IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC, *et al.*, Plaintiffs, vs. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 1:16-CV-0878-ABJ

BRIEF OF *AMICUS CURIAE* SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

OTHER AUTHORITIES

RULES

INTRODUCTION

The Smoke-Free Alternatives Trade Association ("SFATA") submits this brief as *amicus curiae* in support of Plaintiffs' Motions for Summary Judgment.[1]

SFATA agrees that the Food and Drug Administration's ("FDA's") Deeming Rule is invalid for reasons articulated by Plaintiffs Right to Be Smoke-Free Coalition, *et al.* and Nicopure Labs, LLC. Mindful of the Court's admonition to limit duplicative briefing, SFATA submits this brief to emphasize only a single point: Allowing FDA's Deeming Rule to take effect would destroy a blossoming, small business- and entrepreneur-oriented industry geared toward consumer choice, and replace it with a highly-consolidated industry of large companies with limited consumer choice. SFATA is the largest trade association in the "smoke-free" or vapor industry. SFATA's 1,204 members include entrepreneurs and small companies that act as distributors, wholesalers, importers, manufacturers, and retailers of vaporizing units (*e.g.*, electronic cigarettes) and the liquid solutions used therein (*e.g.*, e-Liquids). Collectively, these members represent a large swath of the entire vapor industry. Through surveys, conferences, and communications with its member companies, SFATA has significant and unique insight into the likely effect that FDA's Deeming Rule will have on the small business owners who comprise the majority of the vapor industry.

[1] In accordance with Local Civil Rule 7(o)(5), which incorporates Federal Rule of Appellate Procedure 29(c)(5) by reference, SFATA hereby represents that: (1) no party's counsel authored any part of the brief; (2) no party or party's counsel contributed money that was intended to fund preparation or submission of this brief; and (3) no person—other than amicus curiae, its members, or its counsel—contributed money that was intended to fund preparation or submission of this brief.

ARGUMENT

FDA'S DEEMING RULE WILL FUNDAMENTALLY TRANSFORM AND DESTROY THE EXISTING SMALL- AND MICRO-BUSINESS DOMINATED VAPOR INDUSTRY

The "vapor industry" is really a collection of smaller segments. FDA has estimated that there are approximately 168 to 204 vapor *equipment manufacturers* in the U.S. market, though it admits (and SFATA agrees) that "the total . . . may be far greater." FDA184819 (footnotes omitted). Vaporizers are complex devices, and these equipment manufacturers offer "components to make 800 to 1,000 delivery systems" (at the least). FDA184778. These components include, *inter alia*, batteries, drip-tips (the mouthpiece), atomizers (which heat and vaporize e-Liquid), and cartridges (which hold the e-Liquid). There are also more sophisticated systems, often referred to as "mods," which combine some or all of these components in a single unit. Many of these component manufacturers are artisans who produce small batch or custom-made products for their consumers. To take just one example, Mystery Box Mods, LLC is a SFATA member that sells beautiful hand-engraved "mod" units:



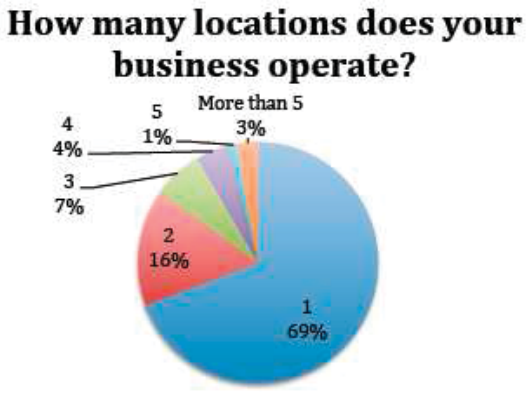
Mystery Box Mods' artisinal operation is a fair representation of many of the small manufacturers that populate the vapor industry.

There is another significant segment within the vapor industry that produces e-Liquids. Those e-Liquids are heated within the vaporizer to produce a flavored vapor without omitting the burned resins, chemicals, ash, and odor typically associated with combustible tobacco (*e.g.*, cigarettes). There are many, many producers of e-Liquids—some of those produce thousands of unique products, while others only a handful. FDA155184 ("Even the smallest e-liquid producers often have dozens of unique products (with individual stock keeping units (SKUs)), while the largest companies produce hundreds or even thousands of unique formulations."). For example, The Vapor Bar is a SFATA member that has four-hundred-and-eighty-eight (488) e-Liquid SKUs in its catalog. It is difficult to determine with any precision how many manufacturers produce e-Liquids, but FDA estimates that there are currently "5,000 to 10,000 e-liquid product-package combinations" available to consumers. *Id.* SFATA's own internal estimate for the number of e-Liquids on the market is significantly higher than FDA's estimate.

The vapor industry also consists of a segmented sales network that includes "vape shops," convenience stores, and Internet websites. Vape shops account for approximately ninety (90) percent of vapor product sales, whereas convenience stores currently account for less than zero-point-one (0.1) percent. *See also* Richard Craver, *Senator Seeks Answers from FDA on e-Cigarette Regulations*, WINSTON-SALEM J., July 18, 2016, at 2, 2016 WLNR 21782843 ("E-cigarettes are mostly sold in convenience stores," whereas "vaporizers and similar products . . . are sold mostly in vape shops and online"). These modes of sale offer consumers distinct experiences. Convenience stores and Internet store fronts are retail establishments where the owner-consumer interaction is largely transactional. Vape shops, on the other hand, offer consumers an immersive, personal experience where shop experts have significant interaction with their customers. For example, SFATA estimates that around eighty-six (86) percent of vape

shops offer a bar or lounge seating to their customers. Thus, unlike convenience stores and Internet websites, vape shops are more than retail outlets—they are places "where vapers can hang out, work, socialize and vape" while also allowing them to "purchase vaping hardware/accessories and sample smoke juice before buying." Wells Fargo, Equity Research, *Vape Shops – Springing Up Across the Country*, Apr. 14, 2014, at 1. A study by Management Science Associates showed that vape shops sell a staggering number of products, on average selling 542 SKUs overall and 300 e-Liquid options. *See* Vape News Magazine, *Vape Shop Owner Survey Results Revealed* (Sept. 5, 2015), *available at* http://vapenewsmagazine.com/agent-vape/vape-shop-owner-survey-results-revealed. Consistent with their goal of personalized, high-end service, many vape shops also act as small-batch manufacturers of e-Liquids. FDA estimates, for example, that approximately 3,500 to 7,000 vape shops mix and sell their own e-Liquids. FDA184776. As explained below, sale of the "in house" e-Liquid formulations is an important revenue source for these vape shops. As these estimates make clear, the vapor industry sales network is one that provides for significant consumer choice.

These various segments of the vapor industry are comprised almost exclusively of entrepreneurs and small business owners. SFATA's surveying shows that ninety-eight (98) percent of respondents operate a brick-and-mortar business, and almost seventy (70) percent of respondents are single-location owners.



Indeed, in a recent SFATA survey of its members, one hundred (100) percent of respondents qualified as "small" businesses under the Small Business Administration's definition. *See* Small Business Administration, *Table of Small Business Size Standards*, Nov. 5, 2010 (defined as businesses with 500 or fewer employees). Further, fifty-eight (58) percent of respondents qualified as "micro" businesses—a business with five (5) or fewer employees. Corporation for Enterprise Development, *Microbusinesses: America's Unsung Entrepreneurs*, May 2013, at 1. It has been estimated that micro businesses are the sole source of income for *three-quarters* of their proprietors. Association for Enterprise Opportunity, *Opinion Poll: The Role of Micro Businesses In Our Economy*, Oct. 9, 2012, at 3.

FDA's Deeming Rule will destroy or at least fundamentally remake the vapor industry by imposing regulatory costs that these small and micro business owners cannot realistically sustain. FDA has broadly defined tobacco product manufacturers to include not only all businesses producing components but also retailers insofar as they "manufacture, fabricate, assemble, process, or label a tobacco product." FDA184819. For example, under the Deeming Rule, "[v]ape shops that engage in e-liquid manufacturing and mixing" must submit each e-Liquid formulation for regulatory approval. *Id.* These so-called "manufacturers" will be required to seek FDA approval through the Pre-Market Tobacco Application ("PMTA" or "pre-market review") process.[2] FDA184828. FDA acknowledges that almost all vaping "products will be subject to premarket review." *Id.* And as FDA admits, obtaining regulatory approval through

[2] "A PMTA must contain sufficient information to show that the marketing of the new tobacco product is appropriate for the protection of the public health. . . . [T]he information required includes, among other things, information on the ingredients, additives, and properties of the product; investigations of the health risks of the products; and the methods of manufacturing. This may or may not require significant outlays on original research and testing, depending on the extent to which firms can compile the expected elements of the PMTA from existing information." FDA184835.

the PMTA process is a costly and burdensome endeavor. With regard to vapor equipment, FDA estimated that a PMTA will cost $1.68 to $2.48 million. FDA184882. As for e-Liquids, FDA estimated that a PMTA will cost $181,686 to $2 million, with subsequent e-Liquid PMTAs costing $12,090 to $1.9 million. FDA184836 (Table 11(a)).

The small business-oriented vapor industry cannot bear these costs. SFATA survey respondents reported mean sales revenue of just $307,200 per year. Over half of vape shop revenue comes from e-Liquid sales, and many SFATA survey respondents reported that one of their top-five (5) revenue generators is sale of their own "in-house" e-Liquid formulations. Even assuming moderate PMTA costs (*i.e.*, $1.09 million), regulatory approval for a *single* e-Liquid formulation would cost more than three times what the typical industry participant makes in yearly revenues. For example, it would cost The Vapor Bar, discussed *supra* at Page 3, an astonishing $531.92 *million* to obtain regulatory approval for all e-Liquids in its store catalog at that moderate PMTA cost. And even aside from the money, such a small company could never perform the original testing and research necessary to secure regulatory approval within two years of the Deeming Rule taking effect. Thus, all but the largest industry participants will cease making e-Liquids, and those few that remain will be able to offer far fewer options. And it seems beyond dispute that, at a cost of $1.68 million for a PMTA for every device, there will be no market left for small producers of equipment. *See e.g.*, Cozen O'Connor, *The E-Cigarettes Industry Fights Back Challenging the FDA in Federal Court*, JD SUPRA, May 18, 2016, at 1, 2016 WLNR 15076065 ("The price tag associated with the FDA approval process alone likely will pose an insurmountable barrier for the small vape shops, device manufacturers and e-liquid producers that currently drive most of the industry."). Indeed, SFATA has surveyed it membership about how many PMTAs each respondent could afford to file at various cost points.

The survey found that: (1) eighty-seven (87) percent could not afford a single PMTA at a cost of $333,554; and (2) ninety-four (94) percent could not afford a single PMTA at a cost of $1 million. Moreover, most respondents stated that they could not remain economically viable if forced to comply with the FDA's Deeming Rule. A few example comments collected from SFATA's member companies demonstrates the dire prospects for the industry under the Deeming Rule:

- "We would not be able to afford to even file one PMTA, let alone the number it would require to continue with our line. Without our line, we'd be out of business."

- "I currently work alone to build box mods for my local community. It took me years to find a hobby that I excelled at and thoroughly enjoy. Business has been steadily increasing and have plans to expand and hire employees. But at the proposed fees, I would have no choice but to stop."

- "[M]y company just launched a couple months ago and is 100% self funded. If the FDA required PMTAs I would no longer be able to stay in business."

- "We have almost $200,000 of personally guaranteed dollars invested in engineering, marketing, machining, and production. At this stage, if we had to pay anything north of $10,000 to register our product with the FDA, we would be out of business and out of our investment just as we are gaining momentum. In addition, this will leave half our team looking for new jobs as most of us have left our careers to pursue the American Dream."

- "Requiring these applications would put my company out of business, causing me to lose my livelihood. My business could not afford even one of these applications."

FDA's own analysis confirms the devastating impact, having concluded that its Deeming Rule will drive many currently-available vapor products from the market. FDA184829 (FDA has stated that it "expect[s] a much larger share of ENDS products to exit rather than submit a premarket application"). FDA concedes that all vape stores will cease component manufacturing and e-Liquid mixing once the Deeming Rule takes full effect. FDA184854 ("We do not estimate the amount of potential exit among manufacturers and importers, but we assume that vape shops will change their business model and switch to pure retailing."). But, even among those

businesses that continue to produce vapor components and e-Liquids, FDA recognizes that there will be a significant reduction in the number of products available on the vapor market. FDA estimates that only forty-six (46) percent of vapor delivery systems will be grandfathered-in or submitted for PMTA review. FDA184834 (Table 9). This means *at least* fifty-four (54) percent of vapor delivery systems currently available to consumers are likely to disappear. *Id*; FDA184420 ("Some manufacturers or importers may cease to sell products in the U.S. rather than bear the cost of complying with this final rule."). FDA further estimates that only twelve-and-a-half (12.5) to fifty (50) percent of e-Liquid formulations will be grandfathered-in or submitted for PMTA review. FDA184834 (Table 9). Thus, FDA recognizes that as much as eighty-seven-and-a-half (87.5) percent of currently available e-Liquid formulations could be forced from the market. *Id*; FDA184854 ("We do not estimate the amount of potential exit among manufacturers and importers, but we assume that vape shops will change their business model and switch to pure retailing."). SFATA believes that even these dire estimates significantly understate the amount of product exit.

By forcing so many products out of the market, the Deeming Rule will fundamentally transform the vapor industry. The small and micro businesses that currently comprise the industry's majority, as well as the artisanal and small batch components and e-Liquids they produce, will quickly disappear from the market. Faced with millions in costs to obtain regulatory approval, manufacturers of components and e-Liquids will be forced to shut down their operations or attempt to sell their businesses to larger, established companies (likely traditional tobacco companies). *See* FDA161084 ("Most small companies lack access to the scientific knowledge base and in-house expertise to properly execute a PTMA and, more

importantly, lack the financial resources to develop such applications, even using outside assistance."). As recently explained by UBS financial analysts assessing the market:

> We believe additional costs including labor hours, investments in clinical studies, as well as opportunity costs may now increase the investment hurdle when allocating resources to e-cigarettes/alternatives—significantly raising the cost of innovation (particularly regarding future products). Of course, the relative cost borne by large-scale incumbents may be less onerous than those borne by smaller-players who lack scale and sophistication—likely facilitating future industry consolidation and raising barriers to entry.

UBS, Altria Group Inc., *Clearing the Vapor Cloud: Deeming Rules Finalized*, May 5, 2016, at 1.[3] The Deeming Rule will also inhibit innovation, as component and e-Liquid manufacturers will no longer prioritize improving upon the quality and safety of existing products since each new product will require an additional, costly PMTA. *See* FDA155181 ("[T]here are thousands of e-cigarette, e-cigarette component and e-liquid manufacturers that make tens and of thousands of products that are constantly being modified to improve safety and to adjust to changing consumer preferences."). And, with only a very minimal number of more commoditized products remaining on the market, there will be little reason for consumers to visit vape shops, as such stores will become largely indistinguishable from the retail establishments (like

[3] *See also* Michael B. Siegel, Opinion, *The FDA's Vaporous Thinking About E-Cigs*, WALL ST. J., May 5, 2016, at 2 ("Since few of the e-cigarette-product makers—most of which are small businesses—can afford to stay in business and pay for this level of resources or expertise, the majority of these companies will shut down. That will leave the market open only for e-cigarette products made by the largest of companies, some of which have already begun buying what once were small-company e-cigarette brands."); Jonathan H. Adler, Opinion, *Why the FDA's new e-Cigarette Regulations Are a Gift to Big Tobacco (and Could Actually Harm Public Health)*, WASH. POST, May 5, 2016, at 2, 2016 WLNR 13720352 ("For tobacco giants such as Reynolds and Altria, this is no big deal. For smaller e-cig makers, however, these rules could be the kiss of death. Even if smaller manufacturers can satisfy the relevant regulatory deadlines, the rules will increase the cost of e-cigs, limiting their cost advantage vis-a-vis traditional cigarettes and inhibit continued product innovation (thereby inhibiting the ability of e-cig manufacturers to make their products even more attractive to current tobacco users). So, as a consequence of the FDA rule, the e-cig market will shrink, and Big Tobacco will be in a better position to dominate what's left. A vibrant competitive market will be replaced with a cartel, much like the one we see in the cigarette market.").

convenience stores) that currently dominate the traditional tobacco market. FDA184798 (concluding vape shops may "exit the market if product variety settles at a level at which not all currently operating vape shops can operate profitably"); *id.* ("[A]fter the initial compliance policy period for submission and FDA receipt of PMTAs, we expect most vape shops to convert to a pure retail model.").

CONCLUSION

For the reasons stated above, FDA's Deeming Rule will destroy the vapor industry as it is currently constituted. SFATA respectfully urges the Court to grant Plaintiffs' Motions for Summary Judgment.

Dated: August 1, 2016

Respectfully submitted,

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