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Compliance to FDA's elimination of free tobacco product sampling at vape shops

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ABSTRACT

Objective: The 2016 FDA's "Deeming Rule" prohibited free samples of vaping products. The purpose of this study was to investigate compliance with or adaptation to this newly established FDA policy.
Methods: Vape shops were recruited in Southern California between November 2017 and December 2018. Data collectors interviewed 121 vape shop employees who responded to questions pertaining to the sampling protocol at their shop. Nicotine levels used for sampling were also assessed for consideration of future policy adoption.
Results: Only 7.4% of shops were non-compliant to federal sampling rules. The remaining shops either: 1) charged a fee for samples (58.7%); 2) deducted the fee from the final purchase price (5.8%); or 3) eliminated product sampling (28.1%). Of the shops that charged for sampling (including membership fees), 94.4% initiated a minimal cost protocol (≤$1) for sampling. Half (50.0%) the shops that allowed sampling offered nicotine-containing samples.
Conclusion: There was high compliance (92.6%) to the change in policy among vape shops. However, minimal modification of sampling protocol was observed due in part to the lack of specificity on parameters of compliance, which lessened the potential impact of the policy. To further protect consumers, policymakers must develop unambiguous and comprehensive policies to achieve intended results and true compliance. At minimum, future tobacco product sampling policies should consider standardized pricing; alternatively, total elimination of tobacco product sampling is suggested.

1. Introduction

As electronic cigarette (e-cigarette) sales have proliferated in recent years, so have vape shops—stores that specialize in the sale and promotion of e-cigarettes, e-liquid, and other vaping products. As vape shops increased in number, common business practices were established, such as the sampling of e-liquids (e.g., a trial of the product before purchase). Such trials of e-liquids were almost always free and required no monetary transaction for the sample. E-cigarettes and related products (e.g., atomizers, e-liquids) sold at vape shops remained largely unregulated until 2016, when the U.S. Food and Drug Administration (FDA) issued a regulation referred to as the federal "Deeming Rule" (U.S. Food and Drug Administration, 2021). The FDA has regulated the manufacturing, distribution, and marketing of tobacco products under the Family Smoking Prevention and Tobacco Control Act (also known as the Tobacco Control Act), which—once signed into law in 2009—gave FDA authority to regulate tobacco products. The 2016 Deeming Rule allowed such regulatory authority to be extended to products not originally covered in the Tobacco Control Act, including e-cigarettes, their specific components or parts (such as atomizers and e-liquid), and other tobacco products (e.g., cigars, hookah and pipe tobacco) (U.S. Food and Drug Administration, 2016; U.S. Food and Drug Administration, 2017). Among other provisions (e.g., no sales to minors, display of health warnings), this rule prohibited provision of free samples of vaping products (U.S. Food and Drug Administration, 2016). The "no free sampling" provision is the topic of the current paper.

Improving public health and protecting future generations from the dangers of tobacco use—which is the single largest cause of preventable

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disease and death in the U.S.—is what the FDA hoped to address with such a significant updated tobacco rule (U.S. Food and Drug Administration, 2016). While there was a slight decline between 2019 and 2020 (U.S. Food and Drug Administration, 2020), e-cigarette use has dramatically increased over the last decade, and in the U.S. in 2020 over 8 million adults and 3.6 million middle- and high school-aged youth used e-cigarette products, many of those being flavored (Wang et al., 2020). Prohibiting free samples of vaping products (including flavored products) may be an important step to help curb initiation rates of e-cigarettes (Rigotti et al., 2005) and will be especially important as future new tobacco products become available. Prior to the Deeming Rule and the Tobacco Control Act, free samples of dangerous tobacco products were easily and freely accessible to youth (U.S. Department of Health and Human Services, 2017). A 2021 study demonstrated that sales to minors were documented in over 14% of a sample of national vape shops between 2017 and 2019 (Sussman et al., 2021). Youth are legally allowed to enter vape shops, thus, the monitoring of compliance to ensure that FDA regulations are followed and enforced is essential.

This study investigated compliance and adaptation to the "no free sample" policy among Southern California vape shops just after implementation of the federal Deeming Rule. We also assessed nicotine levels used for sampling for consideration of future sampling restrictions. We hypothesized that a majority of vape shops would ultimately comply with this rule, but that they might also be able to easily adapt by utilizing practices that lessen the impact of the rule. That is, shops would tweak business practices just slightly to maintain compliance, which would be easy to do given the lack of specificity on parameters of compliance, lessening the intended effects of further protecting customers.

2. Methods

2.1. Sample

Vape shop locations from Google Maps and Yelp were combined with data on neighborhood composition from the U.S. Census. Vape shops selected were those that specialized in the sale of e-cigarettes/e-liquids/devices to consumers and did not sell combustible tobacco products (vape-only shops). From the exhaustive list of eligible vape shops generated from these sources, we reached out to 136 vape shops (refusal rate: 11%) until we reached a desired sample size (N = 121) from ethnically diverse location areas (e.g., areas with higher-than-average concentration of African-American, Korean/Asian, Hispanic/Latino, and non-Hispanic White residents) in the Greater Los Angeles region (Los Angeles, Orange, Riverside, and San Bernardino Counties) in Southern California (Galimov et al., 2020; Huh et al., 2021).

2.2. Procedures, measures, analysis

Trained teams of two or three data collectors visited vape shops in diverse racial/ethnic neighborhoods for recruitment and consent between November 2017 and December 2018. After providing verbal consent, one employee per shop completed a 35-minute anonymous structured interview. The interview contained structured open-ended and structured closed-ended questions which were asked aloud. Among other questions, the employee was asked specifically, "*How do you handle sampling of juices at this shop (all that apply)*". Response options included: *1) Allow free samples; 2) Charge a fee per visit and specify amount of fee; 3) Have a membership fee for samples of juices and describe the terms of membership; 4) Do not allow sampling; and 5) Other, please describe.* Employees responded about the general protocol of sampling at their shop and indicated whether sampling of e-cigarette products at the shop was permitted, whether there was a fee per visit or a membership, the terms of the membership, and the amount of the fee, if any. Those indicating that they allowed sampling were also asked, "*What level(s) of nicotine are provided for sampling (all that apply—zero nicotine; low [1–3 mg/ml]; medium [6–10 mg/ml]; or high [11–30 + mg/ml)]*". A total of 122 employees were surveyed; however, one respondent declined to answer the question about how the sampling of e-liquids were handled at their shop; hence, we excluded this shop from the analysis (total N = 121). Upon completion of the survey, each participating employee received a $50 prepaid gift card. All statistical analyses were conducted using Stata software (version 15.1; Stata Corp, College Station, Texas, USA).

3. Results

Of the total 121 included analyses, 34 (28.1%) shops did not allow sampling (10 shops offered only smelling of e-liquids, 23 shops only permitted visual inspection of the product, while 1 shop offered only a taste/lick), while the other 87 (71.9%) shops allowed sampling in some form (either for a fee or free). Of the 87 shops that allowed sampling, 71 (81.6%) shops charged for samples (as low as 1¢ per visit, and up to $1 per flavor); 7 (8.1%) additional shops allowed the upfront sampling fee to be deducted from the final purchase price (i.e., conditionally free sampling); while 9 (10.3%) shops allowed free samples. Of the 9 shops that allowed free samples, one shop had a jar of loose change [pennies] for customers to use for a sampling fee. Of the 71 shops that charged for samples, 66 shops (93.0%) reported charging a very minimal fee for samples (56 shops charged between 1¢ and $1 per shop visit; 10 shops charged between 3¢ and $1 per flavor), while 2 (2.8%) shops reported offering an annual membership for sampling (ranging from $1 to $10).

The shops that provided sampling (either for a fee or free) often offered multiple levels of nicotine concentrations for the samples. The nicotine levels used in sampling of products reported here are the highest amount offered by the vape shop. While half of the shops (N = 43 [50.0%]) that allowed sampling provided zero nicotine level e-liquids, 41 (47.7%) shops provided "low" nicotine level (as high as 1–3 mg/ml) e-liquids, and only 2 (2.3%) shops provided "medium" nicotine level (as high as 6–10 mg/ml) e-liquids available for sampling. None of the shops reported providing "high" nicotine level (11–30 + mg/ml) e-liquids for sampling (see Table 1).

4. Discussion

Tobacco product sampling was prevalent in this sample of Southern California vape shops. Results of the current study indicated that over two-thirds of shops in our sample allowed sampling of vaping products in some form, either for a minimal fee or free of charge. Sampling at vape shops is used to secure the return of customers, thus motivating purchases of new products not otherwise experienced. Several types of adaptations were observed regarding the "no free sampling" rule, given the lack of specificity on parameters of policy provided by FDA. Most shops charged a minimal fee (e.g., $1 or less) each time a customer

Table 1
Protocol and nicotine levels provided for e-liquid sampling at vape shops.

	Allowed any form of sampling	Allowed free sampling or deducted the fee from the purchase price	Charged for samples	p-value
Total	87 (100%)	16 (18.4%)	71 (81.6%)	–
Nicotine levels provided for sampling				
- Zero (0 mg/ml)	43 (50.0%)	9 (60.0%)	34 (47.9%)	0.71
- Low (1–3 mg/ml)	41 (47.7%)	6 (40.0%)	35 (49.3%)	
- Medium (6–10 mg/ml)	2 (2.3%)	0	2 (2.8%)	
- High (11–30 mg/ml)	0	–	–	–

Notes: One shop that allowed sampling refused to provide nicotine levels; Nicotine levels reported here are the highest amount offered by the vape shop.

wanted to sample e-liquids, while a few others offered annual memberships for sampling (minimal one-time fee for one year of samples). Vape shop retailers are legally allowed to offer memberships for e-liquid sampling. However, they are prohibited from selling memberships that provide *free* samples of tobacco products (e.g., e-liquid) outside of a tobacco product sales transaction (U.S. Department of Health and Human Services, 2017). Therefore, sampling with a membership card must be accompanied with a purchase. Still, if the vape shop has an adequate age verification process, can prove that the customer sampling is the original purchaser of the membership, and the customer purchases a product after sampling, a membership sold at a very minimal cost would be another way to bypass the "no free sampling" policy. Given the stringent details for allowing memberships for sampling, we observed that it might have indeed detered shops from offering sampling memberships, as only N = 2 shops offered such options.

E-liquid sampling at vape shops was a common business practice directly affected by the newly established FDA authority. Yu et al (Yu et al., 2018) found that all vape shops allowed free trials of e-cigarette puffs prior to implementation of the Deeming Rule. Interestingly, the FDA never specified how much shops should charge to sample e-liquids. For example, the rule might have attempted to specify that no trial of a product was permitted at a vape shop, or that the cost of trying a product would need to be at a fixed percent of the price of the product (e.g., at least 20%) (Sussman et al., 2013). Of the total shops that charged for samples in some aspect upfront (N = 78 shops), 95% either charged a fee so minimal ($1 or less), or introduced an alternative savings method, such that it was not likely to affect the customer's buying habits. In fact, about 6% of the total shops in our sample deducted the fee from the purchase price (i.e., conditionally free sampling), which may have actually increased the chances of a purchase.

Some shops (28%) eliminated sampling of e-liquids altogether, or allowed only the smelling of the e-liquid before purchase. E-liquid variety and selection is an essential aspect to the survival of a vape shop's customer base (Galimov et al., 2020). Customers who already have a preferred e-liquid brand and flavor may not sample regularly and it is possible that shops with many such customers, may have decided to eliminate sampling altogether, rather than offer samples for a fee.

There are several limitations that should be taken into account. While no differences in sampling by geographic location was observed, only vape shops in Southern California were assessed, which might limit generalizability to other geographic areas. The COVID-19 pandemic may have also generated changes in vape shop sampling behaviors not accessed here. To enhance generalizability, future research should compare observations across different regions in the U.S. and perhaps different countries around the world. Given the nature of the data, recall and social desirability biases may also have affected the results.

5. Conclusions

A majority of shops were "technically" in compliance to FDA sampling regulations. It was easy for shops to adapt to the rule and permit rather inexpensive or virtually free sampling. However, many shops simply did not permit any sampling, and it is not clear whether they chose not to be troubled by the FDA, or whether they did not understand communications about the change in policy. Of course, not permitting sampling could be a result of the shop anticipating future changes to policy. Certainly, the changing landscape and the pandemic could have changed vaping product sampling in the future due to concerns with sanitation and health. Future research in additional locations is warranted.

As new tobacco products emerge, policy makers should be aware that vaguely worded policies leave room for effortless adaptations, which could lessen the intended impact of compliance. Recommendations for current tobacco product sampling policies might include consideration of the elimination of tobacco product sampling altogether, or at minimum, the introduction of a standard formula price per sample which may be high enough to serve as a deterrent (e.g., 20% of the cost of the product) (Sussman et al., 2013). Further, limiting nicotine content (that is, only nicotine-free sampling of e-liquid) to further protect consumers is recommended if product sampling should remain. We often see history repeating itself; thus we can learn from this analysis of responses to changes in policy, and ensure that future rules are exceedingly thorough. Policies as applied to products sold at vape shops need to be as unambiguous, comprehensive, and as detailed as posssible to achieve consistent and intended results and true compliance. Monitoring of vape shops is needed to ensure compliance with FDA regulatory authority.

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8. Human subjects statement

The University of Southern California Institutional Review Board examined this research protocol and declared it to have exempt status.

CRediT authorship contribution statement

Leah Meza: Methodology, Investigation, Writing – original draft. **Artur Galimov:** Formal analysis, Writing – review & editing. **Jimi Huh:** Writing – review & editing. **Lourdes Baezconde-Garbanati:** Supervision, Writing – review & editing. **Steve Sussman:** Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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