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**Statement by Joel L. Nitzkin, MD, MPH, DPA
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Regarding Duluth City Council ordinances 10-058, 059 and 060 relating to e-cigarettes

Introduction and summary statement

My name is Joel Nitzkin. I am a public health physician. I have been a local health director, a state health director and president of two national public health organizations. I have been in the private practice of public health as a policy consultant since the mid-1990s. The views I express today are entirely my own, and have not been edited or amended by any third party.

I urge the Duluth City Council to extend the age restrictions on the sale of tobacco products to cover e-cigarettes. To facilitate enforcement of this provision, I urge the council to require places selling e-cigarettes to have a tobacco license. These measures are appropriate to effectively prohibit sales to underage youth.

I urge the Duluth City Council not to extend restrictions on smoking to e-cigarettes.

Reasons not to extend restrictions on indoor and outdoor smoking to e-cigarettes

Ordinances 058 and 059 extend restrictions on smoking in indoor and outdoor areas to e-cigarettes. The definitions in ordinance 059 present all tobacco products as presenting the same risks as cigarettes. No justification for these measures is articulated in either ordinance.

The primary purpose of restricting smoking in public places is to protect non-smokers from exposure to carcinogens and other toxic chemicals in cigarette smoke. Smokeless tobacco products and, for all practical purposes, e-cigarettes present no such risk.

My opposition to imposing these restrictions on e-cigarettes is based on two observations:

1. Exhaled e-cigarette vapor presents no threat to non-users that would justify a ban.

2. Misrepresenting e-cigarettes as harmful as cigarettes is both factually incorrect and damaging to the health of the public.

The e-cigarette is one of a number of smoke-free tobacco/nicotine alternatives that can reduce the risk of tobacco-attributable illness and death by 98 percent or better compared to cigarette smoking, while satisfying the user's urge for nicotine.

There is now a substantial and convincing body of research findings confirming these impressions. Misrepresenting e-cigarettes has the practical effect of reinforcing real tobacco cigarettes as the dominant product for nicotine consumption. It does nothing to reduce teen initiation of tobacco/nicotine products and protects cigarettes from competition from these far less-hazardous products.

Cigarettes are the most hazardous and addictive tobacco products, and the product most attractive to teens. There was no pandemic of tobacco-related addiction, illness and death until the advent of the machine-made cigarette. The smoke-free alternatives – including chewing tobacco, snus, e-cigarettes and other products on the American market – pose a risk of tobacco-attributable illness and death less than 2 percent that posed by cigarettes. In addition, available evidence strongly suggests that they are far less attractive to teens. Two recently published studies conducted by public health non-profits – one in the United States and one in the United Kingdom – showed teens were very aware of e-cigarettes, yet it was impossible to find even a single non-smoking teen that had taken them up.

For most of the past half-century, cigarettes were so dominant in the United States that anti-smoking advocates got into the habit of using the terms "cigarette" and "tobacco" as if they were synonymous. Working from the seemingly reasonable, but demonstrably untrue, premise that all tobacco products were equally hazardous (and on the premise that tobacco companies are evil) anti-smoking advocates adopted the policy that blocking the introduction of any new tobacco product would protect the health of the public.

Times have changed.

We now know about huge differences in risk between different classes of tobacco products. We now know more about the attractiveness of different classes of tobacco products to non-smoking teens. We even know more about the fact that, for a large number of mental health patients, nicotine is seen as a highly beneficial drug.

Even a few years ago, none of these new findings could be imagined by most anti-tobacco activists. As far as they were concerned, the science was settled and all tobacco/nicotine products were to be equally condemned. Any new scientific findings that conflict with these views would be routinely dismissed as tobacco company propaganda.

But the possibility now exists to rapidly and dramatically reduce tobacco-attributable addiction, illness and death. Successfully doing so will require honest communication to current smokers as to the differences in risk posed by different types of tobacco products, continued prohibition of sales of all tobacco products to minors and effective federal regulation of the manufacture and marketing of tobacco products.

Given the attractiveness of e-cigarettes to current smokers and their lack of attraction to current non-smokers, the possibility exists to harness natural market forces, in combination with regulatory oversight, to reduce tobacco-related addiction, illness and death. More research is certainly in order. But in the meantime, protecting the public health is best accomplished by implementing what we already know about the determinants of tobacco-related harm.

If the nicotine and trace carcinogens in e-cigarette vapor presented any significant hazard to bystanders, those advocating for this legislation could have and should have included pharmaceutical nicotine inhalers in this ban. The fact that they have not done so strongly suggests a perception on their part that no such hazard exists.

Introduction to Dr. Nitzkin and disclaimer

I have been involved with tobacco control since the late 1970s. From early 2007 through mid-2010, I served as co-chair of the Tobacco Control Task Force of the American Association of Public Health Physicians. During that period, when the Tobacco Control Act was making its way through Congress, my AAPHP colleagues and I decided to do our own independent literature review to determine the best way to reduce tobacco-attributable addiction, illness and death. It was that literature review that drew our attention to tobacco harm reduction as the most promising of public health interventions, and to e-cigarettes as possibly the most promising of tobacco harm reduction modalities.

The views I am expressing in this statement are entirely my own, they do not reflect position statements formally adopted by AAPHP, R Street or any other organization with which I am affiliated. Neither I nor AAPHP have ever received any direct or indirect financial support from any tobacco, e-cigarette or pharmaceutical enterprise. My ability to address legislative issues nationwide is supported by the R Street Institute, a Washington, D.C.-based libertarian think tank that respects the role of government in regulating industry to protect health and the environment, but strongly opposes undue governmental interference with market forces. R Street designated tobacco harm reduction as one of their priority issues after FDA attempted to remove e-cigarettes from the market by declaring them to be an unapproved drug-device combination subject to the provisions of the drug law. R Street policy and decision-making is independent from governmental, tobacco, e-cigarette or pharmaceutical industry influence.

What is environmental tobacco smoke, and how does it harm people?

Environmental tobacco smoke is a witch's brew of toxic chemical substances from the incomplete combustion of tobacco. The main component is carbon monoxide, but it also includes other gasses and tarry particulate residue containing most of the nicotine and the worst of the carcinogens. About 85 percent of environmental tobacco smoke is side-stream smoke: the smoke that curls off the end of the cigarette when no one is puffing on it. The mainstream smoke exhaled by the smoker includes only what is left after much of what was inhaled is absorbed by the smoker.

E-cigarette vapor: inhaled, exhaled and "sidestream"

E-cigarette vapor, as inhaled by the users, is mainly water, propylene glycol and glycerin, with small amounts of nicotine and flavoring. There is no carbon monoxide, no tar and no products of combustion. There is no side-stream smoke or vapor. None. Propylene glycol and glycerin are generally recognized as safe. Propylene glycol has been used as the propellant in asthma inhalers and is the main ingredient in theatrical fog.

Why the objections to e-cigarettes from public health advocates?

Objections to e-cigarettes from public health advocates are theoretical in nature, based on a distrust of all non-pharmaceutical tobacco-related companies and the false premise that we do not know what e-cigarettes contain. We actually know more about e-cigarette liquid and vapor than we do about the chemical make-up of cigarette smoke.

Those opposing e-cigarettes are quick to point out that they have not been approved by FDA. This is true. Unfortunately, this reflects on the sad state of the FDA's newly established Center for Tobacco Products. We are now four years past the establishment of the FDA Center for Tobacco Products by the Family Smoking Prevention and Tobacco Control Act. The center is literally tied in knots by provisions of this poorly written law, by forces in the public health community dedicated to a tobacco-free society on the false premise that all tobacco products are equally harmful and by forces in the tobacco industry that have twice defeated FDA in court.

FDA has yet to specify product safety guidelines for any tobacco product, and has yet to extend its regulatory authority to cover e-cigarettes. The fact that e-cigarettes are not approved by the FDA is not the fault of the e-cigarette companies.

Much of the objection to e-cigarettes is based on an FDA press conference held July 22, 2009, just one month after President Obama signed the Tobacco Control Act into law. This press conference roundly condemned e-cigarettes on the basis that e-cigarette fluid contains trace carcinogens and that one of the twenty samples they tested showed a trace of diethylene glycol – the main ingredient in automobile anti-freeze. What FDA did not say in that press conference was that the e-cigarette fluids, with the exception of the one trace of diethylene glycol, showed the same trace carcinogens in about the same concentrations as the pharmaceutical nicotine replacement therapy products approved by FDA

(Nicorette, Commit, and others). The one trace of diethylene glycol was so small that one would have to consume the e-cigarette equivalent of about 1,500 cigarettes in a single day to reach the minimal toxic dose of this liver toxin, and that the sample was from an e-cigarette company that has since gone out of business.

Over the four years since this press conference, public health advocates have embellished, exaggerated and distorted statements from this press conference to suggest that e-cigarettes might be even more harmful than cigarettes. It simply is not so. FDA, for its part, continues to repeat statements from this conference, but is careful not to compare the hazard posed by e-cigarette vapor to the hazard posed by cigarette smoke.

Anti-tobacco advocates are likely to promote the Duluth ordinances for two incorrect reasons having nothing to do with protection of the health of non-smokers. The first is the belief that all tobacco products are extremely harmful. The second is that any impression that any tobacco is very low in risk would attract large numbers of teens to tobacco/nicotine use who otherwise would not have done so. Framing e-cigarette vapor to be as harmful as harmful as cigarettes is not erring on the side of protecting the public.

The alternative to use of e-cigarettes is not abstention from tobacco use but continuation of cigarette use on the basis that there is nothing to be gained by switching to these much lower-risk products. Condemning e-cigarettes has the practical effect of protecting cigarettes from competition from these products.

Annotated Bibliography

Environmental tobacco smoke

Environmental tobacco smoke (ETS), often incorrectly referred to as "second-hand smoke," is a combination of diluted sidestream smoke and mainstream smoke.¹ Mainstream smoke, in ETS, is the smoke exhaled by the smoker. Sidestream smoke is the smoke that curls off the end of the cigarette when no one is inhaling the cigarette.

The smoke consists of more than 4,000 different chemicals, 30 to 60 of which are known carcinogens. Solid particles make up about 10 percent of the smoke, including the tar and most of the nicotine. The major gas present is carbon monoxide. About 85 percent of the ETS in a room comes from sidestream smoke. ETS increases the risk of lung cancer, other cancers, heart and lung disease, increases the risk of

¹ Terry Martin, "Environmental Tobacco Smoke," About.com, March 29, 2013.
www.quitsmoking.about.com/cs/secondhandsmoke/g/ETS.htm

low birth weight and is suspected as increasing the risk of birth defects. All of this is in addition to the known irritation of eyes, throat and respiratory mucous membranes.^{2 3 4}

There is general consensus that environmental tobacco smoke is highly toxic and a major cause of potentially fatal illness. CDC (USDHHS Centers for Disease Control and Prevention) estimates that approximately 394,000 American smokers die each year from smoking, plus an estimated 49,000 non-smokers die in the United States from exposure to environmental tobacco smoke.⁵

Step-down in risk from cigarette smoking to e-cigarette vapor

1. The 443,000 tobacco related deaths in Americans each year, per CDC estimates, as noted above, are all from cigarette use. The numbers of deaths from all other forms to tobacco, combined, are so small and so hard to estimate that they are not estimated or tracked by CDC authorities.⁶
2. The smokeless tobacco products that have been on the American market since at least the 1980s are estimated to pose a risk of potentially fatal illness less than 2 percent the risk posed by cigarettes. Thus, contrary to common perception, different tobacco products present dramatically different risks of potentially fatal illness.⁷
3. E-cigarette vapor, consisting entirely of the vapor exhaled by the e-cigarette user, will almost assuredly pose less of a risk to bystanders than the risk posed to the e-cigarette user – a risk too small to justify restrictions on environmental e-cigarette vapor.⁸ It is important to note that, despite the lack of long-term studies to verify this perception, it is generally agreed that long-term use of the pharmaceutical nicotine replacement therapy products (Nicorette, Commit, and others) pose no risk of tobacco-attributable mortality.
 - a. "For all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed."⁹

² Canadian Centre for Occupational Health and Safety, "Environmental Tobacco Smoke (ETS): General Information and Health Effects," March 1, 2011. http://www.ccohs.ca/oshanswers/psychosocial/ets_health.html

³ Report of the Surgeon General, "The Health Consequences of Involuntary Exposure to Tobacco Smoke," June 27, 2006. <http://www.surgeongeneral.gov/library/reports/secondhandsmoke/index.html>

⁴ California Environmental Protection Agency Fact Sheet, "Environmental Tobacco Smoke: A Toxic Air Contaminant," October 18, 2006. <http://www.arb.ca.gov/toxics/ets/factsheetets.pdf>

⁵ Centers for Disease Control and Prevention, "Smoking & Tobacco Use: Tobacco-Related Mortality," August 1, 2013. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm

⁶ Ibid.

⁷ Brad Rodu, "The scientific foundation for tobacco harm reduction, 2006-2011," *Harm Reduction Journal*, August 19, 2011. www.harmreductionjournal.com/content/8/1/19

⁸ Igor Burstyn, "Peering through the mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks?" August 2013.

<http://publichealth.drexel.edu/SiteData/docs/ms08/f90349264250e603/ms08.pdf>

⁹ T.R. McAuley, et al, "Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality," *Inhalation Toxicology* October 2012. <http://www.ncbi.nlm.nih.gov/pubmed/23033998>

- b. Nitrosamine levels for e-cigarettes were similar to the levels in Nicorette gum and NicoDerm patches, but less than one-hundredth to one-thousandth the level in a wide range of smokeless tobacco and cigarette products.¹⁰
- c. Passive vaping, compared to cigarette environmental tobacco smoke: Total organic carbon in the test chamber after 5 hours of smoking or vaping, showed no detectable levels of acrolein, toluene, xylene and PAHs for the e-cigarettes, compared to high levels in the cigarette chamber.¹¹
- d. Anti-smoking researcher (Glantz) misleads public with invalid comparison of e-cigs and nicotine inhaler; correct analysis shows that nicotine inhalers have higher amounts of six carcinogens, including five to ten times the amount of three heavy metals. This re-analysis is based on a comparison of user exposure to anticipated daily doses of e-cigarette vapor compared to nicotine inhalers, rather than comparison of amounts of carcinogen in single cartridges.¹²
- e. In tests comparing the effects of e-cigarette vapor to cigarette smoke on cell cultures of myocardial cells, the vapor had minimal impact on the cells, while the smoke killed almost all of them.¹³

Attractiveness of e-cigarettes to teens and other non-smokers

Dr. Jonathan Winickoff is chairman of the American Academy of Pediatrics' Tobacco Consortium. In an article posted online in the Journal of Environmental and Public Health, Dr. Winickoff co-authored a report of a national survey of 3,240 adults (age 18 and above), including 1,802 non-smokers. They were only able to find six nonsmokers who had ever used e-cigarettes.^{14 15}

¹⁰ Zachary Cahn and Michael Siegel, "Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes?" *Journal of Public Health Policy*, 2011.

<http://www.ncbi.nlm.nih.gov/pubmed/21150942>

¹¹ Giorgio Romagna, Konstantinos Farsalinos, et al, 14th Annual Meeting of the Society for Research on Nicotine and Tobacco, 2012.

¹² Michael Siegel, "Anti-Smoking Researcher Misleads Public with Invalid Comparison of E-Cigs and Nicotine Inhaler: Correct Analysis Shows that Nicotine Inhalers Have Higher Amounts of Six Carcinogens," *Tobacco Analysis*, July 25, 2013. www.tobaccoanalysis.blogspot.com/2013/07/anti-smoking-researcher-misleads-public.html

¹³ Konstantinos Farsalinos, et al, Tobacco Marketing Association, 2013.

¹⁴ Michael Siegel, "National Study of Adults Can Find Only Six Nonsmokers Who Have Ever Tried Electronic Cigarettes," *Tobacco Analysis*, May 8, 2013. <http://tobaccoanalysis.blogspot.com/2013/05/national-study-of-adults-can-find-only.html>.

¹⁵ Robert McMillen, et al, "Use of Emerging Tobacco Products in the United States," *Journal of Environmental and Public Health* 2012. www.hindawi.com/journals/jeph/2012/989474/

A second study by Action on Smoking and Health (ASH-UK) was unable to find a single nonsmoker in the United Kingdom - either youth or adult - who regularly uses e-cigarettes.¹⁶ The study involved a survey of 12,171 adults and 2,178 children ages 11 to 18, in February and March 2013. Despite widespread awareness of e-cigarettes among youth and adults, the survey failed to find a single adult or youth never smoker who regularly uses e-cigarettes. Awareness of electronic cigarettes was 67 percent among 11-to-18 year-olds and 83 percent among the 16-to-18 year-olds. Nevertheless, "among young people who have never smoked...0% report continued e-cigarette use and 0% expect to try an e-cigarette soon." The study reports that: "Among adults, electronic cigarette current use...remains at 0% among those who have never smoked."¹⁷

Even with unregulated marketing of e-cigarettes without the warnings required on other smokeless tobacco products, almost no non-smokers were attracted to e-cigarette use in these surveys conducted by anti-smoking advocates. This strongly suggests that e-cigarettes are simply not attractive to teens and other non-smokers and that it should be possible to market these products to smokers without fear that large numbers of teen and other non-smokers who would not have initiated tobacco use would do so in response to such marketing.

Consumption of cigarettes by mental health patients

Adults who suffer from depression are twice as likely to smoke and also smoke more heavily than adults not depressed, according to a survey from the National Center for Health Statistics.¹⁸ Persons with a mental disorder in the month prior consumed approximately 44.3 percent of the cigarettes smoked by those in the National Comorbidity Survey, a nationally representative sample survey conducted from 1991 to 1992.¹⁹

Anecdotal reports indicate that depressed patients and those with bipolar disorder and/or schizophrenia find nicotine to be a highly beneficial drug that enables them to get through the day in emotional balance and with substantially fewer side effects than usually prescribed medications. The reports noted above and beyond these anecdotal observations clearly indicate that nicotine is beneficial for a significant portion of the mental health patient population, and that total elimination of self-prescribed nicotine, as desired by many anti-tobacco advocates, would be harmful to these mental health patients.

Additional bibliographic references dealing with these and other issues are available on request from Dr. Nitzkin.

¹⁶ Action on Smoking and Health, "Use of e-cigarettes in Great Britain among adults and young people," May 2013. http://ash.org.uk/files/documents/ASH_891.pdf

¹⁷ Michael Siegel, "UK Study Fails to Find a Single Nonsmoker - Youth or Adult - Who Regularly Uses Electronic Cigarettes," Tobacco Analysis, May 9, 2013. <http://tobaccoanalysis.blogspot.com/2013/05/uk-study-fails-to-find-single-nonsmoker.html>

¹⁸ "Depressed adults smoke more: study," Phys.org, April 14, 2010. <http://phys.org/print190471659.html>

¹⁹ Karen Lasser, et al, "Smoking and mental illness: A population-based prevalence study," Journal of the American Medical Association, November 2000. <http://www.ncbi.nlm.nih.gov/pubmed/11086367>