

E-cigarette Tipping Points Revisited, with Historical Perspective

Joel L Nitzkin*

New Orleans, Louisiana and Senior Fellow for Tobacco Policy, R Street Institute, Washington, DC, USA

***Corresponding Author:** Joel L Nitzkin, New Orleans, Louisiana, USA.

Received: August 13, 2020; **Published:** September 10, 2020

Abstract

Three years have now transpired since I noted that e-cigarettes had crossed two tipping points [1,2]. The first had to do with popularity, with an estimated 10% of the American adult population using or having used e-cigarette products [3]. The second related to British authorities having endorsed e-cigarettes for tobacco harm reduction (THR) and smoking cessation [4]. These provided grounds for cautious optimism that e-cigarettes might eventually be accepted as beneficial by public health authorities.

Since then, anti-e-cigarette sentiment has turned so far against e-cigarettes that the industry is now facing a September 9, 2020 deadline to submit a viable application to the FDA or face removal from the marketplace.

The questions now facing us are how and why we find ourselves facing the demise of most of the e-cigarette industry in the United States, and what, if anything, should be done about it.

Keywords: *E-cigarette; Tipping Points; Tobacco Harm Reduction (THR); Smoking Cessation*

Goals and Objectives

This paper assumes that both tobacco control advocates and e-cigarette advocates are well intentioned and desire to do all within their power to reduce the burden of tobacco-related addiction, illness, and death in the USA. The difference between them, however, is based what they hope to achieve. The goal of tobacco control appears to be pursuit of a tobacco-free society. This goal, in turn, reflects an absolutist/prohibitionist mindset that rules out use of any non-pharmaceutical nicotine product for tobacco harm reduction. The e-cigarette community, by contrast, sees tobacco harm reduction using e-cigarettes as the only feasible way to make cigarettes obsolete, and by doing so, reduce the risk of cigarette-related heart disease, lung disease and cancer by 95% or more, and do so while not increasing, and likely decreasing teen use of nicotine products. The e-cigarette community also recognizes the benefits of self-administered nicotine for persons suffering from schizophrenia, depression, bipolar disorder, Crohn's disease and other disorders; a benefit not recognized by public health authorities.

The modus operandi also differs between the tobacco control and e-cigarette approaches. The tobacco control approach is based on communication initiatives to discourage use of all non-pharmaceutical tobacco-related products backed up by coercive measures to further discourage such use. The e-cigarette approach is based on consumer choice; advising consumers that they can reduce their risk of potentially fatal cigarette-related disease by 95% or more by switching to a more attractive and equally satisfying product that provides the nicotine they seek without the plethora of toxins present in cigarette smoke. Instead of consumer coercion, they seek sensible governmental regulation to assure the quality of the product and drive bad actors, predatory marketing and toxic products from the marketplace. As they see it, and see their progress to date, they feel that e-cigarettes, if welcomed into the marketplace, can offer public health benefits not likely achievable by any other means. These include but are not limited to rapid and sustained long term cigarette abstinence

in smokers, diversion of large numbers of would-be teen smokers away from cigarettes and a process by which these benefits would not be undercut by a flood of black market cigarettes.

The obvious conflict between these two perspectives, then and now, has to do with whether marketing products as lower risk than cigarettes will attract more teens to nicotine use, and, from there to cigarettes, thus eliminating any possible public health benefit.

The tobacco control perspective is that the tobacco industry is monolithic and evil in the sense that it is only interested in sales and profits, and that any claims of interest in public health objectives are lies. This long-standing distrust was confirmed in their minds in 2006, when seven of the largest big-tobacco cigarette companies were convicted of racketeering by lying to both the public and public health authorities [5].

E-cigarette advocates, especially those representing the vape-shop component of the industry, see the tobacco scene as complex, with different people and different companies having different goals. They see themselves as pro-health, anti-cigarette.

Historical perspective

The American Centers for Disease Control and Prevention (CDC) estimate that smoking directly or indirectly kills about 480,000 Americans each year [6]. This, according to CDC makes smoking the #1 preventable cause of death in the USA. All these deaths are due to a single tobacco product - the combustible cigarette. Deaths from all other tobacco-related products are so few and so difficult to discern from background mortality that CDC offers no estimates of annual deaths from any of these products. Even with that as background, the primary focus of the tobacco control community has been teen recruitment. This thinking, and the nicotine-focus of the FDA regulatory scheme is based on the proposition that, if we, can stop recruitment of teens to nicotine and cigarettes, we can eventually reach the goal of a tobacco-free society.

Since the 1960's, cigarettes have been so prominent as the default nicotine delivery product in the USA that medical and public health authorities became accustomed to using the terms "tobacco use" and "smoking" as if they were synonymous. Despite evidence to the contrary [7], they considered all such use as addictive and deadly, with no offsetting personal or public health benefits.

The one exception to this rule, beginning about 40 years ago, was the licensure of pharmaceutical nicotine gums, patches, etc. as drugs rather than consumer products. This seems to have been based on a marketing decision by the pharmaceutical industry to facilitate their marketing these products to and through physicians at much higher prices than would be possible if sold as consumer products. This, in turn, established the precedent of smoking being defined as a "disease," for regulatory purposes, and efficacy for smoking cessation being defined as a claim that required licensure as a drug. The problem here is that, while e-cigarettes have shown themselves to be more effective for cessation than these pharmaceutical products [8], they cannot make such a claim without being licensed and marketed as a drug. Neither manufacturers, vendors nor users of e-cigarettes consider these products to be drugs. They are attractive alternatives to cigarettes, for use by smokers regardless of whether the smoker is intending to quit smoking.

About 25 years ago, FDA brought the major big-tobacco cigarette companies to court and had them convicted of racketeering, basically for lying to the public about the addictiveness of and danger posed by their cigarette products [5]. This, in turn, solidified three ideas in the minds of public health and medical authorities. These were that these products are addictive and deadly, that the companies that make them are evil and cannot be trusted, and that these companies are the "vectors" of the long-standing pandemic of tobacco-related illness and death, at least in the USA.

Prior to the advent of the FDA tobacco law, introduced into Congress in 2007 and adopted in 2009, no one in the tobacco control community and hardly anyone in tobacco-related industries considered the possibility that there might someday be a non-pharmaceutical

nicotine delivery product that could satisfy the urge to smoke for many, if not most smokers, while presenting less than 5% of the risk of potentially fatal cancer, heart and lung disease, and while, simultaneously diverting teens from a lifetime of nicotine addiction and smoking. Never did they consider the possibility that such a product might be taken up by many smokers with no intention of quitting, only to have them switch to these new products in large numbers.

The FDA tobacco law

What eventually became the FDA tobacco control law began as an initiative by Dr. David Kessler, then FDA Commissioner in the 1990's, to eliminate cigarettes from the marketplace [9].

By a 5 to 4 vote, the US Supreme Court prohibited FDA from doing so without additional congressional authority [10].

After several attempts to secure Congressional authority to ban cigarettes failed due to industry and conservative-principle opposition, secret negotiations ensued between the tobacco control community and the tobacco industry.

While the details of this process are beyond the scope of this paper, suffice it to say that things got turned around. Rather than ban cigarettes or make them safer in any way, this new law grandfathered in all then-currently-marketed cigarettes and imposed extreme restrictions to prevent any new tobacco product from entering the marketplace and extreme restrictions to prevent any new or old tobacco product from claiming less risk from cigarettes.

This historical perspective provides context with which to understand the current threat to the vape shop community and other manufacturers and vendors of nicotine vapor products.

Dysfunctional aspects of American tobacco control programming

If the goal of American tobacco control programming is reduction leading to elimination of tobacco-related addiction, illness and death in the USA, the following list needs to be considered as aspects of current policy and programming that inhibit progress toward this goal.

Assuming honesty and good faith on both sides of this debate, I am providing the following list in hopes that it will provide vehicles by which a vigorous and well-regulated e-cigarette industry can collaborate with public health authorities to all-but-eliminate cigarette smoking, and, by that means transform "tobacco use" from a major to a trivial public health concern.

1. There was a time in the not-too-distant past when Germany, Italy and Japan were Americas worst enemies, and Russia was one of our greatest friends. Now the opposite is true. Times and circumstances change, and we need to change with them. Perhaps the time has come for the tobacco control community to take a fresh look at the tobacco and pharmaceutical industries and reconsider who our friends and enemies may be within them. Perhaps the tobacco industry is not as monolithic as we have imagined, and perhaps the possibility exists to mobilize some of their resources in pursuit of shared public health objectives. We need to decide the degree to which our tobacco control enterprise will be a public health initiative to reduce addiction, illness and death as opposed to a moral crusade against a monolithic and supposedly entirely evil industry intent on addicting our children to a deadly substance.
2. "Smoking" and "tobacco use" are not now and never should have been considered synonymous terms. Smoking kills. Smokeless tobacco, snus, and almost certainly e-cigarettes, while not risk free, present far less risk of potentially fatal illness [7] and are likely significantly less addictive than cigarettes [11]. Harm reduction is now a well-established part of medical and public health practice when dealing with other psycho-active substances. Might it also work for tobacco control?

3. The allegation that e-cigarettes lead teens to nicotine addiction and to smoking is based on poor quality science that does not rule out the possibility of common liability. This allegation is based on bits of data taken out of context, and does not consider the numbers of would-be teen smokers diverted from smoking and from a lifetime of nicotine addiction [12,13]. The term “common liability” refers to the possibility that teens that experiment with one forbidden substance are more likely to experiment with other forbidden substances when compared to teens not prone to such experimentation. Data derived from the very studies used to allege that e-cigarettes recruit teens to smoking show that less than 3% of new teen smokers at Time 2 had experimented with e-cigarettes at Time 1 [12-14]. Does this trivial finding justify the conclusion that eliminating e-cigarettes from the market will significantly reduce teen smoking?
4. FDA considers smoking to be a disease and therefore requires any product claiming efficacy for smoking cessation to be licensed and marketed as a drug. Since randomized clinical trials are considered the only quality evidence of such efficacy, this designation has the practical effect of dismissing all of the survey data and other reports providing evidence that e-cigarettes divert both teens and adults from smoking and may play a role in the accelerated reductions in both teen and adult smoking prevalence in recent years. Re-defining smoking as a behavior could solve this problem and allow consideration of all pertinent evidence.
5. Tobacco-related “regulatory science” seems focused entirely on documenting potential harms without due consideration of well documented personal and public health benefits. This custom perpetuates the mindset that low-risk non-pharmaceutical nicotine delivery products such as e-cigarettes and snus offer only harms, and no possible benefits. This custom militates against ever adding a tobacco harm reduction component to tobacco control programming.
6. CDC survey data has been consistently misleading regarding the following:
 - a. They fail to differentiate between vaping of nicotine, flavor-only, marijuana or other substance. They present their pooled data as if all vaping represents “tobacco use”.
 - b. They fail to differentiate risks due to specific vape products, attributing such risks to all vape products. Examples include the severe “EVALI” pulmonary disease due to marijuana vapes laced with Vitamin E Acetate and the risks of teen addiction due to high-dose JUUL products and JUUL knock-offs. Both have been consistently reported as risks attributable to any vaping product. We would be better served by a surveillance process and regulatory process that differentiated between beneficial and harmful vape products.
 - c. They rarely differentiate between experimentation and consistent use of any vape product. Experimentation that does not lead to use more than 20 days per month does not suggest addiction.
 - d. When presenting high-school data, they fail to differentiate adult students (18 and older) from other students.
 - e. They do not emphasize that vaping is far less hazardous than cigarettes.
 - f. Noting the correlation between increasing use of e-cigarettes and accelerated rates of reduction of teen smoking prevalence, CDC seems never to seriously consider the possibility that e-cigarettes, to some degree, might be driving the accelerated reductions in smoking.
7. Campaigning against the use of e-cigarettes without referencing that they are far lower in risk than cigarettes has the po-

tential to drive vapers and would-be vapers back to cigarettes or to black market products likely more harmful than commercially available e-cigarettes. Tobacco control authorities have not taken steps to explore or reduce these likely adverse impacts.

8. The FDA tobacco law prohibits any product from claiming less risk than cigarettes just because it is smokeless. This is despite the fact that we have long known that combustion is the main determinant of risk.
9. The FDA, based on the text of the FDA tobacco law, seems to presume that the risk posed by cigarette products is primarily due to its chemical composition (as opposed to the manner in which the user is exposed). Extensive laboratory testing is required even though we have no idea which chemicals or which combination of chemicals in cigarette smoke are responsible for what proportion of the cancer, heart and lung disease associated with smoking. We know that reducing or quitting smoking reduces the risk of illness and death. We have no idea as to the degree to which elimination of certain toxins in cigarette smoke might do the same. Furthermore, there is simply no realistic way that a clinical trial can be conducted to document the benefit of reducing any single chemical component or group of such components. Since we already know that nicotine is not a cause of cancer, heart or lung disease, why can we not use this knowledge to guide our regulation of these products?
10. FDA authorities claim to support innovation in the tobacco industry to create less hazardous products [15], yet the provisions of the FDA tobacco law, as they relate to application for pre-market and reduced-risk approvals stifle innovation [16,17].
11. The idealized FDA “end game” relates to mandating reduction of nicotine content in cigarettes to non-addictive levels. In doing so, they frankly admit that, for this to be effective in eliminating smoking, smokers must have alternative low-risk nicotine delivery products readily available on the marketplace, products acceptable to current smokers [18,19]. Does this not mandate a fundamentally different approach to e-cigarettes, snus and other low-risk products?
12. Multiple surgeon general reports have stated that the big-tobacco cigarette companies are the “vectors” of the continuing pandemic of tobacco-related addiction, illness and death [20,21].
13. Despite this, the cost and difficulty of FDA approval for new products makes it all but impossible for any company other than a giant corporation with access to foreign markets to secure such approval. The combination of FDA pre-market approval of the Philip Morris IQOS product and the current plan to eliminate the entire vape-shop industry and most other e-cigarette products from the marketplace, beginning September 6, 2020, has the practical effect of handing the entire e-cigarette marketplace to a company the tobacco control community loves to hate.
14. The tobacco control community continues to rely on pharmaceutical nicotine gums, patches, etc. for smoking cessation despite their lack of appeal to smokers and the fact that, with decades of experience, there is no evidence of public health benefit [22] and no evidence of efficacy for long-term abstinence [23]. Because these nicotine products are not considered tobacco products, they are sold on open shelves with no enforcement of age restrictions and are not subject to CDC surveillance. Are they not subject to possible abuse?
15. Prohibition of alcohol a century ago proved to be such a public health disaster that it had to be repealed. While it did seem to reduce alcohol consumption and cirrhosis, it caused such severe problems related to crime and contraband that it had to be repealed. Tobacco control authorities seem not to have learned from this experience in terms of their approach to e-cigarettes. Do CDC and FDA really believe that eliminating a product currently used by tens of millions of Americans will not

lead many of them back to either or to black market products that might be substantially more harmful than the vape shop and convenience store e-cigarettes now slated for elimination?

Conclusion

Current federal initiatives to eliminate e-cigarettes from the marketplace are likely to do far more harm than good from a public health perspective. The problems appear to be a long-term anti-all-things-tobacco orientation in the public health community, bolstered by dysfunctional provisions of the FDA tobacco law, poor quality tobacco control science and an unwillingness to consider findings strongly suggestive of benefits of e-cigarettes, benefits not likely to be achieved by other means. The time has come for tobacco control leadership to address the dysfunctional aspects of our current tobacco control programming listed in this paper.

Bibliography

1. Gladwell M. "The Tipping Point". Little Brown (2000).
2. Nitzkin J. "E-Cig Tipping Points vs. FDA Deeming Regulations". *Journal of Addiction Research and Therapy* 8.1 (2017): 1-3.
3. Mincer J. "U.S. e-cigarette use stalls as health concerns grow". In: Ipsos Poll (2016).
4. McNeill A., *et al.* "E-cigarettes: An evidence update". A report commissioned by Public Health England. London, England. Public Health England (2015).
5. United States v. Philip Morris. US District Court, District of Columbia (2006).
6. Centers for Disease Control and Prevention. "Current Cigarette Smoking Among Adults in the United States". In: CDC Fact Sheet (2019).
7. Nitzkin J. "The case in favor of e-cigarettes for tobacco harm reduction". *International Journal of Environmental Research and Public Health* 11 (2014): 6459-6471.
8. Hajek P., *et al.* "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy". *New England Journal of Medicine* 380.7 (2019): 629-637.
9. Kessler D. "A Question of Intent: A Great American Battle with a Deadly Industry". Public Affairs (2001).
10. Food and Drug Administration v. Brown and Williamson Tobacco Corp. U.S. Supreme Court. March (2000).
11. Fagerstrom K. "Dependence on tobacco and nicotine". *Nicotine Science and Policy* (2013).
12. Rodu B. "Tobacco Gateway Report Omits Important Information". In: Tobacco Truth (2018).
13. Siegel M. "Landmark Study Fails to Find Any Evidence that Vaping is a Gateway to Smoking Among Youth". In: The Rest of The Story (2019).
14. Watkins S., *et al.* "Association of Noncigarette Tobacco Product Use with Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015". *JAMA Pediatrics* (2018).

15. Zeller M. "The future of nicotine regulation: key questions and challenges". *Nicotine and Tobacco Research* 21.3 (2019): 331-332.
16. Mickle T. "FDA Cloud Hangs Over Vape Shops". In: Article. *The Wall Street Journal* (2015).
17. Office of the Commissioner. Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements (2016).
18. Donny E., *et al.* "Randomized Trial of reduced-nicotine standards for cigarettes". *New England Journal of Medicine* 373.14 (2015): 1340-1349.
19. Food and Drug Administration. Tobacco Product Standard for Nicotine Level of Combusted Cigarettes: A Proposed Rule. FDA (2018): 11818-1143.
20. Office of the Surgeon General. *The Health Consequences of Smoking - 50 Years of Progress* (2014).
21. U.S. Department of Health and Human Services. *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*". In: *A Report of the Surgeon General*. Atlanta, GA; (2010).
22. Zhu S., *et al.* "Interventions to increase smoking cessation at the population level: how much progress has been made in the last two decades?" *Tobacco Control* 21.2 (2010): 110-118.
23. Moore D., *et al.* "Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis". *British Medical Journal* 338.1024 (2009).

Volume 8 Issue 10 October 2020

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