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“Who’s Really Regulating? Who’s Benefiting?” Exploring Black Stakeholders’ Awareness and Trust in the Food and Drug Administration’s Role as a Tobacco Regulator

Sabrina L. Smiley, PhD, MPH, MCHES [Postdoctoral Scholar],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Kacie C.A. Blackman, PhD [Postdoctoral Scholar],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Ricky N. Bluthenthal, PhD [Professor],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Yaneth L. Rodriguez, MPH [Project Manager],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Rosa Barahona [Project Manager],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Steve Sussman, PhD [Professor],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Mary Ann Pentz, PhD [Professor],

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Jonathan M. Samet, MD, MS [Dean],

Colorado School of Public Health, Denver, CO.

Lourdes Baezconde-Garbanati, PhD [Professor]

University of Southern California Tobacco Center of Regulatory Science for Vulnerable Populations, Keck School of Medicine, Los Angeles, CA.

Abstract

Correspondence Dr Smiley; slsmiley@usc.edu.

Human Subjects Statement

This study was approved by the Institutional Review Board at the University of Southern California (Study #13-00647).

Conflict of Interest Statement

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

Objective: Blacks/African Americans have experienced direct public health harm from US governmental agencies (eg, police violence, Tuskegee syphilis experiment) that may influence perceptions of the trustworthiness of government messages regarding tobacco products. Consequently, we sought to explore Black Americans' awareness of and trust in the FDA's role as a tobacco regulator.

Methods: Data were from 2 focus groups conducted with a purposive sample of 23 Black stakeholders in Los Angeles, California. Discussions were audio-recorded and transcribed verbatim for analysis.

Results: Although most (N = 14; 61%) participants were aware of the FDA's role as a tobacco regulator, they all noted that the Black community in Los Angeles is not aware. Recurrent across the focus groups were discussions about distrust in the FDA with 4 main contributing factors: (1) that the FDA is influenced by the tobacco, agricultural, and pharmaceutical industries; (2) that the FDA is influenced by money and politics; (3) that the FDA is a bureaucracy exercising monopoly and power; and (4) that the FDA lacks technical capacity and competence to regulate tobacco products.

Conclusions: Study findings highlight opportunities for the FDA to increase awareness and build trust in their tobacco regulatory role through communication campaigns targeted at Black Americans, and community engagement with Black stakeholders.

Keywords

Food and Drug Administration; tobacco regulation; trust; black Americans; stakeholders; qualitative research

The United States (US) Food and Drug Administration (FDA) is a regulatory agency entrusted with the task of protecting the public's health. Research indicates that public trust in government regulatory agencies is essential to health communication and public engagement efforts.¹⁻³ Greater public trust in regulatory agencies has been found to improve acceptance of public policies, strengthen compliance with regulations, and promote cooperative behavior.^{4,5}

Signed by President Barak Obama in 2009, the Family Smoking Prevention and Tobacco Control Act (hereafter referred to as the Tobacco Control Act) conferred to the FDA regulatory authority over select combustible and noncombustible tobacco products (ie, cigarettes, chewing tobacco), and the final deeming rule issued by the FDA in 2016, extended the agency's regulatory authority to all tobacco products (ie, little cigars and cigarillos, e-cigarettes, and any nicotine-containing product derived from the tobacco leaf).^{6,7} Under the Tobacco Control Act, the FDA has authority to regulate tobacco products and to educate the public, with a focus on communicating the risks of tobacco consumption.⁶

To inform the FDA's regulatory approaches related to tobacco manufacturing, marketing, and sale, it is critical to understand culturally specific views of the trustworthiness of the agency's role through the lens of vulnerable populations, particularly Blacks/African Americans. To date, research on awareness and trust in the FDA's role as a tobacco regulator has focused on predominantly white population samples.⁸⁻¹¹ In a focus group study with 41

US adults (24% self-identified as Black), Jarman et al⁸ found that most participants were unaware of the FDA's authority to regulate tobacco and expressed only partial trust in the FDA. Additionally, in a nationally representative survey of 4758 US adults (19.6% self-identified as Black), Schmidt et al¹⁰ found that credibility perceptions of the FDA were higher among white respondents as compared to Black respondents.

Whereas the trust gap indicated by the Schmidt et al study is not surprising, it does highlight the need for additional studies to describe the specific sources of distrust and to identify promising pathways for improving the perceived trustworthiness of the FDA among Black Americans.¹⁰ Therefore, we conducted a qualitative study in Los Angeles, California, among Black community stakeholders employed in local organizations servicing a predominantly Black clientele. For the purpose of this paper, Black community stakeholders are defined as those with a vested interest or personal stake in activities that affect Black Americans residing in Los Angeles. Qualitative research (eg, focus group discussion) can lead to in-depth understanding of the phenomenological experiences of members of a community.¹² Engaging community stakeholders has become a hallmark of "best practices," in public health.¹³ We sought to explore awareness of the FDA's tobacco regulatory role among Black stakeholders as well as the perceived trustworthiness of the FDA.

METHODS

Study Setting

Los Angeles is the second largest city in the US with a population of over 4 million people.¹⁴ Black Americans account for 9% (360,000) of Los Angeles's population.¹⁵ In recent years, the prevalence of current (past 30 days) cigarette use among adults in Los Angeles mirrored the statewide prevalence, at 11.7%; yet, the prevalence of current smoking among Black men and women in Los Angeles was 32.1% and 19.6%, respectively.¹⁶

Participant Recruitment and Data Collection

The target population of this study was Black stakeholders working in Los Angeles-based organizations that serve a predominantly Black clientele. Purposive sampling was used to recruit Black stakeholder representatives from 5 sectors – health, media, business, faith-based, and education to participate in 2 focus groups in Los Angeles.¹⁷ Staffers at the lead author's institution, along with staffers at Healthy African American Families, a Los Angeles-based non-profit organization, identified prospective participants, and snowball sampling was used to recruit additional prospective participants. Once the target sample size (N = 23) was reached, participants were randomly assigned to one of 2 focus groups.

After providing informed consent, participants completed a brief questionnaire covering demographic information and questions about the FDA. Focus group discussions were held August 2014 and moderated by the second and third authors (KCAB and RNB). The study used an interview guide approach to extract narratives about the stakeholders' (1) awareness of the FDA's tobacco regulation authority; and (2) views of the trustworthiness of FDA's authority, including to provide accurate tobacco product information.¹² Focus group

discussions were digitally recorded and ranged in length from 90 to 120 minutes. Participants received a \$75 gift card for their time in the focus group.

Data Analysis

The focus group discussions were transcribed verbatim, edited to remove personal identifiers, and uploaded into NVivo 10.0 software package.¹⁸ The foci of the study's analysis were responses to questions about overall knowledge of the FDA, awareness of the FDA's role as a tobacco regulator, and views of the trustworthiness of FDA's role: "What do you know about the FDA?" "Are you aware of the FDA's role as a tobacco regulator?" "Do you think people in your community are aware of the FDA's role as a tobacco regulator?" and "What are your thoughts about trusting the FDA to give accurate information about tobacco regulation?" along with a probe, "How can trust in the FDA be improved?"

Thematic analysis methods were used to analyze the data. First, the lead author (SLS) read the transcripts multiple times to become familiar with the data.¹⁹ Then, open coding was used, in which, initial impressions of the data were documented, and broad codes were applied systematically to all passages of text relevant to awareness of the FDA's role as a tobacco regulator and views of the trustworthiness of FDA's role. Sample codes included, "aware of FDA regulating tobacco" and "FDA needs to be more visible." The next phase of analysis, axial coding, involved writing analytical notes to document interpretations of the codes created during the open coding phase and the relation of these codes to the study's objective. Lastly, selective coding was used, in which sample codes were integrated around a core theme (eg, trustworthiness of the FDA) and sub-theme (eg, limited technical capacity and competence). All quotes are provided verbatim, and we have provided pseudonyms to protect the confidentiality of participants.²⁰

RESULTS

Participant Characteristics

Stakeholders were 23 self-identified Black Americans (78% female) who ranged in age from 20 to 60 ($M = 45.39$, $SD = 10.79$). Five (21%) reported current cigarette use. Fourteen (61%) stakeholders reported being aware that FDA can regulate tobacco products and 6 (26%) reported working in tobacco control. Most (74%) of the sample reported that there are far too many, or too many tobacco retail stores in their community. Table 1 presents characteristics of the total sample.

Knowledge of the FDA and Awareness of Tobacco Regulation Role

Focus group narratives were replete with accounts of stakeholders knowing the FDA has authority to "regulate" or "oversee" the agricultural and pharmaceutical industries. Pamela noted: "They [FDA] regulate drugs." Similarly, Cicely stated: "I know they [FDA] regulate medications and items that consumers consume in terms of eating and application." To assess awareness of the FDA as a tobacco regulator, the moderator asked stakeholders if they were aware that the FDA also regulates tobacco. Most stakeholders stated that they were aware of the FDA's role, but some were unaware. For example, Karen declared: "I know nothing about this topic." When asked by the moderator, "Do you think people in your

community are aware of the FDA's role as a tobacco regulator?" most stakeholders uttered "No," with Stephanie chiming in: "I'm in the media and I haven't seen much of discussions or any reporting on that [FDA's tobacco regulation authority]." Echoing this perspective, Tiffany, a tobacco control specialist, reflected on how her clients are unaware of the FDA's role:

I work in health, in African-American health, and clients that are enrolled in our program who are trying to live healthier lives weren't aware of a lot of the new FDA regulations. A lot of what we do determine whether our clients are currently smoking and what they are smoking and how much they are smoking and how long they been smoking. So, in relation to just the general community that we work in, most people aren't aware [of the FDA's role as a tobacco regulator].

Trustworthiness of the FDA as a Tobacco Regulator

The stakeholders in our sample engaged in lively discussions about their views on the trustworthiness of the FDA to regulate tobacco, including, to give the public accurate information about tobacco products. Across the focus groups, stakeholders repeatedly expressed distrust in the FDA's role. Our analyses indicated that they articulated 4 main contributing factors to their distrust: (1) that the FDA is influenced by the tobacco, agricultural, and pharmaceutical industries; (2) that the FDA is influenced by money and politics; (3) that the FDA is a bureaucracy exercising monopoly and power; and (4) that the FDA lacks technical capacity and competence to regulate tobacco products.

Tobacco, agricultural, and pharmaceutical industries' influence.—Recurrent across the focus groups was the perceived link between distrust in the FDA's tobacco regulation authority and the influence of tobacco industry lobbying efforts. Some stakeholders questioned why the FDA is now regulating tobacco. In a discussion about the trustworthiness of the FDA's role, Jason asked: "How come the FDA has never been involved [regulating tobacco] before [passage of the Tobacco Control Act]?" Robin uttered: "The tobacco industry is very powerful." Martin chimed in: "They [tobacco industry] have the lobbyists on Capitol Hill that help underfund agencies or have agencies in their best interest." Stakeholders described a continuum of trust (ie, complete trust, partial trust, distrust) in the FDA to disclose tobacco product ingredients. For example, Deborah stated: "I trust that they give us the ingredients." Glenn articulated partial trust, noting: "I trust them maybe to tell me the ingredients that are in cigarettes." Yet, Wendy articulated distrust, explicitly stating: "No, I don't trust them to tell us the ingredients." In addition to the tobacco industry, much of the distrust in the FDA expressed by stakeholders across the focus groups, was linked to their perceptions of the agency's role in regulating the agricultural and pharmaceutical industries. Chief among these discussions were concerns about the FDA overseeing the distribution of genetically modified foods. Related fears contributed to distrust in the FDA to provide accurate tobacco product information. Typical were the sentiments of Karen, who perceives that the FDA has a history of deception:

I don't trust an agency [FDA] that would allow for genetically engineered food to be issued for human consumption. I just don't believe in the agency [FDA]. I don't

trust them [FDA]. So, why should we trust what they [FDA] say about tobacco and those kinds of products, because they [FDA] are lying for all these years?

Similarly, Joel stated: “I don’t trust you [FDA] with my food and my drugs.” Demonstrating the perceived link between distrust in the FDA and pharmaceutical product advertisements, he remarked:

They [drug advertisements] are like, “This drug will help you with restless knee syndrome. ” The music playing in the background...and then, “You can get nosebleeds, you can pass out, high blood pressure, hypertension.” All these things come along with it [advertised drug], and you’re like, “Wait a minute, how did this [advertised drug] get approved? How is this [advertised drug] approved for sale?” You know, so it’s right here in our faces that they [FDA] are doing this.

According to Joel, the FDA is openly deceiving the public about product harm. Echoing this viewpoint, Anita described how her trust in the FDA has declined as she aged. She reflected:

I remember when I was younger, I used to trust “FDA approved” and now I feel like there is always something coming out about, ok, “This harmful side effects,” and later on it [advertised drug] will say, “FDA approved” maybe in January, but by August, there is a lawyer on TV going “If you have taken this drug there is a lawsuit.” So, I don’t trust it [drug advertisement] anymore. Honestly... FDA...I couldn’t tell you what they [FDA] do at this point.

Two stakeholders, however, did not share this perspective. Tiffany explained: “They [FDA] have identified problems over time that they [FDA] have taken off the market. So that is a good thing. They [FDA] could have left them [harmful products] on the market and people could still be dying or being injured. So, that’s a good thing.”

Money and politics.—The second contributing factor to distrust in the FDA’s tobacco regulatory authority, was the notion that money and politics influence the FDA’s regulations. Perceptions that the FDA benefits financially from the industries it regulates were common, as Jason opined: “They [tobacco industry] are going to grow tobacco to make a profit and the government is going to make their money.” Regina affirmed with: “Deep pockets...that’s pretty much what we deal with living in the world today. It’s all about money. That’s why it comes right back to can you really trust them [FDA]?” Additionally, several stakeholders were vocal in endorsing the perception that industries regulated by the FDA have extensive political power. According to Deborah, the political power of the tobacco, agricultural, and pharmaceutical industries should not outweigh the FDA’s mission. She declared: “They [FDA] should have the community’s [Black] best interest, the health more in mind, as opposed to the politics of it.” Other stakeholders described the FDA as “underfunded” and how regulated industries are exempt from accountability because of their political lobbying efforts. A discussion in which Calvin posed this question best exemplified stakeholders’ perspective on this theme: “Who’s in charge? Who’s really regulating? Who’s benefiting?” He responded: “Obviously, the corporations can get away with all of these things because they do help the lobbyists on Capitol Hill that help underfund agencies or have agencies in their best interest.”

Bureaucratic monopoly.—Recurrent across the focus groups were discussions about the FDA bureaucracy exercising monopoly and power. Several stakeholders described the FDA as “powerful” and as a “giant bureaucracy,” and thus, contributing to their distrust in the agency. When probed by the facilitator to speak more about the FDA being perceived as a “very powerful organization,” Monique remarked that the FDA has used its power to deem potentially harmful products as “FDA Approved.” She explained: “They [FDA] allow things [products] to be put on the market that maybe shouldn’t be on the market. So, going on with the power, they [FDA] are the ones who are determining what’s right, what’s not.” Other stakeholders perceived the FDA as biased in favor of corporations. Will summarized the issue this way:

It’s [FDA] also a giant bureaucracy that is very difficult for innovators or small startups to get their products approved, and in many, many cases, they [FDA] seem to be working with major corporations and favor major corporations more than small businesses.

Will’s comments suggest that the FDA’s product approval process operates in favor of corporations, and as an impediment to entrepreneurs and small businesses.

Limited technical capacity and competence.—The fourth contributing factor to distrust in the FDA’s tobacco regulatory authority was a perceived lack of technical capacity and competence in the agency. Typical of the conversation was one in which a stakeholder declared that the FDA lacks the financial capacity necessary to work with the Black community to enforce tobacco product regulations. Robin stated: “I think there needs to be more of a collaborative partnership, but the FDA’s capacity, they don’t have the capacity to do that. They [FDA] don’t have the money.” Echoing this viewpoint, Pamela stated: “So yeah, it [regulatory enforcement] sounds like a contradiction because they [FDA] can’t possibly handle it [regulatory enforcement].” Other stakeholders described tobacco product regulation as a “broad-based” issue, and questioned the FDA’s staff capacity, and overall competence to enforce compliance. For example, Vince remarked to the group:

Who’s going to be watching from the FDA? Can they tell us who are they going to send out to regulate because... You can tell me this is the rule, and this is the law, but in my own neighborhood, I know no one is going to tell on me and I’m going to do what I want to do. FDA [waves hand to show a form of dismissing]... Who cares? They’re in Washington [DC].

Vince’s comments suggest that because the public is unaware of the FDA’s tobacco regulatory enforcement process, and the staff members charged with implementation, compliance with regulations may be ineffective at the community level, particularly in Black neighborhoods. Asked by the moderator if he would want the FDA to “explain how they are going to enforce these regulations,” Vince answered: “Yeah. What is the mechanism put in place to watch how it’s [regulatory enforcement] going to be done?”

Actionable Strategies for Improving Trust

In response to repeated expressions of distrust in the FDA’s tobacco regulatory role, the focus group moderators probed the stakeholders on questions of how and in what way can

the FDA improve their trust in its tobacco regulatory role. Discussions centered around 3 key strategies: (1) that the FDA should have greater product transparency; (2) that the FDA should have a stronger public visibility; and (3) that the FDA should have greater representation of Black people and other people of color at the decision-making level. When the moderator asked: “How can the FDA improve trust?” across the focus groups, stakeholders discussed how greater transparency about tobacco product ingredients is needed for consumers to make more informed choices and sustainable decisions. Wendy summed up the issue this way:

A lot of times you don’t know what the hell the ingredients are, so if they [FDA] were to list this ingredient actually does this to your body it might have a different effect because you read something, and you say, “Ok, I don’t know what that is, I’m still going to smoke my cigarette.”

Wendy’s statement suggests that cigarette constituents labeling is unclear and may facilitate distrust in the FDA’s tobacco regulatory role among smokers. Her statement also suggests that smokers may opt to reduce their cigarette consumption if warning labels on cigarettes listed the adverse medical conditions inherent to the constituents.

Additionally, perceptions that the FDA should increase its visibility were also common, as Aubrey remarked: “You know...they [FDA] could be more visible, and not just come out when there is a crisis but be more transparent and visible when there is not a crisis.” Furthermore, some participants also perceived that the FDA lacks diversity in its employees, as Tiffany opined:

I would imagine that if you were to look at the employees of the FDA in particular those working in tobacco you’ll find that there’s not a lot of African Americans working there or people of color. So, they need to have more people of color on the decision-making level, at the top, not just out in the trenches, or out in the field all the time. So, that could make a difference, so that they [FDA] are giving a broader input and information from communities and people who lived it, growing up in it, and around it, rather than just what they think is good for people of color or poor.

Tiffany’s narrative suggests that Blacks and other people of color should occupy more managerial roles and fewer service-related roles at the FDA, and that their experiences would benefit the FDA’s mission to protect the public’s health.

DISCUSSION

This study contributes insights into both awareness of and trust in the FDA’s tobacco regulatory authority among a sample of Black community stakeholders in Los Angeles. Awareness of the FDA’s tobacco regulatory authority was common among the stakeholders in our sample. However, there was consensus across the focus groups regarding the perception that the Black community overall in Los Angeles is unaware that the FDA regulates tobacco. This is a troubling finding, given that nearly a decade has passed since the passage of the 2009 Tobacco Control Act. This is also a consistent finding in qualitative and quantitative research^{8,10,21} on public awareness of the FDA’s tobacco regulatory authority. However, the stakeholders in our sample described a perceived lack of media coverage of the

FDA's role, and situational factors (eg, whether the Black smokers they provide cessation services to were aware) that informed their perceptions. These findings suggest possible avenues for intervention, including but not limited to increasing awareness of FDA's role in tobacco campaign messages targeted at Black communities. FDA-sponsored messages could also counter the tobacco industry's lengthy history of subjecting Black communities to targeted marketing strategies.²²⁻²⁴

The stakeholders in our sample revealed that the trustworthiness of the FDA to regulate tobacco is a nuanced and complex notion. Stakeholders described a continuum of trust in the FDA to disclose tobacco product ingredients, which included complete trust, limited trust, and total distrust. However, distrust in the FDA's role was overwhelmingly common among the stakeholders, and contributing factors ranged from perceptions of the FDA's regulatory authority of the agricultural and pharmaceutical industries, to incompetence to regulate tobacco products. The stakeholders also indicated that perceptions of the cons of bureaucracy (ie, industry bias) and expectations of industry lobbying power in tobacco product regulation, contributed to their distrust of the FDA to provide accurate tobacco product information. Such findings are disconcerting, as distrust may negatively impact how the FDA's tobacco campaigns and regulations are received by Black Americans. Future research is needed to examine how determinants of trust and distrust in the FDA's tobacco regulatory authority influence tobacco product risk perception. Furthermore, some stakeholders expressed ambiguity and misunderstanding in not knowing the FDA's tobacco regulatory inspection and enforcement procedures. This finding suggests that trust in the FDA among Black stakeholders may improve if they were educated on the agency's regulatory role, and inspection and enforcement process.

Expectations of a lack of diversity among the FDA's leadership team were described in the focus groups. The Equal Employment Opportunity Commission (EEOC) report on the federal government workplace recently identified the need to increase racial/ethnic diversity among the Senior Executive Service [SES], as Black Americans represent 8% and Latinos less than 4% of the SES.²⁵ Across the focus groups, stakeholders suggested greater racial/ethnic diversity representation in the FDA's leadership and described how the agency could benefit from the intersectional experience of Blacks, Latinos, and individuals from a low socioeconomic group. Such distinct experience may help influence and carry out tobacco regulatory policies that impact communities, thus building stakeholders' trust in the FDA. Furthermore, greater disclosure of product information and increased visibility, were also cited across the focus groups as actionable strategies to improve trust in the FDA. These findings suggest that involving Black stakeholders in the FDA's tobacco regulatory processes may increase both awareness and trust in the agency's role.

Limitations

Our study has several limitations. The sampling methods (purposive and snowball) and qualitative methods employed limit generalization beyond the study's sample and geographic location. Another limitation is that the focus group setting may have prompted stakeholders to convey more socially desirable norms. For example, we found no differences in comments between stakeholders who were smokers compared to non-smokers.

Conducting group interviews with smokers and non-smokers separately may provide information that these 2 groups may not want to express in a mixed group. Notwithstanding, the current study contributes to advancing knowledge about public awareness and trust in the FDA's tobacco regulation authority. We are not aware of prior qualitative or quantitative studies on this topic that have focused on the experiences of Black community stakeholders. This study demonstrates that qualitative methods are important to investigating and understanding the viewpoint of groups that are both influential and affected by tobacco-related health disparities. This is notably the case for Black community stakeholders, whose voices and experiences have been practically invisible in the tobacco regulatory science literature.

Conclusions

Whereas Black community stakeholders are aware of the FDA's tobacco regulatory authority, the Black community overall in Los Angeles may not be. Given the overwhelming distrust expressed by Black stakeholders towards the FDA's role in regulating tobacco products, Black stakeholders may be unreceptive to the FDA's tobacco-related communication and education; they may also represent a challenging target population for specific tobacco regulatory efforts. Thus, actionable strategies for improving trust are warranted.

IMPLICATIONS FOR TOBACCO REGULATION

Our study highlights underlying dimensions of awareness and trust in the FDA as a tobacco regulator among a sample of Black stakeholders in Los Angeles. Although most stakeholders were aware of the FDA's tobacco regulatory authority, perceived distrust in the agency was common and may need to be considered in FDA-sponsored messages directed towards this population. Some stakeholders expressed ambiguity and misunderstanding in not knowing the FDA's tobacco regulatory inspection and enforcement procedures. Educating and informing Black Americans on the FDA's role and its regulatory processes, our research suggests, may lie somewhere between improving trust in the agency among Black stakeholders and challenging the factors that shape their distrust; and engaging stakeholders in the development of a culturally-specific communication campaign to increase awareness and trust in the FDA as a tobacco regulator.

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Table 1

Characteristics of Focus Group Participants (N = 23)

Characteristic	Total sample (N = 23); N (%)
Age Mean/SD	45.39/10.79
Female	18 (78%)
Male	5 (22%)
Employed in Tobacco Control	6 (26%)
Employed in Business Sector	4 (17%)
Employed in Media Sector	2 (9%)
Past-30-Day Cigarette Use	5 (22%)
Perceive Cigarettes as Very Harmful/Harmful	22 (96%)
Perceive Little Cigars/Cigarillos as Very Harmful/Harmful	19 (83%)
Perceive E-Cigarettes as Very Harmful/Harmful	11 (48%)
Believe That There Are Far Too Many/Too Many Tobacco Retail Stores in The Black Community	17 (77%)
Have Seen the FDA Logo	21 (91%)
Have Heard of The FDA	22 (96%)
Aware That the FDA has the Authority to Regulate Tobacco Products	14 (61%)
Believe Tobacco Retailers are Aware That the FDA Has the Authority to Regulate Tobacco Products	9 (39%)
Would Like to Receive Information From the FDA Regarding Tobacco Control Regulation	12 (52%)