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### Memorandum:

**To:** Ken Roy, MD  
**Cc:** AAPHP Policy and Resolutions Committee  
**From:** Joel L. Nitzkin, MD  
**Subject:** Science-based E-cigarette Policy

This note is in response to your July 13 e-mail message requesting literature references to help guide ASAM policy regarding e-cigarettes and similar products (e-cigs).

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## Summary E-cig Recommendations to American Society of Addiction Medicine (ASAM)

Joel L. Nitzkin, MD, July 23, 2017

### Recommendations:

I (JLN) urge ASAM to adopt e-cig policies along the lines recommended by British Authorities in their January 2016 *Electronic cigarettes: A briefing to stop smoking services*.<sup>1</sup> ([http://www.ncsct.co.uk/publication\\_electronic\\_cigarette\\_briefing.php](http://www.ncsct.co.uk/publication_electronic_cigarette_briefing.php)) The British approach to e-cigarettes and related vapor products (e-cigs) differs from the American approach in that the British consider evidence for and against endorsement of e-cigarettes, instead of limiting their consideration to potential harms. When translated to the American scene, they play out as follows:

1. The evidence supporting endorsement of e-cigs for both harm reduction and smoking cessation is overwhelmingly positive. The evidence against is, in general, flawed and only suggestive in nature.
2. Not only are e-cigs not a gateway to teen smoking, available evidence makes a strong case for e-cigs being a gateway away from cigarettes for both teen smokers and teens who otherwise would have started smoking. E-cig recruitment of teens not inclined to smoke has been minimal.
3. Since e-cigs are intended by manufacturers, vendors and users to be recreational alternatives to cigarettes that are lower in risk and easier to quit, they should be regulated as consumer products under the FDA Center for Tobacco Products (CTP); not as drugs under the FDA Center for Drug Evaluation and Research (CDER).
4. At the federal level,
  - a. CTP should establish reasonably uniform marketing and manufacturing standards for all mass-market tobacco-related products to prevent predatory marketing and eliminate shoddy products. While marketing guidelines are written into the TCA, based on the 1999 Master Settlement Agreement,<sup>2</sup> CTP has yet to promulgate manufacturing standards for any product under their jurisdiction.
  - b. In the case of the vape shop component of the e-cig industry, a special set of facility, sanitation and hygiene standards should be developed, in collaboration with industry representatives to meet the needs of these unusual manufacture/service/vendor facilities. Anecdotal impressions suggest that the products and personal service they provide are likely more effective than mass-market convenience store products in terms of getting smokers to rapidly quit smoking and prevent relapse to cigarettes on a long-term basis.
  - c. The text of the Tobacco Control Act (TCA),<sup>3</sup> as currently interpreted by FDA staff, threatens to wipe out the entire vape shop component of the e-cig industry and many of the mass-market products because of the cost of the application procedure and total absence of useful FDA guidelines. If the FDA is unable to eliminate the requirements for product-specific community and clinical studies and other costly provisions, Congressional action may be required to amend the TCA to enable all honest and competent vape shops and e-cig manufacturers to thrive and innovate in a manner supportive of the public health.
  - d. Congressional action to amend the TCA might also be required to enable all products that meet the e-cig class definition to claim reduced risk without having to conduct costly product-specific research.
5. At state and local levels, age restrictions on sale should be consistent across all tobacco-related products, including e-cigs, but taxation should reflect risk posed to the users and bystanders. This means little or no excise tax on e-cigs, but very high excise tax on cigarettes. There is no health-related justification for banning vaping in no-smoking areas. Such bans should be eliminated as another means of encouraging smokers who are unable or unwilling to quit to switch.

### Comment on FDA and CDC tobacco control policy

These findings and recommendations are diametrically opposed to the current recommendations of FDA, CDC, and others in the American tobacco control movement. This difference is due to their commitment to the goal of “a tobacco-free society,” a commitment they interpret as ruling out any consideration of using any non-pharmaceutical tobacco-related product in the context of any public health initiative. This is bolstered by FDA and CDC policy of considering only theoretical harms of such products,<sup>4</sup> summary dismissal of evidence of potential benefits and unconditional acceptance of the demonstrably incorrect premise that advertising any non-pharmaceutical tobacco-related product as lower in risk than cigarettes will recruit large numbers of non-smoking teens to nicotine addiction, and, by so doing, undo all the progress that has been made in tobacco control over the past half century.

## The Case in Favor of E-cigarettes

### **General References:**

The following documents are well referenced reviews of the literature that consider the literature, national and international survey data relative to endorsement of e-cigs for their potential personal and public health benefits.

The following set of British government documents are the most comprehensive and most useful to guiding development of e-cig policies optimal for the protection and enhancement of the health of the public.

1. *Electronic cigarettes: A briefing for stop smoking services.*<sup>1</sup> This document, from January 2016, directly presents guidelines for incorporating e-cigs into ongoing public health and smoking cessation programs.
2. *Towards a Smokefree Generation, A tobacco control plan for England.*<sup>5</sup> This document, posted July 2017, covers the full range of optimal tobacco control policies and programming.
3. *E-cigarettes: an evidence update.*<sup>6</sup> This 2015 report from Public Health England provides the initial definitive literature review leading to the two policy documents noted above.

*American experts call for risk-based reform of FDA regulation of tobacco and nicotine*<sup>7</sup> this July 2017 posting on Clive Bates' web site provides descriptions and links to letters and multiple policy documents by American tobacco control experts external to FDA; again, with links to all referenced documents.

*Rethinking nicotine: implications for U.S. federal tobacco policy: A discussion paper.* June 2017. This paper, also by Clive Bates, reviews the pertinent literature, with direct links to all referenced papers. The most important item is on page 17, showing his graphic presentation of the Monitoring the Future data, demonstrating the acceleration of reduction in smoking by American Teens since 2010.<sup>8</sup>

A group at the University of Vancouver, Canada, did an excellent job of summarizing the literature and survey data for use in development of Canadian Policy.<sup>9</sup>

In 2014, I (JLN) wrote two papers summarizing the literature from an American perspective. One was written for a medical/public health audience,<sup>10</sup> the other for legislators, attorneys and other non-technical policymakers in the Washington, DC area.<sup>11</sup>

### **Harm Reduction and Personal Benefit**

Smokers smoke for the nicotine, but die from the tar.<sup>12</sup> E-cigs have no tobacco, no products of combustion and no tar. They have nicotine extracted from tobacco,

To date, American tobacco control policy makers have ignored the fact that tobacco-related products differ substantially, both in addictiveness<sup>7</sup> and in risk of potentially fatal tobacco-related illnesses.<sup>13-15</sup>

While we have little data on whether it is the nicotine or other substances in tobacco smoke that cause mental health problems in adolescents and adverse outcomes of pregnancy, it seems reasonable to suspect that these other substances may be responsible for at least some of the harm. Also not considered are the behavioral benefits of nicotine to schizophrenic and bipolar individuals that lead to much higher smoking prevalence in these groups and greater difficulty in smoking cessation.<sup>16-18</sup>

While we do not have thirty years of personal experience with e-cig products, we do have a wide array of studies providing substantial evidence of harm reduction, compared to cigarettes. Farsalinos<sup>15,19</sup> and Burstyn<sup>20</sup> have written extensively about the toxicology of e-cig vapor, compared to cigarette smoke, as it affects both vapers (users of e-cigs) and bystanders. Polosa has documented improvements in clinical

status of asthma<sup>21</sup> and cardiovascular disease<sup>22</sup> patients switching to e-cigs. In addition, there have been thousands of anecdotal reports by vapers attesting to the efficacy of e-cigs in improving their breathing, sense of taste and energy level, and ability to completely quit cigarettes. It has been the enthusiasm of these vapers that have fueled the political power of the e-cig movement at local, state and national levels.

### **Smoking Cessation**

Even though recreational use is the intended purpose of e-cigs, they have proven very effective in helping smokers quit. A recently published survey in Great Britain<sup>23</sup> finds that about half of Great Britain's 2.9 million vapers no longer smoke. The same was found to be true in in the 2014 Eurobarometer survey of a representative sample of 28 member states of the European Union.<sup>24</sup> These outcomes are spectacularly better than anything currently projected for NRTs and current American tobacco control efforts.

European studies in adults (not duplicated to date in the United States)<sup>23,24</sup> not only show that, in recent years, more smokers have quit using e-cig devices than the pharmaceutical alternatives. The same can be said for the snus experience in Sweden.<sup>25</sup>

One major problem here is the policy of FDA,<sup>4</sup> CDC and NIH to focus their research efforts on the potential harms to be caused by e-cigs and other non-pharmaceutical tobacco-related products. Since they refuse, as a matter of policy, to explore potential benefits of these products,<sup>4</sup> consideration of the possibility of such benefits requires a careful look at the data in the major American national surveys,<sup>26,27</sup> ignoring the narrative and agency interpretation of the data and considering the data directly.

Promotion of e-cigs and snus for THR provides an alternate pathway to the interim goal of a smoke-free society and the ultimate (but unachievable and arguably undesirable) goal of a tobacco-free society. Since e-cigs serve as recreational substitutes for cigarettes, they have the potential to more directly reduce cigarette consumption over a longer period, compared to short-term treatment with NRTs and other pharmaceutical options. Since they can satisfy the urge to smoke, many more vapers and smokeless users achieve long-term abstinence than has been the experience with NRTs and the other pharmaceutical options. Thus, counter-intuitive as it may seem, promotion of e-cigs and snus (and possibly other low-risk options) for THR, with reasonable regulation and public health oversight, may actually accelerate our progress in the direction of a tobacco-free society.

The issue of efficacy for cessation as documented by randomized controlled trials deserves consideration. The Cochrane Collaborative has reviewed the randomized clinical trials of e-cig products used as if they were NRTs, with only short-term outcomes. This review shows that the e-cig products show short-term results similar to the NRTs, when used as if they were NRTs.<sup>28</sup>

Because of the lack of satisfaction, those treated with the NRTs rapidly relapse to cigarettes once the initial period of treatment has been completed. They go from about 40% abstinent at twelve weeks to about 6% to 10% at six to twelve months, and, from there to about 3% at twenty to twenty-four months.<sup>29</sup> With e-cigs, the percent abstinent increases over time, as relapse is to e-cigs, not to cigarettes.<sup>30</sup> The durability of cigarette abstinence in vapers is also apparent in the recently published national survey in Great Britain that showed that more than half of Great Britain's 2.9 million vapers no longer smoke,<sup>23</sup> and the 2014 Eurobarometer survey of of 28 member states with similar findings<sup>24</sup> national study in Europe. The same can be said for snus.<sup>25</sup>

Thus, the superiority of both e-cigs and snus for smoking cessation, compared to the NRT products, is largely in the reduction in subsequent relapse to cigarettes when the urge to smoke returns.

### **Gateway Issues (i.e. teen recruitment)**

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.<sup>31</sup> 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.

The proof that e-cigs serve as a gateway away from cigarettes is to be found in the series of annual National Youth Tobacco Surveys of middle school and high school students conducted by the CDC.<sup>32</sup> These show dramatic increases in e-cig use by teens from near zero in 2011 to a rate substantially higher than the percentage of teens smoking cigarettes in 2015 and 2016. During this period, the long-standing year to year reduction in percent of teens smoking (30 day and daily) accelerated, compared to prior years.<sup>8,33</sup> All this, with no increase in the overall percentage of teens using any tobacco-related product. If, as postulated by tobacco control authorities, e-cigs were attracting large numbers of non-smoking teens, the percentage of teens using tobacco products would have substantially increased. These survey results data should be considered conclusive evidence that e-cigs have been serving as a gateway away from cigarettes, and, as such, beneficial to the public health.

If one also considers the findings of the SAMHSA Monitoring the Future Surveys from the same period,<sup>27</sup> 60% of teen vapers used flavor-only e-cigs, with no nicotine. If one adjusts the CDC survey data for these zero-nicotine e-cigs, then the percentage of teens using any tobacco-related product would surely have shown decreases year by year. The CDC surveys considered all e-cigs to be “tobacco-related” products and did not separate out those with zero nicotine.

## **The Case Against E-cigs**

The case against THR and e-cigs is presented in the December 2016 Report of the Surgeon General *E-Cigarette Use Among Youth and Young Adults*.<sup>41</sup>

What follows are my (JLN) impressions following a detailed review of this report. My impressions are, to say the least, uncomplimentary. I would encourage those who have not read this report to do so and reach your own conclusions.

This report frames the determination of federal policy with regard to THR and e-cigs from the perspective of non-smoking youth who might be recruited to nicotine addiction and subsequent smoking by e-cigs. By doing so, they dismiss all evidence of potential benefit to adults, and all evidence of the benefit of fruit and candy flavors to inhibit relapse to smoking by adult smokers.<sup>34</sup>

The introductory chapter highlights the fact that e-cig marketing reflects many of the themes of past cigarette marketing, with emotional and symbolic appeal attractive to youth. In doing so the introductory chapter does not reference the fact that if any such company promoted their products as lower in risk than cigarettes or effective for smoking cessation – they would be summarily removed from the market at unlicensed drug-device combinations.<sup>35</sup>

Chapter 2 addresses patterns of use of e-cig products by youth and young adults. It points out that, per CDC surveys, e-cigs are now used by more teens than cigarettes, and that those who, start by

experimenting with e-cigs are more likely than those who do no such experimentation to be using cigarettes six months later. To his credit, the SG recognizes that these data are suggestive, not proof of e-cig causing kids to smoke. Not to his credit are failure to recognize that the studies in question (as referenced in my discussion of Gateway Issues), conflation of experimentation and occasional social use with “initiation of smoking,” and that not dealing with the question as to whether the kids experimenting with e-cigs would have experimented with cigarettes, had e-cigs not been available. It is important to note that these studies do not consider the fact that, per the SAMHSA Monitoring The Future surveys,<sup>27</sup> 60% of the kids experimenting with e-cigs are using flavor-only, zero nicotine products. The only conclusion that can be drawn from these studies is that kids prone to experiment with forbidden substances are more likely to smoke than kids not so inclined. No conclusion can be drawn regarding any alleged “gateway” effect.

Chapter 3 addresses health effects. Here they make the valid point that e-cig vapor contains traces of a variety of toxic substances. Most of the comparisons here, however, are to total abstinence, not comparison to cigarette smoke. Other than fires, explosions and accidental ingestion, there is no evidence of illness or death from these products. Here, too, they decline to provide comparison to cigarette-related fires and accidental ingestions. Much of the text in this chapter is devoted to adverse outcomes of pregnancy, addiction and harm to the developing brain, attributing all these adverse outcomes to nicotine per se. This text does not address the likelihood that at least some of these adverse outcomes might be from other constituents in cigarette smoke, with the implication that e-cigs, while not free of such risks, may be significantly less harmful.

Chapter 4 addresses “activities of the e-cigarette companies,” and deals with issues of advertising and promotion of flavors, supposedly for the purpose of enticing kids to try and to use these products. Reading this chapter can easily leave the impression that e-cigs are a gimmick created by the big-tobacco cigarette companies to recruit children to nicotine addiction. There is minimal recognition that more than half of the e-cig market is from manufacturers and vendors neither owned nor dominated by the big-tobacco cigarette companies. The latest Wells Fargo data<sup>36</sup> shows a total e-cig/vapor market of \$4.4B, of which personal vaporizers (i.e. non-mass market cig-a-likes) are \$3.0B; of which Vape shops are \$1.8B. The mass-market cig-a-likes of the type manufactured by the big-tobacco cigarette companies account for only \$1.4B (32%) of the over-all \$4.4B market.

Chapter 5 presents the SG policy recommendations.

Three sets of issues are addressed.

The first deals with the need for extensive post-market surveillance regarding both use and health impacts, supplemented by a vigorous continuing research agenda. This is one set of recommendations I (JLN) heartily agree with.

The second is notation of the fact that the other SG recommendations are precautionary, recognizing that the evidence of possible harm from these products is suggestive, not confirmed. It seems to me that this precautionary stance is very tentative because of the fact that this SG report did not consider the evidence that e-cigs might offer substantial personal and public health benefits not likely achievable by any other means – benefits in terms of diversion of both teen smokers and those inclined to smoke, away from cigarettes.

The third is a set of recommended actions, short of banning e-cigs, but designed to substantially reduce their availability and attractiveness; apparently based on the premise that these products may present harms, but no likely benefits.

## The Tobacco Control Act

The 2009 Family Smoking Prevention and Tobacco Control Act<sup>3</sup> was developed behind closed doors by Tobacco Free Kids,(TFK) Altria and GlaxoSmithKlein. Their goal was to prevent any new tobacco products from ever entering the market, and any from claiming less risk than cigarettes. TFK asserts (then and now) that the only reason any company would introduce any new product into the market would be to attract more teens to nicotine addiction. Altria and GlaxoSmithKlein did not want any new products (or old ones with new claims) to compete against them for sales and profits. Thus TFK partnered with both big-tobacco and big-pharma to generate a politically viable law to protect what all three saw as their special interests, without regard to science or implications for future rates of tobacco-related addiction, illness and death. With TFK and the American Lung Association playing lead roles, they then sold it to medical and public health communities, and Congress as a bill that would protect our children and save millions of lives. Part of the agreement by which the bill was promoted was the provision that no amendment that might strengthen it from a public health perspective would be considered. This scenario is what unfolded by means of verbal communications with a lead staff person in the office of then-Representative Waxman, as I and a colleague, on behalf of the American Association of Public Health Physicians (AAPHP), proposed a set of amendments to strengthen the bill from a public health perspective, a few months after it was introduced, February 15, 2017. True to this agreement, none of our amendments were considered.

This being the case, intentions aside, the bill was designed to eliminate introduction of any new products into the market and prevent any new or old products from ever claiming less risk than cigarettes. The deeming regulations, by extending the authority of the TCA to cover e-cigs, threaten to eliminate almost all e-cig products from the market by making the “pre-market” (PMTA) application process so expensive that only the largest of corporations can apply. PMTA applications are now required of all e-cig products now on the market, if they were not on the market as of February 15, 2007. None were. FDA estimates the cost per application at \$340,000 for every combination of a device, flavor and strength of nicotine,<sup>37</sup> industry estimates are in excess of \$1 million per application<sup>38</sup> largely due to the cost of the required community and clinical studies.

While imposing impossible cost burdens on e-cig manufacturers, the law has given all major brand cigarettes a free-pass in the sense that no application for FDA approval is required.

### **Anti-e-cig Perceptions and Principles of the Tobacco Control Community**

For most of the past half-century, the tobacco control movement has been guided by a set of perceptions and principles, all of which seemed reasonable at the time, but are now seem dysfunctional by the disruptive innovation of e-cigs. No one envisioned that the tobacco industry would develop a set of products that would be more acceptable to smokers and likely more effective at reducing risk and smoking cessation than the pharmaceutical gums, patches, etc.

These tobacco control perceptions and principles now inhibit our ability to do the best possible job of preventing future tobacco-related addiction, illness and death. They are articulated below, from an American perspective. These same issues are also in play globally, within the international and various national tobacco control movements.

1. As seen by the tobacco control community, e-cigs are gimmicks created by the big-tobacco cigarette companies to recruit a new generation of teens to nicotine addiction.

- a. *(as seen by e-cig manufacturers, vendors and users, e-cigs represents a disruptive technology never imagined by tobacco control or the industry – a product that could satisfy a smoker’s urge to smoke at very low risk, and without attracting teen non-smokers to nicotine addiction.)*
  - b. *(the big-tobacco cigarette companies were late arrivals to the e-cig market, but once there plunged in big-time, buying out already established brands.)*
2. As seen by the tobacco control community, smoking is always a disease, never a behavior. Therefor any claim of efficacy for smoking prevention or cessation requires licensure as a drug.
  - a. *(there is no recognition of the possibility that a recreational substitute for cigarettes can be so attractive to smokers that they will simply switch for lower risk and lower cost, quitting smoking despite having no desire to do so.)*
  - b. *(randomized controlled trials, while considered the only valid evidence of efficacy of a drug for treating a disease, represent the wrong study design for the outcomes of consumer behaviors in an open market setting.)*
  - c. *(Manufacturers will not apply for licensure as a drug because they do not see smoking as a disease and do not see their products as medication.)*
3. As seen by the tobacco control community, it is so self-evident that promoting any non-pharmaceutical nicotine product as lower in risk than cigarettes will attract large numbers of non-smoking teens to nicotine addiction that scientific evidence need not be considered, and evidence to the contrary can be disregarded. Some even fear that such promotion could undo all tobacco control has achieved in the last half century
4. As seen by the tobacco control community, Nicotine Replacement Therapy products (NRTs) (gums, patches, etc) are highly effective for smoking cessation.
  - a. *(they are not, they fail 90% or more of smokers who use them as directed, even under the best of study conditions, when results are measured at 6 to 12 months)*
  - b. *(in fact, in the early years of e-cigs, the vast majority of vapers (e-cig users) were smokers who had tried to quit with pharmaceutical products and failed to do so.)*
5. As seen by the tobacco control community, it is so self-evident that candy and fruit flavors in e-cigs will attract large numbers of non-smoking children and teens to nicotine use, that scientific evidence need not be considered, and evidence to the contrary can be disregarded.
  - a. *(no and no!! The flavors are important to adults to prevent relapse to smoking by making the taste of tobacco abhorrent. As noted in the discussion of gateway issues in this memo, e-cigs are a gateway away from cigarettes for both teen smokers and those who otherwise would have become smokers.)*

## **Commercial and Conflict of Interest Considerations**

### **Private Sector**

While small business enterprises can set their goals as anything the owner pleases, corporations, by their very structure are almost always totally committed to maximizing profit for the company and its shareholders. With only rare exceptions, CEOs are judged on the basis of the financial performance of the company, and this is reflected in their compensation. As legal entities, what they can do to generate these profits can be constrained by governmental law and regulation. In the case of the big-tobacco cigarette companies, their behavior, whether we like it or not, is consistent with what is expected of corporations in Western society. Their goal, while seen as evil by many in the public health community, is expected and proper behavior in their working environment.



This being the case, the question then becomes what the public health community can do about such behavior to protect the health of the public. In general, there are two possibilities. The first is, by law and regulation, inhibit what we see as manufacturing and marketing practices detrimental to the health of the public. Sometimes outlawing a product altogether if all else fails.

The second option is incentivizing the company to manufacture and market products that are beneficial to the health of the public, and, by so doing, mobilize these private sector resources for public health objectives. In these times of cutbacks in funding for both governmental and voluntary funding of public health related services, such mobilization, where it can be secured, is much to be desired.

The major pharmaceutical firms are cut from the same corporate cloth as the tobacco companies, and have the same values and incentives. Yet, our tobacco control community feels comfortable partnering with them and promoting their products as extremely effective for smoking cessation, even though they have long been known to fail 90% or more of the smokers who use them as directed, when results are measured at six to twelve months, even under the best of study conditions.<sup>29</sup> In return, these drug companies have responded by generously supporting CDC, FDA, TFK, Heart, Lung and Cancer Societies, American Academy of Pediatrics, and almost every other organization active in tobacco control.<sup>39</sup>

The advent of e-cigarettes and related vapor devices and the latest research on the safety and efficacy of snus for harm reduction and smoking cessation now raises the question as to the degree to which the leadership of tobacco control entities may be demeaning e-cigs and the smokeless products to protect their relationships with and funding from the major pharmaceutical manufacturers of smoking cessation medication.

### ***Public and Voluntary Sectors***

Tobacco control advocates like to frame their enterprise as a holy crusade of the good public health people against an evil industry intent on addicting their children to a deadly addictive substance. They are very aware of the financial incentives of the tobacco companies, but seem totally blind to possible financial conflicts of interest on the public health side.

The American tobacco control movement is very tightly controlled at the national level, by CDC and FDA in the public sector, and major voluntary groups (TFK, Heart, Lung and Cancer societies, American Academy of Pediatrics and others). National leadership in both public and voluntary sectors learned long ago that they could get more money, more political support and more enthusiastic volunteers by framing their enterprise as a crusade of good against evil. As public health professionals who advocate for e-cigs can tell you, deviating from the preferred prohibitionist party line will get you an invitation to find employment elsewhere.

Adding to this conflict of interest on the tobacco control side is the increasing dependence by both governmental and voluntary agencies on funding from the major pharmaceutical firms. CDC depends on these funds, processed through the Public Health Foundation to support their meetings and some of their research agenda. The major voluntaries depend on such funding to support much of their advocacy agenda. It is hard to imagine the top leaders not being aware of the threat to continuing support from big pharma, should they endorse use of e-cigs for some smokers who otherwise would have continued use of NRTs for smoking cessation.

Even though the lion's share of the addiction, illness and death have always been due to the cigarettes in the USA, tobacco control leadership has always framed the problem as "tobacco," not cigarettes. They have done this so successfully that almost all physicians and almost all the general public believe that, if someone switches from cigarettes to chewing tobacco or a snuff product, they are simply trading a lung

cancer risk for a mouth cancer risk, with no reduction in overall risk. Nothing could be further from the truth.<sup>13</sup> The CDC warnings about the risk posed by smokeless tobacco products is based on “international data”<sup>40</sup> reflecting the risk posed by products not available on the American market. We have known since at least the 1980’s that the smokeless tobacco products on the American market pose little or no risk of mouth cancer or other fatal disease, yet, having framed the problem as “tobacco” and “the evil industry,” tobacco control authorities have kept up their misleading anti-smokeless-tobacco crusading without letup. One can only speculate as to the impact on political supporters and funders, should tobacco control authorities now reverse course by admitting that snus and e-cigs might be more effective for long-term smoking cessation than the currently favored NRTs.

Such an admission would not likely reverse progress made in tobacco control over the past half century. If not skillfully managed, however, such an admission could pull the rug out from under the political and financial support based on a crusade against an evil industry. Even worse, from this perspective, would be the need to acknowledge that the evil big-tobacco cigarette companies have developed and are marketing or proposing to market low-risk e-cig and heat-not-burn products that, to date, have not been shown to recruit additional teens to nicotine addiction, despite the lack of federal regulation of these products. Evidence that such a conflict of interest on the public health side is a major driver of tobacco control policy can be found in their continuing condemnation of e-cig and smokeless products, with disregard or summary dismissal of the evidence in favor of substantial personal and public health benefits. A Surgeon General Report in December 2016,<sup>41</sup> framed in terms of potential recruitment of non-smoking teens, disregarding benefits to teen and adult smokers, and disregarding evidence favorable to e-cigs is one sign of inappropriate condemnation. Local officials speculating that e-cigs may be as hazardous as smoking,<sup>42-46</sup> and alleging possible significant harm to bystanders<sup>47,48</sup> is also factually incorrect, damaging to the health of the public and possibly damaging to the credibility of our entire public health enterprise. Yet other evidence of such inappropriate condemnation is the continuing press for yet more state and local laws and ordinances banning e-cigs wherever smoking is prohibited.

This reluctance to admit that not all tobacco products are deadly, and that not all stakeholders in tobacco-related industries are not evil, is not universal. Herein lies a major difference between British and American tobacco control authorities. The British, recognizing the likely benefits e-cigs can offer, have developed a nuanced approach to tobacco control, incorporating limited endorsement of e-cigs as part of a wider effort to reduce tobacco-related addiction, illness and death.

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