McDonald, Alex - Additional Testimony Submitted 3/12/2017

Hello Chairman and committee members,

For the record my name is Alex McDonald, I live in Fairbanks and own Ice Fog Vapor on Cushman St. downtown Fairbanks.

First off, I would like to say that we are on the same team as for trying to reduce tobacco use and related illness in this state. I lost my Grandmother to lung cancer, I used to smoke, and I know the damage that it does. However, for the fifth year we are hearing this bill and I still oppose it, as written, for reasons I have testified in the past. Every year more and more research and reports are published to support my concerns with this bill.

First, the inclusion of vapor products in this bill is contrary to policy suggestions from experts and organizations around the world. Both Public Health England and the Heartland Institute in the US have came out this year and said that inclusion of vapor products in clean air bills is bad policy. They cite studies that show there is no concern for harm for by standers, and state that forcing former smokers to use their vapor products in smoking areas leads to increase relapse, dual use, or just going back to smoking having the opposite effect intended with such bills. Most people that use vapor products are former smokers, such as myself, or people trying to quit tobacco use, studies confirm this. Asking former smokers, or people trying to quit smoking, to go to smoking areas makes as much sense as asking AA to hold meetings at a bar. Why put people in this position if this bill intends to better public health? This bill would force people into smoking areas, to breath second hand smoke, to use a smokeless product! People do not want the heavy hand of the government to force them back into smoking areas!

Contrary to what was said in the last hearing, vape shops are not exempted from this bill. To comply with this bill I would need to purchase and install a ventilation system, which can run between $30,000 and $50,000 dollars. Also because we are in Fairbanks every suite has an artic entry that opens into a common area, in my case the stairway upstairs. So I would have to receive permission from the property owner to cut a doorway in the outside wall of the building, then pay for the door, installation of that door, and possibly building in the old entrance. This would lead to higher heating costs, and increased security issues if the changes are even allowed to the building. If the changes are not allowed I would have to close shop and the four other people on my payroll would be short a job.

As I stated before, we are all working for the same goal, a healthier Alaska. Removing the vapor language from the bill would increase support, save jobs and small businesses, keep smokeless technology accessible for people trying to quit, and allow people to remain tobacco free without having to breath second hand smoke! After all isn't that what this bill is for?

From: Alex McDonald [mailto:alex@icefogvapor.com]
Sent: Friday, March 10, 2017 1:51 PM

Subject: SB63 Documents

Hello,

I would like all of this submitted for the record for SB63.

The first is a statement by Attorney General Tom Miller of Iowa. He has served in that position for 35 years and has been a strong tobacco opponent. He helped win the Master Settlement Agreement against the tobacco companies which Alaska benefits from as some of the money from tobacco companies now is used for tobacco education and use prevention. As much work and as many years Mr. Miller has put into fighting tobacco use and tobacco companies, he feels that E Cigarettes are a powerful tool to help smokers quit tobacco and to prevent smoking related illness. He has given many presentations on the subject advocating for their uses a tool to combat tobacco use. He cites that E cigarettes have been estimated to be 95% less harmful that traditional combustible cigarette with estimates of up to 98% safer as well. He also gives real information on the youth use, of which regular use is only 2%. Please read this quick statement he wrote to try and get some of the facts straight from much of the misinformation that has been circulated.

The Second document, published yesterday, highlights the result of a joint long term study by scientists from University College London, King's College in London,the Roswell Park Cancer Institute in Buffalo, New York and the U.S Center for Disease Control and Prevention (CDC), to compare the cancer markers in non smokers and people that use E Cigarettes. Their findings show that cancer marker are very similar between the two groups with most exposure coming from environmental factors, air quality, food, beverages etc. It shows that people who use E cigarettes avoid the carcinogens that are produced through traditional combustible cigarettes. This is very important to consider when making a clean air policy. If the people directly using the products are not exposed to carcinogens, why would others around them? Vapor is not smoke and does not have the same make up as smoke. There is no combustion therefore no combustion by products or chemicals associated with that process.

More and more studies are being done every year and more and more doctor, scientist, public health officials, and public policy makers are coming out and saying that E cigarettes can be a powerful tool to help solve the tobacco problem. They are recommending that E cigarettes not be included in tobacco or work place restrictions because it is bad policy. First it forces people trying to quit into smoking areas where they are more likely to relapse or just smoke because they have to breath the second hand smoke, it also does not offer an incentive for people to switch over if they still have to be in a room or area filled with smoke. Public Health England encourages places to restrict smoking and enable vaping to help give smokers an incentive to quit smoking. It must be working as they have their lowest recorded smoking rate to date, further showing that these products do not lead to smoking, they lead smokers away from smoking. If access to devices or testing product is restricted this will prevent current smokers from being able to test and try products that could potentially save their life. If the goal of this bill is truly to improve public health then the language related to use of electronic products needs to be removed. That would help keep the air clean, encourage current smoker to find alternatives to traditional tobacco use, allow them full access to try products, receive instruction on products, and support from other former smokers. My whole family is now tobacco free and has been for around four years. If this bill had been in place when we quit, we would probably all be current smokers as we would be forced into the smoking areas of establishment to not smoke. That is like asking any addict to return the environment that enabled their use. You wouldn't ask a recovering alcoholic to go to the bar when they are trying to quit drinking would you? This bill currently does that.

Thanks,

Alex McDonald

IOWA DEPARTMENT OF JUSTICE
OFFICE OF THE ATTORNEY GENERAL
Thomas J. Miller, Attorney General
www.IowaAttorneyGeneral.gov

CONTACT: Geoff Greenwood • Communications Director • 515-281-6699 • geoff.greenwood@iowa.gov

FOR IMMEDIATE RELEASE
December 23, 2015

Statement by Attorney General Tom Miller on Electronic Cigarette Key Facts

"The harm of the combustible cigarette is dramatically greater than the harm of the e-cigarette"

"The harm of the combustible cigarette is dramatically greater than the harm of the e-cigarette. The combustible cigarette is by far the most harmful consumer product known to mankind, killing 480,000 people each year in the United States alone. This is largely due to the many deadly toxins created and released by the combustion. A panel of experts estimates that the e-cigarette is 95% less harmful. Some push back on this study, in part questioning the ability to put an exact number on it. Another estimate is 90-98% less harmful. But whatever number is correct, e-cigarettes are dramatically less harmful than combustible cigarettes.

"There has been an effort to say that combustible cigarettes and e-cigarettes are equally harmful, that their companies are equally evil, and that they should be strongly regulated the same way. This view is incorrect, but it has gotten significant traction. Polling indicates that 32% of Americans believe that combustible cigarettes and e-cigarettes are equally harmful. This means that as many as 13 million adult smokers believe them to be equally harmful, and are very unlikely to switch when switching may save their lives. People making misstatements about e-cigarettes have the best of intentions—to keep kids from being addicted to nicotine through e-cigarettes. But adults misleading kids to get them to do what *we* want has always been a failed strategy.

"There also is a misconception about the prevalence of teen e-cigarette smoking. According to the National Youth Tobacco Survey, 13% of American high school students smoked an e-cigarette once or more in the last 30 days. This includes regular use and experimental use. As the figure is repeated, the number 13% is used without that qualification. After a few repetitions, people then tend to assume that 13% are regular users. However, regular use—if defined by usage in 20 or more days in the last 30 days—is actually 2%. The numbers should be seen together—13% used e-cigarettes once or more in the last 30 days; 2% have used an e-cigarette 20 or more days in the last 30 days."

###

Tobacco Truth

Tobacco Control has morphed into a crusade intent on demonizing both tobacco users and the industry supplying them. This blog examines and comments on scientific issues surrounding tobacco policies - and fallacies.

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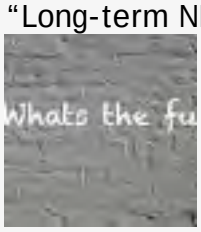

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The U.S. Food & Drug

Thursday, March 9, 2017

E-Cigarette Toxic Chemical Exposure Is Same as for Nonsmokers

The new finding from British and U.S. e-cigarette researchers understated the good news for vapers.

“Long-term NRT-only and e-cigarette-only use…is associated with substantially reduced levels of measured carcinogens and toxins relative to smoking only combustible cigarettes,” reported scientists at the University College London; King's College, London; the Roswell Park Cancer Institute in Buffalo,

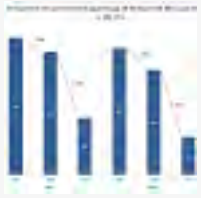
Administration (FDA) on January 23, 2017 published a proposed smokeless tobacco (ST) regulation (here) th…

Regulatory Purgatory: Tobacco Harm Reduction at Risk

I recently testified before the Kansas legislature in support of a resolution asking the state health department to review the scienti…

Experts to FDA: End the Smokeless Tobacco Misinformation Campaign

Two internationally renowned tobacco policy experts are urging "the FDA and like campaigns and health information websites" to "foll…



Complicated Models Can't Alter the Data: Smoking Among Youth and Young Adults Is Way Down

Smoking among high school students declined from almost 16% in 2011 to 9% in 2014 – a reduction of 43% in just three years. That i…

E-Cigarettes Prove Effective for Smoking Cessation

The scientific foundation for tobacco harm reduction is well established. My comprehensive reviews of the evidence in 2006 (here …

For Smokers Only

New York; and the U.S. Centers for Disease Control and Prevention (CDC). Their work, with Lion Shahab as lead author, appeared in the *Annals of Internal Medicine* last month (abstract here).

"The observed carcinogens and toxins" were a group of volatile organic compounds (VOCs), including acrolein, acrylamide, acrylonitrile, butadiene and a combination of ethylene oxide, acrylonitrile and vinyl chloride. The researchers actually measured metabolites – products formed when the body breaks down the VOCs – in the urine.

The finding is good news for vapers, who avoid the thousands of toxins in smoke. But the study and associated media coverage gave the impression that e-cigarette use also resulted in excess exposure to the VOCs. That may not be true.

People are exposed every day to these VOCs, in the air and in our food and drinks. Research published by K. Udeni Alwis et al. in 2012 (abstract here) showed that nonsmokers have measurable levels of these chemicals.

Here are compared results from the Shahab and Alwis studies. The former did not report absolute levels of the VOC metabolites; rather, it designated smokers as the referent group, and reported levels in vapers as a percentage of levels in smokers. The Alwis study reported actual levels in smokers and nonsmokers, allowing me to calculate the percentages.

Percentage Exposures to VOCs in Vapers (Shahab) and NonSmokers (Alwis), Compared to Smokers		
VOC	Percentage in Vapers	Percentage in NonSmokers
Acrolein	33%	26%
Acrylamide	43%	42%
Acrylonitrile	2.9%	2.5%
Butadiene	11%	18%
Combination*	44%	35%

*ethylene oxide, acrylonitrile and vinyl chloride

The table shows that VOC exposures in vapers were similar to exposures in nonsmokers. For example, in the Shahab study, vapers' exposure to acrylamide was 43% of the exposure among smokers, whereas nonsmokers' exposure was 42% of smokers in the Alwis study.

The authors of the Shahab report, particularly Dr. Alwis (who is at the CDC), should have made the connection between the results of the two studies. The fact that vapers' VOC exposures are similar to those of nonsmokers is headline-worthy.

Posted by Brad Rodu at 9:47 AM
Labels: acrolein, acrylamide, acrylonitrile, butadiene, cigarette smoke, contaminants, VOCs, volatile organic compounds

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Blog Archive

My Credentials

Brad Rodu

I am a Professor of Medicine at the University of Louisville, I hold an endowed chair in tobacco harm reduction research, and I am a member of the James Graham Brown Cancer Center at U of L.

For the past 20 years I have been involved in research and policy development regarding tobacco harm reduction (THR). THR advocates acknowledge that there are millions of smokers who are unable or unwilling to quit with conventional cessation methods involving tobacco and nicotine abstinence, and we encourage them to use cigarette substitutes that are far safer.

My research has appeared in a broad range of medical and scientific journals. I have authored commentaries in the general press and I wrote the book, For Smokers Only: How Smokeless Tobacco Can Save Your Life. In 2003 I served as an expert witness at a Congressional hearing on tobacco harm reduction, and I have spoken at numerous international forums, including one held in London at the British Houses of Parliament.

My research is supported by unrestricted grants from tobacco manufacturers to the University of Louisville and by the Kentucky Research Challenge Trust Fund.

View my complete profile

Vaping, E-Cigarettes, and Public Policy Toward Alternatives to Smoking

BY BRAD RODU, DDS, MATTHEW GLANS, AND LINDSEY STROUD

Tobacco harm reduction is a proven strategy for helping smokers reduce their tobacco use or quit altogether.

Contents

THE HEARTLAND INSTITUTE
FREEDOM RISING

E-cigarettes simulate the physical and psychological act of smoking while eliminating most of the harmful chemicals found in conventional cigarettes.

1. Introduction

For decades, lawmakers and regulators have used taxes, bans, and strong regulations in an attempt to reduce the negative health effects of smoking. Recently, some have sought to extend those policies to electronic cigarettes.

E-cigarettes are one of the most popular cigarette replacement products, with a total market of around $2 billion per year. They have proven effective at helping smokers reduce their cigarette use or quit altogether and thus are expected to have significant public health benefits. Efforts by state and local governments to "improve public health" by taxing or heavily regulating e-cigarettes present a real threat to those using a product that already has helped as many as 2.5 million Americans quit smoking or stay smoke-free.

E-cigarettes simulate the physical and behavioral aspects of smoking while eliminating most of the harmful chemicals. The chemical composition of vapor is less toxic than smoke, which means e-cigarettes are far safer for users and virtually harmless for bystanders. There is no justification for imposing cigarette taxes and other punitive policies on e-cigarettes.

Recognizing policymakers' time is often scarce and always valuable, this booklet opens with our recommended policy approaches to e-cigarettes and vaping products. We next address popular myths about these products—claims you may already have heard and certainly will hear when taxes, bans, or e-cigarette regulations make it to your policy agenda.

The remaining sections of this booklet offer support for our policy prescriptions and responses to the myths. We examine the history of the anti-smoking campaign in the United States and describe how the "quit or die" strategy of behavioral therapy and medicine became the norm … but hasn't been successful. We then introduce a third strategy—tobacco harm reduction—and discuss the important role e-cigarettes play in that more successful, *more compassionate*, strategy.

We welcome your comments and questions about this publication. Please don't hesitate to call us at 312/377-4000, send an email to think@heartland.org, or write to us at 3939 North Wilke Road, Arlington Heights, IL 60004.

2. Policy Prescriptions: How to Help Smokers Effectively, Compassionately

Tobacco harm reduction is a proven strategy for helping smokers reduce their tobacco use or quit altogether.[1] Policymakers genuinely interested in the welfare of smokers should avoid policies that punish smokers for switching to e-cigarettes and other vapor products.

Below we discuss the four most common policy approaches to e-cigarettes: taxation, bans on use indoors and/or outdoors, regulations on purchases by minors, and regulations on flavorings.

Taxation

It is becoming common to impose on e-cigarettes the same kind of "sin taxes" levied on gambling, smoking, and alcohol.

Proponents of this approach note taxing activities or products generally viewed as bad will discourage people from engaging in those activities or consuming those products. Lawmakers and some economists also justify sin taxes by demonstrating a "quantifiable negative externality … of the use of a specific product"[2]—that is, they say use of the product imposes

costs on other people. In the case of tobacco cigarettes, taxes are meant to "disincentivize smoking but also to help fund smoking prevention and public health programs."[3]

The goal of responsible tax policy is to generate revenue, not act as a blunt tool to influence consumer choices. Many states are struggling to balance their budgets while tax revenues from conventional tobacco products decline, so legislators now look at vapor products as a potential new revenue stream. As of October 2016, six states—Kansas, Louisiana, Minnesota, North Carolina, Pennsylvania, and West Virginia—were taxing vapor products. In addition, Washington, DC, Chicago, Illinois (Cook County), and Montgomery County, Maryland have imposed local taxes.

Raising tobacco taxes rarely works as intended and has many negative effects, including driving users to buy untaxed or lower-taxed tobacco elsewhere, which harms local retailers. Tobacco taxes prop up government spending with an unsustainable revenue source. They are also highly regressive, unduly burdening moderate- and low-income individuals.

According to recent data from the U.S. Census Bureau, state revenue from tobacco product sales taxes fell 0.9 percent from 2012 to 2013 and 0.5 percent from 2011 to 2012.[4] In 2013, the National Taxpayers Union Foundation found tobacco tax collections failed to meet initial revenue targets in 72 out of 101 recent tax increases.[5]

Targeted taxes on products such as e-cigarettes disproportionately harm low-income taxpayers. In a 2013 study, Kevin Callison and Robert Kaestner found, from "2010 to 2011, smokers earning less than $30,000 per year spent 14.2 percent of their household income on cigarettes, compared to 4.3 percent for smokers earning between $30,000 and $59,999 and 2 percent for smokers earning more than $60,000."[6] This will prove true for vapor products as well, because the overwhelming majority of people who vape are current or former smokers.

In some states, taxes are imposed on vaping products as a percentage of the price, while other states impose taxes based on the amount and concentration of e-liquid. If either rate is too high, consumers may not be able to afford the product they need to quit smoking. States must be careful not to impose a tax so burdensome it reduces demand, effectively killing both the vaping industry and its smoking customers who use the products as cigarette substitutes.

An interesting new twist on traditional sin taxes was proposed in 2015 by three prominent tobacco research and policy experts.[7] In a commentary published in the *New England Journal of Medicine*, economist Frank J. Chaloupka of the University of Illinois–Chicago, attorney David Sweanor of the University of Ottawa, and economist Kenneth E. Warner of the University of Michigan challenged policymakers to "expedite the move away from cigarette smoking" by basing taxes on health risks. They recommended high taxes on high-risk combustible products and lower taxes on low-risk, smoke-free products such as e-cigarettes and smokeless tobacco. They noted "the science supporting a difference in risk between combustible and noncombustible tobacco products is well established" and concluded, "Sizable public health benefits could derive from current cigarette smokers' switching to [e-cigarettes] and other noncombustible products."

Sin taxes generally distort markets, reduce economic competitiveness, and encourage unsustainable increases in government spending while placing an excessive burden on lower-income taxpayers. Instead of creating and increasing discriminatory taxes, legislators should avoid the temptation of sin taxes and instead focus on tax reforms that lower smoking rates, put dollars back in the pockets of taxpayers, and encourage government efficiency by creating reasonable limits on spending. Tax policy should not punish smokers for making the transition to e-cigarettes and other vapor products.

Targeted taxes on products such as e-cigarettes disproportionately harm low-income taxpayers while punishing local businesses.

Such bans are nothing more than a 'public shaming' of vapor product users, a cosmetic regulation aimed at people who 'look like' they are smoking.

Indoor and Outdoor Bans

As e-cigarettes grow in popularity, state and local policymakers have been quick to extend existing smoking bans to the use of vapor products, both indoors and outdoors. Such bans are nothing more than a "public shaming" of vapor product users, a cosmetic regulation aimed at people who "look like" they are smoking. Such bans stigmatize vapor products as just as dangerous as smoking and deter smokers from switching to the less harmful products.

Bans are defended as necessary to limit the exposure of bystanders to toxins—the "secondhand" effect. Secondhand e-cigarette vapor, however, disperses almost immediately. Action on Smoking and Health, a British public health charity, found e-cigarettes offer "little real-world evidence of harm" and should not be subject to smoke-free regulations.[8] In a comprehensive review published by *BioMed Central*, Igor Burstyn of the Department of Environmental and Occupational Health at Drexel University concluded, "Exposures of bystanders [to harmful chemicals] are likely to be orders of magnitude less [with vaping than with smoking], and thus pose no apparent concern," even under what he called worst-case assumptions.[9] The Royal College of Physicians also concluded the "harm to others from vapour exposure is negligible."[10]

E-cigarette bans are often based on the presumption that "detectable" levels of contaminants can be found in the environment after use. Journalist and policy analyst Jacob Sullum refutes that rationale:

Since it's impossible to find undetectable levels of something, [American Lung Association's Kimberly] Amazeen's wording is telling. When an alarmist informs you that "detectable levels" of known toxins have been found somewhere, it is safe to surmise that the levels are very, very low, which is generally the case with the aerosol produced by properly operated vaping products.[11]

Extending smoking bans to e-cigarettes and other vapor products is unwise and counterproductive. Jeff Stier, a senior fellow at the National Center for Public Policy Research, told *Budget & Tax News* such bans do more harm than good:

There's no smoke from e-cigarettes, so the ban won't reduce secondhand exposure. If anything it will increase it by causing more people to keep smoking cigarettes, rather than quit by switching to e-cigarettes. And by treating the dramatically less harmful e-cigarettes like cigarettes, fewer people will be likely to make the switch.[12]

Although vaping simulates the physical and psychological act of smoking, it eliminates the smoke and virtually all of the harmful toxicants of conventional cigarettes. Because e-cigarettes have fewer negative consequences for vapers and virtually no effect on bystanders, there is no justification for including e-cigarettes in ordinances that ban smoking. Requiring private establishments to enforce such bans adds insult to injury, denying property owners their rights while denying smokers access to safer substitutes for tobacco cigarettes.

Prohibiting Purchases by Minors

Prohibiting the sale of e-cigarettes to minors is a policy that enjoys wide support, although such proposals

have been opposed by some anti-smoking groups who are pushing instead for a full ban on e-cigarette purchases.[13]

Expanding existing age restrictions to e-cigarettes is a logical step in protecting against abuse.[14] Enforcing an age limit for those seeking to purchase e-cigarettes is common sense and fits with current laws regulating other products such as tobacco and alcohol. However, legislators must avoid using risks to youths as an excuse for overregulating and overtaxing e-cigarettes, because that would disrupt an increasingly popular and successful method of helping adults reduce smoking or quit altogether.[15]

Although there is nearly unanimous agreement that laws governing e-cigarette use by minors are necessary, it's important to note they have not proven to be very reliable.

For example, the compliance check program run by the Food and Drug Administration applies to sales of tobacco products by both brick-and-mortar and online sellers. If a retailer is not in compliance with the rules, FDA first issues a warning letter, and the agency can impose a "No-Tobacco-Sale Order (NTSO) against retailers that have a total of five or more violations of certain restrictions within 36 months."[16]

In 2011, data from 16 states showed an overall compliance rate of 96 percent.[17] But by 2016, when FDA started to take action against e-cigarette retailers, compliance had fallen to 89 percent of retailers, based on 151,190 inspections. Warning letters resulted from 9 percent (13,124) of the inspections, and fines have been levied on 2 percent (3,015) retailers.[18] Clearly, FDA must do more to ensure retailers comply with existing laws, as regulation at the point of sale is essential to make sure only adults use these products.

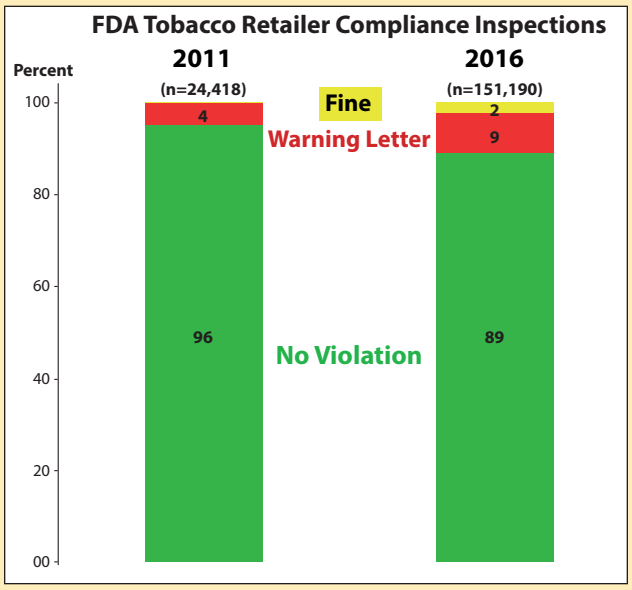
Moreover, the FDA compliance program doesn't affect the major suppliers of tobacco to underage users: adult friends or relatives who legally purchase tobacco products and then provide them to teens. According to a study published in 2004, 65 percent of teen smokers in the United States obtained cigarettes from adults who had purchased them.[19] That is probably why the 2010 Monitoring the Future Survey found 75 percent of 10th graders reported it was "fairly easy" or "very easy" to get cigarettes.[20]

No responsible medical authority condones teen vaping, but many activists overstate the prevalence of the behavior, as a scare tactic. In 2015, the U.S. Centers for Disease Control and Prevention, using data from the 2014 National Youth Tobacco Survey, reported e-cigarette use was threefold higher than in the previous year. Mitch Zeller, director of FDA's Center for Tobacco Products, commented, "the surge in youth use of novel products like e-cigarettes forces us to confront the reality that the progress we have made in reducing youth cigarette smoking rates is being threatened."[21]

No responsible medical authority condones teen vaping, but many activists overstate the prevalence of the behavior, as a scare tactic.

Such reporting completely misrepresented the data. Although e-cigarette use increased, tobacco smoking among high school students *declined* by 28 percent, from 12.7 percent to 9.2 percent. Exclusive cigarette use dropped from 9.7 percent to just 4 percent in 2014, almost a 60 percent reduction in one year.[22] The data show that although e-cigarette use is on the rise among American teens, they are abandoning more hazardous cigarettes at an unprecedented rate.

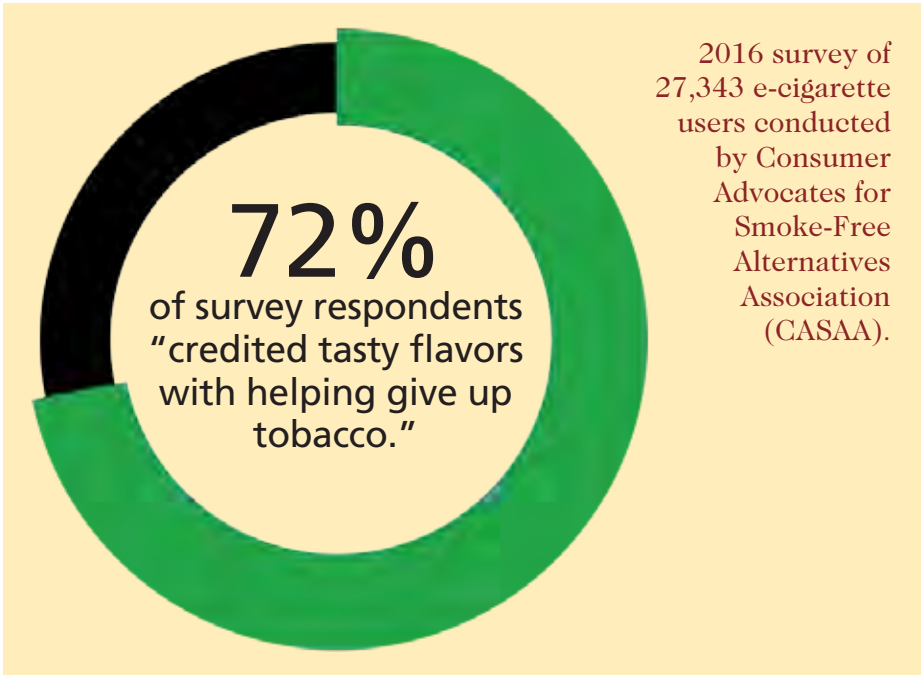
Compliance with ban on sales to minors has fallen from 96% in 2011 to 89% in 2016.



Regulating Flavors

Flavoring is essential to the usefulness of vapor products in smoking cessation. A 2016 Consumer Advocates for Smoke-Free Alternatives Association (CASAA) survey of 27,343 e-cigarette users found 72 percent of respondents "credited tasty flavors with helping them give up tobacco."[23] A 2013 internet study by the Onassis Cardiac Surgery Center concluded flavorings in e-cigarettes "appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking."[24]

Flavors are FDA-approved as generally recognized as safe for foods but



2016 survey of 27,343 e-cigarette users conducted by Consumer Advocates for Smoke-Free Alternatives Association (CASAA).

not for inhalation. Some e-cigarette liquids contain "buttery" flavors produced by the chemicals diacetyl, acetyl propionyl, and acetoin.

A study published in 2015 in the journal *Environmental Health Perspectives* found these chemicals in many types of flavored e-cigarettes.[25] Of the 51 flavored e-cigarettes tested in the study, flavoring chemicals linked to popcorn lung were found in 47 samples, and diacetyl specifically in 39 samples.

Heavy inhalation exposure to these flavorings among workers in microwave popcorn factories is associated with a fatal condition known as popcorn lung (*bronchiolitis obliterans*).[26] Although cigarette smoke also contains these agents, smoking is not a recognized risk factor for popcorn lung.

It is recommended vapers avoid e-liquids with these flavors. They are easily replaced, so manufacturers should remove them from their liquids. Like any other product, reasonable and rational regulations protect consumers, but regulators should not use legitimate concerns as a rationale for imposing unreasonable and onerous regulations.

3. Myths and Facts About E-Cigarettes

As e-cigarettes and other vapor products continue to grow in popularity, opponents stuck in the "quit or die" way of thinking have attempted to demonize the products with unfounded myths. Chances are, you've heard them all. Policymakers face what can be a difficult task: Making decisions based on facts, not widely publicized fallacies.

Below we address four common myths about e-cigarettes:

Myth #1 – There is an epidemic of e-cigarette poisoning of children.

Myth #2 – E-cigarettes are a gateway to smoking.

Myth #3 – E-cigarettes don't help smokers quit.

Myth #4 – E-cigarettes aren't any less harmful than tobacco cigarettes.

Myth #1: There is an epidemic of e-cigarette poisoning of children

Since the rise of e-cigarettes, many people have expressed concern about reports of poisoning of children by e-liquids. Those concerns are based on exaggerated claims from poison control officials.

A June 2016 study in *Pediatrics* claimed e-cigarette poisoning among children aged six years and younger increased by nearly 1,500 percent during a 40-month period.[27] The researchers found roughly 14.2 percent of the 29,141 calls reported by the National Poison Data System during this period were due to e-cigarettes. That's approximately 1,241 calls per year, for the entire United States.

The data cited by the *Pediatrics* article are not representative of actual poisoning risks in the United States. For example, in 2015, in just the Washington, DC metro area, more than 2,000 children under the age of six were poisoned by cosmetics and personal care products, and another 1,900 were poisoned by cleaning products.[28]

A closer look at data from the 2014 American Association of Poison Control Centers report provides better perspective on these incidents.[29] First, a report consists of a call to a poison control center from a concerned parent or other person reporting suspected or assumed exposure to a substance. E-cigarettes accounted for 0.4 percent of the 556,000 reports (excluding 447,000 exposures to pharmaceuticals) involving children under six years old in 2014. Cosmetic and personal care products and household cleaners were responsible for 27 percent and 21 percent of the reports, respectively. In other words, children have far higher rates of exposure to cosmetics, cleaners, pesticides, and alcohol than to e-cigarettes.

Lawmakers have made efforts to reduce the likelihood of e-cigarette poisoning in children, including the Child Nicotine Poisoning Prevention Act of 2015, which established "a child-resistant packaging requirement" for liquid nicotine containers.[30] The resistant packaging requirement was supported by many groups, including the American Vap-

ing Association, which commented, "every effort should be made to make sure [e-cigarettes] are not used—or even tampered with—by children."[31]

Myth #2: E-cigarettes are a gateway to smoking

Anti-tobacco extremists have published numerous studies, most with generous funding by the National Institutes of Health, claiming vapor products are a gateway to teen cigarette smoking. This has been an aggressive campaign: At least eight such studies have been published since 2014.[32] Regrettably, these studies tend to dissuade smokers from switching to safer products, leaving them at greater risk of fatal disease. In addition, they provide "scientific evidence" that FDA will use to impose onerous regulatory actions on e-cigarettes under the rationale of "protecting the children." However, each of these studies has been subject to careful scientific review after publication,[33] and none provides any legitimate evidence for gateway claims.

One major and consistent flaw in these studies is mistaking association—teens who use one substance are more likely to use another one—for causation, in which one behavior causes another. Other frequent tactics include using exaggerated or inconsistent definitions of tobacco use and failing to conduct a robust analysis. In 2015, Carl Phillips analyzed gateway claims in considerable detail, concluding "none of the empirical studies to date that are purported to show a gateway effect from tobacco harm reduction products actually does so."[34]

The use of highly engineered research to fuel gateway rhetoric is not new. It was used previously in publications by anti-tobacco extremists to condemn smokeless tobacco, another smoke-free cigarette substitute that is documented to be safer than cigarettes.[35] The activists used the same tactics then, and researchers raised the same questions about their legitimacy.[36]

There is, in fact, evidence that smokeless tobacco users are less likely to smoke. Using data from a federal survey, Rodu and Cole found, "compared with cigarette initiators, [smokeless tobacco] initiators are significantly less likely to smoke, which suggests that [smokeless tobacco] may play a protective role."[37]

It is entirely logical that the availability of smokeless tobacco may make smoking less likely, and there is evidence that the availability of e-cigarettes may reduce smoking among teens. A study from Yale University[38] in 2015 concluded e-cigarette bans may be detrimental for that reason. Dr. Abigail Friedman, the study's author, concluded,

Across the board, this paper's analyses find that reducing e-cigarette access increases smoking among 12 to 17 year olds. The effect is large: over the 8 years preceding the first bans on e-cigarette sales to minors, smoking in this age group fell an average of 1.3 percentage points per two year period. The estimated 0.9 percentage point rise in smoking due to bans on e-cigarette sales to minors counters 70 percent of the downward pre-trend in states with such bans.[39]

Friedman further noted:

This paper's findings will prove surprising for many: policy discussions to date have not considered that banning e-cigarette sales to minors might increase teen smoking. Assuming that e-cigarettes are indeed less risky to one's health than traditional cigarettes, as suggested by existing evidence on the subject, this result calls such bans into question.[40]

Friedman made a bold suggestion, one that is sensible and defensible: Ban e-cigarette "sales to those younger than 16 instead of 18, as initiation of regular smoking first spikes at the former age."[41]

Friedman's results were confirmed by another study, from Cornell University in 2016.[42] Michael Pesko and colleagues found "[e-cigarette] age purchasing restrictions are associated with a 3.1 percentage

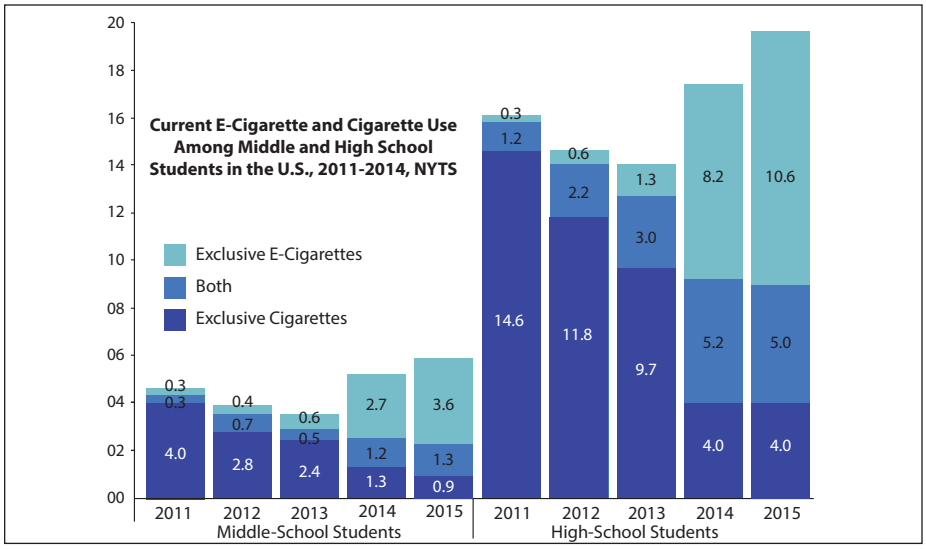
Anti-tobacco extremists have published numerous studies, most with generous funding by the National Institutes of Health, claiming vapor products are a gateway to teen cigarette smoking.

point (17.9% of the mean) increase in adolescent cigarette use ($p < 0.05$) in the period of implementation [of statewide bans on e-cigarette sales to minors]. Most of this effect is accounted for within casual cigarette using adolescents. … Our results suggest that adolescents are willing to substitute [e-cigarettes] for cigarettes depending on legal purchasing opportunities of [e-cigarettes]."[43]

Although there is no significant evidence to conclude the availability of e-cigarettes has resulted in increased cigarette use among teenagers, the Centers for Disease Control and Prevention (CDC) has repeatedly issued press releases containing evidence-free speculation about a new teen epidemic of nicotine and tobacco use.[44]

The evidence points to the opposite conclusion, suggesting e-cigarettes have accelerated the decline in teen smoking. In June 2016, the CDC found, "[c]igarette smoking among high school students dropped to the lowest levels since the National Youth Risk Behavior Survey (YRBS) began in 1991."[45] Further investigation documents "an astounding 28% decline among high school students in all current cigarette use, from 12.7% [in 2013] to 9.2% [in 2014]. Exclusive cigarette use dropped from 9.7% to just 4% in 2014, almost a 60% reduction in one year."[46] In short, smoking rates among American teens have plummeted over the past five years when e-cigarettes have been available.

Most smokers, contrary to social stigma, are not sick and do not want or need to be "treated." Smokers do, however, want truthful information to help them make educated choices that can maximize their health and welfare.



Myth #3: E-cigarettes don't help smokers quit

Clinical trials have produced significant evidence of the effectiveness of e-cigarettes as smoking cessation products. Polosa *et al*. found more than half of smokers quit smoking or reduced cigarette consumption after six months when using e-cigarettes.[47] Caponnetto *et al*. found 19 percent of smokers quit smoking or reduced cigarette consumption after one year.[48] Bullen *et al*. concluded e-cigarettes are just as effective as nicotine patches in helping smokers quit.[49]

In 2016, a Royal College of Physicians (RCP) report, "Nicotine Without Smoke: Tobacco Harm Reduction," provided "a fresh update on the use of harm reduction in tobacco smoking, in relation to all non-tobacco nicotine products and particularly e-cigarettes."[50] The RCP is among the world's oldest and most prestigious medical societies, and its report should have considerable influence among policymakers.

Regarding whether e-cigarettes help smokers quit, the RCP concluded:

There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.

It is important to note these studies report the results of clinical trials. While such trials are powerful tools using sophisticated scientific methods to precisely determine the effectiveness of treatments for specific diseases, *they don't meause consumers' preferences for products in the marketplace*, and they should not be the standard by which these products are judged. Instead, the success or failure of smoke-free products in deterring smoking should be analyzed through post-market surveillance, by observing consumer activity.[51]

Most smokers, contrary to social stigma, are not sick and do not want or need to be "treated." They make a rational choice to consume a risky product.[52] Smokers do, however, want truthful information to help them make educated choices that

can maximize their health and welfare. FDA and other health authorities should endorse e-cigarettes and smokeless tobacco products as safer cigarette substitutes. Only then will an appropriate, consumer-driven test of the effectiveness of e-cigarettes as smoking cessation products be possible.

Myth #4: E-cigarettes aren't any less harmful than tobacco cigarettes

E-cigarettes and vaping products were introduced to the market around 2007. It is not yet possible to know about the possible adverse health effects of long-term use. Recent research, however, explains why vapor products are likely to be much safer than smoked tobacco products.

The previously cited report by The Royal College of Physcians reached the following conclusions about the safety of e-cigarettes:

- "E-cigarettes are marketed as consumer products and are proving much more popular than [nicotine replacement therapy, NRT] as a substitute and competitor for tobacco cigarettes.

- "E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.

- "Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

- "… in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK."

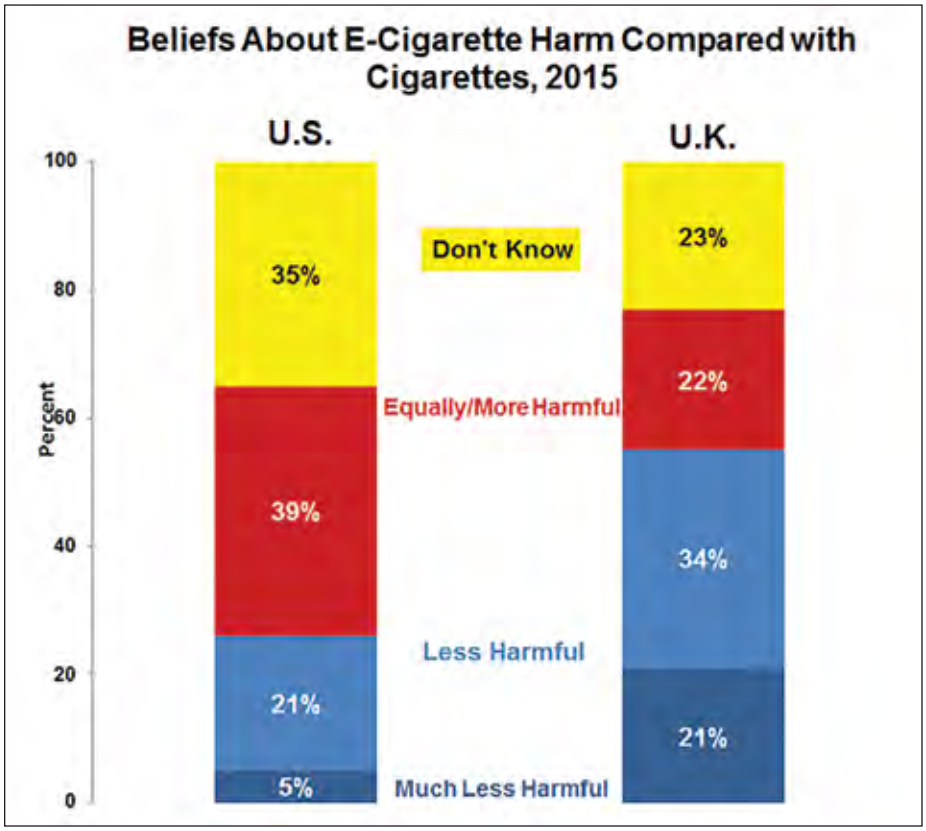
The RCP's strong endorsement of tobacco harm reduction is significant. In 1962, the college became the first organization to conduct a formal study of the health effects of smoking. That report generated global headlines and likely was responsible for President John F. Kennedy being asked on May 23, 1962, whether smoking causes cancer and heart disease. The president dodged the question, but two weeks later he announced Surgeon General Dr. Luther Terry would study the health effects of tobacco, leading to release in 1964 of the seminal report *Smoking and Health*.

Although the 2016 RCP report received some positive press coverage in the United States, the CDC maintained its prohibitionist position, stating: "There is currently no conclusive scientific evidence supporting the use of e-cigarettes as a safe and effective cessation tool at the population level."[53]

The CDC is simply *ignoring* the evidence. A 2014 study assigned a 100 percent rating of maximum relative harm (MRH) to cigarettes. In comparison, "[e-cigarettes] were rated to have only 4% of MRH."[54] A 2015 *Public Health England* study confirmed the estimate, stating, "EC [electronic cigarettes] are around 95% safer than smoking. This appears to remain a reasonable estimate."[55]

It has been well established that the adverse effects of tobacco use "are caused primarily by exposure to combustion products of tobacco."[56] E-cigarettes produce a noncombustible vapor, therefore providing nicotine in a far less harmful way than traditional tobacco cigarettes.

Other studies have concluded vapor is much safer than smoke. Laugesen tested the mist from e-cigarettes for "over 50 cigarette key smoke toxicants [and] found none in any but trace quantity, in Ruyan VA mist."[57] Goniewicz *et al*. analyzed vapors from 12 e-cigarette brands and found though e-cigarette vapor contained "some toxic substances … [t]he levels of the toxicants were 9–450 times lower than in cigarette



smoke."[58] A 2013 report on the results of numerous studies concluded e-cigarettes and vaping devices "appear to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products."[59]

Despite these findings, opponents of e-cigarettes use exaggerated claims to fog the science. One leading assertion has to do with the dangers of formaldehyde, including a *New England Journal of Medicine* article claiming "Hidden Formaldehyde in E-Cigarette Aerosols."[60] The study produced the formaldehyde by overheating an e-cigarette, a condition (called dry puffing) that is familiar to vapers; the resulting product tastes so bad it cannot be inhaled. In other words, the formaldehyde produced under abusive conditions is not "hidden" at all, because it is in vapor that users find intolerable.

Formaldehyde is also present in air, with average daily exposure being 500 to 1,100 µg (micrograms, one millionth of a gram). A smoker who smokes 20 cigarettes a day is exposed to 1,000 to 2,000 µg. A test on the concentration levels of formaldehyde present after six deep puffs in test chambers found cigarettes produced a level of 86 µg/m^3, whereas e-cigarettes had a formaldehyde level of 12 µg/m^3, the same concentration level as in the empty chamber.[61]

4. History of the Failed Anti-Smoking Campaign

The persistence of the myths described above is puzzling. After more than five decades, the anti-smoking campaign in the United States has failed to deliver effective measures to reduce harm from tobacco cigarettes. If the campaign were truly in search of a successful strategy, one might expect its proponents to embrace, rather than demonize, tobacco harm reduction.

The anti-smoking movement began in 1964, when Surgeon General Dr. Luther Terry released the first Surgeon General's report on smoking and health.[62] The report was "the first federal government report linking smoking and ill health, including lung cancer and heart disease."[63]

In 1966, the first government-mandated health warnings were printed on cigarette packages, without using words such as "cancer" and "death." Opponents of tobacco use considered the warnings a victory, and after January 1, 1966, consumers of tobacco cigarettes "could no longer claim ignorance"[64] of the health risks of smoking.

In 1968, attorney John Banzhaf pushed the anti-smoking movement forward by lobbying the federal government for the right to broadcast *free* anti-smoking advertisements. Citing the Federal Communications Commission's Fairness Doctrine, Banzhaf argued "on matters of great public importance, both sides must be fairly represented in the broadcast media."[65] Between 1968 and 1970, one free anti-smoking advertisement was broadcast for every three paid cigarette commercials.

In 1971, the cigarette manufacturers agreed to a total ban on commercial broadcast advertising. As is often the case with ill-considered public policy, the ban would have unintended consequences. Broadcast advertising was expensive; the primary advertising outlets remaining to the tobacco companies, print media such as newspapers and magazines, were much less expensive. The companies used the money they saved to begin a series of mergers and acquisitions, "with many previously prominent brand names disappearing behind layers of corporate entities with more legitimate consumer products and services."[66] Free anti-smoking advertisements were also eliminated, because the Fairness Doctrine no longer applied.

After more than five decades, the anti-smoking campaign in the United States has failed to deliver effective measures to reduce harm from tobacco cigarettes.

In the following decades, other regulatory bodies and public anti-smoking groups would impose additional bans and taxes and implement aggressive campaigns to lobby against tobacco cigarettes.

In 1994, Dr. David Kessler, then-commissioner of the U.S. Food and Drug Administration (FDA), penned a letter in response to a petition from the Coalition on Smoking or Health, a confederation of anti-smoking organizations, in which he "announced his intention to consider regulating cigarettes as a drug delivery system for nicotine." FDA intended to impose on smokers a mandatory national

Opponents stuck in the 'quit or die' way of thinking have attempted to demonize the products with unfounded myths.

withdrawal program by requiring tobacco companies to gradually lower the nicotine concentration levels in cigarettes until they became too low to allow new smokers to become addicted to nicotine.[67]

In 1994 the anti-smoking campaign was focused on *punishing* tobacco manufacturers and their customers, not on helping smokers quit. For example, an article published in the *New England Journal of Medicine* that year outlined the "essential components of a campaign to prevent tobacco use."[68] Strategies included increased federal excise taxes, comprehensive restrictions on smoking, a ban on tobacco company sponsorship and advertising, ending federal tobacco-crop subsidies, and government support for counter-advertising and litigation against manufacturers. Only two of the 11 objectives were aimed at educating smokers and helping them quit.

In the 1990s, states began suing major cigarette manufacturers Philip Morris USA, R.J. Reynolds, Brown & Williams, and Lorillard to recover Medicaid and other costs the states allegedly incurred in treating sick and dying cigarette smokers. On November 23, 1998, the four manufacturers, 46 states, and six U.S. territories signed "the Master Settlement Agreement (MSA), the largest civil litigation settlement in U.S. history."[69] (Florida, Minnesota, Mississippi, and Texas did not participate in the MSA because they had already reached individual agreements with the firms.) To reimburse the states for Medicaid costs of smoking-related illnesses, the companies agreed to "annual payments in perpetuity."[70] Under the agreement, the states represented in the MSA gave up future legal claims against the companies, which agreed to pay "an amount equaling over $200 billion for tobacco-related health care costs."[71]

In 1994 the anti-smoking campaign was focused on punishing tobacco manufacturers and their customers, not on helping smokers quit.

Anti-smoking activists in the United States have mounted a massive campaign with a simple message: 'Quit all tobacco and nicotine products, or take your chances,' often shortened to 'quit or die.'

The MSA included provisions preventing cigarette companies from marketing to young people. The agreement also placed restrictions and prohibitions on advertising, including banning cartoons, "transit advertising, … outdoor advertising, including billboards, product placement, … branded merchandise, free product samples (except in adult-only facilities), and most sponsorships."[72]

The MSA intended for *cigarette manufacturers* to reimburse the states for Medicaid services for smoking-related illnesses and to fund "educational programs to reduce underage smoking."[73] In reality, the funds come from an MSA "tax" transferred from manufacturers to *smokers*.

Whether the settlement monies have reduced smoking rates is unclear. Gross *et al*. concluded because only a small percentage of the funds is "being used for tobacco-control programs, the settlement represents an unrealized opportunity to reduce morbidity and mortality from smoking."[74] Another study determined in 2002 that only three states had apportioned "the recommended 20–25% of MSA funds to tobacco control programmes."[75] The MSA had no requirement for tobacco control measures, so "states increasingly have used this revenue for general purposes and to cover budget shortfalls."[76]

5. Quit or Die as the Only Strategy

Anti-smoking activists in the United States have mounted a massive campaign with a simple message: "Quit all tobacco and nicotine products, or take your chances," often shortened to "quit or die." The campaign's main tactics consist of behavioral therapy (coping tips) and the use of pharmaceutical nicotine and other medications.

These tactics have been remarkably unsuccessful in helping the nation's 39 million smokers. CDC estimates of smoking-related deaths in the United States, currently at 480,000, have not changed appreciably in more than 20 years.

The National Cancer Institute's 1993 publication, *How to Help Your Patients Stop Using Tobacco: A National Cancer Institute Manual for Physicians*, is an excellent example of ineffective behavioral therapy. It

urged physicians to tell their smoking patients to "keep their hands busy, doodle, knit, or type a letter, cut a drinking straw into cigarette-sized pieces and inhale air, and keep a daydream ready to go."[77] Physicians should also suggest "chewing gum, sucking on a cinnamon stick, or eating a carrot stick," as substitutes to reduce cigarette cravings.[78]

Smokefree.gov, a website created by the Tobacco Control Research Branch of the National Cancer Institute, offers smokers some of the same techniques: "keep your mouth busy, do something else, go for a walk or jog, take slow, deep breaths."[79]

Those suggestions are hardly effective coping measures for one of the most powerful of human addictions.

Anti-smoking activists are also obsessed with the idea that smoking is an illness requiring medical treatment with pharmaceutical nicotine and other drugs. According to *Smokefree.gov*, nicotine replacement therapy (NRT) "is the most commonly used family of quit smoking medications." These products contain "a small controlled amount of nicotine" to reduce withdrawal and "satisfy your craving for nicotine and [reduce] the urge to smoke" but have "none of the other chemicals that are found in cigarettes."[80]

NRT products include patches (*NicoDerm*) and gum and lozenges (*Nicorette*) available over the counter, and an inhaler and nasal spray available only by prescription. Other medications without nicotine include bupropion hydrochloride (*Zyban*) and varenicline tartrate (*Chantix*). These may reduce withdrawal symptoms, but they have side effects, including dry mouth and insomnia (bupropion) and nausea and vivid dreams (varenicline). Varenicline is also linked to "mood swings, depression, and suicidal thoughts."[81]

All of these medications are expensive, and they are decidedly ineffective, despite deceptive claims by health authorities. For example, *Smokefree.gov* claims nicotine "medications can double your chances of quitting for good."[82] But doubling a very small success rate is still very small. One meta-analysis of over-the-counter NRT found a success rate at the population level of just 7 percent. Although the authors of the meta-analysis described this as "efficacious" and "modest," they stretch the definitions of these terms, because a 7 percent success rate means a 93 percent failure rate.[83]

It is the *smoke* produced by burning tobacco, not the ingestion of *nicotine*, that ought to be the target of public health campaigns.

Despite this abysmal track record, public health organizations such as *Smokefree.gov* do not distinguish between being smoke-free, which results in a greater than 98 percent reduction in the harms of smoking, and being completely abstinent from all nicotine and tobacco products. Tobacco harm reduction efforts have proven to be effective in helping smokers quit, but health organizations and policymakers have done very little to educate smokers about the vastly safer smoke-free tobacco products. Organizations such as the CDC and American Cancer Society have in fact withheld evidence of the relative safety of smoke-free alternatives.[84]

6. The Case for Tobacco Harm Reduction

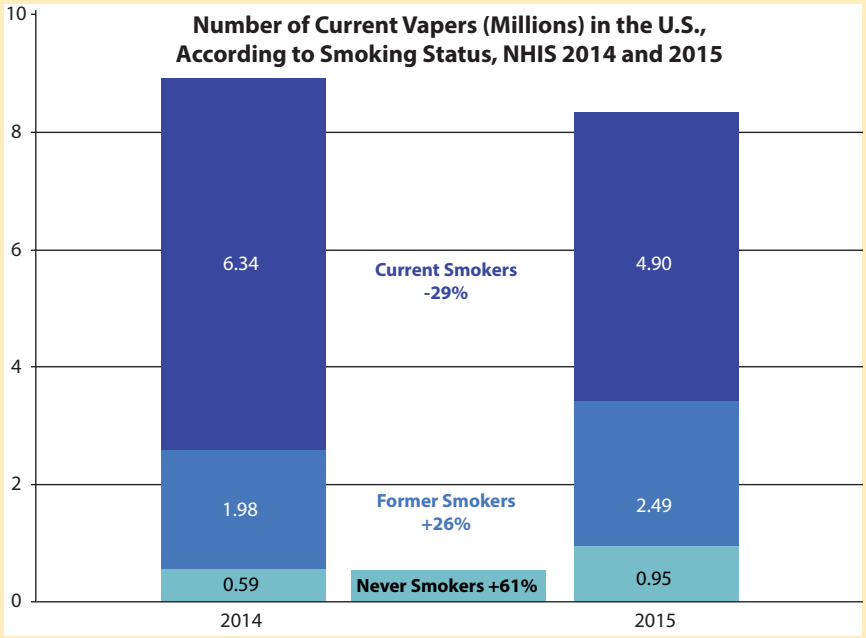
There are an estimated 39 million adult smokers in the United States, and smoking may cause up to 480,000 premature deaths per year. If the status quo persists, more than 9.6 million Americans will die from smoking-related illnesses in the next 20 years.[85] Smoking remains "the leading cause of preventable death" in the United States.[86] All of these deaths will occur among adults who are now over 35 years of age.

Billions of dollars have been spent on the campaign to reduce smoking rates. The quit-or-die campaign has failed, however, because "[h]eavily-addicted, or inveterate, smokers are resistant to conventional cessation strategies emphasizing tobacco and nicotine abstinence."[87] In other words, the campaign unethically presents smokers with only two equally unacceptable options.

There is a third option: tobacco harm reduction, "which explicitly includes the continued use of tobacco or nicotine and is designed to reduce the health effects of tobacco use."[88]

It is the *smoke* produced by burning tobacco, not the ingestion of *nicotine*, that ought to be the target of public health campaigns.[89]

Tobacco harm reduction efforts educate smokers about alternative nicotine delivery systems including smokeless tobacco products, such as snus, and e-cigarettes.[90] Both smokeless tobacco products and e-cigarettes provide satisfying doses of nicotine that mimic the physiological and psychological sensations of smoking and are less harmful. Such products "empower smokers to gain control over the consequences of their nicotine



The overwhelming majority of vapers are current or ex-smokers.

addiction."[91]

A June 2016 study found e-cigarettes to be successful smoking-cessation products and identified many factors driving an individual's use of such products. The researchers found "the concept of harm reduction"[92] was an important factor in a user's decision to move away from traditional tobacco cigarettes to e-cigarettes.

Several studies have found e-cigarettes to be an effective and viable option for smokers seeking a cigarette substitute. A 2013 clinical trial[93] in New Zealand showed e-cigarettes are as effective as nicotine patches in helping smokers quit. In 2010 the American Association of Public Health Physicians concluded smoke-free tobacco products could "save the lives of four million of the eight million current adult American smokers who will otherwise die of a tobacco-related illness over the next twenty years."[94]

7. Decades of Evidence for Tobacco Harm Reduction

Nicotine is one of the most intensively studied drugs in history, and numerous studies document it is a main driver of traditional tobacco cigarette use. Even though it is addictive, nicotine is not considered a "highly hazardous drug."[95] It does not cause cancer, and it does not play any significant role in pulmonary or cardiovascular diseases. Nicotine is a mild stimulant and/or relaxant with many of the same properties as caffeine, another addictive substance consumed by tens of millions of Americans in a wide variety of products.

Nicotine and caffeine are both derived from plants, and both are addictive, with abstention being highly uncomfortable and even "unachievable for many users."[96] Both are stimulants that enhance concentration and mental performance, encourage a sense of well-being, and elevate mood. Both raise heart rates and blood pressure levels transiently during use, but neither is directly responsible for cancer, emphysema, or heart disease.

Smokeless tobacco products have been consumed for several centuries. Smokeless forms of tobacco were the preferred method of consumption and remained "the dominant form of tobacco used in the U.S. until early in the 20th century."[97] Today, the most popular forms of smokeless tobacco are moist snuff, chewing tobacco, and Swedish and American snus.

Smokeless tobacco poses vastly lower health risk than smoking. A 2009 *BioMed Central* study analyzed "all the epidemiologic evidence linking smokeless tobacco use and cancer."[98] Using data from 89 studies, the authors identified "the relative risk (RR) of cancer among smokeless tobacco users, compared with non-users of tobacco." The study found "very little evidence" of smokeless tobacco producing elevated cancer risks. Another review of epidemiologic studies in 2011 found snus and "smokeless tobacco use [to be] 99% less hazardous than smoking."[99]

The best case for tobacco harm reduction comes from Sweden. Swedish men have the highest rate of smokeless tobacco use in Europe, which is directly linked to the lowest smoking rate on the continent. Swedish men also have the lowest rates of lung cancer and other smoking-related diseases in Europe. The effect of this remarkable tobacco use pattern is profound. If men in all other countries of the European Union substituted smokeless tobacco for smoking at the same rates as Swedish men, almost 274,000 deaths per year would be prevented.[100]

8. E-Cigarettes as a Harm-Reduction Alternative

In addition to using traditional smokeless forms of tobacco, tobacco harm reduction now includes "e-cigarettes, personal vaporizers, vape pens, e-cigars, e-hookahs, or vaping devices."[101] E-cigarettes were introduced to the United States in 2007 by Ruyan, a Chinese company that manufactured the first models of e-cigarettes.

In 2008, FDA tried to ban imports of e-cigarettes because they were unapproved drug-delivery devices.[102] The agency blocked a shipment by Sottera, Inc., manufacturer of NJOY.

In April 2009, Sottera filed a lawsuit challenging the ban. During the legal proceedings, which lasted more than a year and a half, both PayPal and Amazon adhered to FDA's ban, canceling accounts and prohibiting the sales of e-cigarettes. The U.S. Court of Appeals ruled in December 2012 "e-cigarettes could be regulated as tobacco products under the 2009 Family Smoking Prevention and Tobacco Control Act," while dismissing FDA's original intent to regulate e-cigarettes as a drug-delivery device.[103]

Research shows vapor products have proven successful at tobacco harm reduction. A study found between 6.1 million and 9.2 million citizens in the European Union have been able to quit smoking traditional tobacco cigarettes by using e-cigarettes.[104] In 2014, the CDC found approximately 3.7 percent of adults in the United States—almost nine million—were e-cigarette users at the time. The CDC also determined that of smokers who had attempted to quit within the past year, "more than one-half had ever tried an e-cigarette and 20.3% were current e-cigarette users."[105] By 2015, CDC data revealed that e-cigarettes were being used by 2.5 million former smokers,[106] proving e-cigarettes' use as a tool to quit smoking.

What Are E-Cigarettes?

E-cigarettes create a vapor "generated by heating a solution containing water, nicotine, propylene glycol, vegetable glycerin and typically also some flavoring."[107] Propylene glycol and vegetable glycerin are found in many consumer products, and per FDA standards they are generally recognized as safe; that is, "among qualified experts, as having been adequately shown to be safe under the conditions of its intended use."[108] However, intended use does not include vapor inhalation.

There are different types of e-cigarettes and vapor products: "first-generation or so-called cig-alikes, second-generation tank systems, and even larger third-generation or personal vaporizers."[109] Cig-alikes, which remain the most popular, are similar in size and shape to traditional cigarettes. They are typically composed of three parts: a cartridge that contains an e-liquid with or without nicotine, an atomizer used to heat the e-liquid to vapor, and a battery.

The second and third-generation models, also known as "vaping" devices, are subgrouped into two categories: closed and open systems. Closed systems contain a disposable cartridge the user discards after consumption. Open systems contain a tank users can refill with e-liquid. Like cig-alikes, closed and open vaping systems contain an e-liquid, an atomizer with a heating element, and a battery and other electronics. Unlike the cig-alikes, however, the vaping systems are customizable, with users choosing their own modules, or "mods," as well as flavorings and nicotine level.

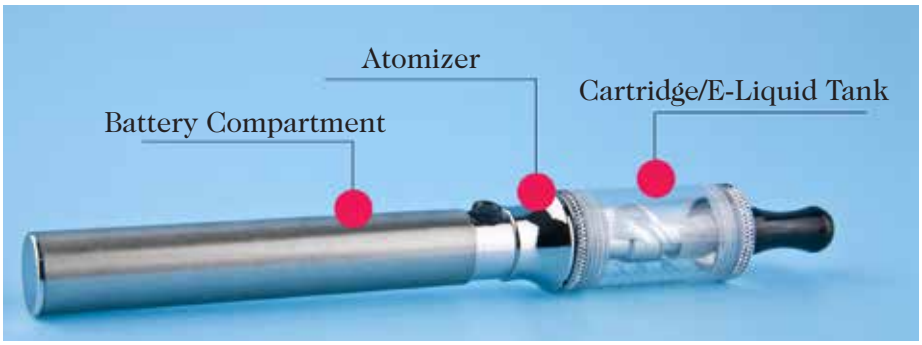
Extending FDA Regulations to E-Cigarettes

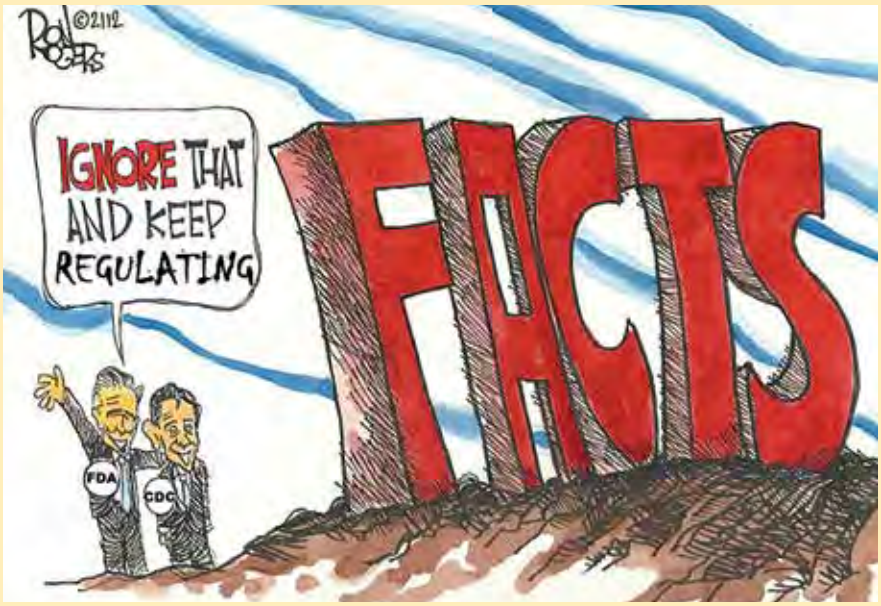
For decades, lawmakers and regulators have attempted to reduce the negative health and economic effects of smoking through taxes, bans, and strong regulations, none of which has proven to be more than modestly successful. On April 25, 2014, FDA released its so-called "deeming" regulations—"Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act."[110] The regulations extend the agency's authority to cigars, e-cigarettes, and other tobacco and tobacco-like products. The deeming regulations raise several important questions FDA must answer, and how FDA responds will go a long way toward determining how new products enter the market and whether the vaping industry can survive at all.

The main hurdle posed by the deeming regulations is the application process these products will have to survive to receive FDA approval. At present, any new tobacco product that does not meet the standard of "substantial equivalency" to another regulated product currently on the market (called a "predicate product") is required to go through a lengthy and expensive study process known as a "premarket tobacco application" (PMTA). The PMTA process is so arduous only one set of products in the past six years has successfully made it over this large regulatory hurdle, according to the Tax Foundation.[111] In 2015, Swedish Match achieved PMTA status for eight snus products, in conjunction with its modified risk application to change inaccurate FDA warnings.[112]

The PMTA process is especially onerous for current vaping products because none qualifies as "substantially equivalent" to products on the market on February 15, 2007. This means all vapor products will be required to obtain PMTA status, an application estimated to cost businesses $3 million to $20 million per product.[113]

The February 15, 2007 date is the starting point for vaping products to receive enhanced review and regulation because it is the date the Tobacco Control Act was introduced for congressional consideration. In 2007,





Proponents of harsh FDA regulations ignore or trivialize the health benefits and health care cost savings that tobacco harm reduction products, including e-cigarettes, can provide.

only one or two models of e-cigarettes were on the market; they are not considered appropriate predicate products for current models, which are completely different. All current e-cigarettes are therefore required to obtain PMTA status under FDA's deeming regulations.

One issue often overlooked is the effect FDA's restrictions will have on product safety. Under the new law, manufacturers are not permitted to change existing products in any way. If a manufacturer wants to develop safer battery technology or a purer, safer e-liquid, it would not be allowed to do so without filing an expensive new PMTA application. Such a barrier to safety improvements is almost unheard of for other consumer products. The main outcome of unnecessary PMTA reviews will be a diminished and stagnant market for these potentially lifesaving products.

Several members of Congress have called for the predicate date to be changed to August 8, 2016, the date the final rule was published.[114] If that effort fails and the 2007 predicate date remains, many existing vapor products will be removed from the marketplace because their manufacturers can't afford the cost of the PMTA applications, leaving limited options for smokers looking for less-harmful cigarette substitutes.

On December 12, 2016, Sen. Ron Johnson (R-WI), chairman of the Senate Homeland Security and Governmental Affairs Committee, and Rep. Duncan Hunter (R-CA) sent a letter to Vice President-elect Mike Pence concerning the FDA's deeming regulation.[115] They warned that the deeming regulation threatened to "crush the e-cigarette industry and potentially hurt the public's health by making it harder for consumers to access products that serve as an alternative to smoking." They urged "the new Administration to consider repealing or suspending the FDA's burdensome deeming regulation over e-cigarettes. With the President-Elect's leadership, we are hopeful that we can protect thousands of small-business owners, employees, and consumers from the FDA's overreach."

Michael Siegel, a professor of community health sciences at the Boston University School of Public Health, argues there is an effective alternative to FDA regulation that provides legitimate public health protection while allowing vapor products to compete with combustible tobacco products in order to save lives: "That approach is to treat electronic cigarettes as consumer products, not as tobacco products, and to directly set uniform safety standards for these products—standards that address battery safety, overcharge protection, temperature control, the safety of flavorings, and basic quality control and manufacturing safety."[116]

9. Conclusion

The FDA's deeming regulations will impose costly compliance measures on the e-cigarette industry. Proponents of harsh FDA regulations ignore or trivialize the health benefits and health care cost savings that tobacco harm reduction products, including e-cigarettes, already provide.

Policymakers should take sound science into consideration when deliberating new regulations or taxes on e-cigarettes. The imposition of bans, excessive regulations, or high taxes on e-cigarettes could encourage smokers to stay with more-harmful traditional cigarettes instead of switching to less-harmful alternatives.

The "quit or die" strategy has failed all Americans, smokers and non-smokers alike. By contrast, tobacco harm reduction is a proven strategy that has helped millions of Americans to quit smoking or stay smoke-free. E-cigarettes have proven to be the most popular, most successful tobacco replacement products.

Policymakers genuinely interested in the welfare of smokers should avoid policies that punish smokers for switching to e-cigarettes and other vapor products. Tobacco harm reduction is compassionate, ethical, and successful.

10. About the Authors

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Dr. Rodu attended The Ohio State University, earning his dental degree in 1977. After an oral pathology residency program at Emory University, Dr. Rodu completed fellowships at the University of Alabama at Birmingham (UAB) sponsored by the American Cancer Society and National Cancer Institute. He was on the UAB faculty from 1981 to 2005, with appointments in the Departments of Pathology, Surgery-Otolaryngology, and Radiation Oncology (School of Medicine), Epidemiology (School of Public Health), and Diagnostic Sciences (School of Dentistry). In 2005 Dr. Rodu joined the University of Louisville.

For the past two decades Dr. Rodu has been in the forefront of research and policy development regarding tobacco harm reduction, informing smokers who are unable or unwilling to quit about vastly safer tobacco products such as smokeless tobacco and e-cigarettes. His research has appeared in a broad range of medical and scientific journals such as *Nature, The American Journal of Medicine, Epidemiology*, *Cancer*, and *Tobacco Control*. Dr. Rodu has written commentaries for the general press and has authored the book *For Smokers Only: How Smokeless Tobacco Can Save Your Life*. He served as an expert witness at a 2003 congressional hearing on tobacco harm reduction and has spoken at international forums on the subject, including one held in London at the British Houses of Parliament.

Matthew Glans joined the staff of The Heartland Institute in November 2007 as legislative specialist for insurance and finance. In 2012 Glans was named senior policy analyst. His responsibilities include interacting with elected officials and staff on a variety of issues; tracking new legislation; and drafting responses to emerging issues via talking points, news releases, and op-ed pieces, with the goal of educating legislators and informing them about free-market ideas.

His work has appeared in several publications, including the *Chicago Tribune*, *Milwauke Journal-Sentinel*, *Los Angeles Times*, *USA Today*, and *St. Louis Dispatch*.

Glans earned a Master's degree in political studies from the University of Illinois at Springfield and a Bachelor of Arts degree in political science from Bradley University. Before coming to Heartland, he worked for the Illinois Department of Healthcare and Family Services in its legislative affairs office in Springfield.

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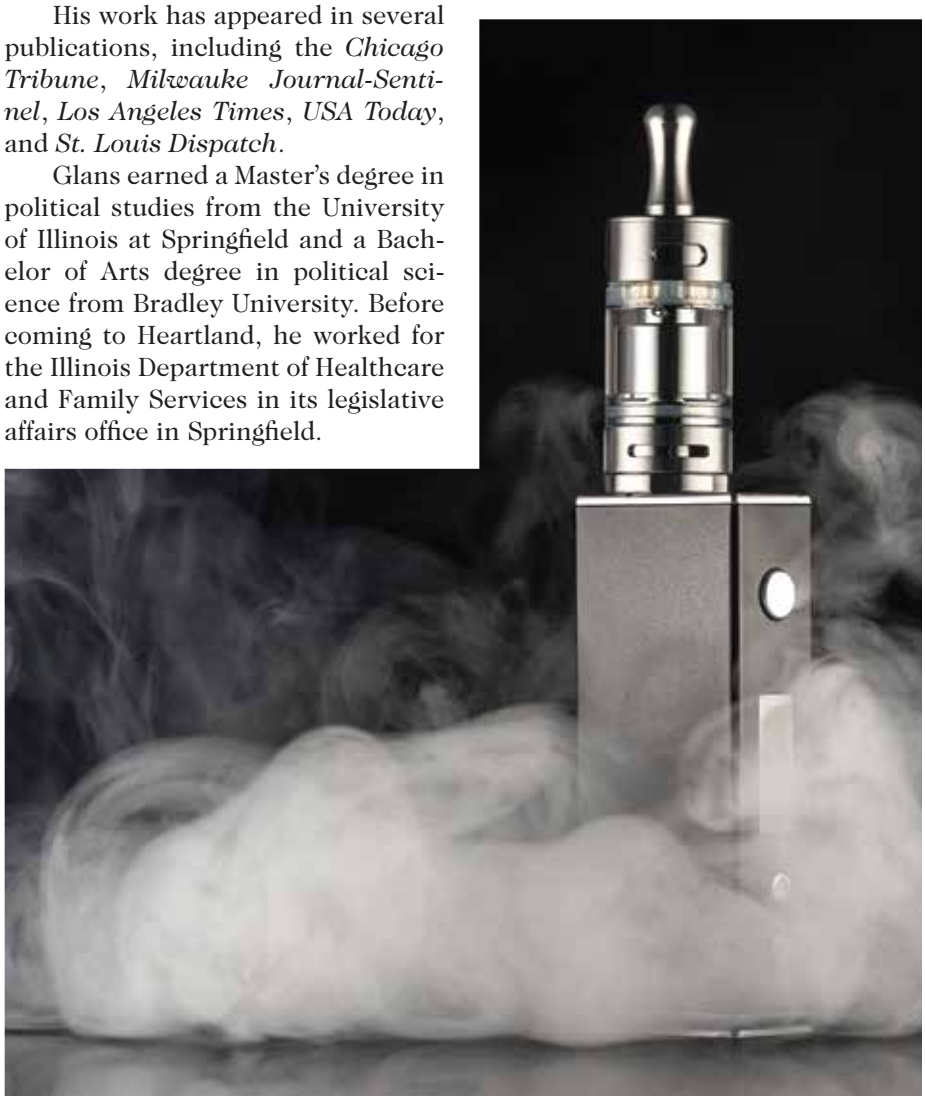

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