December 2, 2016

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave, NW, Suite CC-5610
Washington, DC 20580
FILED ELECTRONICALLY

Electronic Cigarettes: Paperwork Comment, FTC File No. P14504

Dear Commissioners:

I am writing on behalf of the Smoke Free Alternatives Trade Association (SFATA), and the over 1,500 manufacturers and retailers of vapor products in the U.S. whom we represent, in reference to the above PRA comment request regarding your proposal to collect compulsory information on sales and marketing from e-cigarette (vapor product) companies.

As the largest trade association representing both manufacturers and retailers of vapor products, SFATA has several areas of concern regarding the basis for this data collection and the impact it would have on our members, and the health of the American public. We strongly urge you to consider the following points:

1. Vapor products are nicotine replacement products, which are vastly less harmful than combustible cigarettes.
2. Vapor products are playing a significant role in smoking cessation – among both adults and teens – and in tobacco harm reduction for our citizens.
3. The vast majority of vapor products manufacturers are very small businesses
4. Truthful marketing is already restricted by FDA
5. Most of the justification for this regulation is predicated on the “Gateway effect” myth
6. The assumptions in your notice regarding flavors are not supported by the evidence
7. Restrictions on information about vapor products could harm public health and encourage continued or increased smoking of combustible cigarettes – the greatest cause of death among Americans.

We strongly urge you to reconsider the impact of your actions in light of the effect they will have on smoking cessation, and educate yourselves on the large and growing body of peer-reviewed scientific literature regarding the harm reduction effects of vapor products. As an introductory step, you must be aware that the Royal College of Physicians (who published the landmark report showing the dangers of smoking in 1962 – fully two years before the US Surgeon general's report), have recently found that "*Large-scale substitution of e-cigarettes, or other non-tobacco nicotine products, for tobacco smoking has the potential to* ***prevent almost all the harm*** *from smoking in society." (emphasis added)* Clearly, data collection intended to restrict or unduly scrutinize marketing and other public information about switching to vapor products will impede this harm prevention, and ultimately could cost American lives.

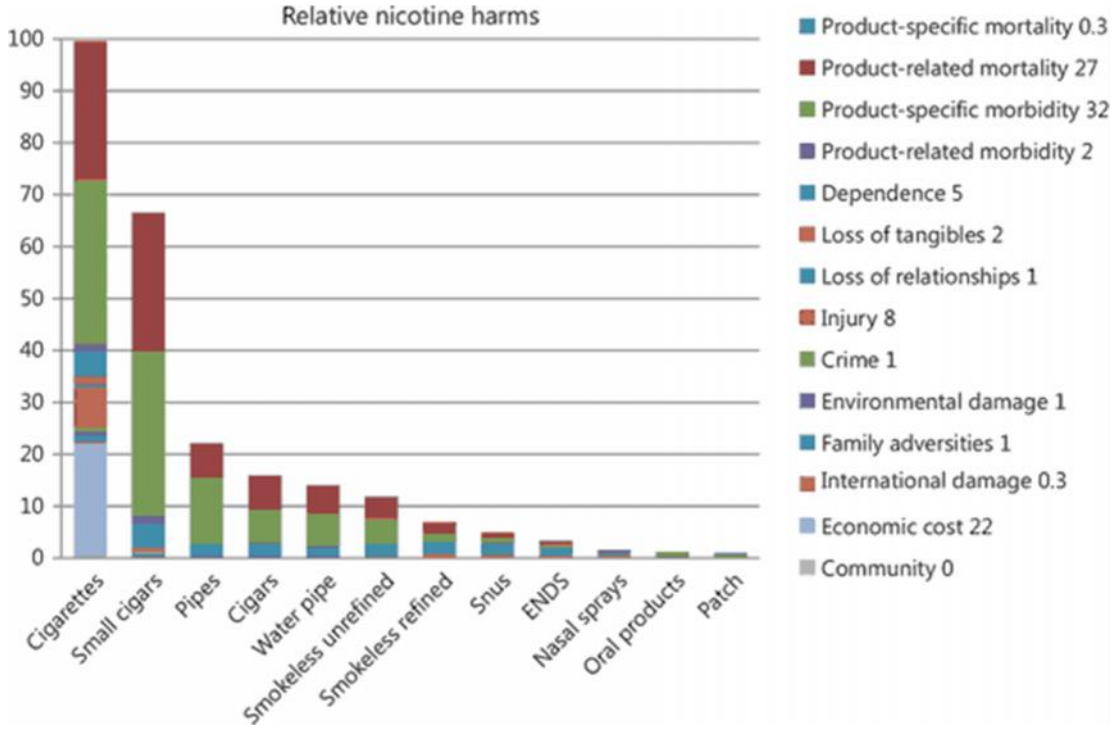
1. Vapor products are nicotine replacement products, which are vastly less harmful than combustible cigarettes

   Smoking conventional cigarettes kills 480,000 Americans every year. It is well known that people smoke for the nicotine, but die from the tar – which comes exclusively from combustion. Vapor products are an effective way for consumers to get nicotine – which is not a carcinogen or harmful in any major way – without the 7,000 chemicals, nor the 70 known carcinogens present in cigarettes.

   The UK's public health body - Public Health England - conducted a comprehensive scientific review, and has determined that the health risks of using electronic cigarettes does not exceed 5% of the health risks posed by combustibles, and may be significantly less. Further, tobacco control researchers led by Georgetown University's Lombardi Cancer Center have found that adoption of vapor products would result in a 21% reduction in smoking attributable deaths in the 1997 birth cohort alone. New regulatory burdens put this progress further at risk.

   It is critical that government regulators understand there is a continuum of risk for nicotine-containing products. Harm reduction is about the lesser of two evils: vaporizers need to be safer than cigarettes, but not necessarily safe. Failure to admit this leads to negative attitudes towards reduced-risk products and to regulations that apply the same restrictions to all products. This is damaging to public health, as it hampers alternatives to combustible cigarettes. In many countries, nicotine vaporizers and smokeless tobacco cannot currently be advertised as reduced-risk products.

   Failure to understand the relative risks and benefits in the US has led to an "abstinence only" approach to some nicotine replacement therapies, and yet not to others. If there is a "gateway effect" for teens using electronic nicotine delivery systems (ENDS), why is there no similar concern about teens use of other NRT such as patches, nasal sprays or gums? Yet these are also nicotine delivery devices that deliver the same nicotine in similar amounts. Since the spending on advertising and marketing of these products on daytime national TV vastly exceeds all spending on e-cigarette marketing, we suggest that FTC collect comprehensive data on sales and marketing of these products as well.



2. <u>Vapor products are playing a significant role in smoking cessation – among both adults and teens – and in tobacco harm reduction for our citizens</u>.

   Vapor products have proven to be a popular nicotine replacement therapy, with 9 to 10 million Americans currently using vapor products according to CDC data, and 2.5 million having used them to quit smoking entirely. Why an agency charged with protecting the public would seek to study and then restrict marketing of such products would very likely run counter to our national public health goals. For the same reasons that FTC is not seeking to monitor other NRTs such at Nicorette® gum or nicotine patches, it makes zero sense for data collection and marketing restrictions to be placed on vapor products. It is crucial that regulatory authorities understand the ultimate impact of their actions, prior to regulating.

3. <u>The vast majority of vapor products manufacturers are very small businesses.</u>

   There are estimated to be over 15,000 retail vape shops selling vapor products, and an additional 2,000 manufacturers in the USA today. The average vape store employs 3 to 5 employees, while the average for a manufacturer is estimated to be closer to 10 employees. Needless to say, these are micro businesses, usually started by someone who quit smoking by using vapor products, and who wanted to help others quit smoking as well. These entrepreneurs are fervently anti-tobacco, strongly support age restrictions and child safety provisions, but cannot understand why their government want to impose a punitive regulatory regime upon them. Regulations that scrutinize normal practices like sales and marketing simply because their product may or may not contain the mild stimulant nicotine. Regulations that impose burdens in advance of having any knowledge that would indicate need for data

collection are a relic of the tobacco control movement's reach away from focus on the only known killer - smoking – and into other products that may contain nicotine, but greatly reduce both the harm from and prevalence of smoking.

4. Truthful marketing is already restricted by FDA.

On May 10, 2016, the FDA at 81 Fed. Reg. 28,794 published a rule which became final August 8, 2016, and which imposes strict regulatory restrictions on marketing audiences as well as claims that may not be made. These restriction prohibit making truthful claims including preventing companies from citing the published, peer reviewed scientific data on health impacts of these products. The impact of this decision may prove to be detrimental to public health, as even the head of the FDA's Center for Tobacco Products has stated that if all smokers switched to these products, the health gains would be enormous and positive.

Laws that prevent truthful communication about this continuum of risk prevent adoption of less harmful alternatives to combustible cigarettes.
The debate is loud and there is often an ideological bias against, and a lack of understanding of, harm reduction principles. There is also a willingness of the press and some scientists to emphasize the negative effects of e-cigarettes. In particular, press releases issued by scientists or by their institutions sometimes do not reflect research findings. This could be prevented by submitting press releases to the same peer-review process as that for scientific articles. The public has the right to an objective assessment of the situation, and to appropriate guidance, but at present this is not what it gets from many scientific articles, press reports and institutions. This would be a much more fruitful area for FTC to turn its marketing oversight upon.

5. Most of the Justification for this regulation is predicated on the "gateway effect" myth

The notion that use of e-cigarettes by minors will lead to future smoking has been widely spread by researchers, public health lobbyists, and the media, and are clearly false. The "gateway effect" was first invented in the 1960s to spread the notion that marijuana experimentation would inexorably lead to heroin use. While that specific notion has been firmly debunked with years of history showing otherwise, the gateway effect has been repurposed for use in the tobacco space, and has been vigorously spread regardless of all evidence to the contrary. While teen use of e-cigarettes and vapor products has increased dramatically over the past 5 years, this has been accompanied by the largest and most rapid declines in smoking rates among teens, to the point that today teen smoking rates are at an all-time low. If vaping led to smoking this would clearly not be the case, and we would see a concomitant increase in smoking rates closely following the increase in vaping. The absence of any gateways effect in population level studies should cause regulators to re-think their entire premise when issuing compulsory information collection requirements.

In fact, the actual effect that appears to be taking place is quite the opposite of the gateway myth. Use of vapor products appears to be acting as more of an "off-ramp" steering teens

away from smoking toward a much less harmful alternative. While we want to be crystal clear that SFATA and our members DO NOT market or sell to minors, and have steadfastly supported age restrictions and verification efforts – if youth are going to initiate risky behaviors due to personality, rebellion, or other factors, we think it commonsense to support a 95% less harmful behavior that diverts youth from other, more risky, and even deadly behaviors. Apparently public health and regulators have not quite caught up with this understanding yet.

Moreover, according to the Monitoring our Youth survey, 78% of high school students report using zero nicotine when the experiment with e-cigarettes. In these vast majority of underage use cases, there is no chance that they could become addicted where zero nicotine is used.

Rather than celebrating these dramatic public health breakthroughs, many are wringing their hands in alarm at the increase in experimentation with a 95% safer product, and diversion from a product that is known to be lethal. It is these commenters for whom this data collection will be beneficial.

6. <u>The assumptions in your notice regarding flavors are not supported by the evidence</u>

Several of your commenters use anecdotal information or pure inference to suggest that characterizing flavors are a major reason for youth initiation. However numerous surveys of youth indicate that "youth-appealing" characterizing flavors are not one of the primary reasons they experiment with vaping. In fact according to surveys, the most cited flavors among youth were "tobacco", "Scotch", and menthol. Shiffman et. al found that characterizing flavors appealed more to smoking adults than to youth.

Moreover, PHE, CDC, and many other studies continue to find that initiation of full time use of vapor products by never-smoking youth remains rare at far less than 1%. Still, it is worth noting the likely "off-ramp" effect that vapor products appear to be having on teens which diverts them from smoking combustible cigarettes. To the extent that this prevents youth smoking, it should probably be encouraged rather than targeted. More clinically and methodologically valid study in this area would be meaningful.

7. <u>Restrictions on information about vapor products could harm public health and encourage continued or increased smoking of combustible cigarettes – the greatest cause of death among Americans</u>.

Dr. David T. Levy (and 6 other tobacco control researchers) have recently determined that "The evidence suggests a strong potential for Vaporized Nicotine Products (VNP) use to improve population health by reducing or displacing cigarette use." Limits on marketing will serve to decrease awareness of these products, and hence would negate this improvement in population health. Your marketing information collection effort appears to us to be predicated on (and justified by) similar efforts in the tobacco industry. We would strongly urge you to

avoid treating vapor products like combustible products for the sole reason that they both deliver nicotine.

Dr. David B. Abrams of the Truth Initiative has written that "A view that treats all tobacco/nicotine use as equally bad is no longer consistent with the evidence base and represents a runaway rhetoric." We agree with this, and believe that the unintended consequences of your compulsory marketing information will have the opposite effect of that intended. The point we urge you to understand is that each additional regulatory restriction or burden on this small American industry may very likely have negative implications for the public health of our citizens.

What FTC has not clearly stated in the information requirement notification was the rationale for collecting such information in terms of ultimate impact on public health. Simply stating that such information has been collected in a different industry (tobacco), or citing an increase in sales or advertising in the infancy of the vapor products industry does not seem to provide either the justification for compulsory data collection nor the desired uses of such data, much less any discussion of desired outcomes resulting from such data collection. We would be very interested in learning what the ultimate intent is, and in what ways (if any) this would provide any protection or beneficial information for American consumers.

In summary, vapor products are a popular and effective nicotine replacement therapy which have been proven effective at vastly reducing the number of Americans who smoke by at least 2.5 million people. The retailers and manufacturers of these products are tens of thousands of American small businesses across the country who have little ability to absorb additional costs and regulatory requirements. Truthful marketing of these products and their proper role in the harm reduction continuum has been severely restricted by FDA rule, and the justification for this notice is predicated on faulty assumptions and incomplete knowledge. We believe it is highly likely that the burden and harms created with compulsory sales and marketing data collection will outweigh any perceived benefits from acquiring such information, and as such, urge you to reconsider this requirement.

We would of course, be pleased to meet with you to discuss issues regarding vapor products including science, marketing, harm reduction gains, impact of FDA regulation, consumer protection or any other issues you may want to learn more about.

Sincerely yours,

Cap O'Rourke
President Board of Directors
Smoke Free Alternatives Trade Association