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Is the E-Liquid Industry Regulating Itself? A Look at E-Liquid Internet Vendors in the United States

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Abstract

Introduction: The objective of this study was to assess whether the nascent, but rapidly growing e-liquid industry prohibits Internet sales to minors and employs safety measures to prevent accidental poisonings.

Methods: A stratified simple random sample (n = 120) was selected from the target population (N = 1107) of US online vendors of e-liquid in July 2015. The vendors were stratified and subsequently oversampled by trade association membership and vendor popularity. Three minors aged 16 to 17, who were supervised by adult research staff, attempted to purchase e-liquid from the 120 online vendors using debit cards issued in their names. Measures included vendors' use of age verification, warning labels on e-liquid bottles, and child-resistant packaging.

Results: Statistically significant differences were observed by vendor popularity, but not by membership in a trade association. The differences by vendor popularity, however, occurred for measures that were limited to an age warning and list of ingredients. The most striking finding was the scant vendors (n = 4) who successfully prevented the sale of e-liquid to the minors. In contrast, 87.5% and 53.9% of the bottles contained child-resistant packaging and a health warning label, respectively.

Conclusions: Irrespective of trade association membership or vendor popularity, online vendors of e-liquids are not taking the proper precautions in preventing sales to minors. The FDA's upcoming deeming rules on e-cigarette products should include explicit requirements for offline and online e-liquid vendors, particularly the use of effective age verification, warning labels, and child-resistant packaging.

Implications: This study demonstrates that, in the absence of any current FDA regulation of e-liquid products, self-regulation among vendors is not effective in preventing product acquisition by minors. Lax oversight of the e-liquid industry may draw consumers to bypass current tobacco control restrictions implemented in face-to-face sales settings. As a consequence, there may be an increase in online sales to minors. Further regulation of the industry may increase the already prevalent use of child-resistant packaging, leading to fewer cases of accidental nicotine poisoning.

Introduction

The use of electronic cigarettes has tripled among middle and high school students between 2013 and 2014.[1] These products are increasingly being equipped with refillable tanks of liquid nicotine (ie, "e-liquid"), a trend which raises concerns about potential nicotine poisoning through ingestion or contact with skin and eyes.[2] The amount of calls made to US poison centers about adverse e-cigarette/e-liquid exposures has steadily increased every year, growing from one call a month in September 2010 to 215 in February 2014; 51.1% of these exposures were among children under 5.[3]

In July 1, 2015, the FDA issued an advance notice of proposed rulemaking (ANPRM) in seeking comments, data, research results, or other information that may inform regulatory actions the FDA might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine.[4] With respect to e-liquid acquisition by adolescents, the federal agency has not acted upon their previous 2011 ANPRM of Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products despite strong support submitted to the agency by various public health experts and tobacco control organizations.[5] There is uncertainty about the efficacy of age verification over the Internet with some public health figures calling for a complete ban of online nicotine sales. Likewise, there is strong support for the inclusion of warning labels and child-resistant packaging on bottles of liquid nicotine.[6]

To our knowledge, there is only one publication on the topic of e-liquid safety measures. Morris et al.[7] surveyed a convenience sample of 21 US internet vendors and reviewed information about their use of child-resistant bottles and warning labels as reported on the vendors' website. Results showed low utilization of both warning labels on vendor websites (29% of sample) and child-resistant packaging (14% of sample). However, this preliminary study did not utilize probability sampling and did not confirm the results via purchase. The current study aims to assess the extent to which online e-liquid retailers are complying with the restrictions public health and consumer safety advocates have called for in forthcoming federal regulations. Furthermore, the study aims to quantify the industry's level of compliance as set out by various self-regulated e-liquid trade organizations. The selected e-liquid vendors were evaluated on their use of active age verification (AAV) in preventing online sales to minors as well as their inclusion of health warnings and child-resistant packaging. The results of this study have the potential to inform the FDA and other policymakers about the regulatory environment of the e-liquid industry.

Methods

Sampling of Online Vendors

There is no existing sampling frame of US domestic online vendors who sell e-liquid. In lieu of conducting a Boolean search of vendors on the Web, we compiled a list of vendors from three notable sources: (1) JuiceDB.com, a popular website for reviewing e-liquid products and vendors, (2) Smoke-Free Alternatives Trade Association (http://SFATA.org), and (3) American E-liquid Manufacturing Standards Association (http://AEMSA.org). SFATA and AEMSA are trade associations that claim to be dedicated to providing e-liquid that is sold ostensibly to adult consumers. A search of the three sources in July 2015 revealed 1128 unique vendors in the United States. SFATA estimates that there are 1200 manufacturers of e-liquid in the United States,[8] an estimate comparable to the number of vendors compiled from the three sources. We chose to limit the study's sampling frame to the online vendors whose smallest bottle size was 30 ml or less (N = 1107). The 30ml cutoff was created for two purposes: to maintain consistency as all vendors had a bottle either 30 ml or less, and for cost containment. These 1107 domestic vendors were treated as the target population from which 120 vendors were randomly sampled.

Prior to the sample selection, the target population was stratified by membership in a trade association (SFATA/AEMSA) (222 members vs. 885 nonmembers). The population was also stratified by a ranking of the most popular websites (top 250 [popular] vs. bottom 857 [less popular]) based on Alexa.com's estimates of the websites' relative traffic ranking.[9] Website ranking is an important consideration for sampling because it has direct implications for sales and minors' potential exposure to e-liquid. After stratifying the population, 30 vendors were randomly selected without replacement from each of the four strata (Figure 1). The population was stratified on the two variables for ensuring representation of the trade association members and popular vendors, both of which were oversampled by design. The two groups were oversampled for increasing statistical power in comparing an equal number of members versus nonmembers (60 vs. 60), and comparing an equal number of popular versus unpopular vendors (60 vs. 60). This sampling strategy is referred to as equal allocation and used when testing hypotheses among strata.[10] A formal sample size calculation was not performed due to the lack of published data on trade association membership and vendor popularity, resulting in an undetermined variance and effect size. Thus, we chose a sample size of 120 vendors based on available resources.

Vendor Information

There are three categories of e-liquid vendors: direct (n = 74), reseller (n = 21), and hybrid (n = 25). A direct vendor manufactures their own line of e-liquid and sells it directly online. A hybrid vendor carries their own line of e-liquid as well as stocks products from other manufacturers. A reseller vendor does not create their own line of e-liquid and instead stocks e-liquid from other online vendors and wholesalers. Among the sampled direct and hybrid vendors, the in-house brand was selected for purchase. Among the sampled reseller vendors, a single brand was randomly selected into the sample for

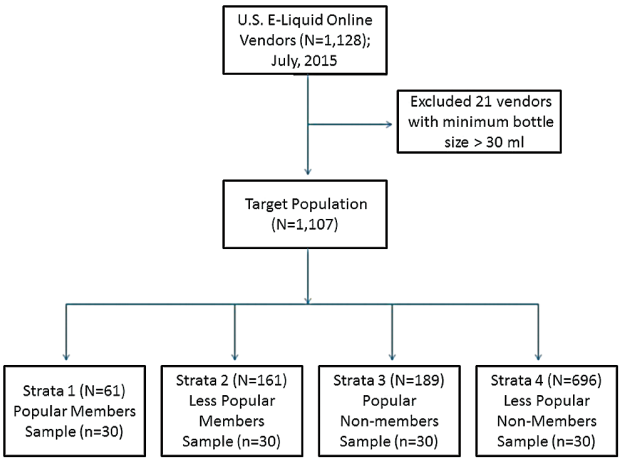

Figure 1. Diagram illustrating stratified simple random sample (n = 120) of domestic online vendors.

purchase. The vendors' locations were determined based on the return address on package shipping labels.

Age Verification

Previous research on youth access to tobacco products over the Internet has revealed several strategies that vendors have taken to verify a consumer's age, not all of which are valid.[11] Some online vendors make the claim that submitting an order legally certifies the buyer as an adult. We define an age gate as a prompt on a vendor's website for a visitor to confirm that they are of legal smoking age. Another false claim is that using a debit/credit card at purchase ensures that only adults can make the purchase.[12] However, the minors in our study were able to legally acquire debit cards in their name without falsifying their age. A vendor was classified as using AAV if it rejected a minor's order due to the use of third party age verification software, request of photo identification, or request of an adult signature upon delivery of the order.[13]

Child-Resistant Packaging

A bottle of e-liquid was defined as being child-resistant if it contains a cap that requires a push down-and-turn movement to open, similar to that of an aspirin bottle. This mechanism satisfies the Consumer Product Safety Commission's (CPSC) protocol for child-resistant packaging.[14] Regardless of being child-resistant or not, each bottle had one of two types of openings: (1) a sealed opening covered with a plastic needle tip that requires a user to squeeze the bottle to extract the liquid nicotine, or (2) an unsealed opening that allowed for pouring of liquid nicotine out of the container.

Ingredients and Warning Labels

Bottles of e-liquid were assessed on their inclusion of three factors: ingredients listings, age warnings, and health warnings. We defined health warnings as messages that reference: (1) Proposition 65, (2) any other text that referred to nicotine or e-liquid as being harmful (or potentially harmful) to health, or (3) a disclaimer that the product has not been evaluated by the FDA. Proposition 65 states that nicotine, among others, is a "chemical known to the state of California to cause birth defects or other reproductive harm."

E-liquid Purchases

Three minors ranging in age from 16 to 17 were recruited from a local high school to attempt to purchase the e-liquid products via the Internet. When queried on vendor websites, the minors provided correct names, addresses and Social Security numbers, but not correct birthdates; the provided birthdates corresponded to individuals in their mid-twenties. The minors made the purchases using debit cards that listed their names, but not ages. They were instructed to provide a valid photo ID or driver's license in the case that vendors requested such identification upon delivery or via email. Falsified identification was not provided to the minors because the objective of the study was to determine whether vendors verified age, not whether minors could evade existing safeguards.

The e-liquid products were purchased by the minors under one-on-one adult staff supervision using computers in our laboratory from July 2015 through September 2015. Given the wide range of available bottle sizes, the minors purchased the smallest bottle from any given vendor for reducing cost. This was based on the assumption that child-proof caps do not vary as a function of bottle size. A similar assumption was made regarding e-liquid flavors. For the sake of consistency, fruit flavored e-liquid were purchased. If a minor was unsuccessful in purchasing a product due to age verification, then an adult research member purchased the product to complete the sample for inspecting child-resistant packaging and warning labels.

The Institutional Review Board (IRB) at the University of California, Irvine deemed that the research protocol did not entail the use of human subjects. In lieu of IRB approval, the Irvine Police Department, the UC Irvine Police Department, and the Orange County District Attorney provided signed letters stating that the minors and research staff would be immune to any criminal prosecution arising from study participation. In addition, the minors' parents provided verbal consent and agreed to intercept the shipped packages of e-liquid upon home delivery. The unopened packages were then sent to our laboratory for examination.

Statistical Analysis

Age-verification methods and child-proof caps/warning labels were examined by trade association membership and popularity ranking of vendor websites using survey-based statistics (ie, Rao and Scott second-order correction F Test).[15] Estimates had to be weighted due to the oversampling of trade association members and popular vendors. Two sets of sampling weights were used in adjusting estimates for age verification and child-proof caps/warning labels, corresponding to vendors and e-liquid brands, respectively. The distinction was warranted because the probability of selecting a vendor was not necessarily equal to the probability of selecting a brand. Multiple brands that are sold by a single vendor (ie, reseller) do not differ with respect to age verification, but do differ with respect to the presence of a child-proof cap or warning label.

The sampling weight for the vendor was calculated as the reciprocal of the sampling fraction ($1/(n/N)$) for each of the four strata. The probability of selecting a brand within a given stratum was not uniform because resellers sell multiple brands, some of which appear repeatedly throughout the target population. Thus, the sampling weight for a given brand was calculated as the inverse probability of the sum of the probabilities of selecting the brand from each vendor, including the resellers and manufacturers. The estimates for bottles that were not part of the original sample (ie, complementary bottles) were unweighted. Analyses were conducted using the software package STATA v12.1.[16]

Results

Vendor Information

Youth buyers made purchases from 120 vendors, but received a total of 183 bottles of liquid nicotine. The 63 additional bottles included sample packs of identical bottles and bottles received free of charge for promotional purposes. The primary analysis was restricted to the 120 bottles that were purchased from the 120 vendors. The average cost per order was $13.16 with a standard deviation of 5.55; two vendors failed to charge the recipient despite fulfilling the order. Shipments were received from 34 different US states. The number of vendors per state was commensurate with overall population figures, with California (24.2% of total shipments), Texas (9.2%), Florida (9.2%) housing the largest share of vendors. Notably, the state of New York, while being the fourth most populous state, was home to only 1 (.83%) e-liquid vendor in our sample. Table 1 describes the safety measures used by the 120 vendors and the characteristics of the bottles that correspond with the original purchase. The percentages

Table 1. Weighted Comparison of Youth Safety Measures by Trade Association Membership and Vendor Popularity (n = 120)

		Trade association membership[a]			Vendor popularity[a]		
Safety measure	Overall	Member	Nonmember	F test[b]	Popular (top 250)[c]	Less popular	F test[b]
Sample size	120	60	60		60	60	
Age verification							
Age gate	80.8%	85.8%	79.5%	0.7	88.4%	78.5%	1.9
Active age verification[f]	3.3%	3.3%	3.3%	0	3.3%	3.3%	0
Child-proof container							
Child-resistant cap	87.5%	93.8%	85.8%	0.9	92.5%	83.4%	1.3
Sealed bottle opening[d]	54.8%	64.4%	52.1%	0.9	48.2%	60.2%	0.7
Bottle labels							
Health warning							
Proposition 65	26.3%	34.1%	24.2%	0.7	25.0%	27.4%	0[e]
General health warning	39.1%	35.8%	40.1%	0.1	35.8%	41.9%	0.2
Not FDA approved	7.1%	2.9%	8.3%	2.7	8.9%	5.7%	0.3
Age warning							
Must be 18/21+	70.6%	71.9%	70.2%	0[e]	86.5%	57.6%	11.2**
Keep out of reach of children	81.8%	67.9%	85.6%	2.7	87.6%	77.1%	1.1
Ingredients listed							
Nicotine	90.3%	95.4%	89.0%	2.1	90.1%	90.5%	0[e]
Flavorings	68.9%	79.3%	66.1%	1.8	82.1%	58.1%	5.3*
PG/ VG	80.5%	88.6%	78.3%	1.3	90.8%	72.1%	4.0*
Other ingredients	14.1%	19.6%	12.6%	1.1	7.3%	19.7%	4.6*

PG = propylene glycol; VG = vegetable glycerin.

[a]Reported as percentage.

[b]Rao and Scott second-order correction (F Test)[15].

[c]250 most popular e-liquid websites based on Alexa rankings.

[d]All bottles contain either a sealed (needle tip) or unsealed opening.

[e]Values rounded down to 0.

[f]Fisher's exact test (unweighted) yielded same results.

*P < .05; **P < .01.

listed in Table 1 are not mutually exclusive and do not add to 100%. For example, a bottle may include multiple age warnings.

Age Verification

Of the 120 purchase attempts, only 4 were rejected due to the vendors' use of AAV. Three vendors utilized 3rd party age verification software (IDology's "ExpectID Age" and Veratad's "AgeMatch") and all three rejected the youth purchases using the provided names and addresses. A fourth vendor required the minor to upload an image of her ID to complete the order, and rejected the order after the buyer uploaded an underage ID. One vendor made the claim that the recipient's photo identification would be checked upon delivery; however, the parcel was simply left in the youth's mailbox by the US Postal Service.

The results show that a vendor's membership in a trade association is neither associated with having an age gate on their website nor utilizing AAV (third party check, photo identification request, check ID at delivery). Fifty-eight of the 60 sampled vendors who belonged to a trade organization fulfilled the order to a minor without checking their age. Similar to trade association membership, vendor popularity was not significantly correlated with AAV use.

Child-Resistant Packaging

87.5% of the bottles in our primary analysis (n = 120) had a child-resistant cap. Among the complementary bottles received (n = 45), 82.2% were child-resistant. A review of all 183 bottles confirms our suggestion that child-proof caps do not vary as a function of bottle size with the exception of 3ml bottles (n = 5), none of which carried child-resistant caps. Of the analyzed bottles (n = 120), 54.8% had a sealed needle-tip that required the user to squeeze the bottle to extract the liquid nicotine. The remaining bottles had glass pipette tops with an unsealed opening susceptible to spillage.

In addition to free samples of e-liquid, 15 of the orders arrived with promotional materials including playing cards, Mike and Ike candy, Laffy Taffy candy, Sweet Tarts candy, bracelets, B'loonies Plastic Balloons, and a collection of branded stickers.

Ingredients and Warning Labels

Given the small real estate of the bottle, there were few variations of warnings found on the packaging. Six vendors included additional health warnings in print form. However, the messages did not differ between labels found on the bottle or leaflets included with the order. The warnings, as seen in Table 1, include general health warnings of nicotine consumption, notice that the consumer must be above the age of 18/21, and listing of ingredients (nicotine, propylene glycol, vegetable glycerin, and flavorings). Both age warnings and list of ingredients appeared more frequently among popular versus less popular vendors. 86.5% of popular vendors versus 57.6% of the less popular vendors listed an age warning. Overall, 90.3% of bottles noted that they contained nicotine, but only 53.9% made any mention of a health warning associated with nicotine use.

Discussion

Our study results show a mixed outlook on the e-liquid industry in regards to their ability to prevent online sales to minors and reduce the risk of accidental exposure to liquid nicotine. While 87.5% of

the received bottles of liquid nicotine carried child-resistant caps, only four of our sampled 120 vendors rejected orders based on age verification. E-liquid trade organizations SFATA and AEMSA both make claims on their websites that their members do not sell nicotine products to minors. Despite these claims, 96.7% of sampled vendors who belonged to either trade association sold e-liquid products to minors. The use of 3rd party age checks, IDology's "ExpectID Age" and Veratad's "AgeMatch," was effective in blocking the purchases made by the minors under study conditions, providing their real names and addresses at checkout. In a real world situation, however, it is unlikely that a teen would provide age verification information that would make it obvious that they were underage; thus it is likely that sales rates to minors in the real world are even higher.

The low uptake of third party age checks may be due to cost; IDology and Veratad's solutions operate as a Software as a Service (SaaS) model that requires a vendor to pay a fee for each ID verification performed. When not required by law, this solution may not be considered cost-effective or otherwise worthwhile by vendors. While requiring photo identification to confirm the age of a tobacco purchase is the norm for face-to-face sales, this method is not widely used among online e-liquid vendors. The discrepancy of use of photo ID between brick-and-mortar stores and Internet vendors may be due to customer concerns about privacy and higher potential of forgery when sent over the Internet. Photo ID checks at delivery may reduce these risks but are still dependent on the delivery employee to carry out the check. This is evidenced by research on Internet alcohol sales to minors, which has shown that age verification delivery services offered by UPS and FedEx are quite unreliable.[17]

The results of this study suggest that minors do not face any significant barriers in purchasing liquid nicotine over the Internet. The percentage of study participants who were able to successfully complete and receive their order was 96.7%. This study did not examine the purchase of prefilled cartridges of liquid nicotine or electronic cigarette devices. However, previous studies[18] have shown similar rates among these related industries, with 93.7% of sampled e-cigarette vendors failing to reject orders made by minors.

Given the current fragmented set of state-level rules regarding electronic cigarette use, there is a strong need for a national set of guidelines. The FDA's ANPRM in July of 2015 has requested information regarding liquid nicotine products and their inclusion of nicotine exposure warnings and child-resistant packaging. Since the announcement of the 2011 ANPRM, the FDA has not enacted any regulations pertaining to the non-face-to-face sale of tobacco products. On October 19, 2015, the FDA submitted their final deeming regulations from the 2014 ANPRM to the White House Office of Management & Budget that would require electronic cigarette manufacturers to register their facilities with the FDA, impose a minimum age of purchase, and require a health warning.[19] On January 28, 2016, President Obama signed the Child Nicotine Poisoning Prevention Act of 2015, legislation that "requires the packaging of liquid nicotine containers for use in electronic cigarettes to be subject to existing child poisoning prevention packaging standards." [20] Our results show that most vendors are prepared for requirements to use child-resistant packaging, as 87.5% of sampled bottles did include a child-proof cap. The discrepancy between the percentage of child-proof caps found in this study as compared to the Morris et al.[7] study, 87.5% versus 14%, can be explained by the fact that the latter study reviewed information presented at the point of sale and did not confirm their results with actual purchases.

It is unclear as to what role the anticipation of upcoming FDA rules had on the vendors' decisions to use child-resistant bottles, if any. There still may be a risk of harmful nicotine exposure with bottles not equipped with a plastic needle tip. Once opened, bottles with unsealed openings allow for oral or skin contact with liquid nicotine. A requirement of using child-resistant bottles with a needle-tip sealed opening may stymie the growing incidence of nicotine ingestion by children.

This study benefitted from actual purchases made by minors with debit cards issued under their own names and products delivered to their homes. With physical access to the material, our study team was able to confirm the safety characteristics of the e-liquid bottles. Furthermore, use of stratified random sampling allowed us to estimate the practices of the larger population of online e-liquid vendors. We have chosen to identify our target population using an online directory of liquid nicotine vendors nationwide (http://JuiceDB.com). The directory is maintained by site moderators and allows for vendor and product reviews by users. This list was supplemented with member lists of the two trade associations, SFATA and AEMSA. A majority of the trade association vendors were already included in the target population due to their listing on http://JuiceDB.com, suggesting that the online directory provides a comprehensive pool of vendors from which we could select a nationally representative sample. Furthermore, the total number of vendors from which we sampled (N = 1128) is close to SFATA's estimate of 1200.

This study did not examine sellers of e-liquid who operate on social networking platforms such as Facebook, Reddit, and vaping-related forums. We are not aware of any studies or estimates of the number of sellers who operate their business through these channels. Thus, it is possible that there exists an even larger number of vendors from which minors can access liquid nicotine products without the barrier of AAV. This limitation should be considered in light of this study being the first to look at the e-liquid industry. The online tobacco retail environment is rapidly changing to accommodate changing consumer demands as well as regulatory parameters. Further studies should examine other available any trends in the e-liquid industry, particularly after the implementation of any federal guidelines concerning youth access.

Our study results show a mixed outlook on the e-liquid industry in regards to their ability to prevent sales to minors as well as unintended exposure to liquid nicotine. The bottles used to store liquid nicotine largely use child-resistant packaging. However, very few vendors take the necessary precautions of checking a customer's age during purchase. These results were consistent by trade association membership, suggesting that efforts to protect consumer safety cannot be implemented voluntarily and require more comprehensive regulation and enforcement.

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Declaration of Interests

None declared.

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