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PUBLIC OPINION ABOUT FDA REGULATION OF MENTHOL AND NICOTINE

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Abstract

Objective—Regulations that reduce nicotine and eliminate menthol in cigarettes have been proposed to the U.S. Food and Drug Administration as product alterations that could reduce smoking prevalence in the United States. This study sought to assess the public response to either action.

Methods—A mail survey of a representative sample of 1074 adults was conducted in two major metropolitan areas to determine the level of support for immediate, gradual or no reduction of menthol and nicotine in cigarettes.

Results—There was more support for reducing nicotine (79%) than for reducing or removing menthol (59.5%). Most smokers (59.2%; 95% CI 50.7–67.2) and 36% of nonsmokers (95% CI 31.7–40.8) opposed eliminating menthol, but few smokers (23.8%) or nonsmokers (20.3%) were opposed to reducing nicotine. Logistic regression showed no significant effect of smoking status on reductions in nicotine, but that smokers were significantly less supportive than non-smokers of FDA action on menthol (OR =0.32, 95% CI=0.21 – 0.49). A significant race by smoking status interaction showed that African American smokers were more supportive of removing menthol than non-African American smokers.

Conclusions—The greater smoker support for reductions in nicotine than menthol could be due to inaccurate beliefs about the disease risk associated with the two substances (i.e. a belief that nicotine is more harmful than menthol), or to greater awareness of the sensory role that menthol plays in smokers' satisfaction. In any case, if FDA goes ahead with regulations to remove menthol, it will be important to develop strategies to reduce smoker resistance.

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COMPETING INTERESTS

The authors have no competing interests to declare.

ETHICS APPROVAL

The study protocol was reviewed and approved by the IRB at the University of Massachusetts Boston

CONTRIBUTORS

LB conceived of the study, DB had a role in designing and evaluating the survey questions and supervised the data collection and carried out the analysis. Both authors had input into the writing and editing of the paper.

Introduction

The enactment of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in June 2009 granted the Food and Drug Administration (FDA) the authority to regulate tobacco products, including to set standards for the content of cigarettes.¹ One of the first actions taken, and the only one to date affecting the content of products, was to ban characterizing flavors in cigarettes, other than tobacco or menthol.² Two potential actions that have had a great deal of attention are the elimination of menthol flavoring^{3, 4} and the reduction of nicotine levels in cigarettes.⁵ In July of 2013, the FDA issued an advance notice of proposed rulemaking and solicited input regarding the potential regulation of menthol in cigarettes. Similar discussions are currently taking place in the Europe Union, since European Parliament recently proposed to ban fruit and menthol flavors in an effort to make tobacco products less attractive to young people.²⁰ So the stage is set for a regulation regarding this issue. As part of a larger population survey about the use of new tobacco products, our study asked a subset of respondents about their opinions regarding FDA regulation of menthol and nicotine in cigarettes. We wanted to learn whether certain subpopulations are more or less in favor of such government interventions and what policy implications can be drawn from these findings. Assuming that product users would be most committed to the status quo, we predicted that smokers would be more opposed than non-smokers to changes in cigarette design, and that African American smokers, who are more likely than other groups to use menthol cigarettes,⁶⁻⁹ would be more opposed than others to the elimination of menthol.

The role of menthol in promoting addiction and leading to specific health risks has been examined in great depth, and was the subject of an intensive research review by the Tobacco Products Scientific Advisory Committee (TPSAC) and the recently released FDA report "Preliminary scientific evaluation of the possible public health effects of menthol versus nonmenthol cigarettes."¹⁰ Although the agency did not find sufficient evidence that smokers of menthol cigarettes have increased risk of smoking related diseases compared to smokers of non-menthol cigarettes, it did find sufficient evidence that the availability of menthol cigarettes increases experimentation and regular smoking, particularly among African Americans and youth smokers; that it increases the likelihood of addiction and the level of addiction in youth smokers; that it lowers the likelihood of smoking cessation success in African Americans; and that menthol cigarette marketing increases prevalence of smoking in general population, and especially among youth and African Americans.

It is well accepted that nicotine is the primary agent of addiction in cigarettes.¹¹ Although the FDA does not have authority to ban nicotine in cigarettes, it can require that nicotine be reduced to a level that would not support addiction. A body of research exists which suggests that reducing the level of nicotine available in the cigarette, can make it easier for smokers to quit⁵ and can reduce the likelihood that young people who experiment will become addicted.^{12, 13}

To our knowledge, only one other study has been published showing attitudes toward regulating both menthol and nicotine.¹⁴ Fix and colleagues asked a representative sample of smokers if they would support or oppose a ban on menthol cigarettes and if they would

support or oppose reduction of nicotine in cigarettes if it were available in other forms. There was much more support for reducing nicotine than for banning menthol (67% versus 19%), but it isn't clear how much that difference could be ascribed to the different contexts of the two questions. Two other studies examined attitudes toward banning menthol in cigarettes.^{6, 15} Winickoff and colleagues⁶ asked a national sample of both smokers and nonsmokers whether menthol should be prohibited "just like other flavored cigarettes", and found only slightly more support for this than Fix et al., with 28.4% of smokers supporting the ban. Much more support for banning menthol was demonstrated among former (59.2%) and never smokers (67.3%). Pearson and colleagues found even lower levels for support for banning menthol among the population as a whole (20%) and menthol smokers (12.8%).¹⁵ With regard to nicotine, Connolly and colleagues¹⁶ asked a sample of smokers and nonsmokers about support for reducing nicotine either immediately or over the course of 15 years, and found a high level of support for either quick or gradual reduction among both smokers (58%) and nonsmokers (73%). These findings suggest that among both non-smokers and smokers there is a considerable support for changes in cigarette make-up, but there tends to be greater support for reducing nicotine than for eliminating menthol. However, the rates vary by study, and the questions were asked quite differently.

This paper reports on the findings from a more recent study, conducted January-June 2012, which specifically asked U.S. adults whether they feel that the FDA should make immediate or gradual changes in the content of menthol and nicotine in cigarettes versus no change at all.

Methods

Data for this analysis are from a larger telephone survey that examined tobacco product use in Indianapolis and Dallas/Fort Worth, two former test markets for new tobacco products. One sample frame was based on the USPS Delivery Sequence File (DSF), which covers virtually all residential addresses in the United States. For approximately 50% of the addresses, a telephone number was obtained using a commercial matching service. A brief mail survey was sent in late December, 2011 to a random sample of 4000 addresses for which no telephone number could be found. Policy questions including attitudes toward potential FDA regulations on menthol and nicotine were included in the mail survey alone to increase the interest of the study for potential respondents. Data from the mail survey only are included in this analysis.

The mail protocol included a one dollar bill in the first mailing (as a token of appreciation for taking the time to respond), a postcard sent to the entire sample one week later to thank respondents for completing the survey if they had, and reminding them to do so if they had not, and a second mailing of the survey to non-respondents several weeks later. Within a household person with the earliest birthday was asked to complete the survey.

Measures

To measure people's opinion about FDA's potential action regarding menthol flavor in cigarettes, we asked the following question: A panel of scientists has told the Food and Administration (FDA) that getting rid of menthol flavored cigarettes would reduce the

number of people who start smoking. What do you think the FDA should do? 1) Require that cigarette manufacturers remove menthol from all cigarettes immediately; 2) Set a limit for the amount of menthol permitted in cigarettes, and gradually lower it over the next 10 years; 3) Do nothing about menthol flavored cigarettes.

To measure opinion about FDA's potential action regarding the amount of nicotine in cigarettes, we asked the following question: Nicotine is the substance in cigarettes that makes people get addicted to smoking. The FDA has the authority to reduce the amount of nicotine in cigarettes to a very low level. What do you think the FDA should do? 1) Require that cigarette manufacturers reduce the level of nicotine to the lowest level possible; 2) Set a limit for the amount of nicotine permitted in cigarettes, and gradually lower that level over the next 10 years; 3) Do nothing about nicotine in cigarettes. Smoking status was measured with two items: "Have you smoked 100 cigarettes in your life?" and "How often do you now smoke cigarettes? Every day/ Some days/Not at all" The questionnaire collected the following socio-demographic characteristics: gender, age, education, and race. and smoking status.

Analyses

Data were weighted to account for the probability of selection and survey non-response, and were then post-stratified to match the sample to the age, gender, and smoking status of the two geographic regions being sampled. Estimates of opinions on regulation of menthol and nicotine were obtained using IBM_SPSS version 20. All analyses were carried out with complex sample procedures which take account of the survey design effect. Multivariate logistic analyses computed the impact of demographics and smoking status on the support for regulation of menthol and nicotine. Post hoc contrasts for selected comparison were calculated using chi squared tests.

Results

Of the 4000 mailings sent, 284 were determined to be bad addresses (either unoccupied or non-existent). Completed surveys were received from 1,074 households for an overall response rate of 32%. Analyses included data from the 934 respondents who were between 18 and 65 (the age eligibility for the larger study) and who completed the questions related to menthol and nicotine. Respondents were equally split between males and females, and had an average age of 41 years. Current smokers comprised 18.8% of the sample.

Both smokers and nonsmokers were more supportive of reducing the nicotine level of cigarettes (79%) than reducing or removing menthol (59.5%). With regard to nicotine, only 23.8% of smokers and 20.3% of nonsmokers were opposed to any FDA reductions, while the majority of smokers (59.2%) and more than a third of nonsmokers (36.1%) were opposed to eliminating menthol. (See table 1.) Among those in favor of regulation of menthol, smokers were significantly more likely to prefer that it be done gradually over a period of time ($p < .01$), but non-smokers were about equally likely to endorse immediate removal or gradual reduction. Among those in favor of reducing nicotine, smokers were indifferent to the speed of the change, but nonsmokers were significantly more likely to support immediate reduction to the lowest level permitted ($p < .001$). Our sample of African

American smokers is too small ($n = 23$) to provide a precise estimate of their opinions, but with regard to both menthol and nicotine, they seem more amenable to FDA regulations than non-African Americans. Only 29% of African American smokers are opposed to FDA action on menthol while 62.3% of non-African American smokers are opposed (Chi-Square = 7.52, $p < .01$, not shown). Among non-smokers, the racial differences on attitudes about menthol regulation are quite small.

One advantage to including attitudes about regulation of both these substances was that we could examine whether there was a general tendency to either support or reject regulation of cigarette content (additional analyses not shown). Surprisingly, smokers and non-smokers were equally likely to reject regulation of both substances (21% and 19% respectively). However nonsmokers (62.9%) were significantly more likely than smokers (38.5%) to support regulation of both substances ($p = .001$).

To examine the independent impact of respondent characteristics on support for FDA action on menthol, we conducted logistic regression analysis, combining immediate and gradual reductions and contrasting that with opposition to FDA action. Results indicated that for both menthol and nicotine, females were significantly more supportive of FDA actions than males (menthol: OR =1.89; 95% CI=1.32 – 2.70) ; nicotine: OR = 2.44, 95% CI = 1.52 – 3.90). We found that controlling for other factors, smokers were significantly less supportive than non-smokers of FDA action on menthol (OR =0.32, 95% CI=0.21 – 0.49), but smoker/ nonsmoker attitudes regarding action on nicotine did not differ significantly. To examine the sensitivity of results to alternative model formulations, we also ran a logistic regression model using a 3-level categorization of smoking status (current, former and never smoker). This did not alter findings with regard to nicotine, but showed that former smokers were significantly less supportive than never smokers of menthol regulation. Education level was not significantly associated with attitudes toward FDA regulation of either substance. After examining the main effects for demographics and smoking status, we ran a second analysis which included an interaction term, smoking status by race, in the multivariate model in order to examine the hypothesis that African American smokers would be more opposed to removal of menthol than other racial/ethnic groups (See Table 2). Model II, which included the interaction between race and smoking status, revealed a significant interaction for opinions on the regulation of menthol, but no significant interaction with regard to nicotine. Contrary to our predictions, the analysis of the four race by smoking status groups showed that African American smokers were considerably *more* favorable toward the idea of removing menthol flavoring from cigarettes than non-African American smokers.

Discussion

There are some important limitations to this research which should be taken into account when considering the findings. The sample, although probability based, is limited to adults in two sections of the country. To the extent that these areas differ from other sections of the country, generalizability may be limited. Also, our sample of African American smokers was quite small, and the related estimates have wide confidence intervals. However, the benefits of the study are that it is based on a representative sample and to a large extent yields findings consistent with earlier studies. This analysis increases our confidence that

there is more support for reducing the nicotine level of cigarettes than for reducing or removing menthol.

We found that contrary to expectations, it was non-African American smokers rather than African Americans who were most opposed to FDA action on menthol. Among those smokers who do support removal of menthol flavoring, they are significantly more likely to prefer that it be done gradually over a period of years than to be done immediately.

Our findings show somewhat more support for reducing nicotine levels in cigarettes than the previous studies. Fix and colleagues¹⁴ reported 67% of smokers supported nicotine level reduction; Connolly and colleagues¹⁶ reported 58% of smokers and 73% of non-smokers supporting immediately or gradually reducing nicotine levels in cigarettes, and our study found 76.2% of smokers and 79.6% of nonsmokers supporting either immediate or gradual reduction of nicotine to the lowest level possible. The difference could be due to our metropolitan area sample as opposed to the national samples in the other studies, or to the fact that attitudes toward nicotine may be changing over time. Although we expected smokers to be more averse to FDA changes in cigarette content, it is interesting that this is not the case for nicotine. It is also noteworthy that smokers are more amenable to reductions in nicotine than to removal of menthol flavoring. The difference could be accounted for in a number of ways. Perhaps smokers see nicotine as a more harmful substance than menthol. It has been demonstrated that smokers over-estimate the harmfulness of nicotine in relation to other constituents of tobacco smoke.¹⁷ The reluctance to remove menthol, may be due to the common erroneous perception that menthol-flavored cigarettes are less harmful than non-menthol cigarettes.^{18, 19} On the other hand, the differing attitudes may be due to a belief that menthol is more central to the sensory satisfaction of smokers than nicotine. More exploration of the beliefs underlying attitudes toward regulation of menthol and nicotine is an important focus for future research. Greater understanding of these attitudes will help the FDA to develop strategies to reduce smoker resistance should the agency decide to move ahead with regulation of menthol.

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WHAT THIS PAPER ADDS

This study is the first to assess attitudes toward alterations in nicotine and menthol among both smokers and nonsmokers, allowing for a comparison of attitudes by smoking status and by substance. We demonstrate an important difference in smokers' attitudes and highlight the need for research into the basis of those different attitudes.

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Table 1

Support for Food and Drug Administration (FDA) regulation of Menthol and Nicotine in Cigarettes among 934 adults.

	Menthol			Nicotine		
	Remove menthol immediately %	Reduce menthol over time %	Do nothing about menthol %	Reduce nicotine to lowest level %	Limit nicotine and reduce over time %	Do nothing about nicotine %
Total Sample	30.5	29.0	40.5	46.6	32.5	21.0
Smokers (n = 189)	11.5 (7.3-17.8)	29.3 (22.1-37.6)	59.2 (50.7-67.2)	32.6 (25.2-41.1)	43.6 (35.2-52.3)	23.8 (17.4-31.7)
Gender						
Male (104)	14.1 (8.0-23.9)	21.6 (13.7-32.4)	64.2 (52.8-74.2)	30.4 (21.0-41.8)	44.3 (33.2-56.1)	25.2 (16.5-36.4)
Female (85)	8.5 (3.9-17.5)	38.0 (26.6-51.0)	53.4 (40.7-65.7)	35.0 (24.0-47.9)	42.7 (30.7-55.7)	22.3 (13.6-34.2)
Age group						
18-30 (30)	8.0 (2.1-26.7)	40.6 (21.2-63.4)	51.4 (29.9-72.3)	23.9 (10.3-46.4)	55.3 (33.7-75.1)	20.7 (8.5-42.3)
31 – 49 (83)	8.3 (3.7-17.5)	27.6 (18.2-39.6)	64.1 (51.7-74.8)	25.6 (16.0-38.3)	43.0 (31.1-55.7)	31.4 (21.0-44.2)
50-65 (70)	13.5 (6.8-25.2)	23.8 (13.8-37.9)	62.7 (48.6-74.9)	43.0 (29.9-57.2)	39.6 (26.8-54.1)	17.4 (9.4-29.8)
Race						
African American (23)	21.7 (8.3-45.9)	49.2 (26.3-72.6)	29.0 (11.8-55.6)	64.0 (37.8-83.9)	20.4 (6.2-50.0)	15.6 (4.5-42.2)
Not AA (165)	10.5 (6.2-17.2)	27.2 (19.9-36.0)	62.3 (53.2-70.6)	29.3 (21.7-38.3)	46.2 (37.3-55.4)	24.5 (17.6-33.0)
Education						
HS or less (70)	11.5 (5.2-23.5)	33.6 (21.8-47.8)	54.9 (41.0-68.2)	39.5 (26.8-53.9)	39.3 (26.7-53.4)	21.2 (11.8-35.1)
More than HS (119)	11.6 (6.5-19.6)	26.7 (18.2-37.4)	61.7 (50.9-71.5)	28.4 (19.9-38.8)	46.2 (35.5-57.2)	25.4 (17.3-35.6)
Non-Smokers (n = 745)	34.7 (30.5-39.2)	29.1 (25.1-33.5)	36.1 (31.7-40.8)	49.7 (45.1-54.4)	29.9 (26.0-34.3)	20.3 (16.7-24.5)
Gender						
Male (336)	30.4 (24.8-36.7)	25.0 (19.7-31.1)	44.6 (38.2-51.1)	41.5 (35.3-48.0)	29.1 (23.5-35.5)	29.4 (23.7-35.7)
Female (409)	39.0 (32.9-45.5)	33.3 (27.5-39.6)	27.7 (21.8-34.5)	57.9 (51.3-64.2)	30.8 (25.3-36.8)	11.4 (7.4-17.1)
Age group						
18-30 (183)	25.2 (18.1-34.0)	37.4 (28.4-47.3)	37.4 (27.9-48.0)	52.8 (42.8-62.6)	29.4 (21.6-38.6)	17.9 (10.9-27.9)
31 – 49 (330)	38.5 (32.1-45.4)	28.3 (22.7-34.8)	33.1 (27.0-39.9)	49.1 (42.3-55.9)	29.9 (24.0-36.5)	21.1 (15.8-27.6)
50-65 (224)	38.3 (30.8-46.4)	23.0 (17.0-30.2)	38.8 (31.3-46.7)	47.9 (40.0-55.9)	31.3 (24.4-39.1)	20.9 (15.1-28.1)
Race						

	Menthol			Nicotine		
	Remove menthol immediately %	Reduce menthol over time %	Do nothing about menthol %	Reduce nicotine to lowest level %	Limit nicotine and reduce over time %	Do nothing about nicotine %
African-American (204)	41.3 (28.8-55.1)	27.1 (17.0-40.3)	31.6 (18.7-48.0)	66.7 (52.5-78.4)	21.7 (12.6-34.8)	11.6 (5.0-24.5)
Not AA (541)	33.9 (29.5-38.7)	29.5 (25.2-34.2)	36.6 (32.0-41.5)	47.4 (42.5-52.3)	31.2 (26.9-35.9)	21.4 (17.4-25.9)
Education						
HS or less (110)	39.9 (28.6-52.5)	32.9 (22.0-46.0)	27.1 (18.3-38.2)	58.8 (46.7-69.9)	30.8 (21.0-42.6)	10.5 (5.6-18.6)
More than HS (635)	34.0 (29.6-38.8)	28.6 (24.4-33.2)	37.3 (32.5-42.4)	48.4 (43.4-53.4)	30.0 (25.7-34.7)	21.6 (17.5-26.3)

Table 2

Support for FDA's regulation vs. no regulation of menthol and nicotine in cigarettes, reported as odds ratios (95% confidence interval)

Variables	<i>Menthol</i>		<i>Nicotine</i>
	Model I OR (95% CI)	Model II OR (95% CI)	Model I γ^2 OR (95% CI)
Gender			
Female	1.89** (1.32-2.70)	1.93*** (1.38-2.80)	2.44*** (1.52-3.90)
Male (Ref)	1.00		1.00
Age			
18-30	1.10 (0.65 -1.85)	--	1.08 (0.56-2.08)
31-49	1.20 (0.81-1.78)		0.82 (0.50-1.34)
50-65 (Ref)	1.00		1.00
Education			
High school or less	1.52 (0.98-2.37)	--	1.74 (0.99 – 3.06)
More than HS	1.00		1.00
Race			
African American (AA)	1.39 (0.66-2.92)		1.92 (0.81-4.54)
Non-African American (NAA)	1.00		1.00
Smoking status			
Smoker	0.32*** (0.21-0.49)	--	0.72 (0.45 – 1.18)
Non-smoker(Ref)	1.00		1.00
Race X Smoking Status			
NAA Non-smoker		0.68 (0.24 - 2.04)	--
NAA Smoker		0.24* (0.08 - .73)	
AA Non-smoker		0.77 (0.21 – 2.80)	
AA Smoker (Ref)		1.00	

Notes: CI=confidence interval; OR=odds ratios; AA = African American; NAA = Non-African American

*
p<.05,

**
p<.01 ,

p<.001 level of confidence

γ^2 Model II was not run because the race by smoking status interaction was not significant.