inhalers, which have a spotless safety record and no allegations of potential harm. The article also quoted FDA spokesperson Rita Chappelle saying of e-cigarettes:

“We are concerned about the potential for addiction

96. Daniel J. DeNoon, “No-Smoke Electronic Cigarettes Draw Criticism from FDA, Medical Groups,” *WebMD*, Sept. 19, 2013. <http://www.webmd.com/smoking-cessation/features/ecigarettes-under-fire>

and abuse of these products. We don't want the public to perceive them as a safer alternative to cigarettes."

Chapelle apparently does not know or chooses to ignore that the cancer, heart and lung disease associated with cigarettes are due to the witch's brew of chemicals present in cigarette smoke, not the nicotine. She also seems unconcerned about the potential for abuse of NRT products that are sold on open shelves in drug and grocery stores with no enforcement of age restrictions on sales.

Some anti-smoking researchers – such as Dr. Stanton Glantz, director of the Center for Tobacco Control Research and Education at the University of California at San Francisco – have offered misleading comparisons of e-cigarettes and nicotine inhalers that compare the amount of carcinogen in single cartridges of each product. But when daily doses of e-cigarette vapor and nicotine inhalers were compared directly, it was demonstrated that users of nicotine inhalers are exposed to higher amounts of six carcinogens, including five to ten times the amount of three heavy metals.⁹⁷

Declaring e-cigarette vapor to be as harmful as cigarettes is not erring on the side of protecting the public. For millions of smokers, the alternative to using e-cigarettes is not abstinence from tobacco use, but continued cigarette use. Misrepresenting e-cigarettes has the practical effect of reinforcing tobacco cigarettes as the dominant product for nicotine consumption. It does nothing to reduce teen initiation of tobacco/nicotine products. It protects cigarettes from competition from these much less-hazardous products

Elements of the public health community also gradually have replaced "scientific evidence" with a newly minted "self-evident" standard. In other words, if a guideline is sufficiently self-evident, no amount of contrary scientific evidence need be considered. Examples can be seen in the assertions that exhaled e-cigarette vapor is a hazard to bystanders and that e-cigarette flavoring is for the sole purpose of attracting non-smoking teens to tobacco use.⁹⁸ Notably, this objection is not generally raised against fruit- and candy-flavored pharmaceutical nicotine gum⁹⁹ and lozenges¹⁰⁰ sold over the counter by drug stores, discount stores and supermarkets.

As noted above, some tobacco control advocates appear unable to consider the possibility that a non-pharmaceutical tobacco/nicotine product could be beneficial to public health. Also, contrary to the common perception in the tobacco-control community, the tobacco industry is far from

monolithic, and there are many companies and individuals who would sincerely welcome the opportunity to partner in pursuit of shared public health objectives.

Finally, there are statements alleging that dual use of cigarettes and e-cigarettes constitute increased harm. There is ample literature showing that dual use is a very common intermediate stage when switching from cigarettes to a smokeless or e-cigarette product and that, during this period, the number of cigarettes smoked are substantially reduced.¹⁰¹

OTHER PERTINENT ISSUES

FDA REGULATION: OPTIMAL FDA regulation would involve strict quality control on the manufacture and marketing of e-cigarettes, without threatening to remove them from the market, even on a temporary basis, and without stifling continued product improvement. Optimal regulation would enable e-cigarettes to honestly portray the risk they pose, as compared to cigarettes, and impose restrictions on marketing similar to the restrictions imposed on cigarettes, such as banning sales to minors and prohibiting psychological and symbolic themes (sexy, cool, stylish, etc.) in advertising.

Some have urged that FDA ban fruit and candy flavoring of e-cigarettes and limit the nicotine content of e-cigarette fluid to a very low level. The problem with these proposed rules is that they would sharply reduce the attractiveness of e-cigarettes to current smokers, while doing little or nothing to reduce teen use of these products. Fruit and candy flavors have long been allowed by FDA in pharmaceutical nicotine lozenges available for sale on open shelves without enforced age restrictions on sales. Not only has no one objected to these products, but FDA has recently allowed changes in labeling that would allow unlimited use of these products while smoking, with no restrictions on dosage or duration of use.¹⁰²

After years of delay, FDA finally released the text of proposed "deeming regulations" to bring e-cigarettes under FDA regulatory authority. Released in April 2014, these draft regulations would provide a 24-month grace period before imposing regulations that likely would force smaller e-cigarette companies out of the market by requiring huge amounts of research and paperwork to "prove" the safety and efficacy of their respective products. This regulatory burden likely could only be borne by the largest companies.¹⁰³ Adoption of the currently proposed deeming regulations also likely would stifle continued product improvement.

97. Siegel, July 25, 2013.

98. Lee, December 2013.

99. Rodu, July 29, 2011.

100. Phillips, et al., 2006.

101. Kimberly Frost-Pineda, et al., "Does Dual Use Jeopardize the Potential Role of Smokeless Tobacco in Harm Reduction?," *Nicotine & Tobacco Research*, Sept. 16, 2010. <http://ntr.oxfordjournals.org/content/early/2010/09/16/ntr.ntq147.full>

102. FDA, April 1, 2013.

103. CASAA., May 21, 2014.

If adopted as currently proposed and envisioned, the deeming regulations would do more harm than good, in terms of future rates of addiction, illness and death. However, this outcome nonetheless would be welcomed by those within the tobacco-control community who prefer to ban all non-pharmaceutical tobacco products. The regulations also would be welcomed by the pharmaceutical firms and tobacco companies who would be protected from competition from these less hazardous and less addictive products.

The huge delays to date in FDA processing of “substantial equivalence” applications for products already under their jurisdiction is taken by many as a sign of FDA intentions to be unreasonably strict in their interpretation of the various provisions of the Tobacco Control Act, whether or not the such a stance would protect public health.

To be fair, it is important to note that many of the challenges the FDA faces stems from provisions in the Tobacco Control Act that require exceedingly difficult and expensive research documentation, especially for new and “modified risk” products. Some of these appear to have been written into the law to protect major tobacco and pharmaceutical firms from competition from lower-risk products.¹⁰⁴

Mental health patients: Adults who suffer from depression are twice as likely to smoke as other adults, and they also smoke more heavily, according to a survey from the National Center for Health Statistics.¹⁰⁵ One national comorbidity survey found that persons with a mental disorder consumed approximately 44.3 percent of all of the cigarettes smoked by this nationally representative sample in the month prior to the survey.¹⁰⁶

Anecdotal reports indicate that many of the roughly 7 percent to 15 percent of the population with such mental illnesses as schizophrenia, depression and bipolar disorder find nicotine to be a highly beneficial drug that enables them to get through the day in emotional balance and with substantially fewer side effects than typical prescribed medications.^{107 108 109} In January 2014, Jacques le Houezec published

an essay presenting positive effects of nicotine for an even wider range of conditions.¹¹⁰

The reports noted above and huge numbers of anecdotal observations by e-cigarette users clearly indicate that nicotine is beneficial for a significant portion of the population, and that total elimination of non-prescription nicotine, as desired by many anti-tobacco advocates, would be harmful to these individuals.

Smokeless tobacco warnings: The most damaging of the “self-evident” perceptions held by much of the tobacco-control community, and the one standing directly in the way of any consideration of implementing THR as a public health initiative, is the perception that all tobacco products present a similar risk of potentially fatal illness. This perception is reinforced by the warnings mandated on all packages of smokeless tobacco sold in the United States.

There are four rotating warnings. One warns of mouth cancer; the second of tooth and gum disease; the third states that smokeless tobacco is not a safe alternative to cigarettes; and the fourth warns of addiction. Of these warnings, the first is technically incorrect, and the next two are grossly misleading. Only the warning about addiction is both correct and not misleading. These warnings have left more than 80 percent of smokers with the impression that these smokeless products are at least as hazardous as cigarettes and that switching from cigarettes to a smokeless alternative would simply result in swapping a risk of lung cancer for a risk of mouth cancer.¹¹¹

These warnings would be appropriate for a family of products available in India, sometimes referred to as “gutkha” or “pan masala with tobacco.” This family of products does pose a high risk of mouth cancer and tooth and gum disease, but it has not been and likely never will be available in the U.S. market. The chewing tobacco, snuff, *snus* and other smokeless products actually available in the American market do not pose any risk of these diseases warranting any such warning, and this lack of risk has been firmly established since at least 2004.¹¹² This lack of risk has been further reinforced by

104. Ibid.

105. AFP, “Depressed Patients Smoke More: Study,” Phys.org, April 14, 2010. <http://phys.org/print190471659.html>

106. Karen Lasser, et al., “Smoking and mental illness: A population-based prevalence study,” *Journal of the American Medical Association*, Nov. 22, 2000. <http://www.ncbi.nlm.nih.gov/pubmed/11086367>

107. Veena Kumari and Peggy Postma, “Nicotine use in schizophrenia: The self-medication hypotheses,” *Neuroscience and Biobehavioral Reviews*, 2005. <http://web.as.uky.edu/biology/faculty/cooper/Bio401G/nicotineSchiz.pdf>

108. Kristi A. Sacco, et al., “Effects of cigarette smoking on spatial working memory and attentional deficits in schizophrenia: Involvement of nicotinic receptor mechanisms,” *Archives of General Psychiatry*, June 2005. <http://www.ncbi.nlm.nih.gov/pubmed/15939842>

109. Victoria C. Wing, et al., “Neuropsychological performance in patients with schizophrenia and controls as a function of cigarette smoking status,” *Psychiatry Research*,

Aug. 15, 2011. <http://www.ncbi.nlm.nih.gov/pubmed/21669462>

110. Jacques le Houezec, “The Positive Effects of Nicotine,” *Nicotine Policy*, Jan. 12, 2014. <http://nicotinepolicy.net/all-authors/85-jacques-le-houezec/640-the-positive-effects-of-nicotine> (Accessed January 14, 2014).

111. Ron Borland, et al., “Trends in beliefs about the harmfulness and use of stop-smoking medications and smokeless tobacco products among cigarettes smokers: Findings from the ITC four-country survey,” *Harm Reduction Journal*, Aug. 23, 2011. <http://www.harmreductionjournal.com/content/8/1/21>

112. David Levy, et al., “The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes; estimates of a panel of experts,” *Cancer Epidemiology, Biomarkers and Prevention*, 2004.

additional studies of this subject published since that time.^{113 114}

Contraband: A recent survey of cigarette pack litter in five Northeast cities found that 58.7 percent of cigarette packs did not have a proper local tax stamp. Between 30.5 percent and 42.1 percent of the discarded cigarette packs were believed to have been trafficked. Researchers concluded that reducing illicit cigarette trafficking would reduce smoking and generate additional tax revenue.¹¹⁵ Wherever steps have been taken to significantly increase the cost of cigarettes, there are major problems with contraband. Plans to eliminate menthol from cigarettes or reduce their nicotine content also would, predictably, increase demand for illicit cigarettes. A THR strategy, with a prominent role for e-cigarettes, should decrease contraband by decreasing the demand for cigarettes.

Flavored e-cigarettes: Nicotine has an extremely harsh taste and, unless sweetened or flavored in a smokeless tobacco product or e-cigarette, it would be unpalatable to almost all potential users. Flavors, and the ability to change flavors at will, are important to adult users of e-cigarettes.¹¹⁶ Even the over-the-counter pharmaceutical nicotine products available on drugstore, discount store and supermarket shelves come in a variety of fruit and candy flavors. The flavoring of these FDA-approved pharmaceuticals is a concern never raised by those who oppose flavored e-cigarettes.

Age of Initiation in adult smokers: In its latest statistical report, the federal Substance Abuse and Mental Health Administration (SAMHSA) noted that 31.6 percent of those surveyed in 2002 reported they started smoking after their 18th birthday. By 2012, that number had jumped to 47.8 percent.¹¹⁷ While not diminishing the need to prohibit tobacco sales to minors, this report provides strong support for upping the age cut-off for tobacco sales from 18 to 21. This should also eliminate any thought that, by prohibiting the sale of tobacco to minors, we will eventually eliminate all tobacco use in the United States.

WHAT ARE STATE AND LOCAL GOVERNMENTS TO DO?

1. Fully enforce age restrictions on purchase of all tobacco products. To eliminate even the theoretical possibility of teen initiation of any tobacco product, extend the marketing restrictions imposed on cigarettes to all tobacco products, possibly including over-the-counter NRT pharmaceuticals. There are two issues relating to teens. The first is damage that nicotine can do to the adolescent brain. The second is that people who start smoking before 18 years of age are far more likely to become long-term smokers than those who do not start until later in life.
2. Consider upping the age to purchase any tobacco product from 18 to 21. This would remove cigarettes from the high school environment.¹¹⁸
3. To encourage users to switch, heavily tax cigarettes, but only lightly tax lower-risk products.
4. Implement policies and programming needed to identify and eliminate contraband.
5. Consider implementing non-pharmaceutical smoking cessation protocols that could prove to be more effective for long-term abstinence.^{119 120}
6. Urge tobacco-control leaders to open dialogue with those in the public health community who endorse THR and e-cigarettes and those in the various tobacco-related industries who would welcome the opportunity to partner with the public health community in pursuit of shared public health objectives.
7. Urge the FDA to sensibly regulate e-cigarettes and other low-risk tobacco products by prohibiting sales to minors, restricting marketing and assuring quality and consistency of manufacture. Urge them not to impose restrictions on flavoring or nicotine content that would make these products unpalatable to smokers who otherwise would switch.

113. Rodu, July 29, 2011

114. Phillips, et al., 2006.

115. Kevin C. Davis, et al., "Cigarette Trafficking in Five Northeastern US Cities," *Tobacco Control*, Dec. 11, 2013. <http://tobaccocontrol.bmj.com/content/early/2013/12/11/tobaccocontrol-2013-051244.abstract.html>

116. Konstantinos Farsalinos, et al., "Impact of flavour variability on electronic cigarette use experience: An internet survey," *International Journal of Environmental Research and Public Health*, Dec. 17, 2013. <http://www.mdpi.com/1660-4601/10/12/7272>

117. SAMHSA, "Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings," USDHHS: Substance Abuse and Mental Health Services Administration, September 2013. <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch5.10>

118. Jonathan P. Winickoff, Mark Gottlieb and Michelle Mello, "Tobacco 21 -- an idea whose time has come," *New England Journal of Medicine*, Jan. 23, 2014. <http://www.nejm.org/doi/full/10.1056/NEJMp1314626>

119. H-P Hutter, Hanns Moshhammer and Manfred Neuberger, "Smoking cessation at the workplace: 1 year success of short seminars," *International Archives of Occupational and Environmental Health*, January 2006. <http://www.ncbi.nlm.nih.gov/pubmed/16133522>

120. Hanns Moshhammer and Manfred Neuberger, "Long term success of short smoking cessation seminars supported by occupational health care," *Addictive Behaviours*, July 2007. <http://www.ncbi.nlm.nih.gov/pubmed/17097816>

WHAT SHOULD STATE AND LOCAL GOVERNMENTS NOT DO?

STATES, COUNTIES AND cities should not prohibit use of e-cigarettes or other smoke-free tobacco products in non-smoking areas. Such a law or regulation could do harm by leaving the impression that these products are as hazardous to bystanders as cigarettes. State and local governments also should not tax e-cigarettes as if they are tobacco products. Taxation of e-cigarettes should be similar to the taxation of over-the-counter pharmaceutical nicotine lozenges, gum, patches and inhalers.

CONCLUSION

TOBACCO HARM REDUCTION, with e-cigarettes as a major component, is the only feasible policy option likely to substantially reduce tobacco-attributable illness and death in the United States over the next 20 years. Our experience to date with e-cigarettes, now well-documented in the scientific literature, suggests they have already reduced cigarette sales and already secure substantial public health benefits among smokers without increasing teen initiation of tobacco/nicotine use.

Simply changing the public health goal from a “tobacco-free society” to a “smoke-free society” would align tobacco-control policy with the science and evidence base. It would open the door to recommending e-cigarettes to help smokers unable or unwilling to quit.

E-cigarettes pose a risk of potentially fatal tobacco-attributable illness similar to the risk posed by pharmaceutical patches, gum, lozenges and inhalers, a risk well below 2 percent of the risk posed by combustible cigarettes. For all practical purposes, they pose no risk to bystanders. The continuing condemnation of e-cigarettes by many tobacco-control advocates suggests a strong bias against use of any non-pharmaceutical tobacco/nicotine product in the context of any public health initiative, and possibly, an unwillingness to propose policy guidelines unfavorable to their pharmaceutical industry partners.

While sales to minors of all tobacco and other non-prescription nicotine products should be prohibited, there is no reason to ban use of e-cigarettes and related devices in no-smoking areas. E-cigarettes should be taxed at the same rate as non-prescription pharmaceutical patches, gum, lozenges and inhalers, not at the much higher rate imposed on cigarettes and other combustible tobacco products.

ABOUT THE AUTHOR

Dr. Joel L. Nitzkin is a public health physician with a master’s in public health and a doctorate in public administration. He is board certified in preventive medicine as his medical specialty. He has been a local health director, state health director and president of two national public health organizations.

Since the mid-1990s, Dr. Nitzkin has been in the private practice of public health as a health policy consultant. In this capacity, he has taken on a number of research and teaching assignments for federal, state and local public health agencies; assisted with accreditation of a managed care organization; and done substantial expert witness work related to communicable disease control, quality of health care and tobacco control.

Beginning in 2007, while serving as co-chair of the Tobacco Control Task Force of the American Association of Public Health Physicians, Dr. Nitzkin played a lead role in exploring policy options for reducing tobacco-attributable illness, death and property damage in the United States. It was that analysis and subsequent follow-up work that drew his attention first to tobacco harm reduction, then to e-cigarettes as the only feasible policy option likely to substantially reduce tobacco-attributable illness and death in the United States over the next 20 years.

Since AAPHP did not have the infrastructure or other resources to get this message out to state and local legislatures, Dr. Nitzkin sought a neutral sponsor that would be willing to help him play this role. This led to his affiliation with the R Street Institute.

Dr. Nitzkin has never received financial support from any tobacco, e-cigarette or pharmaceutical enterprise. His affiliation with R Street is based on shared concerns about the direction of federal tobacco policy since adoption of the FDA tobacco law. The R Street Institute is a Washington-based think tank that respects the role of government in regulating industry to protect health and the environment, but strongly opposes undue governmental interference with market forces. R Street designated tobacco harm reduction as one of their priority issues after the FDA attempted to remove e-cigarettes from the market by declaring them to be an unapproved drug-device combination subject to the provisions of the drug law. At the time of his initial affiliation with R Street, R Street had no support from any tobacco industry entity. Since then, R Street has secured a modicum of such support, with the understanding that industry representatives would have no role whatever in setting R Street tobacco-related policy and no role with regard to the work done by Dr. Nitzkin or other R Street tobacco policy fellows.

The views expressed in this paper are entirely those of Dr. Nitzkin. They do not reflect position statements formally adopted by AAPHP, R Street or any other organization he is affiliated with.

Additional bibliographic references dealing with these and other issues are available on request from Dr. Nitzkin at jl@jln-md.com.