Evaluation of Tobacco Nonusers' Intentions Toward an Oral Tobacco-derived Nicotine Pouch Product as the Result of Viewing Promotional Materials

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ABSTRACT

FDA must determine whether a new tobacco product is appropriate for the protection of public health to grant authorization to market a new tobacco product. One of the considerations in this determination is evidence regarding the impact of marketing and advertising (promotional material) on likelihood of using the new tobacco product among users and nonusers of tobacco products. We present here results from a study examining this impact for a portfolio (five nicotine levels and seven flavors) of on!® nicotine pouches, an oral tobacco product containing ingredients that are either pharmaceutical grade or used in food and do not contain cut or ground tobacco leaf. We present here results from nonusers.

A convenience sample of self-reported adult former (n=666) and never tobacco users (n=665), including an oversample of legal age to 24-year-olds (n=690), were assigned to either a (1) full exposure (print marketing materials, front pack shots of on!® products), or (2) reduced exposure (front pack shots) condition. Participants completed a pre- and post-test survey assessing validated measures of intentions to try and intentions to use on! products. Additionally, likelihood to try and use were determined based on positive intentions and a "yes" response to purchase intention.

The pre-test intentions to try the on!® pouch products were between "strongly disagree/very likely" and "disagree/definitely not", across groups and exposure conditions. Additionally, there were no statistically significant differences after exposure to the promotional materials in either condition. A relatively small proportion of nonusers indicated likelihood to try (3.3% to 9.5%) and likelihood to use (3.3% to 9.2%) across conditions. In conclusion, the nonusers had low intentions and likelihood to try and use the on!® products regardless of nicotine levels or flavors with no significant impact of promotional materials.

BACKGROUND

- FDA must determine whether a new tobacco product is appropriate for the protection of public health to grant authorization for marketing a new tobacco product.
- One of the considerations in this determination is evidence regarding the impact of promotional material on likelihood of using the new tobacco product among users and nonusers of tobacco products (Premarket Tobacco Product Application Proposed Rule, FDA, 2019).
- ► We present here results from a study examining this impact for a portfolio of on!® nicotine pouches. on!® is an oral tobacco product containing tobacco-derived nicotine and ingredients that are either pharmaceutical grade or used in food and do not contain cut or ground tobacco leaf. The on!® products are available in five nicotine levels and seven flavor variants (35 total
- Specifically, we present data regarding behavioral intentions (intentions to try and use on!® nicotine pouches) and likelihood (likelihood of trial, and use on!® nicotine pouches) for tobacco nonusers.

CONCLUSIONS

We found nonusers had low intentions and likelihood to try and use the on!® products regardless of the level of promotional material exposure, and that young adults (LA-24) did not appear to have higher intentions than the other adult nonuser subgroups in this study.

STRENGTHS AND LIMITATIONS

STRENGTHS

The current study utilized quota-based sampling to increase the generalizability of results to the adult former users and adult never users of tobacco products in the United States. Additionally, an oversampling of LA to 24-year-olds was conducted to allow for specific analyses with this subpopulation of interest.

LIMITATIONS

- Although participants were able to view the promotional materials as needed throughout the study, one limitation of this study is that participants were only formally exposed to the marketing materials at a single timepoint.
- In the current study, we utilized self-report of behavioral intentions as a proxy for actual behavior to address FDA guidance. Self-reported behavioral intentions and likelihood outcomes may be overinflated and might not reflect actual use behavior. Additional data from actual use studies with adult tobacco users will be important to complement and extend these findings. Additionally, the science could benefit from research exploring the predictive relationship between the ALCS behavioral intention metrics and actual behavior.

REFERENCES

FDA. (2019). Premarket Tobacco Product Applications and Recordkeeping Requirements. Federal Registrar, 84 (186). Retrieved from https://www.federalregister.gov/documents/2019/09/25/2019-20315/premarket-tobacco-product-applicationsand-recordkeeping-requirements

McCaffrey, S., Black, R. A., Plunkett, S. (2020, March). Psychometric evaluation of behavioral intention item functioning across tobacco product categories. Poster presented at the Society for Research on Nicotine and Tobacco 26th Annual Meeting, New Orleans, LA.

Parker Zdinak, P., Black, R. A., Plunkett, S., McCaffrey, S., & Chow, S. (2018, February). Validation of Perceptions and Behavioral Intentions Survey: Psychometric evaluation of tobacco-related behavioral intentions to try, use, dual use, and switch. Poster presented at the Society for Research on Nicotine and Tobacco 24th Annual Meeting, Baltimore, MD.

METHODS

STUDY DESIGN

We used an online survey design where participants were quasi-randomized to either (1) full exposure (print marketing materials, front pack shots of on!® nicotine pouches, website screen shot, health information) (2) reduced exposure condition

consisting of front pack shots

This study included the following

tobacco nonuser groups, where

target quotas were based on the

2018 National Health Interview

Survey across the following

demographics: gender, age,

race/ethnicity, education and

and health information.

PARTICIPANTS

region.

Figure 1. Study Flow Random Assignment Quota-Filled PROMOTIONAL MATERIALS: PROMOTIONAL MATERIALS REDUCED EXPOSURE information, Picture of lineup of products) Picture of lineup of products) SURVEY EXIT QUESTIONS AND DEBRIEF (Demographic questions and debrief)

OR other tobacco products on a consistent basis

Has NOT used any tobacco in the past 30 days

Never used on!® Nicotine Pouch

All of the above OR never tried

Never used on!® Nicotine Pouch

Does NOT use any tobacco "every day" or "some days"

Has not used any tobacco products in the last 6 months

Does NOT use tobacco "every day" or "some days"

Has NOT used tobacco in the past 30 days

STUDY MEASURES

Participants completed pre- and post-test surveys which included ALCS' validated intention metrics (Parker Zdinak et al., 2018; McCaffrey et al., 2020) as well as questions pertaining to purchase intent.

Intention to Try:

3 items utilizing either a 6-point fully-labeled rating scale (1) from "strongly disagree" to "strongly agree" or (2) from "definitely not" to "definitely".

The 3 items were averaged together to generate a composite.

Intention to Use:

4 items utilizing a 6-point fully-labeled rating scale (1) from "strongly disagree" to "strongly agree." The 4 items were averaged together to generate a composite.

Likelihood

Participants were classified as either likely or not likely to try, use, dual use (as appropriate), and switch (as appropriate). Classification of "likely" required a (1) positive endorsement on the corresponding behavioral intention scale (i.e., a score of ≥3.5, corresponding to "somewhat agree" or higher on the response scale) and (2) a response of "yes" to the binary intention to purchase item (i.e., Would you like to buy one of the on!® Nicotine Pouch products now to use?)

Table 1 ALCS Behavioral Intention Scales

Table 1. ALCS Deliavioral intention Scales		
Scale	Item #	Item Content
Intention to Try	Try1	I am open to trying an on!® Nicotine Pouch product in the next 30 days.
	Try2	Based on what you know about on!® Nicotine Pouch products, how likely or unlikely are you…? To try an on!® Nicotine Pouch product
	Try3	Based on what you know about on!® Nicotine Pouch products, how likely or unlikely are you? to try an on!® Nicotine Pouch product if one of your best friends were to offer an on!® Nicotine Pouch product to you
Intention to Use	Use1	I would consider using an on!® Nicotine Pouch product more than once
	Use2	I expect to use an on!® Nicotine Pouch product
	Use3	It is likely that I will regularly use an on!® Nicotine Pouch product in the next 6 months
	Use4	An on!® Nicotine Pouch product will be my regular brand of oral tobacco in the next 30 days

Rating scale: 1=Strongly disagree, 2=Disagree, 3=Somewhat disagree, 4=Somewhat agree, 5=Agree, 6=Strongly

> Paired t-tests were utilized to evaluate whether there were differences in the behavioral intention metrics from pre- to post-test.

▶ Used cigarettes to its lifetime criterion OR smokeless tobacco to its lifetime criterion OR cigars to its lifetime criterion

Never used cigarettes, cigars, or smokeless tobacco to its lifetime criterion NOR other tobacco products on a

Legal age to purchase tobacco in the location of residents, but not older than 24 years old

Met Adult Former Tobacco User or Adult Never User definitions above

ANALYTIC PLAN Descriptive statistics were used to evaluate the percentage of participants who were classified as likely to try, use, dual use, and switch based on the likelihood definition presented above. No statistical testing was conducted.

Figure 3: Likelihood to Try on!® Nicotine Pouches Before and After Exposure to Promotional Materials.

Reduced Exposure

(n=332)

Full Exposure

► A relatively small proportion of nonusers indicated likelihood to try (3.3% to 11.0%) and likelihood to use (3.3% to 10.7%).

► While there were small increases (~1.5%) seen in the proportion of former users and LA-24 nonusers indicating likelihood to

try and use, these increases are not consistent across conditions. Additionally, upon further inspection these participants

The likelihood outcome measures were similar regardless of full or reduced exposure.

were more likely to indicate intention to use other tobacco products at screening.

RESULTS

BEHAVIORAL INTENTIONS

Figure 1: Average Intention to Try Scores in the Reduced Exposure Condition Before and After Exposure to Promotional Materials.

dult Former Tobacc

sers (n=666)

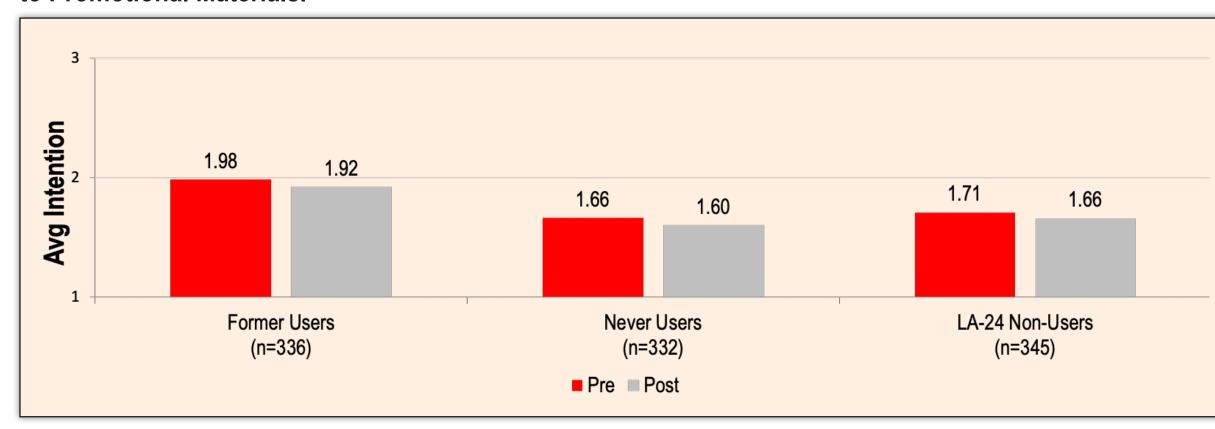
Adult Never Users

Oversample of

onuser Adult Leg

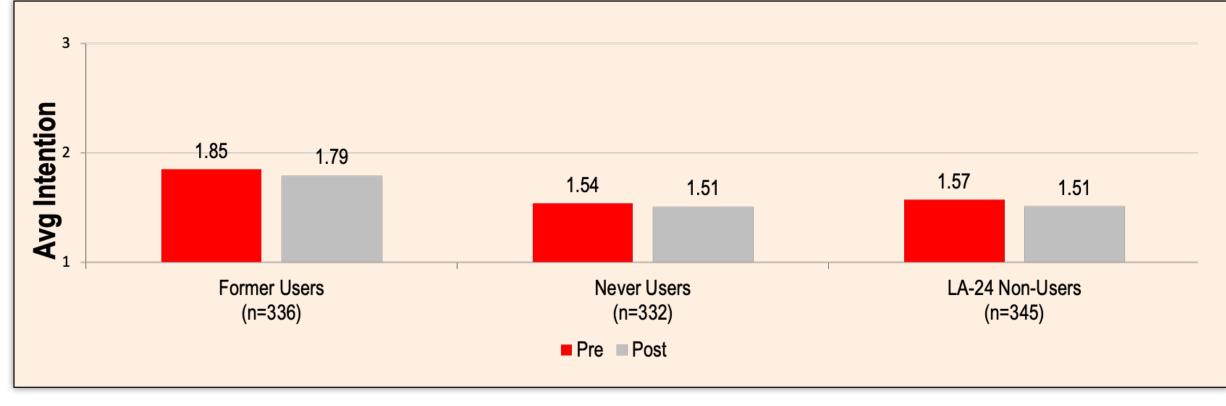
Age to 24-Year-Old

(LA-24) (n=690)



Average pre-test intention to try and use composites generally corresponded to "strongly disagree/very likely" to "disagree/ definitely not" across groups and exposure conditions. There were no statistically significant differences.

Figure 2: Average Intention to Use Scores in the Reduced Exposure Condition Before and After **Exposure to Promotional Materials.**



- There were no statistically significant differences in intention to try and use, following exposure to the promotional materials

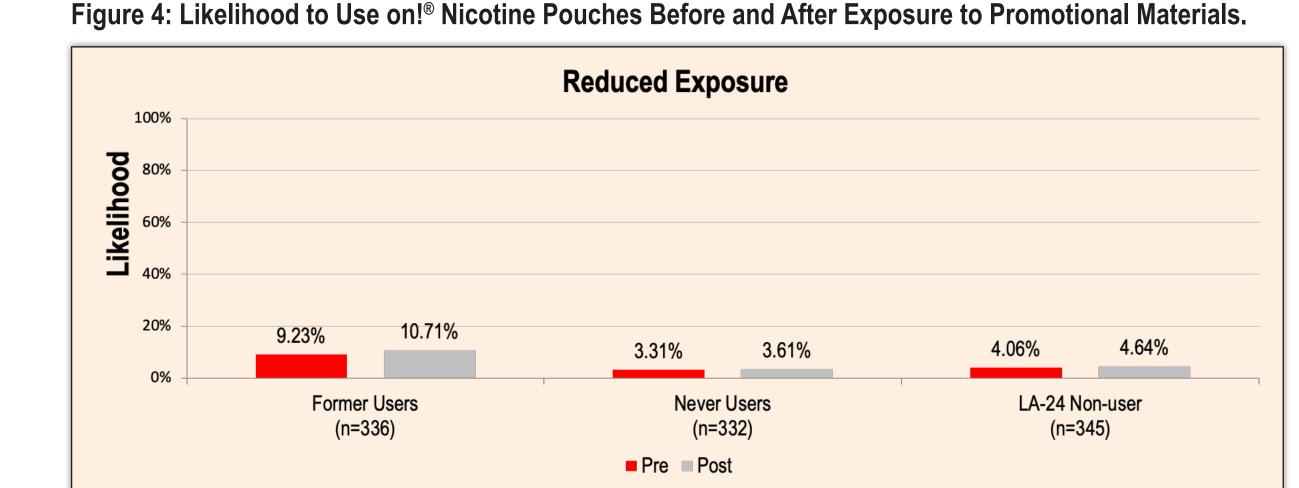
for any of the tobacco nonuser groups for either condition.

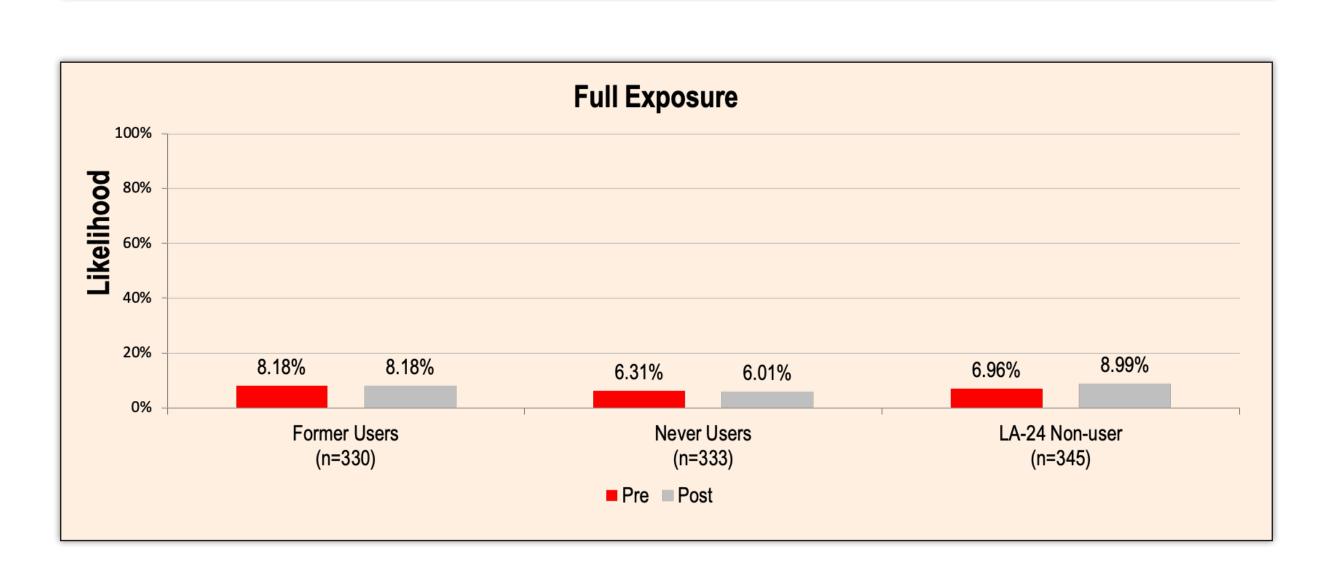
Results were not significantly different across conditions (i.e., based on the amount of promotional material shown). - Since there were no statistically significant differences in intention to try and use in either exposure condition, reduced exposure was shown due to the likely exposure level of the nonusers.

LA-24 Non-user

LA-24 Non-user

Figure 4: Likelihood to Use on!® Nicotine Pouches Before and After Exposure to Promotional Materials.





LIKELIHOOD