# Impact of Proposed MRTP Claims on Behavioral Intentions and Risk Perceptions for the Ploom® System Among U.S. Adults

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#### INTRODUCTION

- The use of combustible tobacco products, such as conventional cigarettes, is a cause of serious disease, while the use of heated tobacco products (HTPs) has the potential to reduce the harm associated with smoking.1,2
- The Ploom<sup>®</sup> System (Ploom<sup>®</sup> heated tobacco device and Marlboro<sup>®</sup> heated tobacco sticks [HTS]) is an HTP intended as a potentially reduced-harm product for U.S. adults age 21+ who smoke and are seeking smoke-free alternatives.
- FDA authorization of modified risk tobacco product (MRTP) claims is informed by understanding how they may affect risk perceptions and behavioral intentions among users and nonusers of tobacco products.
- We conducted an online between-subjects experimental study evaluating the effects of the MRTP claims on risk perceptions and behavioral intentions for the Ploom® System among adults who use and do not use tobacco products.

#### AIMS

To evaluate the effect of MRTP claims on risk perceptions and behavioral intentions associated with the Ploom® System.

#### METHODS

The study included 7,065 US adults (adults who smoke cigarettes [AS], adults who use tobacco products other than cigarettes [not shown], or adults who do not currently use any tobacco products [Former Users, Never Users]). The study oversampled for ages 21-24 (not shown) and included a separate cohort of adults underage to purchase tobacco products, ages 18-20 (Age 18-20 Users [not shown], Age 18-20 Nonusers). Participants were recruited from online consumer panels via email invitation, online advertisements, and in-person intercept, with demographic quotas based on the 2021 National Health Interview Study (NHIS) for gender, age, race/ethnicity, education, and US region.

Participants were randomized to one of three study conditions:

- 1 CONCEPT (n=2356) viewed product concept only (not shown)
- 2 PMTA Promo Bundle (n=2355) viewed product concept and portfolio of promotional materials
- 3 MRTPA Promo Bundle (n=2354) viewed product concept and portfolio of promotional materials with proposed MRTP claim statements

The large sample size provided adequate statistical power for all analyses. The survey contained questions about socio-demographics and prior and current tobacco use behavior, followed by the presentation of study stimuli and post-exposure behavioral intention and risk perception Consumer Reported Outcome Measures, described in more detail in the Results section.

Table 1. Demographics

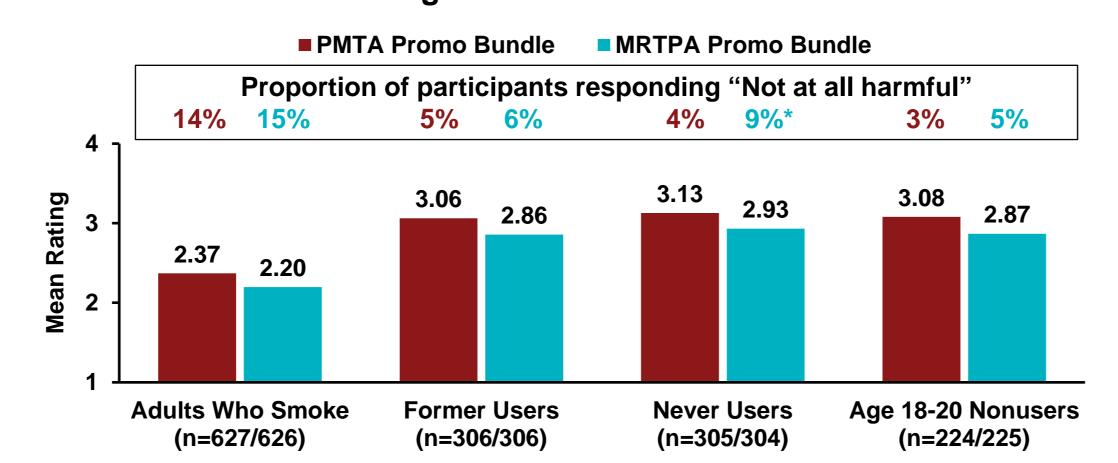
| Table 1. Delliographics |                        |                     |                 |                |                       |
|-------------------------|------------------------|---------------------|-----------------|----------------|-----------------------|
|                         |                        | Adults<br>Who Smoke | Former<br>Users | Never<br>Users | Age 18-20<br>Nonusers |
| N                       |                        | 1253                | 612             | 609            | 449                   |
| Gender (%)              | Male                   | 53.9                | 57.4            | 35.3           | 52.3                  |
| Age (%)                 | 18-20                  |                     |                 |                | 100                   |
|                         | 21-24                  | 5.5                 | 4.2             | 8.9            |                       |
|                         | 25+                    | 94.5                | 95.8            | 91.1           |                       |
| Race/Ethnicity (%)      | White NH               | 56.8                | 72.1            | 54.4           | 50.6                  |
| US Region (%)           | Northeast              | 15.1                | 17 6            | 18.1           | 12.5                  |
|                         | Midwest                | 23.5                | 20.9            | 18.6           | 22.3                  |
|                         | South                  | 35.8                | 36.3            | 38.9           | 41.9                  |
|                         | West                   | 25.6                | 25.2            | 24.5           | 23.4                  |
| Education (%)           | Less than college      | 55.6                | 32 5            | 34.2           | 53.9                  |
|                         | Some/graduated college | 44.4                | 67.5            | 65.8           | 46.1                  |

Notes: Only select subgroups from the overall study are presented here. Adults Who Smoke were inclusive of other tobacco product use.

#### **RESULTS**

# Perceptions of General Harm

• Few participants (3%-15%) perceived the Ploom® system to be not at all harmful after viewing the MRTP claims.

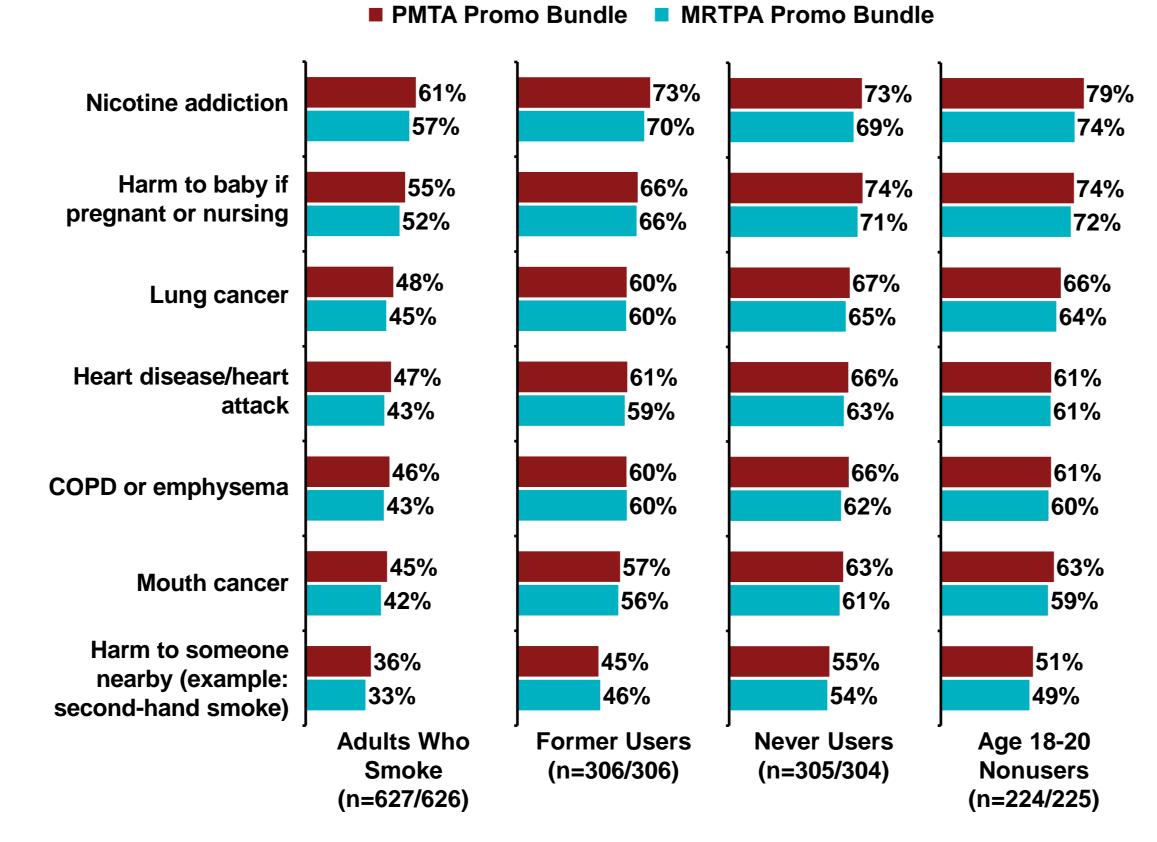


\*Indicates statistically significant difference between conditions at  $\alpha$ =.05

**Question:** How harmful is using Ploom® heated tobacco products to a person's health? (4-point scale; 1 Not at all harmful to 4 Very harmful)

# Risk Perceptions for Tobacco-Related Health Outcomes

- Exposure to the MRTP claims had no statistically significant effect on risk perceptions for tobacco-related health outcomes, but
- Perceptions generally trended lower among participants, particularly adults who smoke, who viewed the MRTP claims than among those who did not.



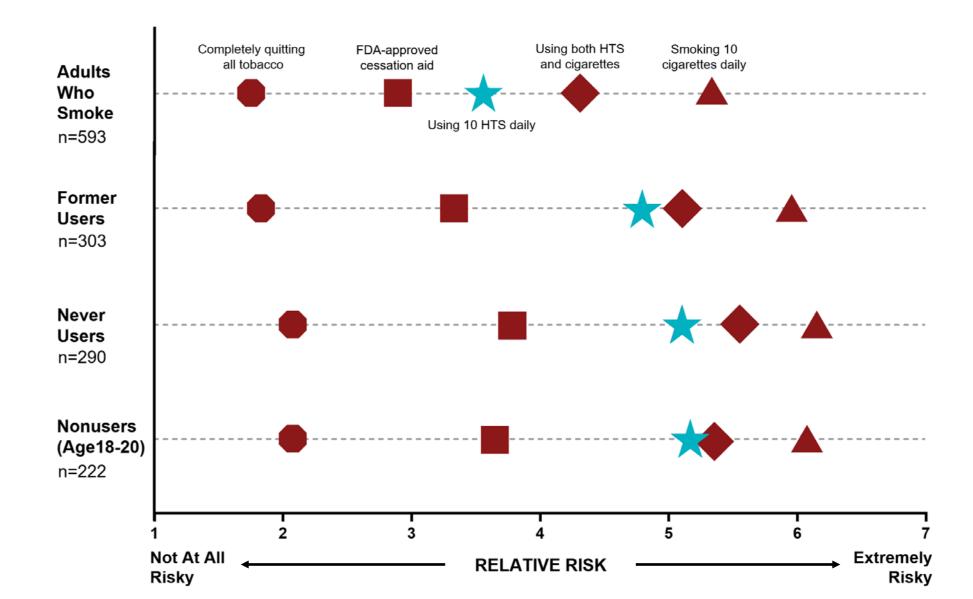
No statistically significant differences between conditions at  $\alpha$ =.05

Question: How likely is it that these things will happen to a person who only uses Ploom® heated tobacco products daily?

(11-point scale; 0% Extremely unlikely to 100% Extremely likely, in units of 10%)

# Relative Risk Perceptions -MRTP Promo Bundle Condition

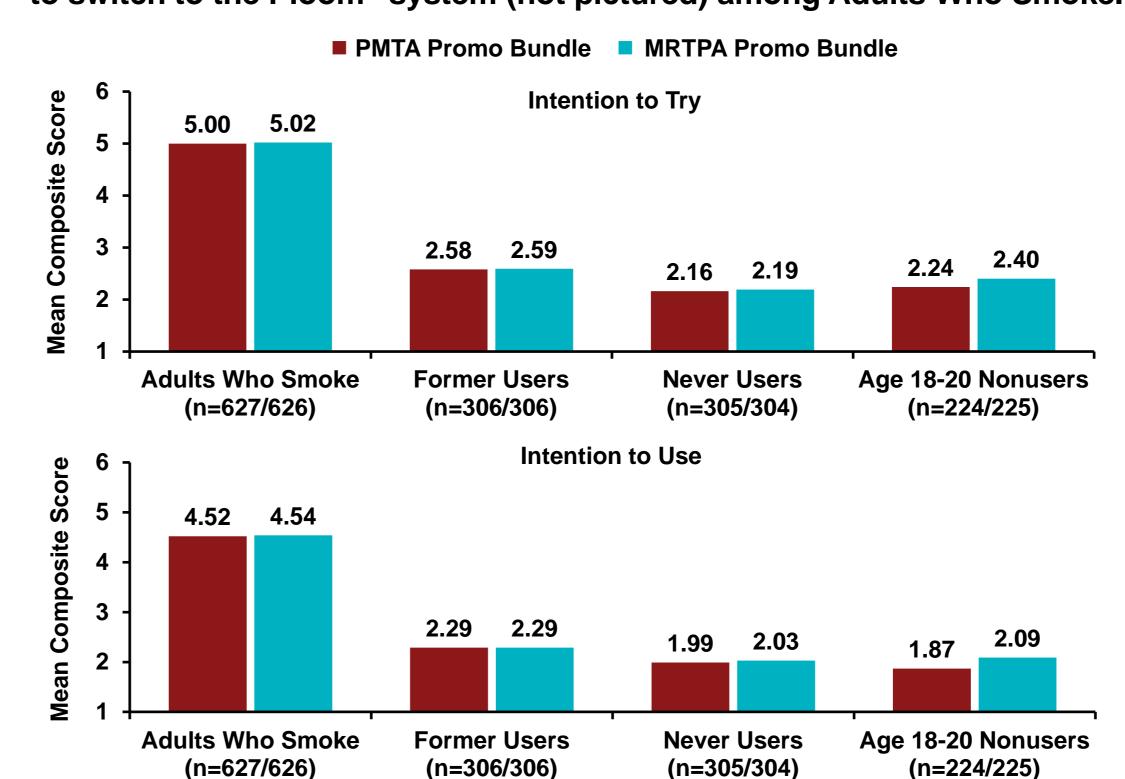
 Those exposed to the MRTP claims perceived the risk of using the Ploom® System to be less than the risk of smoking combustible cigarettes, but greater than the risk of using NRTs and quitting all tobacco use.



Question: Please rate each item for the risk you feel it could pose to a person's health. (7-point scale; 1 Not at all risky to 7 Extremely risky, Don't know)

### Intention to Try and Intention to Use<sup>3</sup>

- After viewing the MRTP claims, Adults Who Smoke indicated high intentions to try and use the Ploom® System, and nonusers had much lower intentions.
- Exposure to the MRTP claims had no statistically significant effect on intentions to try and use among any of the study groups or on intentions to switch to the Ploom® system (not pictured) among Adults Who Smoke.



No statistically significant differences between conditions at  $\alpha$ =.05

#### REFERENCES

- 1. Murkett R, Rugh M and Ding B. Nicotine products relative risk assessment: an updated systematic review and meta-analysis. F1000Research 2022, 9:1225. https://doi.org/10.12688/f1000research.26762.2
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- 3. McCaffrey et al. (2021). Development and validation of behavioral intention measures of an E-vapor product: intention to try, use, dual use, and switch. Health Qual Life Outcomes 19:123. https://doi.org/10.1186/s12955-021-01764-2

#### CONCLUSIONS

The study results suggest that in the context of the proposed MRTP claims, tobacco users and nonusers perceived that the Ploom<sup>®</sup> System is generally associated with some level of risk, including nicotine addiction.

- Tobacco users and nonusers also perceived the risk of using the Ploom® System to be less than the risk of smoking combustible cigarettes, but greater than the risk of using NRTs and quitting all tobacco product use.
- Single exposure to the MRTP claims had minimal impact on risk perceptions.
- **Exposure to the MRTP claims also did** not impact intention to try or use the Ploom<sup>®</sup> System among tobacco users and nonusers.
- While single exposure to the proposed MRTP claims did not have a significant effect on behavioral intentions, repeated exposure to the claims may enhance understanding of the harm reduction potential of the Ploom® system and motivate adults who smoke to switch completely away from cigarettes.

LIMITATIONS: The sample was recruited through non-probabilistic methods (online panels, intercepts, and databases), so quota-based sampling techniques were used to ensure a sample representative of the US adult population on basic sociodemographic characteristics. However, due to a protocol deviation, the Adults Who Smoke group did not align with the quotas on all criteria. The data were weighted, and analysis of the weighted data showed similar results to the unweighted data. Results from unweighted analyses are reported here.



