

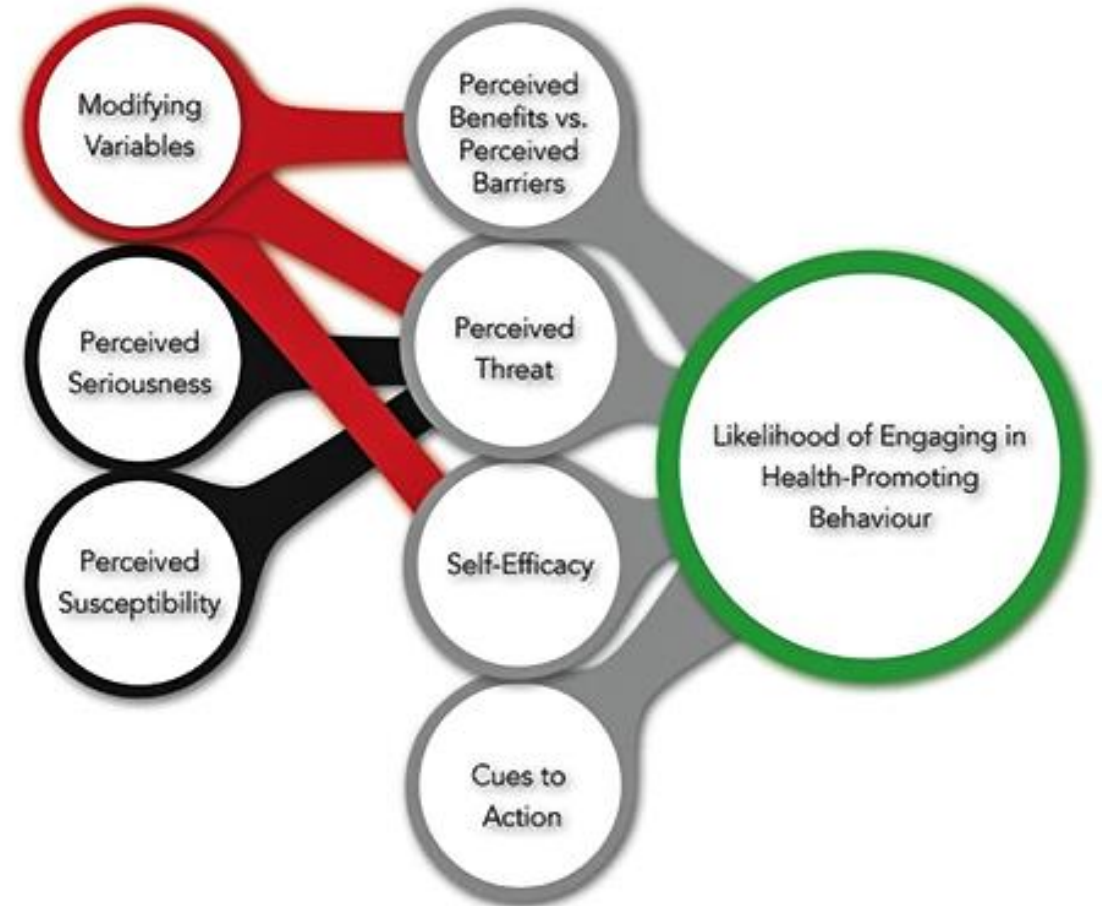
# The Effects of a Modified-Risk Claim for an ENDS Product to Increase Smokers' Behavioral Intentions to Use the Product Are Completely Mediated by the Claim's Effects on Risk Perceptions

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# Why Do We Care About Risk Perceptions?


- Because facts matter
- Because they influence behavior
- Health-behavior models posit causal link between risk perceptions and behavior
- The Modified-Risk provisions in the Tobacco Control Act implicitly assume that link




# Modified Risk Tobacco Product Application (MRTPA) Provisions

- The Tobacco Control Act allows manufacturers to communicate to consumers regarding reduced disease risk [Sec 911g(1)] or reduced exposure to toxicants [Sec 911g(2)], subject to FDA review and authorization (APPH standard)
- For MRTPA, FDA asks applicants to provide data on the effect of the proposed claim on:
  - Behavioral intentions
  - Risk perceptions

# Proposed Reduced Exposure Claim (g2) for JUUL 5% nicotine US product

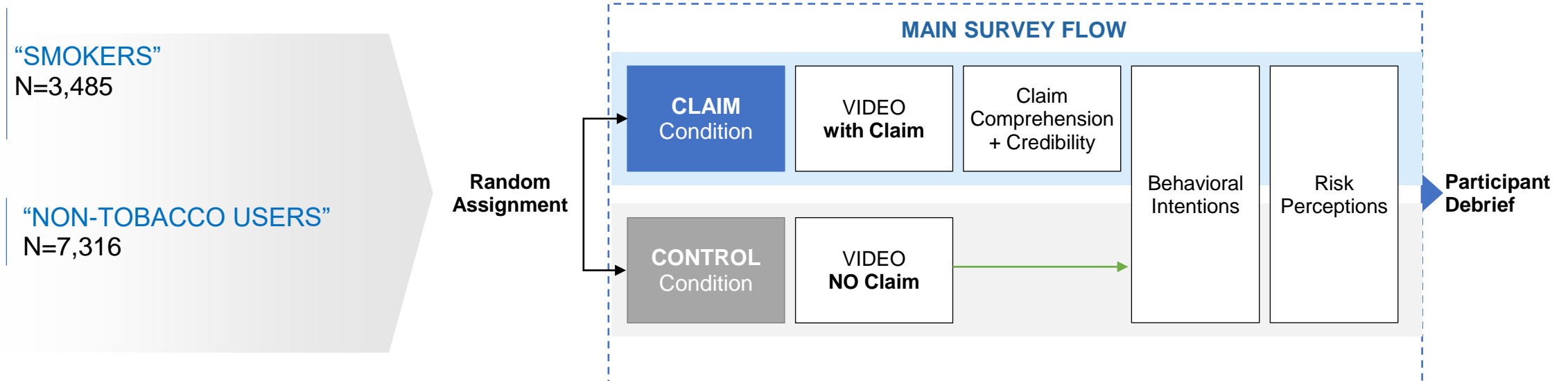


JUUL does not burn tobacco  
or produce smoke



EVIDENCE TO DATE SHOWS:  
Switching completely from  
cigarettes to JUUL reduces  
exposure to harmful chemicals  
in cigarette smoke to you and  
to those around you.

# Claims Testing Overview: Randomized Test

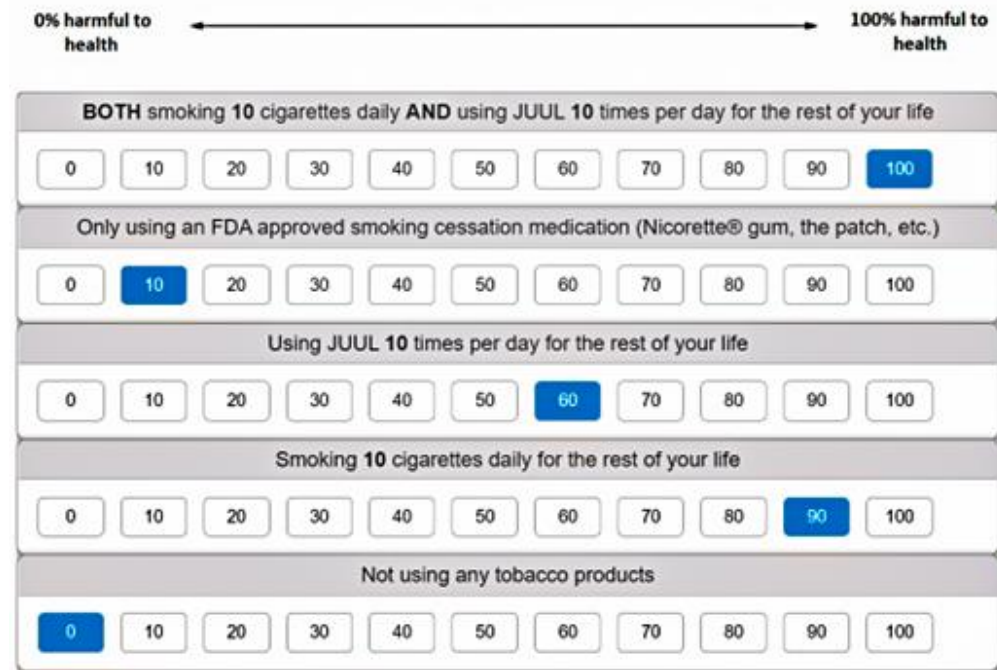


This study was reviewed by an institutional review board (IRB), which determined the study to be exempt from IRB oversight.

# The Claims Testing Relative Risk Rating Task: Indirect Assessment of Relative-Risk Perceptions

- Respondents shown multiple target behaviors (inc. cigarettes and JUUL), in randomized order
- Choose most harmful and least harmful
- Shown list, least harmful at top, most harmful at bottom, rest randomized
- Rate each on 0%-100% scale

Q26. In your opinion, how harmful are these behaviors to your health?



Highest Risk

**COMBUSTIBLES**

**NONCOMBUSTIBLES**

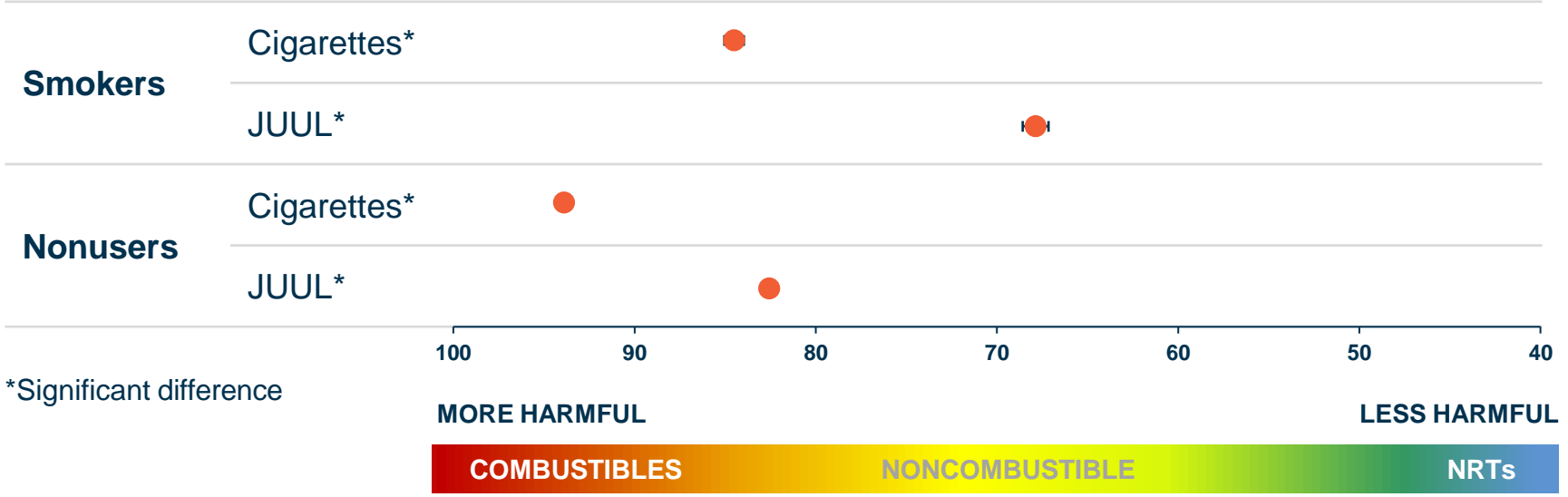
**NRTs**

Lowest Risk

**RISK CONTINUUM**

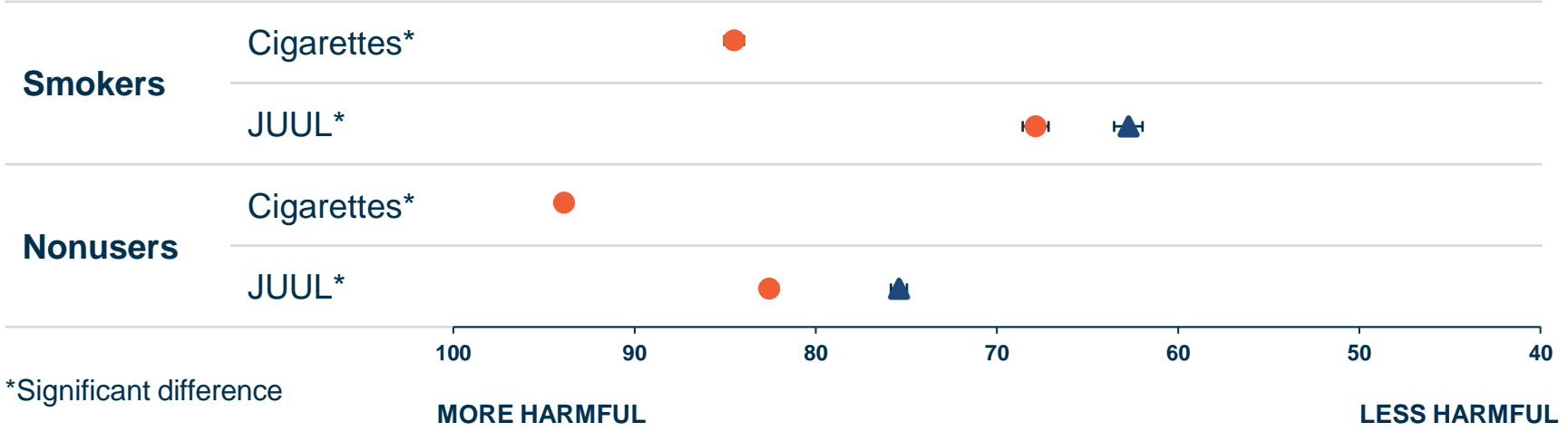
# RELATIVE RISK RATINGS

● Control



# RELATIVE RISK RATINGS

● Control ▲ Message



\*Significant difference

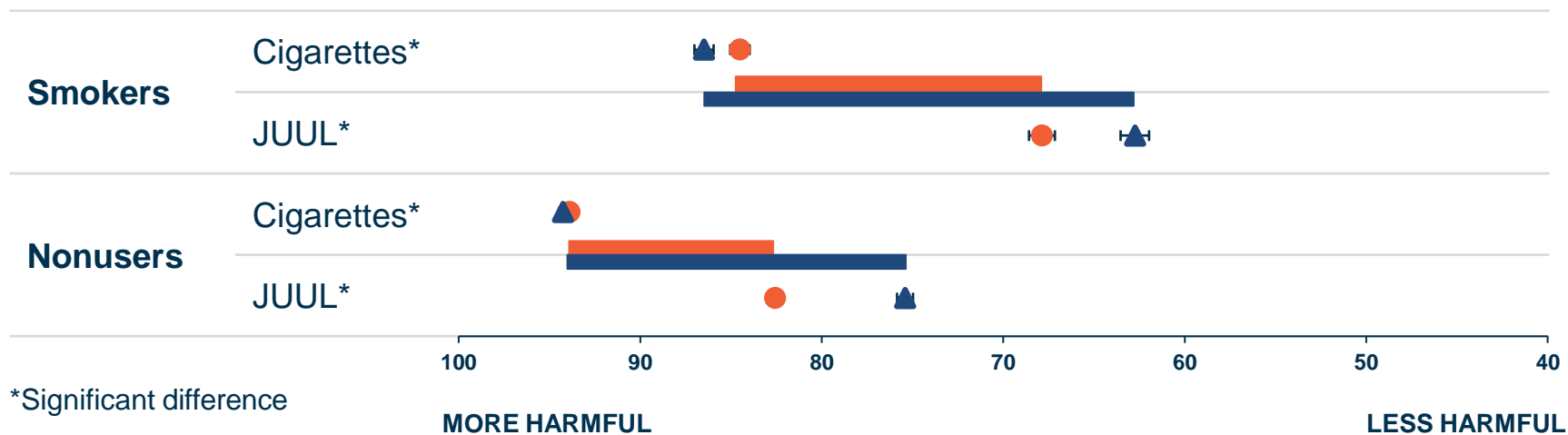
Exposure to the message decreased perceived risk of using JUUL





# RELATIVE RISK RATINGS

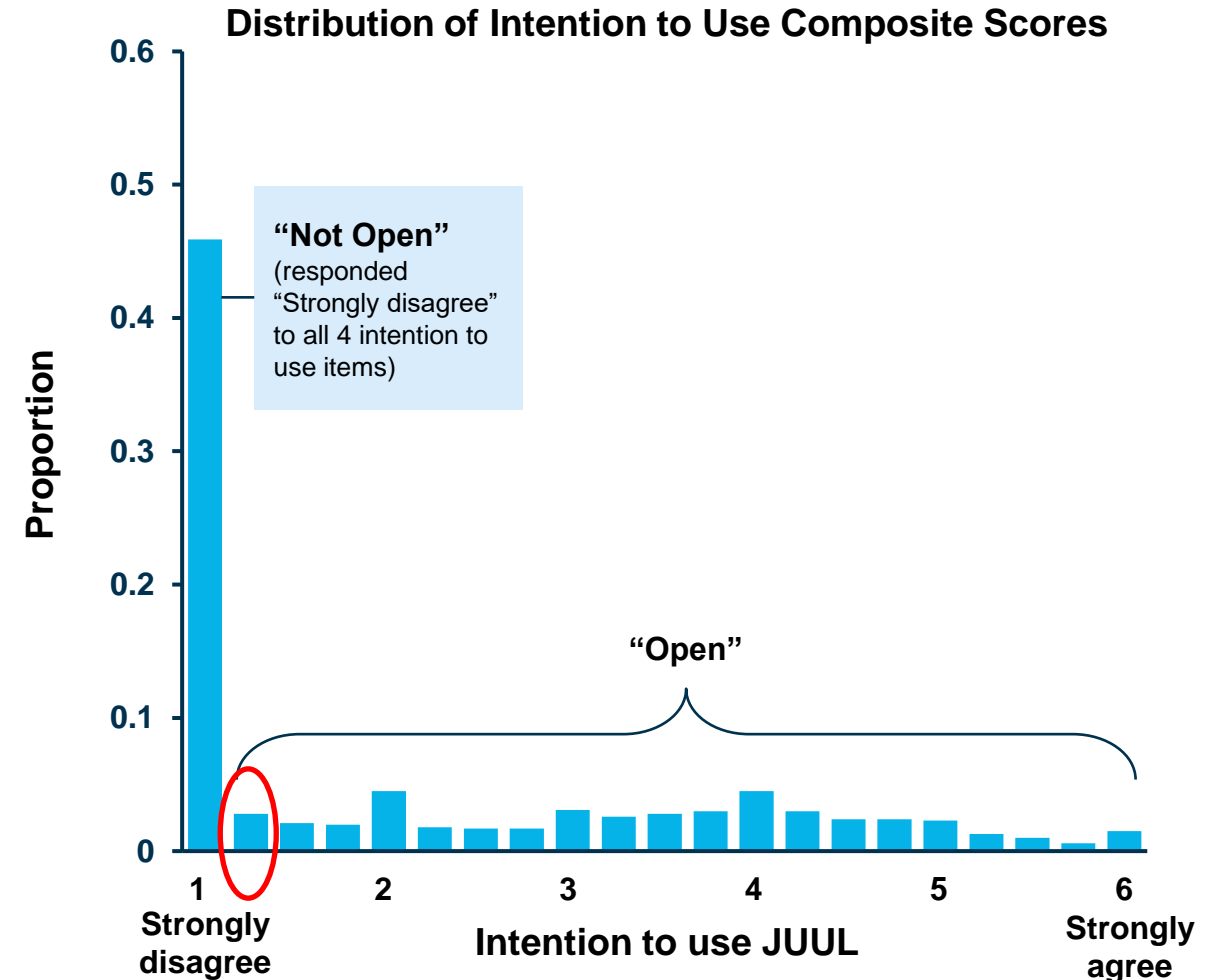
● Control ▲ Message



Exposure to the message increased perceived risk ***differential*** between cigarette smoking and using JUUL

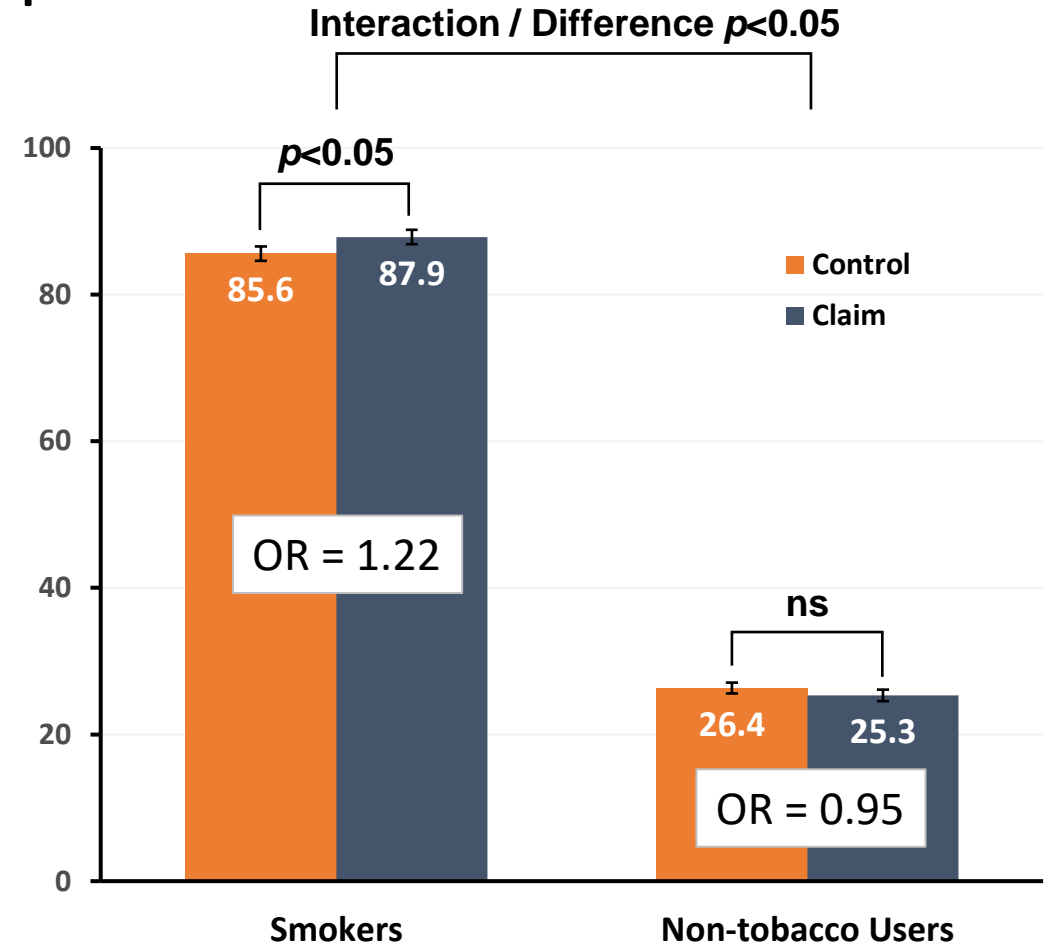
# “Openness to Use” = Absence of Complete Rejection of Use

- **4-item Intention to Use assessment**
- e.g., “I would consider using a JUUL e-cigarette more than once”
  - **Strongly disagree**
  - Disagree
  - Somewhat disagree
  - Somewhat agree
  - Agree
  - Strongly agree
- **“Not Open”** = *Strongly disagree* to all items
- **“Open”** = any response other than *Strongly disagree* to even a single item
- Very low-threshold criterion

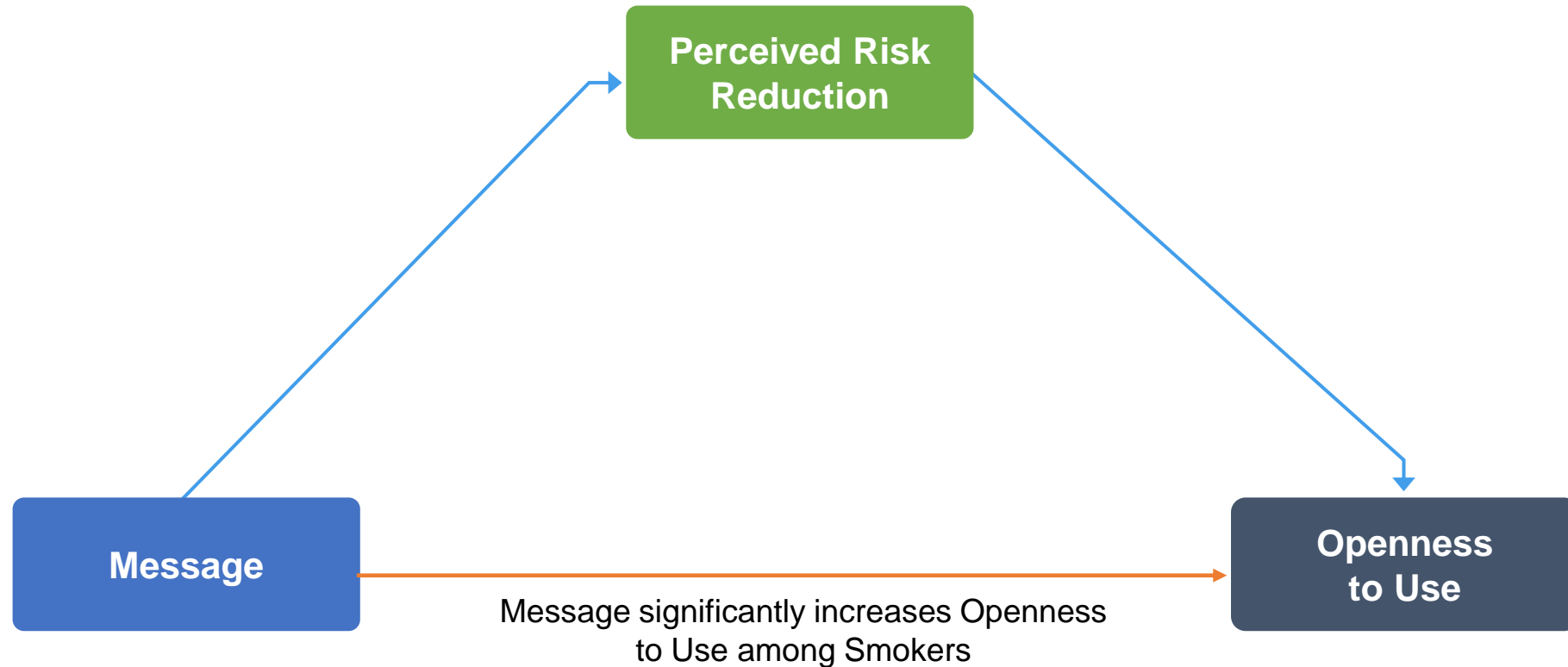


# Effects of the Message Exposure

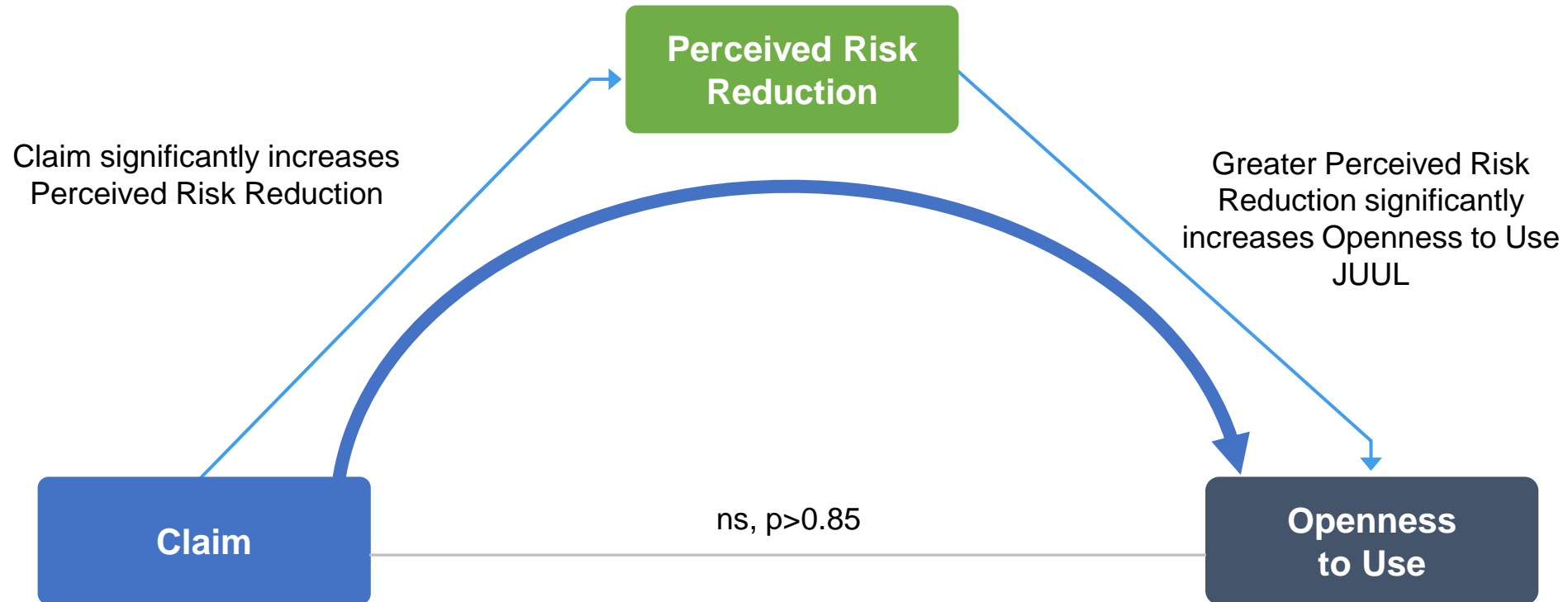
- **4-item Openness to Use assessment**
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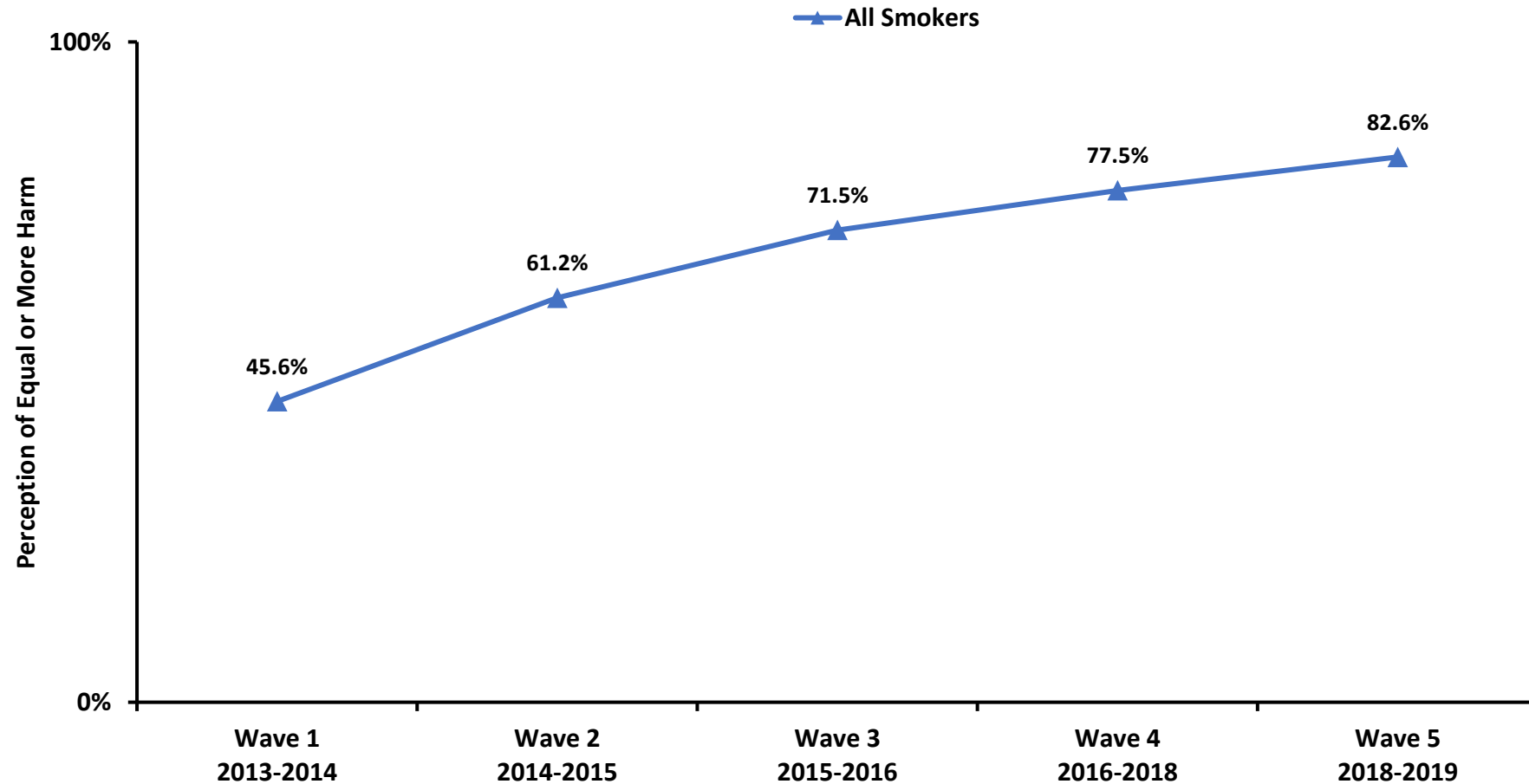


Perceived Risk Reduction completely accounts for the impact of the claim on Openness

# Conclusions

- As posited by theory and assumed by the TCA
- Reduced-exposure (reduced-risk?) communications affect behavioral use intentions ***by affecting risk perceptions***
- Consistent with observational data that risk perceptions predict use (and switching away from cigarette smoking)

# Headed in the Wrong Direction: Misperceptions of Relative Risk of ENDS Increasing





# Correcting Misperceptions of Noncombustible Tobacco Products

*“Opportunities exist to educate adult smokers about the relative risks of tobacco products, including e-cigarettes...  
FDA recently initiated formative research to inform potential messaging related to misperceptions about nicotine and the continuum of risk among adult smokers.”*

*King, BA\*, Toll, BA. Commentary on Wackowski et al.: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers. Addiction. 2023. <https://doi.org/10.1111/add.16296>*

*\*Director of the FDA’s Center for Tobacco Products*