Vapor Technology Association Presentation
EO 12866 Meeting with Office of Information and Regulatory Affairs
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Introduction:

- What and who is the Vapor Technology Association.
- Overarching concern is that the PMTA Rule as drafted will have two certain outcomes: (1) more than 95% of vapor companies will be put out of business; (2) with few exceptions, the largest cigarette companies will dominate the market, stifling the prospect of new business growth.
- Top level consideration is how the Rule will stifle the significant economic impact of the vapor industry on the U.S. economy through the inevitable closure of thousands of small and medium sized businesses.
- The *Vapor Industry Economic Impact Study*, prepared for VTA by John Dunham & Associates highlights:
    a. More than 11,000 vape shops, many of which are small manufacturers.
    b. More than 150,000 jobs created by the vapor industry.
    c. More than $7.8 billion in wages created by the vapor industry.
    d. More than $24 billion in overall economic impact of the vapor industry.
    e. More than $13 billion in state and local taxes created by the vapor industry.
- Overview of Issues to be covered.

Issues of Concern:

1. **FDA has failed to create a true application process, and we are concerned the proposed Rule does not close this gap. Currently, FDA has created an indeterminate application process on which companies cannot rely. FDA reviews everything on a case-by-case basis and via Office of Science company-specific meetings. The net result produces inconsistent testing and reporting and does not result in an objective framework for applicants to follow.**

    - FDA's reliance on draft guidance has hindered companies. First, in July 2017 FDA told companies to wait for its revised final guidance. Then, in June 2019, FDA published its final guidance the day before FDA recommended that the Maryland District Court impose a 10-month deadline for PMTA applications.
    - FDA and other commentators have mentioned that FDA Office of Science is open to meetings with industry to provide guidance on the PMTA process. In reality, the

outcome of these meetings is dependent upon the Office of Science team which attends and can produce inconsistent guidance across industry.

- Some companies have indicated that Office of Science has accepted lowered requirements in some areas.
- Other companies have indicated that Office of Science required the full testing gamut as indicated in the draft guidance.

- If the goal of the agency is the "protection of the public health," then standards articulated in this rule should be uniform across the industry. Individual workarounds for individual companies should not be acceptable. Further this type of regulation by whim does not give the consistency necessary to regulate a wide range of products – industry wide standards are required.

2. The regulatory burden that the PMTA process imposes on ENDS businesses, particularly medium- and small businesses is overly onerous in scope and cost.

- The scope of the PMTA process is exceptionally broad including issues such as clinical trials.
- The cost of the PMTA process is exceptionally high. On June 11, 2019, FDA finally presented its final PTMA guidance.
  - FDA's Regulatory Impact Analysis stated that a single PMTA application for an e-liquid would cost between $300,000 and $500,000 per SKU. But, virtually everyone else knows that estimate to be grossly understated.
  - Actual costs based on actual laboratory testing reveal that FDA's estimate of $300-500,000 per application is exceed with only three of the many components. See PMTA *Limited* Cost Summary below.
    i. Combined HPHC, Environmental Assessment and Stability Testing costs for just one SKU is $342,947.
    ii. For only 10 SKUS, a company would spend $1,629,470 on these 3 tests alone.
    iii. A company with 100 SKUs would spend $ $14,494,700 on these 3 tests alone.
    iv. These costs do not include all of the other work that FDA apparently requires such as literature review, clinical trials, other toxicology testing,

and behavioral studies or surveys on consumer perceptions, label comprehension, etc.

- Moreover, Stability Testing is another FDA expectation. Typical stability testing requires testing a product with a shelf life of one year + 30% + testing + write-up + submission. It is impossible to accomplish this within the now 9-month window left.

- However, FDA has told companies "No" when it comes to doing accelerated testing. Given FDA's refusal to compromise or adjust its requirements, this raises an additional concern that the Rule *cannot* be complied with in the timeframe given even if all resources are available to a company.

3. **Is the proposed Rule even workable within the context of the Maryland District Court Litigation?**

    - On May 31, 2019 the FDA sent the proposed final PMTA Rule to OIRA.

    - On June 11, 2019, the FDA published its Final PMTA Guidance document.

    - On June 12, 2019, in the Maryland District Court litigation, the FDA recommended that the Court imposed a PMTA application deadline of 10 months.

    - On July 12, 2019, the Maryland District Court entered an order imposing the FDA's required deadline such that all PMTA applications must now be filed by May 12, 2020.

    - There is a serious question of whether the proposed PMTA Rule contains burdens that cannot be complied with by May 12, 2020.

    - We request that OIRA ask FDA to revisit the proposed Rule and consider the ramifications of the Maryland suit, including whether the Rule (issued before the resolution of the litigation) even contemplated such an aggressive change in the PMTA application deadline.

    - In fact, it may be appropriate to suspend further consideration of the Rule until OIRA has a clear understanding of how FDA is going to proceed.

4. **Other aspects of the proposed rule – and in particular the fact that the process is entirely subjective – are entirely anti-business.**

    - Any rule should eliminate subjectivity in the requirements and the evaluation of those requirements.

- Those companies which are being asked to spend millions of dollars to FDA's PMTA requirements today still have no knowledge that their applications and effort will be reward with approvals because of the case-by-case subjective approach of FDA.

- Further, *FDA's 12 month review of an application is untenable.* Per the FDA's Final Guidance, products may remain on the market for one year after the filing of a PMTA application. HOWEVER, if FDA fails to act on the application, companies will be threatened if not forced to pull their product off of the market since, by definition, even if FDA has application but fails to promptly act, the company's product is "unlawfully" on the market. Suggestion: The Rule should make clear that a product lawfully remains on the market until FDA evaluates the application and makes a decision.

- Also, per the Final Guidance, FDA will not declare an application complete until FDA requests samples. This standard makes the timing of filing the application virtually irrelevant because the 12-month clock does not run until the sample is requested.

- Companies cannot properly run their business and make any planning decisions without any certainty on these kinds of timeframes. Industry should be able to reasonably rely on the regulations and, specifically, if and for how long they will be able to keep products on the market.

5. **Other regulatory schemes, such as EUTPD provide consistent, achievable goals while protecting their populations.**

- EUTPD requires industry to provide key information on ingredients, emissions and toxicological data.
  - The reported information allows European Member Nations to assess ENDS products based on a single set of standards.
- Health Canada, like the EU, expects a lower burden for tobacco products. While vapor regulations have not yet been promulgated, for other tobacco products Health Canada requires reports on manufacturing, ingredients, constituents, sales, emissions and toxicity. A significantly lower burden than the PMTA process.
- The standard testing and report formats provide industry consistency and the ability to enter the market without excessive regulatory burdens.

6. **Alternative Phased Approach. Absent a serious reconsideration of the adverse economic impact that the proposed Rule, as drafted, likely will on this vital new industry, the only potentially reasonable way to continue down the same path is to require a phased approach.**

- **Phase 1:** FDA only requires companies to provide the statutory requirements within a reasonable and rational timeframe (i.e., not 10 months). These statutory requirements are:
  a. Environmental Assessment
  b. Description of Manufacturing Process
  c. HPHC Testing
  d. Literature Review

- **Phase 2:** After companies have cleared Phase 1, only then should FDA require companies to address FDA's additional requests for information. These additional requests include:
  e. Stability Testing.
  f. Limited Behavioral Studies.
  g. Label Comprehension studies.

- **Phase Out:** Certain of the desired requirements should be altogether eliminated as requirements and phased "out" as an ENDS PMTA requirement.
  h. Biomarker studies. (Note: these studies are generally designed for a 2-year process; there is no demonstrable need for these studies and there is no realistic way to complete them under *any* of the deadlines that FDA has suggested).
  i. Inhalation studies.

<u>Conclusion</u>:

- Companies need certainty and a clear Rule in order to be able to comply.
- FDA's current process will, by design, allow FDA to pick and choose which products remain on the market.
- *With over 3 million SKUs* already registered with the FDA, FDA is demanding the most unrealistic expenditure of funds to be spent on a process for which the final Rule has not been publicized and now with an accelerated 9 – month deadline.
- The Rule needs to take all these factors into account and also consider that the potential negative public health impact that, according the to FDA's Declaration in the Maryland Litigation, the precipitous removal of these products from the market will have.

PMTA *Limited** Cost Summary

No. of SKUs	HPHC Testing	Environmental Assessment	Stability Testing	Sub-Total for only 3 tests
1	$65,779	$200,000	$77,168	$342,947
10	$657,790	$200,000	$771,680	$1,629,470
50	$3,288,950	$200,000	$3,858,400	$7,347,350
100	$6,577,900	$200,000	$7,716,800	$14,494,700
500	$32,889,500	$200,000	$38,584,000	$71,673,500

* This summary includes only 2 statutory requirements and 1 FDA requirement

- These are actual costs from laboratories
- For reference: FDA estimated $300,000 - $500,000 total cost per SKU for entire PMTA in its Regulatory Impact Analysis, May 2016, p. 88.