

A Public Health Perspective on Tobacco Harm Reduction
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to AMA Reference Committee D and House of Delegates
On behalf of the American Association of Public Health Physicians
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Introduction and Summary

This White Paper has been generated in response to the AMA CSAPH Report 5-A-18, titled “Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking (Resolution 403-A-17).”

Based on the analysis presented herein, the American Association of Public Health Physicians (**AAPHP**) **recommends that CSAPH 5-A-18 report be referred back to CSAPH for further development.** As seen by AAPHP, the current report is incomplete and contains multiple misleading and technically incorrect assertions.

As seen by AAPHP, the Council, in its review of this literature, did not consider federally sponsored survey data from the US, Great Britain, and other countries that show substantial reductions in both teen and adult smoking in response to the introduction of e-cigarettes, related vapor products and other relatively low-risk alternatives to cigarettes. They seemed to uncritically accept deeply flawed studies dealing with teen recruitment, smoking cessation and toxicity of these relatively low risk products. The Council disregarded the long-term limitations of current pharmaceutical protocols and did not consider the inherent bias against tobacco harm reduction implied by the goal of “a tobacco-free society.”

Our AAPHP 14-page White Paper provides specific information about the additional work that will facilitate Council re-analysis of the issue of tobacco harm reduction. By aligning policy with science, we hope our AMA will play a more substantial role in guiding national policy toward a future virtually free of tobacco-related addiction, illness and death.

Current tobacco control policy appears to be rooted in questionable concepts. The first questionable concept is that smoking is a disease, not a behavior. The second questionable concept is that all non-pharmaceutical nicotine products are similar in addictiveness and risk.

Because non-pharmaceutical nicotine products are deemed, in current tobacco control policy, to be similar to each other in addictiveness and risk, federal and AMA policy documents tend to use the terms “tobacco use” and “smoking” as if they were essentially synonymous. From a quantitative risk perspective, nothing could be further from the truth.

There are major differences in the risk of disease and death, and possibly differences in the risk of addictiveness, among the different classes of non-pharmaceutical tobacco products. To most effectively prevent tobacco-related harm, we must understand and communicate accurately the truth about relative risks.

With rare exceptions, E-cigs and other smokeless products are not manufactured, promoted, or sold as drugs. They are consumer-product alternatives to cigarettes whose popularity among smokers is based

on satisfaction, cost, taste, and a reasonable presumption of reduced risk. Randomized clinical trials of behavioral interventions and consumer products may be of limited value for determining their efficacy and public health benefit, because the characteristics most important to their use tend to be the very factors controlled for in such clinical trials. The optimal research agenda should consider the full range of evidence outlined in the Bradford Hill criteria for determining causation in epidemiologic studies.¹ Such evidence is available, but is not given the weight it deserves in CSAPH 5-A-18.

The complexity of determinants of cigarette use, especially by teens, is well described in Surgeon General Reports.^{2,3} This mix of behavioral, symbolic and drug-related factors should be considered in the context of tobacco control policy development. Time trends suggest that the tendency of e-cigs to make cigarettes and other combusted tobacco products “uncool” seems to have contributed to the remarkable reductions in teen smoking during the e-cig era.

The false impression that e-cigs recruit non-smoking teens to cigarette use is based on studies that compares youth inclined to experiment with those not so inclined, and conflates one-time experimentation with continuing use.

Careful consideration of tobacco harm reduction is recommended because of evidence that it could offer personal and public health benefits not likely achievable by other means, and do so while reducing the recruitment of teens to a lifetime of nicotine addiction.

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Problematic Aspects of Current CSAPH Report, requiring referral for re-examination and correction:

1. **The report fails to recognize currently available evidence for potential benefits that could be secured with Tobacco Harm Reduction (THR).**
2. The report fails to acknowledge the accelerated reductions in both teen and adult smoking prevalence concurrent with the introduction of e-cigs into the American market.
3. This report fails to recognize the large magnitude of difference in risk between combustible cigarettes, and smokeless tobacco and other non-combustible tobacco-related products.
4. In particular, this report fails to recognize published literature demonstrating that the smokeless tobacco products most prominent on the American market since the 1980's present no statistically significant risk of mouth cancer or any other potentially fatal tobacco-related disease in never-smokers⁴⁻⁸ – even in a large and recently published meta-analysis.⁴
5. This report erroneously asserts that non-combustible products may make smokers less inclined to quit smoking.
6. This report fails to acknowledge the evidence that e-cigs are likely to have played a major role in diverting teen and adult smokers, and potential teen smokers, away from cigarettes and away from a lifetime of tobacco-related addiction.
7. This report erroneously asserts that dual use represents harm, when most dual use represents substitution of e-cigs for cigarettes.
8. This report uncritically accepts poor-quality evidence that noncombustible products may lead to teens to cigarette use, that they may be ineffective for smoking cessation, or that they may present excessive toxicity. Such literature abounds in errors in study design and data interpretation. Some published studies even reach conclusions opposite what their data show, possibly in order to be consistent with currently preferred policy options.
9. This report fails to recognize the remarkable long-term ineffectiveness of the so-called “evidence-based” smoking cessation protocols. This report refers to them in ways that erroneously imply high effectiveness.
10. This report fails to recognize action taken by FDA to authorize a change in labeling for the pharmaceutical nicotine replacement therapy products to allow unlimited use with unlimited dose and use while continuing to smoke, based on uncontrolled studies by investigators largely dependent on pharmaceutical funding.⁹
11. This report fails to acknowledge that the claim that light cigarettes are safer than full-flavor cigarettes originated with the American Cancer Society, not the “big-tobacco” cigarette companies.¹⁰⁻¹²
12. This report fails to recognize the defects in the text of the federal tobacco control law and FDA implementation of the law in ways that have now resulted in years of federal regulatory paralysis.
13. This report fails to recognize that the FDA plan to reduce nicotine in cigarettes to non-addictive levels cannot possibly secure the desired public health benefits unless low-risk non-pharmaceutical nicotine delivery products are readily available on the market that can satisfy the urge to smoke for most smokers.
14. This report fails to recognize the need for improvement and updating of AMA tobacco policy relative to separation of smoking from other tobacco use. (Current text of most AMA tobacco policy appears to use the terms “smoking” and “tobacco use” as if they were synonymous.)

These problematic aspects are not unique to this CSAPH report. They have largely guided AMA policy these past few years, and are reflected in CDC, FDA, Heart, Lung, Cancer and other pronouncements. Addressing these issues in a more technically sound manner could enable AMA to play a major role in helping guide national tobacco control policy.

[To save paper and copying costs, most paper copies will stop here. Please access the full 14-page report at <http://www.aaphp.org/TobaccoHarmReductionJune2018> .]

Prior Experience with Tobacco Harm Reduction

The only historical model that we have that illustrates the impact of health authorities endorsing tobacco-related products for harm reduction is the experience with health authorities urging smokers to switch from “full flavor” to filter and low-tar cigarettes. It took about 30 years for smokers and manufacturers to switch from full flavor cigarettes to more than 90% filter and low tar cigarettes.¹³ This experience did not reduce illness or death, but it taught us two things: 1) both smokers and manufacturers will respond to harm reduction messaging; 2) advising the public that filter and low tar cigarettes may be less hazardous than cigarettes did not result in a surge of teen and other non-smokers being recruited to tobacco use.

Teen Recruitment

The case in favor of e-cigs recruiting teens to smoking

The Soneji meta-analysis and nine studies

The most commonly referenced American studies in favor of e-cigs recruiting teens to smoking is the 2017 Soneji meta-analysis of nine surveys.¹⁴ While there are some differences in methodology between them, they all looked at kids whose only baseline exposure was experimentation with e-cigs and kids who had not used any tobacco-related product at baseline, then followed up at a later date to document cigarette use. All showed that the e-cig group was more likely to smoke at follow-up than the baseline zero-exposure group. From this they concluded that e-cigs serve as a gateway to lifelong addiction to cigarettes. Unfortunately, major flaws in study design create a situation in which no such conclusions can be drawn.

The only reasonable conclusion from this set of studies is that kids prone to experiment with nicotine delivery products are more likely to smoke than kids not prone to such experimentation. Furthermore, the failure of these studies to separate one-time or occasional experimentation with cigarettes with continuing use of cigarettes eliminates any conclusions relative to future life-long addiction.

For e-cigs or any other low-risk product to serve as a “gateway” to smoking, one would have to show initial experimentation leading to consistent daily use of e-cigs, then a transition to smoking for a bigger and faster nicotine “hit.” None of the Soneji studies show such progression. In fact, Leventhal, one of the Soneji authors, noted, in informal communications, that so few kids used e-cigs more than 3 days a month, that he could show no such progression.

The Watkins/Chafee/Glantz studies

Two 2018 papers by Watkins, Chafee and Glantz are referenced in the CSAPH report as their evidence for e-cigs recruiting kids to smoking.

The first of these papers, titled “Association of Noncigarette Tobacco Product Use with Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015”¹⁵ found a correlation between the number of teens smoking cigarettes at follow-up, and prior ever-use of other “tobacco products” Of the 219 new teen smokers, 175 were “never tobacco users” at baseline; 11 had used e-cigarettes; 18 had used other products; and 15 had used two or more products. Although the Odds Ratios were higher for baseline users, the numbers were small. A full 79.9% of the observed youth smoking could not be associated, either causally or via unmeasured confounding variables, with preceding E-cig use or use of any other tobacco product at baseline.¹⁶

The second paper, titled “Electronic Cigarette Use and Progression from Experimentation to Established Smoking”^{17a} had an even more substantial flaw. When Rodu and Plurphanswat further stratified “adolescent cigarette experimenters” by the number of lifetime cigarettes smoked at baseline, the supposed differences in “progression to established smoking” were markedly reduced and lost statistical significance in every subgroup.^{17b} In response, Chaffee et al. concede that the “number of cigarettes smoked” is “a predictor of established smoking”, but defend their failure to adjust by speculating (without visible evidence) that “trial of e-cigarettes leads youth to smoke more conventional cigarettes on the way to becoming established smokers”.^{17c} Rodu claimed full vindication.^{17d}

We analyze these articles, and their responses, at some length – even though it may be a “side argument” to the broader debate about Tobacco Harm Reduction – because these exchanges show two critically important points.

The first is that – because smokeless products (including, but not limited to, e-cigarettes) have much lower toxin exposures, and are thus likely to be much less dangerous, than combustible cigarettes – the effect of smokeless products on uptake and maintenance of combustible cigarettes is the only Public Health battleground on which moral crusaders in “Tobacco Control” can respectably engage. The lengths to which Harm Reduction’s opponents will go to make their case are significant because the underlying premise of Harm Reduction – that different tobacco-related products have markedly different risk characteristics – is conceded by almost all serious researchers, though not yet communicated adequately to the profession or the public.

The second is that, especially when a paper’s conclusions are popular, it is vital to verify whether the underlying data and the study methods validate the case that is made in the summary. (This is a necessary, but easily omitted, step in “peer review”.) Based on data that were not adjusted for a clearly established predictor variable that was linked to the variable under study, Chaffee et al. concluded that, “For these youth, e-cigarettes appear to encourage progression to established smoking.” The actual data show that for “these youth”, the number of cigarettes smoked is a powerful predictor of subsequent smoking – to such an extent, that the purported “encouragement” effect of e-cigs mostly disappears! – so the Chaffee paper’s data do not support its conclusions.

Case in favor of e-cigs diverting teens away from cigarettes

The question as to whether e-cigarettes recruit American teens to nicotine addiction may already have been answered. In June 2017, the Centers for Disease Control (CDC) published its 6th annual report showing use of tobacco-related products by high school students, by type or product, including e-cigarettes.¹⁸ During this period, e-cigarette use has gone from 1.5% of high school students in 2011 to 16.0% in 2015 and 11.3% in 2016, with significant reductions in cigarette use almost every year and no significant change in the percentage of high school students using any tobacco-related product. The data on middle school students reflects the same pattern, with much smaller numbers. If, as alleged by Soneji et al, e-cigarettes were attracting significant numbers of teens who otherwise would not have used any tobacco product, there should have been significant year to year increases in the percent of teens using tobacco-related products. This did not occur! The fact that this has occurred year after year validates the impression that the teens attracted to e-cigarettes are those who would have used

cigarettes, had e-cigarettes not been available. **These survey results are strong evidence that e-cigs have reduced youth cigarette use, and, as such, have been beneficial to the public’s health.**

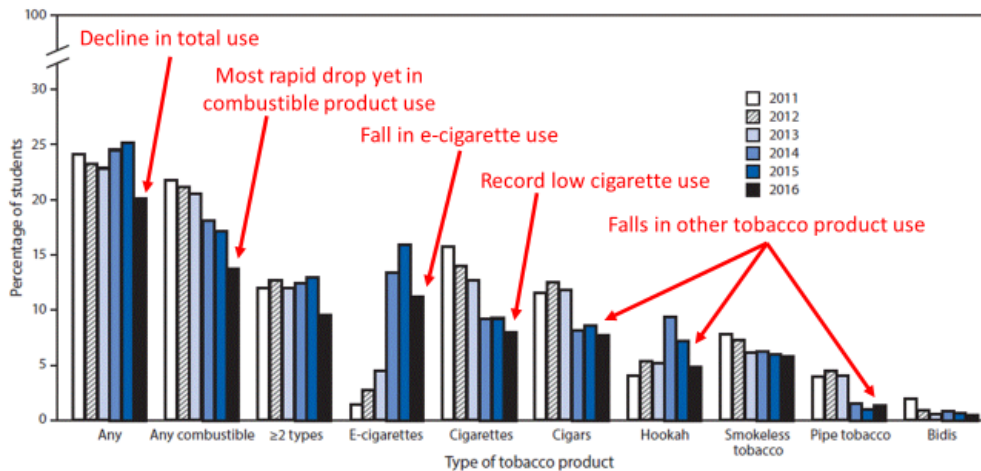
In the SAMHSA Monitoring the Future Surveys from the same period,¹⁹ 60% of teen vapers used flavor-only e-cigs, with no nicotine. The CDC surveys considered all e-cigs to be “tobacco-related” products and did not separate out those with zero nicotine. If CDC had adjusted survey data for these zero-nicotine e-cigs, then the percentage of teens using any nicotine-containing product would have shown decreases year by year.

These population survey data represent one of the best possible ways of documenting the efficacy of e-cigs for reducing cigarette consumption. These conclusions are biologically plausible and meet other Bradford Hill criteria. Given the way these products are manufactured, sold, and used, and given the embedding of all “tobacco-related” products in a social and cultural context, it makes no sense to dismiss these findings because they are not from clinical trials.

Graphics showing Reductions in Smoking in U.S. Teens Concurrent With Increased Use of E-cigs

CDC graphic and Bates graphic of Monitoring the Future (SAMHSA) data; cut and pasted from Bates, June 2017. The two charts that follow are annotated to show salient features of data on youth smoking in the United States. The first chart is from the National Youth Tobacco Survey, published June 2017.¹⁸

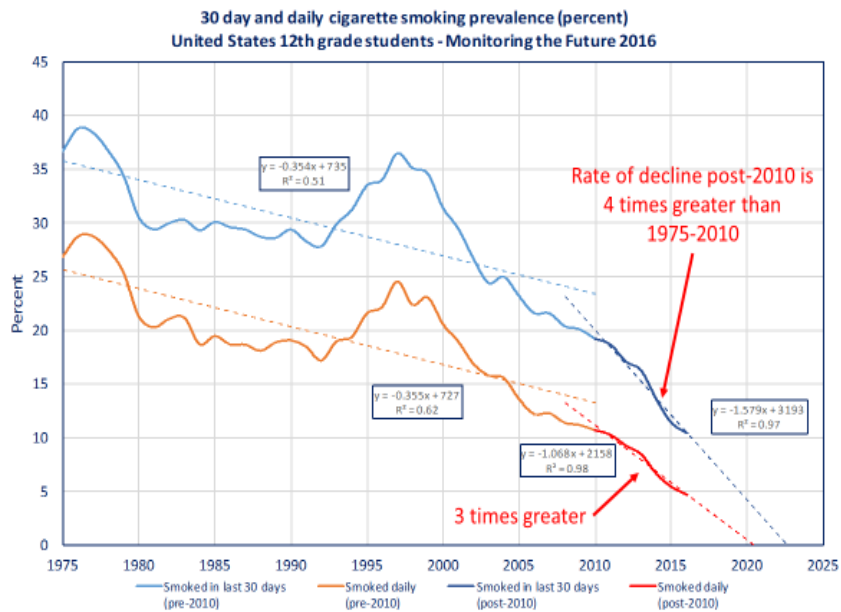
FIGURE 1. Estimated percentage of high school students who currently use any tobacco products,* any combustible tobacco products,[†] ≥2 tobacco products,[‡] and selected tobacco products – National Youth Tobacco Survey, United States, 2011–2016^{§,¶,††}



* Any tobacco product use is defined as past 30-day use of electronic cigarettes, cigarettes, cigars, hookahs, smokeless tobacco, pipe tobacco and/or bidis.

Figure 1 is from the MMWR of June 16, 2017. The supplemental red notations and arrows were inserted by Clive Bates. This graph shows declines in use of all combustible tobacco products, 2011-2016, with huge increases in e-cig use 2011-2015, then a decrease in 2016. From 2011 through 2015 there was no significant change in the percentage of students using tobacco products, despite the huge increase in e-cig use. 2016 showed a decline in the percentage of teens using any tobacco product. These data provide strong evidence that the vast majority of students using e-cigs were students already using, or likely to use, tobacco products. They suggest very strongly that the reductions in use of the other tobacco-related products (including cigarettes) may have largely been due to teens using e-cigarettes instead.

The second graphic, as shown on this page, is derived from data from the 2016 University of Michigan Monitoring the Future survey, which has a time series dating back to 1975 for 12th grade smoking.¹⁹ Clive Bates generated this graphic to show the increase in rate of decline after introduction of e-cigarettes (2010-2015). This provides further evidence that this accelerated rate of decline is likely due to teen smokers switching to e-cigarettes plus teens who otherwise would have initiated smoking being diverted to e-cigarettes.



Two Papers by Konstantinos Farsalinos and one by Villanti et al

Konstantinos Farsalinos is a Cardiologist in Greece who has been very active in e-cig research. In 2018 he published two papers of interest here. One, in the American Journal of Preventive Medicine²⁰, summarizes the data showing that almost all e-cig use by American adolescents is by teen smokers, with e-cig use rare among never-smoking adolescents. The second paper, published in the Harm Reduction Journal,²¹ shows the same for teens in Greece.

The same conclusion was reached by Villanti et al in a 2017 paper published in Nicotine and Tobacco Research. This one was based on 2014 National Youth Tobacco survey (NTYS) data.²²

The difference in findings between these papers and the ones previously referenced by Soneji, Watkins, Chafee and Glantz, is because Soneji et al conflated one-time experimentation with continuing use, while Farsalinos and Villanti only looked at continuing or frequent use. In other words, a significant number of non-smoking youth experiment with e-cigs, but very few follow through.

A brief note about flavoring in tobacco-related products

If, as noted above, e-cigs are not attracting non-smoking teens to either cigarettes or long-term use of any tobacco-related product, there is no justification for banning flavoring of e-cig products to reduce their attractiveness to teens. Contrary to conventional wisdom in the tobacco-control community, such flavoring is not intended to attract teens to e-cig use. It is essential for attracting smokers to e-cig use,

then preventing their future relapse to cigarettes by making the taste of tobacco unpleasant. This issue is discussed in yet another paper by Farsalinos.²³

Smoking Cessation

The problem with published studies and tobacco control pronouncements is that FDA considers all smoking to be a disease (not a behavior), with any claim for efficacy to require licensure as a drug. That being said, the studies by which the pharmaceutical gums, patches, etc. were licensed were all short-term studies. Generally speaking, cigarette abstinence rates at 12 weeks, the end of the usual trial, are about 40%. This falls to about 6% to 10% when results are measured at 6-12 months, compared to a usual control rate of about 3% per year. In the only study I know of that tracked cases and controls to 20 months,²⁴ the abstinence rate among cases was less than that of controls. The problem here is two-fold. First, the pharmaceutical nicotine products do not fully satisfy the urge to smoke for most smokers. The second, is that habituation and addiction to cigarette smoke are chronic, not acute phenomena. Thus, while a short-term treatment might result in short-term abstinence, the urge to smoke will return for most smokers, who will then return to cigarettes. The bottom line is this: The pharmaceutical nicotine products (Nicotine Replacement Therapy –NRT products) fail 90% or more of smokers who use them, when results are measured at 6-12 months, even under the best of study conditions.

With e-cigarettes, and likely with other low-risk non-pharmaceutical options, the dynamics are quite different. Since they satisfy the urge to smoke, smokers are more likely to use them, and more likely to return to them when the urge to smoke returns. This creates a dynamic in which abstinence rates tend to increase, not decrease, over time. Here, flavoring plays an important role. **** Once switched to a fruit or candy flavor, many vapers then find the taste of tobacco to be objectionable, further reinforcing the return to e-cigs rather than cigarettes when the urge to smoke returns. There are even several small studies by Dr. Polosa, a pulmonologist in Italy, demonstrating the tendency for smokers with no intention to quit smoking, to quit.^{25,26} To my (JLN) knowledge, such a e has not been demonstrated for any other product.

Curiously, there is one, and likely more studies by “tobacco control” enthusiasts that claim E-cigarettes are ineffective for cessation, despite study data showing excellent efficacy. A paper by Popova and Ling, in the American Journal of Public Health, in 2013 is one such study.^{27,28} This is mentioned here for two reasons. The first is the efficacy of e-cigs and other THR products for smoking cessation. The other is the tendency of at least some authors to reach conclusions opposite to what their data show, perhaps to be consistent with currently preferred policy options.

Is Smoking a Disease or a Behavior?

As seen by experimenters, novice users, and vapers, smoking is a behavior, not a disease. The efficacy of e-cigs is based on pleasure, satisfaction, low cost, convenience, and, for many, a “coolness,” and ability to be part of a community of vapers. Relying on randomized controlled trials as the “gold standard” for proof of efficacy is problematic, because the factors determining efficacy include social, cultural, and other factors that are largely the ones controlled for in a clinical trial. Considering smoking a behavior (rather than a disease) opens up new possibilities for effective research using the Bradford-Hill criteria for epidemiologic determination of a causal relationship.¹ The nine criteria are strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experimental evidence and analogy. These criteria also open the door to consideration that e-cigs serve as a gateway away from cigarettes for smokers and potential smokers.^{29,30}

One key issue in this debate is the ability of a product to satisfy the urge to smoke, a concept not often addressed in the published literature, but one of importance to both smokers and regulators. The complexity of this issue was addressed early in the e-cig debate within a letter to the editor of Tobacco Control by Tom Eissenberg in 2010,³¹ in which he demonstrated that an early version of the e-cigarette could satisfy the urge to smoke for about one third of smokers, even if it delivered no nicotine. A key difference between the pharmaceutical nicotine replacement therapy medications and consumer tobacco-related products is whether some degree of self-control is required for their use, as opposed to the product effectively delivering the satisfaction previously delivered by cigarettes.

Safety for Users and Bystanders

Safety of e-cigs for users and bystanders is now generally conceded by public health authorities, and by CSAPH report 5. While most hedge on the percentage reduction in risk of potentially fatal cigarette-attributable disease, available data to date show no increase in risk for any such disease. Because of uncertainty due to lack of 30-year follow-up data, based on a paper by Nutt et al in 2014 in European Addiction Research,³² Public Health England³³ quotes the risk as 5% or less the risk posed by cigarettes.

Biologic Plausibility

In the case of e-cigs, biologic plausibility is probably the most important of the Bradford-Hill criteria. Cigarettes are unique in their production of tiny and highly toxic bits of solid material that make their way to the pulmonary alveoli, where they lodge for very long periods of time. Thus, the toxins they carry expose the smoker 24 hours a day, 7 days a week, for months, if not years on end. Other combustible products are likely less hazardous because of the size of the particles and the degree to which they are commonly inhaled so deep into the lung that natural defenses cannot remove them. The smokeless tobacco products widely available on the American market, vapor products and Heat-not-Burn products, by contrast, have no combustion and few if any solid particles. Nothing is lodged deep within the lung or anywhere else, limiting exposure to their smaller array of toxins to the time the product is in use. Thus, it is not surprising that e-cigs and smokeless whole-tobacco products appear to present a risk of potentially fatal cigarette-related disease orders of magnitude less than cigarettes.

Another remarkable thing about these families of products is their ability to satisfy the urge to smoke, something the pharmaceutical nicotine replacement therapy (NRT) products have never done. Thus, these alternative products are willingly used by smokers as an alternative to cigarettes. Once informed of the reduced risk, and once free of cigarettes, future relapses appear most likely to be to the reduced risk product, not cigarettes, should the urge to smoke ever return.

The current array of low-risk nicotine delivery products now available has the potential to make cigarettes and other combustible tobacco products obsolete within the next thirty years, and, by doing so, virtually eliminate cigarette-related illness and death, and reduce long-term use of nicotine delivery products, but only if FDA will allow them on the market and allow honest communication of the differences in risk between the lower risk products and cigarettes.

The troublesome issue of bias within the public health community

There are four major elements of public health bias against tobacco harm reduction (THR), in general, and e-cigs, in particular. The first bias comes from prior experience with adding a THR component to tobacco control programming, when early ACS research, and cigarette industry response, led to “light

cigarettes”. The second bias is the perception of the “tobacco industry” as a uniformly evil cabal still intent on addicting our children to a deadly substance for profit. The third bias is the widely shared tobacco-control goal of a “tobacco-free society,” as opposed to a “smoke-free society.”

The fourth bias, and the most troublesome to me, is the funding, publication and hyping of research studies so badly flawed that the data do not support – and sometimes conflict with – the conclusions and recommendations in the study abstract. As previously noted, these errors are present in the studies most referenced as evidence in favor of teen recruitment and efficacy for smoking cessation. Similar errors are frequent in much of the literature alleging toxic exposure of vapers and bystanders. Such errors are nearly universal in the many studies condemning e-cigs and tobacco harm reduction emanating from the Glantz team at the University of California at San Francisco. Since the major journals appear reluctant to retract grossly defective papers, or even to publish letters to the editor demonstrating errors that should have been picked up by the reviewers, three blogs have been set up to respond to erroneous and misleading papers and news releases on any side of the e-cig and THR Issues. The first is Tobacco Truth by Brad Rodu from the University of Louisville at <https://rodutobaccotruth.blogspot.com> . The second is “The rest of the Story” by Mike Siegel at Boston University at <https://tobaccoanalysis.blogspot.com> . The third is by Konstantinos Farsalinos, in Athens Greece, at the Onassis Cardiac Surgery Center and National School of Public Health, Greece at <http://www.ecigarette-research.org>. A fourth pertinent blog, focusing on government sponsored surveys and policy pronouncement, globally is Counterfactual by Clive Bates at the Counterfactual at <https://www.clivebates.com/> Readers are urged to consider the analyses presented in these blogs before referencing any paper for or against e-cigs or THR.

The story of how I (JLN) became an advocate for e-cigs and THR is presented in detail at the end of a paper I wrote for the Food and Drug Law Institute (FDLI) in 2014.³⁴ Neither I, nor any of the blog-authors referenced in the prior paragraph, came to this advocacy stance on behalf of any tobacco-related industry. Each of us followed a different path to this advocacy position, based on personal experience, independent review of pertinent literature and a desire to reduce tobacco-related addiction, illness and death.

These overlapping elements of bias combine to create a mindset in the tobacco control community that all non-pharmaceutical tobacco products are so hazardous that none can be permitted, and that, since the “industry” is seen as an enemy, there can be no consideration of industry-sponsored research and no collaboration in pursuit of shared public health objectives.

None of this was a major problem until 2007 – when two things occurred in the United States. First was the introduction of the Family Smoking Prevention and Tobacco Control Act (the FDA tobacco law) into Congress. The other, not apparent until a year or two later, was the introduction of e-cigarettes into the American market.

Prior to the advent of the e-cigarette, no one in either the tobacco control movement or the family of tobacco-related industries ever imagined that there could be a product that could satisfy the urge to smoke for many, if not most smokers, and would reduce risk by 95% or more, without addicting teen non-smokers – while being easier to quit than cigarettes. There is now solid evidence that e-cigarettes and related vapor products, snus, the chewing tobaccos currently on the American market, and, more likely than not, the new Heat-not-Burn (HnB) products are likely to meet these specifications.

All the biases noted above were written into the FDA tobacco law.³⁵ This law, as written, grandfathers in all cigarette and smokeless tobacco products on the American market as of February 15, 2007 (the day the law was introduced into Congress) while imposing extreme requirements that basically all-but-ban introduction of any new tobacco-related product into the marketplace and all-but-prohibit any product from claiming less risk than cigarettes, no matter how strong the scientific evidence. Much of the law is technically unsound in that it fails to acknowledge the risk posed by products of combustion and how the user and bystander are exposed. These restrictions in the law have been magnified by the FDA staff response, which to date, has not approved any fundamentally new product, and, despite 100 years of experience and 30+ years of good epidemiologic evidence, has not allowed Swedish Snus to claim lower risk than cigarettes.

Despite recognition of a “continuum of risk” by which tobacco products are known to vary substantially in risk and addictiveness, and despite FDA’s stated intent to vary the intensity of regulation with the risk posed by the product and to base FDA policy on the best possible science, this intent has not been fulfilled. Instead, the actions taken to date by the FDA are consistent with the impression that their goal is to use the power to regulate to prohibit introduction of new products, and to prohibit commercial communication of differences in risk.

Thus, while we know that a single tobacco product, the cigarette, is responsible for virtually all the usually quoted illness, death and other harms from tobacco products, and we know that illnesses and deaths from all other tobacco products are so rare that none are statistically tracked on an annual basis, cigarettes have been grandfathered in without restriction (except for marketing). All other products are prohibited from claiming lower risk, and many are threatened with removal from the marketplace within the next few years.

To date, the only progress that has been made in the direction of THR in the USA has been limited to limited recognition of the evidence that e-cigs and smokeless products may be less hazardous than cigarettes and delays in implementation of the most onerous and most technically unsound FDA regulations. Potential benefits relative to diversion of teens away from cigarettes and efficacy for smoking cessation have yet to be acknowledged.

Hopefully, reformulation of the CSAPH 5-A-18 report will begin a process by which the potential public health benefits of non-pharmaceutical THR products will be formally recognized and begin to be incorporated into tobacco control programming to enable us to secure personal and public health benefits not likely achievable by other means.

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