

Presentation re House Bills 4073 and 4115
Oregon House Committee on Human Services and Housing
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and

Proposed Update to R Street E-Cigarette Policy Study # 11

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Dr. Nitzkin's Verbal Presentation

Introduction

Thank you for the opportunity to speak before you.

I am here to speak in favor of extending the cigarette age restrictions to e-cigarettes and against prohibiting use of e-cigarettes in areas where smoking is prohibited.

I have provided the Committee with two handouts detailing the issues surrounding House Bills 4073 and 4115.

The first is a recent R Street policy statement addressing the relative safety of e-cigarette vapor, the lack of attractiveness of e-cigarettes to teens and the objections to e-cigarettes by public health authorities. The second is a copy of today's presentation, plus additional background material.

All this is provided to help you to better understand the proposed ban on e-cigarettes in the context of an absolute refusal by the tobacco control community to consider tobacco harm reduction as a possible public health initiative. They have a laser-like focus on preventing teen initiation of tobacco use while ignoring potential benefits to current adult smokers.

I am a public health physician whose home base is New Orleans, Louisiana. I have been a local health director, a state health director and President of two national public health organizations. I have been actively involved with tobacco control since the 1980's, with major involvement since February 2007 on behalf of the American Association of Public Health Physicians, and, since late 2012, with assistance from the R Street Institute. I would be happy to answer any questions you might have about my current activities in this arena after this presentation.

Specific provisions of House Bills 4073 and 4115

Age restrictions

There are two reasons to implement and enforce prohibition of sales of nicotine delivery products to minors. The first has to do with adverse impacts of nicotine on the still-developing adolescent brain. The second is documented fact that, if a person does not initiate tobacco use until after about 24 years of age, he or she is unlikely to ever become addicted to nicotine. With this in mind, not only should you to extend the age restrictions currently in place to e-cigarettes, you should also consider moving the age cut-off from the 18th to the 21st birthday. Upping the age of purchase would remove cigarettes from the high school environment.¹

It is important to note that the nicotine products most accessible to teens are the pharmaceutical nicotine replacement therapy patches, gum and lozenges available on open shelves at every drug store, discount store and most supermarkets. They are sold without enforcement of age restrictions and are exempted in current Oregon law. The gum and lozenge products are offered in a variety of fruit and candy flavors.^{2,3} We do not know the extent to which these products are being used by children and teens to abuse nicotine because these products are not covered in any of the federally sponsored

surveillance activities. This may be an issue worth exploring on behalf of legislators concerned about teen use of nicotine products.

Banning e-cigarettes in no-smoking areas

There is no credible public health justification for banning e-cigarettes in no-smoking areas.

An estimated 70% to 80% of the indoor air pollution from cigarettes is due to sidestream smoke – the smoke that curls off the end of the cigarette when no one is sucking on it. The smoke exhaled by the smoker contributes relatively little to this pollution. E-cigarettes have no sidestream smoke. The vapor exhaled by the user of the e-cigarette contains traces of hazardous organic chemicals so small that they are not readily measurable above background levels in indoor environments. Propylene glycol – the propellant vehicle used in many e-cigarettes is generally recognized as safe. It is used for theatrical fog, and has even used in some asthma inhalers.

Those alleging a possible health hazard from exhaled vapor like to quote studies showing tiny traces of a variety of organic chemical substances in exhaled vapor. What they do not tell you is that persons not smoking or vaping exhale similar trace quantities of many of these same chemicals and that, when measured in an enclosed chamber, exhaled vapor shows no measurable increases of these chemicals above background levels. They also tend to blur the difference between the vapor inhaled by the user and the vapor exhaled, particularly with regard to trace metals.

Some object to allowing vaping in no-smoking areas believing that smokers would not be able to tell the difference between a vapor device and a cigarette. They then speculate that vaping in no-smoking areas would undo progress made since the 1980's in protecting bystanders from smoke in indoor air. I know of no published data on this topic, but this speculation seems very unlikely, at least to me. Given the fact that we now have had several years' experience with e-cigarettes, those proposing such a ban should be able to demonstrate whether or not such e-cigarette use to date has had an adverse effect on enforcement of clean indoor air regulations.

Banning e-cigarettes in no-smoking areas could do harm from a public health perspective by signaling to smokers that e-cigarettes pose the same risk as cigarettes, and, by that means, inhibiting smokers from switching to these far less hazardous products.

Objections to e-cigarettes by the tobacco control community

I think it important that you, as legislators, understand why tobacco control people so strongly object to e-cigarettes.

There are four major reasons, as I see them, as follows:

1. A **Commitment to a “tobacco free society”** in which the term “tobacco use” is used as synonymous with the term “smoking.” This implies that all non-pharmaceutical tobacco products present the same risk of potentially fatal tobacco-attributable illness. This, in turn, rules out any consideration of using any non-pharmaceutical nicotine product as part of any public health initiative, no matter what the potential benefits.

2. **Replacement of “scientific evidence” with a newly minted “self-evident” standard.** In other words, if a guideline is sufficiently self-evident, no amount of contrary scientific evidence need be considered. Two examples of this new standard can be seen in the assertion that exhaled e-cigarette vapor is a hazard to bystanders and the assertion that flavoring of e-cigarettes is for the sole purpose of attracting non-smoking teens to tobacco use.⁴ This precept, of course, does not apply to fruit and candy flavored nicotine gum² and lozenges³ sold over the counter by drug stores, discount stores and supermarkets everywhere.
3. **The issue of FDA approval.** The fact that none of these products are FDA approved is the fault of the FDA, not the manufacturers of e-cigarettes. FDA has yet to generate the needed regulations.
4. **The hidden influence of the pharmaceutical industry.** Finally, it must be noted that the upper reaches of the American tobacco control community enjoy large and continuing grants, contracts and contributions from the major pharmaceutical firms. The drug companies pay for much of the research in this arena, generously contribute to the Heart, Lung and Cancer societies, Tobacco Free Kids, the Centers for Disease Control and even to NIH. Many, if not all of the federally sponsored national tobacco control meetings are co-sponsored by or otherwise generously supported by drug companies. If there was any doubt as to the attitude of the pharmaceutical companies relative to the threat posed by e-cigarettes, their actions behind the scenes, suggest that they are doing everything within their power to eliminate competition from e-cigarettes⁵

Tobacco harm reduction and e-cigarettes

Tobacco harm reduction is an educational initiative by which smokers who are unable or unwilling to quit are advised that they can lower their risk of a potentially fatal tobacco-attributable illness by 98% or better by switching to any one of the smokeless products now on the American market. These data are based on long-term epidemiological studies of Snus use in Sweden and on use of “smokeless tobacco” in the USA since the mid 1980’s. Since e-cigarettes are basically a nicotine-only product with only the smallest traces of the carcinogens and other toxins found in smokeless tobacco product, e-cigarettes likely carry even less risk.

“Harm reduction” does not mean “harmless.” All of these products, including the pharmaceutical nicotine products pose more of a potential health risk than usually accepted in other consumer products. None are risk free. It is only in comparison to cigarettes that they can be considered very low risk.

Nicotine addicts, but it is the other toxins in cigarette smoke, when inhaled deep into the lung, that kill.

All of the 480,000 estimated tobacco-attributable deaths each year in the USA are due to a single tobacco product – the cigarette.⁶ Deaths from all other tobacco products are so low in number and so hard to distinguish from background that they are not tracked by our federal agencies. Simply changing the mantra from a “tobacco free society” to a “smoke-free society” would align tobacco control policy with the science and evidence base.

The vast majority of the 9.6 million deaths due to cigarettes projected to occur over the next 20 years (480,000 per year x 20) will be in current adult smokers who are now over 35 years of age. This means that our efforts to reduce teen initiation of tobacco use will do almost nothing to reduce deaths due to smoking during the next 20 years.

Right now, the best we have to offer current smokers is a set of pharmaceutical-based smoking cessation protocols that we know will fail about 90% percent of smokers who use them under the best of study conditions, with results measured at six to twelve months. The flaws in the current “evidence-based” policies are fairly obvious. They do not satisfy the urge to smoke in the majority of smokers, the dose is too low, the duration of treatment too short and there is no built-in provision for self-reinforcement when the urge to smoke returns.

A modestly successful tobacco harm reduction initiative, if added to current tobacco control programming, would satisfy the urge to smoke in a majority of smokers, and would likely save the lives of 1.5 to 4.8 million current adult American smokers , with the numbers depended on the rate of switching to lower risk smoke-free products. In Year 20 of such an intervention, again, depending on switch rates, the annual numbers of smokers and deaths would likely be down 30% to 80% from current levels. ,⁷

In addition to being less hazardous, e-cigarettes promise to be less addictive⁸ easier to quit than cigarettes,⁹ and far less attractive to teens and other non-smokers.^{10,11}

There is no other feasible tobacco control policy that has the potential to secure public health benefits of this magnitude

The THR initiative would be free to the taxpayer. It would consist of simply telling the truth to the American public about the differences in risk, comparing cigarettes to lower risk smoke-free options. There would be no drugs to buy and no expensive health education and counseling programming.

All this would be in addition to, not a replacement for current tobacco control programming. Prohibition of sales to minors, strict regulation of manufacture and marketing, clean indoor air regulations, tax policy and control of contraband would remain in place, and hopefully be strengthened.

It is these potential public health benefits that propel me and other public health professionals to advocate on behalf of THR, and on behalf of e-cigarettes as a promising THR modality.

With all this in mind, I again urge you to vote in favor of extending the age restrictions in current legislation to e-cigarettes and urge you to vote against banning e-cigarettes in no-smoking areas.

More complete information, replete with bibliographic references, is provided in my handout.

I would be happy to take any questions.

Additional Background Material

In the three months since publication of the R Street Policy Study No. 11, a number of issues have come into sharper focus and important new research has been published or has otherwise come to my attention.

“Self-Evident” vs. Science and Data

The following anti-THR and anti-ENDS policies are considered “self-evident” by many in tobacco control, with the understanding that these policies and assertions are so self-evident that they can be accepted even in the face of contrary scientific evidence. This has been described by some pundits as the “if it walks like a duck . . .” standard. (i.e. if it walks like a duck and quacks like a duck, it must be a duck).

The “Self-Evident” Perception	What Science and Data Show
1. The terms “tobacco” and “smoking” can and should be used interchangeably, since all tobacco products present similar high risk of potentially fatal illness.	The smokeless tobacco products on the American market show substantially less risk of tobacco-attributable mortality than cigarettes. ¹²⁻¹⁴ (also see discussion of smokeless tobacco warnings immediately following this table)
2. Since ENDS are not currently regulated by FDA, we have no idea what is in them.	With known ingredients and studies done by independent labs hired by the manufacturers, we know more about what is in ENDS fluid and vapor than we know about what is in cigarette smoke. ¹⁵
3. Since ENDS are not currently regulated by FDA, they must be considered more hazardous than cigarettes.	We can confidently estimate the risk posed by ENDS based on what we know of the risks posed by smokeless tobacco products and by the NRT products.
4. Since NRTs are regulated by FDA they must be both safe and highly effective.	They are safe, but with very limited efficacy. ¹⁶
5. Since NRT products are regulated by FDA, they may be sold over the counter without age restriction and without concern that they might be used by teen non-smokers.	We have no idea whether NRT products are being abused by teens because no federal agency tracks teen use of these products in any of their tobacco-related surveillance systems
6. Exhaled ENDS vapor is sure to be hazardous to bystanders.	Exhaled ENDS vapor includes traces of nicotine, but no measurable amounts of organic chemical toxins above baseline and none above any industrial or other standard. (see discussion below this table)
7. Allowing use of ENDS in no-smoking areas is sure to encourage smokers to light up since they will not be able to tell e-cigarettes from the real thing.	Bystanders can easily tell the difference between an e-cigarette and the real thing
8. Marketing ENDS as less hazardous than cigarettes is sure to recruit large numbers of non-smoking teens and other non-smokers to nicotine use and addiction, and from there to cigarette use.	CDC data ¹⁷ and major studies done in the USA ¹⁰ and Great Britain ¹¹ show this perception not to be true. In fact, the CDC study showed that both cigarette use and overall tobacco use among both middle schoolers and high schoolers decreased from 2011 to 2012 as e-cigarette use increased ¹⁷⁻¹⁹

<p>9. Since all tobacco companies are inherently evil, there is no possibility of a public health benefit from THR or use of ENDS.</p> <p>10. Since all tobacco companies are inherently evil, any and all statements by researchers or advocates with any support from any tobacco-related enterprise can be summarily dismissed as commercially biased and antithetical to the health of the public.</p>	<p>Contrary to the common perception in the tobacco control community, the tobacco industry is far from monolithic, and there are many companies and individuals who would sincerely welcome the opportunity to partner with public health in pursuit of shared public health objectives.</p>
<p>11. All nicotine-containing products are equally addictive.</p>	<p>A recent literature review, published as a blog posting, clearly shows this not to be true (see discussion below this table)</p>
<p>12. Dual use of cigarettes and ENDS devices is declared to be increased harm.</p>	<p>Dual use would increase harm only if it resulted in more cigarettes being smoked. There is an ample literature showing that dual use is a very common intermediate stage when switching from cigarettes to a smokeless or ENDS product, and that, during this period the numbers of cigarettes smoked are substantially reduced.²⁰</p>
<p>13. Since we have safe and effective smoking-cessation pharmaceuticals, there is no need for THR.</p>	<p>a: Smoking cessation pharmaceuticals have had no public health impact on a population level.(see discussion below this table)</p> <p>b: The prevalence of smoking in the USA, as measured by the numbers of smokers has not gone down since 2004,²¹ despite ever more aggressive marketing and use of pharmaceutical smoking cessation products.</p> <p>c: The data noted above clearly indicates that, if we are to reduce the prevalence of smoking in the USA, we must add one or more new components to current tobacco control programming, with THR as a promising new component.</p>
<p>14. Policy making by tobacco control authorities is totally free of commercial influence.</p> <p>15. Tobacco control policy is firmly grounded in scientific evidence.</p>	<p>a: Both federal agencies (CDC, NIH, etc) and the major voluntary organizations involved with tobacco control (Heart, Lung, Cancer societies and major medical societies) receive funding from pharmaceutical companies. ***</p> <p>b: Smoking cessation protocols reliant on pharmaceuticals are promoted as the “standard of practice” for physicians*** despite the fact that such protocols fail about 90% of smokers who use them as directed, even under the best of study conditions. ***</p> <p>c: Multiple tobacco control policies openly conflict with the best available scientific evidence.</p>

The issue of smokeless tobacco warnings

The most damaging of the “self-evident” perceptions and the one standing directly in the way of any consideration of incorporating a THR element into tobacco control programming is the perception that all tobacco products present a similar risk of potentially fatal illness. This perception is reinforced by the warnings mandated on all packages of smokeless tobacco sold in the USA. There are four rotating warnings. One warns of mouth cancer, the second of tooth and gum disease, the third states that smokeless tobacco is not a safe alternative to cigarettes and the fourth warns of addiction. **Of these warnings, the first is technically incorrect, and the next two are grossly misleading.** Only the warning of addiction is correct and not misleading. These warnings have left over 80% of smokers with the impression that these smokeless products are as hazardous, if not more hazardous than cigarettes, and that switching from cigarettes to a smokeless alternative will simply result in swapping a risk for lung cancer for a risk for mouth cancer.²² These warnings would be appropriate for a family of products available in India, sometimes referred to as gutkha, and sometimes referred to as pan masala with tobacco. This family of products does pose high risk of mouth cancer and tooth and gum disease, but it has not been and likely will never be available on the American market. As noted above, the chewing tobacco, snuff, snus and other smokeless products on the American market do not pose any risk of these diseases warranting any such warning, and this lack of risk has been firmly established at least since 2004. This lack of risk has been further reinforced by additional studies of this subject published since that time.^{13,14}

Newly published data relates to the following issues:

Contraband

In a recent survey of cigarette pack litter in five northeastern cities, Davis et al found that 58.7% of cigarette packs did not have a proper local tax stamp. 30.5-42.1% were attributed to trafficking. They concluded that reducing cigarette trafficking would increase the effectiveness of tobacco taxes in reducing smoking and generate additional tax revenue.²³

Percentage of smokers who initiated tobacco use after their 18th birthday

In their latest statistical report, SAMHSA (federal Substance Abuse and Mental Health Administration) noted that, among persons above 12 years of age that have initiated smoking, 31.6% of those surveyed in 2002 initiated smoking after their 18th birthday. Of those surveyed in 2012, 47.8% did so after their 18th birthday. While not diminishing the need to prohibit tobacco sales to persons under 18 years of age,²⁴ this report provides strong support for upping the age cut-off for tobacco sales from 18 to 21. This should also eliminate any thought that, by prohibiting sale of tobacco to minors, we could eventually eliminate all tobacco use in the USA.

Relative addictiveness of different classes of tobacco/nicotine product

On December 14, 2013, Dr. Karl Fagerstrom posted a well referenced essay entitled “Dependence on Tobacco and Nicotine” on the Nicotine Science and Policy website.⁸ In this essay he makes a very strong case for their being a “continuum of dependence” in which cigarettes foster the strongest dependence, NRT pharmaceuticals the least, with smokeless products, e-cigarettes and other products in-between. Elements relating to the strength of the dependence include other chemical substances in cigarette

smoke, habituation to the cigarette-handling ritual and social and psychological factors. The practical implication of this essay is to the effect that when a smoker switches to a lower risk smokeless product, not only does he or she dramatically reduce future risk of potentially fatal tobacco-attributable illness, he or she is switching to a product that will be easier to quit than cigarettes

Toxins in exhaled e-cigarette vapor

A number of studies have been very recently published dealing with the concentration of organic chemicals in exhaled e-cigarette vapor. Basically, these studies show that when the e-cigarette user exhales into a glass tube or similar container, trace quantities of a variety of organic chemicals can be detected, but, when in an 8 cubic meter test chamber or similar room, for a half hour or more, e-cigarette use does not measurably increase the trace quantities of these chemical substances above background levels, while cigarettes cause dramatic rapid increases.²⁵⁻²⁷ Perhaps the most interesting finding in these studies is that persons not using any form of tobacco routinely exhale trace amounts of acetone, ethane, pentane and isoprene and other endogenous volatile organic compounds²⁸⁻³¹

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