Health claims made in vape shops: an observational study and content analysis

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ABSTRACT

Background Prior to the final deeming rule, federal law in the USA prohibited electronic cigarettes (e-cigarettes) from being marketed as smoking cessation products; for other therapeutic purposes and in ways that conveyed Food and Drug Administration (FDA) approval/endorsement. After August 2016, additional federal prohibitions were added including false/misleading and unauthorised modified risk tobacco product (MRTP) claims. No systematic investigation of e-cigarette health claims has been conducted in the retail environment. We sought to document and characterise claims made in vape shops.

Methods Between November 2015 and February 2016, before final deeming rule implementation, two trained data collectors conducted unannounced observational assessments of 46 vape shops in North Carolina. Data collectors used wearable imaging technology to document health claims about e-cigarettes. Photos were coded for five claim types: (1) cessation device; (2) drug effect/device; (3) FDA-approved/endorsed; (4) false/misleading and (5) MRTP. Photos were double coded; differences between coders were adjudicated and reviewed by an expert panel.

Results At least one health claim was displayed in 41.3% (n=19) of retailers, ranging from 0 to 27 claims per retailer. All claim types were found. Cessation device claims were the most prevalent (62.2%, n=84), followed by MRTP (27.4%, n=37), drug effect/device (8.1%, n=11), false/misleading (1.5%, n=2), and FDA approved/endorsed (0.7%, n=1). Retail chains made the majority of claims compared with independent shops (88.9% vs 11.1%).

Conclusions Many vape shops displayed e-cigarette health claims, which are all now FDA prohibited. These claims could mislead consumers and influence behaviour. Findings highlight the need for retailer education, continued surveillance, enforcement specific to advertising and research on consumer perceptions of claims.

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BACKGROUND

Electronic nicotine delivery systems (herein referred to as e-cigarettes) have gained popularity since their introduction in the USA in 2007, with over 5 million adults reporting past 30-day use.[1 2] E-cigarettes have become the most commonly used tobacco product among youth.[2–4] These products, which are expected to reach $10 billion in sales by 2020,[5] are widely available in retail outlets and online.

Although now regulated by the US Food and Drug Administration (FDA), e-cigarettes were sold in the USA with little regulation for almost a decade. It was not until 2016 that the FDA issued a final deeming rule, expanding its tobacco regulatory authority to include e-cigarettes.[6] Prior to the deeming rule being finalised, the FDA had the authority to regulate e-cigarette marketing for claims that the products could be used for smoking cessation or for other therapeutic purposes, such as to improve respiratory function. These claims would classify the product as a drug or drug delivery device, requiring premarket approval from the FDA's Center for Drug Evaluation and Research (CDER) (see table 1).[6 7] Additionally, product labelling and advertisements could not indicate FDA approval or endorsement.[8] To date, no e-cigarette manufacturer or retailer has received approval to make these claims.

When the deeming rule was finalised, e-cigarettes became subject to the majority of the provisions applicable to other tobacco products, including prohibiting sales to underage persons and free sampling.[6] Two advertising and marketing restrictions were added to the existing rules to reduce consumer misperceptions about e-cigarettes. First, the final deeming rule made it illegal for the labelling or advertising of e-cigarettes to be false or misleading.[6] These unsubstantiated claims may cause consumer confusion, misleading consumers to initiate or sustain product use or dissuade them from quitting. Although false and/or misleading claims are banned through the Tobacco Control Act (TCA), the FDA did not have the authority to enforce this rule on e-cigarettes until the products were brought under its authority.[9] Since regulating e-cigarettes under deeming, the FDA has issued a number of warning letters to manufacturers for making false/misleading claims that appeal to children.[10]

Second, the final deeming rule made it illegal to market e-cigarettes as a modified risk tobacco product (MRTP)[6] without approval from the FDA's Center for Tobacco Products (CTP). MRTP claims convey that the product presents a lower risk of tobacco-related disease, is less harmful or has less of a constituent than other tobacco products.[6] This includes any use of the descriptors *light*, *mild* and *low* as well as any other 'similar descriptors'.[11–16] As of October 2018, no e-cigarette product had received approval from FDA's CTP to be marketed as a MRTP.

Table 1 Regulations for e-cigarette advertising

Health claim type	Health claim definition	Applicable Law	Date Enforceable
1.Cessation device*	The product will help an individual smoker transition away from combustible tobacco products.	FD&C Act; *Sottera Inc vs FDA* court decision; requires CDER approval	Enforceable prior to final deeming rule
2.Drug effect/ device	The product is intended (1) for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease; or (2) to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to 3/21/00.	FD&C Act; *Sottera Inc vs FDA* court decision; requires CDER approval	
3.FDA approved/ endorsed	The product and/or ingredients are approved by the FDA, endorsed by the FDA, or are safe or less harmful by virtue of regulation by FDA.	FD&C Act; Section 103 (tt)	
4.False and/or misleading	Information conveyed to the consumer is false, misleading or deceptive.	TCA; Section 902 & 903	Enforceable August 8, 2016
5.Modified risk tobacco product	The product or its smoke (1) presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (2) contains a reduced level of a substance or presents a reduced exposure to a substance or (3) does not contain or is free of a substance. (4) The label, labelling or advertising uses the descriptors 'light', 'mild' or 'low' or similar descriptors.	Final deeming rule; TCA, Section 911; requires CTP authorisation	

* The FDA may choose to apply a more narrow definition of "cessation device," as discussed in the text.
CDER, Center for Drug Evaluation and Research; CTP, Center for Tobacco Products; FDA, Food and Drug Administration; FD&C, Food, Drug & Cosmetic ; TCA, Tobacco Control Act.

Despite these regulations, illicit health claims have been documented online and in print advertisements.[17–21] However, no systematic investigation of e-cigarette health claims in the retail environment has been conducted, particularly among specialty stores like vape shops. These retailers cater to e-cigarette users and have emerged as a primary information centre for consumers to obtain e-cigarette knowledge and support.[22 23] The limited research conducted in vape shops has assessed attitudes and practices of shop owners,[23–25] consumer perceptions of shops,[26 27] and product availability.[26]

To address this gap, we conducted observational assessments of vape shops to document all health claims, defined as any marketing, advertising or promotion that conveyed e-cigarette information in an image or text. We then conducted a content analysis to classify the claims into the five claim types. Because assessments were conducted prior to the final deeming rule, two of the claim types were not prohibited for e-cigarettes at the time of data collection (false/misleading and MRTP). However, all five claim types are now prohibited by the FDA.

METHODS

Vape shop identification

Vape shops were defined as retail outlets that primarily sold e-cigarettes, other vaping devices and e-liquids. We adapted methodologies from previous studies to create a sampling frame of shops in North Carolina (NC) using ReferenceUSA[28] and web searches of the top search engines and review websites (bing.com, google.com, yahoo.com and yelp.com) using the keywords: *electronic cigarette*, *e-cig*, *vape and vapor*. Previous studies have validated the use of such databases in identifying tobacco retailers.[29–33] Duplicate shops were removed. Shops were called to determine whether they were in business and to confirm the products offered. Retailers that did not primarily sell e-cigarettes were removed (eg, head shops that sold paraphernalia for tobacco and cannabis consumption or other items related to cannabis culture such as incense, water pipes or posters). Using this methodology, we identified 228 vape shops in NC. We selected cities with at least 10 vape shops to maximise efficiency of data collection and included all vape shops within each selected city. The final sample included four cities, ranging in population from approximately 90 000 to 840 000,[34] and 54 vape shops, representing 23.7% of NC shops. Assessments were conducted between November 2015 and February 2016, prior to the final deeming rule.

Data collection procedure

Because e-cigarettes are the primary product sold in vape shops, there is ample space throughout the shop for health claims to be made to consumers. Content analysing those health claims cannot be reliably completed during real-time data collection (ie, while in the vape shop).[35] Therefore, photos of the health claims were needed for post-assessment analysis. We developed methods to unobtrusively and systematically capture all health claims made in this retail environment. Previous studies have unobtrusively collected data in traditional tobacco retailers using mobile technology to photographically document interior and exterior advertising.[36–40] Wearable imaging technology allows for health claims to be photographically documented at timed increments, making this method more efficient and less obtrusive than taking photos with tablets or mobile phones.[37] Therefore, we used a wearable imaging technology, Pivothead glasses with a built-in camera, to photographically document health claims displayed at the shops.

We developed a data collection protocol and assessment form based on previous studies.[37 39 41] Two research assistants were trained on the study protocol and use of the data collection instruments, which were piloted in two local vape shops. They visited shops together; one collected photographic data, and the other documented general information about the retailer, described below, using an electronic assessment form accessed through a mobile phone.

Prior to taking photos, data collectors confirmed 'NO PHOTOGRAPHY' signs were not displayed on the shop's exterior or interior. If signs were present, the assessment was terminated. If no sign was present, data collection proceeded. One data collector systematically scanned the shop's interior with the glasses, preset to automatically take one image/second, starting in the back of the shop and working clockwise to capture claims on walls, doors, windows and countertops. The second data collector used the electronic assessment form to note additional shop characteristics. Once the interior assessment was complete, data collectors proceeded outside and documented the exterior.

All photos were downloaded to a laptop and uploaded to a secure server at the end of each day. The Institutional Review Board at Wake Forest School of Medicine deemed the study protocol nonhuman subjects and exempt from review.

Shop characteristic measures

Using the electronic assessment form, general information about the retailer was documented including store name and address; date and time of assessment; presence of age of sale (yes/no) and age of entry signs (yes/no); shop location (strip mall/kiosk/stand-alone/other); presence of people vaping inside (yes/no) and presence of free tasting area (yes/no).

Analysis

Frequencies were calculated for the shop characteristics. The goal of the photo analysis was to identify photos that contained a health claim. Photos were subjected to a sorting protocol, followed by a content analysis.

Photo sorting

Each data collector sorted photos for half of the shops, and the first author reviewed the sorting to ensure no health claims were omitted. Every unique image of a product or text regarding e-cigarettes was included. Images of informational brochures were included. Excluded images included blurry or unreadable images, and images of vape-themed magazines, non-e-cigarette promotions and price tags. Photos that included store patrons or employees were used only if the individual(s) could be cropped out of the photo.

Coding and content analysis

After sorting, eligible photos were content analysed to document the presence of the health claims. The research team developed a codebook based on the existing literature[17] and a legal analysis to determine the relevant language and claim definitions from the TCA,[9] the Food, Drug and Cosmetic Act[8] and FDA guidance documents[42] (see table 1). After data collection had been completed, the FDA finalized a rule intended to clarify when e-cigarettes or other tobacco products are subject to regulation as cessation devices.[43] Though the language of the rule is unclear, the FDA could take the position that "cessation" claims are limited to assertions that the product can be used "in the cure or treatment of nicotine addiction." [43] For the purposes of this paper, however, we used a broad interpretation of "cessation" that refers to helping a smoker transition away from combustible tobacco products. Using the codebook, the photos were coded to reflect claim type present, if any, and whether the claim was explicit (ie, used direct language without hiding message meaning) or implicit (ie, indirectly or inferred message meaning).[44] A health claim could have more than one claim code (eg, cessation and MRTP). Prior to coding the final sample, we pilot tested the sorting protocol and codebook on data collected during the training session. The first author reviewed the coding and identified discrepancies between coders. Discrepancies were discussed and settled and the codebook was revised to reflect any changes. Next, two coders independently coded all photos from the study sample that contained a health claim (n=456). The first author reviewed the coding, identified discrepancies and led consensus meetings to resolve disagreements. Cohen's alpha, post-consensus meetings, was 0.98, reflecting high reliability.[45] Next, a panel consisting of experts (n=7) in tobacco, health communication and tobacco regulation held two meetings to review photos that were coded as including one or more claims. The panel reviewed and finalised codes. Disagreements within the expert panel were discussed and resolved by a majority vote.

Table 2 Health claims made by shop type

	Total N (%)	Retail chain shop N (%)	Independent shop N (%)
Total number of shops	46	25 (54.3%)	21 (45.7%)
Shops displaying at least one of the five claim types	19 (41.3%)	8 (32%)	11 (52.4%)
Number of health claims displayed	135	120 (88.9%)	15 (11.1%)
Range and mean number of health claims displayed	0–27	0–27;15.0	0–2;1.4

RESULTS

Of the sample of 54 vape shops, data collectors completed 46 assessments. Eight assessments were not completed due to battery failure of glasses (n=2), safety concern (n=1), incorrect address (n=3) and store was not a vape shop (n=2). Most shops (89.1%) were located in a strip mall, and about half (54.3%) of the shops were part of a retail chain (ie, >2 locations) (table 2). Signage restricting photography was not posted at any shop; age of sale and age of entry signage were posted by 41.3% (n=19) and 30.4% (n=14) of shops, respectively. Most shops offered free sampling of e-liquid flavours (89.1%, n=41); people were actively vaping in 50% (n=23) of the shops.

Health claims

During the assessments, 14,574 photographs were taken (figure 1). After the sorting procedure, 456 photos included an image or text containing a potential claim. Of the 456 photos that included an image or text, 104 photos (22.8%) were coded as having 135 health claims, representing all five claim types. Because retail chains were included in the sample, identical claims were found in multiple shops. Thus, the 104 photos reflect 47 unique claims.

Over 40% of shops displayed at least one health claim (table 2). Approximately one-third (32%) of shops that were part of retail chains displayed at least one health claim, compared with 52.4% of independent retailers. However, the majority of health claims were found in retail chain shops versus independent retailers (88.9% vs 11.1%); chains displayed, on average, more claims compared with independent retailers (15.0 claims/shop vs 1.4 claims/shop, respectively).

Cessation device claims

These FDA-prohibited claims promoted e-cigarettes as a device to help smokers quit smoking or as a substitute for combustible cigarettes and were the most prevalent claim type displayed, found in 32.6% of vape shops visited (table 3). We documented 84 (62.2%) cessation claims with 39.3% (n=33) using explicit language to convey the product was a cessation aid, marketed in testimonials and through imagery, such as a broken cigarette. Shops also encouraged customers to take selfies with a sign the shop provided, indicating how many days they had been smoke free since starting to vape (n=5) and offered gift cards promoted with the tagline, 'Give the gift of quitting' (n=1).

The majority (60.7%, n=51) of cessation claims were implicit claims that marketed e-cigarettes as *alternatives* or *substitutes* for combustible cigarettes. These claims did not explicitly indicate that e-cigarettes are cessation devices; instead, they suggested to consumers that they could quit smoking if they started vaping,

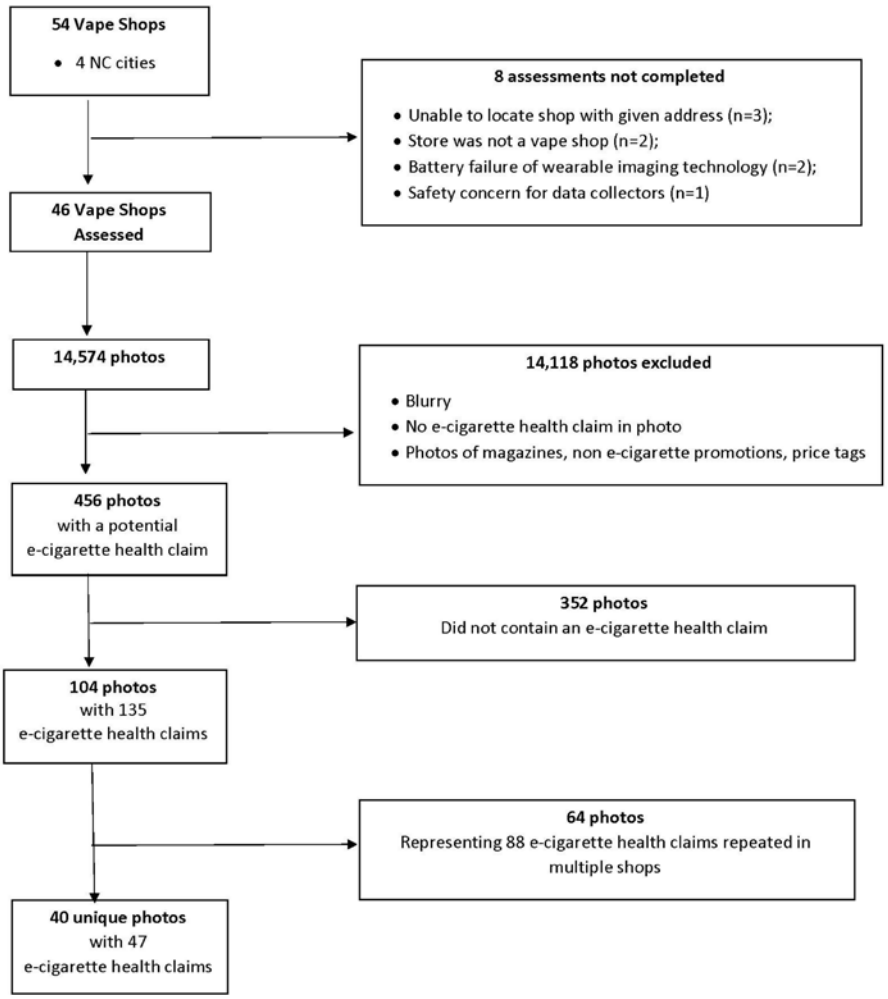

Figure 1 Diagram of Claim Identification Process. NC, North Carolina

substitute e-cigarettes for combustible cigarettes or make a switch from combustible cigarettes to e-cigarettes. Examples include, 'Quit smoking…. Start vaping!' 'Don't smoke—Vape!' and 'Goodbye cigarettes. Hello vapor'. One retail chain created a small booklet for consumers to help them 'make the switch', outlining what to expect when they stop smoking combustible cigarettes and start vaping.

Drug effect/device claims

We documented 11 FDA-prohibited claims in 13.0% (n=6) of vape shops that promoted e-cigarettes as having therapeutic purposes. Some claims promoted the products as helping to treat tobacco-related illness, typically referring to better respiratory function with phrases such as 'I breathe better'. Several of the health claims focused on how the products could affect different parts of the body. For example, one shop used a sidewalk sign to promote therapeutic purposes for its e-liquids to help one sleep or provide additional energy (bold for emphasis).

> Tired of smelling like smoke? Tired of going outside to smoke while others enjoy sitting inside?… If you answered yes … come get your alternative today!!! Over 80 flavors, **sleep aid, and energy line**. Fully stocked.

Table 3 Frequency of claim types

Claim types	Number of shops (N=46), N (%)	Number of claims, (N=135) N (%)	Number of unique claims (N=47) N (%)	Sample claim
Cessation device	15 (32.6%)	84 (62.2%)	30 (63.8%)	*Stop smoking and start vaping*.
Drug effect/device	6 (13.0%)	11 (8.1%)	4 (8.5%)	(e-juices)…*sleep aid and energy line*.
FDA approved/ endorsed	1 (2.2%)	1 (0.7%)	1 (2.1%)	…*manufactured in a FDA-registered lab*.
False and/or misleading	2 (4.3%)	2 (1.5%)	2 (4.3%)	*Relax. It's just vapor*.
Modified risk tobacco product	7 (15.2%)	37 (27.4%)	10 (21.3%)	*No Smoke. No Tar. No Problem*.
Total	**19***	**135**	**47**	

*Total for column, **Number of Shops,** is not a sum of the shops displaying each claim type. Some shops displayed more than one claim type.
FDA, Food and Drug Administration.

FDA-approved/endorsed claims

FDA-approved/endorsed claims, also prohibited by the FDA at the time of data collection, were the least prevalent among the sample of shops. Only one claim was documented that indicated the lab in which the shop's e-juices were manufactured was an 'FDA-registered lab'.

False and/or misleading claims

This claim type was not prohibited at the time of data collection for e-cigarettes but is now prohibited by the FDA. We documented two false/misleading claims, 'Relax, it's just vapor' and 'It's Vapor. You're Welcome'. These unsubstantiated claims may mislead consumers to believe the aerosol emitted by the user is only water vapour, although studies have shown there are ultra-fine particles and toxins such as acetaldehyde found in the aerosol.[46–51]

Modified risk tobacco product claims

MRTP claims were the second most common health claim type documented. These claims were not prohibited at the time of data collection but are now prohibited by the FDA. We found 37 MRTP claims (27.4%) in seven vape shops (15.2%). All of the MRTP claims we documented compared e-cigarettes with combustible cigarettes. Of the 37 claims we documented, 73.0% (n=27) claimed e-cigarettes posed less risk compared with combustible cigarettes. Promotions included testimonials of former smokers with taglines such as 'I breathe better. I smell better. I feel better' and 40.5% (n=15) made declarations about the absence of constituents, such as 'no tar', or directly asserted reduced exposure to constituents found in combustible cigarettes. Two chains displayed posters that listed the numerous chemicals found in combustible cigarettes, which represented a very long list, to the few ingredients found in e-cigarettes, such as 'vegetable glycerine, propylene glycol, flavoring and nicotine' with taglines including 'It's your choice' and 'Kick some ash!'

DISCUSSION

This study is the first to document health claims made in vape shops. Over 40% of shops made at least one health claim. All claim types were found, highlighting that retailers are making a variety of claims to consumers. At the time of data collection, 74.5% (n=35) of the unique claims documented were already prohibited by the FDA; 25.5% (n=12) became prohibited with the final deeming rule, underscoring the need for additional surveillance to determine if these claims are still displayed.

Cessation claims, prohibited at the time of data collection, were the most prevalent claim type documented and often promoted smoking cessation broadly, including quitting combustible cigarettes altogether, switching from combustible cigarettes to e-cigarettes or substituting e-cigarettes for combustible cigarettes. While 39.3% of these claims were explicit, the majority (60.7%) promoted substituting e-cigarettes for combustible cigarettes, which do not as clearly violate the law compared with the explicit claims. As noted above, the language in the final rule on regulation as cessation devices is unclear, but suggests that the FDA could take the position that cessation claims are limited to assertions that the product can be used in the "cure and treatment of nicotine addiction."[43] Such an interpretation might not include the implicit claims of substitution and alternatives that we found to be common in vape shops. These implied claims depend on how consumers interpret them. The FDA has indicated that it '…intends to closely scrutinize "smoking cessation" claims to ensure that consumers are not misled about the intended use of a product made or derived from tobacco',[43] recognising that switching from combustible cigarettes to e-cigarettes or 'substituting' products to cut back on smoking may be interpreted by consumers to mean smoking cessation. Research is needed on how consumers interpret *switching* and *substituting*, as they may imply that e-cigarettes are an approved smoking cessation device.

Vape shops are likely making these claims because their primary clientele are current or former smokers,[52] many of whom may be seeking cessation support. Vape shop employees may provide advice and support and help smokers transition to e-cigarettes, often times by sharing personal stories as to how e-cigarettes helped them quit smoking.[27 53]

MRTP claims, which were not prohibited at the time of data collection but now are prohibited, were also common, representing 27.4% of all claims. Previous research has shown these to be the most prevalent claim types online.[18] It is possible that the online marketplace is targeting different audiences, perhaps trying to influence smokers and non-tobacco users to try a reduced risk product, whereas vape shops may be more focused on attracting smokers to help them quit combustible cigarettes. In our study, no MRTP claims used the specifically prohibited language *light*, *mild* or *low*. Retailers may be avoiding these words, but using other language to evade scrutiny from the FDA while still communicating less risk to consumers such as 'It's just vapor', 'Certified organic…' and '…purity and quality…' These claims may be more difficult to detect since they do not explicitly state that e-cigarettes are safer or have less risk compared with combustible cigarettes. Instead, the language implies 'safety' and 'less harm' to consumers.

Drug effect/drug device claims represented 8.1% of the claims documented. The majority indicated the product affected the structure or function of the body in ways that are not related to the effects of nicotine that were commonly marketed for cigarettes and smokeless tobacco.[8] These claims were FDA prohibited at the time of data collection, and although less common, deserve attention since the marketing is for an intended use that classifies it as a drug or drug device, and thus requires approval from FDA's CDER.

Finally, FDA-approved/FDA-endorsed claims and false and/or misleading claims were minimal. The FDA has issued a handful of warning letters to online manufacturers and retailers for making FDA-related claims and most recently, false and misleading advertising for selling e-liquids that resemble child-friendly products, like juice boxes and candy.[10]

The FDA has noted its concern about consumer misperceptions of tobacco products, especially e-cigarettes.[54] Importantly, all of these claims are likely to influence consumer perceptions of e-cigarettes[55] and may reinforce existing misperceptions about e-cigarettes as users and non-users already perceive e-cigarettes to be effective smoking cessation aids and safe to use,[56 57] although no e-cigarette product has been approved by the FDA as a smoking cessation device or MRTP. Research is needed to determine how consumers are interpreting the prohibited claims and the impact on future use. Research specific to implicit claims is critically needed to identify words or phrases that imply meaning of safety and less harm, such as *water vapor* and *organic flavourings*, as it could aid the FDA in identifying 'similar descriptors'.

Our data suggest that enforcement efforts targeting prohibited advertising need to expand to brick and mortar retailers and could begin by focusing on retail chain vape shops. Although more independent shops displayed a claim compared with chains (52.4% vs 32%), retail chains accounted for 88.9% of the claims documented. This could be due to larger budgets for retail chains

to market to consumers compared with independent retailers. Enforcing regulations at retail chains has the potential to reduce the number of claims consumers are exposed to at that specific shop, as well as other shops that are part of the company.

In addition to enforcement efforts, retailer education about FDA marketing regulations is needed. The FDA has been proactive in creating materials to educate retailers about FDA compliance, such as webinars and guidance documents.[42] However, these materials primarily focus on age of sale laws, restricting free sampling, and the required warning labels for e-cigarettes, cigars and other covered tobacco products. Information regarding prohibited claim types is necessary to educate retailers and reduce the prevalence of prohibited claims, highlighting cessation and unauthorised MRTP claims, as they are the most common.[18] Because it appears that shops are not using the expressly prohibited language (eg, low, mild, light), clear examples of 'similar descriptors' that qualify as MRTP claims are needed to educate retailers on potentially prohibited language. It is also worth noting that retailers may not be the only source of prohibited claims. Manufacturers or other companies may also make claims, in which case the retailer may be distributing illicit materials. Identifying the claim source could impact potential policies and enforcement efforts and identify targets for interventions to reduce prohibited claims in the retail environment.

Finally, this study demonstrated the feasibility of collecting photographic data in retailers for post-assessment content analysis. Using this methodology, only 3.6% (n=2) of assessments were not completed due to equipment-related issues. This novel methodology enabled a team of experts to analyse documented claims and discuss the intricacies of claims communicated to consumers. Analysing the claim content during data collection is not practical, as it would require substantial training for data collectors to determine which claims are prohibited. Our approach enabled data to be collected efficiently, with health claim content analysed through a systematic process that included an expert team to reach a consensus on the claim's meaning.

This study has several limitations. First, it was limited to a single state. We attempted to create a census of vape shops in the state; however, our methodology may have missed some retailers. Our sampling strategy of selecting cities with at least 10 retailers may have resulted in assessing shops in urban settings, and thus limiting our generalisability.[30] Finally, the study was conducted before the deeming rule was finalised; therefore, all claim types were not prohibited at the time of data collection. However, all claims types were documented, highlighting the need for post-deeming research on claims made in retailers.

What this paper adds

What was already known on this subject?

- Electronic cigarette (e-cigarette) retailers and manufacturers have been prohibited from marketing e-cigarettes as a cessation device; for other therapeutic purposes or in a way that conveys Food and Drug Administration (FDA) approv/FDA endorsement. After the final deeming rule, e-cigarettes could also not be marketed with false and/or misleading claims, or as a modified risk tobacco product (MRTP) without prior FDA approval.
- The FDA has issued warning letters to e-cigarette retailers and manufacturers for making prohibited claims online and in print media.
- Vape shops are a growing sector of the e-cigarette retail market and their marketing to consumers has been largely ignored.

What important gaps in knowledge exist on this topic?

- The extent to which e-cigarette health claims are being made in vape shops is unknown.

What this paper adds?

- This study was the first to assess health claims made in vape shops, showing that these unique retailers are making e-cigarette health claims that are prohibited by the FDA. Cessation device claims and MRTP claims were the most common types of health claim found. Retail chain shops made the vast majority of prohibited claims.

Collaborators The following are members of the E-cigarette Claims Work Group: KGW (Wake Forest School of Medicine); MB (The Ohio State University College of Public Health and Moritz College of Law); SR (Truth Initiative, Schroeder Institute for Tobacco Research and Policy Studies); ES (Wake Forest School of Medicine); JCR (Wake Forest School of Medicine); EGK (The Ohio State University College of Public Health); DEK (University of North Carolina at Chapel Hill); JLK (Wake Forest School of Medicine); MW (Wake Forest School of Medicine); ELS (Wake Forest School of Medicine).

Contributors KGW and ELS designed the study. KGW, MB, SR, ES, JCR, MW and ELS contributed to the implementation of the study. MB performed the legal analysis. MB, EGK, DEK, SR, MW, JCR and ELS made up the expert panel for the content analysis. KW and JLK wrote the manuscript. All authors contributed to revising the manuscript.

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