Testimony on H.171 – February 10, 2016

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Reinvigorating the fight against tobacco products and tobacco substitutes: e-cigarettes and clean indoor air laws.

Tobacco, as a public health issue has not gone away and many of us worry that e-cigarettes, and their potential health effects, could be a giant step backwards.

E-cigarette use by high school students has tripled in a single year and U.S. sales are projected to rise almost 25 percent each year. Perceptions about the safety of e-cigarettes are rampant, but unsupported by scientific evidence, and their lack of regulation represents a growing public health concern. The Vermont legislature can do something about this.

As a former health commissioner, professor, and public health physician, I would like to focus on the specific benefits of H.171, in reducing exposure to e-cigarette vapor and promoting a positive social norm about health, and I am happy to answer questions about other aspects of e-cigarette use as a public health concern. Here are a few stats:

In September 2013, many of our nation's attorney generals wrote the FDA Commissioner about e-cigarette concerns, including their allure to children and adolescents, marketing and promotions, *perceived* effectiveness in smoking cessation, and their meteoric rise in sales, all in the absence of Federal regulation. Public comment closed on the FDA's proposed regulation on July 2, 2015. But we're not there yet, and Vermont must act.

Background - Youth Data

In a 2015 study,[1] published in *Nicotine Tobacco Research*, data from the 2011, 2012, and 2013 National Youth Tobacco Surveys of students in grades 6–12 showed: Between 2011 and 2013, the number of never-smoking youth who used e-cigarettes increased 3-fold, from 79,000 to more than 263,000. Intention to smoke conventional cigarettes was 43.9% among ever e-cigarette users and 21.5% among never users. Ever e-cigarette users had higher adjusted odds for having smoking intentions than never users (adjusted odds ratio = 1.70, 95% confidence interval = 1.24–2.32). In 2013, more than a quarter million never-smoking youth used e-cigarettes. **E-cigarette use is associated with increased intentions to smoke cigarettes, and enhanced prevention efforts for youth are important for all forms of tobacco, including e-cigarettes.**[1]

In April 2015, CDC reported in the MMWR that current e-cigarette use tripled in a single year! In 2014, for the first time, e-cigarettes were the most commonly used tobacco product among middle and high school students, offsetting decreases in cigarettes and cigars, resulting in **no change** in overall tobacco use among young people. [2] **And an August 2015 JAMA article reported that high school students in Los Angeles, California, who had ever used e-cigarettes were more likely to use other tobacco products in the next year.**[3]

E-Cigarettes and Clean Indoor Air

What's in the E-Cigarette Vapor? A 2014 study by Pisinger and Dossing published in *Preventive Medicine* was a review of the current literature (76 studies) on the health consequences of c-cigarettes. [4] The authors concluded:

- **Electronic cigarettes can hardly be considered harmless**[4]

Metals: One study found that concentrations of **lead and chromium** in e-cigarette vapor were within the range of conventional cigarettes (CCs), while **nickel** was up to 100 times higher than in CCs Williams et al., 2013 One puff of E-cigarette (EC) vapor contained numerous particles, mainly tin, silver, nickel and aluminum. Tin, chromium, and nickel were found as nano-particles.[4]

Tobacco-specific nitrosamines (TSNAs): Some studies found high maximum concentrations of total TSNAs in the vapor of most (Goniewicz et al., 2013a), or almost all e-cigarette fluids (Kim and Shin, 2013). [4]

Carbonyls: **In one study, the potential human carcinogens formaldehyde, acetaldehyde and acrolein were detected in the vapors of almost all ECs** (Goniewicz et al., 2013a). Exposure to formaldehyde was comparable with smoking (Goniewicz et al., 2013a), as was also the case with vapor from high-voltage devices (Kosmider et al., 2014). The highest levels of carbonyls were observed in vapors generated from propylene glycol-based solutions (Kosmider et al., 2014) or in the second half of a vaping period. Volatile organic compounds (VOCs) such as toluene Czogala et al. (2014) and p,m-xylene were identified in almost all vapors (Goniewicz et al., 2013a).[4]

Polycyclic aromatic hydrocarbons (PAHs): One study found probably carcinogenic PAHs in indoor air increased by 20% after vaping (Schober et al., 2014).[5]

Other: Human bronchial cells that contained mutations found in smokers at risk of lung cancer were grown in a culture medium that had been exposed to vapor. The researchers found that cells exposed to high-nicotine vapor showed a similar pattern of gene expression to those exposed to tobacco smoke (Park et al., 2014).[5]

And, in January 2016, researchers published a study showing that cherry-flavored e-cigarettes exposure users to the inhalation irritant benzaldehyde.[6] Benzaldehyde, a key ingredient in natural fruit flavors, has been shown to cause irritation of respiratory airways in animal and

occupational exposure studies. Given the potential inhalation toxicity of this compound, they measured and detected benzaldehyde in 108 out of 145 products. The highest levels of benzaldehyde were detected in cherry-flavored products.[6]

Indoor Air Data:

There are generally 2 types of studies, ones simulating secondhand vapor exposure, called "chamber" studies and those simulating "real-life" exposure, like bars or cafes.

A 2014 study (by Czogala and colleagues) simulated secondhand exposure in an exposure chamber. They compared secondhand exposure with e-cigarette vapor and tobacco smoke generated by 5 dual users. **The authors concluded that using an e-cigarette in indoor environments may involuntarily expose nonusers to nicotine**. [7]

Formaldehyde is a known degradation product of propylene glycol that reacts with propylene glycol and glycerol during vaporization (e-cigarette vaping).[8] According to a recent study, "how formaldehyde-releasing agents behave in the respiratory tract is unknown, but formaldehyde is an International Agency for Research on Cancer group 1 carcinogen." [8] Jensen and colleagues published a study called ***Hidden Formaldehyde in E-Cigarette Aerosols*** in the NEJM in 2015 calculated that, according to their study, long-term vaping is associated with an incremental lifetime cancer risk of 4.2×10−3. This risk is 5 times as high (or as much as 15 times as high) as the risk associated with long-term smoking.[8]

A 2014 study by Ballbe and colleagues published in Environmental Research[9] looked at passive exposure to e-cigarette vapor under real conditions. They conducted an observational study with 54 non-smoker volunteers from different homes: 25 living at home with conventional smokers, 5 living with nicotine e-cigarette users, and 24 from control homes (not using conventional cigarettes neither e-cigarettes), and measured airborne nicotine at home and biomarkers (cotinine in saliva and urine). [9] **The results show that non-smokers passively exposed to e-cigarettes absorb nicotine.[9]**

Schober and colleagues in 2014 studied e-cigarettes and indoor air quality in a café-like setting.[5] Their study looked at e-cigarette emissions in terms of particulate matter (PM), particle number concentrations (PNC), volatile organic compounds (VOC), polycyclic aromatic hydrocarbons (PAH), carbonyls, and metals. In six vaping sessions nine volunteers consumed e-cigarettes with and without nicotine in a thoroughly ventilated room for two hours. They analyzed the levels of e-cigarette pollutants in indoor air and monitored effects on FeNO (exhaled nitric oxide, a measure of inflammation). [5]

(As an aside, measurement of fractional nitric oxide (NO) concentration in exhaled breath (FENO) is a quantitative, noninvasive, simple, and safe method of measuring airway inflammation, according to the American Thoracic Society (ATS). Nitric oxide (NO) is now recognized as a biological mediator in animals and humans. NO is produced by the human lung and is present in the exhaled breath. It has been implicated in the pathophysiology of lung diseases, including asthma.) [10]

During the vaping sessions, they found, **"substantial amounts of 1,2-propanediol, glycerine and nicotine were found in the gas-phase, as well as high concentrations of PM2.5(mean 197 _g/m3). The concentration of putative carcinogenic PAH in indoor air increased by 20% to 147 ng/m3, and aluminum showed a 2.4-fold increase. PNC ranged from 48,620 to 88,386 particles/cm3(median), with peaks at diameters 24–36 nm. FeNO increased in 7 of 9 individuals."**

The authors concluded that "e**-cigarettes are not emission-free and their pollutants could be of health concern for users and secondhand smokers**." [5]

An American Heart Association Scientific Review of E-cigarettes published in Circulation in 2014[11] also tells us about second-hand vapor concerns:

From this paper we know, laboratory studies (called Chamber studies) of second-hand vapor from e-cigarettes contained low levels of formaldehyde, acetaldehyde, isoprene, acetic acid, 2-butanodione, acetone, propanol, propylene glycol, and diacetin (from flavoring), traces of apple oil (3- methylbutyl-3-methylbutanoate), and nicotine emitted into the air.[11]

Other studies, including ones simulating a bar environment, similarly noted indoor air pollution from e-cigarette vapor, including polycyclic aromatic hydrocarbons - classified as probable human carcinogens. [11]

From this same American Heart Association Scientific Review, we know that propylene glycol and glycerin are the primary ingredients of the liquid in e-cigarettes. Adverse effects from propylene glycol include to eye and respiratory irritation, and prolonged or repeated inhalation may affect the central nervous system and behavior. Also, when heated and vaporized, propylene glycol can form propylene oxide, an International Agency for Research on Cancer (IARC) class 2B carcinogen (possibly carcinogenic to humans), and glycerol forms acrolein, which can cause upper respiratory tract irritation.[11] (Material taken from citation: Gran R et al. E-Cigarettes, A Scientific Review. Circulation 2014: 129:1972-1986 http://circ.ahajournals.org/content/129/19/1972.full)

In summary, experts from the American Heart Association state, "the particle size distribution and number of particles delivered by e-cigarettes are similar to those of conventional cigarettes, with most particles in the ultrafine range (modes, ≈100–200 nm)."

"Smokers exhale some of these particles, which exposes bystanders to "passive vaping." Like cigarettes, e-cigarette particles are small enough to reach deep into the lungs and cross into the systemic circulation. **At a minimum, these studies show that e-cigarette aerosol is not merely "water vapor" as is often claimed in the marketing for these products.** Tests on e-cigarettes show much lower levels of most toxicants, but not particles, than conventional cigarettes. The thresholds for human toxicity of potential toxicants in e-cigarette vapor are not known…".[11]

At UVM, our Tobacco-Free Policy for the UVM Campus, effective August 1, 2015 (see http://www.uvm.edu/tobaccofree/) was the product of a several-year process involving a campus-wide conversation. The policy defines Tobacco-Free as prohibiting the use of **all** forms of tobacco, and all products derived in whole or in part from tobacco, **including e-cigarettes.** At UVM, we are concerned about e-cigarettes, and included them in our policy. From a campus-wide survey conducted last fall we learned that more than 25% of freshman undergraduates used e-cigarettes in the last 30 days and underclassmen were nearly 3 times more likely to use e-cigarettes than upperclassmen.

In a follow-up survey conducted a year later, and only about 3 months after the policy was implemented, we have already seen a significant decrease in reported exposure to second-hand smoke, and a significant decrease in tobacco use in undergraduate students. This speaks volumes to the strength of tobacco and e-cigarette-free policies in promoting a non-smoking norm. In our case, it happened after only 3 months. At UVM, we are concerned about e-cigarettes, and included them in our policy.

The impact of Tobacco-Free policies is well known. They result in health improvements, in part, due to less smoking. If we think about our progress in youth, maintaining Tobacco-Free (including all tobacco products and substitutes) in public places, workplaces, schools, and other environments is critical to maintaining our progress in reducing tobacco use and its disastrous health impacts.

In summary, what do we know about e-cigarette vapor? That secondhand vapor from e-cigarettes is not harmless water vapor. It contains nicotine, particles, irritants, and potential carcinogens. Studies recently-published highlight our concern for public health effects.

What are the benefits to public health from H.171?

- You will reduce exposure to second-hand vapor from e-cigarettes.
- You will contribute to keeping and strengthening our non-smoking norm, essential to public health in Vermont, and continue to reduce the adverse impact of tobacco and tobacco products, including tobacco substitutes.
- This is critically important for children and adolescents to preserve the progress we have made in reducing youth smoking. Our non-smoking norm, established by years of hard work by the legislature, health experts and advocates, helps to reduce smoking and the harmful effects of second-hand smoke in Vermont. The impact of including e-cigarettes will be especially positive for youth and will benefit all Vermonters' health.
- In a similar way that policies and laws restricting exposure to secondhand cigarette smoke also contribute to declines in smoking, including e-cigarettes in our laws (because so many smokers continue smoking while using them), will also help reinforce the messages that it is essential to quit altogether. For young people, because we know risks associated with e-cigarettes alone (e.g. nicotine), and the later related risks for cigarette

smoking, it is critical to include tobacco substitutes in our tobacco laws, including public places, workplaces, school grounds, etc. to best protect the health of children, adolescents, and younger Vermonters.

Currently, there are so many unresolved questions:

- What **are** the long-term health effects from using e-cigarettes?
- Why would we allow an entire generation of adolescents to be so easily addicted to nicotine? And why should we allow our social norms that promote health (through Vermont's strong laws and policies) to be eroded by e-cigarettes? We must include them in our tobacco laws and policies.
- Why should we allow indoor air pollution from e-cigarettes, given what we know from scientific studies?
- How can we make sure e-cigarettes are included in our research, education, policies, and our legislation, both nationally and in Vermont, as fast as we possibly can?

H.171 is a strong public health step. It considers potential harms from exposure to second hand vapor, and includes them in the same places we do not allow cigarette smoking. It preserves the progress we have made in creating social norms that promote not smoking, critically important for the health of children, adolescents, and all Vermonters. Thank you for considering this bill. I strongly support its passage.

Cessation: The AHA scientific findings also challenge the widespread perception that e-cigarettes are highly effective in smoking cessation and point out that many individuals continue to use cigarettes and e-cigarettes together. (Material taken from Gran R et al. E-Cigarettes, A Scientific Review. Circulation 2014: 129:1972-1986 http://circ.ahajournals.org/content/129/19/1972.full) This is supported by another recent 2014 article in JAMA Internal Medicine, "adding to the evidence that e-cigarettes may not increase rates of smoking cessation." [12]

A word about Public Health England's claims. International news from Public Health England claimed that "E-cigarettes were 95% less harmful than tobacco."[13] However, when you look at the study on which it was based, [14] the authors (2 of whom received funds from the industry), used the Multi-Criteria Decision Analysis (MCDA) method (previously used to rank potential harm of 20 psychoactive drugs), chose a small committee and ranked harms from cigarettes to nicotine replacement treatments. No scientific studies were used or mentioned. The study authors state that "a limitation of this study is the lack of hard evidence for the harms of most products on most of the criteria." [14] This is a paper describing the opinions of a small group of authors, two of whom have financial industry ties. An editorial in the Lancet (*called E-Cigarettes: Public Health England's evidence-based confusion*) aptly states that this "raises serious questions not only about the conclusions of the Public Health England report, but also about the quality of the agency's peer review process."[13]

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