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Food and Drug Administration Tobacco Regulation and Product Judgments

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Abstract

Background—The Family Smoking Prevention and Tobacco Control Act granted the Food and Drug Administration (FDA) the authority to regulate tobacco products in the U.S. However, little is known about how regulation may be related to judgments about tobacco product–related risks.

Purpose—To understand how FDA tobacco regulation beliefs are associated with judgments about tobacco product–related risks.

Methods—The Health Information National Trends Survey is a national survey of the U.S. adult population. Data used in this analysis were collected from October 2012 through January 2013 (N=43,630) by mailed questionnaire and analyzed in 2013. Weighted bivariate chi-square analyses were used to assess associations among FDA regulation belief, tobacco harm judgments, sociodemographics, and smoking status. A weighted multinomial logistic regression was conducted where FDA regulation belief was regressed on tobacco product judgments, controlling for sociodemographic variables and smoking status.

Results—About 41% believed that the FDA regulates tobacco products in the U.S., 23.6% reported the FDA does not, and 35.3% did not know. Chi-square analyses showed that smoking status was significantly related to harm judgments about electronic cigarettes ($p < 0.0001$). The multinomial logistic regression revealed that uncertainty about FDA regulation was associated with tobacco product harm judgment uncertainty.

Conclusions—Tobacco product harm perceptions are associated with beliefs about tobacco product regulation by the FDA. These findings suggest the need for increased public awareness and understanding of the role of tobacco product regulation in protecting public health.

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Introduction

In 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) granting the Food and Drug Administration (FDA) the authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health.¹ A substantial body of research demonstrates that many cigarette smokers underestimate the negative health consequences of smoking or fail to fully comprehend the risk to themselves as individuals.²⁻⁵ More recently, a range of novel tobacco products have appeared on the market, including modified cigarettes, moist snuff products, flavored waterpipe tobacco, and high-tech electronic (e)-cigarettes,⁶ and surveys have shown a high level of awareness and interest among current smokers in novel and potential “reduced harm” tobacco products.⁷⁻¹⁰

However, data are lacking on how beliefs about tobacco product regulation may be related to judgments about tobacco product risks. A study conducted prior to the Tobacco Control Act examined a U.S. nationally representative sample of current smokers and found that those who believed that the FDA evaluates cigarettes for safety were more likely to hold misconceptions about the beneficial effects of smoking low-tar cigarettes and about the number of smokers who die as a result of their smoking.¹¹

Given the FDA's emerging regulatory authority over tobacco products to protect public health and the evolving tobacco product market, it is important to understand how public perceptions of government regulation may be related to judgments about tobacco product health risks. The current study utilizes a nationally representative sample from the Health Information National Trends Survey (HINTS) to (1) characterize who in the population endorses tobacco harm judgments and belief about FDA regulation and (2) explore the association between product harm judgments and FDA regulation, controlling for sociodemographic characteristics.

Methods

Data were from HINTS 4, collected from October 2012 through January 2013 (N=3,630) by mailed questionnaire and analyzed in 2013.^{12,13} HINTS 4 was approved by the chair of the Westat IRB in an expedited review and was deemed exempt from IRB review by the NIH Office of Human Subjects. The final response rate was 39.97%. Additional sampling, design, and weighting strategies for HINTS 4 have been published elsewhere.¹³

Smoking status was determined based on responses to the survey questions: (1) Have you smoked at least 100 cigarettes in your entire life? (*yes, no*) and (2) *How often do you now smoke cigarettes? (every day, some days, not at all)*. The following four smoking status categories were derived: everyday smoker, someday smoker, former smoker, and never smoker. Three items were included in the survey to assess respondents' judgments about use of tobacco products and harm. One item assessed judgments about smoking frequency harm. One item assessed belief in FDA regulation. All items were developed and extensively cognitively tested for the HINTS survey (Table 1). Standard measures assessed sample

demographics (HINTS downloadable at hints.cancer.gov/docs/HINTS_4_Cycle_2_English.pdf).

Descriptive analyses were conducted to examine associations among sociodemographics, smoking status, tobacco product judgments, and FDA tobacco regulation belief. Owing to the multiple chi-square tests conducted, Bonferroni adjustment was used to determine a significance level of $p < 0.001$. Product judgments that had a significant association with FDA regulation belief at the bivariate level were entered into a multinomial logistic regression to explore independent associations between product judgments and FDA tobacco regulation belief, controlling for sociodemographics and smoking status. Data were analyzed in 2013 using SUDAAN, version 11.0.0, to estimate SEs of point estimates for the complex survey data and were weighted to adjust for oversampling, non-responsiveness, and to provide representative estimates of the adult U.S. population.

Results

Table 1 shows weighted, unadjusted prevalence estimates for sociodemographics, tobacco product judgments, and FDA regulation belief. About 41% of respondents believed (correctly) that the FDA regulates tobacco products in the U.S. Also summarized in Table 1 are the results from bivariate chi-square analyses examining relationships among judgments about tobacco products, FDA regulation belief, smoking status, and sociodemographic characteristics. Smoking status was significantly related to judgments about e-cigarettes ($p < 0.0001$).

A weighted multinomial logistic regression was employed to assess the predicted probability that tobacco product judgments (controlling for sociodemographic variables and smoking status) were associated with FDA tobacco regulation belief (Table 2). Compared to those who did not believe that some cigarettes are less harmful to a person's health than other types of cigarettes, people who reported not knowing whether some cigarettes are less harmful were almost twice as likely to report not knowing whether the FDA regulates tobacco. Compared to people who said that smokeless tobacco products are not less harmful than cigarettes, those who did not know whether smokeless tobacco products are less harmful than cigarettes were significantly less likely to say that FDA does not regulate tobacco. Compared to those who believed that e-cigarettes are just as harmful as smoking cigarettes, those who had never heard of e-cigarettes were almost twice as likely to report not knowing whether FDA regulates tobacco.

Discussion

This study examined associations between FDA regulation belief and tobacco product harm judgments in a nationally representative sample. This study builds on previous work, which demonstrated disparities in tobacco product harm judgments by sociodemographics and smoking status and provides initial support for the presence of disparities in beliefs about FDA regulation.^{11,14} FDA regulation belief was associated with tobacco product harm judgments but not with smoking frequency harm judgment (smoking some days versus every day).

Less than half of the population correctly indicated that the FDA regulates tobacco products. Current smokers were more likely than nonsmokers to believe that the FDA regulates tobacco products. As suggested in other studies, this may reflect a false sense of security among smokers rather than increased awareness given that smokers were more likely than nonsmokers to believe that e-cigarettes are less harmful than conventional cigarettes.^{14,15} At the same time, those who reported that they did not know if the FDA regulates tobacco were also more likely to report uncertainty about cigarette type harm and more likely to have never heard of e-cigarettes. Research has found that “don’t know” responding is more prevalent in populations affected by health disparities and may be significant for understanding risk perceptions.¹⁶

Belief about FDA regulation was assessed with a single item, and the concept of government regulation of tobacco is complex. The cross-sectional nature of the survey does not allow determination of a causal relationship between FDA regulation belief and judgments about product harm. The tobacco product harm judgment items were comparative in nature (e.g., compared to cigarettes). Despite these limitations, this initial research may generate more interest and inform future studies in this area.

The findings from this study suggest that uncertainty about tobacco product regulation is associated with uncertainty about tobacco product harm. However, if increased awareness of regulation is conflated with “approval” or “safety” of tobacco products, it is important to develop messaging strategies that increase the public's understanding and awareness of the role of tobacco product regulation in protecting public health.

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Table 1

Weighted bivariate descriptives of tobacco judgments and FDA regulation belief (N=3,630)

Variable	% weighted (n)	In your opinion, do you think that some types of cigarettes are less harmful to a person's health than other types?			In your opinion, do you think that some smokeless tobacco products, such as chewing tobacco, snus, and snuff, are less harmful to a person's health than cigarettes?			New types of cigarettes are now available called electronic cigarettes (also known as e-cigarettes or personal vaporizers). These products deliver nicotine through a vapor. Compared to smoking cigarettes, would you say that electronic cigarettes are ...				Compared to people who smoke every day, do you think people who smoke just some days have less or more risk of getting health problems in their lifetime?			Do you believe that the United States Food and Drug Administration (FDA) regulates tobacco products in the U.S.?		
		Yes	No	Don't know	Yes	No	Don't know	Much less or harmful	Just as harmful	More or more harmful	Never heard of e-cig	Much less or less risk	About the same	More or much more risk	Yes	No	Don't know
Total	N= 3,630	12.6 (432)	64.9 (2,299)	22.6 (813)	9.4 (300)	73.5 (2,602)	17.1 (648)	39.1 (1,222)	35.8 (1,305)	2.1 (82)	22.9 (878)	33.6 (1,041)	57.9 (2,166)	8.6 (312)	41.1 (1,377)	23.6 (840)	35.4 (1,306)
Smoking status	n= 3,577																
Never	58.6 (2,052)	9.9	64.1	26.0	9.9	71.0	19.9	33.5	37.0	2.5	27.0	32.2	57.7	10.0	38.9	24.6	36.4
Former	22.7 (939)	12.5	69.0	18.6	12.5	77.3	13.0	38.7	37.7	1.8	21.7	35.5	57.9	6.6	40.8	25.8	33.5
Some day	4.7 (144)	24.6	63.8	11.6	24.6	76.5	12.3	51.1	28.1	0.9	19.9	38.5	48.2	13.3	39.9	17.4	42.7
Every day	14.1 (442)	20.3	61.4	18.3	20.3	76.9	13.5	59.7	29.8	1.9	8.6	33.8	62.0	4.3	50.3	17.8	31.9
			p<0.0081			p=0.0892			p<0.0001				p=0.0143			p=0.1284	
Gender	n= 3,562																
Male	48.6 (1,390)	14.7	62.8	22.6	11.4	70.9	17.7	46.5	31.8	1.3	20.4	38.4	52.9	8.7	46.6	24.8	28.6
Female	51.4 (2,172)	10.6	66.8	22.6	7.5	76.0	16.5	32.4	40.3	2.9	24.4	29.3	63.0	7.7	35.8	22.7	41.5
			p=0.0757			p=0.1399			p<0.0001				p=0.0069			p=0.0001	
Age	n= 3,511																
17-29	21.6 (299)	12.6	66.5	21.0	11.2	76.4	12.4	47.5	31.1	1.3	20.1	44.3	48.1	7.5	44.5	24.9	30.6
30-49	35.4 (1,075)	13.8	68.6	17.7	9.7	75.2	15.2	45.2	36.0	2.8	16.0	31.8	60.3	7.9	43.6	23.6	32.8
50-69	31.0 (1,500)	12.8	66.4	20.8	9.0	75.0	16.0	36.2	38.6	2.0	23.2	32.5	58.8	8.7	40.9	24.1	35.0
70	12.0 (637)	7.3	50.6	42.1	6.3	61.8	32.0	16.8	34.2	2.3	46.7	23.5	64.8	11.8	28.9	20.5	50.6
			p<0.0001			p<0.0001			p<0.0001				p=0.0015			p=0.0001	
Education	n= 3,557																
Less than high school	13.4 (329)	13.9	57.7	28.5	13.3	63.5	23.2	26.6	34.4	3.9	35.0	22.9	59.7	17.4	29.0	23.6	47.5
12 years or high school	20.2 (775)	7.8	66.9	25.2	8.3	73.6	18.1	33.4	35.8	3.6	27.2	27.9	63.0	9.1	37.9	22.8	39.3

Variable	% weighted (n)	In your opinion, do you think that some types of cigarettes are less harmful to a person's health than other types?			In your opinion, do you think that some smokeless tobacco products, such as chewing tobacco, snus, and snuff, are less harmful to a person's health than cigarettes?			New types of cigarettes are now available called electronic cigarettes (also known as e-cigarettes or personal vaporizers). These products deliver nicotine through a vapor. Compared to smoking cigarettes, would you say that electronic cigarettes are ...				Compared to people who smoke every day, do you think people who smoke just some days have less or more risk of getting health problems in their lifetime?			Do you believe that the United States Food and Drug Administration (FDA) regulates tobacco products in the U.S.?		
		Yes	No	Don't know	Yes	No	Don't know	Much less or less harmful	Just as harmful	More or much more harmful	Never heard of e-cig	Much less or less risk	About the same	More or much more risk	Yes	No	Don't know
Total		12.8	66.5	20.7	9.4	74.8	15.8	41.0	37.4	1.7	19.9	35.2	58.9	45.0	22.6	32.4	
Post-high school training other than college	37.9 (1,073)																
College	18.2 (845)	15.5	65.1	19.4	7.7	78.0	14.3	49.3	31.5	1.1	18.0	41.5	50.3	39.8	25.5	34.7	
Postgraduate	10.3 (535)	14.1	64.1	21.8	9.9	73.8	16.4	41.9	38.6	0.9	18.6	40.0	52.9	50.1	24.3	25.5	
			<i>p</i> =0.0132			<i>p</i> <0.0756			<i>p</i> <0.0001				<i>p</i> =0.0002		<i>p</i> =0.0012		
Race/ethnicity	<i>n</i> =3,258																
Non-Hispanic white	67.1 (2,043)	12.7	66.9	20.5	9.1	79.1	11.8	43.8	36.1	1.5	18.7	38.3	55.5	43.7	24.5	31.7	
Non-Hispanic black	10.9 (496)	7.9	69.4	22.7	4.9	69.1	26.0	32.9	42.2	2.9	21.9	16.1	73.5	41.0	21.5	37.5	
Hispanic	15.0 (511)	12.7	64.1	23.1	12.7	66.2	21.1	34.4	27.5	2.4	35.7	26.7	61.3	32.2	23.7	44.1	
Other	7.1 (208)	14.3	57.1	28.7	10.8	58.1	31.1	31.0	36.4	4.9	27.7	34.4	46.3	39.7	20.0	40.3	
			<i>p</i> =0.1857			<i>p</i> =0.0004			<i>p</i> =0.0003				<i>p</i> <0.0001		<i>p</i> =0.0657		
Income	<i>N</i> =3,630																
OK-14,999	14.7 (536)	14.8	62.0	23.2	9.4	71.8	18.9	37.4	32.7	5.0	24.9	31.6	55.6	39.1	18.9	42.0	
15K-34,999	18.3 (705)	13.7	61.8	24.5	5.8	73.7	20.6	35.6	35.9	2.8	25.7	31.6	59.1	36.1	22.9	41.0	
35K-74,999	28.9 (983)	11.8	67.6	20.6	10.6	75.8	13.6	39.7	36.9	1.6	21.9	31.2	60.9	42.2	26.8	31.1	
75K	27.7 (926)	12.2	67.2	20.6	10.5	74.8	14.7	45.7	35.9	0.9	17.5	39.5	54.8	46.4	23.9	29.7	
			<i>p</i> =0.1280			<i>p</i> =0.0053			<i>p</i> =0.0248				<i>p</i> =0.0798		<i>p</i> =0.0064		
FDA regulation	<i>n</i> =3,523																
Yes	41.1 (1,377)	15.3	67.4	17.3	11.0	75.9	13.2	48.8	34.4	2.2	14.7	37.8	54.5	-	-	-	
No	23.6 (840)	12.7	75.7	11.6	10.0	83.7	6.3	39.2	42.6	2.2	16.1	30.6	59.7	-	-	-	
Don't know	35.4 (1,306)	9.3	54.7	36.1	7.2	63.9	28.9	28.0	32.8	2.2	37.0	30.9	60.4	-	-	-	
			<i>p</i> <0.0001			<i>p</i> <0.0001			<i>p</i> <0.0001				<i>p</i> =0.2433				

Note: Boldface indicates statistical significance at *p* 0.001 (with Bonferroni adjustment). All *p*-values were derived from weighted χ^2 analyses. FDA, Food and Drug Administration.

Table 2

Weighted multinomial logistic regression: tobacco judgments predicting FDA regulation belief ($n=3,045$), conditional OR (95% CI)

Variable	No FDA regulation versus yes FDA regulation	Don't know versus yes FDA regulation	Overall p-value
...do you think that some types of cigarettes are less harmful to a person's health than other types?			0.0058
Yes	1.00 (0.54, 1.86)	0.83 (0.53, 1.32)	
No	ref	ref	
Don't know	0.81 (0.50, 1.33)	1.84 (1.18, 2.87)	
...do you think that some smokeless tobacco products... are less harmful to a person's health than cigarettes?			0.0009
Yes	0.90 (0.34, 2.33)	0.74 (0.40, 1.35)	
No	ref	ref	
Don't know	0.40 (0.25, 0.65)	1.20 (0.76, 1.91)	
Compared to smoking cigarettes, would you say that electronic cigarettes are...			0.0013
Much less or less harmful	0.73 (0.48, 1.12)	0.74 (0.51, 1.08)	
Just as harmful	ref	ref	
More or much more harmful	0.49 (0.12, 1.97)	0.84 (0.23, 3.05)	
Never heard of e-cig	0.91 (0.56, 1.47)	1.89 (1.17, 3.04)	

Note: Boldface indicates statistical significance ($p < 0.01$). List-wise deletion was used to perform a complete case analysis wherein only respondents answering all relevant questions were included as observations. This analysis adjusted for gender, age, education, race/ethnicity, income, and smoking status.

FDA, Food and Drug Administration.