'No, the government doesn't need to, it's already self-regulated': a qualitative study among vape shop operators on perceptions of electronic vapor product regulation

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Abstract

While the market share of electronic vapor products (EVPs), sold primarily through vape shops and other outlets, has increased rapidly, these products remained largely unregulated until 2016. This study, conducted prior to announcement of the deeming regulations, provides insights into vape shop operator attitudes toward potential government regulations of EVPs. In 2015, we conducted 37 in-person interviews of vape shop operators across nine US cities. Shops were identified through extensive websearches. We used QSR International's NVivo 11 qualitative data analysis software to analyze the transcripts. Many vape shop operators viewed regulations requiring safe production of e-liquids, child-resistant bottles and listing ejuice ingredients as acceptable. They disagreed with the elimination of free samples and bans on flavored e-liquid sales, which generate significant revenue for their stores. Many held negative perceptions of pre-market review of new product lines and EVP-specific taxes. All agreed that EVPs should not be sold to minors, but most felt that owners should not be fined if minors visited vape shops. Findings from this study offer insights into the acceptability of proposed

regulations, as well as barriers to effective regulation implementation.

Introduction

Vaping is a relatively new cultural phenomenon [1]. In less than a decade, electronic vapor products (EVPs) have evolved from the initial 'cig-alike' models, which resembled traditional combustible cigarettes with limited flavor choices, to rechargeable tanks that offer thousands of flavors and the ability to modify the nicotine dosage and amount of aerosol produced [2]. In the United States, EVPs have become increasingly popular among current smokers and recent quitters, as well as individuals who have never smoked cigarettes [3-6]. Sales of EVPs in the United States were estimated at US\$3.7 billion in 2015 [6–8] and expected to reach US\$4.4B in 2017, with vape shops revenues expected to represent more than 40% of total sales[9].

With the growing popularity of personalized tank systems, an estimated 10 000 independently owned retail establishments, known as 'vape shops', have opened across the country [10–12]. Vape shops are retail outlets devoted to the sale of EVPs; owners and employees help customers select and sample flavors,

determine nicotine levels and learn how to use the technology [10, 13, 14]. The products offered at any particular vape shop can vary widely. Some vape shops sell hardware and e-liquids supplied by manufacturers, some manufacture their own equipment and/or e-liquids sold in their shops, and others sell a combination of products purchased from wholesalers and custom products they manufacture [15]. While conventional tobacco product retailers are required to comply with both federal and state/ local regulations that restrict the marketing and sale of tobacco products, [16] the vaping industry remained largely unregulated with no restrictions on marketing and product characteristics until August, 2016 [17]. With profit margins as high as 200-400%, operating a vape shop was considered a fairly straight-forward, low-risk and potentially lucrative prospect [8]. This unfettered expansion of the EVP market raised concerns among health officials, the U.S. Food and Drug Administration (FDA), the public health community and a range of consumer advocacy groups [18].

In mid-2016, the landscape for EVPs, cigars and other tobacco products changed when the FDA issued its final 'deeming' rule that extended its regulatory authority over tobacco products to include EVPS, cigars, pipe tobacco, hookah tobacco, dissolvable tobacco products and any other product containing tobacco or nicotine derived from tobacco, as well as components used for consumption of these products [19]. Specifically, the FDA considers EVPs to be tobacco products if they use a power source to heat liquids, tobacco or materials derived from tobacco for inhalation [15, 20]. Any person or entity who manufactures, distributes or sells EVPs is subject to FDA regulations [15, 20]. The FDA considers a manufacturer to be any entity that produces or repackages the devices, their components or e-liquids [15].

As a result of the deeming rule, sales of these tobacco products to persons under 18 years of age are prohibited. In addition, manufacturers of these newly deemed products, including EVPs and e-liquids, are required to register products with the FDA; disclose ingredients, substances, compounds and additives in the products; and undergo product

review. Furthermore, product claims are restricted to only those supported by evidence and reviewed by the FDA, and distribution of free samples is prohibited [19]. In addition, the agency has mandated that all nicotine-containing EVPs display the following warning statement: 'WARNING: This product contains nicotine. Nicotine is an addictive chemical'. Although the deeming regulations were scheduled to be in effect as of August 2017, the FDA announced an extension of enforcement deadlines affecting vape shops in November 2017, some of which extend to August 2022 [21].

The deeming regulation was criticized by the vaping industry with claims that it would incur significant costs to manufactures, retailers and consumers due to the required product review, and that it was unnecessary government intrusion [8]. As of 1 November 2017, there were at least six lawsuits either pending or under appeal challenging various aspects of the deeming rule on a variety of grounds, including the onerous burden of the premarket review of tobacco products process, the FDA exceeding its lawful authority and the definition of what constitutes a 'tobacco product' subject to the regulations [22].

In addition to the deeming rule, states and local jurisdictions across the country have also begun to regulate how and where EVPs can be sold or used. There are some significant local taxes, and many localities regulate EVP use via second-hand smoke laws and EVP sales via tobacco retailer license laws. As of December 2016, 24% of states and the District of Columbia had laws defining EVPs as tobacco products, 16% had EVP-specific taxes, 47% required special packaging of nicotine-containing e-liquids, 96% restricted sales and access to minors, 33% required a special business license to operate a vape store and 61% had at least some restrictions on where EVPs can be used [23].

Given the rapidly evolving EVP regulatory and policy landscape, this exploratory study aimed to understand how proposed regulations on EVPs might affect marketing practices in vape shops by eliciting vape store operators' attitudes toward the proposed 2015 regulations, prior to the issuance of the 'final' deeming rule. The findings from this

study can offer insight into the acceptability of the proposed regulations, as well as identify potential barriers to their effective implementation.

Materials and methods

Vape stores were selected from nine cities: Atlanta (GA), Chicago (IL), Henderson (NV), Oklahoma City (OK), Phoenix (AZ), San Jose (CA), Seattle (WA), Thousand Oaks (CA) and Ventura (CA). A convenience sample of nine cities was selected based on the various locations of the research team, budgetary resources and expected variability in vape shop marketing based on geographic region of the country. For each city, we conducted an extensive internet search for vape shops using multiple sources (Google Maps, Yelp.com, YellowPages.com, Provape.com, Vaporsearch.com, Ecigarette-forum.com [store locator], Vapelocate.com and Vape Maps App on the iPhone). The searches were conducted across these multiple sources using multiple terms, including electronic cigarette, e-cig*, e-liquid, e-juice or a vape- related term. The validity of this enumeration method for identifying vape shops was documented in a recent study [24]. The comprehensive list of all vape shops within the nine cities identified from these sources was then compiled and screened for the following inclusion criteria: located within the city limits and matching the definition of a vape shop. For this study, a vape shop was defined as a retail outlet primarily engaged in sales of EVPs and their components (e.g. e-liquids) to the public. At least 50% of the store's merchandise needed to be EVP-related. Stand-alone public vape lounges (referring to business establishments where patrons can both purchase and use vaping devices and liquids) and private vape clubs/lounges were excluded.

A random sample of 37 vape shops was then selected from this enumeration list, with five stores each from the cities of Atlanta, Chicago, Henderson, Oklahoma, Phoenix, and San Jose; four stores from Seattle; two stores from Thousand Oaks; and one store from Ventura County. The research staff called the selected businesses, verified that the store met the study criteria and invited the

business operators to participate in the study. An interview and on-site store audit were scheduled for each vape shop operator who agreed to participate. Participants had to be a shop owners or managers, English-speaking and 18-years and older. The research team members then visited the vape shop, reconfirmed eligibility and obtained written consent. The data collectors were trained by the research team lead (PI/co-investigators). The training was a 3-h program that included interactive role-playing scenarios to refine interview skills, review human subjects and ethics and practice the administration of informed consent. An in-person interview was then conducted by two research team members using a structured interview guide. The interviews were audio recorded and the researchers took notes in parallel. Thirty-two vape store operators gave permission to be recorded. The interviews lasted approximately 45 min and consisted of questions about the shop operator's perception of proposed government regulations at the time of the interview and their long-term business plans, as well as questions related to marketing strategies. In addition, data collectors conducted an on-site store audit of EVP products and marketing materials. The participating vape store operators were compensated with a US\$50 American Express gift card. All interviews were conducted between March and August 2015. The protocol and survey instruments were approved by the IRB (UIC IRB# 2015-0110; GSU IRB# H15535).

Data analysis

The recorded interviews were transcribed, and all interview data were analyzed using NVIVO® analytical software. Data analysis was carried out in a three-step process. First, three transcripts were selected and independently analyzed by two coauthors (PN and CK). Relevant themes were identified and entered into NVIVO to create a master list. In the second step, another set of three transcripts were selected and coded independently by the first two coauthors (PN and DB) using the master list. New themes that emerged were added to the master list. The master list was refined iteratively when a new theme emerged. Theme saturation was reached after

reviewing 8–10 transcripts. In the last step, using the refined master list, two coauthors (PN and CK) coded all remaining transcripts independently. Discrepancies were resolved through consensus among the coauthors. Inter-rater reliability κ coefficient was 0.8. Kappa values of 0.61 or higher indicate substantial agreement, while values of 0.81 and above are considered almost perfect agreement between raters.

Results

Sample profile

As shown in Table I, vape shop operators in the sample were primarily non-Hispanic White (75.7%), male (81.1%) and with age ranging from 22 to 65 (mean: 37.4, standard deviation: 10.8). Almost all had previously smoked traditional cigarettes (86.5%), but only one-fifth (21.6%) were still smoking at the time of the interview. Only one vape shop operator was not currently using EVPs. More than three-fifth of respondents (64.9%) were owners, two of which ran stores at multiple locations. Most shops had been in business for more than 1 year (72.9%). All shops were located in urban areas, with the majority (67.6%) containing both a retail outlet and a vape lounge.

Awareness and sources of information of the FDA's proposed regulation of EVPs

Almost all vape store operators were aware of at least some of the proposed FDA regulations; this was especially true for operators who had their own line of e-liquids. Examples of related comments:

'The FDA is right now considering deeming regulations that would basically put the vape industry out of business by requiring SKUs [stock keeping unit] for anything manufactured after 2007. That includes flavor. I've got 50 flavors, average SKU would cost me \$330, 000, times 50.' (ID# 26; > 45 years old; Male).

The operators anticipated the eventual regulation of vaping devices and e-liquids, and some were already self-regulating. To obtain information on

Table I. Sample characteristics

	#	% (range)
Vape operators socio-demograp	hic cha	aracteristics
Gender		
Male	30	81.1
Female	7	18.9
Mean age, SD (age range)	_	37.4, 10.8 (22-65)
Ethnicity		
Non-hispanic White	28	75.7
Other	9	24.3
Traditional cigarette use		
Current smoker	8	21.6
Former smoker	24	64.9
Never smoker	5	13.5
EVP use		
Current user	36	97.3
Former user	1	2.7
Shop ownership		
Self, own one shop	22	59.5
Self, own multiple locations	2	5.4
Other ^a	13	35.1
Vape shop characteristics		
Shop location		
Urban	37	100
Length of time shop open		
< 12 months	10	27.0
12-23 months	13	35.1
24 months or more	14	37.8
Shop type		
Retail store only	12	32.4
Retail store and lounge	25	67.6

^aManagers or client representatives.

regulations, most of the operators cited websites of vape associations or other online sources. These included the Smoke-free Alternatives Trade Association (http://sfata.org), Consumer Advocates for Smoke-free Alternatives Association (http://casaa.org), Facebook groups of the local vape associations (Nevada Vaping Association; Oklahoma Vapor Advocacy League), the FDA website, vaping advocacy websites, and YouTube. One of the operators commented that 'It's a digital world' (ID# 20; 20–45 years old; Male). Operators also reported learning about regulations through informal social networks with vape store owners and manufacturers of e-liquids. TV, radio, and print sources, with the exception of vape magazines, were the least

popular sources for information about EVP regulations.

Perceptions of proposed FDA regulation of EVPs

List the ingredients contained in e-liquid on the bottle label

Most operators agreed with the proposed requirement to list all ingredients in e-liquids, noting that such regulations would minimize the chance that low-quality, illegitimate products might enter the supply chain and would help drive less credible operators out of business. Among the 21 operators marketing their own e-liquid brands, three indicated that they already list the main ingredients on the packaging of their house-made brands, primarily to ensure the integrity of their product and to help consumers manage any sensitivities to particular ingredients. One operator with their own brand did not want to list the flavor ingredients, fearing a loss of trade secrets that other businesses would want to replicate. Examples of statements made by operators expressing their attitudes toward potential FDA regulations requiring registration of products and ingredients, as well as other proposed regulations, are presented in Table II.

Register ingredients contained in e-liquids

Some operators felt that having to register all the ingredients was unnecessary, 'stupid', 'excessive' and placed an undue burden given that '[T]hese are all ingredients that are widely used in every area of human consumption – food, cosmetics, to drugs and chemicals' (ID# 26; >45 years old; Male). Increased business costs as a result of regulation were an issue raised by a few operators, who worried that the cost would have to be passed on to the customers.

A shared concern was that if every formula had to be registered, the cost of manufacturing and supplying the formula would cripple the vaping industry, forcing many shops' businesses to fail; some operators expressed that such registration requirements would only benefit the tobacco industry since they have the resources to afford such costs (Table II). Operators who bought pre-packaged e-liquids were less resistant to the proposed regulation because they felt that the responsibility of complying with the regulation would fall on the manufacturers of the e-liquids. One operator suggested that it might be feasible to allow only a few companies to manufacture e-liquids and sell them to retail shops. One operator who mixed their own e-liquids commented that e-liquids contained essentially the same ingredients as those commonly used in packaged food preparation, except for nicotine, so the need for registering the ingredients was too extreme.

Eliminate the distribution of free samples

Almost all operators wanted to continue to distribute free samples as it helped them attract customers and increased product sales. They felt regulating the use of e-liquid samples that did not contain nicotine was unnecessary. However, a few operators viewed this regulation positively due to the cost associated with giving free product as samples (Table II). One operator shared his experience and said that too many free samples kills business because the consumers do not purchase the juices:

'Yes, I like that idea. When the vape summit is here and those assholes come in here, they give everything away and the businesses die, almost die, because nobody needs anything because they got a six-pack of juice, must be nice to be rich and give that much product away.' (ID#13; 20–45 years old; Male).

Another operator felt that offering free samples is poor marketing that is not often found in other industries:

'We don't give free samples, and we go to these shows and these guys are giving out all these free samples. That's bad for business. To me, that's poor marketing, but it's not something, there shouldn't be a government regulation against it.' (ID# 26; >45 years old; Male).

Overall, most of the operators stated the government should not regulate or restrict the distribution of free e-liquid samples.

Table II. Themes and excerpts/quotations regarding vape shop operators' towards proposed FDA regulations of EVPs

Themes	Example excerpt/quotation	^a n/ ^b N
List ingree	lients contained in the e-liquid on the bottle label	
']	think customers should know what's inside, so that's good.'	23/25
']	am all for it. At least at our shop, full disclosure is something that we pride ourselves onWe want	
	people to not question what's inside of it. I'd rather you know what's inside the bottle rather than	
	not know because of maybe allergies or so on and so forth. I'm all for putting ingredients on bottles.'	
'(Can you get all that information on a tiny little label? No. That's where you need packaging.'	
']	For me, I wouldn't mind if they put in the propylene glycol, vegetable glycerin, or the nicotine, or	
	what kind of nicotine they use, or PG based/VG based. But the flavoring, I would like it to be a	
	little bit secretive, just because it gives them a little leverage on other brands. I don't want them	
	to be taking out their secret, you know, just by flavoring.'	
Register in	agredients contained in e-liquids	21/30
-	Yes. I think the flavor companies either have to have it registered in order to sell to us, I think	
	that's the way it ought to be gone through if they want to stay in the game.'	
67	The way the FDA has it set up is you have to submit each one of those ingredients separately,	
	then combine them It's not cost effective for us to test that juice, it's just not.'	
']	'm against that. That will cost thousands and thousands of dollars to register every flavor. That will	
	probably put a large, large amount of shops out of business.'	
']	f it's every manufacturer has to register every formula that they come up with, it will pretty much	
	kill everyone but the tobacco industry.'	
Eliminate	the distribution of free samples	2/32
']	No, that would not be a good thing. It's like buying a car without test riding it.'	
	Yeah, I don't like that. If you're 18 years old, you should be able to do whatever is legal.'	
	That I'm against just because customers are a coin flip. Sometimes they'll buy it just because, and	
	some people are like, you know, I really want to try it before I buy it. I'd definitely be against	
	restricting it just because the simple fact that a lot of customers, I can't even give the number,	
	if they don't try it, they're not going to want it.'	
Ban some	or all flavored e-liquids	
	Absolutely not. We're targeting people's taste buds, not kids with bubble gum flavoring. If that	2/31
	was the deal, then flavored condoms and flavored alcohol shouldn't be sold either.'	
67	They might, or they'd have less incentive to switch from cigarettes.'	
	Only banning them if there's something that's dangerous about it'. 'That is something that rubs me	
	the wrong way 110%, because when people are trying to get away from cigarettes, they want to	
	get away from the flavor of cigarettes.'	
Reauire p	re-market review of new product lines	
	The beauty of this industry is that it's not as complex as making medicine or something like	11/30
	that. That's why it's grown up so much in this country, is because it's like the American dream	
	of making your own business But to say that the FDA wants to step in and preview every	
	single line, most of these companies can't afford to get FDA approval the way they're	
	proposing it now.'	
	I think regulations like that are intended to just shut down these companies because,	
•	let's face it, who benefits by shutting down these companies? Big tobacco and big pharmaceutical.'	

 $^{^{}a}$ n = number of participants who responded affirmatively (yes);

Ban some or all flavored e-liquids

Operators responding to this question strongly disapproved of the idea of banning e-liquid flavorings, explaining that the flavors are what make EVPs a successful alternative to smoking and such a ban

would result in consumers reverting back to smoking. They expressed strong disagreement with the notion that flavorings make EVPs attractive to youth. They argued that flavored alcohol available on the market could be just as enticing: e.g. 'with

^bN=number of participants who responded to this theme of the 37 vape store operators who participated in this study.

alcohol, there's Swedish Fish-flavored alcohol. That appeals to kids like nothing I've ever seen before' (ID# 15; 20-45 years old; Male), yet there is no such restriction on those products, nor on other related industries: 'And it's not applied in any other industry' (ID# 15; 20–45 years old; Male). These operators felt that adult consumers should be allowed to make their own choices without government interference.

Require pre-market review of new product lines

Operators had mixed perceptions of pre-market reviews, with a small majority expressing overall negatively opinions. Some felt such reviews of eliquids would help eliminate unsafe juices from the market and improve the consumer confidence, while others expressed that this review should not include the devices (Table II). In contrast, some operators strongly disagreed with pre-market product reviews, seeing them as redundant to requiring e-liquid ingredients to be registered; they pointed to the added costs of such additional regulations making their products prohibitively expensive as well as introducing implementation challenges to the already continuously evolving and quickly expanding industry. Some operators indicated

they lacked sufficient knowledge of the details of the proposed regulations and the FDA plan for implementation.

Perceptions of state and/or local vaping policies

Restrict vaping in restaurants, bars, and public places

In general, the operators were divided with respect to regulations on where vaping is allowed (e.g. restaurants, bars and public places; Table III). About half felt that EVPs should not be banned in public places but should be used responsibly and with consideration of others, such as not blowing the vapor toward others, in the same way that smokers of regular cigarettes know to blow smoke away from others. Some operators agreed with bans in bars and restaurants and with restricting vaping to designated smoking areas. Some felt that vaping should be allowed wherever smoking was allowed. However, others argued that without any indication of harm from second-hand vapor, vaping should be considered safe; thus, it should not be banned, nor restricted in public places. They further elaborated that the amount of nicotine in second-hand vapor was negligible and that it was definitely better to have someone vaping rather than smoking next to

Table III. Themes and excerpts/quotations regarding vape shop operators' perceptions of state and/or local vaping policies

Themes	Example excerpts/quotations	^a n/ ^b N
Restrict vapi	ng in restaurants, bars and public places	
	'I think that's stupid because vapor is not the same as that, they're saying it's smoke.'	15/31
	'It depends on if the bar allows people to smoke cigarettes. If you can smoke cigarettes, you	
	definitely ought to be able to vape. If you can't smoke cigarettes, you've got to have	
	common sense and not vape.'	
	'I think it should be up to the private businesses as to what they want to do.'	
Impose excis	re taxes, similar to those on tobacco, to vapor products	
	'Hell, no. It's not a tobacco product, number one. Number two, we all see through the BS, it's	4/31
	just a way for them to make more money because they know it's a thriving industry, which	
	I find shameful to put a sin tax on something that is exponentially safer than smoking.'	
	'I disagree that they should be there, but if they're going to be, it shouldn't be any more taxed than is put on cigarettes because it's clearly healthier than smoking cigarettes.'	

 $^{{}^{}a}n =$ number of participants who responded affirmatively (yes);

^bN=number of participants who responded to this theme of the 37 vape store operators who participated in this study.

them. Many felt strongly that the government should not intervene but should allow private business owners to determine whether to allow or restrict vaping within their place of business: 'I feel like that should be left up to the establishment, especially restaurants and bars' (ID# 19; 20–45 years old; Female).

Impose excise taxes similar to those on tobacco, to vapor products

Many operators disagreed with levying a 'sin tax' and argued that such a tax would destroy their industry Table III. Operators contended that with vaping being a cheaper and healthier alternative to cigarettes, additional taxes would result in consumers reverting to unhealthy smoking behaviors. They viewed taxation as a way for the state to raise revenue in the short term because the vaping industry is thriving, but pointed out that it would be taxing something that is serving the public good by reducing the number of smokers.

Perceptions of other government vaping policies

Require on-site inspection

Almost all operators who responded welcomed onsite inspections to ensure that juices were mixed in controlled, clean environments. With respect to listing ingredients, operators felt that regulations should establish minimum standards without restricting innovation (Table IV). Others felt that manufacturers of e-liquids should only be held to the same standards as bartenders, e.g. who must wash their hands and follow basic public health practices of cleanliness. One operator pointed out that operators of tobacco shops did not have to comply with similar regulations (Table IV).

Fine stores if minors are present inside vape shops

Most operators agreed with prohibiting EVP sales to minors but disagreed with fines imposed for minor(s)

Table IV. Themes and excerpts/quotations regarding vape shop operators' perceptions of other government vaping policies

Themes	Example excerpts/quotations	^a n/ ^b N
Require on-site inspection		
'Bring it on. As long	as they tell me what they're checking for because I should know.'	29/31
'I think it should be r	regulated and inspected, in a similar way that if you wanted to bake cookies at your	
own house, you cou	ald, but you have to have it zoned as a business and then you have health inspections.	
I think it should be	like that for vape stores, too.'	
Fine stores if minors (youth y	younger than 18 years) are present inside vape shops	10/31
'That's a tricky thing.	We don't sell to anyone under 18 and we card people. But we have parents coming	
in with their childre	en, and currently it's not the law that you can't be in a vape store unless you're 18.	
	e coming in with their children because they're out doing errands and this is just	
	some people, they have to go pick up juice and coils, and we don't want them	
to leave their kids of		
	ere. There's no second-hand smoke. I used to vape around my kids. Completely safe.	
	tion or second-hand smoke. Customers bring their kids all the time.'	
	ging for nicotine-containing e-liquid(s)	
	resistant bottles. We don't let children in our store, but people are taking this home	31/31
•	ds and they have pets and everything else.'	
	I to get a hold of this stuff when they're not supposed to be. Again, the industry,	
•	ly 95% of the bottles that we have are child-proof'	
	re going to be child-proof and tamper-proof. If you put it on the floor, that's	
a parenting issue. I	'hat's not a vaping issue.'	

 $^{^{}a}n =$ number of participants who responded affirmatively (yes);

^bN=number of participants who responded to this theme of the 37 vape store operators who participated in this study.

being present in a vape shop (Table IV), explaining that parents come to vape shops to pick up e-liquids and batteries and may have kids accompanying them: 'If they're (little kid) on the couch and like 120 degrees outside, I will let her sit on the couch. I'm not going to be like lock your kid in the car, good luck' (ID# 23; 20–45 years old; Male). Vape stores offer a different type of environment: 'To start fining as though we were a night club or a bar or a strip club, I kind of object to that because we don't offer that kind of environment' (ID# 26; >45 years old; Male). Some operators thought that if it was permissible to let minors use zero nicotine juices, that it might prevent smoking among children: 'I wish when I was 16, that there was vapor, because it might have just been the whole thing of fixation of smoking, then I wouldn't have been smoking for the last 57 years' (ID# 27; > 45 years old; Male).

Provide child-resistant packaging for nicotine-containing e-liquid(s)

All operators responding to this question welcomed the requirement of childproof caps on e-juice bottles: 'I fully support policy' (ID# 32; 20–45 years; Male). All opposition verbalized was due to potential inconvenience to mobility-impaired customers: 'Yes and no at the same time. I have a lady who comes in here, she has MS, she shakes real bad and she can't open them' (ID# 23; 20-45 years; Male) or because they didn't feel the regulation was necessary for something they already required. They emphasized that the industry was already self-regulating to prevent children from being exposed to the products. The operators felt that childproof bottles also provided vapers with a sense of safety regarding their use of vaping products. Statements made by operators exemplifying their perception of these other potential regulations are presented in Table IV.

Discussion

Despite the rapidly changing EVP regulatory environment in the United States, little is known about vape shop business owners' or operators' attitudes about current and potential future EVP regulations

at both the federal and state/local levels. An accurate understanding of how vape shops might respond to EVP related policies and regulations is critically important for their successful implementation and ensuring high rates of compliance. This paper begins to fill this critical research gap by assessing vape store operators' attitudes towards a comprehensive set of potential FDA regulations prior to the final deeming rule, as well as state/local policies on the vaping industry proposed or in existence at the time of the study in 2015.

Overall, our findings suggest that these early entrepreneurs in the vape shop industry will accept, and willingly comply, with federal and state/local regulations if they perceive these requirements as nondetrimental to their profit margins and in line with their business plan to promote safe EVPs and to eliminate competitors marketing low-quality products. These requirements include on-site inspections, ingredient listings and the use of childproof caps/ packaging. Although we did not specifically ask about product warning labels, vape shop operators' acceptance of ingredient listing and their emphasis on safe use of products indicate that vape shop operators are likely to be comfortable with upcoming regulations to place warning labels on product packaging and ads. Most vape shop operators also agreed with state policies already in place that prohibit sales to minors. As such, federal and state/local enforcement of these types of regulations are likely to be met with little resistance by the vape shop industry.

In contrast, vape shop operators in general perceive regulations associated with the manufacturing and preparation of EVPs as a significant hurdle for small businesses. Costs associated with registering ingredients and premarket product review could ultimately result in business closures, reducing the competition among vape shops and simultaneously increasing the role of the tobacco industry in the vape market. In addition to the newly announced compliance date extensions, regulators may need to identify additional ways to reduce these filing barriers, including providing low-cost filing technical assistance.

Regulators are also likely to encounter strong resistance from vape shop operators on banning EVPs

flavors. Vape shop operators perceive their ability to sell flavored EVPs as a major component of their marketing plan to encourage consumers to use their products and a major contribution to helping smokers quit combustible cigarettes. The lack of concern about how flavored products might entice non-vaping youth may be due to a general lack of knowledge about the influence of flavored products on the uptake of combustible tobacco products. This knowledge gap likely derives from their current information sources, which were reported as mainly trade associations and word of mouth among other vape shop operators and manufacturers. Regardless of what regulation is proposed or implemented, the public health community will need to play a major role in collaborating with vape shop associations to educate vape shop operators, as well as collaborate with the vape shop industry and regulators to propose policies that ensure access to safe EVPs for adult smokers seeking to quit smoking combustible cigarettes while prohibiting access to youth who have yet to start vaping. Lessons learned from the last two decades to regulate traditional tobacco retailers may be applicable, including those limiting sales around schools and linking compliance to the retention of business retail licenses.

Our study has several limitations. This exploratory study used a convenience sample of vape store owners and operators from nine communities in the United States. It was not a representative sample of all vape shops in the United States and our findings may not be generalizable to non-sampled regions and communities. However, when selecting communities to be included in this study, we strived for diversity in geography and policy environments, as attitudes may differ from state to state based on state-specific policies. Secondly, personal differences in styles of communication and probing during the vape shop operator interviews may have influenced how much information the vape shop owners and operators were willing to share. To maintain uniformity across the eight communities and ensure data quality, all interviewers received equivalent training and instruction materials prior to conducting the interviews. To ensure the quality of data capture, all but five participants consented to audio-recording of the interviews; interviewers also made handwritten notes to capture the information shared by participants.

Despite these limitations, our study provides timely evidence on vape shop operators' attitudes about current and pending government regulations to help inform implementation of these policies. The findings from our study suggest that vape shop operators, similar to many small business owners and entrepreneurs in the United States, are more likely to rebuff regulations that may negatively affect their profits. Given the encroachment of the tobacco industry on the vaping marketplace, regulators and the public health community should acknowledge whether the ongoing viability of the independent vape shop is a mutual goal. If so, regulators need to continue to seek input from the vape shop industry about how best to proceed with implementing new timelines and contentious policies, including those associated with non-compliance penalties. The public health community should initiate communication lines with the vape shop community to position itself as the primary and supportive messenger of ongoing scientific findings about the safety of EVPs.

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Conflict of interest statement

None declared.

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