

# Critical review of Background Paper on E-cigarettes by Stanton Glantz

*“Youth are rapidly adopting E-cigarettes” (page 2 line 4)*

Youth are still trying tobacco at a rate of 25.9%, compared to the increase from 4.7% to 10% for E-cigarettes (CDC data). It is worth mentioning, the vast majority of young vapers began with tobacco, and Stanton Glantz reports an association with youth, and effectively using Vapor Devices to quit Tobacco. *(page 30 lines 23-25)*

*“High Levels of Dual Use” (page 2, line 6)*

While any tobacco usage does indeed increase risk of death significantly, vapor devices are used primarily by smokers as stated on page 29 lines 8-9, page 31 line 12, page 32 line 26, and page 33 line 17, of Background Paper on E-cigarettes by Stanton Glantz. Glantz goes on to confirm that “reduction in cigarettes per day were observed in several of the clinical studies” (page 71 line 3), again on page 59 where he reports “89% (of vapers) decreased cigarettes per day by an average of 39%” and again on page 68 lines 16-21:

*Fifty-seven percent of participants in the nicotine e-cigarette group reduced their cigarettes per day by  $\geq 50\%$  by 6 months compared to 41% in the patch group ( $p=0.002$ ) and 45% in the non-nicotine e-cigarette group ( $p=0.08$ ). Those randomized to the nicotine patch group were less adherent to the treatment (46%) than the 16mg e-cigarette group (78%) and the no-nicotine e-cigarette group (82%). (page 68 lines 16-21)*

Tobacco in any amount kills, there’s no question, but on page 75 lines 10-11 Glantz reports dual users “would have a longer lifespan.”

*“youth who use E-cigarettes are heavier (not lighter) smokers; youth who use e-cigarettes are much less likely to have stopped smoking” (page 2 lines 7-8)*

Unfortunately, Glantz does not provide the research he bases this conclusion on, but it is important to note, correlation does not entail causation. It is equally possible that heavier youth smokers who are unable to quit, are turning to vapor devices as means of replacing their tobacco addiction.

*“the temporal and causal relationships between e-cigarette use and smoking have not been determined”(page 2 line 10-11)*

As is the case with most of Glantz's conclusions, unknowns are presented as facts, and facts are ignored in arriving at conclusions; Fortunately, he at least reports the facts:

*"88% (of vapers) reported being "ex-smokers," with an average of 9 quit attempts before using e-cigarettes. Two-thirds had tried previously to quit by using FDA approved cessation devices and 99% felt the e-cigarettes helped with quit attempt. (page 32 lines 26-28)*

Individuals begin with tobacco, and the cause to switch to E-cigarettes is a desire to quit, and the inefficacy of traditional NRT products.

*"E-cigarettes have not been proven to help people quit smoking"*

Again, it is unclear as to how Glantz arrives at this conclusion; from Glantz's own report:

*22% of smokers (occasional and daily) at baseline had quit smoking at one-month, and 46% had quit at one year. (Page 31 lines 30-31)*

*31% (of vapers) reported they were not smoking tobacco cigarettes at the 6 month Survey timepoint. (Page 33 line 4)*

*"42% (of vapers) reported that they achieved complete substitution in the first month of using the devices" (page 33, lines 30-31)*

*"41% and 66% (of vapers) reported no conventional tobacco cigarette smoking at the time of survey" (page 33 line 19)*

*"two-thirds had tried previously to quit using FDA approved cessation devices, and 99% felt the e-cigarettes helped with quit attempt" (page 32 lines 27-28)*

*Smokers who had used e-cigarettes to quit were younger, more highly motivated to quit, had greater self-efficacy for quitting, and reported a longer recent quit duration than smokers who had not used e-cigarettes to quit. (page 30 lines 23-25)*

*"Seventy-four percent of respondents (vapers) who had used an e-cigarette reported not smoking for at least a few weeks." (page 33, lines 10-11)*

*"It is possible that e-cigarettes even without nicotine act as substitutes for the sensory and behavioral effects of conventional cigarettes. (page 70, lines 11-12)*

*"73% of users started with intention to quit smoking and 88% reported being "ex-smokers," with an average of 9 quit attempts before using e-cigarettes. Two-thirds had tried previously to quit by using FDA approved cessation devices and 99% felt the e-cigarettes helped with quit attempt. (page 32 lines 26-28)*

{Aside from the remarkable result of 88% of the respondents actually reporting they had quit tobacco altogether, it is equally as impressive that 15% quit, even though they had not originally intended to.}

The effectiveness of quitting with traditional NRT therapies is 7%; the data presented by Glantz indicates that vapor devices range from 314%-1257% more effective than traditional NRT therapy.

*E-cigarettes pollute the air less than conventional cigarettes, but they pollute the air"*

Glantz confirms that vapor is primarily composed of well studied compounds generally regarded as safe by the FDA, and presents data showing the levels of detected potentially harmful VOCs in exhaled vapor are in line with VOC production of exhaled breath.

*"aerosol in both nicotine and non-nicotine e-cigarettes was primarily comprised of propylene glycol and glycerol" (page 43 lines 13-14. {both propylene glycol and glycerol have been granted GRAS (Generally Regarded As Safe) status by the FDA}*

*"the level of minor alkaloids in aerosol were below the limit of detection for both e-cigarettes" (page 40, lines 14-15)*

*"Table 3" (page 43) [showing levels of VOCs in e-cigarettes that are undetectable, or on par with normal human exhalation.]*

In the original paper referenced by Glantz, the author states the detected VOCs

*"might be caused by the person in the chamber itself, because people are known to exhale formaldehyde in low amounts...the rising concentrations of acetic acid and acetone during e-cigarette operation may also be attributed to the metabolism of the consumer." (T Shripp, 2012 page 28).*

It should also be noted that most VOCs in tobacco are not detectable at any level in vapor, and even those that are found in both, tobacco VOCs are at levels approaching 6000% higher than vapor.

*"People passively exposed to e-cigarettes aerosol absorb nicotine (measured as cotinine) with one study showing levels comparable to passive smokers"*

This study Glantz references by Flouris et al, is fundamentally flawed as generates main stream using an air pump at unrealistic concentrations, then erroneously calls this "second hand vapor" (page 62 line 13)

There is no side stream vapor with vapor devices, the only "2<sup>nd</sup> hand vapor" comes from human exhalation. 98% of nicotine from E-cigarettes is absorbed by the human lungs; an air pump is only capable of generating "main stream" vapor that has never

passed through a primary users' lungs, thus the study's conclusions are fundamentally flawed and deliberately misleading.

Glantz admits the study's conditions:

*"are extremely high, {and} may not be realistic for indoor spaces" (page 62, line 16, page 64 line 6)*

Also, there was no ventilation specified (*page 62 10-11*)

*"There is little research on direct effects"*

Direct effects are irrelevant to a public use ban however it's worth nothing "direct effects" must be compared to direct use of tobacco cigarettes, which Glantz agrees are much more harmful.

*"Prohibit the use of e-cigarettes anywhere where the use of conventional cigarettes is prohibited" (page 3, line 8-9)*

to follow this recommendation would take away the immense benefits as stated by Glantz and discussed above, based on nothing more than conjecture and supposition of potential future harm, and willful ignorance of data Glantz himself presents.

*"the majority of e-cigarette users were cigarette smokers when they initiated e-cigarette use" (pp 33 ln 16-17) and "the most common reason given to try e-cigarettes was to use them in places where smoking is restricted." (pp 37, ln 28-29)*

It is a utterly baffling how one can conclude that public use should be banned, when public use is a strong reason for adoption of a product that Glantz confirms saves lives by acting as the most effective cessation tool on the market, and pose little to 0 risk to bystanders.

*"Ban the use of characterizing flavors in E-cigarettes" (page 3 line 12)*

The myriad of flavors is another aspect of vapor devices that draw smokers away from tobacco, and keep them quit. To ban them, ostensibly because they appeal to children, sets a very dangerous precedent; are we also going to ban flavoring in coffee because caffeine has potential for addiction?

*"Prohibit claims that e-cigarettes are effective smoking cessation aids until such time as there is convincing scientific evidence that such claims are true for e-cigarettes as they are actually used in the general population." (page 3 lines 12-15)*

If the future of a life saving device did not hang in the balance, this statement would actually be comical. Glantz himself provides no fewer than 8 scientific studies

characterizing use in the general population, all of which showed quit rates at 314%-1257% the quit rate of approved NRT therapy.

Both sides of the debate can agree however, that strong quality control standards need to be put in place, and this is not a product that should be marketed to children; this however falls into the jurisdiction of the federal, not state government.

*“Interest in the products has been increasing (Ayers et al., 2011) and an exponential rise in sales over the past 3 years (2010- 2013) has been due, at least in part, to widespread advertising via television commercials and print advertisements, that often feature celebrities, for the most popular brands” (page 6)*

Vapor devices are a new product, and exponential growth is common in any new product adoption curve.

*“In 2009, the WHO Study Group on Tobacco Product Regulation (TobReg) addressed the emerging regulatory issues pertaining to e-cigarettes. TobReg noted that there was very little published scientific evidence on the health effects of e-cigarettes, or their efficacy for smoking cessation (stated in TobReg Report 955)(World Health Organization, 2009) and that there was not sufficient evidence to support the cessation and health claims made by companies and those in the public health community who were advocating e-cigarettes for harm reduction.” (page 6)*

Its been 5 years since this was published, and Glantz himself has published an excellent body of research confirming that vapor devices are effective cessation and harm reduction tools.

*“There is concern about potential health effects of chronic inhalation of the vaporized base components of the e-liquid.” (page 15 lines 24-25)*

This statement is vague and misleading. Unfortunately to make the case against vapor devices, one must rely on these vague “concern about potential” risk that are completely unsubstantiated, because the substantiated evidence indicates there is little to no harm.

*“For example, claims that e-cigarettes are less harmful than cigarettes may encourage adoption by non-smokers (potentially children)” (page 17 lines 26-27)*

Again, Glantz contradicts his own admission that they are indeed less harmful than tobacco, and can only allude to potential future harm, because the actual data he presents indicates:

*“As with adult population-based studies, data suggest that e-cigarette use is most appealing and prevalent among youth who are also experimenting with or current users of tobacco cigarettes.” (page 38 lines 18-20)*

*“3.2% of never smokers had tried an E-cigarette” (page 37, lines 7-8)*

*“1.1% current use among non-smokers or former smokers” (page 35 line 9)*

The data presented on *page 29 lines 8-9, page 31 line 12, page 32 line 26, page and 33 line 17*, also confirm that this product is used principally by smokers and the rate of new user initiation is well below that of tobacco adoption or current use by both adults and youth.

*Whether the levels of toxicants in e-cigarette aerosol indicate an actual health risk compared to the nicotine inhaler is unknown, but toxic deliveries from both were far lower than from conventional cigarettes. (page 41, lines 23-25)*

Again, Glantz treats an unknown as a fact, and ignores actual quantitative facts in arriving at his conclusion.

*Given these uncertainties, it is not clear to what extent the ultrafine particles delivered by e-cigarettes will have similar health effects and toxicity as ambient fine particles*

Glantz, in what appears to be a strained attempt to find something harmful about vapor, results to essentially saying “they’re the same size particle as harmful stuff, so they might\* be harmful.” They’re also the same size particle as life saving drugs!

*Cytotoxicity was related to the concentration and number of flavorings used.*

In vitro analysis bears no relevance to this discussion; if you pour alcohol on cells in a petri dish, they’re going to die, if you pour vinegar on cells in a petri dish, they will die, if you pour lemon juice on cells in a petri dish they die; all of these are consumed regularly by humans.

*“The thresholds for human toxicity of potential toxicants in e-cigarette aerosol are not known” (page 53 line 8-9)*

Glantz is deliberately ignoring the facts, and at best can only raise questions regarding potential harm. No evidence has ever proved harm from propylene glycol or glycerin, (FDA GRAS compound) and the levels of VOCs and trace elements are in line with being in a close space with another human being, or outside in a large metro area.

*“E-cigarette use, with or without nicotine, decreased some nicotine/tobacco abstinence withdrawal symptoms, including cigarette craving, although not to as great an extent as smoking a conventional cigarette.” (Page 54, lines 1-3)*

This quote gives us some insight into why we see such phenomenal quit rates with vapor devices, and also clarifies the impact a ban would have on the public health. Smoking is an incredibly tough habit to break; making vaping as attractive as possible through allowing public may eclipse the perceived deficit in satisfaction from making the switch.

*“The authors concluded that e-cigarettes deliver nicotine, can reduce withdrawal symptoms and appear have lower abuse potential compared to conventional cigarettes”*

Glantz confirms again, that vapor devices are an effective quitting tool, with low abuse potential.

*Active e-cigarette use and passive exposure to e-cigarette aerosol did not result in a statistically significant increase in these biomarkers over one hour of exposure. this study suggests that the increase in white cell count is mediated more by tobacco combustion products than by nicotine.*

The bio makers analyzed were white blood cells, and Glantz’s again confirms that vapor devices and tobacco cigarettes are completely different, and no demonstrated harm has come to bystanders from passive vaping.

*As part of what appears to be a broad consensus in the UK that the introduction of e-cigarettes will reduce the harm of smoking, the anti-smoking advocacy group Action on Smoking and Health (ASH) UK has announced that it "does not consider it appropriate to include e-cigarettes under smokefree regulations" (page 84 lines 13-16)*

This anti-smoking group has looked at the facts, and came to the conclusion that e-cigarettes pose no danger to bystanders, and are immensely helpful at ending the #1 preventable cause of death worldwide.