

**FDLI'S** FOOD  
*and* DRUG  
POLICY FORUM

E-Cigarettes: A Life-Saving Technology or a  
Way for Tobacco Companies to Re-Normalize  
Smoking in American Society?

*Joel L. Nitzkin, MD, MPH, DPA*  
Senior Fellow for Tobacco Policy  
R Street Institute

VOLUME 4, ISSUE 6 // JUNE 30, 2014

THE FOOD AND DRUG LAW INSTITUTE  
1155 15TH STREET NW, SUITE 800 // WASHINGTON, DC 20005  
[www.fdpi.org](http://www.fdpi.org)



## INFORMATION FOR SUBSCRIBERS AND PURCHASERS

### License Agreement (the “Agreement”) and Terms of Use for End Users of FDLI Digital Publication Product Services (the “Services”)

THIS IS AN AGREEMENT BETWEEN YOU, (THE “END USER”), AND THE FOOD AND DRUG LAW INSTITUTE (“FDLI”). FDLI IS THE PROVIDER OF THE SERVICES THAT PERMIT END USERS, (LIMITED TO FDLI MEMBERS OR NONMEMBER SUBSCRIBERS OR PURCHASERS OR OTHERS AS DETERMINED BY FDLI) TO LICENSE DIGITAL PUBLICATION PRODUCTS (THE “DIGITAL PUBLICATION PRODUCTS”) FOR END USER USE ONLY UNDER THE TERMS AND CONDITIONS SET FORTH IN THIS AGREEMENT. PLEASE READ THIS LICENSE AGREEMENT AND TERMS OF USE, AND ALL RULES AND POLICIES FOR THE SERVICES (INCLUDING, BUT NOT LIMITED TO, ANY RULES OR USAGE PROVISIONS SPECIFIED ON THE FDLI WEBSITE) BEFORE USING THE PRODUCTS. BY USING THE PRODUCTS, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT.

### Digital Publication Products

**FDLI website:** The FDLI website enables the End User to download this Digital Publication Product to a personal computer or personal handheld device solely for personal use.

**Use of Digital Publication Products:** Upon your payment of the applicable fees, FDLI grants you the non-exclusive right to retain a permanent copy of the applicable Digital Publication Product and to view, print and use such Digital Publication Product an unlimited number of times, solely for your personal, non-commercial use.

**Restrictions:** The End User agrees that Digital Publication Products contain proprietary material that is owned by FDLI, and is protected by United States copyright laws. For reprint permissions or distribution inquiries, contact FDLI at (202) 371-1420.

For subscription or purchasing information, visit [www.fdpi.org](http://www.fdpi.org).

### Disclaimer

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction.

The views, opinions and statements expressed in this article are those of the author(s). The Food and Drug Law Institute neither contributes to nor endorses Forum articles. *As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.*

©2014 FDLI

All rights reserved. ISSN pending.

Authorization to photocopy items for internal or personal use of specific clients is granted by the Food and Drug Law Institute, provided that the base fee of US \$.75 per page is paid directly to the Copyright Clearance Center (CCC), 222 Rosewood Drive, Danvers, MA 01923, USA. For those organizations that have been granted a photocopy license by CCC, a separate system of payment has been arranged. The fee code for users of the Transactional Reporting Service is: ISSN pending 02.75.

To order additional copies of this publication, please visit our website at [www.fdpi.org](http://www.fdpi.org).



1155 15th Street NW, Ste. 800, Washington, D.C. 20005

Tel: (202) 371-1420; Fax: (202) 371-0649

email: [comments@fdpi.org](mailto:comments@fdpi.org)

website: [www.fdpi.org](http://www.fdpi.org)

[www.fdpi.org](http://www.fdpi.org)

## FDLI'S FOOD AND DRUG POLICY FORUM

**Michael D. Levin-Epstein, JD, MEd**  
Editor-in-Chief

**Elizabeth A. Stevulak, Esq.**  
Editor

---

## FDLI'S FOOD AND DRUG POLICY FORUM

**Victoria W. Girard (Chair)**  
Georgetown University

**Gary C. Messplay (Vice Chair)**  
Hunton & Williams LLP

**Barbara A. Binzak Blumenfeld PhD, JD (Board Liaison)** Buchanan Ingersoll & Rooney PC

Erik R. Lieberman  
U.S. Food Imports LLC

James A Boiani  
Epstein Becker & Green, P.C.

Jonathan R. McKnight  
FDA - CBER

Thomas Cluderay  
Environmental Working Group

Nicholas J. Nowakowski  
Oakland Law Group, PLLC

Lisa E. Davis  
Quarles & Brady LLP

Megan L. Olsen  
Kelley Drye & Warren LLP

Eric Feldman  
University of Pennsylvania

Kirsten Paulson  
The Pew Charitable Trusts

Jeffrey K. Francer  
PhRMA

Christine Perez  
ADVI

Robert L. Guenther  
United Fresh Produce Association

Peter Pitts  
Center for Medicine in the Public Interest

Jennifer J. Hillman  
University Health System

Robert Rosado  
Food Marketing Institute

Elizabeth Isbey  
McDermott Will & Emery

Mark I. Schwartz  
FDA - CBER

Ralph F. Ives  
AdvaMed

Josephine M. Torrente  
Hyman, Phelps & McNamara, P.C.

Mary Clare Kimber  
Plasma Protein Therapeutics Association

Alan Traettino  
Stryker Corporation

Beth A Krewson  
Incyte Corporation Experimental Station

Brian Joseph Wesoloski  
Mylan Pharmaceuticals, Inc.

Marian Lee  
King & Spalding LLP

## TABLE OF CONTENTS

I.	Introduction.....	1
	Policy Recommendations.....	1
II.	Background.....	2
	A. Nicotine Addicts, but Cigarette Smoke Kills .....	2
	B. Tobacco Harm Reduction (THR).....	3
	C. The Case Against Tobacco Harm Reduction .....	4
	D. What Are E-Cigarettes, and Why Are They So Controversial? .....	4
	E. FDA Decisions and Options .....	5
	F. When Is FDA Likely to Act? .....	6
III.	Major Issues in Dispute.....	7
IV.	Research and Response .....	7
	A. Are E-Cigarettes an Effective Way to Quit Smoking?.....	7
	B. Can They Be Marketed without Recruiting Teens? .....	8
	C. Will Their Use Expand or Reduce Nicotine Addiction?.....	9
	D. Proof and Level of Risk .....	9
V.	Impact of Policy Recommendations.....	10
	A. Revise the Goal from “A Tobacco-Free Society” to “A Smoke Free Society” .....	10
	B. Promulgate Sensible FDA Regulations .....	10
	C. Add a Tobacco Harm Reduction Component to Tobacco Control Programming .....	10
	D. Open New Lines of Communication .....	10
	E. Redevelop Pertinent Federally Sponsored Surveillance Systems.....	10
VI.	Conclusion.....	11
	Endnotes .....	11
	About the Author .....	15
	About the Food and Drug Policy Forum.....	17
	About FDLI .....	17

# E-Cigarettes: A Life-Saving Technology or a Way for Tobacco Companies to Re-Normalize Smoking in American Society?\*

## I. INTRODUCTION

Electronic cigarettes, commonly referred to as “e-cigarettes,” are devices that enable the user to inhale nicotine-containing vapor without the witches’ brew of toxic chemicals found in cigarette smoke. They have proven to be extremely popular among smokers who have been unable or unwilling to quit smoking and appear to be very effective in enabling users to cut down or quit cigarettes entirely. They are seen by tobacco control advocates as an unproven and unregulated gimmick developed by tobacco companies to addict another generation of children, teens and young adults and, by that means, to unravel the progress we have made in tobacco control over the past half century.

The so-called e-cigarette debate is based on advocates promoting the benefits of e-cigarettes and opponents arguing either that no such benefits exist, or that, even if they do, that harms are sure to outweigh benefits given the corrupting influence of the tobacco industry. The major potential harm referenced by almost all tobacco control advocates is the potential that e-cigarettes will recruit large numbers of teen non-smokers to nicotine use and eventually, many will transition to tobacco cigarettes.

In this policy forum I assert that the case in favor of e-cigarettes is so substantial that a tobacco harm reduction (THR) initiative using e-cigarettes is the only feasible policy alternative that would enable us to substantially reduce tobacco-attributable illness and death in the United States over the next 20 years. This could be done while further reducing teen initiation of nicotine use. I find much of the case against e-cigarettes to be biologically implausible, biased, deeply flawed and frequently in conflict with scientific evidence.

1

## POLICY RECOMMENDATIONS

1. Revise the goal from “a tobacco-free society” to “a smoke free society.”
2. Add a tobacco harm reduction (THR) component to tobacco control programming with e-cigarettes as a prominent harm reduction modality.
3. Promulgate FDA regulations that recognize the difference in risk between different types of tobacco-related products and the potential benefits of THR.
4. Open new lines of communication between the public health community and the tobacco and e-cigarette industries.
5. Redevelop pertinent federally sponsored surveillance systems to track use and abuse of the pharmaceutical nicotine products and to better track the dynamics by which people initiate use of tobacco-related products and transition between products of higher and lower risk.

## II. BACKGROUND

### A. Nicotine Addicts, but Cigarette Smoke Kills

There are about 46 million smokers in the United States, and an estimated 480,000 deaths per year attributed to cigarette smoking. Despite our best efforts, these numbers have been essentially stable since 2004.<sup>1</sup> Further reducing the number of smokers and number of deaths will require adding one or more new elements to current tobacco control programming.

The recent Surgeon General Report<sup>2</sup> 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 additional diseases attributable to cigarette smoking. All of the 480,000 estimated tobacco-attributable deaths each year in the United States are due to a single tobacco product – the machine-made cigarette.<sup>3</sup> Deaths from all other tobacco products are so low in number and so hard to distinguish from background statistical noise that they are not tracked by the American Centers for Disease Control and Prevention (CDC).

The Surgeon General considers the tobacco industry to be the root cause and vector of tobacco-attributable addiction, illness and death, by virtue of its predatory marketing and manufacturing techniques to make its products both more attractive and more addictive.<sup>4</sup> In addition, the “big tobacco” cigarette manufacturers have effectively used their financial resources and political clout to escape liability and block legislation that would have harmed their financial interests. Distrust and hatred of the tobacco industry is so strong within the public health community that they cannot envision ever endorsing any non-pharmaceutical tobacco-related product in the context of any public health initiative, no matter what the potential benefits.

If the current flat trend continues, as appears likely, an estimated 9,600,000 Americans will die of a cigarette-related illness over the next 20 years (480,000 deaths per year x 20 years). Since there is a 15-20 year delay between initiation of cigarette use and onset of potentially fatal tobacco-attributable cancer, heart, lung and other disease, and another 10-20 year delay from onset of illness to death – the vast majority of the 9.6 million deaths due to cigarette use in the United States over the next 20 years will be in current adult smokers who are now over 35 years of age. This means that reduction in teen smoking will not measurably reduce the number of deaths until 25-40 years from now.

Different types of tobacco products present different levels of risk of potentially fatal illness.

At the risk of considerable oversimplification, the epidemiologic findings describing the differences in risk posed by different types of tobacco-related products is as follows:

1. When consistently used over a period of years, cigarettes kill one-third to one-half of consistent users, with the risk dependent on pack-years of use and host factors.<sup>5</sup>
2. Pipes and cigars probably pose a risk equivalent to 20 percent to 100 percent of the risk posed by cigarettes.<sup>6</sup> This difference in risk, while not insignificant, pales in comparison to the reduction in risk offered by smoke-free options and nicotine-only products. The 100 percent risk is intended to reflect the likely risk posed by small cigars and cigar-like products that are really cigarettes in disguise. Thus, while most other combustible products are lower in risk than

cigarettes, they are not low enough in risk to deserve consideration in a THR initiative. In addition, the entire family of combustible products present health risks from environmental tobacco smoke, as well as fire hazards.

3. Hookahs, shishas and water pipes are poorly studied epidemiologically because there are so few users who do not also smoke cigarettes. Given what we know, it appears they likely pose a risk as high or higher than cigarettes, due to the inhalation of charcoal fumes and extreme exposure to carbon monoxide. Charcoal fumes contain an array of carcinogens and other toxins, similar to those found in tobacco smoke.<sup>7</sup>
4. Chewing tobacco, snus and other smoke-free products that have been on the American and Scandinavian markets since the 1980s pose a risk of potentially fatal illness that is less than 2 percent of the risk posed by cigarettes.<sup>8</sup>
5. Dissolvables (sticks, strips and orbs) and e-cigarettes are too new to have been subject to long-term epidemiologic study. They almost certainly pose even less risk than the other THR products noted above. A good guess might be a risk less than 0.1 percent the risk posed by cigarettes. That is a guess, based on experience to date with the NRT products.
6. The NRTs have been in common use since the 1980s and have been extensively studied. There is nothing in the literature alleging any increased risk of potentially fatal tobacco-attributable illness due to use of these products.<sup>9</sup>

The differences in risk of potentially fatal illness posed by the different classes of tobacco products appear to be almost entirely based on the way the person using the product is exposed.<sup>10</sup> Burning tobacco creates both gaseous and tarry products of combustion that are inhaled deeply into the lung, with cigarettes inhaled most deeply. The further the toxins enter the lungs, the more the gaseous substances are likely to be absorbed and the more likely tarry residues are to stick in place. Tar stuck in place results in intimate long-term exposure to the chemical toxins and radioactive trace elements that may be present in the tar. Cigars and pipes are not usually inhaled as deeply, and therefore convey less risk. Smoke-free tobacco products are not inhaled at all. They mainly expose the oral mucosa, a less delicate surface than the pulmonary alveoli, and one constantly washed with saliva and other fluids. The nicotine-only products likely convey even less risk, having eliminated all but the tiniest traces of other tobacco-related toxins.

## **B. Tobacco Harm Reduction (THR)**

THR is a communication initiative by which smokers who are unable or unwilling to quit are advised that they could reduce their risk of a potentially fatal tobacco-attributable illness by 98 percent or more by switching to any one of a number of lower risk products.<sup>11</sup>

The smoke-free whole tobacco options include chewing tobacco, snuff, snus (a form of moist snuff) and dissolvables (strips, sticks and orbs). The nicotine-only options consist of e-cigarettes and nicotine replacement therapy (NRT) products used on a long-term basis in a harm-reduction mode. NRTs are the pharmaceutical patches, gums, lozenges and inhalers, most of which are available on open store shelves, without prescription. The lozenges are available in a variety of fruit and candy flavors and generally sold without age restriction.

Due to its extreme popularity among smokers and what appears to be extremely low toxicity, e-cigarettes are likely to prove to be the most prominent of THR modalities.

The final element in the case in favor of THR is the fact that there are significant numbers of Americans who gain substantial benefit from self-administered nicotine. These include, but are likely not limited to, persons with schizophrenia, depression and/or bipolar disorder.<sup>12</sup> This phenomenon needs to be formally recognized by the tobacco control community and incorporated into its policies and programming. For these individuals, THR utilizing a relatively low-risk smoke-free or nicotine-only product is likely to be a better option than total cessation of nicotine use.

### C. The Case Against Tobacco Harm Reduction

Since no nicotine delivery product can be considered totally risk free, both American and international tobacco control communities have strongly objected to any consideration of a THR component in tobacco control programming. Feelings on this topic are so strong that smoke-free options are banned throughout most of continental Europe and, since 1986, American federal authorities have mandated technically incorrect and grossly misleading warnings on all smoke-free products on the American market. The chewing tobacco, snuff and snus products that have been available nationwide in the United States since the early 1980s pose no measurable risk of mouth or throat cancer.<sup>13</sup> The warnings that these products cause tooth and gum disease and are not “safe alternatives” to smoking are grossly exaggerated.<sup>14</sup> Only the warning about potential addiction is accurate as stated. These warnings have left more than 80% of Americans and most American physicians with the mistaken impression that these products pose the same risk as cigarettes, simply swapping the risk of lung cancer for the risk of mouth cancer,<sup>15</sup> which is simply not true.

If one asks the Office of Smoking and Health of the CDC about these warnings, they will tell you that they are based on international data.<sup>16</sup> What they will not tell you (unless you press them very hard) is that the international data are based on a family of products commonly referred to as “gutkha” or “pan masala with tobacco,” highly alkaline mixtures of tobacco and other substances in common use in Asia and Africa,<sup>17</sup> but not available on the American market.

4

### D. What Are E-Cigarettes, and Why Are They So Controversial?

E-cigarettes did not enter the American market until 2006. Beginning about 2008, sales of e-cigarettes have more than doubled each year. A combination of the attractiveness of the product to smokers, and FDA attempts to remove them from the market<sup>18</sup> has created a substantial and energetic community of “vapers” (e-cigarette users) dedicated to political action to keep these products on the market. Since these products were not envisioned in the FDA tobacco law, these products are currently unregulated.

The public health community does not consider the nicotine-only pharmaceutical NRT products to be tobacco products because they contain no tobacco and are clearly intended for a therapeutic purpose. Since e-cigarettes are developed, made and marketed by non-pharmaceutical companies, presumably for recreational purposes, the public health community is up in arms against them as a gimmick intended to addict more teens to tobacco use. The fact that e-cigarettes contain no tobacco is considered irrelevant to most within the public health community because of what they perceive to be the intended purpose of this family of products.

The vaper community consists almost entirely of long-term smokers who have tried and failed to quit many times using available NRT products, then discovered that they could partially or entirely give up cigarettes by transitioning to e-cigarettes. Many see e-cigarettes as life-saving products that have transformed their lives, both physically and psychologically. They fear the FDA will ban them, forcing them onto unreliable black market sources or back onto the cigarettes they now hate.

Until about a year ago, the e-cigarette market was dominated by small disposable and rechargeable e-cigarettes made to look like tobacco cigarettes. Over the past few years, most long-term e-cigarette users and many beginners have transitioned to more expensive and more elaborate devices commonly referred to as “mod” or “tank” units that no longer resemble tobacco cigarettes. These more elaborate products deliver a higher and more consistent dose of nicotine and enable users to customize the nicotine dose and flavor to their personal preferences, and do so at a tiny fraction of the cost per puff of either tobacco cigarettes or the smaller “cig-a-like” products. This movement, in turn, has led to the current explosion of “vape shops” nationwide. Wall Street gurus now estimate that these more elaborate products constitute about half of the e-cigarette market and are continuing to grow at a rapid pace.<sup>19</sup>

## E. FDA Decisions and Options

The Family Smoking Prevention and Tobacco Control Act (FDA Tobacco Law)<sup>20</sup> was signed into law by President Obama in June 2009. In April 2014, the FDA released proposed “deeming” regulations for comment.<sup>21</sup> These would give the FDA’s Center for Tobacco Products (CTP) authority to regulate e-cigarettes, cigars, hookahs and a variety of other non-pharmaceutical tobacco-related products not covered by the initial legislation. As written into the law, and as seen by CTP, tobacco-related products marketed for therapeutic purposes are pharmaceuticals to be regulated by the Center for Drug Evaluation and Research (CEDR). The law, as written, grandfathers in all major brands of tobacco cigarettes, while placing nearly impossible impediments to approval of new alternative products and similar impediments prohibiting manufacturers and vendors from claiming their products present less risk than cigarettes. The proposed regulations do nothing to soften these onerous requirements. They do, however, soften the impact by allowing a 24-month grace period before any of the newer products now on the market face forced removal by FDA.

To date, FDA’s response to e-cigarettes has been outright condemnation based on theoretical fears and questionable data.<sup>22</sup> In 2010, FDA attempted to remove e-cigarettes from the market as unlicensed drug-device combinations. This resulted in a lawsuit which the agency lost.<sup>23</sup>

Meanwhile, there has been a veritable avalanche of new research attesting to e-cigarette safety, efficacy and relative un-attractiveness to non-smokers. This new research, in the light of their loss in the above-mentioned lawsuit presents FDA with a range of options, the most extreme of which are as follows:

1. FDA could require studies so difficult and so expensive that all but the biggest of the “big tobacco” cigarette companies would be driven from the market. This would threaten removal of more than 99% of current e-cigarette products from the market and be sure to generate yet more lawsuits that FDA would likely lose.
2. FDA could set paperwork, quality of manufacturing standards and marketing restrictions that could be met by the vast majority of e-cigarette manufacturers for the purpose of maximize potential benefits and minimize theoretical harms

of THR with e-cigarettes as a prominent THR modality. While not generating lawsuits, this would further accelerate e-cigarette sales at the expense of cigarettes and pharmaceutical nicotine replacement therapy products, an outcome that would severely upset tobacco control advocates.

The main difference between FDA's current stance and what I (JLN) would consider to be a reasonable regulatory structure seems rooted in an unwritten policy within CTP by which each proposed new or low-risk product is considered so unique that no research not specifically limited to that product will be considered. I therefore urge FDA to consider the massive body of epidemiological literature demonstrating the long-term relative safety of smoke-free and NRT products, and allow products in those classes to reference that literature, more reasonable regulations would follow almost automatically. Confirmatory long-term epidemiological or case-control studies of specific new products would take 30 years to complete and would only be possible if large numbers of people were using the product. This would be physically impossible if FDA required the results of the study prior to approving the product for widespread use.

Another part of the difference between the current FDA stance and what I would consider to be a reasonable regulatory profile has to do with the wording of the FDA law relative to chemical analyses of tobacco products. The law, as written, presumes that the differences in risk between tobacco products are based on their chemical profiles, as opposed to whether they are combustible or smoke-free. This, in turn, seems to be leading to excessive requirements for very expensive laboratory analyses. These studies will prove to be uninterpretable, since we have no idea how much of the heart cancer, lung, cancer or other disease attributable to tobacco use is due to any given chemical in tobacco smoke. One study that attempted to estimate the reduction in risk that could be expected from eliminating one of the most prominent carcinogens in tobacco smoke concluded that the reduction in risk of lung cancer would be less than four percent.<sup>24</sup> The problem here is that the cost of excessive laboratory work could drive smaller companies from this market.

If proposed regulations are finalized, FDA regulation of tobacco products will do more harm than good in terms of future rates of tobacco-attributable addiction, illness and death. Whether or not this comes to pass will depend on what FDA decides to do and what happens in response to the lawsuits to be brought against FDA by companies that feel they have both common sense and science on their side. The most likely outcome, should FDA stick to its current anti-THR, anti-e-cigarette stance will be years of litigation during which e-cigarettes will remain unregulated.

#### **F. When Is FDA Likely to Act?**

Even without such litigation, FDA currently does not project release of these regulations until June 2015, to be followed by another comment period before they come into effect, and then the 24-month grace period proposed in the current preliminary proposed deeming regulations. Thus, no matter what happens, it will be at least two years and possibly as long as ten before we see any final FDA regulations for e-cigarettes.

Anticipating this delay, and to provide a level of public confidence, the e-cigarette industry has promulgated and implemented an extensive set of quality standards for e-cigarette fluid.<sup>25</sup> In further anticipation of this delay, public health authorities and others should consider how best to manage THR and e-cigarettes on an interim basis.

### III. MAJOR ISSUES IN DISPUTE

1. Are e-cigarettes a safe and effective way to reduce or eliminate tobacco cigarette use by current smokers?
2. Can they be marketed without recruiting large numbers of teens and other non-smokers who otherwise would have avoided nicotine use?
3. Will their use expand or reduce nicotine addiction in America?
4. What types and levels of evidence should be required to determine their safety, benefits and harms?
5. To what degree is American tobacco control policy based on bias in favor of major pharmaceutical firms and against the tobacco industry?

### IV. RESEARCH AND RESPONSE

#### A. Are E-Cigarettes an Effective Way to Quit Smoking?

##### 1. Ineffectiveness of Smoking-Cessation Therapy

The remarkable ineffectiveness of currently favored pharmaceutical-based smoking cessation therapy creates the need for a THR initiative. The current “standard of care” for smoking cessation involves use of one of a number of smoking-cessation medications. These consist of the NRTs (nicotine gum, lozenges, patches and inhalers), varenicline (Chantix) and bupropion (Zyban).<sup>26</sup> 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.<sup>27</sup> This failure rate is the reason that a THR element needs to be added to tobacco-control programming.

The flaws in the smoking cessation protocols based on these “evidence-based” 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 when results are measured at six to twelve months.<sup>28</sup> 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.<sup>29</sup>

##### 2. 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 options<sup>30</sup> to substantially better.<sup>31</sup> There have been no reports of e-cigarettes being inferior in efficacy to the pharmaceutical options in smokers who want to quit, and no reports showing any benefit of the pharmaceutical options to smokers who are not interested in quitting.

## B. Can They Be Marketed without Recruiting Teens?

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.<sup>32</sup>

A second study from Action on Smoking and Health (ASH-UK) also contradicts the anti-smoking groups' contention that electronic cigarettes appeal to nonsmokers, especially youth. ASH-UK were unable to find a single nonsmoker in Great Britain – either youth or adult – who regularly uses electronic cigarettes.<sup>33</sup> The group's study was based on a survey of 12,171 adults and 2,178 children aged 11-18 in February and March of 2013.

The ASH-UK study found awareness of electronic cigarettes was 67% among those between the ages of 11 and 18 and 83% among those between the ages of 16 and 18. Nevertheless, it found that among young people who had never smoked, "0% report continued e-cigarette use and 0% expect to try an e-cigarette soon." The study also found that, among adults who had never smoked, none reported current electronic cigarette use.<sup>34</sup>

In early September 2013, CDC published a study showing that e-cigarette use among middle and high school students had doubled from 2011 to 2012.<sup>35</sup> 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 may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes." A similar sentiment was restated in a 2014 re-analysis of this same CDC surveillance data.<sup>36</sup> Despite the hype surrounding these publications, the survey data equally support the opposite conclusion, that e-cigarettes are attractive only to teen smokers who wish to use them to transition away from cigarettes, and that e-cigarettes are likely to result in future declines in teen smoking.<sup>37</sup>

This impression is supported by the CDC data showing that this increase in e-cigarette use was associated with a further reduction in teen smoking.<sup>38</sup> As a public health physician, I am troubled by these purposeful misinterpretations of CDC survey data. A careful review of the underlying CDC 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 in 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 American<sup>39</sup> and ASH-UK surveys, referenced above.<sup>40</sup>

The surveys noted above show that the currently unregulated e-cigarettes attract almost no non-smokers. This, in turn, suggests that 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 such endorsement.

### C. Will Their Use Expand or Reduce Nicotine Addiction?

E-cigarettes and other lower-risk products are less addictive than cigarettes. In a well-referenced essay published online in December 2013,<sup>41</sup> Karl Fagerstrom makes a very strong case for a “continuum of dependence” in which cigarettes foster the strongest dependence and NRTs 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.<sup>42</sup>

### D. Proof and Level of Risk

Perhaps the best way to put all this into perspective is with an analogy: tobacco use can be compared to skydiving.

As previously noted, a lifetime smoker has a 33% to 50% chance of dying from a tobacco-related illness. The risk from the chewing tobacco, snus and other snuff products available on the American market is less than 2% the risk posed by cigarettes. The risks posed by the dissolvable products, e-cigarettes and the NRTs when used in a harm reduction mode promise to be even lower.

Let’s consider skydiving. If, for any reason, you decide that you would like to try jumping out of an airplane for fun, the first decision is whether or not to wear a parachute. Sounds like a silly question. Sure, it seems obvious that jumping out of the plane without a parachute carries a 99% or more risk of killing yourself. Using a parachute, while not eliminating all the risk, should eliminate about 99% of the risk. The problem here is that there has never been a controlled clinical trial comparing death rates from people jumping out of planes with and without parachutes. Thus, the safety of a parachute would seem to be unproven.

When it comes to e-cigarettes, many in the tobacco-control world will tell you that, since there has never been a clinical trial comparing death rates from cigarettes to death rates from e-cigarettes, their risk profile is unproven. This preferred policy approach is akin to outlawing parachutes for people who are already being forced to jump out of planes. Sure, a 98 percent reduction in risk does not mean risk-free, but it seems good enough to open the sport of sky diving to those willing to take such a risk.

Given the overwhelming, although indirect evidence that e-cigarettes should be able to reduce the risk of potentially fatal tobacco-attributable illness by 98 percent or better,<sup>43</sup> it is more reasonable for the public health community to actively promote tobacco harm reduction with e-cigarettes as a prominent THR modality.

## V. IMPACT OF POLICY RECOMMENDATIONS

### A. Revise the Goal from “A Tobacco-Free Society” to “A Smoke Free Society”

The goal of a “tobacco free society” is seen by tobacco control advocates as ruling out any consideration of any use of a non-pharmaceutical nicotine delivery product as a public health initiative. Simply changing this goal to “a smoke-free society virtually free of tobacco-related addiction, illness and death” would open the door to THR and public health benefits not otherwise obtainable with current tobacco control policies.

### B. Promulgate Sensible FDA Regulations

Optimal FDA regulation would involve strict control of quality of manufacture and marketing without threatening the removal of e-cigarettes and related nicotine vapor devices from the market, even on a temporary basis, and without stifling continuing product improvement. This regulatory approach, in turn, will pave the way for adding a THR component to current tobacco control programming. The alternative is most likely to be many years of fruitless litigation during which e-cigarettes and other new and relatively low risk products are neither regulated nor removed from the market.

### C. Add a Tobacco Harm Reduction Component to Tobacco Control Programming

My (JLN) analysis of these issues has brought me to the conclusion that the case in favor of e-cigarettes is so substantial that a THR initiative, using e-cigarettes as a prominent THR modality, is the only feasible policy option that will enable us to substantially reduce tobacco-attributable illness and death in the United States over the next twenty years.

### D. Open New Lines of Communication

Currently, communication between the public health community and the tobacco industry only occurs in the context of a highly formalized FDA regulatory process.

Opening informal channels of communication between the tobacco control community and the tobacco and e-cigarette industries is probably the only means by which we can sidestep the lawsuits that will almost certainly occur if the industry sees what it considers to be FDA restrictions on manufacturing and marketing far in excess of what can be justified for protection of the public health. Such informal dialogue could accelerate implementation of a more reasonable FDA regulatory approach.

Another major benefit of such informal communication could be public health/ industry collaboration on the elimination of illicit and contraband products from the marketplace. This is not a trivial issue, since the latest study shows that about 56% of cigarettes now sold in New York City are contraband products imported to avoid the high city and state tax rates.<sup>44</sup>

### E. Redevelop Pertinent Federally Sponsored Surveillance Systems

There are currently multiple, seemingly uncoordinated, tobacco-related surveillance systems run by CDC, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Bureau of Alcohol and Tobacco. None of these systems track the full range of non-pharmaceutical nicotine delivery products and none track the NRTs (patches, gum, lozenges and inhalers). None have the capacity to assess the impact

of educational or regulatory initiatives to influence rates of purchase and use. None have the capacity to differentiate experimentation from continuing use of a product. More information is also needed with regard to behavioral determinants of nicotine use and the health impacts of specific products on high risk and high use communities such as high school dropouts, LGBTs (lesbian, gay, bisexual, and transsexual), minority and indigent populations.

A better set of surveillance systems would fill in data gaps that cannot be addressed in an ongoing way by any other means. It would also give FDA, CDC, and others in the tobacco control community an improved capacity for mid-course correction when disturbing trends are detected.

## VI. CONCLUSION

E-cigarettes should be promoted to smokers who are unable or unwilling to quit so they can secure the nicotine they crave at less than two percent of the risk posed by tobacco cigarettes. The risk of renormalizing smoking is minimal. Since it will take at least two years and possibly as long as ten years for FDA to implement manufacturing and marketing standards for e-cigarettes, public health authorities need to consider how best to manage both e-cigarettes and related issues on an interim basis. This interim period would be an excellent time to explore steps that could be taken to remove illicit and contraband products from the American market and to promote informal dialogue between the public health community and the tobacco and e-cigarette industries for the purpose of optimizing both FDA regulations and overall tobacco control policy.

## ENDNOTES

1. Centers for Disease Control and Prevention, 2013, 1/August, *Tobacco-Related Mortality*, in CDC Fact Sheet-Tobacco Related Mortality Smoking and Tobacco Use <<[http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/tobacco\\_related\\_mortality/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm)>>. Office of the Surgeon General U. The health consequences of smoking - 50 years of progress, 2014.
2. Office of the Surgeon General U. The health consequences of smoking - 50 years of progress, 2014.
3. *Id.*
4. *Id.*
5. *See supra* endnote 1.
6. Nutt DJ, Phillips LD, Balfour D, Curran HV, Dockrell M, Joulds J et al. Estimating the harms of nicotine-containing products using the MCDA Approach. *Addiction Research* 2014 April 3;20:218-25
7. Monzer B, Sepetdjian E, Saliba N, Shihadeh A. Charcoal emissions as a source of CO and carcinogenicPAH in mainstream narghile waterpipe smoke. *Food Chem Toxicol* 2008;46:2991-

See also Eisenberg T, Shihadeh A. Waterpipe tobacco and cigarette smoking: Direct comparison of toxicant exposure. *Am J Prev Med* 2009 December;37(6):518-23.

8. Rodu B. The Scientific Foundation for Tobacco Harm Reduction, 2006-2011. *Harm Reduction Journal* 2011;8(19):8-19. Lee P. Epidemiologic Evidence relating snus to health - an updated review based on recent publications. *Harm Reduction Journal* 2013 6/Dec;10(36).
9. Food and Drug Administration, 2013, 1 April, *Modifications to Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use* <[http://www.ofr.gov/OFRUpload/OFRData/2013-07528\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2013-07528_PI.pdf)> (Accessed 2 April 2013).
10. See *supra* endnote 6.
11. Rodu B. The Scientific Foundation for Tobacco Harm Reduction, 2006-2011. *Harm Reduction Journal* 2011; 8(19):8-19.
12. Kumari V, Postma P. Nicotine use in schizophrenia: The self medication hypotheses. *Neuroscience Biobehavioral Reviews* 2005;29(6):1021-34. See Sacco K, Termine A, Seyal A, Dudas M, Vessicchio J, Krishnan-Sarin S et al. Effects of cigarette smoking on spatial working memory and attentional deficits in schizophrenia: Involvement of nicotinic receptor mechanisms. *Arch Gen Psychiatry* 2005 Jun;62(6):649-59. Wing V, Bacher I, Sacco K, George T. Neuropsychological performance in patients with schizophrenia and controls as a function of cigarette smoking status. *Psychiatry Res* 2011 Aug;188(3):320-6. See Houezec JI, 2014, 12 Jan, *The Positive Effects of Nicotine* <<http://nicotinepolicy.net/all-authors/85-jacques-le-houezec/640-the-positive-effects-of-nicotine>> (Accessed January 14, 2014).
13. See *supra* endnote 8.
14. Kallischnigg G, Wietkunat R, Lee P. Systematic review of the relation between smokeless tobacco and non-neoplastic oral diseases in Europe and the United States. *BMC Oral Health* 2008 1 May;8(13):1-16.
15. Borland R, Cooper J, McNeill A, O'Connor R, Cummings K. 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* 2011 23/August;8(21). O'Connor R, Hyland A, Giovino G, Fong G, Cummings K. Smoker awareness of and beliefs about supposedly less-harmful tobacco products. *Am J Prev Med* 2005 Aug; 29(2):85-90.
16. Mazurek JM, Syamlal G, King BA, Castellan RM. Smokeless tobacco use among working adults - United States, 2005 and 2010. *Morbidity and Mortality Weekly Report* 2014 6 June;63(22):477-82.
17. Gupta P, Ray C. Smokeless tobacco and health in India and South Asia. *Respirology* 2003 December;8(4):419-31. Javed F, Chotai M, Mehmood A, Almas K. Oral mucosal disorders

associated with habitual gutka usage: A review. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2010 June;109(6):857-64.

18. Leon R, 2010, 14 Jan, *Sottera, Inc, Doing Business as NJOY v. Food & Drug Administration et al*, Judge Richard Leon's Ruling striking down FDA's e-cig ban as unlawful <[https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-54](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54) and [https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-55](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-55)> (Accessed January 7, 2014).
19. Herzog B. "Tobacco Talk" Survey -- c-stores excited about vapor growth. Equity Research; Wells Fargo Securities 2014 11 June.
20. Waxman HA, 2009, *Family Smoking Prevention and Tobacco Control Act. Public Law 111-31, 111th Congress*, text of legislation (Accessed 29 September 2010).
21. Food and Drug Administration, 2014, 25 April, *Proposed Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. 21 CFR Parts 1100, 1140 and 1143; Docket No. FDA-2014-N-0189; RIN 0910-AG38. 25* <. <<https://www.federalregister.gov/articles/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>>> (Accessed 25 April 2014).
22. Nitzkin Joel L, 2010, 7 February, *Citizen Petition (to FDA) to Follow-up July 22, 2009 Press Conference on E-Cigarettes*, in Tobacco Issues, Petition to FDA <<<http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0095-0001>> or <<http://www.aaphp.org/Tobacco>>> (Accessed 7 February 2010). See also Nitzkin Joel L, 2010, 7 February, *Citizen Petition (to FDA) to Reclassify E-Cigarettes from "Drug-Device Combination" to "Tobacco Product,"* in Tobacco Issues, Petition to FDA <<<http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0093-0001>>; or <<http://www.aaphp.org/Tobacco>>> (Accessed 7 February 2010).
23. Leon R, 2010, 14 Jan, *Sottera, Inc, Doing Business as NJOY v. Food & Drug Administration et al*, Judge Richard Leon's Ruling striking down FDA's e-cig ban as unlawful <[https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-54](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54) and [https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-55](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-55)> (Accessed January 7, 2014).
24. Pankow J, Watanabe K, Toccalino P, Luo W, Austin D. Calculated Cancer Risks for Conventional and "Potentially Reduced Exposure Product" Cigarettes. *Cancer Epidemiol Biomarkers Prev* 2007;16(3):584-92.
25. American E-Liquid Manufacturing Standards Association, 2014, 14 Jan, *E-Liquid Manufacturing Standards, V.1.8* <[http://www.aemsa.org/wp-content/uploads/2014/02/AEMSA-Standards\\_Version-1-8.pdf](http://www.aemsa.org/wp-content/uploads/2014/02/AEMSA-Standards_Version-1-8.pdf)> (Accessed May 27, 2014).
26. Apelberg BJ, Onicescu G, Avila-Tang E, Samet JM, 2009, 17 December, *Estimating the Risks and Benefits of Nicotine Replacement Therapy for Smoking Cessation in the United States*. *Am J Public*

Health, published on line ahead of print <<http://ajph.aphapublications.org/cgi/doi/10.2105/AJPH.2008.147223>> (Accessed 12 August 2010).

27. Moore D, Aveyard P, Connock M, Wang D, Fry-smith A, Barton P, 2009, 2 April, *Effectiveness and Safety of Nicotine Replacement Therapy Assisted Reduction to Stop Smoking: Systematic Review and Meta-Analysis*. Br Med J;338 <[http://www.bmj.com/cgi/content/full/338/apr02\\_3/b1024](http://www.bmj.com/cgi/content/full/338/apr02_3/b1024)> (Accessed 24 September 2009).
28. *Id.*
29. Zhu SH, Lee M, Zhuang Y, Garnst A, Wolfson T. Interventions to increase smoking cessation at the population level: How much progress has been made in the last two decades? Tob Control 2012;21:110-8.
30. Bullen C, Howe C Laugesen, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: A randomised controlled trial. The Lancet 2013;382:1629-37.
31. Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. Addiction 2014 May. Siegel M, 2014, 21 May, *New Population-Based Study Reports That e-Cigarettes Outperform NRT for Self-Assisted Smoking Cessation Among Smokers Who Choose These Approaches* < <http://tobaccoanalysis.blogspot.com/2014/05/new-population-based-study-reports-that.html>> (Accessed 21 May 2014).
32. McMillen R, Maduka J, Winickoff J. Use of emerging tobacco products in the United States. Journal of Environmental Public Health 2012 10/May;2012.
33. Action on Smoking and Health. ASH fact sheet on the use of e-cigarettes in Great Britain among adults and young people. ASH, UK, 2013.
34. *Id.*
35. Centers for Disease Control and Prevention, 2013, 06/Sep, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students -- United States, 2011-2012*. Morbidity and Mortality Weekly Report;62(35) <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>> (Accessed 30Nov2013).
36. Dutra L, Glantz S. Electronic cigarettes and conventional cigarette use among US adolescents a cross-sectional study. JAMA Pediatrics 2014 06/March:E1-8.
37. Siegel M, 2014, 7 Jan, *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* <<http://tobaccoanalysis.blogspot.com/2014/01/if-electronic-cigarettes-are-gateway-to.html>> (Accessed January 7, 2014). See also Siegel M, 2014, 10 March, *Glantz Press Release is Dishonest with Public; Authors Appear to Be Intentionally Lying to Mislead the Media and the Public*. The Rest of the Story <<http://tobaccoanalysis.blogspot.com/2014/03/glantz-press-release-isdishonest-with.html>>

(Accessed March 10, 2014). Phillips C, 2014, 7/March, *Stanton Glantz is Such a Liar That Even the ACS Balks: His Latest Ecig Gateway "Study,"* in *Anti-THR Lies and Related Topics* <<http://antithrlies.com/2014/03/07/stanton-glantz-is-such-a-liar-that-even-the-acs-balks/>> (Accessed 7 March 2014).

38. See *supra* endnote 35.

39. See *supra* endnote 32.

40. See *supra* endnote 33.

41. Fagerstrom K, 2013, 14/Dec, *Dependence on Tobacco and Nicotine*, in *Nicotine Science and Policy* <<<http://nicotinepolicy.net/karl-fagerstrom/520-dependence-on-tobacco-and-nicotine>>> (Accessed 2Jan2014).

42. Lechner WV, Tackett AP, Grant D M, Tahirkheli NN, Driskill LM, Wagener TL. Effects of duration of electronic cigarette use. *Nicotine & Tobacco Research* 2014 13 May. See also Siegel M, 2014, 22 May, *New Study of Trajectory of e-Cigarette Use Suggests a Pattern of Decreasing Cigarette and Nicotine Addiction*, in *The Rest of The Story* < <http://tobaccoanalysis.blogspot.com/2014/05/new-study-of-trajectory-of-e-cigarette.html>> (Accessed May 22, 2014).

43. See *supra* endnote 11.

44. Davis K, Grimshaw V, Merriman D, Farley M, Chernick H, Coady M et al., 2013, 11/Dec, *Cigarette Trafficking in Five Northeastern US Cities* <<http://tobaccocontrol.bmj.com/content/early/2013/12/11/tobaccocontrol-2013-051244.abstract.html>?> (Accessed 31Dec2013).

### ABOUT THE AUTHOR

**Dr. Joel Nitzkin** is a public health physician with a Master's Degree 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. Thus, 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. R Street Institute is a Washington-DC 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 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 may or may not reflect position statements formally adopted by AAPHP, R Street or any other organization he is affiliated with.

Additional bibliographic references dealing with THR and e-cigarettes are available on request from Dr. Nitzkin at [jln@jln-md.com](mailto:jln@jln-md.com). A current review of the case in favor of e-cigarettes can be found at <http://www.mdpi.com/1660-4601/11/6/6459>. Yet additional materials can be found on the AAPHP web site at <http://aaphp.org/Tobacco> , and, at the R Street web site at <http://www.rstreet.org/tag/tobacco-harm-reduction/?author=jnitzkin>.

## ABOUT THE FOOD AND DRUG POLICY FORUM

FDLI's Food and Drug Policy Forum provides a marketplace for the exchange of policy ideas regarding food and drug law issues. The Forum welcomes articles on cutting-edge state, national and international policy issues related to food and drug law.

FDLI's Food and Drug Policy Forum is designed to provide a venue for the presentation of information, analysis and policy recommendations in these areas food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices and tobacco.

Each issue of the Forum presents an important policy topic in the form of a question, provides background information and detailed discussion of the issues involved in the policy question, relevant research, pertinent sources and policy recommendations. This publication is digital-only, peer-reviewed and smartphone enabled.

The Forum is published monthly (12 times a year) and is provided as a complimentary benefit to FDLI members, and by subscription to members of associations on the Forum Editorial Advisory Board and non-members. Individual issues of the Forum are also available for separate purchase.

The 24-member Food and Drug Policy Forum Editorial Advisory Board, comprised of eight representatives of leading associations interested in food and drug law issues and 16 food and drug and healthcare professionals, provides peer review and guidance on articles considered for publication in the Forum.

## ABOUT FDLI

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction. FDLI's scope includes food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices and tobacco. As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.

FDLI's Mission is to provide education, training, and publications on food and drug law; act as a liaison to promote networking as a means to develop professional relationships and idea generation; and ensure an open, balanced marketplace of ideas to inform innovative public policy, law, and regulation.

In addition to the Forum, FDLI publishes the quarterly, peer-reviewed Food and Drug Law Journal presenting in-depth scholarly analysis of food and drug law developments; Update magazine, which provides members with concise analytical articles on cutting-edge food and drug issues; the FDLI Monograph Series, an annual six-publication set of practical guides on contemporary food and drug law topics, and numerous comprehensive new books each year.