How Public Health Failed America and How America Failed Public Health

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Note: The minor edits include link updates, grammar errors, clarifications, and removal of synthetic nicotine use by manufacturers statement (found to be incorrect as only some use it due to high cost). The use of the term ENDS (electronic nicotine delivery system) is to add distinction between nicotine vaping and THC/CBD vaping.

The following is my opinion as a person who has used an ENDS product *(nicotine vaping)* as a way to quit smoking combustible cigarettes. I do not work in nor do I receive any compensation from the vape industry. I am a consumer who chooses a less harmful option with the intention to eventually quit. Also I am in no way affiliated with anything to do with any health or related industry. I am a Professional Land Surveyor (PLS).

I first tried vaping back in 2009 using what is termed a cig-a-like style with tobacco flavors. I continued smoking and eventually went back to combustible cigarettes exclusively. Periodically I would try again with mostly tobacco flavors and cig-a-likes to quit combustible cigarettes. During this period of time I also tried nicotine patches, gum, lozenges, and even Chantix with absolutely no success, but I did get adverse side effects from Chantix. Success did not occur until 2017, when I went into a vape shop and I got set up with a sub-ohm open system. I started by using an apple flavor named green blast at 6 mg/ml nicotine. Less than a week vaping and I had accidentally quit smoking combustible cigarettes after 25+ years of 1 to 1 ½ packs per day. I now vape mostly fruit flavors and currently use 3 mg/ml nicotine. I intend to continue reducing my nicotine levels until I am at 0 mg/ml. Personally, I will most likely continue vaping flavored e-liquid at 0 mg/ml nicotine to eliminate relapse potential due to the physical aspect of a long term smoking addiction. These are extremely low levels of nicotine for the average cigarette smoker to completely quit a combustible cigarette habit. Obviously for certain people like me the flavors are the most important aspect of switching to a less harmful nicotine delivery system. Since I have been cigarette free for 2+ years my health has drastically improved! It is a harm reduction product designed by consumers for adults who currently smoke cigarettes and would like to choose a less harmful substitute to eventually end a nicotine habit.

I read an article that seemed to be applicable concerning the current Public Health issues surrounding the use of combustible cigarettes, electronic nicotine delivery systems (ENDS), and e-cigarettes as a delivery system for THC and CBD. The article is titled "*Avoiding the Public Health Triple Fail,*" dated January 14, 2017, by Sandro Galea, MD, DrPH, Dean and Professor, Boston University. It discusses how Public Health failed concerning the opioid epidemic and

obesity. The article has nothing to do with vaping, but it is a good source of information that explains the ***"triple aim"*** concept of Public Health.

The article stated that "*The **"triple aim"** in health care was articulated by the Institute for Healthcare Improvement as a framework to facilitate the advancement of health system performance in the United States.*" The ***"triple aim"*** includes "*improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations.*"

The following is my opinion on how the ***"triple aim"*** can be applied to the Public Health aspect of the harm reduction benefit that would be achieved through the use of ENDS products as a replacement for deadly combustible tobacco cigarettes. I will include some aspects of the use of e-cigarettes as a delivery system for THC and CBD due to the fact that the continued lung injuries associated with said components is an example of Public Health failure. I will hopefully demonstrate how the banning of ENDS (vape) products, including flavors, would be a ***"triple fail,"*** as described in the referenced article. My opinion of how Public Health has already failed, concerning "vaping," will be after the "would be triple fail."

How proposed bans of ENDS products, including flavors, would be a ***"triple fail"*** by Public Health

1) Improve the individual experience of care:

> As an ex-smoker, who has many friends that are also ex-smokers or current smokers, I have some insight into what is important to myself and others in our health care. First off I believe we are all individuals and all aspects of life affect us in different ways, particularly health care. Individual care is about customizing the solution to the particular health issue that is being addressed. The customization is probably the main reason for successful treatment, particularly when the health issue concerns addiction.
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> The proposed bans of ENDS would **fail** to *improve the individual experience of care* because if an individual is a current smoker trying to quit combustible cigarettes and they prefer using an ENDS product with flavored e-liquid to reduce the harm of their nicotine habit, then this should be considered individual experience or customized care.
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> > Many alluded to or argued that ENDS products are the cause of the recent lung injuries and/or <u>not</u> less harmful than combustible cigarettes, including Parents Against Vaping (PAVE), Truth Initiative, Tobacco Free Kids, American Heart Association (AHA), American Lung Association (ALA), American Medical Association (AMA), CDC, FDA, HHS, and most media outlets. However, 35,000 EU doctors and Public Health England (PHE) disagree. The reason for the

disagreement is that PHE analyzed many studies, by the Royal College of Physicians and others, on the harmful side effects of using an ENDS product vs combustible cigarettes and determined that ENDS product use is at least 95% less harmful than combustible cigarettes. This conclusion has been confirmed by 35,000+ EU doctors. Also a VESUVIUS study, as published, on November 15, 2019, in the Journal of the American College of Cardiology, reported on the cardiovascular effects of ENDS use vs combustible cigarettes and it showed the fact that ENDS product use is less harmful than combustible cigarettes. The following are links to studies and/or information associated with ENDS products:

ENDS Studies (spreadsheet of ENDS studies, includes links)

@ravin187 (document written by a biotech scientist, includes links)

Dr. Konstantinos Farsalinos, M.D.-ENDS research (webpage with research specific to ENDS, includes links)

An aspect that short term ENDS or cigarette users do not typically deal with is the physical (action of smoking) aspect of the addiction that only comes from long term use. This is something that becomes muscle memory after so many years, hence why ENDS products work so well for many people to quit combustible cigarettes. It gives them the ability to slowly lower the nicotine but keep the action of smoking. The action part, which also consists of socializing with others in smoking areas, becomes a part of people's personalities and thus the difficulty of quitting. Personality changes are very difficult and can even become impossible depending on the individual's circumstance and general well being.

2) Improve the health of populations:

The health of a population is built upon the individual experience of care and an individual's overall health. This relationship can be affected by actions that affect the individual, but also by the actions of an individual that adversely affect another person, such as smoking combustible cigarettes. It is a well known fact that smoking traditional cigarettes will cause extensive harm to the individual user and the people around them, therefore I am not going to delve into that subject. The fact that ENDS use is 95% less harmful than traditional cigarettes has been substantiated in No. 1 of the ***"triple fail,"*** therefore I will not repeat the supporting information. PHE has been very clear on their position that ENDS use will improve the health of their population. They actively encourage all users of combustible cigarettes to switch to an ENDS product with the goal of being traditional cigarette free by 2030, see Tobacco_Control_Plan_for_England_2017 They even have shops that sell ENDS products in hospitals and allow indoor use of

ENDS. In the United States, prior to the recent anti-vape campaigns, many including, but not limited to the FDA, ALA, AHA, HHS and AMA, were making statements that ENDS product use was considered harm reduction and recommended versus using traditional tobacco products.

The proposed bans of ENDS would **fail** to *improve the health of the population* in the following ways.

> If all products are banned many current ENDS users will just go back to smoking combustible cigarettes. This would most likely occur even if ENDS with tobacco flavors remained on the market. As demonstrated by the above information and PHE this would put the individual people at a higher risk (95% higher) of harm from smoking traditional cigarettes. The fact that more people would be smoking combustible cigarettes would put the rest of the population that are non-users at a much higher risk due to second and third hand smoke.
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> If flavors are banned then people determined not to go back to traditional cigarettes will find other ways of getting flavored e-liquid. This would create a black market of un-regulated products that would grow exponentially similar to the black market for alcohol during prohibition. For the most part in the beginning of the black market there would be knowledgeable people producing the e-liquids so the main risk would be prosecution. The reason for this short lived phenomenon is that the current people in the ENDS industry believe in the harm reduction aspect and want to help people prolong their lives. However, once the criminal syndicates realize it is a 24 billion dollar industry they will become heavily involved, which as we all know they are about money and not helping people, so contamination and improper production are a guarantee. This puts all at risk, see "lung illnesses associated with vaping" catastrophe.

The health of a population has <u>never</u> been shown to improve with prohibition of a substance that is considered by some to be harmful. Many times in history it has been demonstrated that the prohibition is based on misinformation and/or propaganda that convinces some that the substance is so harmful it should be prohibited. The prohibition of alcohol and cannabis are two such examples. Both have a history of use for the purposes of recreation and self medication, which both are believed to have some medical benefit at certain levels. Nicotine seems to be in the same category since it also has a history of use for the purposes of recreation and self medication. The recreation use of nicotine is well known but there are also some medical aspects as described in an article published by Harvard Health Publishing, in March 2014, titled "*Nicotine: it may have a good side*" that stated "*But the rogue substance has a wide range of effects on the brain, which may*

include some healing properties. Researchers are testing nicotine and related compounds as treatments for Alzheimer's disease, Parkinson's disease, attention deficit/hyperactivity disorder (ADHD), and other conditions." This indicates that many that start and continue using products with nicotine may actually unknowingly be self medicating all the while believing they are just addicted. Again I am no expert and this is just my opinion.

My grandpa was a neurologist and one thing I remember is that him and many others of his generation had the line of thinking that if any substance for human consumption that has risk (examples are recreational drugs, nicotine, and alcohol) is going to be used, it should be in moderation to better mitigate the associated risks. I am sure many will disagree and are in the opinion that humans should not put any substance in their body unless it is shown to be 100% safe. I believe nothing in the world is 100% safe and I also believe it is an inherent human right to decide what risks we as individuals want to take concerning all aspects of life. In the case of ENDS use, it is an adult's right to choose something that is harm reduction.

3) Reduce the per capita costs of care for populations:

This is the subject that typically gets all of the attention, Health Care Costs, both to the individual and to Public Health. As everyone knows the cost of health care continues to rise and could be one of the biggest expenses in an individual's life. Everyone should know the financial costs of healthcare associated with smoking traditional cigarettes. It has been shown that many major diseases are caused by smoking combustible cigarettes. These diseases take a lot of money to treat and typically it is just putting off the inevitable. Even if traditional cigarettes were taken out of the health equation, people would still get those diseases, but at a much lower rate. The 2009 Amendment of the Tobacco Control Act's (Public Law 111-31, June 22, 2009) Sec. 2, Pt. 13, states "*Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking."* If ENDS products replaced cigarettes then it is reasonable to conclude, same as PHE, that the population of nicotine users would be 95% less likely to get the diseases associated with traditional cigarettes. This can translate to massive financial savings concerning smoking related illnesses.

The proposed bans of ENDS would **fail** to *reduce the per capita costs of care for populations* in the fact that the costs associated with smoking related illnesses would continue to skyrocket instead of declining. This will be directly attributed to current ENDS users going back to traditional cigarettes and current smokers not having the option to use a product that is less harmful.

My personal healthcare costs have significantly dropped in the 2 years that I have been using an ENDS product. I have always made it a point to not smoke indoors to keep my kids safe from my choice to use traditional cigarettes. However, I do know that even the smoke residue on clothing could have harmful effects, therefore I feel I am providing a safer environment for my kids by having switched to an ENDS product. I have also noticed that in the last two years my kid has not been to the doctor except for normal checkups and once for a respiratory virus that affected many in the community including people who do not use nicotine products.

My personal conclusion is that a ban on ENDS products or flavors is truly a **"triple fail"** by Public Health.

How Public Health has already failed concerning ENDS products

One of the biggest factors of our healthcare is communication between the patient and doctor. Many people are <u>not</u> honest with healthcare providers about personal choices fearing judgement, criticism, or legal prosecution. It is understood that this is the purpose of doctor patient confidentiality, however it seems many are still reluctant to be honest, especially minor children. This was a major factor in the 2019 lung injuries (EVALI) that were reportedly associated with vaping. The doctors had relied on self reporting concerning what products the patients had used prior to the lung injuries, which could easily be skewed due to the concerns mentioned above. Initially the CDC reports of possible causes clearly included ENDS products as a possible source. The mainstream media, as usual, jumped on this misinformation and created a panic driven anti-vape campaign. An article written by David Downs titled *"Illicit cannabis vape carts hospitalized 7 in California, doctors say,"* published by Leafly on August 16, 2019, made it clear that at that time many experts believed the cause of the lung injuries were associated with the use of e-cigarettes as a delivery system for THC and CBD. However the CDC, doctors, and the mainstream media were <u>not</u> clear that ENDS were <u>not</u> involved in the injuries. They continued reporting that vaping was the cause, which your average person, including health experts, do not understand that there is a difference between ENDS products and e-cigarettes as delivery systems for THC and CBD.

The fact that ENDS have been in use for 10+ years without any issues related to lung injuries should be enough evidence that ENDS products were most likely **<u>not</u>** the cause of the lung injuries. The conclusion by PHE and EU doctors along with the links of information provided above are substantial evidence that ENDS products are 95% less harmful than combustible cigarettes. However, due to patients not being honest about their product use, particularly minor children, some people claimed that the ENDS liquids may have had a contaminate recently introduced into the supply chain. This is always a possibility with any type of product on the

market as demonstrated by recalls regularly issued for lettuce and other products. The likelihood of regulated ENDS products having a contaminate recently introduced is very low, particularly with the commercially produced e-liquids. The fact is that according to FDA's deeming rule, finalized on May 10, 2016, with an effective date of August 8, 2016, required all "tobacco product" producers to disclose the ingredients, substances, compounds, and additives in the products by May 8, 2018. 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. This regulation by the FDA would not allow any "new" ingredient or new product. The lack of new ingredients or products would lead one to believe that regulated ENDS products were **not** contributing to the lung injuries. The black market products such as counterfeit juul pods, illegal THC cartridges, and CBD liquids could contain anything and therefore are most likely the sources of the lung injuries. Another possibility of a source is that users can alter regulated products with unknown additives or attempt to produce their own e-liquids using unsafe ingredients. These black market issues can not be addressed except through education and law enforcement.

Considering all these facts that show ENDS products are not associated with the lung injuries, it is impossible to **not** come to the conclusion that ENDS products were never a contributing factor to the lung injuries. This is a failure by Public Health because they failed to clearly communicate the cause of the lung injuries which created confusion and risk to Public Health. The mainstream media was responsible for the spreading of false unverified information which was pushed on the world through propaganda filled campaigns by anti-vape organizations. In today's society digital communication is the way that many citizens obtain their information, including but not limited to social media, TV, and representatives of federal agencies tasked with Public Health. This digital environment is very fast paced and the vaping misinformation is a perfect example of what Winston Churchill once said *"A lie gets halfway around the world before the truth has a chance to get its pants on."* The spread of misinformation resulted in many current vapers and users of combustible cigarettes to become afraid of a product that is shown to be 95% less harmful than traditional cigarettes. This also caused many of the non "tobacco product" using public (up to 60% according to some polls) to believe that ENDS products are more dangerous and harmful than traditional tobacco products. There are 443,000 deaths per year attributable to smoking combustible cigarettes and the spread of propaganda that created hysteria around a product shown to be 95% less harmful is unacceptable and should be considered a failure by Public Health and society. The communication failure may have had world wide consequences as many look to the United States for leadership in Public Health and have now made decisions based on misinformation.

Another aspect of failed communication by Public Health is that the lack of clarity caused many, particularly minor children, to continue using illegal THC cartridges thereby extending the epidemic resulting in additional deaths. Many people have reported that their children and peers believe ENDS products, specifically juul, were the cause of the lung injuries. It has also been reported that many children have moved on from juul and are now using e-cigarettes solely as a delivery system for THC. This risky behaviour supports the conclusion that the Public Health communication about the lung injuries was a failure. The people who continued the risky behaviour of using non-regulated black market products were the possible victims of the reckless spreading of misinformation by the mainstream media, Public Health agencies, and various anti-vape/tobacco organizations.

On November 21, 2019, the CDC website was updated to read *"CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). Recent CDC laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in all of the samples. Vitamin E acetate is used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products. CDC recommends that people should not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, or family, or in-person or online dealers. While this investigation is ongoing, vitamin E acetate should not be added to e-cigarette, or vaping, products. In addition, people should not add any substance to e-cigarette or vaping products that are not intended by the manufacturer, including products purchased through retail establishments. CDC will continue to update guidance, as appropriate, as new data become available from this outbreak investigation."* This statement is somewhat clearer than previous statements about the lung injuries being associated with THC use, but the name EVALI creates confusion because of the general lack of understanding the difference between ENDS and e-cigarettes being used as a delivery system for THC. This is another example of the miscommunication by the CDC concerning Public Health.

It is interesting to note that the August 16 article published by Leafly was pretty clear that many experts believed the lung injuries were associated with THC use not ENDS, whereas the CDC did not clearly report that until November. It is very disappointing that the federal agency we all rely on for the facts and truth on Public Health, the CDC, failed to properly communicate the facts concerning the lung injuries. Obviously the doctors reliance on self reporting of substance use was also in error due to the above described concerns. The patients used illegal THC cartridges so of course they would be less likely to be truthful with the doctors due to the fear of legal prosecution, particularly minor children.

> Communication is a known issue in Public Health as demonstrated with a quote from a response about the vape issue that I received from Senator Kaine dated November 22, 2019. *"I am also deeply troubled by the multistate outbreak of lung illnesses linked to*

e-cigarette use. Public health surveillance and data systems are essential to detecting health threats and expediting our response to save lives. The success of these surveillance systems depends on the ability of state, local, territorial, and tribal health departments, as well as other public health partners, to communicate with one another and accurately report their data to the CDC in a timely way. That's why on June 12, 2019, I introduced the bipartisan Savings Lives Through Better Data Act (S. 1793) to fund investments in health departments' data collection, transmission, and analysis capacities. I was pleased key portions of this bill were also included in the Lower Health Care Costs Act when it passed out of committee on June 26th."

The failure by Public Health has many consequences including the fact that many will discontinue using ENDS products or current smokers will not consider them an option for harm reduction. As previously stated, many people now believe that ENDS products are more dangerous and harmful than traditional cigarettes. This failure also affects many small businesses and families that rely on that income to survive. The "vape shops" are just normal people that enjoy helping others with harm reduction, which for some will eventually result in abstinence from nicotine. ENDS products were initially created by consumers using innovation, which is the foundation of progress. Without innovation the world would not be as progressive concerning healthcare, particularly considering that current life saving procedures and equipment were created with it. Many shops have already closed and laid off employees due to the hysteria surrounding the lung injuries and the supposed youth "vaping epidemic."

The youth "vaping epidemic" was <u>not</u> due to availability of ENDS products in adult only vape shops. The sudden rise in youth vaping is coincidentally about the same time that Juul was released with nicotine levels much higher than free base e-liquids. These high levels (3% = 39 mg/ml and 5% = 59 mg/ml) give <u>new</u> users a buzz that is similar to caffeine and other drugs. They are meant as an alternative for adult smokers but we all know kids and their natural desire for experimentation. I am not a doctor or in the health industry, but I was a kid once and I can tell you if Juul were available then I would have used it. Since ENDS were not available at the time, I started experimenting with smoking combustible cigarettes at about 13. I became a full time smoker by 14 and as previously stated I continued for 25+ years. The high levels of nicotine are a possibility as to why teens initially try ENDS, but more than likely it is the fact that they are current smokers practicing harm reduction, curiosity, or peer pressure. Another factor that most likely contributed to the rise in youth use of ENDS is that many anti-vape ads actually had the opposite effect of the intended purpose. The youth were most likely introduced to ENDS products by the ads and as we all know when you tell a kid not to do something they will then want to do it.

After using those high levels for an extended period the individual could become "addicted" to nicotine. However, an article titled "*Nicotine-no worse than cup of coffee-Report,*" published by Skynews on August 12, 2015, describes a report from the Royal Society for Public Health (RSPH)

that indicates nicotine addiction is on par with caffeine. This quote from the article sums it up *"The research suggests nine out of 10 people falsely believe nicotine is very harmful to their health, when in fact it is no more dangerous than the caffeine in a cup of coffee. Shirley Cramer, chief executive of the RSPH, said: "Getting people on to nicotine rather than using tobacco would make a big difference to the public's health."* ***see*** *RSPH-UK_nicotine--no-more-harmful-to-health-than-caffeine* & Article - RSPH_report_Nicotine same as Caffeine. Considering this report's conclusion, it could be said that dependence to Juul would be like being dependent on energy drinks or espresso, whereas the lower levels of nicotine would be equivalent to soda or coffee. Both nicotine and caffeine are stimulants, therefore both can be over used and/or abused. There have been several cases of youth and young adults being hospitalized due to overuse of energy drinks. I was told by a doctor in a hospital, that was caring for a patient hospitalized due to overuse of energy drinks, stated that energy drinks cause heart and neurological problems when used in excess or are very harmful when used by someone who unknowingly is predisposed to health issues related to either cardiovascular or neurological. Should we ban caffeine? I do not agree with any bans, but it makes a point.

The addiction to combustible cigarettes can mostly be attributed to several of the other 7000 chemicals that are present while the cigarette is being burned. A quote from ALA about chemicals in traditional cigarettes is that *"There are approximately 600* ***ingredients*** *in* ***cigarettes****. When burned,* ***cigarettes*** *create more than 7,000* ***chemicals****. At least 69 of these* ***chemicals*** *are known to cause cancer, and* ***many*** *are toxic.* ***Many*** *of these* ***chemicals*** *also are found in consumer products, but these products have warning labels—such as rat poison packaging. Aug 20, 2019."*

This all seems to indicate that the ENDS products that use free base e-liquids would be as dependent causing as caffeine at levels as seen in soda or coffee. The problem with youth is that they are less likely to practice moderation, particularly with substances that give a high. Tolerance builds quickly so the amount of use naturally goes up as time passes and before it is noticed they are on the extreme end of use.

With all these things in mind I personally conclude that the youth "vaping epidemic" has been blown out of proportion by the anti-vape propaganda campaigns to further some unclear agenda. The agenda could possibly be connected to the funding from "Big Tobacco" through the Master Settlement Agreement, 1998. USA v. Philip Morris, USA, Inc., et al *(MSA).* From my understanding the MSA was an agreement developed to force "Big Tobacco" to pay reparations for all of the past and future damage caused by combustible cigarettes. At the beginning an initial lump sum was distributed to states and new funds would be based on the amount of cigarettes sold in a given period. The funding was intended to go to youth prevention, grants for studies on the effects of using tobacco, and other Public Health needs as determined by the states. Due to what can only be assumed to be budget shortfalls, states decided to take out bonds on future MSA funds. Since the bond money is borrowing future MSA money that is based on cigarette sales the states

overestimated the amount. The overestimation can be attributed to the fact that they did not account for the reduction of sales due to people switching to ENDS products. This puts them in a situation where they have bonds due to be repaid that are a larger sum of money than what they actually received from the MSA funds. I would assume some of the prevention money would be going to the non-profit anti-tobacco organizations and research programs in various academia. This may explain why the recent anti-vape propaganda campaign has been promoted by certain states and organizations. ENDS products are reducing MSA funding by lowering combustible cigarette sales, therefore any recipient of MSA money would have motive to eliminate ENDS products.

Another interesting item to note is that Bloomberg recently donated 160 million dollars to anti-vape campaigns. Interesting since he happens to have a financial interest in the Hale device (new nicotine delivery system similar to nicotine inhalers), see Village Global Featured Luminaries/investors *(Bloomberg name removed from site at some point after initial date on this paper)*, which is listed on the official Hale website as "Backers." see HALE *(Bloomberg name removed from site at some point after initial date on this paper)*. The hale device is actually going through a process with FDA to be classified as a smoking cessation treatment product similar to nicotine patches and gum. The thing that gets me is the fact that it uses technology with two different oil formulations. Well from what I understand the big thing with the lung injuries is that they are being classified as lipoid pneumonia, which is caused by inhaling oil. Free base e-liquid does not contain any oil substances. The FDA deeming rule has a statement which reads "*In addition, this final rule deems any additional current and future tobacco products that meet the statutory definition of "tobacco product," except accessories of such newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act. For example, FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery through means (e.g., via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be "tobacco products" and subject to FDA's chapter IX authorities in accordance with this final deeming rule.*" This is interesting considering the fact that Hale is similar to nicotine inhalers (current marketed medicinal product) but is being processed for approval as a smoking cessation product. I also believe the liquid would fall under this statement, because it contains nicotine, which according to how FDA treats free base e-liquid it should be classified as a "tobacco product."

This is where the FDA PMTA process comes back into play. 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 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 ENDS, which was developed by consumers not a big industry. It is also a product that has been proven to be so much safer than traditional cigarettes.

With all the information I have personally absorbed I would say FDA should not even be overseeing the regulation as a "tobacco product." The main reason being that ENDS are Tobacco Harm Reduction and therefore should not be regulated or taxed in the same manner as tobacco. They should be promoted and encouraged for the overall Public Health benefits. Also the classification of it 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, hereinbefore described, is what actually determined that the FDA would be regulating ENDS products 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, ehookah, 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 ENDS that fits the definition is the nicotine and it is the same nicotine as what is used in approved Nicotine Replacement Therapies (NRTs) which include nicotine gum, lozenges, inhalers, and others. A product that is at least 95% less harmful than cigarettes and contains the same nicotine as approved NRTs is regulated as a tobacco product. This does not make any sense.

CONCLUSION

The 2016 FDA deeming rule, the 2009 amendment to the Tobacco Control Act, and the anti-tobacco/vaping organizations are clear that the main concern about tobacco regulation in general is youth addiction to "tobacco products." I pretty well covered my opinion on the supposed youth "vaping epidemic," however I also do not want youth to become addicted to anything or develop a dependence to things such as "tobacco products." I believe the solution to the youth issue lies in education and harm reduction. Youth have proven throughout history that experimenting with substances like alcohol, recreational drugs, and nicotine, is something that will continue. There are multitudes of laws that restrict youth access to adult products, including

"tobacco products," and yet they continue to break said laws. The youth that make the choice to break the law should be punished and not idolized as victims of some supposed malicious attempt by someone to harm them. It is well known that traditional "tobacco products" are deadly, so it is very hard for me to understand why something that is proven to be 95% less harmful would not be embraced by individuals and Public Health. The adults trying to use an item that is safer than their current vice should not be oppressed in the name of youth health, particularly when it is based on propaganda. I have kids and if they decided to experiment with nicotine I would, without question, prefer them to try ENDS products with low level nicotine, such as free base e-liquids, over any traditional combustible tobacco product. When asked by a reporter *"these youth that are now addicted to nicotine, will now revert to actual tobacco,"* New York's Attorney General made the statement *"I don't think we should be concerned about um the collateral consequences. I think what we need to do is take action against JUUL for the harm that it's caused and the destruction that it's caused."* In my opinion she is referring to kids smoking combustible cigarettes vs. ENDS products, so her collateral damage is that youth will turn to a deadly product for their nicotine due to proposed ENDS bans. In my scenario the collateral damage would be youth experimenting with a product shown to be 95% less harmful than her cause of collateral damage, common sense says choose the less harmful form of collateral damage.

Ideas for Possible Solutions:

This is a very in-depth complex sociological issue that has no easy solutions. However, I do know punishing law abiding adults, for making a choice to take a risk with something that they seem to enjoy, particularly harm reduction products, through extreme bans, restrictions, or abhorrently high taxes, is absolutely wrong. I am a firm believer that education is the most important aspect of any solution to most issues. The whole "vaping epidemic," both the lung injuries and the youth, is an example of a failure by society. When issues arose about vaping then the powers that be should have brought in Subject Matter Experts (SME), which in this case would have been as simple as going to a vape shop to learn the difference between using an ENDS product and using an e-cigarette as a delivery system for THC. Sometimes the SMEs on a particular subject are not the prominent people of society such as doctors, Public Health Officials, scientists, or government representatives, they could be just a simple consumer like me. Society failed because individuals will believe anything that they read from any source they think is trustworthy. In reality any complex subject should be at least minimally researched, ie. confirm with other sources, particularly opposing views. This societal failure actually has a simple solution, which is to use the internet for research not just funny gifs!

The disagreement over the science seems to be caused by "new" studies conducted by people that lack the knowledge of how ENDS products are actually used by consumers. One I am aware of actually only proves that when an ENDS device is used improperly the carbon monoxide levels are harmful. The way the ENDS product was used in the experiment is not how any consumer would

use it. see Bucknell University-ENDS study The issue with the concept of "proper use is ok, but we want to show it can cause harm when improperly used" is a very biased view and does not make sense considering there are lots of products on the market that when used improperly will cause harm. For example, the Tide pod and cinnamon eating challenges as well as the condom snorting challenge that have gone viral on the internet in recent years. It appears to me that MSA funds and Bloomberg donations are being used to fund biased studies that assist in pushing a hidden agenda to remove ENDS products from the market for financial gain by some. The big point that ENDS advocates, certain doctors, and PHE, are trying to make is that ENDS use is LESS HARMFUL not 100% safe. I think the only solution to the science disagreement is to have several world Public Health organizations conduct a cooperative analysis of pertinent previous studies and determine how to move forward with new non-biased ones. This could involve studying long term ENDS users' individual health while comparing to a traditional combustible cigarette subjects' health. I personally am satisfied with the conclusion that 35,000 EU doctors, some American doctors and scientists, and PHE, already reached. *See* Evidence, alarm, and the debate over e-cigarettes By: Amy Fairchild, Cheryl Healton, James Curran, David Abrams, & Ronald Bayer

Again I am not a health expert, just a person concerned that the whole ENDS fiasco will cause permanent harm to our society by promoting Corporatocracy (recent term used to refer to an economic and political system **controlled by corporations** or corporate interests) through the oppression of a consumer designed product and small businesses associated with it. I also am concerned about our nation's Public Health as it seems to be going down the wrong path guided by a few very biased individuals. As pointed out throughout this document, there are many factors about this subject that are definitely unethical and may even verge on illegal *(not a lawyer either)*. The fact that the states that are upside down, with the bonds borrowed against future MSA funds, were the first ones to enact knee jerk bans is hard to ignore. Again it seems anti-tobacco/vaping organizations took advantage of the lung injuries caused by THC cartridges to push an anti-vape propaganda campaign based on fear. When it was determined that ENDS products were not associated with the injuries the tone of the anti-vape campaign changed to the youth "vaping epidemic." Considering the traction gained from the fear mongering it has been easy to continue the propaganda convincing people that ENDS product are so dangerous for youth. The fact is that they are not 100% safe, but they have been proven by reputable doctors, scientists, and health organizations to be 95% less harmful. But apparently as New York Governor Cuomo said about this fact "*Vaping is better than smoking. Technically yes, but so what.*"

The FDA 2016 deeming rule seems to be an overreaching regulation that from what I can tell has some biased tones to it. 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)*. Let alone the fact that ENDS should not be regulated as a "tobacco product," due to its harm reduction and Public

Health benefits. The media should take a large portion of the responsibility for the current issues with ENDS due to their spreading of misinformation and lack of clarity on the difference between products. The federal agencies responsible for aspects of Public Health need to improve communication and consider all factors in the development of regulations, particularly concerning products that are developed by consumers for harm reduction, ie. use SMEs. Dr. Herbert Ley, former commissioner of the FDA, made the following statement in 1969 "*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.*"

I want to reiterate all opinions in this document are mine and no one else's. I am sure there are others that have written about this subject so please do not rely on my words as all inclusive concerning this matter.

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Links to other interesting papers / viewpoints

Synthetic Nicotine - Regulatory Gap Opinion-MK

ecigclick.co.uk/bloomberg-flavour-ban-plan-a-conflict-of-interest

Vaping: what people are getting wrong | The Economist