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Knowledge and Perceptions of FDA Tobacco Regulation among U.S. Adults in 2015

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Abstract

Introduction: The U.S. Food and Drug Administration (FDA) is interested in understanding the factors which influence knowledge and perceptions of the FDA as a credible source for information related to tobacco products. This study examined knowledge and beliefs about FDA regulation of tobacco products among U.S. adults in 2015.

Methods: Data was obtained from the Health Information National Trends Survey (HINTS) collected from May to September 2015. Respondents (U.S. adults) reported demographic characteristics, ever tobacco product use, knowledge of FDA tobacco product regulation, and their perception of the FDA's qualification to regulate tobacco. T-tests and chi-square analyses were conducted to determine differences between respondents who believed the FDA was qualified to regulate tobacco products and those who did not. Logistic regression was run to determine factors associated with believing the FDA was qualified to regulate tobacco.

Results: Almost half (47.5%) of U.S. adults reported knowing that the FDA regulates tobacco products and 65.7% believed that the FDA is qualified to regulate them. Significant predictors of believing the FDA was qualified to regulate tobacco products included having a college degree, never trying an e-cig, and knowing that the FDA regulates tobacco products in the U.S.

Conclusions: Five years after FDA was given regulatory authority for tobacco products, less than half of U.S. adults knew that the FDA regulates tobacco, and two thirds believed FDA was well qualified to do so. Those with less education and those willing to try new products like e-cigs were the least likely to believe that the FDA was qualified to regulate tobacco.

Keywords: tobacco, FDA regulation, public opinion

1. Introduction

In 2009, the Tobacco Control Act gave the United States Food and Drug Administration (FDA) broad authority to regulate the manufacturing, marketing, and distribution of certain tobacco products [1, 6]. In 2014, a deeming rule was proposed and later finalized on August 8th, 2016 that gave authority to the FDA to regulate all tobacco products, including electronic cigarettes (e-cigs) [6]. Since the FDA is tasked with making regulatory decisions based on science, the FDA and the Center for Tobacco Products (CTP) have outlined several research priorities. One of the research priorities is to understand "what factors influence public perception of the FDA as a credible source of information related to tobacco products" [1].

It is important to understand public perceptions of the FDA as a credible source of information because the perceived credibility could impact the effectiveness of FDA communications and consequently influence the attitudes and behaviors of U.S. adults. For example, if an organization is viewed as credible, their messaging more effectively initiates behavior change [12, 13]. Since it is known that perceptions of credibility could impact attitudes and behaviors, research is needed to understand the public perception of FDA in relation to tobacco regulation.

Several nationally representative survey studies have attempted to understand public perceptions, knowledge, and beliefs of tobacco regulation among U.S. adults [3, 5, 7, 16]. One study, using Health Information National Trends Survey (HINTS) data collected from October 2012 to January 2013, reported that less than half (41.1%) of U.S. adults knew that the FDA regulates tobacco products. This study also compared knowledge of regulation between current, former, and never smokers to find that current smokers were the most likely to believe the FDA regulates tobacco, however the difference was not significant [7]. Finally, a study in early April 2014 (data collected April 1-14, 2014) measured attitudes surrounding e-cig policies and FDA regulation. This study found more than half of current smokers (62.5%) were unaware that the FDA did

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not regulate e-cigs and many (83.5%) agreed that e-cigs should be regulated for safety and quality reasons. Of interest, current smokers who thought e-cigs were less harmful than cigarettes were less likely to support several of the policies presented [16].

Since the aforementioned studies were conducted [3, 5, 7, 16], the FDA's deeming rule was proposed (April 24th, 2014) and finalized [6]. This rule gave the FDA authority to regulate the manufacturing, distribution, and marketing of all tobacco products [6]. With any changes to the FDA's authority, such as the deeming rule, re-evaluation of public perception is needed to identify changes in knowledge and beliefs of regulation [5]. One study by Boynton et al. conducted after deeming was announced (data collected from September 2014 to May 2015) found that most smokers (66.6%) believed that the FDA could effectively regulate tobacco products [3]; however, this study did not measure actual knowledge of FDA tobacco regulation or report any factors that may be related to beliefs. A study by Schmidt et al., also conducted after deeming was announced, did measure knowledge of FDA regulation and found that less than half of U.S. adults knew that the FDA regulated how cigarettes are made, how they were advertised, or how they were sold in stores [14]. While these studies have evaluated perceptions widely, more research is needed to understand perceptions of the FDA and tobacco regulation among sub-populations who may be most affected by changes in regulation, including users of new products like e-cigs.

To better understand perceptions of FDA regulation among U.S. adults and specifically users of tobacco products, the current study evaluated data collected from the FDA Wave of the Health Information National Trends Survey. This wave of the survey was the first to ask respondents to report ever tobacco product use, including the use of e-cigs, and to ask respondents about perceptions of FDA tobacco regulation. The current study aimed to describe knowledge and perceptions of FDA regulation after the deeming regulation was proposed in April 2014 and to identify factors, such as demographics and tobacco use, which may impact knowledge or perceptions.

2. Methods

2.1. Data and Participant Selection

Data for this study was obtained from the Health Information National Trends Survey (HINTS) FDA cycle 1. The HINTS-FDA survey was a self-administered mailed questionnaire collected from May to September 2015, conducted by the National Cancer Institute (NCI) and the FDA [9]. The survey was completed by one adult in each household using the Next Birthday Method for respondent selection. Because of the specific goals of the FDA wave of the survey, current and former smokers were oversampled by using county-level smoking rates obtained from The Behavioral Risk Factor Surveillance System (BRFSS) to select addresses for participation that fell into a stratum with high or medium-high smoking rates. Each mailed survey was sent up to four times and included a $2 monetary incentive to encourage participation. Complete sampling details can be found in the HINTS Methodology Report [11, 17]. The overall response rate was 33%, and the final HINTS sample for this wave consisted of 3,738 respondents [2]. Respondents included in the current analysis (n=2900) had complete data for age, gender, current smoking status, ever tobacco product use, and had answered both questions pertaining to FDA regulation (described below).

2.2. Measures

Respondents completed questionnaires about basic demographics, smoking history, and knowledge of FDA regulation. Respondents were asked, "Have you smoked at least 100 cigarettes in your entire life", and "Do you now smoke cigarettes every day, some days, or not at all". Current smokers were those who reported smoking at least 100 cigarettes in their lifetime and who reported smoking every day or some days. Respondents were also asked to report ever use of the following tobacco products (yes, no): hookah or water pipe filled with tobacco, electronic cigarettes, pipe filled with tobacco, "roll your own" cigarettes, or snus. For the first time, two questions about FDA regulation were asked, "Do you believe that the United States Food and Drug Administration (FDA) regulates tobacco products in the U.S.?" (yes, no, dont know) and "In your opinion, how qualified is the United States Food and Drug Administration (FDA) to regulate tobacco products?" (not at all, a little, somewhat, very). Respondents reporting "yes" to the first question were considered knowledgeable about FDA regulation and those reporting "somewhat" or "very" to the second question were considered to believe the FDA was qualified to regulate tobacco.

2.3. Data Analysis

SAS 9.4 software (SAS Institute Inc., Cary, NC, USA) was used to conduct all statistical analyses. Data was weighted according to the analytic recommendations for HINTS-FDA [8] to produce a nationally representative sample of the U.S. population. Weighting procedures were used in all analyses. Means and frequencies were calculated to describe the overall sample. Chi-square analysis and two-sided t-tests were used to determine differences between those who believed the FDA was qualified to regulate tobacco and those who did not. Covariates that were significantly different between groups during bivariate analysis were entered into a logistic regression model to predict variables associated with the belief that the FDA is qualified to regulate tobacco. In addition, since researchers were interested in differences in knowledge and perceptions among respondents who have tried new tobacco products like e-cigs, chi-square analysis and two-sided t-tests were used to determine differences between ever and never e-cig users.

3. Results

Overall, the sample (n=2900) was 50.2% male, 77.7% white, with a mean age of 45.8 years. A third of the sample received a college degree (36.7%) and the majority (59.5%) were employed. The sample was 16.6% current cigarette smokers, with 60.6% reporting ever trying any tobacco product and

Characteristic	Overall (n=2900)	Believe FDA qualified to regulate tobacco products (n=1957)	Do not believe FDA qualified to regulate tobacco products (n=943)	P-value
Mean Age (95% CI)	45.8 (45.3-46.3)	46.3 (45.4-47.3)	44.7 (43.1-46.3)	.1675
% Male	50.2	49.3	52.0	.4822
% White	77.7	78.5	85.3	.0683
% Receiving College Degree	**36.7**	**41.4**	**27.9**	**<.0001**
% Employed	59.5	61.4	59.8	.6765
% Married	53.2	54.5	51.2	.3321
% Ever tried a tobacco product	**60.6**	**58.0**	**65.8**	**.0253**
% Current Smoker	16.6	15.0	19.6	.1141
Other Tobacco Use				
% Ever tried e-cig	**21.6**	**18.1**	**28.2**	**.0115**
% Ever tried hookah	20.2	18.8	22.9	.2265
% Ever tried cigar	41.6	40.5	43.6	.3558
% Ever tried roll-own cigs	24.9	23.4	27.9	.2355
% Ever tried pipe	17.6	18.0	16.7	.6322
% Ever tried snus	9.9	8.9	11.9	.2723
% believe that the FDA regulates tobacco products	**47.5**	**55.8**	**31.5**	**<.0001**
% believe that the FDA is qualified to regulate tobacco products	65.7	-	-	-

Table 1: Differences between respondents who believe the FDA is qualified to regulate tobacco products and those who do not.

21.6% reporting ever trying an e-cig. About half (47.5%) of the sample correctly identified that the FDA regulates tobacco products and 65.7% believed that the FDA was qualified to regulate them. Approximately a third of participants (36.7%) agreed to both statements. Among respondents who reported ever trying a tobacco product (60.6%), knowledge and beliefs of FDA regulation were similar (48.4% knew the FDA regulated tobacco and 62.8% believed they were qualified to regulate).

Differences between respondents who believed the FDA was qualified to regulate tobacco products and those who did not are displayed in Table 1. Logistic regression identified significant predictors of believing the FDA is qualified to regulate tobacco products as having a college degree (β=.4209, p<.01), never trying an e-cig (β =.5193, p=.02), and knowing that the FDA regulates tobacco products in the U.S. (β =1.01, p<.01).

Since ever e-cig use was identified as an important predictor of perceptions, further evaluation of the differences between ever and never e-cig users were conducted. Compared to never e-cig users, those who reported ever trying an e-cig were younger (p<.01), less likely to have received a college degree (p<.01), less likely to be married (p<.01), and more likely to report current smoking (p<.01). About half (55.2%) of ever e-cig users reported believing the FDA was qualified to regulate tobacco products, compared to 68.6% of never e-cig users (p=.01). There was no significant difference between groups in the percentage of respondents correctly identifying that the FDA regulates tobacco products (ever e-cig user 51.8% v. never 46.3%, p=.26).

4. Discussion

Overall, less than half of survey respondents (47.5% of U.S. adults and 48.5% of those who identified as ever tobacco users) correctly reported that the FDA regulates tobacco products. The current result is only slightly higher than the 43.4% of ever smokers reported from HINTS wave four data collected in October 2012 – January 2013 using an identical question in a similar population [7]. This suggests that knowledge of FDA regulation has only slightly increased in the two and a half years between the data collection periods of these studies. Importantly, there is not an indication that knowledge of FDA tobacco regulation has changed since the deeming regulations were announced, despite the announcement through media channels [10, 15]. Although only a minority of respondents knew that the FDA regulated tobacco products, more than half (65.7%) reported believing the FDA was somewhat or very qualified to regulate tobacco products. This result is very similar to findings from two other studies among U.S. adults conducted slightly before the current study. One study found that 66.6% of smokers and 65.0% of non-smokers believed the FDA could effectively regulate tobacco [3], while another found that 67.2% trusted the FDA to inform the public about the risks of

tobacco products, and 61.1% thought the FDA was capable of doing a good job regulating tobacco products [14].

This study identified that ever e-cig users, those without a college degree, and those not aware that the FDA regulates tobacco products were the least likely to agree that the FDA was qualified to regulate tobacco products. Prior studies evaluating the impact of education on knowledge and perceptions of regulation found that those with lower education were less likely to have heard of the FDA or to know that it regulates tobacco, but differences in belief of the FDA's qualification to regulate were not different [3, 16]. Although these studies did not find a difference in perceptions by education level, it is not surprising that the current study found differences since those with less education generally report being less trusting of the government [4].

Further comparison of ever to never e-cig users revealed that ever e-cig users are less likely to believe the FDA is qualified to regulate tobacco, despite no differences in knowing that the FDA does regulate tobacco. A prior study looking at the opinions of FDA regulation in a sample of current smokers by level of e-cig use (never, former, and current) found a similar result. Current e-cig users, compared to never and former, were the least likely to agree that the FDA should regulate e-cigs in that study; however, the difference between groups in that study was not significant [16]. The current study was unable to evaluate differences in opinion between former and current e-cig users because the HINTS survey question only asked users if they have ever tried an e-cig. Further research on this topic should measure duration and frequency of use to understand what factors of e-cig use impact views of regulation.

Overall, this study suggests that the majority of U.S. adults remain unaware that the FDA regulates tobacco products. Despite lacking knowledge, almost two-thirds of respondents agreed that the FDA was qualified to regulate tobacco; however, ever e-cig users and those without a college degree were significantly less likely to agree. Since it is known that perceptions of the information source affect behavior [13], this data suggests that e-cig users and those less educated may be the least likely to change their behaviors based on messaging delivered by the FDA.

The datasets generated and/or analyzed during the current study are available in the Health Information National Trends Survey repository, https://hints.cancer.gov/.

5. Declaration of Conflicting Interest

JF has done paid consulting work for pharmaceutical companies that manufacture or develop smoking cessation medicines (including Pfizer, GSK, J&J).

6. Disclaimer

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7. Article Information

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