

Original investigation

# Warning Statements and Safety Practices Among Manufacturers and Distributors of Electronic Cigarette Liquids in the United States

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## Abstract

**Introduction:** Prior to the US Food and Drug Administration's (FDA) regulation of electronic cigarettes and warning statements related to nicotine addiction, there was no critical examination of manufacturer/distributor voluntary practices that could potentially inform FDA actions aimed to protect consumers. This study examined the content of warning statements and safety characteristics of electronic cigarette liquid bottles using a national sample.

**Methods:** Research staff randomly selected four electronic cigarette liquid manufacturers/distributors from four US geographic regions. Staff documented the characteristics of product packaging and content of warning statements on 147 electronic cigarette liquids (0–30 mg/ml of nicotine) purchased online from 16 manufacturers/distributors in April of 2016.

**Results:** Data showed that 97.9% of the electronic cigarette liquid bottles included a warning statement, most of which focused on nicotine exposure rather than health. Only 22.4% of bottles used a warning

statement that indicated the product “contained nicotine.” Of bottles that advertised a nicotine-based concentration of 12 mg/ml, 26% had a warning statements stated that the product “contains nicotine.” None of the statements that indicated that the product “contained nicotine” stated that nicotine was “addictive.” All bottles had a safety cap and 12% were in plastic shrink-wrap. Fifty-six percent of the websites had a minimum age requirement barrier that prevented under-aged persons from entering.

**Conclusions:** Most manufacturers/distributors printed a warning statement on electronic cigarette liquid bottles, but avoided warning consumers about the presence and the addictiveness of nicotine. Studies are needed to examine manufacturer/distributor modifications to product packaging and how packaging affects consumer behaviors.

**Implications:** These data can inform future FDA requirements related to the packaging and advertising of e-cigarette liquids; regulation related to the content of warning statements, including exposure warning statements, which are not currently mandated; and requirements on websites or language on packaging to help manufacturers adhere to the minimum age of purchase regulation. The data can also be used to help FDA develop additional guidance on the framing of statements on packaging that helps consumers make informed decisions about purchasing the product or protecting young people from use or unintentional exposure to the product.

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## Introduction

The regulation of tobacco product packaging and labeling can be critical to protecting the public from the harms of tobacco. Health warnings on cigarettes packaging and labeling were first governed by the United States Federal Cigarette Labeling and Advertising Act of 1965, which required warnings on packaging only.<sup>1</sup> Multiple iterations of this Act have been passed and informed by industry practices. The Act later required manufacturers, packagers, and importers of cigarettes to place statutorily-prescribed health warning statements on cigarette packages and in advertisements as approved by the Federal Trade Commission (FTC). Other amendments to the Act evolved as well and in 1984, the Comprehensive Smoking Education Act required that the phrase, “Surgeon General’s Warning,” followed by a specific warning (ie, cigarette smoke contains carbon monoxide), be placed on cigarette packaging and in print advertisements.<sup>2</sup>

Groundbreaking legislation, the US Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA),<sup>3</sup> led to the transfer of the responsibility of regulating cigarette warnings and product advertisement and labeling to the Department of Health and Humans Services. The FSPTCA gave the US Food and Drug Administration (FDA) the authority to regulate the manufacturing, distribution, and marketing of tobacco products including product labeling and packaging.<sup>3</sup> On May 10, 2016, the FDA announced that it would extend its authority to regulate electronic cigarettes (e-cigarettes), cigars, hookah, pipes, dissolvables, and any future tobacco products that meet the definition of a covered tobacco product.<sup>4</sup> The 2016 regulation provides the FDA the same minimum authority as specified in the FSPTCA. The 2016 FDA deeming of e-cigarettes and other products specified regulation related to health warning statements, packaging, descriptors, risk claims, and other aspects of labeling that may influence consumer perceptions and use behaviors.<sup>4</sup> The FDA suggested that new health warning statements and the 18 years of age minimum purchase requirements are important steps for addressing the increasing use of e-cigarette among young people.<sup>4</sup>

The packaging and labeling associated with e-cigarettes may be more complex than cigarettes. E-cigarettes are a class of battery-powered devices that can be used to aerosolize liquid when heated, which is inhaled by consumers. Many models of e-cigarettes exist within the product class and they contain numerous variations of

parts and components (eg, flavored e-cigarette liquids, vials, batteries) regulated by the FDA.<sup>4</sup> E-cigarette liquids often contain nicotine, water, glycerin, propylene glycol, flavorants, and other additives and constituents. E-cigarette liquids can be purchased by the gallon or in eye-drop size or larger bottles from the Internet or retail stores.

The FDA’s final deeming of e-cigarettes requires that health warning statements be placed on all product packages and advertisements.<sup>4</sup> E-cigarette manufacturers must use at least 12-point font size print. Health warning statements must be conspicuous and legible on the bottle or on the carton, outer container, wrapper, or tag if the product package is too small to accommodate the warning statement.<sup>4</sup> The 2016 FDA ruling stated that the FDA is revising the health warning statement requirements for product packaging and advertisements to state: “WARNING: this product contains nicotine. Nicotine is an addictive chemical.”<sup>4</sup> In addition, FDA stated that if the manufacturer submits certification that the product is not made or derived from tobacco, then the product would not be required to bear an alternative statement. However, if the product is made or derived from tobacco, but does not contain nicotine, then FDA has stated that the product must bear an alternative statement which is being revised by the FDA (“this product is made from tobacco”).<sup>4</sup> Such requirements will take place 24 months after the publication of the final rule on August 8, 2016.<sup>4</sup> Neither nicotine or e-cigarette product exposure warning statements were included in the new regulation,<sup>4</sup> leaving a critical gap in mandatory messages that would protect children and adults from dermal and oral exposures.

Little is known about e-cigarette manufacturer voluntarily practices related to health or exposure warning statements, packaging, and minimum age of purchase practices. One recent study that collected data prior to FDA’s deeming of e-cigarettes found that 63.8% of the products had some health warning statement.<sup>5</sup> Packaging e-cigarette liquids in plastic bottles may pose more safety concerns than glass bottles since these materials could potentially alter the tobacco’s constituents or characteristics.<sup>4</sup> Information on the type of packaging could inform future regulation regarding product packaging. Further, although the Child Nicotine Poisoning Prevention Act (CNPPA) of 2015 requires child-resistant packaging of nicotine liquids,<sup>6</sup> the CNPPA is limited to nicotine, and the effects of this policy, which was implemented prior to the FDA deeming of e-cigarettes, are not clear.

Thus, the purpose of this study was to examine the content of warning statements and safety characteristics of flavored e-cigarette liquids using a national sample of brands produced and sold by manufacturers/distributors on the Internet in the United States. The data from this study are significant for several reasons. First, the FDA has stated that the required warnings are a foundational rule and they are concerned about the health risk and hazards related to nicotine exposure warnings and use of child-proof packaging. The FDA received prior comments suggesting that e-cigarette warning labels should contain content about the toxicity to the user, dangers to the skin and eyes, and keeping out of reach of children.<sup>4</sup> However, the FDA has not developed regulation to include such warnings submitted by industry and the public health community. The data from this study can provide valuable information on exposure warning statements that could be tested for their efficacy on user and nonuser safety practices in future studies. No exposure warning statements are currently covered under the new deeming rule. Second, voluntary messages developed by e-cigarette manufacturers (eg, keep away from children) are similar to messages developed by the American Association for Poison Control Centers' (eg, keep e-cigarettes and liquid nicotine locked up and out of the reach of children) prior to FDA's deeming rule.<sup>6</sup> However, no studies have tested their efficacy even though the public is exposed to these statements. While it is not clear that the warning statements on the e-cigarette bottles had an impact on the declines in reported cases of nicotine poisonings in the United States in the past 2 years,<sup>6</sup> it is possible that the "messages" themselves were effective. Existing statements developed by e-cigarette industry on the known dangers of e-cigarettes may be helpful for future studies that test the efficacy of the messages and media channels on consumer behaviors. Third, these data, which were collected prior to the FDA deeming of e-cigarettes, can be used by the FDA to determine if existing statements should remain voluntary, mandated, or even prohibited. Manufacturers can still put whatever they like on e-cigarette bottles as long they are compliant with what FDA requires. At this time, there is no evidence to suggest that the messages on the packages are inadequate. Increasing our understanding of existing manufacturer/distributor safety practices, the content of warning statements, and aspects of their practices that go beyond the new FDA 2016 regulations will help optimize future product packaging regulations needed to protect the public's health.

## Methods

No national database of vape shops existed prior to the FDA deeming of e-cigarettes since companies were not required to register with any entity. Therefore, two sources were used to collect data on vape shops in the United States: Yelp.com<sup>7</sup> and the World Vapor Expo Exhibitor lists.<sup>8</sup> Yelp is a search engine used to help people find businesses in their community, events, or communicate with other Yelpers. By the end of the first quarter of 2016, Yelp had a monthly average of 21 million unique visitors, 69 million unique mobile phone visitors, and more than a total of 102 million reviews.<sup>7</sup> We used the search term "vape shop" and typed in each state or US territory into the location dialogue box in Yelp.com. "Vape shop" was the term that produced the most results as compared to "electronic cigarettes" or "tobacco shop." We selected three retail shops with the highest number of reviews in each state. To complement Yelp, we documented all the vape shops that were listed on the World Vapor Expo Exhibitor lists from 2014 and 2015 since we expected that vape shops that were popular or have large

retail sales would likely participate in this expo.<sup>8</sup> We reviewed the website for each vape shop and recorded the name, email address, company location, retail stores (yes/no), number of locations, number of country locations, wholesale distributions (yes/no), sell own brand of e-cigarette liquids (yes/no), sell other e-cigarette components (yes/no), franchise capacity (yes/no), Internet sales (yes/no), and contact phone and address. Vape shops were included in the sampling frame if they sold e-cigarette liquid through the Internet, sold their own e-cigarette liquid brand, had at least one retail store, and had a contact phone and address visible on the website. We included the vape shop retail location because based on our experience, these shops are likely to sell their own brand, allow users to experiment, and mix different combinations of their own brand of e-cigarette liquids. We used our inclusion criteria to validate the legitimacy of the vape shops. Our inclusion criteria also helped us to understand the distribution capacity of the shops online and in retail stores and monitor these changes over time as policy changes. Our sampling frame yielded a total of 285 unique shops. From qualifying stores on our list, using an online computer based program, we randomly sampled 4 stores (manufacturers/distributors) per US Census geographic region: West/Pacific, Northeast, Midwest, and South in April of 2016.

For each manufacturer/distributor that sold its own flavored e-cigarette liquid brand, we selected a tobacco, menthol and apple flavor for our larger study that examined constituents in each sample. Apple flavor was selected as the sweet/fruity flavor because it is ranked as the top fruit choice in the United States that is consumed in all four possible forms: fresh, frozen, canned, dried, or as a juice.<sup>9</sup> We included tobacco and menthol flavors because they are likely popular flavors in e-cigarettes as they are in cigarettes. For each flavor, we selected a 0, 12, and 24 mg/ml concentration of nicotine. If a 12 or 24 mg/ml concentration of nicotine was not available, we ordered the next closest concentration. All samples were ordered in April of 2016 via US mail and were received within 3–7 days. No age verification was required to receive the package. Some stores called to verify the orders because samples were being mailed to Hawaii and because sales representatives wanted to make sure that we intended to order different levels of nicotine concentration. We received three free flavored e-cigarette liquid bottles (0, 12, 24 mg/ml) from one manufacturer/distributor as a gratuity for spending a certain amount of money. Free samples are prohibited under the 2016 deeming of e-cigarettes.<sup>4</sup> Upon receipt of the samples, staff documented the characteristics of the shipping packaging, the packaging of the flavored e-cigarette liquid bottles, and the content of the information on each e-cigarette liquid bottle ( $n = 147$ ). Samples were stored in a dry, cool, and dark location.

After the information on each e-cigarette liquid was entered into a database, a third staff member verified the information entered by two research staff. Three independent observers coded the warning statements based on information relevant to the FDA's current and future covered tobacco regulation. Research staff documented the type of bottle (glass or plastic); packaging/container outside of the bottle including shrink plastic wrap; and presence of a "safety" cap. The type of bottle could potentially influence the degradation of the product and release of certain chemicals when exposed to heat or light. Staff documented the existence of warning statements and content of statements related to nicotine and other constituents; minimum age of purchase; and reproductive or other health harms. We report the frequency of safety practices and type of warning statement as part of our results.

## Results

### Characteristics of E-cigarette Liquid Manufacturers/Distributors

Supplementary Table 1 shows general characteristics of vape shop manufacturers/distributors of e-cigarette liquids included in the sample for each geographic region. The number of retail stores ranged from 1 to 17. Only one store included a retail store in another country (Hong Kong, China). Of the 16 manufacturers/distributors, 37.5% offered a wholesale option, 25% offered franchise opportunities, and 81% sold components, parts, or e-cigarette accessories on their website.

### Safety and Warning Characteristics of Flavored E-cigarette Liquids

Table 1 shows the safety characteristics and health and exposure warning statements on e-cigarette liquids manufactured/distributed by vape shops. Data show that 93.8% of flavored e-cigarette liquids were in plastic bottles, 12% were shrink wrapped, and 100% used a “safety” cap. Each of these characteristics are of interest to the FDA with regard to future regulation of product packaging to protect children from opening the bottles, ingesting the fluid or becoming dermally exposed. Nearly all flavored e-cigarette liquid bottles (97.9%) contained a warning statement, but only 33.3% used the word “Warning” on the product labels (“Warning: may contain nicotine. Keep away from children and pets”). None of the font sizes on the e-cigarette liquid warning statements was at least 12-point font and statements were difficult to read.

Twenty-two percent of the samples indicated that the product contained nicotine and 31.2% stated that the product “may contain nicotine” even when the product contained nicotine. A few of the flavored e-cigarette liquid bottles contained information about the harms of nicotine exposure. About 12.1% of bottle labels indicated that nicotine was toxic or poisonous (“Warning: nicotine is poisonous. Keep out of reach of children and pets. If swallowed, seek medical help immediately”); 0% stated that that nicotine was addictive (excluding products that said the product may contain nicotine); and 6.1% of the bottles indicated that nicotine was “habit forming”. Statements related to avoiding dermal contact or ingesting the e-cigarette liquid were not specific to nicotine but the entire e-cigarette liquid. Most prevalent were statements that cautioned consumers to keep the product away from children and pets (87.7% and 69.3%, respectively). Some e-cigarette liquid warnings included statements from the state of California law that indicated that e-cigarettes cause reproductive harm (“Contains nicotine, a chemical known to the state of California to cause birth defects or other reproductive harm. Please keep out of reach of children and pets. For use by 18 and over only”).

Statements related to the sales of the product to persons under or over aged 18 were positively and negatively framed. Although more than half of e-cigarette liquid bottles had some information related to the sales of the product to persons under or over aged 18, 28.8% stated that the product was intended for use by persons aged 18 and over (positively framed), and 25.1% stated that no sales to minors or persons under aged 18 were allowed (negatively framed). Only 56.3% of the websites used a “screener” to reduce the number of persons under aged 18 from entering the Internet sales site. To enter the website, some websites asked for user birth dates while others allowed the user to check a box indicating that he/she is (1) age 18 and over or (2) under age 18. Upon purchase, no age verification information was required on any of the websites.

### Warning Statements on Nicotine Content and Addictiveness by Nicotine Concentration and Flavor

Table 2 shows the percentage of flavor e-cigarettes that stated that they “may contain nicotine,” “contains nicotine,” or stated that they “may contain nicotine, which is both toxic and addictive” by nicotine concentration. Most of the 0 mg/ml nicotine concentration e-cigarette liquids stated that they “may contain” or “contain nicotine.” Zero percent of the 11 mg/ml samples, 26% of the 12 mg/ml, 57% of the 18 mg/ml, and 0% of the 25 or 30 mg/ml samples stated that they “contain nicotine.” Notably, 31.2% of the 24 mg/ml samples stated that “may contain nicotine,” whereas 9.4% stated that they “contain nicotine.”

Table 2 also shows the percentage of menthol, tobacco, and apple flavor for each warning statement. Warning statements were largely a reflection of the manufacturer and not the flavor.

## Discussion

Our investigation of the safety practices and warning statements of e-cigarette liquid manufacturers and distributors showed that many companies implemented voluntary practices related to health and exposure warning statements and safety practices, some of which are covered by FSPTCA<sup>3</sup> and the CNPPA of 2015,<sup>6</sup> and others which are not. Manufacturers and distributors will need to modify their product packaging and health warning statements to comply with the FDA, but they are not precluded from including exposure warning statements on their product packaging and labeling. The FDA has yet to rule on warnings other than health warnings and studies have not investigated the effectiveness of mandated or un-mandated warning statements on consumer awareness of the risk and behavioral intentions.

Results showed that product packaging was confined to individual flavored e-cigarette liquid bottles, which presents challenges regarding the recognition, legibility and comprehension of warning statements presented on eye-drop size bottles. The FDA stated that the warning statement must be at least 12-point font.<sup>4</sup> The FDA also indicated that, “if a product package is too small or otherwise unable to accommodate a label with sufficient space to bear such information, it will be exempt from the requirement to place the warning statement directly on the product if the warning appears on the outer carton or other outer container or wrapper or on a tag otherwise permanently affixed to the tobacco product package.” Although most manufacturers/distributors of flavored e-cigarette liquids in our sample included a warning statement on e-cigarette liquid bottles, the bottles were too small to bear a minimum of a 12-point font, and did not contain an outer package that would allow them to place the warning statement.<sup>4</sup>

Similar to another study that examined the content of e-cigarette warning statements,<sup>5</sup> we used a national sample, but one that was slight larger. Our study examined the content of samples from different US regions since practices could vary within and across geographic region. We did not find this to be the case. We were surprised to find the extent of warning information on the products, but the information may be misleading because the FDA has indicated that misleading claims include suggestions that a tobacco product contains a reduced level or is free from a harmful substance.<sup>10</sup> For example, 42.9% of the bottles that advertised a nicotine-based concentration of 18 mg/ml stated that the product “may contain nicotine” in the warning statement. This language may be confusing and could potentially influence consumer perceptions about the harms



**Table 1.** Safety Characteristics and Health and Exposure Warning Statements on Flavored E-Cigarette Liquids Purchased From Manufacturers/Distributors in US Geographic Regions (*n* = 147)

Characteristics	<i>n</i>	%
Type of bottle <sup>a</sup>		
Plastic	138	93.8
Glass	9	5.1
Packaging		
Packaged in second container (yes)	18	12.2
Plastic shrink wrap (yes)	18	12.2
Safety cap (yes)	147	100
Warning statement contents <sup>a</sup>		
Warning statement of some type on bottle	144	97.9
Use of “Warning” on statement	49	33.3
Use of “Caution” on statement	9	6.1
Product contains nicotine	33	22.4
May contain nicotine	46	31.2
Nicotine is toxic or poisonous <sup>b</sup>	18	12.1
Nicotine is addictive <sup>c</sup>	0	0
Nicotine is habit forming	9	6.1
Toxic if contact with skin	3	2.0
Do not ingest, drink, or swallow	38	25.8
Product may contain peanuts or nuts	9	6.1
Very harmful to children	3	1.6
Keep away or out of reach from children/kids	129	87.7
Keep away or out of reach from pets/animals	102	69.3
No sales to minors, persons of legal age, or under aged 18 <sup>d</sup>	37	25.1
Product intended for use by persons of legal age of smoking; must be 18 to consume; 18+ only <sup>e</sup>	51	28.8
Product may cause reproductive harm, harm to pregnant women	33	22.4
Product contains chemicals known by state of California to cause cancer	9	5.1
Product is only intended for use in e-cigarettes	4	2.7
Seek medical care promptly if you feel unwell	3	2.0
Not FDA approved	9	6.1
May damage Ce4/CE5 clearomizer tanks	1	0.5
Minimum age requirement of 18 years to enter website <sup>f</sup>		
Yes	9	56.3

FDA = US Food and Drug Administration.

<sup>a</sup>The denominator is the total sample, *n* = 147.

<sup>b</sup>Excluded those that said the product “may” contain nicotine which is toxic or poisonous.

<sup>c</sup>Excluded those that said that the product “may” contain nicotine which is addictive.

<sup>d</sup>Messages are negatively framed.

<sup>e</sup>Messages are positively framed.

<sup>f</sup>The denominator is *n* = 16.

of nicotine and its relationship to disease causation,<sup>11</sup> its addictive properties, and toxicity when ingested or dermally exposed.<sup>12</sup> This finding is concerning because youth have a higher prevalence of e-cigarette use than adults.<sup>13,14</sup> In 2014, 3.9% of middle school and 13.4% of high school students reported the use of e-cigarettes in the past 30 days.<sup>13</sup> Only 3.7% of adults aged 18 and over reported e-cigarette use in 2014.<sup>14</sup> The brains of youth are more susceptible to nicotine dependence and nicotine affects brain development.<sup>15</sup> Our content analysis of e-cigarette liquid bottles suggests that manufacturers/distributors will need to substantially modify their warning statements related to nicotine. It is also possible that some will

choose to retain exposure statements that may be protective, but not yet mandated by the FDA.

Nearly 88% of e-liquid bottles had an exposure warning statement that directed consumers to keep the product away from children. A prior study also concluded that most of the products they investigated had an exposure warning statement.<sup>5</sup> This prevention message may be largely due to the trends in e-cigarette liquid poisoning cases reported since 2011<sup>16</sup> or the reported death of a 1-year old in 2014.<sup>17</sup> Reported cases of poisoning increased from 2011 to 2015 and began to decline prior to FDA deeming of e-cigarettes. Nearly 1400 cases were reported in 2016.<sup>14</sup> Studies are needed to determine if the exposure warning statements provided by manufacturers, which are similar to those provided by the American Association for Poison Control Centers, influenced consumer safety precautions.

Consistent with the message to protect children from the known dangers of e-cigarettes, we found that 100% of the bottles used a “safety” cap. Our findings were similar to Chaudhry<sup>5</sup> who also found that 100% of the bottles had safety caps. Our team has previously tested the safety of “safety” caps and found that they were easy to open, unlike prescription or over-the-counter medicine safety caps. The FDA has indicated that it will continue to investigate the type of packaging requirements needed for flavored e-cigarette liquids as a means to protect children from these products.<sup>4</sup>

We also found that most of the bottles were plastic and only nine were in glass bottles, all from the same manufacturer, Smoque Vapours. It is not clear how the type of bottle influences the performance, composition, constituents, or characteristics of the tobacco products. For example, when exposed to heat or sunlight, the plastic could leak harmful chemicals into the product and could affect the product’s shelf-life. Plastic shrink wrapping could influence both access to and the product’s shelf-life. However, it did not protect us from the unintended exposure to flavored nicotine odor, which was overwhelming. Studies are needed to examine how the materials of the e-liquid bottles and wrapping influence product safety.

The FDA’s 2016 deeming of e-cigarettes did not ban flavors in e-cigarettes or other newly covered products, but the FDA established a minimum purchase age of 18 for all covered tobacco products. Over 40 states had already established minimum age standards for the sales of e-cigarettes to minors prior to the deeming.<sup>18</sup> One-fourth of the labels on the bottles used messages that aimed to reduce sales to minors and one-third of labels affirmed that the product was intended for use by persons aged 18 and over. Studies are needed to determine if the positively and negatively frame messages differentially influence e-cigarettes use among young people.<sup>19</sup> Our staff found that it was easy to enter manufacturer/distributor websites; there was no age verification used upon Internet purchase or upon product delivery. The FDA is issuing warning letters to retailers who continue to sell to minors via the Internet.<sup>20</sup> The FDA stated that it will assess whether additional restrictions will be appropriate.

### Study Limitations

At the time of the study, there was no national database of vape shops and we relied on existing sources to develop a sampling frame. Yelp’s “most reviewed” rankings of businesses may change from day to day; the top most reviewed “vape shop” may not be the most reviewed at a different date. There are numerous vape conferences and we only selected one to compliment Yelp, World Vapor Expo. Yelp indicated that there are over 10 000 vape shops in the United States,<sup>21</sup> but we unable to obtain the list. We limited our sample to

**Table 2.** Percentage of Flavored E-Cigarette Liquids that Contain Warning Statements that Specific that the Product Contains Nicotine or Declares that the Nicotine is Addictive by Nicotine Concentration and Flavor ( $n = 147$ )

Characteristic	$n$	May contain nicotine <sup>a</sup> ( $n = 46$ )	Contains nicotine ( $n = 33$ )	May contain nicotine, which is both toxic and addictive ( $n = 4$ )
		% yes	% yes	% yes
Nicotine (mg/ml)				
0	50	32	20	2
11	3	0	0	0
12	46	28.3	26	2.1
18	14	42.9	57	0
24	32	31.2	9.4	3.1
25	1	100	0	100
30	1	0	0	0
Flavor <sup>b</sup>				
Tobacco	48	29.2	22.9	0
Menthol	48	35.4	22.9	6.2
Apple	48	27.0	22.9	0

<sup>a</sup>Four samples included in this column are also include in the column that states, may contain nicotine, which is both toxic and addictive.

<sup>b</sup>The three free sample flavors are not included as they were not tobacco, menthol, or apple flavor.

three flavors and nicotine concentration levels as part of a larger study to examine constituents in e-cigarette liquids. This study included specific brands of US-based manufacturers/distributors who sold e-cigarette liquids at retail sites and online. Credit card fraud was a problem for online purchases. One company stated that they were no longer selling to out-of-state customers because of high credit card fraud.

## Conclusions

In summary, most e-cigarette liquid manufacturers prior to the announcement of the FDA's authority to regulate e-cigarettes included both health and exposure warning statements on the e-cigarette liquid bottles. Warning statements were difficult to read and contained little information on the harms of nicotine. Studies are needed to examine changes in health and exposure warning statements, the type of packaging used to communicate messages, and how statements and packaging influence consumer behaviors. The FDA is seeking data that will inform future actions, including the use of child-resistant packaging on e-cigarettes and Internet sales restrictions. Data from this study are available to FDA and the field to expeditiously inform modification to mandates or create new ones to protect the public's health.

## Supplementary Material

Supplementary data are available at *Nicotine & Tobacco Research* online.

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## Declaration of Interests

*None declared.*

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## References

1. Federal Cigarette Labeling and Advertising Act of 1965. 1965. [www.govtrack.us/congress/bills/89/s559/text](http://www.govtrack.us/congress/bills/89/s559/text). Accessed September 21, 2016.
2. Comprehensive Smoking Education Act of 1984. 1984. [www.govtrack.us/congress/bills/98/hr3979/text](http://www.govtrack.us/congress/bills/98/hr3979/text). Accessed September 21, 2016.
3. U.S. Food and Drug Administration. Family Smoking Prevention and Tobacco Control Act, 2009. 2009. [www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf](http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf). Accessed February 19, 2016.
4. United States Government, Department of Health and Human Services, Food and Drug Administration. Deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; restrictions on the sale and distribution of tobacco products and required warning statements for tobacco products. Final Rule. *Fed Regist.* 2016;81(90):28973-9106. [www.ncbi.nlm.nih.gov/pubmed/27192730](http://www.ncbi.nlm.nih.gov/pubmed/27192730). Accessed June 27, 2016.
5. Chaudhry IW, Leigh NJ, Smith DM, O'Conner RJ, Goniewicz ML. Labeling information on electronic nicotine delivery systems. *Tobacco Regulatory Science.* 2017;3(1):3-9.
6. Child Nicotine Poisoning Prevention Act of 2015. 2016. [www.congress.gov/bill/114th-congress/senate-bill/142](http://www.congress.gov/bill/114th-congress/senate-bill/142). Accessed September 21, 2016.
7. Yelp.com. 2017. [www.yelp.com/about](http://www.yelp.com/about). Accessed June 27, 2016.
8. World Vapor Expo. Exhibitors list 2014 and 2015. <http://worldvapor-expo.com>. Accessed January 12, 2016.
9. U.S. Department of Agriculture. Food Availability and Consumption. The most commonly consumed fruits among U.S. consumers, 2013. U.S. Department of Agriculture Economic Research Service. 2016. [www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/food-availability-and-consumption.aspx](http://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/food-availability-and-consumption.aspx). Accessed March 1, 2016.
10. U.S. Food and Drug Administration educational information on misleading claims. 2017. [www.fda.gov/TobaccoProducts/PublicHealthEducation/HealthInformation/ucm255658.htm](http://www.fda.gov/TobaccoProducts/PublicHealthEducation/HealthInformation/ucm255658.htm). Accessed December 27, 2016

11. U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.
12. Connolly GN, Richter P, Aleguas A Jr, Pechacek TF, Stanfill SB, Alpert HR. Unintentional child poisonings through ingestion of conventional and novel tobacco products. *Pediatrics*. 2010;125(5):896–899.
13. Arrazola RA, Singh T, Corey CG, et al.; Centers for Disease Control and Prevention (CDC). Tobacco use among middle and high school students—United States, 2011–2014. *MMWR Morb Mortal Wkly Rep*. 2015;64(14):381–385. [www.ncbi.nlm.nih.gov/pubmed/25879896](http://www.ncbi.nlm.nih.gov/pubmed/25879896). Accessed December 27, 2016.
14. Schoenborn CA, Gindi RM. Electronic cigarette use among adults: United States, 2014. *NCHS Data Brief*. 2015;217:1–8. [www.ncbi.nlm.nih.gov/pubmed/26555932](http://www.ncbi.nlm.nih.gov/pubmed/26555932). Accessed June 6, 2016.
15. Dwyer JB, McQuown SC, Leslie FM. The dynamic effects of nicotine on the developing brain. *Pharmacol Ther*. 2009;122(2):125–139.
16. American Association for Poison Control Centers. Electronic Cigarette Alerts. 2017. [www.aapcc.org/alerts/e-cigarettes/](http://www.aapcc.org/alerts/e-cigarettes/). Accessed June 27, 2016.
17. American Association for Poison Control Centers. Press Release. 2014. [www.aapcc.org/press/37/](http://www.aapcc.org/press/37/). Accessed June 27, 2016.
18. Marynak K, Holmes CB, King BA, Promoff G, Bunnell R, McAfee T; Centers for Disease Control and Prevention (CDC). State laws prohibiting sales to minors and indoor use of electronic nicotine delivery systems—United States, November 2014. *MMWR Morb Mortal Wkly Rep*. 2014;63(49):1145–1150. [www.ncbi.nlm.nih.gov/pubmed/25503916](http://www.ncbi.nlm.nih.gov/pubmed/25503916). Accessed June 27, 2016.
19. Akl EA, Oxman AD, Herrin J, et al. Framing of health information messages. *Cochrane Database Syst Rev*. 2011;12:CD006777. doi:10.1002/14651858.CD006777.
20. FDA Warning Letters to Retailers for the Internet sales of e-cigarettes. 2016. [www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm534324.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm534324.htm). Accessed December 27, 2016.
21. Quartz. What Yelp data reveal about the sudden rise of vape shops in America. 2016. <http://qz.com/608469/what-yelp-data-tells-us-about-vaping/>. Accessed June 27, 2016.