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#### Journal of Cancer Policy

journal homepage: www.elsevier.com/locate/jcpo



## Is the cigarette pack just a wrapper or a characteristic of the product itself? A qualitative study of adult smokers to inform U.S. regulations



Joseph G.L. Lee<sup>a,\*</sup>, Paige E. Averett<sup>b</sup>, Tiffany Blanchflower<sup>c</sup>, Kyle R. Gregory<sup>a</sup>

- a Department of Health Education and Promotion, College of Health and Human Performance, East Carolina University, Mail Stop 529, 1000 E 5th St, Greenville, NC, United States
- b School of Social Work, College of Health and Human Performance, East Carolina University, Mail Stop 505, 1000 E 5th St, Greenville, NC, United States
- <sup>c</sup> Department of Interior Design and Merchandising, College of Health and Human Performance, East Carolina University, Mail Stop 505, 1000 E 5th St, Greenville, NC, United States

#### ARTICLE INFO

# Keywords: Marketing Product packaging Smoking United States Food and Drug Administration Tobacco products

#### ABSTRACT

*Purpose*: In the U.S., tobacco products are now regulated by the Food and Drug Administration (FDA). Litigation has quickly followed. One area of controversy is when a change to the design of the cigarette pack requires approval through FDA's rigorous premarket review process. In this paper, we examine how adult U.S. smokers view the connection between the design of cigarette packs and the characteristics of the cigarettes within.

Methods: Data for this qualitative study came from six focus groups conducted in March 2017 with adult smokers. Two groups consisted of lesbian, gay, and bisexual (LGB) participants; two groups of participants with less than four years of college education; one group of LGB and straight identity; and, one group of the general population. All groups were selected for regional, gender, and racial/ethnic diversity. Participants (n = 33) represented all nine U.S. Census divisions. We conducted constant comparison qualitative analysis utilizing a grounded theory approach.

Results: Participants' views reflected a belief that pack design is clearly a reflection of the cigarettes within and that a change in the pack signaled a change in the cigarettes. However, some participants felt price was the salient characteristic of cigarettes and design mattered more for enticing young people to smoke.

Conclusions: Changes in pack design signal changes to the product for smokers. Pack design and changes to pack design are seen as particularly relevant to new and young smokers. These findings provide support for regulations that require assessment of cigarette pack design changes for impacts on public health.

#### 1. Introduction

Regret at having started to smoke is a nearly universal experience among smokers [1], and over 480,000 adults die early due to smoking annually in the United States [2]. In the U.S., tobacco products, which were less regulated than strawberry jam until 2009 [3], are now regulated by the Food and Drug Administration (FDA). Litigation by the tobacco industry has quickly followed [4]. One area of controversy is whether a change to the design of the cigarette pack requires review by FDA, even if the cigarettes inside are not changed. If package design changes do require review, such changes could need FDA approval under an exacting premarket review standard designed to protect public health [5]. A 2016 federal court decision accepted FDA arguments that a change in quantity of cigarettes in a pack could trigger this review, but rejected arguments that changes to cigarette packaging would require review [4]. More recent FDA decisions show that design

changes remain important to FDA when they alter or affect the product's performance or characteristics [6]. In this paper, we bring the voices of U.S. adult smokers into this debate by exploring what cigarette packaging signals about the characteristics of the product inside the package.

The ultimate outcomes of judicial and policy processes about cigarette packaging are relevant to population health [7]. Tobacco industry documents show careful attention to how cigarette pack design can be used to influence consumers [8,9]. There are clear examples of how cigarette pack design changes have shifted population distributions of smokers. For example, RJ Reynolds created a sleek pink and black cigarette package that was linked with a substantial increase in adolescent female smoking [10], and tobacco industry documents show careful calibration of cigarette packaging to increase smoking among women [11]. Public health researchers have also shown how pack designs are used to convey health risks (e.g., level of tar) by manipulating

E-mail addresses: leejose14@ecu.edu (J.G.L. Lee), averettp@ecu.edu (P.E. Averett), blanchflowert15@ecu.edu (T. Blanchflower), gregoryky17@ecu.edu (K.R. Gregory).

<sup>\*</sup> Corresponding author.

the size of pack design elements and other information (e.g., filter ventilation or "lightness") by using color [12–14].

Industry lawyers, government lawyers, tobacco control advocacy lawyers, and researchers have weighed in on the issue of cigarette packaging being part of, or distinct from, the product. The aim of this tobacco regulatory science-based [15] paper is to address the question: How do U.S. adult smokers view the cigarette pack's visual design in relation to the cigarettes inside the package?

#### 2. Methods

We conducted six telephone-based focus groups with adult U.S. smokers from across the country in March 2017. We used the AmeriSpeak Panel from National Opinion Research Center (NORC) at the University of Chicago. This panel is probability-based and was designed to include households without internet access. From the AmeriSpeak Panel, staff at NORC purposively recruited participants to maximize diversity. We conducted six focus groups: Two groups of lesbian, gay, and bisexual (LGB) participants; two groups of participants with less than four years of college education; one group mixing LGB and straight participants; and, one group with no limitations by sexual orientation or socioeconomic status. Each group was recruited to maximize racial, ethnic, gender, and regional diversity. We focused on LGB participants and participants with fewer years of formal education due to the higher smoking prevalence in these populations [16].

To maximize participation (i.e., to include households with no internet access) and regional diversity, we conducted focus groups by phone. Use of a phone-based focus group opens access to participation to people who could not travel to attend and enhances the geographic representation of the group [17,18]. An experienced staff member at NORC moderated the focus groups, which lasted 60–90 min. Participants received AmeriSpeak "points" for their time. Two authors attended each group to confirm saturation of themes (JGLL, PEA). Audio recordings were professionally transcribed using a smooth verbatim protocol.

We used a semi-structured focus group guide designed to generate thoughts and discussion about the meaning and design of cigarette packs. It included both cognitive and affective responses to the visual design of cigarette packs. The guide was based on a theory-informed framework of the influence of visual product design on consumer behaviors [19] and is available online [20]. There were no visual stimuli in this study. Participants discussed what was salient to them and what they remembered about cigarette packs. For example, we asked participants to describe the pack design of the first cigarette they ever smoked. The guide was piloted in a test focus group comprised of NORC call center staff. We followed a qualitative study reporting checklist [21]. The East Carolina University and Medical Center IRB approved the study protocol (#16-001200).

#### 2.1. Participants

Thirty-three adults aged 22–62 (mean 46, sd = 11.5) participated in the groups. Of these, 29 completed the entire group. Participants filled out a screening survey as part of recruitment. Of the 33, 64% reported female gender, 36% reported LGB identity, 49% White race, 24% Black race, 9% Hispanic ethnicity, 3% American Indian race, and 15% being multi-racial. Almost half (49%) had less than four years of college education, and 18% had no internet access at home. Participants represented all nine U.S. census divisions. Ninety-four percent smoked every day, 58% smoked their first cigarette within 30 min of waking, and 46% usually smoked menthol.

#### 2.2. Analysis

We approached analysis from a grounded theory perspective [22]. Grounded theory allows data to speak on its own and allows concepts to

emerge based on participant views rather than based on existing theory. Analysis of the data was completed via the constant comparison method [23]. This method includes open coding, axial coding, and selective coding. Open coding occurred when the lead analyst (PEA, a professor of social work who specializes in qualitative methodology), with feedback from the team, sorted the data into initial themes and attached a code or descriptor to them. Axial coding occurred next, and the initial themes were reconsidered for potential groupings into larger themes based on overlap and connection. Finally, in selective coding, the team further grouped the data and interpreted it for larger meanings. The team iteratively discussed findings and provided feedback to one another until we reached agreement in the resulting themes. The analysis team included researchers with formal training in consumer behavior. health behavior/tobacco control, and social work. While two members of the team had smoked, none were current smokers. From this process, three final themes were identified: (1) pack design is a reflection of the cigarettes within, (2) change in pack design signals a change in the cigarettes, and (3) price matters to me but visual design can influence others.

#### 3. Results

Adult U.S. smokers in our groups had one of two perspectives about the connection between the visual design of the cigarette pack and its cigarettes. The first two themes, (1) pack design is a reflection of the cigarettes within and (2) change in pack signals a change in the cigarettes, both support the idea that pack design is perceived by consumers to be connected to the cigarettes within the pack. However, these views were not universal, as some participants articulated views aligned with the third theme: (3) price matters to me but visual design can influence others. In this theme, participants indicated that pack design and design changes are less salient influences on their choices than the ability of the cigarette within to provide nicotine at an affordable cost. However, this idea was tempered by the belief that pack design matters more to new and potential smokers (e.g., youth). We did not identify differences in themes between groups.

#### 3.1. Theme 1: pack design is a reflection of the cigarettes within

Much of the discussion focused on how the pack design is a reflection of the cigarettes. Specifically, our participants discussed how color is used as a guide for strength and flavor of the cigarettes.

"You've got your typical Marlboro Reds with the red and white, you've got your 100 s with the gold and white, you've got your lights with like a light gray and white, then, when you get into the menthols, you've got the black and green, the green and white, the black and white. To me, it just helps me identify the difference in the flavors or the styles of cigarette." (Group 1, LGB)

"Well so they did away with like the Reds, the Lights, the Ultralights but the packages have stayed the red, gold and silver and green for menthol so there's no guessing. I mean if you've been around long enough, you know that the red is the hardest cigarette and then there's the lights and you know so it doesn't matter what it's being called at this point. You know it's still the same." (Group 5, lower education)

It was clear that many of our participants believed that cigarette packs were an indication of the type of cigarettes within the pack. As the following quote demonstrates, a simple package signaled a simple cigarette.

"The packaging is simple, the cigarette in and of itself in my opinion is simple, and that's what I get from it." (Group 1, LGB)

The participants often discussed that different pack styles were associated with various cigarette characteristics. In the next quote a

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