

statement by
Joel L. Nitzkin, MD, MPH, DPA
with extensive background material and annotated bibliography
in opposition to **SB 648** – a bill to extend bans on smoking to include use of e-cigarettes
California Assembly Governmental Org. Committee, August 14, 2013

Joel L. Nitzkin, MD, MPH, DPA
Principal Consultant, JLN, MD Associates, LLC
Past Co-Chair, Tobacco Control Task Force
American Association of Public Health Physicians
Senior Fellow for Tobacco Policy, R Street Institute
4939 Chestnut Street, New Orleans, LA 70115-2941
Phone 504 899 7893; Fax 504 899 7557; Cell 504 606 7043
www.jln-md.com; jln@jln-md.com
jln--md@mindspring.com

Verbal Presentation:

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-1990's. The views I am expressing today are entirely my own, and not on behalf of any third party.

I am here to speak against SB 648. This bill would prohibit e-cigarette use in areas where smoking is banned. My opposition is based on two observations: 1) exhaled e-cigarette vapor presents no threat to non-users that would justify such a ban; and 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 to the cigarette that can reduce the risk of tobacco-attributable illness and death by 98% or better, 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.

The cigarette is the most hazardous and most addictive of 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 the chewing tobacco, snus, e-cigarette and other products on the American market pose a risk of tobacco-attributable illness and death less than 2% the risk 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 USA, and one in Great Britain, showed that 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, the cigarette was so dominant a tobacco product in the USA 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, the 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 the huge differences in risk, comparing 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.

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

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, continuing 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 lack of attractiveness 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.

Yes, more research is certainly in order. Meanwhile protecting the health of the public is best done by implementing what we already know about the determinants of tobacco-related harm.

SB 648 is a step in the wrong direction. It will do more harm than good in terms of protecting the health of the public. I urge its defeat.

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.

This statement is supplemented with a written handout that includes much more detail as to who I am and why I am here, plus a brief annotated bibliography to back up statements made in this presentation.

One of the problems in coming in from out of state and not being immersed in the California policy milieu is not being sure which issues are uppermost in the mind of the legislators who will be voting on a particular bill. One issue, in particular I would welcome the opportunity to discuss, if it is of interest to the committee, is the issue of conflicts of interest. I would welcome the opportunity to discuss this or any other issues of concern on this bill, not otherwise addressed in this presentation.

Thank you.

Introduction to Dr. Nitzkin and Disclaimer

I have been involved with tobacco control since the late 1970's. 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, I, and my AAPHP colleagues decided to do our own independent literature review to determine the best way for the USA 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 today are entirely my own, they do not reflect position statements formally adopted by AAPHP, R Street or any other organization I am affiliated with. Neither I nor AAPHP have ever received any direct or indirect financial support from any tobacco, e-cigarette or pharmaceutical enterprise. My travel here, today, is supported by the R Street Institute, a Washington-DC 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% 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 newly established Center for Tobacco Products of the FDA. We are now four years past the establishment of the FDA Center for Tobacco Products by the Family Smoking Prevention and Tobacco Control Act. This FDA 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 SB 648 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 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 far-lower- risk products.

Condemning e-cigarettes has the practical effect of protecting cigarettes from competition from these far-lower-risk 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.

www.quitsmoking.about.com/cs/secondhandsmoke/g/ETS.htm

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% of the smoke, including the tar and most of the nicotine. The major gas present is carbon monoxide. About 85% of the ETS in a room comes from side-stream smoke. ETS increases the risk of lung cancer, other cancers, heart and lung disease, increases the risk of low birth weight and is suspected as increasing the risk of birth defects. All this is in addition to the known irritation of eyes, throat and respiratory mucous membranes.

www.ccohs.ca OSH Answers, Environmental Tobacco Smoke.

2006 Report of the Surgeon General The Health Consequences of Involuntary Exposure to Tobacco Smoke

California Environmental Protection Agency Fact Sheet: Environmental Tobacco Smoke: A Toxic Air Contaminant

JLN note: 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 USA from exposure to environmental tobacco smoke. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm

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. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm
2. The smokeless tobacco products that have been on the American market since at least the 1980's are estimated to pose a risk of potentially fatal illness less than 2% the risk posed by cigarettes. Thus, contrary to common perception, different tobacco products present dramatically different risks of potentially fatal illness.

Rodu B: The scientific foundation for tobacco harm reduction, 2006-2011. Harm Reduction Journal 8:19 2011.
www.harmreductionjournal.com/content/8/1/19

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. 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.

Burstyn I: Peering through the mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks?
<http://publichealth.drexel.edu/SiteData/docs/ms08/f90349264250c603/ms08.pdf> August 2013.

- 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.” McAuley TR et al: Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhal Toxicol* 24(12) 850-857 2012.

- b. Nitrosamine levels for e-cigarettes were similar to the levels in Nicorette gum and NicoDerm patches, but less than 100th to 1,000th the level in a wide range of smokeless tobacco and cigarette products. Cahn & Siegel, J Public Health Policy 2011.
- 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. Romagna, Farsalinos et al SRNT Europe 2012.
- 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. Siegel M: www.tobaccoanalysis.blogspot.com/2013/07/anti-smoking-researcher-misleads-public.html . July, 2013
- 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. Farsalinos et al, TMA 2013.

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 6(six) nonsmokers who had ever used e-cigarettes. Siegel M: Blogpost May 2013 <http://tobaccoanalysis.blogspot.com/2013/05/national-study-of-adults-can-find-only.html>
McMillen R et al: Use of Emerging Tobacco Products in the United States. Journal of Environmental and Public Health 2012 Article ID 989474 www.hindawi.com/journals/jep/2012/989474/

In a second study that blows out of the water the anti-smoking groups' contention that electronic cigarettes appeal to nonsmokers, especially youth, and will lead to increased smoking, Action on Smoking and Health (ASH-UK) was unable to find a single nonsmoker in Great Britain - either youth or adult - who regularly uses electronic cigarettes. The study, released this week, involved a survey of 12,171 adults and 2,178 children ages 11-18 in February and March of this year. Despite widespread awareness of electronic cigarettes among youth and adults, the survey failed to find a single adult or youth never smoker who regularly uses electronic cigarettes. Awareness of electronic cigarettes was 67% among 11-18 year-olds and 83% among the 16-18 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." Siegel, M Blogpost dated May 2013: <http://tobaccoanalysis.blogspot.com/2013/05/uk-study-fails-to-find-single-nonsmoker.html>. ASH/UK Factsheet dated May 2013: www.ash.org/uk/files/documents.ash.891.pdf

JLN Note: 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 per a survey from the National Center for Health Statistics, May 2013. www.physorg.com/print190471659.html

Persons with a mental disorder in the month prior to this national comorbidity survey consumed approximately 44.3% of the cigarettes smoked by this nationally representative sample. Lasser K et al Smoking and mental illness: A population-based prevalence study. JAMA 2000; 284:2606-2610.

JLN note: 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 less side effects than usually prescribed medications. The reports noted above and these anecdotal observations clearly indicate that nicotine is beneficial for a significant portion of the 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.