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Online E-cigarette Marketing Claims: A Systematic Content and Legal Analysis

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Abstract

Objectives—Electronic nicotine delivery systems (ENDS), or e-cigarettes, are heavily marketed online. The purpose of our study was to perform a systematic identification and evaluation of claims made within ENDS retailer and manufacturer websites, and the legal status of such claims.

Methods—We employed a systematic search protocol with popular search engines using 6 terms: (1) e-cigarettes; (2) e-cigs; (3) e-juice; (4) e-liquid; (5) e-hookah; and (6) vape pen. We analyzed English-language websites where ENDS are sold for implicit and explicit health-related claims. A legal analysis determined whether such claims are permissible under the US Food and Drug Administration's regulations.

Results—The vast majority of ENDS manufacturer (N = 78) and retailer (N = 32) websites made at least one health-related claim (77% and 65%, respectively). Modified risk claims and secondhand smoke-related claims were most prevalent, with an average of 2 claims per site.

Conclusions—Health-related claims are plentiful within ENDS manufacturer and retailer websites. Results demonstrate that these sites focus on potential benefits while minimizing or eliminating information about possible harmful effects of ENDS. These claims are subject to the current regulatory authority by the FDA, and pose a risk of misinforming consumers.

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Conflict of Interest Statement

The authors of this manuscript have no conflicts of interest to declare.

Human Subjects Statement

The study protocol was reviewed by The Ohio State University Institutional Review Board and deemed as ineligible for ethical review as it involved public websites and did not involve human subjects.

Keywords

electronic cigarettes; ENDS; claims; communications; online; health

Electronic nicotine delivery systems (ENDS), also known as electronic cigarettes or e-cigarettes, are rapidly increasing in popularity in the United States (US). As ENDS sales rise approximately 25% a year, some estimates suggest that they may overtake combustible cigarette sales within the next decade.^{1, 2} Already, ENDS use among middle- and high-school students is more prevalent than cigarette use.³

Current research data suggest that these devices pose some health risks.⁴⁻⁷ When used for smoking cessation, data are inconsistent regarding whether ENDS users have comparable or lower odds of successfully quitting compared to nicotine replacement products.⁸ Given the limited research available on these products, there is ongoing debate within the public health community about the likely public health impact of ENDS and the best way to regulate them.⁹ It is clear, however, that whether the public health effects of ENDS are positive or negative depends on who uses them, how they are used, and for what purpose. Because advertising shapes how, why, and by whom the products are used, careful examination and surveillance of the promotional efforts of ENDS manufacturers and retailers is warranted.

ENDS are heavily promoted through a various online media channels, including company websites, retailer websites, and social media platforms such as YouTube and Twitter.¹⁰⁻¹² Although there are no reliable data regarding online sales, a 2014 estimate by Wells Fargo Securities revealed that online purchases accounted for more than 25% of total ENDS sales.¹⁰ Although only 12% to 28% of consumers became aware of ENDS online,¹³ previous research suggests that consumers are paying attention to and are interested in the online messages conveyed about ENDS,¹⁴ and that the unfounded health claims being made in advertisements have the potential to mislead consumers.^{15, 16}

Using 2011 data, Grana and Ling¹⁶ conducted a systematic content analysis of the English-language health communication messages on websites of ENDS manufacturers; 95% of the websites reviewed made either explicit or implicit health-related claims. Grana and Ling's paper, however, did not focus on legal distinctions between different types of claims that might influence how or whether the US Food and Drug Administration (FDA) could respond to such claims. In addition, given the rapidly evolving nature of the ENDS industry and online advertising, more current analyses are warranted for these communication messages targeted to consumers.

In May 2016, the FDA announced its final "deeming" rule, which stated that the FDA deems all products meeting the statutory definition of a "tobacco product" subject to its jurisdiction.¹⁷ "Tobacco product" is defined as "any product made or derived from tobacco that is intended for human consumption," and includes ENDS products that contain nicotine derived from tobacco.¹⁸ Under this newly deemed authority, the FDA has the authority to regulate Modified Risk Tobacco Product (MRTP) claims made by ENDS manufacturers and retailers. As we discuss below, MRTP claims are those that assert, either directly or indirectly, that a product reduces health risks or harmful exposures in comparison to other

tobacco products. Even prior to the finalized deeming rule, the FDA possessed the authority to regulate ENDS (whether or not they contain nicotine) that make unauthorized claims to assist in smoking cessation or otherwise provide therapeutic benefits.⁹

There is a need for detailed analysis and legal review of health claims being made about ENDS in online advertising. Our study aimed to identify and categorize ENDS claims relevant to the FDA's regulatory authority.

METHODS

The search protocol was designed to capture the information that ENDS users or potential users were likely to encounter in an online search. Researchers used software (disconnect.me) that prevented the use of historical data or "cookies" to ensure that the search results were anonymous, and thus, unaffected by previous searches. To identify relevant websites for analysis, we first used 3 popular search engines (Google, Yahoo, and Bing) to search for 6 search terms: (1) e-cigarettes; (2) e-cigs; (3) e-juice; (4) e-liquid; (5) e-hookah; and (6) vape pen. The 3 search engines were selected because they collectively represent more than 95% of the search engine market,¹⁹ and these 6 terms were chosen to capture the range of ENDS products on the market. Sites eligible for inclusion were those that appeared within the first 3 pages of content produced for each search term, given that the vast majority of Internet users (97.4%) will not scroll beyond the first 3 pages of an Internet search.²⁰ Preferences were set to load 6–10 entries per search.

Within this sampling frame, 2 types of websites were eligible for the study sample: ENDS manufacturers and ENDS retailers. Manufacturers were vendors that engaged in direct to consumer retailing of their own products, and retailers were those vendors who resold many different brands of products directly to consumers. Websites were included if they sold any ENDS-related components, including e-liquid or parts for ENDS. We excluded websites that did not sell products directly to consumers or websites that only provided reviews or opinions about products, such as blogs sites or news websites. Websites were excluded if the written materials were not in English, but any country of origin was eligible for inclusion in the sample.

All eligible identified websites were downloaded using Offline Explorer Pro software (http://www.metaproducts.com/mp/Offline_Explorer_Pro.htm) to archive each website in its entirety, allowing full review of all site content off-line. Data were captured during a 7-day period in December 2014.

Prior to coding the website, we (MB and NH) conducted a legal analysis to review the legal status of ENDS advertising claims identified by previous research. This included a review of: (1) the relevant language of the TCA and the Federal Food, Drug and Cosmetic Act; (2) guidance documents issued by the FDA; and (3) federal case law drawn from the Westlaw database relating to the regulation of ENDS and health-related claims.

Building on this legal review, we developed a codebook by modifying a tool used in previous research¹⁶ to focus on characteristics relevant to potential regulatory action by the FDA. We pilot-tested a modified version of the codebook on 2 websites for further

clarification and expansion of categories. Two trained coders pilot-coded 10 websites (excluded from the final sample). After ensuring clarity and understanding of the codebook by researchers, and using the captured websites, the 2 data coders independently reviewed each eligible website in its entirety to extract text relevant to a set of health-related themes (Table 1).

A 2-part review of content was conducted. Two independent coders (SH and CC) recorded all text of all relevant messaging within all pages of each website; in addition, they documented relevant video, photographic images, or other visual depictions of such claims. Consensus meetings were held to confirm that no claims were omitted between the 2 coders; inter-rater reliability²¹ of the inclusion of relevant text by the independent reviewers was deemed moderate (Cohen's kappa = 0.57); although this value is not high, it was considered to be in an acceptable range.²² In a second phase of coding, 2 researchers (EK and NH) independently reviewed each text string to categorize it into the stated themes in Table 1 (Cohen's kappa = 0.58). To increase precision and data set quality, we held a consensus meeting to resolve any coding discrepancies. Descriptive, summary statistics were calculated using SAS 9.3 (SAS Institute, Cary, NC).

RESULTS

From the 6 search terms, we identified 163 unique sites. Ineligible sites (N = 53) included vendors selling only accessories (N = 14), blog/review sites (N = 14), trial or subscription only (N = 5), wholesale only (N = 3), in-person sales only (N = 1), or websites unable to be coded due to page load errors or out-of-date links (N = 16). The final eligible study sample included a total of 110 unique websites: 78 manufacturers and 32 retailers. Table 2 shows the proportion and mean number of claims made per website, by manufacturers and retailers. Results present a brief legal analysis of the themes identified in a content analysis, followed by a summary and illustrations of the study's findings with respect to that theme. The legal analysis reports the interpretation of the relevant law by the lawyers on the research team. Although these are the researchers' best projection of how courts would interpret the law, legal predictions are better construed as plausible interpretations rather than guarantees of how the FDA would act.

Modified Risk Claims

Legal status—Under the TCA, before claiming that a regulated tobacco product is (or may be) less harmful than other tobacco products, a manufacturer or retailer must seek review and approval of the claim by the FDA.²³ Without such approval, these so-called “modified risk” claims are prohibited. When reviewing such applications, the FDA considers a variety of factors, set forth in the TCA, to determine whether the product can be marketed with a health-related claim.

More specifically, Section 911 of the TCA defines a modified risk claim as one that asserts that that product or its smoke:

“presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

“contains a reduced level of a substance or presents a reduced exposure to a substance;” or “does not contain or is free of a substance.”²³

These definitions fall into 2 general categories: (1) reduced harm/risk claims (used when evidence supports that there is a reduction in tobacco related disease); and (2) reduced exposure claims (used when longitudinal health outcome evidence is unavailable).

The reason for prior review of modified risk claims stems from tobacco industry’s history of promoting products (such as “light” and “low tar” cigarettes) as less harmful alternatives for smokers, even when it knew that these products would not, in fact, reduce tobacco-related harms.²⁴ In enacting the law, Congress referenced this history and stated that “[t]he only way to effectively protect the public health [is] to require that products [sold] for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified.”²³ Thus, modified risk claims, even if truthful statements of scientific fact, require prior review by the FDA before they can be made. This requirement for the FDA to review “modified risk” claims and ensure their accuracy has been upheld in court against free speech challenges by the tobacco industry²⁴

The TCA mandates FDA review modified risk claims, whether those claims are made explicitly or implicitly. Although the TCA does not define these terms, the general legal meaning of an explicit claim is as claim that is made outright, without hiding the meaning of the message. In contrast, implicit claims are those that are communicated “only vaguely or indirectly”²⁵ In other words, implicit claims express a message to readers without stating that message overtly.

Now that the deeming rule has been finalized, ENDS products have been “deemed” to fall under the FDA’s authority as “tobacco products.” The FDA has indicated that a prohibition on unauthorized MRTP claims will be in effect as of August 8, 2016. This means that ENDS companies that would like to market their products as healthier or safer than other forms of tobacco must first apply to the FDA, providing evidentiary support for their claims, and obtaining an authorization from the FDA before making such claims.¹⁷

Study results—As Table 2 shows, modified risk claims were highly prevalent on both manufacturer (70.5%) and retailer sites (46.9%). Several sub-themes were identified within this category, including claims that ENDS are safer than combustible cigarettes, include fewer chemicals, and reduce the risk of fire. In a further attempt to illustrate the various types of claims that TCA prohibits without prior authorization, several direct quotations from the websites are offered, along with an explanation of the characterization.

Many of the claims were stated explicitly. Specific examples of explicit reduced harm/risk claims included:

The realistic experience of smoking without the serious health issues associated with tobacco cigarettes.

(Manufacturer: Triple 7 e-cigarettes)

...you won't inhale any of the carcinogens or other harmful components found in smoking.

(Manufacturer: Blaze Depot)

Why cause more health issues with smoking a cigarette just to get the nicotine addiction when you are able to get the nicotine with our product without having to worry about more health issues when smoking a cigarette?

(Retailer: Vape It Now)

When making what would be classified as explicit reduced exposure claims, several sites referenced that ENDS had far fewer than the "4000 chemicals in cigarettes." The most commonly mentioned chemical constituent claimed to be absent from ENDS was tar.

An option for smokers to "smoke" nicotine without the fire, flame, tobacco, tar, carbon monoxide, ash, stub, smell and all the other chemicals found in traditional cigarette.

(Retailer: Ecig Best Save)

Traditional Cigarettes have over 4000 harmful chemicals that are not found in SMOOTH Disposable Electronic Cigarettes.

(Manufacturer: Smooth Cigs)

Some types of claims could be considered either implicit or explicit, depending on how they were framed. This was the case with claims relating to reductions in secondhand smoke exposure. Half of manufacturers and one-fourth of retailers made claims suggesting that ENDS reduced harm to bystanders, were less bothersome to bystanders, or could be used "anywhere" because they did not give off smoke.

To the extent these claims directly asserted a reduced exposure to chemicals or toxicants in the smoke, they would likely be interpreted as explicit reduced exposure claims.

Finally, the dangers of secondhand smoke are significantly lower with the use of electronic cigarettes. While there may still be some nicotine exposure with ecigs, studies have discovered that exposure to be much less with vapors from electronic cigarettes than with the smoke produced by conventional tobacco cigarettes.

(Manufacturer: Unlimited eCigs)

On the other hand, claims made about the well-being of bystanders or the ability to get around smoke-free laws could be considered implicit reduced risk or reduced exposure claims.

You can smoke around your family and friends and not feel bad about it.

(Retailer: Ehookah)

Many of the implicit reduced harm/risk claims demonstrate the creativity of sellers trying to avoid directly making a health-related claim. Whereas not explicitly saying that their products reduce harm or risk of disease, some companies more indirectly alluded to the use of their product as a way to reduce smoking related disease and death.

Based on the World Health Organization, every 6.3 seconds a present or previous smoker dies because of tobacco related diseases which equates about 6.1 million deaths per year. Hookah Coals Company hopes to supply smokers with a different route to traditional cigarettes with our Portable Hookah|E-Hookah Pen.

(Manufacturer: Hookah Coals)

Do you want to be Healthier, breathe easier and live a longer and happier life?

(Manufacturer: ECigarette USA)

We are dedicated to the eradication of tobacco related illness worldwide.

(Manufacturer: NJOY)

Implicit reduced exposure claims were also present. For example, “environmentally-friendly” claims, such as those referring to products being natural, organic, “green,” etc, were made by 28.2% of manufacturers and 18.8% of retailers. The term “natural” or “organic” implicitly leads the user to believe that the product presents a reduced exposure to things like chemicals or toxins. In fact, the FDA recently warned American Spirit Cigarettes that use of the word “natural” in marketing combustible cigarettes constituted an implied modified risk claim and could not be done without prior application.²⁶ Similarly, claims that a product reduces pollution is healthier for the environment can also imply that the products reduce chemicals or toxins and are safer for the person using them.

All our Vapor Flavor products are made with all natural ingredients.

(Retailer: EHookah Electronic Cigarettes Wholesale)

At Virgin Vapor we only use USDA certified organic flavorings. Our e-liquids do not contain any artificial flavorings, artificial colors, or artificial sweeteners of any kind.

(Manufacturer: Virgin Vapor)

... you can smoke E-Cig anywhere healthily without environmental pollution.

(Manufacturer: E-cig.com)

Another category of common implicit claims was those alluding to products being “cleaner.” These claims were made by 43.6% of manufacturers and 21.9% of retailers. “Cleaner” claims could be interpreted as implicit claims because they suggest that the user is protected from the chemicals or toxins in the ash or odor of combustible cigarettes.

Using advanced technology, the South Beach Smoke e-cig’s revolutionary smoking alternative allows for a smoking experience without the flame, ash, tobacco, tar, carbon monoxide, or horrible and offensive smell found in traditional cigarettes.

(Manufacturer: South Beach Smoke)

A blu™ electronic cigarette simulates the smoking experience without the tobacco smoke, ash and smell associated with traditional tobacco cigarettes.

(Manufacturer: blu Cigs)

Drug/Device Claims

Legal status—In 2010, a federal court ruled that if the FDA wanted to regulate ENDS, it would have to regulate them under its tobacco regulatory authorities (by promulgating a “deeming rule”) unless the products were marketed for “therapeutic purposes.”²⁷ ENDS marketed for therapeutic purposes are classified as drugs, medical devices, or combination drug/device products, regardless of whether or not they are derived from tobacco. Under the regulatory scheme applicable to such products, they cannot be sold without the FDA’s prior review and approval.

The FDA has issued a proposed rule intended to clarify which types of marketing claims would result in ENDS (or other products derived from tobacco) being classified as drugs, devices, or combination products.²⁸ In general terms, that proposed rule stated that any product “intended for use in smoking cessation,” or that is otherwise intended to prevent disease or “affect... any function of the body in a way that is different from effects related to nicotine,” is subject to regulation as a drug, medical device, or combination drug/device. Because the FDA has not approved any ENDS products for sale as a drug or device, any ENDS products making cessation or health-benefit claims are violating the law by marketing unapproved products. Manufacturers and retailers of these products are subject to enforcement action, including seizure and monetary penalties, by the FDA.

Notably, enforcement of this type does not depend on the FDA finalizing the deeming rule (unlike the modified risk claims discussed above); the FDA has possessed the current authority to stop the marketing of unapproved drugs, devices, and combination products. Furthermore, even though under the deeming rule the FDA is unable to regulate e-cigarette products with no nicotine (because they do not meet the definition of a “tobacco product”), no such restriction applies to the FDA’s regulation of non-nicotine products that make unapproved therapeutic claims.

Study results—There was notable variability in the presence of cessation claims, with a much higher proportion of ENDS manufacturers (43.6%) making such claims, as opposed to retailers (15.4%).

The claims varied widely in their form and specificity. Some went so far as to make specific claims about the rate of success in completely quitting smoking:

Have helped 85% of people to stop smoking

(Manufacturer: Cloud Cig)

By contrast, several websites, perhaps fearing legal liability, made cessation claims indirectly through reference to or use of customer testimonials:

Q: Can NE Where be used to quit smoking? A: NE Where is not a cessation device and should not be used as a way to quit smoking. That being said, many of our users have testified that our product has helped them in their efforts to cut down and transition out of their habitual behavior.

(Manufacturer: NE Where Electronic Cigarettes)

Some of the websites also made reference to or comparisons to nicotine replacement therapies.

Similar to the patch and gum, Hookah Sticks with Nicotine offer the nicotine the smoker craves while also imitating the motion, allowing for the smoker to fulfill their oral fixation.

(Retailer: Hookah Shisha)

Like cessation claims, claims of an affirmative health benefit are also drug/device claims that are impermissible without prior approval; in the present sample, 5.1% of ENDS manufacturers and 6.3% of retailers made such claims on their websites.

Health benefit claims were often associated with specific e-liquid blends, and included claims of increased energy, sexual enhancement, relaxation, and improved sleep.

We only stock products that align with our desire to provide maximum relaxation and therapeutic benefit. (Retailer: Vaporizer Pen Shop)

DISCUSSION

Our study confirms that websites offering ENDS for sale to consumers persist in making a wide variety of health-related claims. A majority of websites reviewed (65% of retailers and 77% of manufacturers) made at least one of the types of marketing claims discussed above on their websites.

In particular, half of retailers and 70% of manufacturers made claims that could be classified as modified risk claims under the TCA. Now that the deeming rule is finalized, these claims (as of August 2016) are prohibited without prior review and authorization by the FDA.¹⁷ Assuming that manufacturers and retailers comply with the law, this suggests that the FDA is likely to be inundated with applications for modified risk claims from ENDS companies.

This research also suggests that both manufacturers and retailers selling ENDS are aggressively moving to shape consumer perceptions of ENDS prior to the FDA's regulation of modified risk claims. In explaining why it was appropriate to require FDA review of modified risk claims before a product could be sold, a federal appellate court noted that, particularly in the context of an addictive product, "it would be virtually impossible to unring the bell of misinformation after it has been rung."²⁴ Although this study did not verify the scientific accuracy of the modified risk claims identified, it is likely that some ENDS manufacturers and retailers are making unsupported health-related claims that would not pass the evidentiary bar needed for a MRTP authorization. Based on the powerful influence of cigarette advertising on consumer behavior,²⁹ these health-related claims are likely influencing consumer perceptions and may be driving the increase in ENDS product use. Thus, it will be difficult, if not impossible, to "unring the bell" of this misinformation.

We also found that substantial proportions of ENDS manufacturer websites, and a smaller proportion of retailer websites, are currently making impermissible smoking cessation claims. It supports the assertion made in an October 2015 letter to the FDA from leading public health groups that "violations of federal law on a massive scale are taking place in the

marketing of e-cigarettes.”³⁰ Although the FDA promised to open an investigation in response to that letter,³¹ at press time for this publication no enforcement action has been taken against any ENDS company for cessation-related claims since the 2010 court ruling.

One reason for this lack of enforcement may be that the FDA only recently finalized the deeming rule. Prior to the finalization of the deeming rule and the prohibition of MRTP claims without prior authorization, an ENDS manufacturer or retailer could easily change the wording of a cessation claim to reframe it as a modified risk claim in order to skirt regulation. Now that ENDS products are deemed as tobacco products, it will be important for the FDA’s Center for Tobacco Products to work closely with the FDA’s other centers that regulate drugs and devices to ensure that the FDA acts consistently to prevent all unapproved claims. In its final deeming rule, the FDA noted that “if an ENDS products seeks to be marketed as a cessation product, the manufacturer must file an application with the FDA’s Center for Drug Evaluation and Research,” and it pointed out that, to date, no ENDS products had done so.¹⁷

Our study also suggests that the FDA may want to focus future enforcement on manufacturers, as both modified risk claims and cessation claims were more prevalent in this group. This difference in messaging between the 2 categories of sellers could be related to the need to explain the product and differentiate one manufacturer from another. In other words, manufacturers that directly sell their products to consumers need to explain the benefits of their products and make a case that their products are superior to other products on the market. Retailers, however, are selling many different brands and primarily need to compete with other retailers with regard to price.

Although our study did not specifically code for the scientific accuracy of the claims recorded, it is apparent that several of the claims being made - including both modified risk claims and cessation claims - may violate the TCAs prohibition on false and misleading claims. This is an additional requirement that the FDA is now able to enforce against newly-deemed products, including ENDS. In the finalized deeming rule, the FDA stated that “labeling and advertising [for ENDS and other newly-deemed products] cannot be false or misleading, which will help reduce consumer confusion and misperception.”¹⁷ As an example of a claim that may be “false or misleading,” some websites claim that the emissions from ENDS are “simply... water vapor” (Manufacturer: E Cigs Brand), even though numerous studies have shown that there are small amounts of concerning toxicants found in the emissions from ENDS.^{32–36} Claims that lack scientific support or those that manipulate the science to overstate a product’s benefits may mislead consumers into purchasing and using ENDS products.¹⁴

There are a number of limitations of our study. The study focused on text-based health claims, and did not consider the role of photographs or other imagery that also may imply health claims. This may account for why the frequency of claims observed in our study was somewhat lower than previous estimates.¹⁶ Our sampling strategy used several popular terms for ENDS, but may not include terms used for these devices that remain popular among specific populations. In addition, the sampling frame included only websites in English, as businesses serving American consumers, regardless of their location, remain

subject to the authority of the FDA; however, the sampling frame did not include foreign-language websites that may also be selling to US consumers. Interrater reliability for coding was modest, yet most discrepancies during each round related to variation in category assignment, not disagreement on whether text was considered a claim. Whereas reconciliation of coding differences minimized coding error, the modest inter-coder reliabilities illustrate the ambiguity in the statutory standards that the FDA is tasked with enforcing. This ambiguity will be a challenge for regulators if the FDA does seek to regulate such claims more strictly. Finally, given the rapidly changing nature of online communications and marketing campaigns, it is possible that health claims may continue to change over time. In particular, ENDS websites may change their marketing significantly enforcement of the the deeming rule begins.

At the time of data collection and coding, ENDS products were not yet subject to the FDA's authority, because the deeming rule had not been finalized. However, because the definitions and legal analysis were based on the TCA's statutory language that was extended to cover ENDS products in the final deeming rule, the analysis was not hindered and the final rule only confirmed the accuracy of the methods used.

Conclusion

Health-related claims are common on ENDS manufacturer and retailer websites. These claims may exaggerate potential benefits while playing down or ignoring information about possible harmful effects of ENDS. Now that the deeming rule has been finalized, the FDA can and should take action to ensure that inaccurate and misleading claims are discontinued. This includes addressing both unsubstantiated cessation claims and "modified risk" claims that have not gone through the required FDA review process. In this marketplace where the majority of smokers are interested in quitting, it is essential for the FDA to ensure that consumers are not misled into choosing products based on misleading or inaccurate health-related claims. In this way, enforcement by the FDA can lead to the promotion of public health and the protection of vulnerable consumers.

IMPLICATIONS FOR TOBACCO REGULATION

This research highlights the need for the FDA to develop a coordinated approach for effective and comprehensive regulation of ENDS marketing claims. Tobacco regulatory science researchers can support the FDA in such an effort by carefully tracking and categorizing ENDS marketing claims, particularly those made online. Such research and surveillance should be communicated directly to the FDA to assist the agency in identifying potential violations and in setting priorities for enforcement. The FDA should consider developing a designated e-mail address and website portal to facilitate the reporting of advertising that may violate FDA regulations (similar to the FDA's "Bad Ad Program" that encourages healthcare providers to report misleading prescription drug promotions).

In addition to enforcing the prohibition against unauthorized cessation and health benefit claims, the FDA will need to make decisions about whether health-related claims by ENDS companies are truthful and not misleading, and meet the other requirements for Modified Risk claims, including that permitting such claims would be "appropriate to promote the

public health.” Using the various types of marketing examples presented in this paper, researchers can assist the FDA by examining the veracity of ENDS marketing claims, consumer perceptions of such claims, and the impact of ENDS marketing on consumer use and use intentions. Research on consumer responses to ENDS-related marketing claims can also help to inform the FDA’s public health education efforts.

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Table 1 Claims and Definitions for ENDS Manufacturers and Retailers, Modified from Grana and Ling¹⁶

Claim	Description
Modified risk	Explicit or implicit statements about the health risk of this product in relation to other products (other ENDS or other types of tobacco products) or statements that the product contains lower amounts of or reduces levels of exposure to the user of any harmful substance. Statements that the product contains fewer harmful chemicals, has 50% less nicotine, or reduces risk of lung cancer would qualify for this claim.
Health benefit	Explicit or implicit statements that the product can be used to mitigate, cure, or prevent any disease or condition or otherwise provide some health-related benefit (other than cessation of smoking). Claims that the product improves digestion or helps with weight loss would qualify for this claim.
Smoking cessation	Explicit or implicit statements that convey the product will help a tobacco smoker quit smoking. Examples might include: Stop smoking for good, switch completely and never use tobacco again, or never smoke cigarettes again, or use the different strength cartridges to step down to no-nicotine.
Secondhand smoke exposure	Explicit or implicit statements that other people will not be harmed or have negative health consequences from being exposed to the vapor, or that the vapor is safe, that the vapor is not like secondhand smoke or ETS, that the products will not bother or annoy nonsmokers.
Products are cleaner to use than tobacco cigarettes	Explicit or implicit statements about the product being cleaner to use than tobacco products. Statements may include the following: no ash, won't stain teeth, fingers, fingernails, make their hair smell, no smoke, only vapor.
Products are environmentally friendly	Explicit or implicit statements about the product being more environmentally-friendly, eco-friendly or producing less waste (ie, cigarette butts) than smoking tobacco products. Also this might be signified by recycling signs, clean earth imagery, and lush, green outdoors images.
Other	Any other health-relevant claim to target adults or any claim to target youth not previously described.

Table 2

Frequencies of Health Claims and Mean Number of Claims Made within ENDS Manufacturer and Retailer Websites (N = 110)

Health claims	Manufacturers (N= 78)		Retailers (N = 32)	
	Percentage	Mean	Percentage	Mean
Modified risk	70.5%	2.4	46.9%	2.3
Cessation	43.6%	2.0	15.4%	1.7
Health benefit claims	5.1%	1.5	6.3%	2.0
Secondhand smoke	50.0%	1.9	25.0%	1.9
Cleaner product	43.6%	1.4	21.9%	1.9
Environmentally-friendly	28.2%	1.1	18.8%	1.0