Tony Abboud Remarks before the Senate Committee on Judiciary, Indiana General Assembly

January 25, 2017

Chairman BRAY, **Ranking Member YOUNG**, distinguished members of the Committee, my name is Tony Abboud. I am the National Legislative Director of the Vapor Technology Association. I want to thank you, and **Senator Head**, for giving me the opportunity to appear before you today and speak on behalf of the thousands of small and mid-sized vapor businesses across the country and here in the great State of Indiana.

The Vapor Technology Association is the leading national trade organization representing the manufacturers, wholesalers, small business owners and entrepreneurs who have developed innovative and quality vapor products, providing adult consumers with a safer alternative to traditional combustible products.

There has been a lot of distorted and misleading information propagated by some, but leading scientific organizations have made clear that vapor products are not only a safer alternative to traditional combustible products, but also provide many individuals with a viable path to reduce tobacco smoking and even quit altogether. *IMPORTANTLY, vapor products do not deliver the numerous harmful or potentially harmful inhaled constituents that lead to adverse health outcomes for tobacco cigarette smokers and do not produce harmful second-hand smoke.*

In fact the FDA's Center for Tobacco Products Director Mitch Zeller, a life-long anti-smoking advocate, has clearly and repeatedly stated the potential benefits of e-cigarettes. During a Senate Health, Education, Labor and Pensions hearing in 2014, Director Zeller stated: "If we could get all those people [who smoke] to completely switch all of their cigarettes to noncombustible cigarettes, it would be good for public health."

This, Members of the Committee, is why it is imperative that we PROPERLY regulate vapor products. Vapor products are the first game-changing technology in the ongoing campaign to reduce cigarette smoking. And, they are driving truly entrepreneurial innovation around the country and in the process creating jobs.

As many of you are well aware, the vapor industry in Indiana is primarily made up of small businesses – businesses owned by entrepreneurs who once faced a promising future. However, these small business owners and innovators have been crushed, not only by burdensome federal regulations, but also by legislative action right here in Indiana.

Now, we have the chance to right these wrongs and provide these important businesses an opportunity to compete and thrive.

CURRENT STATE OF BUSINESS / RUSE

Many of our member companies are manufacturers of e-liquids and vapor devices that sell in all 50 states, that is until the passage of Indiana's current law which created a monopoly by giving ONE security company the power to choose which handful of companies it would permit to do business in Indiana.

The problem is that the entire basis upon which the current law was promoted is essentially a ruse; a fiction created to justify the imposition of a security firm monopoly.

Specifically, this body was wrongly told that a security firm and security protocols were somehow germaine to the proper or safe manufacturing processes.

Here's the reality: We are not aware of a single incident of "tainting" or adulteration of e-liquids in the manufacturing process that has somehow caused any illness, sickness or injury to any person, either here in Indiana or in all 49 other states that don't have Indiana's security firm requirements.

Let's be very clear: a special locksmith or credentialed security company are simply NOT relevant to the proper manufacture of e-liquids, or for that matter, the manufacture of any other consumable in Indiana which is not forced to follow the same regulations.

SB1 does away with the fiction, and replaces it with the reality that e-liquids can be properly regulated in a manner that protects consumers, preserves competition and encourages businesses to grow.

WHY IT IS APPROPRIATE TO RELY ON FEDERAL REGULATIONS

FDA Is FULLY Regulating E-Liquids and Vapor Products

In 2009, Congress enacted The Family Smoking Prevention and Tobacco Control Act. The law imposed significant new requirements on the sale and advertising of cigarettes, roll-your-own tobacco (RYO), and smokeless tobacco and placed those products under the authority of FDA. Congress also stated that FDA could expand its jurisdiction to other tobacco products if it so chose by issuing regulations. In 2014, FDA issued proposed regulations that would bring under its control a variety of products including hookah tobacco, vapor products and e-cigarettes, e-liquids and other components.

The FDA engaged in a 2+ year regulatory process during which the Agency received and processed hundreds of thousands of comments from thousands of companies, associations, interest groups, and public health groups. Not to mention, hundreds of meetings between the FDA and interested stakeholders.

The product of that process was the FDA's FINAL 450+ page Deeming Regulation and Guidance Documents that it published in the Federal Register on May 10, 2016.

Now, some of you may have been told (or may be told) that the Deeming Regulation is merely a proposal. I assure you that is false: the FDA's sweeping Deeming Regulation took effect on August 8, 2016.

On that day, the FDA began exercising broad regulatory authority and control over what it calls **Electronic Nicotine Delivery Systems** (ENDS) products through all stages of development, manufacturing, advertising, and retail sales.

The Deeming Regulation represents the most comprehensive set of regulations that could govern the vapor product industry, of which e-liquids are a central regulated component. Let me take a few moments and explain how:

First, the FDA DEEMED ENDS products as tobacco products. A "tobacco product" is a product that contains, is made, or is derived from tobacco (in no matter how small an amount) **and** is intended for human consumption; AND/OR the parts and components thereof.

ENDS products that contain nicotine or any other ingredient or component derived from tobacco are covered by the new rule. Specifically, FDA had defined 3 sub-classes of ENDS products

- E-liquids,
- aerosolizing apparatus and
- ENDS products that package e-liquids and aerosolizing apparatus together.

Importantly, if any non-nicotine e-liquid is intended or reasonably expected to be mixed with an e-liquid made from or derived from tobacco, FDA announced its intention to treat it as a tobacco product.

In fact, the FDA has extended its regulation to virtually **every component**[1] of these products.

"A component is anything that is intended or reasonably expected to either: (1) alter or affect the performance, composition, constituents or characteristics of a tobacco product, OR (2) be used with or for the consumption of a tobacco product."

The FDA has expressly stated that ALL of the following are considered COMPONENTS:

- e-liquids,
- atomizers (device that turns the liquid into a vapor),
- batteries (with or without variable voltage),
- cartomizers (atomizer plus replaceable fluid-filled cartridge),
- clearomisers (similar but different style),
- tank systems,
- digital display/lights to adjust settings ,
- flavors,
- bottles that contain e-liquids, and
- programmable software.

Yes, the programmable software is now considered a "tobacco product" and regulated by the FDA.

FDA Imposes Stringent Regulations on All E-Liquids and Vapor Products

Before going through the FDA's comprehensive regulatory scheme which took effect on August 8, 2016, it is important that you understand a couple basic points:

1. THE ONLY PRODUCTS THAT CAN BE SOLD ARE THOSE THAT ALREADY WERE ON THE MARKET AS OF AUGUST 8, 2016.

2. COMPANIES ARE PROHIBITED FROM MANUFACTURING AND SELLING ANY NEW PRODUCTS WITHOUT FIRST GETTING PRIOR FDA APPROVAL AFTER GOING THROUGH A MULTI-YEAR MARKET AUTHORIZATION PROCESS.

So, let's look at the regulations in place now.

[1] **A component is anything that is intended or reaonably expected to either: (1) alter or affect the performance, composition, constituents or characteristics of a tobacco product, OR (2) be used with or for the consumption of a tobacco product.**

Date	Rule Implemented / Requirements	Citation
August 8, 2016	**Effective Date of FDA Authority over Electronic Nicotine Delivery Systems–**Newly deemed "tobacco products," including Electronic Nicotine Delivery Systems (ENDS), become subject to FDA authority.	21 CFR part 1100
	Sale to Minors Banned – Sale prohibited to anyone under 18 years of age (or older if state law requires). Retailers must see photo ID of anyone who appears 26 or under.	21 CFR part 1140
	Product Adulteration – All manufacturers must operate their facilities in a sanitary manner such that no products are manufactured or shipped that are contaminated in a manner that might injure the public health beyond the risks that may be inherent in the product. 21 U.S. Code § 387b - Adulterated tobacco products A tobacco product shall be deemed to be adulterated if— **(1)** it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health; **(2)** it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; **(3)** its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; **Important point: FDA has a BROAD definition of manufacturer.** "If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any "tobacco product," then you are considered a tobacco product "manufacturer.""	Food Drug & Cosmetic Act (FDCA) §902(1)

Vape Shops That Mix E-Liquids or Modify Products

If you operate a vape shop that mixes or prepares liquid nicotine or nicotine-containing e-liquids, or creates or modifies any type of ENDS, you are considered a manufacturer and must comply with all of the legal requirements for tobacco product manufacturers. As a result, some vape shops may have legal responsibilities as both manufacturers and retailers of tobacco products.

	Modified Risk Claims – Companies may not make any **advertising claims** or other public statements directed to consumers that their product may have less risk, be less harmful, have fewer or no additives as compared to other tobacco products prohibited. Prohibition on use of "light," "low", "mild" or similar descriptors.	FDCA §902(8)
	New Products – No new products can be introduced until FDA has issued a marketing order authorizing sale based on an SE or PMTA.	FDCA §910(2)(A)
	Misbranding – FDA will begin enforcement on false or misleading labeling and advertising.	FDCA §903(a)(1)
	Vending Machines – Vending machines are prohibited except in facility where retailer ensures that no one under 18 (or higher legal age) is present or permitted to enter at any time.	21 CFR 1140.14(b)
	Free Samples Banned – Free samples no longer permitted in any venue.	
February 8, 2017	**Tobacco Health Documents Submission for Large Manufacturers** Large-scale manufacturers required to submit to the FDA documents developed after June 22, 2009, that relate to "health, toxicological, behavioral, or physiologic effects" of products, constituents (including smoke constituents), ingredients, components and additives. Large-scale manufacturers are those companies with more than 150 full time employees & annual revenue of more than $5M. *Small-scale manufacturers, see August 8, 2017 deadline below.*	FDCA §904(a)(4)
June 30, 2017	**Companies Must Register with FDA –** All domestic facilities ("establishments") that "manufacture, prepare, compound, or process" tobacco products, including those who repackage or otherwise change the container, wrapper, or labeling, must register their facility with the FDA.	FDCA §905(b), (c), (d), (h)
	Product Listings Submissions – Manufacturers must provide FDA a list of every product they sell, including all labeling and representative advertising. Listings must be updated each June and December to add new products not previously listed and delete discontinued products.	FDCA §905(i)(l), 905(i)(3)

August 8, 2017	**Ingredient Listing Submissions Required for Large Manufacturers** Large-scale manufacturers must submit full listing of all ingredients by quantity, by brand, and sub-brand. **FEB. 8, 2018:** Small-scale manufacturers must submit full listing of all ingredients by quantity, by brand, and sub-brand.	FDCA §904(a)(1)
	Substantial Equivalence Exemption Requests Due – Any company seeking *exemption* from SE requirements for a minor modification to an additive for products on market as of August 8, 2016 must be filed with the FDA.	FDCA §905(j)(3)
	Modified Risk Tobacco Product Labels – Manufacturers must **end production** of all products in packaging that contains a prohibited descriptor - "light," "mild," or "low" or similar descriptors.	FDCA §911(b)(2)(A)(ii)
February 8, 2018	**Substantial Equivalence *Applications* Due –** Applications for substantial equivalence authorization for products on market as of August 8, 2016 must be filed. But, given the absence of any true predicate for ENDS products, most companies will be unable to use this SE application process. *Notes:* • *Filing will allow products to stay on the market until at least **February 8, 2019.*** • *Additional time may be given to small-scale manufacturers to respond to SE application deficiency letters on a case-by-case basis.*	FDCA §905(j)(1)
	Warning Statements – All covered ENDS products must bear the following warning statement on labels and in advertising: "**WARNING: This product contains nicotine. Nicotine is an addictive chemical**." Manufacturers of **nicotine-free tobacco products** may instead certify to FDA that their products contain zero nicotine and that they have the data to prove it. **Such products may instead use the statement "This product is made from tobacco" using the same size and format as the nicotine warning statement.**	21 CFR part 1143

	Warnings on packages must comprise 30% of each of the two principal display panels. Alternate means of compliance are available for small packages. Warnings on advertisements must comprise 20% of the top of the advertisement. This applies to all advertising with a visual component – print ads, websites, e-mails, social media postings, videos, etc. Manufacturers of **nicotine-free tobacco products** may instead certify to FDA that their products contain zero nicotine and that they have the data to prove it. **Such products may instead use the statement "This product is made from tobacco" using the same size and format as the nicotine warning statement.** Product manufactured prior to that May 10, 2018, without warning statement labels may be distributed by the manufacturer until **June 9, 2018.**	
May 10, 2018	**Additional Label Requirements –** All product labels must bear the following: • Name and location of manufacturer, packer or distributor • Net quantity of contents by weight, measure or count • Percentage of tobacco used in the product that is domestic, percentage foreign • "Sale only allowed in the United States" which must also appear on packaging and shipping cartons.	FDCA §903(a)(2), (a)(4), (a)(8), 920(a)
	Premarket Tobacco Applications Due– Full premarket tobacco applications must be filed for all products on market as of August 8, 2016. These applications will cost approximately $1M *per sku.* Companies sell hundreds of skus.	FDCA §910
August 8, 2018	**Tobacco Product Standard –** Prohibits use of foreign or domestic tobacco that contains a pesticide chemical residue that is at a level greater than is specified by any	FDCA §907(a)(1)(B)

	tolerance applicable under Federal law to domestically grown tobacco.	
	Reporting of Harmful and Potentially Harmful Constituents – Requires testing and reporting of Harmful and Potentially Harmful Constituents (HPHCs) pursuant to a guidance and, subsequently, a regulation to be issued by FDA.	FDCA §904(a)(3), 915

OTHER CONSIDERATIONS

ENFORCEMENT

Historically, FDA has numerous times enforced against tobacco products adulteration and misbranding as witnessed by FDA's warning letters dashboard at:

http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=CTP-OCE-regulatory-and-enforcement-actions-outside-compliance-inspections-quarterly

And because e-liquids are now "tobacco product," the FDA's tobacco enforcement regime already is being implemented. Between August 8, 2016, and November 30, 2016, the FDA has conducted 1,400 facility inspections **in Indiana alone.**

Indiana Alcohol and Tobacco Commission

Initial Award: 8/3/2011
Most Recent Award: 9/15/2015
Most Recent Amount: $878,349.13
Total Amount: $4,891,657.59

PRE-EMPTION: The Tobacco Control Act provides for express preemption that is very broad.

"No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products."

21 U.S.C. § 387p(a)(2) (2009) Family Smoking Prevention and Tobacco Control Act (2009)

CONCLUSION

In sum, since August 8, 2016:

- On any given day, the FDA can inspect any ENDS manufacturing facility and retailer.
- On any given day, the FDA can find any product adulterated and take it off the market.
- Not only does the FDA have full oversight over advertising, labeling and all consumer communication, but it can also intervene if communication is misleading or in violation of the Tobacco Control Act.

And, in the coming months:

- The FDA will have insight into all companies and their products:
    - Company Registration – June 30, 2017
    - Product Registration – June 30, 2017
- The FDA will have insight into ENDS ingredients (deadline for submission Aug 7, 2017) and can therefore prevent sales of any product that contains questionable ingredients.

THANK YOU.