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Presence of Nicotine Warning Statement on US Electronic Nicotine Delivery Systems (ENDS) Advertisements 6 Months Before and After the August 10, 2018 Effective Date

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Abstract

Introduction: Effective in August 10, 2018, FDA requires advertisements for electronic nicotine delivery systems (ENDS) that meet the definition of a "covered tobacco product" to feature a standard nicotine warning statement. To date, limited data exist on the presence of warning statements in ENDS advertising.

Methods: We acquired ENDS ads (n = 459) that first ran six months before (February 10, 2018–August 9, 2018) and after (August 10, 2018–February 9, 2019) the effective date. The sample included online, print, and outdoor static ads (ie, without video or animated graphics) (n = 166 before, n = 198 after), online and television video ads (n = 16 before, n = 49 after), and radio ads (n = 9 before, n = 21 after). We coded ads for the presence of the verbatim FDA warning. Ads with verbatim warnings were coded for required formatting and additional features.

Results: Overall, 28% of static (n = 46/166), 62% of video (n = 10/16), and 67% of radio (n = 6/9) ads that ran before the effective date contained the verbatim warning versus 84% (n = 167/198, p < .001), 96% (n = 47/49, p = .002), and 86% (n = 18/21, p =.329) of ads that ran after, respectively. Following the effective date, nearly all static ads placed the warning as required at the top of the ad (76% [n = 35/46] before, 97% [n = 162/167] after, p < .001), and many video ads featured the warning statement for the entire ad duration (0% [n = 0/10] before, 60% [n = 28/47]

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Declaration of Interests

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Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at https://academic.oup.com/ntr.

after, $p < .001$). Half ($n = 9/18$) of radio warnings running after the effective date were read faster than the other promotional content.

Conclusions: The presence of the nicotine warning statement on paid promotional static, video, and radio ENDS ads in this sample increased after August 10, 2018, but a notable number still lacked the warning.

Implications: Results from this study provide initial insights into the extent to which required nicotine warning statements appear in ENDS ads in the study sample across traditional (eg, magazines, television, radio) and digital (eg, online/mobile ads) advertising mediums. Following the August 10, 2018, effective date, we observed a substantial increase in the presence of the required FDA warning statement on the ENDS ads in this sample. However, a notable number of ads in the study lacked the required warning and warnings did not always include the required formatting displays.

Introduction

In 2021, one in ten (11.3%) high school students reported currently using electronic nicotine delivery systems (ENDS), or e-cigarettes.[1] While fewer adults reported current use of ENDS (4.5% of the US adults ages 18 years and older), this share doubles (9.3%) when looking at young adults ages 18–24 years.[2] Most ENDS contain nicotine, which, in addition to being addictive, can harm youth and young adult development.[3]

Warning statements inform the public about the harms of nicotine addiction associated with ENDS use.[3,4] In 2016, the US Food and Drug Administration (FDA) extended its regulatory authority to ENDS[5] and required that all ENDS packages and advertisements that meet the definition for a covered tobacco product, (ie, any tobacco product deemed under the deeming final rule to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act, but excludes any component, or part that is not made or derived from tobacco), include the following nicotine warning statement: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.” The requirement went into effect on August 10, 2018.[6] The requirement states, in part, that all ENDS print advertisements or other ads with a visual component (eg, online ads, television ads) must include the verbatim warning text under specific visual display requirements that include but are not limited to the following:

- Warnings must appear on the upper portion of the advertisement within the trim area;
- Warnings must be positioned such that the required warning statement text and other text in the advertisement have the same orientation; and,
- Warnings must be written in black text on a white background or white text on a black background and surrounded by a rectangular border that is the same color as the warning text.[6]

Audio-only ENDS advertisements (eg, radio ads) are required to include the verbatim warning text[6]

Experimental evidence suggests that FDA's current warning statement is effective at increasing ENDS-related risk perceptions among adult tobacco users and non-users[7–11] and may help prevent product initiation among young people.[8,11,12] However, other studies indicate that the nicotine-based warning may not reduce intentions to try or use ENDS among current tobacco users and other messages may be needed.[12–14] For any warning to be effective, best practices indicate that warning statements must be consistently presented and displayed in a visually distinct manner that attracts attention and can reach the broader population with information on tobacco-related risks, including addiction.[15,16]

Relatively few studies have investigated the extent to which manufacturers include any warning statements on ENDS advertising, including both federally required warnings, state-required warnings (eg, California), and voluntary, industry-designed warnings (ie. not required warnings). Data collected prior to the August 10, 2018, effective date suggest that the industry regularly integrated voluntary warning statements into ENDS packaging, and print advertising.[17–20] Many of these statements included language indicating that the product "contained nicotine," and some were identical to the current required FDA warning.[18,19]

Studies conducted following in August 2018 suggest that a small proportion of social media ENDS and e-liquid ads on Instagram and YouTube included the required nicotine warning statement. For example, one study found that 13.6% of industry-sponsored e-liquid Instagram posts following the effective date (August 2018–September 2018) contained the required nicotine warning statement[21]; while another study observed that only 4 of the 22 (18.2%) industry-sponsored ENDS YouTube videos they found posted January–June 2019 contained the FDA-required warning.[22]

The current study builds on this prior work and examines the presence of the FDA nicotine warning statement on static print or digital (eg, online/mobile) ads without video or animated graphics, and video (ie, television, online video) and radio ENDS ads during two time periods: Six months before and six months after August 10, 2018, the date when the nicotine warning statement requirement went into effect. In addition, we reviewed the visual and audio characteristics of the warning, including whether warnings included required formatting elements for the visual presentation of the warning.[6]

Methods

Data were obtained from a license with Numerator (formerly Competitrack), a market surveillance and research firm that monitors ads from over 10 000 print, mobile, online, radio, and television media outlet sources across the United States.[23] Numerator maintains its proprietary, national ad tracking universe based on several key factors including audience proportion and company spend on advertising, the feasibility of monitoring or licensing the platforms, and the US market coverage.[23] A wide range of studies have previously used Numerator to examine trends in tobacco product advertising.[24–29]

In this study, we included ads from Numerator's database in our sample if they met the following criteria: 1. ads that were English language only, 2. ads that promoted ENDS

products only, and 3. ads that first appeared or ran in the United States from February 10, 2018 to February 9, 2019. Ads that first appeared from February 10, 2018 to August 9, 2018, were considered ads that first ran during the six-month periods before the August 10, 2018, effective date; ads that first ran or appeared from August 10, 2018 to February 9, 2019, were considered ads that first ran during the six-month period after the effective date. Our total sample of 459 ads consisted of 191 ads that first ran before the effective date (n = 166 static ads, n = 16 video ads, n = 9 radio ads) and 268 ads that first ran after the effective date (n = 198 static ads, n = 49 video ads, n = 21 radio ads). Static ads included online/mobile ads without video or animated graphics (n = 108 pre, n = 112 post), print ads (eg, magazines, newspapers; n = 53 pre, n = 74 post), and outdoor ads (eg, billboards; n = 5 pre, n = 12 post). Video ads included online ads with video or animated graphics (n = 14 pre, n = 42 post) and television ads (n = 2 pre, n = 7 post). Of the 459 ads included in the sample, two ads were unclear as to whether or not they promote a product containing nicotine. These ads were retained in the sample as the inclusion or exclusion of these ads does not affect the results.

A digital copy of each ad was downloaded from Numerator. A team of four trained coders reviewed all ads and coded for the presence or absence of the verbatim FDA warning statement text: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.” Coders only captured the presence or absence of the FDA-required warning and did not code for the presence or absence of any other warning, including voluntary, industry-designed messages or any other required statement such as one required by a local or state government. All visual depictions of the FDA-required warning statement are required to appear at the top of the ad, in white text on a black background or black text on a white background, surrounded by a border the same color as the text, and written in the same orientation as other text featured in the ad. Therefore, ads with the visual warning text present were coded for these additional elements. For static and video ads, we coded for the location of the warning on the ad (top third, middle third, bottom third), the color of the warning text (white text on black background, black text on white background, something else), whether the color of the warning border was the same as the color of the warning text (yes, no, no border present), and whether the orientation of the warning text was the same as the other textual elements of the ad (yes, no).

Of interest, we categorized the timing and delivery of warnings presented in video and radio ads to characterize how manufacturers present the required warning text to consumers. Radio and video ads were coded for each time point at which the warning visually appeared (for video) or was read (for radio). Coders were instructed to divide the full duration of the ad (eg, 15 seconds) into three sections (eg, first five seconds, middle five seconds, last five seconds) and code where the warning appeared or was read (ie, during the beginning third of the ad, during the middle third of the ad, during the last third of the ad, or throughout the entire ad [for video only]). For ad durations not divisible by three into whole seconds, the extra time was added to the last third of the ad. Finally, radio ads were coded for the number of times the warning was read (numeric count), the speed at which the warning was read versus the rest of the promotional content (measured subjectively as slower speed, same speed, faster speed), and whether the voice used to read the warning was the same or different than the voice(s) used to read the promotional content. Due to the low prevalence of warning-relevant audio content in videos, video ads were not coded for any audio-related

features of the nicotine warning statement. None of the video ads included just an audio reading of the warning statement (ie, audio with no visual presentation of the warning statement), and only one video ad included both an audio reading and a visual presentation of the warning statement.

All ads were independently coded by four trained coders. Reliability between coders across variables was substantial (Krippendorff's alpha for all codes ≥ 0.80), with any discrepancies in coding resolved by a trained third-party reviewer. We used Fisher's exact tests and unpaired t-tests with unequal variance to assess differences in the presence of verbatim warning statements and warning statement features in ENDS ads that ran during the consecutive six-month periods before and after August 10, 2018, effective date. All tests of association were two-sided ($p < .05$).

Results

Table 1 presents the proportion of ENDS ads with the verbatim FDA warning statement present for ads that first ran in the six-month periods before and after August 10, 2018. Overall, the proportion of all ENDS ads in this sample with the verbatim warning statement present increased from 32.5% ($n = 62/191$ ads) before the effective date to 86.6 % ($n = 232/268$ ads) after the effective date ($p < .001$). By advertising medium, 27.7% ($n = 46/166$ ads) of static ads that ran during the six-month period before the effective date included the warning statement compared to 84.3% ($n = 167/198$ ads) after ($p < .001$), and the proportion of video ads with the warning statement present increased from 62.5% ($n = 10/16$ ads) before the effective date to 95.9% ($n = 47/49$ ad) after the effective date ($p = .002$). There was little evidence of an increase in the proportion of radio ads containing the warning statement before versus after the warning statement requirement went into effect (66.7% [$n = 6/9$ ads] versus 85.7% [$n = 18/21$ ads], $p = .329$).

Table 2 displays features of verbatim FDA nicotine warning statements on ENDS ads before and after the effective date, by advertising medium. The proportion of static ads with the warning statement located at the top of the ad per the FDA requirement increased from 76.1% ($n = 35/46$ ads) before the effective date to 97.0% ($n = 162/167$ ads) after the effective date, while the proportion of static ads with a warning located at the bottom of the ad decreased after the required warning statement went into effect (23.9% [$n = 11/46$ ads] before versus 3.0% [$n = 5/167$ ads] after, $p < .001$). Throughout the entire study period, most static ads with a warning statement displayed the warning per the FDA requirement as black text on a white background or white text on a black background (89.1% [$n = 41/46$ ads] before versus 100% [$n = 167/167$ ads] after, $p < .001$) surrounded by a border of the same color as the warning text (84.8% [$n = 39/46$ ads] before versus 94.6% [$n = 158/167$ ads] after, $p = .083$). All static ads with a warning present before and after the effective date displayed the warning text in the same orientation as other text in the ad as required.

The proportion of video ads that displayed the warning at the top of the ad as required by the FDA was 0.0% ($n = 0/10$ ads) before versus 57.4% ($n = 27/47$ ads) after the effective date. At the same time, (Table 2), the proportion of video ads with the warning statement located at the bottom of the screen declined from 100.0% ($n = 10/10$ ads) before the effective date to

4.3% (n = 2/47 ads) after. Similarly, the proportion of video ads that displayed the warning as a full screen image increased from 0.0% (n = 0/10 ads) before the effective date to 38.3% (n = 18/47 ads) after the effective date (p < .001). Overall, 20.0% (n = 2/10 ads) of video ads that ran before the effective date presented the warning in the required black/white text and background combination and 10.0% (n = 1/10 ads) included a border of the same color as the warning text. All video ads with a warning that ran after the effective date displayed the warning statement with the required text, background, and border color (all p's < .001). The proportion of video ads that visually displayed the warning during the beginning third of the ad remained the same both before (40.0% [n = 4/10 ads]) and after (40.4% [n = 19/47 ads], p = 1.000) the effective date, while the proportion of video ads where the warning visually appeared during the middle or last third decreased following the effective date (all p's <.001). The proportion of video ads that visually displayed the warning statement throughout the entire ad increased from 0.0% (n = 0/10) before to 59.6% (n = 28/47 ads) after (p = .001). Only one video ad in this sample included an audio reading of the warning statement along with the visual presentation of the warning

Among radio ads with a warning present (Table 2), warnings were almost exclusively read during the last third of the radio advertisement for both time periods. In addition, 100.0% (n = 6/6 ads) of radio ads that ran before the effective date featured warnings that were read at a faster speed than the rest of the ad content versus 50.0% (n = 8/16 ads) of radio ads that ran after the effective date (p = .052). Finally, there was little evidence of an increase in the proportion of radio ads that used the same narrator's voice to read the warning statement and the promotional ad content before and after the nicotine warning statement requirement went into effect (50.0% [n = 3/6 ads] versus 77.8% [n = 14/18 ads], p = .307).

Discussion

Results from this study provide initial insights into the extent to which required warning statements appear in ENDS ads across traditional (eg, magazines, television, radio) and digital (eg, online/mobile ads) advertising mediums before and after the effective date. Overall, we observed a substantial increase in the presence of the required FDA warning statement in advertisements following August 10, 2018, when the warning statement requirement on ENDS ads went into effect. The proportion of ENDS ads in our sample with the required warning more than doubled from 32.5% of ads six months before the effective date to 86.6% of ads six months after the effective date. However, 13.4% of ENDS ads in our sample that first appeared or ran following the effective date did not contain the required warning.

Our study results align with prior studies documenting voluntary action by the industry to incorporate the verbatim FDA warning statement into ENDS marketing prior to the effective date.[18,19] Notably, our estimates of the proportion of ENDS ads with a required warning statement following the effective date are much higher than previous estimates, including two studies that found that less than 20.0% of industry-sponsored ENDS or e-liquid social media ads contained required warning statements following August 10, 2018.[21,22] Although our study sample did not include industry-sponsored social media ads, preventing direct comparison with other studies, our results can offer an initial insight into possible variation

regarding the extent to which manufacturers include warning statements on traditional and digital advertising versus social media advertising.

Findings from this study offer new insight into the visual features of warning statements present on ENDS ads. While all ads in our sample with a warning statement included the verbatim warning text, some static and video ads did not adhere to FDA's specific formatting requirements (eg, a warning was located at bottom of the ad instead of the top of the ad). While one-third (38.3% [n = 18/47 ads], data not shown) of video ads that ran after August 10, 2018, displayed the warning statement at the top of the ad as required and throughout the entire duration of the video, another one-third displayed the warning only once as a full screen image. The placement or location of a warning statement on an advertisement affects how much visual attention consumer's pay to the warning and their ability to recall message content.[30–33] It is possible that attention and recall would be different for a fullscreen image versus a smaller image located at the top of the video advertisement.[15]

Additionally, our study documents audio features of radio ad warning statements, including the time point and speed at which audio warning statements were read. Nearly all radio ad warning statements in this study were read only once at the end of the radio ad, either at the same speed (0% before, 50% after the effective date) or at a faster speed (100% before, 50% after the effective date) than the promotional ad content; most radio ads that ran after the effective date used the same narrator's voice to read the warning statement and promotional content. Similar to visual presentation, audio presentation of the warning could impact consumer attention to and recall of the warning content. Limited tobacco control research on audio warnings in advertising is available; however, research on pharmaceutical industry advertising suggests that audio warnings should be set apart and distinct from the rest of the advertising content and read at the same speed to ensure optimal recall and consumer learning.[34] FDA previously released draft guidance for industry on presenting risk information in prescription drug and medical device promotion,[35] which can provide insights into how to improve attention to and comprehension of warning statements included in radio and other forms of non–print advertising. It is important to note that draft guidance is non–binding and only reflects the FDA's current thinking on a topic when the guidance is finalized.

Although this study provides unique insights into the presence of verbatim FDA-required warning statements on ENDS ads, our results are subject to several limitations. First, our study was designed to only capture the presence or absence of the verbatim FDA-required warning and we do not provide estimates of the extent to which other warnings were present in ads, including voluntary industry warnings noted by previous content analyzes of ENDS advertising.[17–19] Second, our sample is limited to the English language ENDS ads available from Numerator and may not reflect all ENDS ads that first ran in the United States during the study time period, particularly ads on social media. Third, we only examined the presence and features of warning statements on ENDS ads that first ran during the consecutive six-month periods before and after the effective date and it is possible that the presence of warnings changed over a longer period. Finally, our coding did not capture all

required formatting elements of warning statements, such as font type and text size or the area covered by the warning statement (eg, top occupies at least 20% of the ad).

Results from this study suggest that the presence of required ENDS advertising warnings on paid promotional static, video, and radio ENDS ads in this sample increased after August 10, 2018, when the warning statement requirement went into effect. However, a notable number of ENDS ads were still missing the required warning and the presentation of visual warnings on video ads did not always adhere to the required formatting displays.

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Data Availability

The data underlying this article were provided by Numerator under license. Data are unable to be shared.

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Table 1.

Proportion of ENDS Ads With the Verbatim US Food and Drug Administration (FDA) Nicotine Warning Statement Present That First Ran Either During the Six-Month Period Before or After August 10, 2018,[a] by Medium.

	Before effective date (February 10, 2018–August 9, 2018)		after effective date (August 10, 2018–February 9, 2019)		*p*-value
	Total *n*	***n* (%) Verbatim FDA warning present**	**Total *n***	***n* (%) Verbatim FDA warning present**	
All ads	**191**	**62 (32.5)**	**268**	**232 (86.6)**	**< .001**
Static ads only[b]	166	46 (27.7)	198	167 (84.3)	< .001
Video ads only[c]	16	10 (62.5)	49	47 (95.9)	.002
Radio ads only	9	6 (66.7)	21	18 (85.7)	.329

Notes: ENDS = Electronic nicotine delivery systems; *p*-values significant at the 0.05 level and derived from Fisher's exact tests to account for small cell size.

[a]Date at which the nicotine warning statement requirement for ENDS ads went into effect.

[b]Static ads included non-video online/mobile, print (eg, magazines, newspapers), and outdoor (eg, billboards) ads.

[c]Video ads included online/mobile video advertisement, online/mobile ads that contained animated graphics (eg, GIFs), and television commercials.

Table 2.

Features of verbatim US Food and Drug Administration (FDA) Nicotine Warning Statement Present on ENDS Ads That First Ran Either During the Six-Month Period Before or After August 10, 2018,[a] by medium.

	Static ads Only[b]			Video Ads Only[c]			Radio Ads Only		*p*-value
	Before (*n* = 166ads)	After (*n* = 198 ads)		Before (*n* = 16 ads)	After (*n* = 49 ads)		Before (*n* = 9 ads)	After (*n* = 21 ads)	
	n (%)	*n* (%)	*p*-value	*n* (%)	*n* (%)	*p*-value	*n* (%)	*n* (%)	
Ads with verbatim FDA warning present	**46 (27.7)**	**167 (84.3)**		**10 (62.5)**	**47 (95.9)**		**6 (66.7)**	**18 (85.7)**	
Warning features[d]									
Location of warning									
Top third of ad[e]	35 (76.1)	162 (97.0)	< .001	0 (0.0)	27 (57.4)	< .001	-	-	-
Middle third of ad	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		-	-	
Bottom third of ad	11 (23.9)	5 (3.0)		10 (100.0)	2 (4.3)		-	-	
Full screen	-	-		0 (0.0)	18 (38.3)		-	-	
Text and background of warning									
White text on black background	7 (15.2)	64 (38.3)	< .001	0 (0.0)	27 (57.5)	< .001	-	-	-
Black text on white background	34 (73.9)	103 (61.7)		2 (20.0)	20 (42.5)		-	-	
Something else	5 (10.9)	0 (0.0)		8 (80.0)	0 (0.0)		-	-	
Border same color as warning text									
Yes	39 (84.8)	158 (94.6)	.083	1 (10.0)	47 (100.0)	< .001	-	-	-
No	1 (2.2)	1 (0.6)		0 (0.0)	0 (0.0)		-	-	
No border present	6 (13.0)	8 (4.8)		9 (90.0)	0 (0.0)		-	-	
Warning text in same orientation as ad text									
Yes	46 (100.0)	167(100.0)	-	10 (100.0)	47 (100.0)	-	-	-	-
No	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		-	-	
Timing: visual appearance of video warning									
Beginning third of video	-	-	-	4 (40.0)	19 (40.4)	1.000	-	-	
Middle third of video	-	-	-	8 (80.0)	1 (2.1)	< .001	-	-	
Last third of video	-	-	-	8 (80.0)	0 (0.0)	< .001	-	-	
Throughout entire video	-	-	-	0 (0.0)	28 (59.6)	.001	-	-	-
Timing: read audio warning [f]									

	Static ads Only[b]			Video Ads Only[c]			Radio Ads Only		*p*-value
	Before (*n* = 166ads)	After (*n* = 198 ads)		Before (*n* = 16 ads)	After (*n* = 49 ads)		Before (*n* = 9 ads)	After (*n* = 21 ads)	
	n (%)	*n* (%)	*p*-value	*n* (%)	*n* (%)	*p*-value	*n* (%)	*n* (%)	
Beginning third of radio spot	-	-	-	-	-	-	0 (0.0)	0 (0.0)	-
Middle third of radio spot	-	-	-	-	-	-	0 (0.0)	1 (5.6)	1.000
Last third of radio spot	-	-	-	-	-	-	6 (100.0)	18 (100.0)	-
No. times warning read [mean (std.)]	-	-	-	-	-	-	[1.0(0)]	[1.05 (0.23)]	.331
Relative speed at which audio warning read [f]									
Slower speed than rest of ad	-	-	-	-	-	-	0 (0.0)	0 (0.0)	-
Same speed as rest of ad	-	-	-	-	-	-	0 (0.0)	9 (50.0)	.052
Faster speed than rest of ad	-	-	-	-	-	-	6 (100.0)	9 (50.0)	.052
Voice of narrator reading audio warning									
Same as voice used for rest of ad	-	-	-	-	-	-	3 (50.0)	14 (77.8)	.307
Different than voice used for rest of ad	-	-		-	-		3 (50.0)	4 (22.2)	

Note: ENDS = Electronic nicotine delivery systems; *p*-values significant at 0.05 level and derived from unpaired t-test with unequal variance for continuous variables or Fisher's exact tests for proportions, which account for small cell size.

[a]Date at which the nicotine warning statement requirement for ENDS ads went into effect.

[b]Static ads included non-video online/mobile, print (eg, magazines, newspapers), and outdoor (eg, billboards) ads.

[c]Video ads included online/mobile video advertisement, online/mobile ads that contained animated graphics (eg, GIFs), and television commercials. Only the appearance and timing of visual elements of the nicotine warning statements were coded for video ads.

[d]Proportions for warning feature categories are calculated using the number of ads with the nicotine warning statement present per each medium as the denominator.

[e]Based on the required FDA formatting, "must appear in the upper portion of the area of the advertisement within the trim area… " and "occupy at least 20 percent of the area of the advertisement.".

[f]Non–exclusive response categories to account for multiple occurrences of a nicotine warning statement in a video or a radio ad.