NJVRC

NEW JERSEY VAPOR RETAILER'S COALITION

The New Jersey Vapor Retailer's Coalition currently represents 43 members. These members are part of a wide cross section of the vapor products category, an industry that includes distributors, manufacturers, retailers of Personal Electronic Vaporizing Units such as electronic cigarettes, and the liquid solutions they contain.

NJVRC membership is comprised of responsible business owners who understand that model corporate citizenship is vital to gaining the acceptance of the skeptics. This is borne out as 100% of our members currently card for legal age of consumers, do not carry any tobacco products in their stores currently and offer very little in the way of devices that mimic combustible smoking characteristics. This challenges those who believe the industry is driven or influenced by big tobacco.

The vapor products industry is the embodiment of the American Dream; built by entrepreneurs and visionaries. It has grown organically and become a vibrant multibillion-dollar industry that is constantly innovating and creating. This continued innovation of products that researchers worldwide have agreed could eliminate the public health hazards caused by use of combustible tobacco cigarettes is significantly in jeopardy by the FDA proposed regulations.

These Vapor Store owners are the antithesis of what the health advocates say they are. They are not a front for big tobacco in fact they do not carry the cigalike products from the major tobacco companies at all. The predominantly sell personal vapor products with custom liquid solutions designed to not taste like a cigarette at all. Some in the health industry call this a ploy to attract children, but our store owners abide by the law and only sell to legal age adults. In New Jersey that age restriction is currently set at 19 years of age.

Our association is made up of predominately small business owners who have had success with personal vaporizers and as such have opened their first business as 44.44% of ownership is by first time business The vapor products industry is the embodiment of the American Dream; built by entrepreneurs and visionaries who see the value they can bring to their community.

The proposed deeming regulations would have a destructive effect on the vapor products industry, in part because the cost burden on manufacturers of e-liquids containing nicotine would cause them to be disproportionately disadvantaged in their attempts to comply with the proposed regulation:

Substantial Equivalence (SE)

According to FDA's comments, *"the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the exemption pathway put into place by this rule provides an option that potentially*

reduces costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities".[1]

This statement alone is a false statement that does not take into account the Vape Shop owner and we at the NJVRC believe that the regulations will have significant economic impact to our coalition members. As we state later there are significant principles of science that many if not all shop owners lack as they are selling prepackaged products.

FDA fails to account for the fact that currently the SE pathway is not available to the thousands of manufacturers currently in the market.

The grandfather date of February 15, 2007 is a date before many of our members were even open not to mention that there is no one that would want those devices today with the safety and quality standards that are built into the products that our coalition members currently sell. This time frame in and of itself guarantees Substantial Equivalence (SE) Reports cannot be submitted to the FDA, creating a de-facto ban of >99.9% of the vapor product manufacturers in the US. Further the SE process is opaque and entirely arbitrary, denying participants the ability to pre-plan, coordinate, or ensure they could comply (if it were ever available to them).

Pre-Market Tobacco Approval Application Process
The FDA has estimated the cost of applying for a Pre-Market Tobacco Approval (PMTA) for each vapor product at 5,000 hours and $333,554.

These estimates are also totally unrealistic, as experts estimate the actual cost of completing a PMTA application at approximately more than $3.3 million, and perhaps more than $33 million per SKU.

Only several vapor product manufacturers, the world's largest tobacco companies, have the financial and personnel resources to submit a PMTA for an e-cigarette to the FDA.

The largest component of the vapor supply chain is the vape store, which provides the only avenue (aside from online) for consumers to learn about and purchase their vapor products. Our coalition members do not sell big tobacco companies products as their consumers demand better and greater diversity in their products.

While Congress intended that FDA should not pursue any action that would selectively shut down the vape shop these stores, New Jersey number over 300, will be left with no option but to close their doors as they primarily only sell vapor products.

[1] https://www.federalregister.gov/articles/2011/07/05/2011-16766/tobacco-products-exemptions-from-substantial-equivalence-requirements

Section 906 of the Tobacco Act protects against restrictions that would selectively "prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets"

In a survey conducted, it is estimated that vape shops sell in New Jersey the order of $237,099,600 to $315,000,00 of vapor products per year across 300 stores. This translates to:

Type of Store	Estimated sales for vapor products	% Sales represented by vapor products
Vape Shop	~$65,860 / mo.	> 95%

Given that our coalition members are dependent on vapor product availability for their viability as a business, any action that would remove the vast majority of vapor products from the shelves of the coalition's vape shops could selectively cause them to go out of business.

Vape shop owners in New Jersey are responsible for creating 300+ new businesses in the past 3 years. With never before business owners becoming first time entrepreneurs at a rate of 44.44% of stores opened in New Jersey.

New Jersey vape stores have serviced over 892,200 customers with a 72% rate of consumers claiming to have switched totally over to vape products, giving up on combustible cigarettes totally. Many consumers have also claimed that flavors other than tobacco and menthol are primary reasons for this switch with stores reporting an 81.71% sale of flavors. A ban on flavors by the FDA would unduly put a financial burden on our coalition members by forcing consumers to choose between unpopular flavors or black market products that will go unregulated

New Jersey Vape Shop owners are responsible for $16,590,000 in sales tax revenue; they contribute to the real estate market $9-14 million in rental space. Many of our coalition member's average 2 stores and 61% intend to open a new store in the next year, while 22% has postponed plans to open a new store with the uncertainty of the deeming regulations.

New Jersey Vape Shop owners average 7 employees per store. The burdens proposed on the industry by the FDA will put 2,100 New Jerseyan's on the un-employment line.

To declare these regulations without doing economic studies on the industry and people it effects is irresponsible and burdensome and we will show later why we believe the FDA has violated executive order 12866.

The New Jersey survey shows that the FDA wants a ban on products that contain less than 0.7% nicotine in formulation. That this is what they declare to be a tobacco product. We just do not agree with this assessment that formulations that have 99.3% of other ingredients than nicotine should not be deemed tobacco products. Our state survey show consumers are buying 69% of their liquids with .7% or lower in it.

This does not fit the regulatory authority of the Family Tobacco Control act of 2009 as there is almost no tobacco derived nicotine in the products our coalition sells.

- In the proposed rule the FDA admits that:
    - "This proposed rule would have a significant economic impact on a substantial number of small entities" (page 6)
    - "We cannot predict the size of these benefits (of deeming) at this time" (page 7)

At no time do they consider the possibility that restricting access through regulation would cause harm to the public. Therefore, the benefit would actually be negative.

- The FDA does allow that not regulating new products like e-cigarettes "may induce people to switch to products that FDA does not regulate at all or with the same stringency" (page11). In the case of people switching from cigarettes to ENDS, this would improve public health - so not regulating would convey a benefit and the proposed rule would convey harm. This is not considered in the cost benefit analysis.

- In the RIA Benefit Analysis, FDA anticipates that "the largest benefit of the proposed provisions would be the improvements in health and life expectancy resulting from reductions in the use of combustible tobacco products deemed under this proposed rule" (page 13) but those benefits will be reduced by the rule's application to electronic cigarettes which are not combustible tobacco products, and provide a safer alternative.

- There is no discussion of ENDS during the analysis of welfare gains, expected life years saved, or reduced mortality other than the final statement "The effect of other tobacco products on morbidity may differ".

- In section 2(b) of the RIA, "Electronic Cigarettes and Other Non-combustible, Novel Tobacco Products" FDA plainly states: "The benefits of including electronic cigarettes in this proposed rule are unknown and therefore cannot be quantified". (Page 19)

- The proposed rule goes on to evaluate possible relative health effects of ENDS on health and welfare, and concludes that: If electronic cigarettes are safer (as most literature shows clearly) and if they are substitutes for smoking (again, all data points this way), then there would be positive health and welfare effects from increasing consumption of electronic cigarettes (Table 12, page 20).

- FDA admits that deeming would likely require premarket application, which would limit products from coming to market, and would require warnings that would serve as a negative signal to consumers and possibly discourage use. These two bullets alone show that the rule could harm public health and welfare, and that the rule would be the direct cause.

- The FDA's cost analysis does NOT estimate number of manufacturers or importers affected. They do not include any data on establishments that sell e-cigarettes. They do not estimate the costs for e-cig manufacturers or importers. They do not quantify the costs for adulteration and misbranding, they do not quantify the costs for restricting free samples, they do not estimate the costs for advertising restrictions on e-cigs, and they do not know the benefits of: registration and product listing; ingredient listing, labeling requirements or warning label requirements. **In fact, they fail to count 6 of the 10 categories of costs, and fail to identify ANY benefit from deeming E-cigs. (Table 36, page 51)**

- FDA estimates that "Considerable product consolidation and exit (from the market entirely) would occur…"(page 27) and they estimate that 50 (TOTAL) electronic cigarette product applications would be submitted in the first two years, and 15 products over the next 18 years. (Table 21, Page 36). That is a grand-total of 65 products over 20 years, including e-liquid flavors, mods, atomizers, wicks, coils, and every other product that is part of vaping.

Executive Order 12866, Section 1(b)(6) states: "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."

The benefits of the proposed regulations do not justify the costs. The public health benefits of the regulations are indirect and minimal. But the intended actions of the FDA will force most if not all Vape Shops in New Jersey to close with minimal public health being addressed but millions of dollars lost from the New Jersey economy with the closing of these stores. Moreover, FDA review of complex PMTAs does little to directly address safety issues. The regulations do not actually specify any safety standards that need to be followed.

Finally, the FDA has violated section 6 of the Executive Order by failing to identify the costs of the proposed regulation in terms of the following:

a. Effects on the potential future growth of safer nicotine delivery products to the market;
b. The decreased availability of vaping products to consumers;
c. The stifling of innovation in the vaping market;
d. The effects on ex-smokers who have quit using e-cigarettes of having their electronic cigarette or e-liquid brand potentially removed from the market;

The regulations violate Executive Order 12866, Section 1(b)(8): "Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt."

The FDA failed to identify and assess an alternative form of regulation, specifically, one which would specify performance objectives rather than requiring a complex and burdensome manner of compliance that the vape shop owners would be unable to comply with. As an alternative, the FDA could have simply promulgated uniform safety standards for all electronic cigarette and vaping products. These standards could have included issues such as battery safety and overcharge protection, quality assurance and control, leak-proof containers, childproof packaging, adequate regulation of temperature to avoid the production of formaldehyde and other degradation products. These standards are exactly what the group of vape shop owners of our coalition are doing now. 99.67% sell liquids with childproof packaging, selling devices that offer overheating and circuit protection.

Executive Order 12866, Section 1(b)(5) states: "When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective."

In our opinion the proposed regulations are far from the most cost-effective manner to achieve the regulatory objective. Far more cost-effective would have been to propose regulations which would have specified performance objectives rather than requiring a complex and burdensome manner of compliance that the vape shop owners must adopt. In fact the agency has not even provided guidelines for how our owners would even start the process.

As an alternative, the FDA could have simply promulgated uniform safety standards for all electronic cigarette and vaping products. These standards could have included issues that deal directly with the safety of the product being offered for sale. They could include manufacturing standards, registry of contents of liquid.

Executive Order 12866, section 1(b)(11) states: "Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations."

The proposed regulations impose the most burdensome possible requirements on businesses, particular those of moderate and small size, while a much less burdensome alternative (direct regulation of vaping products via the establishment of uniform, minimum safety standards) is readily available and which would achieve the regulatory objectives not only more efficiently, but more effectively as well. This type of approach would have allowed our small businesses to continue to operate and serve our clients.

Executive Order 12866, Section 1(b)(12) states: "Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty."

The proposed regulations are about as complex as could be imagined. The process proscribed for preparing PMTAs is complex, tedious, burdensome, and scientifically complicated. It would take a group of expert scientists in multiple areas, including epidemiology, toxicology, chemistry, population modeling, statistical modeling, human behavior, communication and perception, marketing behavior, and biostatistics to understand the multitude and nature of specific studies that would be required to derive the information necessary to make the required demonstrations specified for the PMTA. The overwhelming majority if not all of our shop owners, vendors and manufacturers that would be regulated do not have the necessary expertise to understand the regulation, much less to comply with it.

In contrast, if the agency simply set uniform safety standards, these could easily be understood by all regulated business

In conclusion, NJVRC requests that OMB/OIRA consider the following three points when making its' recommendations to the FDA:

Industry should have a minimum of 3-4 years (large/small entity) to comply with any PMTA requirements, once PMTA requirements are defined.

That the FDA goes to a reasonable regulation format when considering the small business owner as they are currently putting a tremendous burden on our coalition members and our consumers with the current proposed deeming regulation.

The industry has been **"on notice"** for the past year by FDA that the PMTA process was a moving target under internal review, and to expect an **expedited** PMTA. Industry has been waiting to find out what the e-cigarette-specific PMTA requirements would be so that they could begin to prepare for them. There is a drastic difference between expedited EU-like requirements, which take months to prepare for, vs. full PMTA, which takes years.

Industry perception was that "expedited" meant that marketing authorization, similar to EU requirements, would be based on the harm reduction potential for the individual smoker based on meeting quality and HPHC requirements, and that population requirements would primarily be dealt with in a post-market surveillance manner, and through evidence-based FDA product standards regarding product attractiveness.