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Economic Impact of the FDA's Deeming Regulations of ENDS on Small Business

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Background

- Los Angeles based company established in December 2013
- Merger in 2015 between an online retailer and a manufacturer
- $5.5M in annual revenue with projected growth to $11M in 2016
- Currently employs 42 people, directly responsible for the livelihood of 113 family members
- Engaged in 4 business verticals in vaping:
  - Subscription & Membership Services
  - Online Retail (e-commerce)
  - Wholesale Distribution
  - Liquid Manufacturing
- CRAFT's consumer businesses, all provided online, deliver products – typically available only in specialty shops – direct to consumers, making these products available to hundreds of thousands who would not otherwise have access to them. We require all of our vendors to have a Certificate of Analysis, MSDA data sheets on file, proper warnings and CRC enclosures on all products sold.
- CRAFT's wholesale and manufacturing businesses follow industry best practices, including the use of ISO 7 clean rooms, carbonyl assays for all flavors created for detection of diketones, clear labeling and packaging including all warnings and disclosures, non-child friendly branding and packaging, and child resistant and tamper evident packaging.

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Who We Are

We are NOT "Big Tobacco"

- CEO – Omri Agam
- COO – Joshua Krane

We Are the American dream. We are small business.
We are NOT Big Tobacco.

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Consumer Reach

- 650k total number of customers reached
  - ~550k direct to customer
  - ~100k indirect through wholesale distribution
- Geographic Breakdown – most customers are where specialty Vape shops simply don't exist...

Arizona	**Illinois**	**US Armed Forces**
Florida	**Virginia**	**Oregon**
New York	**Pennsylvania**	**Tennessee**
Texas	**Indiana**	**Alabama**
New Jersey	**Massachusetts**	**Minnesota**
North Carolina	**California**	**Colorado**
Ohio	**Michigan**	

- Average Spend: $76 / month
- Average purchase: 6.5 bottles / month
- They consume an average of 5ml day of 6mg nicotine (0.6% by volume)

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Economic Spread

CRAFT Manufacturing	Distributors	Retailers
• Produces 135k units / month • Average cost of manufacturing $1.25 / unit • Average sale price $2.25 / unit *CRAFT estimates there are ~2k similar businesses in the US market today*	• Distributes 135k units / month • Average mark-up is 80-100% over manufacturer cost • Average Sale Price: $5.50 *CRAFT estimates there are ~150 independent distributors in the US market today*	• Retails 135k units / month • Average mark-up is 80-100% over distributor cost • Average Sale Price: $11.00 *SFATA estimates there are ~8k specialty vapor shops in the US market today*
CRAFT REVENUE: ~$303,750 MONTHLY	DISTRIBUTOR REVENUE: ~$742,500 MONTHLY	RETAILER REVENUE: ~$1,485,000 MONTHLY

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Potential Federal Tax Revenue

CRAFT VAPERY's potential Federal Tax contribution

Bottles sold per year		Tax per bottle	Potential Federal Tax Revenue
Manufacturing:	1,620,000	$2.02	$3,272,400
Distribution:	264,000	$2.02	$533,280
Online Commerce:	186,000	$2.02	$375,720

(CRAFT; November 2015, 12-month projected run rate)

Vape Industry potential Federal Tax contribution

Bottles sold per year		Tax per bottle	Potential Federal Tax Revenue
Manufacturing:	972,000,000	$2.02	$1,963,440,000

(assumes 1000 manufacturers, 135k bottles per month / manufacturer, 60% of sales domestic US, $2.02 / bottle flat tax)

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Impact of Regulations Online Sales

- Craft 's position is that the TCA's prohibition against internet sales does not currently apply to vapor products. (79 CFR 23184). However, Craft is concerned that FDA may ban online sales in the future given FDA's comments on this issue.
- Because CRAFT doesn't have the overhead of a brick and mortar store, we can offer more products, more variety and more affordable products to a wider array of customers in a wider geographic region.
  - Many consumers do not have access to premium products due to a lack of nearby retail locations, poor selection within those locations, and inflated pricing due to retail overhead.
- CRAFT's online platform is not just a source for products, it's a source of information and educational materials for vapers including safe usage guidelines, tutorials, warnings and disclosures of potential risks associated with vaping and vapor products.
- We can employ any age verification system that would satisfy the FDA's requirements to keep products out of the hands of minors, including requiring customers to provide ID digitally, 3rd party verified databases, and age verification at the point of delivery.

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Impact of Regulations Online Sales

If CRAFT is unable to continue selling products online

- $2M loss in revenue annually
- 550k customers who could potentially choose to return to cigarettes
- 14 jobs directly lost due to the loss of online sales channels for CRAFT
- $1.1M revenue lost to other companies CRAFT sources products from

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Impact of Regulations Technology & Innovation

- Pace of innovation in the technology of vaporizers is staggering; product cycles are months, not years.
- Innovation would be stifled under the FDA, where devices and batteries become "tobacco products".
- The three largest companies in vaping hardware are Chinese companies.
- Innovation will be forced overseas and to foreign markets where regulations are more favorable at the expense of American jobs, revenue and taxes.

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Impact of Regulations Industry Fitness

The vaping industry, while estimated at $2B in annual revenue, is largely comprised of micro, small, and medium sized businesses that would no longer be able to operate under the FDA's deeming regulations of ENDS

- The largest players like VaporShark and Five Pawns have testified to this committee that they would not be able to afford the costs of the PMTA process with the FDA.
- The vast majority of businesses in this space are 10-20X smaller than VaporShark, and would never be able to continue operations under these regulations.
- Of CRAFT's 255 vendors, only 1 is large enough to shoulder the financial burden of PMTA, and even they stated that they would focus solely on international sales and exit the US market if subjected with PMTA fees.
- Even if online sales were preserved, CRAFT would not be able to source the best products from across the industry, irrevocably damaging CRAFT's brand, market position, and ability to generate revenue.

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Impact of Regulations Financial

- CRAFT manufactures 168 SKUs
  - 42 flavors, available in 4 strengths each
  - The FDA estimates PMTA would cost ~$300k / SKU
  - CRAFT estimates that participating in the PMTA process will cost between $55M and and $504M (based on estimates from the FDA and several outside consultants)
  - For a business that generates $10M / year in revenue, it would take 4-40 years for CRAFT to recoup its investment in the PMTA process based on current profits, without a single guarantee that any of these SKUs would be approved for sale by the FDA.
- CRAFT sources products from a variety of vendors who are of similar revenue but manufacture 30-70 SKUs. None of these businesses can afford the PMTA process as currently outlined.

Even if CRAFT could afford the PMTA process and is allowed to continue to sell vaping products to adults online, the current proposed PMTA process would shut down nearly ALL of our current vendors, which would force CRAFT to close its consumer businesses.

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What the FDA can do to mitigate the impact on small business

FDA should republish a Supplemental IRFA for additional public comment before proceeding with this rulemaking so that a proper Regulatory Flexibility Analysis can be performed by the Agency as the current analysis lacks essential information required under the Regulatory Flexibility Act.

The Information Alternative:

- Grant the FDA regulatory authority over all tobacco products listed under the proposed rule
- Enact all of the informational provisions outlined under that regime, including the following provisions:
  - Establishment registration, product listing, ingredient listing, harmful constituents listing, the disclosure of all tobacco health documents, and labeling.
- Under this alternative deemed products would not be subject to premarket review, nor would sampling, minimum age and vending restrictions apply to these items at the federal level.

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What the FDA can do to mitigate the impact on small business

The Grandfather Date Alternative:

- Change the grandfather date for deemed tobacco products to the date that the proposed rule is published in final form (or at a date into the future).
- Grandfathered products to stay on the market without premarket review or approval (unless they are modified).
- Under this alternative, all of the other aspects of the FDA's proposed rule, including sampling and access restrictions would be implemented.
- Allow products made prior to the date of enactment to serve as predicate products for SE purposes.

...this still might not help if FDA continues to interpret SE so narrowly

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What the FDA can do to mitigate the impact on small business

The Enforcement Discretion Alternative:

- Under this alternative, FDA would exercise its enforcement discretion to enforce section 910's premarket review requirements only against deemed products launched or modified after the date of publication of the final rule.
- Products on the market of the date of publication of the final rule would not require a marketing order, but unlike in the grandfather date scenario, could not serve as predicate products in SE reports for new or modified product launched after the date of publication.
- Under this alternative, all of the other aspects of the FDA's proposed rule, including sampling and access restrictions would be implemented.

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What the FDA can do to mitigate the impact on small business

The Vapor Control Act Alternative:

- Clearly, Congress did not intend for the TCA to govern vapor technology products. Alternative legislation can be drafted.
- "It is in the public interest for Congress to adopt legislation to address the public health crisis created by the actions of the **tobacco industry**." Tobacco Act § 2 (Finding No. 29) (emphasis added).
- "Tobacco use...causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking" Tobacco Act § 2 (Finding No. 13).
- "a 50% reduction in youth smoking would result in approximately $75,000,000,000 in savings attributable to reduced health care costs. Tobacco Act § 2 (Finding No. 14).

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What the FDA can do to mitigate the impact on small business

Exercise regulatory flexibility:

- The TCA was written for leaf-containing tobacco products, NOT technology products.
- FDA can decide that identical regulations for these two classes of products would not be appropriate to protect public health.
- Establish quality standards (GMPs), a list of prohibited substances, etc.

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Big Tobacco Vs. Small Vaping

FDA's Deeming Regulation hands the vapor industry to Big Tobacco

Altria · RJReynolds · JTI · Lorillard Tobacco Company · Imperial Tobacco · PM Philip Morris International

(from RJR's comment on the FDA's proposed deeming regulation)

In contrast, there are a growing number of open-system manufacturers—namely, aerosol tank manufacturers (which are typically located in China) and retail "vape shops" in the United States that sell, mix, and compound flavored liquid nicotine solutions that can be used across or within other aerosol tank products. By their very nature, open-system vapor products present a unique risk for adulteration, tampering, and quality control not exhibited by any other class of tobacco products. Moreover, due to their variability and use with any number of components, it is unclear if or how these products could gain clearance from the Agency, regardless of the pathway prescribed. For this reason, FDA should, in its final rule, ban the sale of open-system e-cigarettes, including all component parts.

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Conclusion

The Deeming Regulations Decimate Craft's Business without sufficient justification, jurisdiction or economic analysis