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Perceptions of the Food and Drug Administration as a Tobacco Regulator

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Abstract

Objectives—The U. S. Food and Drug Administration (FDA) now has regulatory authority over all tobacco products. Little is known about public awareness and perceptions of FDA in their new role as a tobacco regulator. This research utilizes focus groups to examine perceptions of FDA as a tobacco regulator so that FDA can better communicate with the public about this role.

Methods—We conducted 6 focus groups in 2014 among a diverse sample of smokers and non-smokers. Participants were asked if they had heard of FDA, what they knew about FDA, if they associated FDA with tobacco, and their thoughts about this FDA role.

Results—A total of 41 individuals participated. Although nearly all participants had heard of FDA, most were not aware of FDA's regulatory authority over tobacco products, did not associate the role of FDA with tobacco, and some drew comparisons between FDA's work in tobacco and their work regulating food and drugs.

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Human Subjects Statement

This study was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill on 12/18/2013 (Study #13-2822).

Conflict of Interest Statement

All authors of this article declare they have no conflicts of interest.

Conclusion—Data suggest that although public awareness of FDA regulatory authority over tobacco is low, with proper public education, the public may find FDA to be a trustworthy source of tobacco regulation.

Keywords

Food and Drug Administration; Credibility; Regulation

INTRODUCTION

The US Food and Drug Administration (FDA) received broad regulatory authority over certain tobacco products in 2009 under the Family Smoking Prevention and Tobacco Control Act (FSPTCA).^{1,2} In May 2016 FDA issued a final rule extending their oversight from products covered in the FSPTCA to e-cigarettes, hookah, and cigars, and applying new regulations to these products.^{3,4} The FSPTCA mandates that FDA restrict sales and advertising of tobacco products to minors, require warning labels on cigarettes and other tobacco products, and require manufacturers to disclose ingredients and open facilities up for inspections.^{1,5}

The FSPTCA also charges FDA with educating the public about the harms of using regulated tobacco products and the constituents in such products. To date, FDA has used this mandate to create multiple public awareness campaigns that target various demographics. These include *The Real Cost*,⁶ reaching youth susceptible to or already experimenting with cigarettes, *Fresh Empire*,⁷ which targets multicultural youth identifying with hip hop culture, and most recently a campaign, *This Free Life*,⁸ designed to prevent and reduce tobacco use among lesbian, gay, bisexual, and transgender (LGBT) young adults.

The public's perception of FDA in general and as a tobacco regulator may influence how their communication about the harms of tobacco products is received.⁹ Currently, little data exists to explore the perceptions of FDA and their role as tobacco regulator. The limited research that has examined public perceptions of FDA's regulatory and communication roles over tobacco products indicates low awareness of these roles among the general US population, particularly among smokers.^{10,11} However, a majority of adults in the US say that the FDA can effectively regulate tobacco products.¹²

Before 2009, FDA's activities focused on regulating and ensuring the safety of food and drugs. Although other federal agencies regulate inherently harmful products (ie the Environmental Protection Agency regulating hazardous waste), FDA had previously only been charged with ensuring the safety of food and drug products. Regulating an inherently harmful product like tobacco is a different type of role for FDA. Soon after passage of the FSPTCA, national survey data indicated that the majority of Americans disapproved of the expansion of tobacco regulation.¹³ Interestingly, by 2015, the majority of Americans believed that e-cigarettes should be regulated like regular cigarettes.¹⁴ Approval of FDA in general has fluctuated over the years. Findings from a survey in September 2015 indicated that the US public is fairly split when asked if they view FDA favorably (51%) or unfavorably (39%), with 1% reporting they had never heard of FDA.¹⁵ This compares to a 58% favorable rating in 2010 and 65% in 2013.¹⁵

No qualitative research has been conducted to assess public perception of FDA as a tobacco regulator. Similarly, little research exists on how the public interprets FDA's inverse role of regulating a product that is inherently harmful to public health.^{16,17} This information would not only allow us to understand how and why people form opinions about FDA in the role of tobacco regulator, but it may ultimately improve FDA's communication to the public about the harms of tobacco products. Therefore, as part of a qualitative study on source credibility in health communication, we analyzed focus group data among adults to examine public awareness and perceptions of FDA's dual roles as regulator of tobacco products and communicator about the harms of tobacco use.

METHODS

We conducted 6 focus groups among adults in the Triangle area (Raleigh, Durham, and Chapel Hill) of North Carolina in 2014 to assess existing perceptions of FDA. Focus group data were analyzed to address the research question: What is the public's awareness and perception of FDA as the regulatory authority over tobacco products?

We recruited smokers and non-smokers from the general population, and to ensure that we included the views of potentially at-risk groups, we recruited African American and GLB (gay, lesbian and bisexual) smokers to participate in 2 separate groups. The other 4 groups included young adult (ages 18–25) tobacco users and non-users and adult (ages 26+) tobacco users and non-users. Although we recruited a diverse sample in order to hear a spectrum of opinions, our intention was not to contrast the opinions of certain groups against each other.

Participants were recruited via bus and newspaper advertisements, listserv emails, flyers, and in person recruitment at community and GLB centers and were told that we were conducting focus groups about tobacco products. Research and recruitment methods were approved by the University of North Carolina at Chapel Hill's Institutional Review Board (IRB number 13-2822).

Focus groups were held in a private room in locations around Chapel Hill and Durham, NC. Each 90-minute focus group was audio recorded with consent from the participants and conducted by 3 research staff members. A moderator and co-moderator trained in qualitative research methods guided the participants in a discussion using planned questions from a focus group guide (Appendix A). An additional staff member acted as a note-taker and made detailed notes of the discussion. After each focus group, the staff members debriefed and added additional information to the notes where necessary. Participation was incentivized with a \$50 gift card upon completion of the focus group discussion. These semi-structured discussions followed an interview guide focusing on three topics, 1) health information channels, 2) agencies that disseminate tobacco and health information (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Public Health Service and Surgeon General, Environmental Protection Agency (EPA), National Cancer Institute (NCI), FDA, American Legacy Foundation) and 3) knowledge and attitudes about FDA regulation of tobacco products. This manuscript describes participants' views of the last topic, FDA's role as a tobacco regulator.

After participants discussed where they seek health information and the trustworthiness of agencies that deliver health information, the moderators guided a discussion specifically related to FDA and its regulatory authority over tobacco products. Participants were asked if they had heard of FDA, what they knew about the agency, and whether they recalled seeing the agency associated with information about smoking or tobacco products. Participants were then informed about FDA's new role under FSPTCA and were guided in a discussion about FDA's new authority.

Digital recordings of focus groups were transcribed verbatim by a professional service and sections of the transcripts relevant to FDA were uploaded into Atlas.ti 7.5 (Atlas.ti Scientific Software Development GmbH, Hardenbergstr. 7, Berlin, Germany). Four (KLJ, HMB, LMR, QMV) coders created the codebook with codes and definitions based on a preliminary reading of the data. Only sections of the focus group transcripts that included mention of FDA were coded to address the research question. Two of the 4 coders participated in conducting the focus groups. During analysis, inductive coding techniques¹⁸ and the constant comparison method¹⁹ were used. The inductive coding process consisted of multiple coders reviewing transcribed text and developing codes to describe coalescent ideas that emerged from participant responses within and between focus groups. Coders created an initial list of codes and their definitions by reading the transcripts and identifying topics that were covered in the transcripts. Coders then reviewed and discussed the coding guide and came to consensus on how to use the codes. Two coders read and coded each transcript then discussed and came to agreement on how to code segments that were initially coded differently. After coding had been completed and discrepancies adjudicated, codes were categorized into themes. The authors then reviewed coded segments of text by theme. Reviewing coded text by theme allows researchers to gain an understanding of the range of comments that were made on a given theme across focus groups. By coding and categorizing the qualitative data thematically, the research team was able to identify patterns across focus groups and distill the large amount of qualitative data into succinct, meaningful themes.

RESULTS

A total of 41 people participated in the six focus groups, with a fairly even split between men and women (Table 1). Participants were primarily white and non-Hispanic, and 24% were African American. Everyday smokers comprised 49% of focus group participants, some day smokers comprised 10%, and 41% were current non-smokers. Comments centered around five themes: 1) General awareness about FDA; 2) Overall trust in FDA; 3) FDA as a tobacco regulator; 4) Specific FDA tobacco regulation; and 5) FDA communication on risks of tobacco use. The quotes presented in this manuscript were taken from each of the focus groups conducted.

1. General Awareness about FDA

Almost all participants indicated they had heard of FDA, and they knew that FDA oversees food and drug regulation in the US. When probed about what else they know about FDA, many responded that they had little specific knowledge.

Not much. I know that it exists. That's about it. And I know it's the Food and Drug Administration. But that's about it.

Some mentioned that they knew FDA ensures the safety of food and drugs but were unsure of how far FDA's regulatory authority extends.

So, does the FDA give subsidies to agriculture? Or is that different?

2. Overall Trust in FDA

Participants expressed ambivalence when asked if they trust FDA. Participants were glad that there is a government agency with the responsibility of regulating food and drugs, but many thought FDA could do a better job than they are doing currently.

See, I think I trust them. Because there is so much they research and look into. I would trust them. I would rather go with something FDA approved than not.

I think it gives it [FDA] credibility, but I wouldn't say trust with a capital "T." Not like CDC. ... And without it, things could be a lot worse and we could have a lot less information. So even though I think it's positive, I would say it probably doesn't instill as much trust as like the CDC.

And the reality is we almost have to trust them because that's the game. That's what they're doing. These are the folks that make the decisions.

Yeah. Their standards are a little lower. They could be higher standards for the FDA.

Although most participants expressed partial trust in FDA, some participants expressed complete distrust of FDA.

Like, the FDA -- why would we trust anything they tell us, anyway? Because as far as what we eat they have the control, anyway, you know?

Finally, some participants voiced concerns about the trustworthiness of FDA due to the perception that FDA is unduly influenced by the agricultural and pharmaceutical industries.

A lot of times you hear about the people who work in the FDA. When they retire they end up going to work for the people that they were supposed to be monitoring, and then you wonder was there a, "Hey, let our drug go through and we'll give you a swanky job when you retire?"

Well, there is no reason to have this particular painkiller other than a corporation to make profit. Yet, they will approve it. So whose benefit are they looking out for?

3. FDA as a Tobacco Regulator

A limited number of participants associated FDA with tobacco or had any awareness of FDA's regulatory authority over tobacco. After moderators described FDA's role as tobacco regulator, some participants mentioned they hadn't noticed anything different since the 2009 enactment of the FSPTCA, they hadn't heard anything about this change, and they didn't understand what actions FDA would be able to take as a tobacco regulator.

I don't remember anything different since 2009 ...And as far as like regulating it, it's still the same age to buy it [tobacco products]; it's just more expensive. So I don't see the impact that there has probably been since it's been under them [FDA].

I mean, that's my main source of information -- is television and internet... I had no idea that the FDA was now associated with cigarettes. So they need to publicize that.

Well, what exactly is the FDA's ability here? They can't not approve it, right? That's not within their power. Or is it?

Although participants voiced concerns, some were also more positive about FDA overseeing tobacco products.

That brings the agency, for me, into a much more positive light. Seeing how they handle what I believe to be a dangerous product. Seeing how they handle that really does increase my approval of the FDA.

I really approve of the FDA being in charge of cigarette information, just because ... I think of them more with pharmaceuticals and drugs in general... I have more trust in it [FDA] now. And I have trust in the information they're giving out on cigarettes.

A few participants weren't sure how tobacco would fit in with FDA's other responsibilities or voiced opinions that the government shouldn't be regulating tobacco products at all.

Their title is the "Food and Drug Administration," so I mean they're labeling smoking as a drug. It's not a food. So I don't know.

I think it is a major priority mismatch in the FDA getting into tobacco. Because the FDA would rather do a better job controlling chemicals in food, or genetically modified food. Or bad things which we end up eating.

I don't think it's the government's job to be attacking one particular group of products.

Participants conveyed concern that the public may come to the conclusion that tobacco products are safe if they learn that FDA regulates them. These concerns were about the inherent difference between approving something that is safe, such as food, compared to overseeing tobacco products, which are dangerous.

It stands for approval. FDA generally stands for approval.

People think pharmaceuticals are safe because they're approved by the FDA. That's something that the FDA does. And so putting them on nicotine might have that same effect.

And they've looked through it, and done the research, and have regulated and evaluated everything -- and the product is still out there. They haven't taken it off the market, so it must not be that bad.

Finally, some mentioned that they are concerned about FDA having conflicts of interest because of their dealings with the agricultural and pharmaceutical industry, which may influence their ability to fairly regulate tobacco.

And I personally have a feeling that there's some kind of corporation government conflicts of interest. Actually, I know people flip-flop between their jobs in the corporations and the government. And I have a concern, since there is such a big lobbying group for tobacco. I wonder how that might occur. So that worries me. But that involves anything being sold.

With what you said about how tobacco is like a major profiting crop for America, and given that they are a government agency, is it not kind of -- they have like the wrong kind of vested interest?

4. Specific FDA Tobacco Regulation

After discussing FDA in general and asking about their association with tobacco, participants were informed by the moderator about specific regulatory activities of FDA (eg manufacturing, distribution and sales). Participants were mostly positive about specific aspects of FDA's tobacco regulatory activities, even though they were at times dubious about whether FDA was the correct agency for this type of regulation given their product safety role over food and drugs.

a. Disclosing ingredients—Participants expressed generally positive thoughts about mandated ingredient labeling, although they weren't sure that would deter use of tobacco products. Participants equated ingredient labeling in tobacco products with ingredient labeling in food. Participants also hoped that labeling of tobacco ingredients might lead to fewer additives in the tobacco products themselves.

I really do agree with knowing what exactly is in there. I think you have a really powerful tool, since you have [to] list those out, of correlating those with health effects.

So, I mean, if they're going to list on a packet of Kool-Aid what's in there, or what's in the chicken or everything else that you're eating and consuming inside your body, I think they should put it on cigarettes, too, because it's also a consumption.

... you can tell me what the ingredients are but I can't pronounce them or I don't know what they do... nobody really looks at the ingredients of their ice cream and looks at it and then like, "I can't pronounce that." So keep eating it. To know that somebody is regulating it, and somebody is actually being big brother kind of feels good.

I don't know how it really connects, but I'd really like to see them [Tobacco Companies] not put so many crazy additives in there. And I think people should be more aware that they're putting these really crazy additives in there, on purpose.

b. Tobacco warnings—Participants talked about the perceived effectiveness of warning labels more than they discussed the specific impact of FDA gaining oversight of warning labels on tobacco products. Participants noted that they think many tobacco users don't pay attention to current Surgeon General warnings because of their size and location.

It's on the side. How many times do you pick up a pack of cigarettes and actually look at the side of it? I think that if it was at the top, where you have to rip everything off and open it up ...

I think if you've already bought the pack and you've opened it to the point that you're looking at it like that, then you are probably going to go ahead and smoke.

Some believed smokers would likely ignore new warning labels on a pack because they are making a choice to smoke them, regardless of the label.

It's going to be ignored just like the surgeon general warning, because therefore people are still going to want to smoke cigarettes, whether it's there or not, you know what I'm saying?

Everything they're telling us there, anything they could put on the side of that box -- even if there were pictures of people with their throats wide open -- people know this. And we've been seeing it. We're desensitized to it now.

c. Tobacco retail sales and advertising—Participants expressed differing opinions on FDA tobacco retail advertising and inspections at the point of sale. Some participants voiced opinions that this type of enforcement activity by FDA was not a good use of resources while others stated the value of these inspections in limiting youth access to tobacco products.

Well, they shouldn't be paying public servants to go around and inspect advertisements. That's crazy. You know?

[In response to quote above] Well, I disagree with that. Because they do project it towards the youth, you know?

And if a shopkeeper puts up inappropriate ads geared toward kids, you have the right not to shop there and vote with your dollars not to support that.

5. FDA Communication on Risks of Tobacco Use

While most participants were supportive of public education about the risks of tobacco, many felt that smokers already know that cigarettes are harmful and that communication efforts should focus on youth who have not started smoking yet. Other participants wondered why FDA was chosen to communicate risks to the public when other agencies may have more expertise in the domain of communication.

...I feel like there's a pivotal age at which people make the decision, for one reason or another, whether they want to smoke or not. ... But just present all the facts to them at a young enough age where they can have time to think about it, and understand what they're getting into before they get into it.

I was thinking why was it them [FDA] that were designated to do this? And I understand drug administration, and tobacco and cigarette smoking is a drug. But why is it not a group that ...knows all the facts about cigarettes and smoking, and can market the consequences in a way that is actually more real and reliable?

DISCUSSION

This study is the first qualitative assessment specific to FDA's regulatory authority over tobacco products, and it sheds new light on public perception of this role. Participants in our study expressed varying degrees of current trust in FDA, with few expressing absolute trust in the agency and most expressing partial trust with a few reservations. Participants' level of trust in FDA was based primarily on their knowledge and opinion of FDA as a regulator of food and drugs. Similarly, participants seemed to approve of FDA taking on the role of tobacco regulator, although participants were not quite sure how that will fit in with their other responsibilities. Some participants were concerned about conflicts of interest with the agricultural, pharmaceutical and tobacco industries. In terms of specific regulatory authority, participants believed that it is good for FDA to communicate the risks of tobacco smoke to young people, but were more ambivalent about FDA inspections of tobacco retailers. Importantly, participants were concerned that FDA regulation of tobacco products may have the unintended consequence of people perceiving them as safer. Participants also expressed their thoughts that this is a potential mismatch with FDA's existing regulatory authority over food and prescription drugs, which is intended to ensure that these products are safe.

Our results are consistent with previous quantitative evidence that public awareness and understanding of FDA's tobacco role is low,^{10,11} but that there is support for increased tobacco regulation and communication about the risks of tobacco use.¹¹ This work also supports and builds upon previous quantitative evidence that FDA is seen as a capable regulator of tobacco products¹² by detailing some factors the public considers when forming an opinion on this topic. To our knowledge, no published literature addresses public opinion of FDA's specific tobacco regulatory responsibilities. Although participants in our focus groups expressed support for disclosing ingredients, they were more skeptical about the effectiveness and utility of tobacco warnings and oversight of retailers and advertisers. These differing views may be attributed to any number of factors. One possibility is that analogous reporting of ingredients for food is already required, so requiring similar reporting for tobacco has face validity. Participants also discussed the perceived cost of conducting point of sale inspections in retail establishments and advertiser compliance enforcement as a reason against these programs. More research on these topics in the future will be necessary for a complete understanding of public perception of FDA.

Similarly, no published work to date explores support for FDA communication of tobacco risks. Our data indicate that the participants in our focus groups were mostly supportive of tobacco health communication from FDA, particularly if they target efforts towards youth. Early evaluation of *The Real Cost* campaign, which targets youth susceptible to tobacco, have shown high awareness and perceived effectiveness of the campaign among this population.²⁰ Given the evidence that source credibility may impact campaign effectiveness,⁹ additional research should explore the impact of FDA source on their

communications like *The Real Cost* campaign and newer campaigns like *This Free Life* and *Fresh Empire*.

Limitations

This research was conducted in a state with a history of tobacco farming and manufacturing.²¹ Since our recruitment and focus group design were intended to include individuals from several different points of view and tobacco use patterns but not to make comparisons between them, we did not contrast the views from different focus groups. Similarly, in this manuscript we describe instances where some, but not all, of our participants expressed a certain opinion, to indicate that a viewpoint was expressed but there was not general consensus.

The five themes that emerged from the focus group data somewhat follow the semi-structured focus group guide but also go beyond the scope of the questions and provide additional insight when participants discussed their perspectives of the FDA. This is the benefit of using a qualitative approach rather than a quantitative one; as researchers, we can explore in-depth the nuanced perspectives on a topic about which little is already known.

Due to the design and broader nature of our focus groups, we were not able to describe in detail each aspect of FDA oversight of tobacco products under the FSPTCA, which may have clarified some aspects of their role for participants. Although FDA has regulatory oversight over the manufacture of tobacco products, very little of our data, aside from the mention of additives, was relevant to manufacturing specifically.

However, our focus group discussions provided rich data on a specialized and important topic. Along with talking to general population smokers and non-smokers, we specifically recruited groups that are particularly vulnerable to tobacco use. Tobacco companies have historically targeted LGBT individuals and African Americans and those groups suffer a disproportionate burden of tobacco-related health outcomes;^{22–25} therefore it is important to include these groups in research related to tobacco regulatory activities. Future qualitative work should include additional focus groups and could benefit from including people from around the country. Our group is also developing manuscripts describing public perspectives of FDA from a quantitative standpoint, and this work is better suited to describing important differences among populations.

Conclusion

These data suggest that although public awareness of FDA regulatory authority over tobacco is low, once informed about this regulatory role, the public may find FDA to be a trustworthy source of tobacco regulation, with some caveats. Future research should further examine the role of trust in government, trust in FDA and awareness of FDA tobacco regulation, and the impact of the credibility of FDA as a tobacco regulator to determine factors that play a role in the receptivity to FDA tobacco regulatory communication.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Family Smoking Prevention and Tobacco Control Act, H.R. 1256 (2009).
2. Zeller M. Three years later: an assessment of the implementation of the Family Smoking Prevention and Tobacco Control Act. *Tobacco control*. 2012; 21(5):453–454. [PubMed: 22859058]
3. FDA takes significant steps to protect Americans from dangers of tobacco through new regulation [press release]. May 5, 2016 2016.
4. U.S. Food and Drug Administration. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Final rule. *Federal register*. 2016; 81(90):28973. [PubMed: 27192730]
5. U.S. Food and Drug Administration. [Accessed July 1, 2016] Tobacco Control Act. 2016. <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm>
6. U.S. Food and Drug Administration. [Accessed July 1, 2016] The Real Cost Campaign. 2016. <http://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/TheRealCostCampaign/default.htm>
7. U.S. Food and Drug Administration. [Accessed July 1, 2016] Fresh Empire Campaign. 2015. <http://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/FreshEmpireCampaign/default.htm>
8. U.S. Food and Drug Administration. [Accessed July 1, 2016] This Free Life Campaign. 2016. <http://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/ThisFreeLifeCampaign/default.htm>
9. Schmidt AM, Ranney LM, Pepper JK, Goldstein AO. Source Credibility in Tobacco Control Messaging. *Tobacco Regulatory Science*. 2016; 2(1):31–37. [PubMed: 27525298]
10. Kaufman AR, Rutten LJF, Parascandola M, Blake KD, Augustson EM. Food and drug administration tobacco regulation and product judgments. *American journal of preventive medicine*. 2015; 48(4):445–451. [PubMed: 25726094]
11. Fix BV, O'Connor RJ, Fong GT, Borland R, Cummings K, Hyland A. Smokers' reactions to FDA regulation of tobacco products: Findings from the 2009 ITC United States survey. *BMC public health*. 2011; 11(1):1. [PubMed: 21199570]
12. Boynton MH, Agans RP, Bowling JM, et al. Understanding how perceptions of tobacco constituents and the FDA relate to effective and credible tobacco risk messaging: A national phone survey of US adults, 2014–2015. *BMC Public Health*. 2016; 16:516. [PubMed: 27333921]
13. Gallup. [Accessed July 5, 2016] Majority Disapproves of New Law Regulating Tobacco. 2009. <http://www.gallup.com/poll/121079/majority-disapproves-new-law-regulating-tobacco.aspx>
14. Gallup. [Accessed July 5, 2016] Americans Say E-Cigs Should Be Regulated Like Tobacco Cigs. 2016. <http://www.gallup.com/poll/189716/americans-say-cigs-regulated-tobacco-cigs.aspx>
15. Pew Research Center. Beyond Distrust: How Americans View Their Government. 2015.
16. Deyton LR. FDA Tobacco Product Regulations: A Powerful Tool for Tobacco Control. *Public Health Reports*. 2011; 126(2):167–169. [PubMed: 21387945]

17. Surgeon General. The health consequences of smoking—50 years of progress: a report of the surgeon general. Paper presented at: US Department of Health and Human Services; 2014.
18. Strauss, AL., Corbin, JM. Basics of qualitative research. Vol. 15. Newbury Park, CA: Sage; 1990.
19. Miles, MB., Huberman, AM. Qualitative data analysis: A sourcebook of new methods. Sage; 1984.
20. Duke JC, Alexander TN, Zhao X, et al. Youth's Awareness of and Reactions to The Real Cost National Tobacco Public Education Campaign. PloS one. 2015; 10(12):e0144827. [PubMed: 26679504]
21. Washington M, Barnes RL, Glantz S. Chipping Away at Tobacco Traditions in Tobacco Country: Tobacco Industry Political Influence and Tobacco Policy Making in North Carolina 1969–2011. 2011
22. Centers for Disease Control and Prevention. [Accessed July 5, 2016] African Americans and Tobacco Use. 2015. <http://www.cdc.gov/tobacco/disparities/african-americans/index.htm>
23. Campaign for Tobacco-Free Kids. TOBACCO USE AMONG AFRICAN AMERICANS. 2016.
24. American Lung Association. [Accessed July 5, 2016] Tobacco Use in Racial and Ethnic Populations. <http://www.lung.org/stop-smoking/smoking-facts/tobacco-use-racial-and-ethnic.html>
25. Centers for Disease Control and Prevention. [Accessed July 5, 2016] Lesbian, Gay, Bisexual, and Transgender Persons and Tobacco Use. 2016. <http://www.cdc.gov/tobacco/disparities/lgbt/index.htm>

IMPLICATIONS FOR TOBACCO REGULATION

Credibility of FDA as a tobacco regulator may impact how their communications and regulations are received by the public.⁹ This is the first qualitative analysis exploring the public perceptions about FDA's role as a tobacco regulator. A better understanding of FDA credibility informs both regulators and health communication professionals tasked with communicating about risks of tobacco use.

Table 1

Characteristics of Focus Group Participants

Variable	Total (N=41)
Age in years, Mean (Standard Deviation)	33 (11)
Range	18–58
Sex, N (%)	
Women	23 (56)
Race, N (%)	
White	25 (61)
African American	10 (24)
Asian	4 (10)
American Indian	1 (2)
More than one race	1 (2)
Hispanic Origin, N (%)	
Non-Hispanic	35 (85)
Hispanic	6 (15)
Lifetime Ever Smoker (more than 100 cigs), N (%)	
No	16 (39)
Yes	25 (61)
Frequency of Current Smoking, N (%)	
Not at all	17 (41)
Some days	4 (10)
Everyday	20 (49)