

# The Great Vape War

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My name is Monte L. King and I am a Professional Land Surveyor that used vaping to quit a 26+ year smoking habit. I previously wrote an opinion paper addressing how I believe Public Health is failing America concerning nicotine vaping, see [Triple Fail-MLK](#). As stated in my previous paper I have no affiliation with any industry involved in vaping, medicine, tobacco, or Public Health. I am just a land surveyor that consumes nicotine by vaping and advocates for an industry that saves lives by allowing people a choice of a less harmful product for using nicotine. It is a rights issue involving personal choice and actually could help revolutionize Public Health concerning tobacco use.

I believe society as a whole should encourage vaping and other tobacco harm reduction products with the goal to eventually eliminate demand for combustible cigarettes, therefore eliminating the production of cigarettes. However, I do not feel we as a society have the right to take away personal choices such as smoking. As the saying goes you can lead a horse to water but you can't force them to drink, i.e. can not force smokers to switch.

Vaping has been demonized by anti-vape organizations and media, but is also being eliminated through regulations by FDA. This paper expands on my opinion about several facets of vaping including FDA's regulations and the anti-vape campaign, which includes political weaponization of vaping and the mainstream media's misinformation dissemination. The term vaping can be associated with nicotine or THC use by many, however in this document the term vaping refers to nicotine. And when referring to using an e-cigarette as a delivery system for THC, the term "dabbing" will be utilized. This terminology will hopefully be clear and therefore refrain from conflating the 2 very different forms of vaping.

A statistic to consider when developing an opinion on vaping and other tobacco harm reduction is that 480,000 people die each year in the U.S. from smoking related illnesses. These deaths can be directly attributed to the use of combustible cigarettes which has hindered Public Health for generations.

Another statistic is that there are people that have been vaping for 10+ years and 0 deaths can be attributed to nicotine vaping. I know, I know, EVALI! However, those cases have been proven to have been attributed to vaping illicit THC cartridges that contained vitamin E. Read the above linked paper.....

## **The Anti-Vape Campaign**

The concept of being anti-harm reduction is something I can not understand. Vaping is proven to be at least 95% less harmful than combustible cigarettes yet many are very adamant about trying to eliminate the industry for various reasons. These reasons seem to mostly revolve around money, specifically funding from pharmaceutical companies (*Big Pharma*) and prohibitionists like Bloomberg and of course the Master Settlement Agreement's (*MSA*) yearly payments to state governments.

Big Pharma and Bloomberg funded campaigns:

The anti-vape campaign is very well funded. The list of organizations that appear to have accepted this money is very extensive. It includes Campaign for Tobacco Free Kids, Parents Against Vaping (*PAVE*), Truth Initiative, American Lung Association (*ALA*) and many other body part organizations, FDA, and CDC. The list is not all inclusive as there are too many to name.

One tactic used by the campaign is trying to dis-credit the science that shows vaping is at least 95% less harmful than cigarettes, by funding studies to be conducted by individuals/groups that are biased. These individuals/groups have published documents that have been proven by peer review to incorrectly interpret and/or report the results in a manner that is mis-leading. The result reporting is obviously an attempt to sway opinions of policy makers and the general public to be against vaping. Some of the studies even seemed to actually be designed to prove that when a vaping product is mis-used it will cause harm. Fact is there are many products on the market that when mis-used will cause harm. Some of the obvious ones are alcohol, caffeine, sugar, cars, guns, cars, and of course many more. *"The only way to refute science is with better science not feelings, religion, favorite politician, or a half-baked opinion after watching two YouTube videos,"* credit to unknown.

Another tactic continuously used is the typical one that claims nicotine is the root cause of addiction to cigarettes, therefore any product containing nicotine will be extremely addictive. The idea that nicotine is the main addictive aspect of tobacco use seems to have begun with a U.S. Surgeon General's 1988 opinion that is perceived as saying that nicotine is as addictive as heroin and cocaine. See [NY-Times: 1988-US Surgeon General "asserts-smoking-is-an-addiction"](#) The Royal College of Physicians and others have concluded that nicotine is no more harmful to health than caffeine. See ["nicotine--no-more-harmful-to-health-than-caffeine"](#) Nicotine has also been shown to be beneficial for many reasons. I am not going to go into details about the benefits as I am

more concerned about the simple common sense aspects of nicotine use in a recreational manner.

An interesting fact is that the nicotine used in cessation products developed by the Big Pharma such as patches, inhalers, and gum, is the same exact nicotine as what is used in vaping and other nicotine products. Many people are of the opinion that the tobacco industry (*Big Tobacco*) is the nefarious actor that gains the most from people smoking and therefore encourages the use of products produced by them. It is a business so of course they want people to use their products, but as a business I am guessing they would be open to eliminating production of cigarettes if they can profit from an alternative. Business 101 if you ask me, eliminates the liability of MSA and still profits. The issue with Big Tobacco being involved in the vape industry is that vaping was developed by consumers and has created a scenario where small businesses can succeed without a large industry aspect. There is no such thing as Big Vape. Good joke but not true. I personally believe that Big Pharma is the true nefarious player that gains the most by people smoking because they produce the products that treat the associated illnesses and also the products that are medically approved as cessation. The more people that smoke is a Win Win for them, because eventually people become sick from or want to quit cigarettes. The fact is that vaping and other products such as nicotine pouches are in direct competition with Big Pharma. The harm reduction products provide something that can be used for cessation to completely quit nicotine or for those of us that do not want to quit nicotine for various reasons we have a less harmful way of ingesting nicotine. Big Pharma's profits and influence over regulations/policy is threatened so I am sure they are happily funding anti-vape campaigns. A 1969 quote by Dr. Herbert Ley, Harvard Professor, ex-FDA commissioner, "*The FDA protects the big drug companies, and is subsequently rewarded, and using the government's police powers, they attack those who threaten the big drug companies. People think that the FDA is protecting them. It isn't. What the FDA is doing, and what the public thinks it is doing are as different as night and day.*" Interesting that even in 1969 an ex-FDA commissioner believes that Big Pharma influenced government regulation and policy.

As a parent my all time favorite tactic (*sarcasm*) that is used by anti-vape groups is the "save the youth" concept. I go into detail about this in my previous paper but I want to reiterate a couple of things. First off I want to again say that as a parent I firmly believe that if one of my kids wanted to experiment with nicotine I would rather they vape or use nicotine pouches than use traditional tobacco products. My reasoning is that I know youth are by nature curious and will experiment with many things. I would prefer it be the least harmful version no matter the product. Caffeine for instance, I would rather they drink a

soda than energy drinks that contain excess amounts or are a mixture of items known to cause neurological damage in some people. The concept of harm reduction is not new. Something that is scary about the concept of saving the youth is the fact that in history several oppressive regimes have used this to convince people to give up individual freedoms in exchange for the safety of their youth. A promise of youth safety creates complacency in the population which would be the goal of a government trying to control its citizens.

#### State MSA payments:

State governments have come to rely on the MSA payments to fill budget holes. The MSA payments are based on the annual amount of combustible cigarettes sold in the particular state. Therefore it is common sense that states would be against vaping because it reduces the MSA payments. The states dug the hole even deeper by taking bonds out based on future MSA payments. When the bond comes due it is realized actual MSA payments are below the estimate, therefore the state would need to supplement funds from elsewhere to pay the bond. Naturally the reduction in MSA payments can be attributed to the fact many smokers are switching to vaping as cessation or for a less harmful way to consume nicotine; Harm Reduction! The MSA also requires states to spend a certain amount of the annual payments on tobacco prevention and cessation. The information I have personally seen showed that the states have not followed through with this aspect.

Seems to be a good reason for state and local governments to ban vaping altogether, ban certain aspects of vaping (flavored e-liquid), or create an extreme tax, all of which discourage if not eliminate vaping as an option to reduce risk from cigarettes. This will increase cigarette sales due to people going back to smoking because of no alternative or being restricted to a product that is too similar to cigarettes such as tobacco flavored e-liquid. The anti-harm reduction attitude will also only leave traditional tobacco products as an option for curious youth. They will experiment so common sense says better it be something less harmful than cigarettes.

#### Mainstream Media and misinformation:

I will start with a quote by Winston S. Churchill, "*A lie gets halfway around the world before the truth has a chance to get its pants on.*" This is the epitome of today's high speed digital world. Many media outlets create misinformation by using story titles that misrepresent the facts and also by not reporting all aspects of the story. This was described in my prior paper concerning "EVALI." The actual cause of the lung injuries was known to be from illicit THC cartridges with vitamin E back in August of 2019 and yet many people

still thought it was from nicotine vaping. The problem was that the media and government agencies, such as FDA and CDC, kept conflating vaping and dabbing. The CDC even took credit in January 2020 for determining the cause of the lung injuries although it was reported by media outlets such as Leafly and Reason back in August 2019. Interesting timeline considering the CDC, FDA, and many media outlets, kept reporting that vaping caused the injuries until early 2020, therefore a majority of people, including policy makers, continued or began to believe nicotine vaping was dangerous (*0 deaths in 10+ years*). This influence had worldwide effects as many governments look to the U.S. as an authority on Public Health. This misinformation appears as fear mongering to sway people into demonizing an industry that is competing with Big Pharma. Hard to ignore the connection with an industry that would lose the most from vaping and is worldwide. Also interesting to note that Bloomberg has financial interests in media distribution. Could the anti-vape funding be the reason for the conflation trying to eliminate business competition? I go back to the quote by ex-FDA commissioner, when Big Pharma is threatened then the FDA attacks the threat. ....I believe the same could be said about CDC, media, and politicians.

#### Politics of vaping:

First off I am not affiliated with any political organization or party. I am moderate and would say I fall in the middle of all political parties. Not a democrat, not a republican, not a libertarian. I am an advocate for all rights, but do not believe being offended by someone exercising an individual right is a justification to take away said person's rights. We are all human and individuals with different opinions and desires. Politics are necessary in America for the concept of democracy to work, however it seems lately there is a chasm between parties. This has created an environment where personal attacks are the normal and no one is willing to even try to see the other points of view. Vaping has become a weapon for politicians in an attempt to discredit others. Many have criticized President Trump for actually listening to the consumers and supporting vaping as harm reduction. My issue is why does it have to become political, it is a genius invention that could revolutionize Public health, and should be promoted as such by all politicians. One observation I would like to point out is it seems that vaping support is a partisan thing. Democrat politicians are generally anti-vape, whereas Republican politicians generally support it as a personal choice right. Hmmm odd considering Democrats typically support abortion (*personal choice*) and legalization of cannabis (*banned substance with recreational and medical uses*), whereas Republicans are typically against abortion and cannabis legalization. Makes me wonder who is donating to the anti-vape politicians, maybe Big Pharma?

## **FDA Regulations**

As a reminder I will start with this 1969 quote by Dr. Herbert Ley, Harvard Professor, ex-FDA commissioner, *“The FDA protects the big drug companies, and is subsequently rewarded, and using the government’s police powers, they attack those who threaten the big drug companies. People think that the FDA is protecting them. It isn’t. What the FDA is doing, and what the public thinks it is doing are as different as night and day.”*

The classification of nicotine vaping as being a tobacco product by the FDA is incorrect in my opinion. The 2009 amendment of the Tobacco Control Act defined “tobacco products” as *“any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product),”* and nicotine as *“The term ‘nicotine’ means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.”* The amended act required the FDA to regulate *“cigarettes, cigarette tobacco, smokeless tobacco, and roll your own tobacco,”* and also stated *“To regulate all other products, the agency was required to issue a rule that “deems” those products to be within the FDA’s authority.”* The 2016 FDA deeming rule, finalized on May 10, 2016, with an effective date of August 8, 2016, is what actually determined that the FDA would be regulating nicotine vaping products the same as tobacco. It contains the statement *“Products that meet the statutory definition of “tobacco products” include currently marketed products such as dissolvables not already regulated by FDA, gels, waterpipe tobacco, ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.”* This statement seems to be contradictory to the actual statutory definition of “tobacco products.” The definition is clear that “tobacco products” are derived from tobacco. The only aspect of vaping that fits the definition is the nicotine and, as previously stated, it is the same nicotine that is used in approved Nicotine Replacement Therapies (NRTs) developed by Big Pharma, which include nicotine gum, lozenges, inhalers, and others.

Another aspect of the deeming rule setup deadlines for all “tobacco products” to be approved for sale through the PreMarket Tobacco Application (PMTA) process while allowing current products to be sold prior to their PMTA approval. However, any new products introduced to the market after the deeming rule took effect would be required to go through the PMTA process prior to being sold. The current deadline is September 9, 2020. The PMTA is a very expensive process that only large producers such as the makers of NJoy, Juul (Altria owns 35%), Hale (Hava Health), and IQOS (Phillip Morris) can afford to get done. The approximate cost of PMTA for each liquid would range from

\$12,112 to \$398,324 (*average of \$131,643*) and for devices it ranges from \$28,566 to \$2,595,224 (*average of \$466,563*). These kinds of prices would be way out of reach for any small business. A requirement by a federal agency should **not** exclude small businesses by overpricing of fees, because that appears to give a large industry an extreme advantage. This should not be the purpose of regulation particularly with a product such as vaping, which was developed by consumers **not** a big industry. These types of high fees are charged for other approval processes for drugs and other products. Hmmm exorbitant fees paid by Big Pharma to FDA for approvals. Is this the reward that is referenced by Dr. Herbert Ley? Hard to ignore...

Overall the FDA 2016 deeming rule seems to be an overreaching regulation that from what I can tell has some biased tones to it (*Big Pharma influence?*). It appears to be an attempt by an agency to force an interpretation of a portion of the 2009 amendment to the Tobacco Control Act in a manner that allows them to enact regulations that create an advantage for large corporations (*Corporatocracy*). This advantage for Big Tobacco would greatly benefit Big Pharma because it eliminates a large portion of their competition from small vape businesses.

Many believe that there is nothing that can be done to stop the PMTAs from eliminating all vaping businesses except large corporations. I am of the opinion that the administration has the authority and legal right to request that the FDA amend the deeming rule to exclude all vape products, including all ingredients in e-liquid, except nicotine. This would be within the 2009 TCA's requirements. It defines tobacco products as derived from tobacco, so by the FDA deeming vaping as a tobacco product I believe they are outside their authority, except concerning nicotine. To truly be within the statutory definition of tobacco product the only aspect of vaping that should be required to have a PMTA is nicotine. In my opinion one company such as Njoy could have a PMTA on nicotine and it should apply to all e-liquid manufacturers, i.e. one PMTA for all e-liquid manufacturers. The vape devices and accessories should be treated as consumer products. A new regulatory category could be created for harm reduction products that can contain nicotine (*0 mg nicotine e-liquids = 0 nicotine*). The regs could include age restrictions similar to tobacco for purchasing vape products. A separate regulatory category would also allow for reduction in taxes and reasonable safety regs similar to other consumer products. The reasonable regulations would benefit small businesses, Public Health, and allow for the continuous development of better products. The only way to truly eliminate combustible cigarettes is to promote less harmful nicotine products by keeping costs low, encouraging switching using flavors, and allowing personal choice.

For those that read this and my previous paper in their entirety I appreciate you taking the time. If you are anti-vape I truly hope I at least convince you to see the issue from a different perspective. It is not black and white, there are many grey areas in societal issues such as substance use. One big thing for me is that no one should be ostracized for making a personal choice to use substances. I

enjoy nicotine in the same way I enjoy coffee, a beer, chocolate, and many other things I consider joys in life. How about you?

Useful links about vaping and/or nicotine:

[@Ravin187 - Vaping facts and why these bans are plainly scientifically unjustifiable](#)

[Unknown - Vaping Study Compilation - 100+](#)

[Vaping what people are getting wrong by The Economist-youtube](#)

[Clive Bates-vaping-tobacco-harm-reduction-nicotine-science-and-policy-q/a](#)

[Discover Magazine-nicotine-the-wonder-drug](#)

[If the data contradict the theory, throw out the data: Nicotine addiction in the 2010 report of the Surgeon General](#)

[Economist-2018: e-cigarettes-are-almost-certainly-better-than-smoking](#)