



Supplement Article

Interest in Illicit Purchase of Cigarettes Under a Very Low Nicotine Content Product Standard

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Abstract

Significance: The US Food and Drug Administration (FDA) is considering a very low nicotine content (VLNC) product standard to substantially reduce nicotine in cigarettes. We examined whether learning about a potential VLNC standard increased smokers' interest in illicit purchases of cigarettes with regular nicotine content if such a standard were adopted.

Methods: Participants were a national convenience sample of 1712 US adult smokers. In an online experiment, we randomly assigned smokers to view information about a new VLNC standard (experimental condition) or no information (control condition). The experimental condition explained that a VLNC standard would remove 95% of the nicotine in cigarettes and would require stores to only sell VLNC cigarettes. Then, the survey assessed smokers' interest in purchasing regular cigarettes from three illicit sources.

Results: Smokers who learned about the VLNC standard were more likely to be very or extremely interested in purchasing regular cigarettes illicitly from a Web site compared to smokers in the control group (24% vs. 16%, $p < .001$). They were also more interested in illicitly buying cigarettes from a street vendor (19% vs. 13%, $p < .001$) and a store on an Indian reservation (28% vs. 22%, $p < .05$), compared to the control. The impact of learning about the VLNC standard on interest in illicit purchases did not differ by smoking frequency or current e-cigarette use.

Conclusions: A VLNC standard could increase smokers' interest in illicit purchases of regular nicotine cigarettes. To prevent VLNC-induced illicit trade from undermining public health, FDA should consider proven measures such as track and trace for these products.

Implications: Little is known about how a VLNC cigarette standard would affect consumer interest in regular content cigarettes purchased from illicit sources (eg, the Internet). We found that smokers informed about a potential VLNC product standard had greater interest in illicit cigarette purchases, compared to controls. This suggests the importance of proactive measures accompanying a VLNC standard, such as track-and-trace cigarette packaging regulations and communication campaigns, in order to maximize the standard's public health impact.

Introduction

In July 2017, the US Food and Drug Administration (FDA) announced a comprehensive plan for tobacco regulation that included

a very low nicotine content (VLNC) standard.¹ This VLNC standard, if implemented, would reduce nicotine in cigarettes to minimally addictive or nonaddictive levels. Clinical trials have shown that using

VLNC cigarettes has led smokers to smoke fewer cigarettes and make more quit attempts.²⁻⁴ In addition, a recent simulation model estimated that a VLNC standard in the United States would prevent 2.8 million tobacco-related deaths by 2060.⁵

If FDA implemented a VLNC standard, however, some smokers might seek banned regular nicotine content cigarettes.⁶ Such increased illicit cigarette trade could undermine some of the public health benefits of a VLNC standard. Illicitly purchased cigarettes, which tend to be substantially cheaper than cigarettes purchased legally,⁷⁻⁹ account for between 7% and 21% of the total US cigarette market.¹⁰ Illicit purchases in the United States arise from many sources, including sales from the Internet, tribal lands, and street vendors.¹⁰ Previous studies have shown an uptick in online searches for illicit products after the 2009 federal tax increase¹¹ and modest increases in illicit sales after cigarette excise tax increases.^{12,13} However, the extent to which a VLNC standard could increase illicit tobacco trade is unknown.

Clinical trials that state that participants should only smoke VLNC cigarettes during the trial have found substantial nonadherence,^{3,14} suggesting that, under a VLNC standard, smokers' interest in banned regular nicotine content cigarettes would likely increase. However, studies have not explored smokers' interest in illicit purchases of cigarettes in response to a VLNC standard. Our study aimed to examine whether learning about a potential VLNC standard would increase smokers' interest in illicitly buying cigarettes with regular nicotine content if such a standard were adopted. We predicted that informing smokers of a potential VLNC standard would increase interest in illicit purchases of cigarettes.

Methods

Participants

In August 2018, we recruited a convenience sample of US adults aged 18 years or older as part of a larger online study about e-cigarette health messages.¹⁵ Online convenience samples are a quick and low-cost way to study health behavior and can yield highly generalizable findings for experiments.¹⁶ Participants in this study were current smokers (defined as having smoked at least 100 cigarettes and now smoking every day or some days).^{17,18} Recruitment occurred through Prime Panels (www.turkprime.com), an online platform with access to over 20 million participants for behavioral research.

Procedures

Participants provided informed consent before taking the survey. We randomly assigned participants to one of two conditions. Participants in the experimental condition viewed the following prompt: "Imagine a new law requiring tobacco companies to remove 95% of the nicotine in cigarettes. Stores could legally sell only these new *very low nicotine* cigarettes, but not cigarettes that have regular amounts of nicotine." Participants in the control condition did not see a prompt. Then, participants responded to questions assessing purchase interest as described later. Participants received incentives in cash, gift cards, or reward points from Prime Panels. The University of North Carolina institutional review board approved the study procedures. Prior to data collection, we preregistered the study on AsPredicted.org (<https://aspredicted.org/sp8s5.pdf>).

Measures

The survey assessed interest in illicit purchases of cigarettes from three sources: the Internet, street vendors, and retailers on tribal lands. We selected these sources because an FDA draft paper

predicted that these would be among the most likely sources to sell illicit regular nicotine content cigarettes if a VLNC standard were enacted.¹⁹ The three items for the control group read: "How interested would you be in buying cigarettes from the following places, even if it is not legal? ... A website, A street vendor, A store on an Indian reservation." The items for the experimental group were identical except for the addition of the phrase "regular nicotine" as follows: "How interested would you be in buying *regular nicotine* cigarettes from the following places, even if it is not legal?" The phrase "A store on an Indian reservation" came from the Population Assessment of Tobacco and Health study.²⁰ The items had a five-point response scale ranging from "not at all interested" (coded as 1) to "extremely interested" (coded as 5). We averaged the items to form a scale for interest in illicit purchases of cigarettes ($\alpha = .83$). Participants then answered items about tobacco use and standard demographic items.

Data Analysis

Analyses used Stata/SE version 14.1 with two-tailed tests and a critical α of .05. The analytic sample included 1712 smokers randomized to the VLNC experiment with complete data on the outcomes (only two smokers had missing data; we excluded them from analyses). In preliminary analyses, we examined whether randomization created equivalent groups using chi-squared tests for categorical variables and t tests for continuous variables. We found no differences (Table 1). We used chi-square tests to determine if the proportion of participants who answered "very interested" or "extremely interested" to each item was higher in the experimental group than the control group (compared to those answering "somewhat interested," "a little interested," or "not at all interested").

In the main analyses, we examined the impact of experimental condition on the interest in illicit purchases scale (aggregated across all three sources) using a t test. Finally, we examined whether daily smoking status (vs. nondaily) moderated the impact of experimental condition on interest in illicit purchases across the three sources. This model used linear regression with the continuously measured purchase interest variable as the outcome; predictors were experimental condition, daily smoking status, and an interaction term of experimental condition with daily smoking status. Using the same approach, we examined two additional moderators: number of cigarettes smoked per day and current e-cigarette use (defined as currently using e-cigarettes some days or every day). All analyses followed our pre-registration with the exception of moderation by e-cigarette use; we conducted this unplanned exploratory analysis in response to peer reviewers' feedback.

Results

Smokers' mean age was 44 years (Table 1). Most (63%) participants had less than a college education and 49% were low income. About half of smokers (51%) were also current e-cigarette users. In the past year, 11% of smokers had bought cigarettes from a Web site, 17% had bought cigarettes from a street vendor, and 23% had bought cigarettes from a retailer on tribal lands.

Smokers who learned about the VLNC standard were more likely to be very or extremely interested in illicit purchases of cigarettes from all three sources (Supplementary Table 1). Twenty-four percent of smokers who learned about the VLNC standard were interested (ie, answered "very interested" or "extremely interested") in purchasing cigarettes illicitly from a Web site compared to 16% of smokers in the control group ($p < .001$; Figure 1). Similarly, 19% of smokers

Table 1. Participant Characteristics (*N* = 1712)

	Control group (<i>n</i> = 855)		VLNC group (<i>n</i> = 857)	
	<i>n</i>	%	<i>n</i>	%
Gender				
Female	473	55.3	481	56.1
Male	383	44.7	376	43.9
Gay, lesbian, or bisexual	78	9.1	80	9.4
Hispanic	78	9.1	88	10.3
Race				
American Indian or Alaskan Native	19	2.3	14	1.7
Asian	28	3.3	28	3.3
Black or African American	92	10.9	76	9.0
Native Hawaiian or Pacific Islander	8	1.0	2	.2
White	673	79.9	701	83.4
Other	22	2.6	20	2.4
Education				
High school graduate or less	271	31.7	277	32.5
Some college	271	31.7	251	29.5
College graduate or associate's degree	263	30.8	267	31.3
Graduate degree	49	5.7	57	6.7
Household income, annual				
\$0–\$24,999	233	27.3	249	29.1
\$25,000–\$49,999	282	33.0	284	33.1
\$50,000–\$74,999	166	19.4	153	17.9
\$75,000+	174	20.4	171	20.0
Low income, <200% of 2018 federal poverty level	423	49.7	419	49.2
E-cigarette use				
Current smoker only	407	47.6	430	50.2
Dual current e-cigarette user and smoker	448	52.4	427	49.8
In past year, bought cigarettes from a ...				
Web site	92	10.8	92	10.8
Street vendor	148	17.3	135	15.8
Store on an Indian reservation	190	22.3	200	23.4

The mean age in the control group was 43 years (SD: 14 years) and the mean age in the VLNC group was 45 years (SD: 15 years). Missing demographic data range from 0% to 1.7%. Participant characteristics did not differ by experimental condition (all $p > .05$). SD = standard deviation.

who learned about a VLNC standard were interested in purchasing cigarettes from a street vendor compared to 13% in the control group ($p < .001$). Over a quarter (28%) of smokers who learned about the VLNC standard were interested in purchasing cigarettes illicitly from a retailer on tribal lands compared to 22% in the control group ($p < .01$). Among smokers who learned about a potential VLNC standard, 36% were very or extremely interested in illicit cigarettes from any source, compared with 30% in the control group ($p < .01$).

Next, we looked at interest in purchasing cigarettes illegally as a continuous outcome, averaged across sources. Learning about a potential VLNC standard increased smokers' interest in purchasing cigarettes illegally from the three different sources (mean [*M*] in experimental group = 2.3, standard deviation = 1.2, $p < .001$ vs. *M* in control group = 2.0, standard deviation = 1.1). The impact of learning about the VLNC standard on overall interest in illegal purchases did not differ by daily smoking status (interaction $p = .40$), smoking frequency (interaction $p = .53$), or current e-cigarette user status (interaction $p = .62$).

Discussion

US smokers who learned about a possible VLNC standard in our brief online experiment were more interested in illicitly purchasing

cigarettes, compared to smokers who did not learn about the VLNC standard. The magnitude of the effect was modest; across the three sources, 36% of smokers who learned about the VLNC standard were interested in illicit cigarettes compared with 30% in the control group. The finding held for illicit purchases from Web sites, street vendors, and tribal lands. Moreover, the findings did not differ based on smoking frequency or e-cigarette use. Smokers in this study were most interested in buying cigarettes from retailers on tribal lands, followed by the Internet and then street vendors. These findings build on prior research that has demonstrated greater illicit cigarette sales following cigarette excise tax increases.^{11–13} Assuming a VLNC standard is not accompanied by a tax increase, however, the motivator would likely not be cost savings but rather gaining access to regular nicotine cigarettes banned under a VLNC standard.

Coupled with prior research on tax evasion, our study findings suggest that FDA and other US governing agencies should proactively plan to prevent illicit cigarette trade under a VLNC standard. If sufficient demand exists for regular content cigarettes under a VLNC standard, it is likely that some illicit product will be available and illicit sales will result unless measures are undertaken to reduce illicit trade. A recent article suggested several key regulatory actions for controlling the illicit market under a VLNC standard.⁶ For instance, the United States could require encrypted tax stamps as part of a

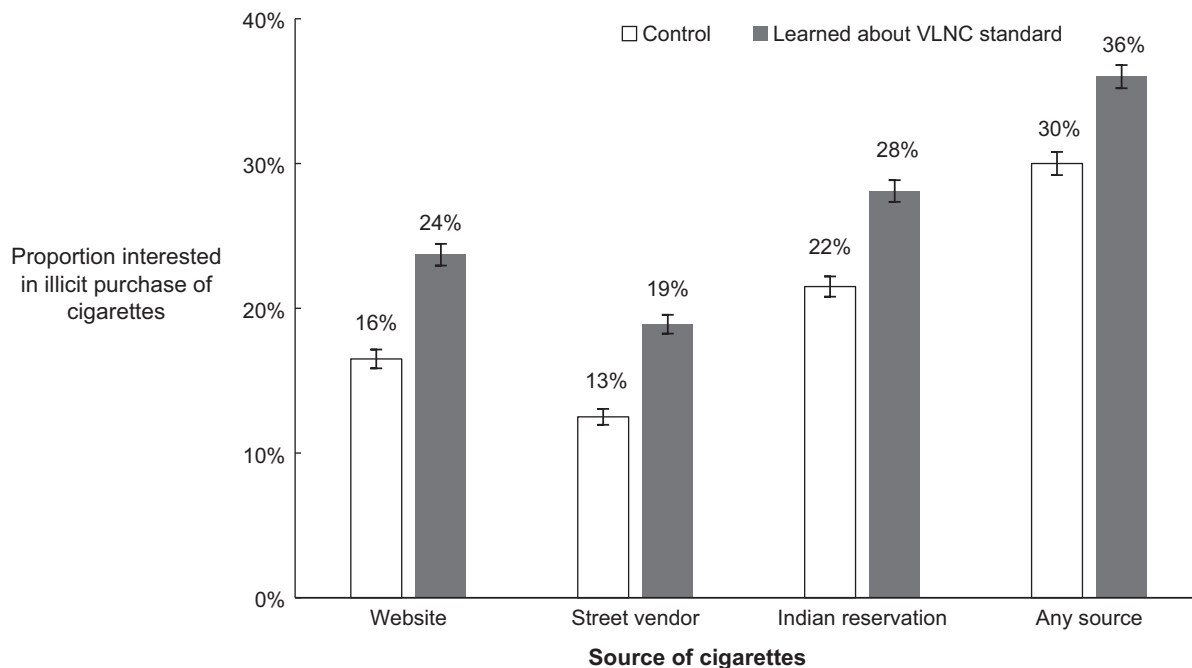


Figure 1. Impact of learning about a potential very low nicotine content (VLNC) standard on interest in illicit purchase of cigarettes (proportion answering “very interested” or “extremely interested”), $N = 1712$. Error bars show standard errors. All $p < .01$.

“track and trace” system for tobacco products, strengthen and enforce regulations banning online cigarette vendors from processing payments and shipping orders, and strengthen licensing requirements, compliance and enforcement, and illicit trade penalties for tobacco manufacturers and distributors. These types of measures have previously proven effective in combating illicit cigarette sales due to tax evasion.^{10,21,22} Moreover, the United States should ensure that cessation products and less harmful nicotine products (eg, e-cigarettes, Swedish snus) are both widely available and affordable to help smokers handle nicotine cravings and reduce the motivation to seek regular nicotine content cigarettes from illicit sources.⁶ Our findings should also be taken in proper context. Although they suggest greater smoker interest in purchasing illicit regular nicotine products, the magnitude of the observed effect was modest and should not be a deterrent for FDA or any other regulatory agency for implementing a VLNC product standard. Moreover, if an illicit market grew large, it would not be invisible to enforcement agencies.⁶

In addition to these regulatory measures, health communications (eg, mass-media campaigns) could help to maximize the impact of a new VLNC product standard. These communications could deter smokers from seeking banned regular nicotine content cigarettes by informing them about penalties for illicit purchases and encouraging them to quit smoking altogether. Campaigns could also encourage smokers to use this change as the time to quit smoking, remind smokers of cessation products and less harmful nicotine products, and educate smokers that VLNC cigarettes are not less harmful than current cigarettes (a common misperception).^{23–26} Future studies should test various campaign messages’ ability to avert possible unintended consequences of a VLNC standard, including illicit cigarette trade and misperceptions of harm.^{27,28}

Strengths of our study include the use of an experimental design with successful randomization and the inclusion of a large national sample of smokers. One limitation is that the outcome of interest in illicit purchases could have overestimated the potential impact of a

VLNC standard on actual illicit cigarette purchases given that intentions do not perfectly predict behavior.²⁹ However, we guarded against this possibility by categorizing smokers as being interested in illicit cigarettes only if they answered “very interested” or “extremely interested.” The small difference in item wording for the two study conditions could have contributed to differences across conditions. We did not assess reasons for interest in illicit cigarettes; future studies should consider examining these reasons both quantitatively and qualitatively. Finally, the use of a convenience sample limits the ability to infer population prevalence estimates, although online convenience samples tend to provide valid results for experiments, accurately estimating the impact of experimentally manipulated variables.^{16,30,31}

Conclusions

This experiment found that learning about a potential low nicotine content product standard increased US smokers’ interest in illicit purchases of regular nicotine content cigarettes. These findings suggest the potential for an increased demand for illicit cigarette trade following a VLNC product standard. FDA and other US government agencies should consider regulatory actions such as track and trace to prevent illicit cigarette sales from weakening the public health impact of a VLNC standard. They could also develop effective communications to help smokers understand the new standard and provide support to help smokers quit smoking altogether.

Supplementary Material

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

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Declaration of Interests

NB and KR have served as paid expert consultants in litigation against tobacco companies. The other authors declare no conflicts of interest.

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