

CONSUMER UNDERSTANDING OF THE MODIFIED RISK INFORMATION

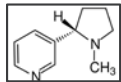
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Statutory requirements for public understanding of the modified risk information.



Background on U.S. public's misperceptions about nicotine.



Description of the proposed VLN™ labeling and advertising.



Preliminary evaluation of applicant's studies related to understanding.



911 (g)(2) (B)(iii)

UNDERSTANDING

Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, **consumers will not be misled** into believing that the product:

- is or has been demonstrated to be less harmful; or
- presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products.

911 (h)(1)

UNDERSTANDING

The advertising/labeling **enables the public** to:

- comprehend the information concerning modified risk, and
- understand the relative significance of such information
 - in the context of total health, and
 - in relation to all tobacco-related diseases and health conditions.



DISCUSSION QUESTION 4



4

UNDERSTANDING

Discuss whether the labeling enables consumers to accurately understand the following effects of using the products:

- Addiction risk
- Disease risks

EVIDENCE EVALUATED



🔍 The proposed labeling and advertising submitted.

🔍 The applicant's studies:

- Quantitative consumer perception study.
- Qualitative consumer perception studies.

🔍 Peer-reviewed studies of perceptions of nicotine and low nicotine content cigarettes.

KEY COMPONENTS OF VLN™ CONSUMER UNDERSTANDING



FDA is evaluating consumer understanding, including whether the labeling would enable people to understand the following:

 VLN™ cigarettes are less addictive than other cigarettes and similarly addictive as NRT.

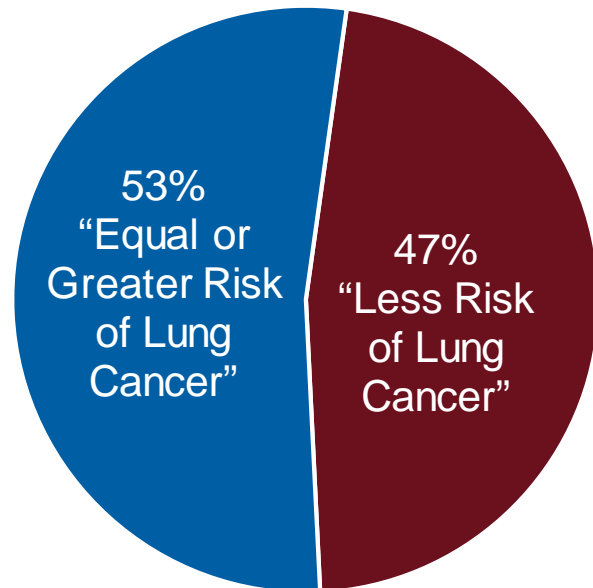
 VLN™ cigarettes have same disease risk as other cigarettes when smoked in the same way.

BACKGROUND: NICOTINE MISPERCEPTIONS



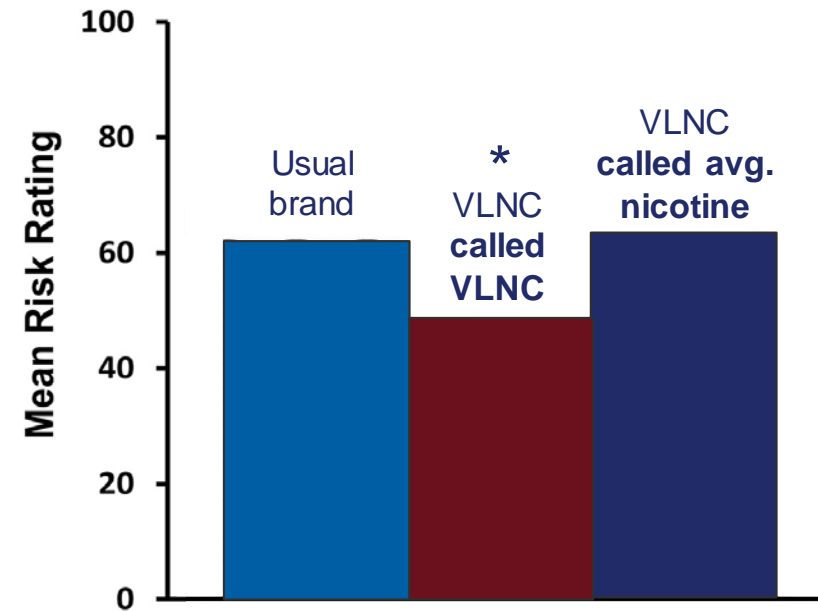
U.S. public has misperceptions about nicotine and very low nicotine content (VLNC) cigarettes.

“Compared to smoking current cigarettes, smoking cigarettes with much less nicotine for 30 years would cause...”



U.S. Adult Smokers in 2015-6¹

Perceived lung cancer risk, assuming maintenance of current smoking rate



U.S. Adult Smokers in VLNC Trial²

1. Byron et al., 2018
2. Denlinger-Apte et al., 2017

PROPOSED LABELING



Proposed labeling for non-menthol product. Source: Section V – Labels, Labeling, and Advertising.

PROPOSED ADVERTISING: EXAMPLE PRINT ADS



IF YOU SMOKE, CONSIDER VLN™

95%
LESS
NICOTINE

Made with real tobacco, VLN™ smells, burns, and tastes like a conventional cigarette, but greatly reduces your nicotine consumption.

For the nearest retailer, visit vncigarettes.com/stores or call: 800-225-1838 ext. 221

Nicotine is addictive. Less nicotine does NOT mean safer. All cigarettes can cause disease and death.

**SURGEON GENERAL'S WARNING:
Cigarette Smoke Contains Carbon Monoxide**

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**SURGEON GENERAL'S WARNING:
Cigarette Smoke Contains Carbon Monoxide**

Source: Section V – VLN Marketing Outline.

QUANTITATIVE RESEARCH ON UNDERSTANDING



Online study: Participants randomized to view VLN™ or Marlboro Gold packs and rate their risks.

Products Assessed

- Marlboro Gold or VLN™ (depending on condition)
- Comparator categories: conventional cigarettes, e-cigarettes, NRTs, snuff

Constructs Assessed

Perceived Risk of Addiction (6 items)

Examples:

- *being addicted to...*
- *being unable to quit...*
- *having to use... to feel better*
- *feeling like you have to use...*

Perceived Health Risks (18 items)

Examples:

- *lung cancer*
- *emphysema*
- *mouth/ throat cancer*
- *respiratory infection*
- *heart disease*
- *aging faster*
- *earlier death*
- *serious illness*

Participants (*n* ≈ 29,000)

Adult Current Smokers

- Intending to Quit
- Not Intending to Quit

Adult Former Smokers

- Past-Year Quitters
- Long-Term Quitters

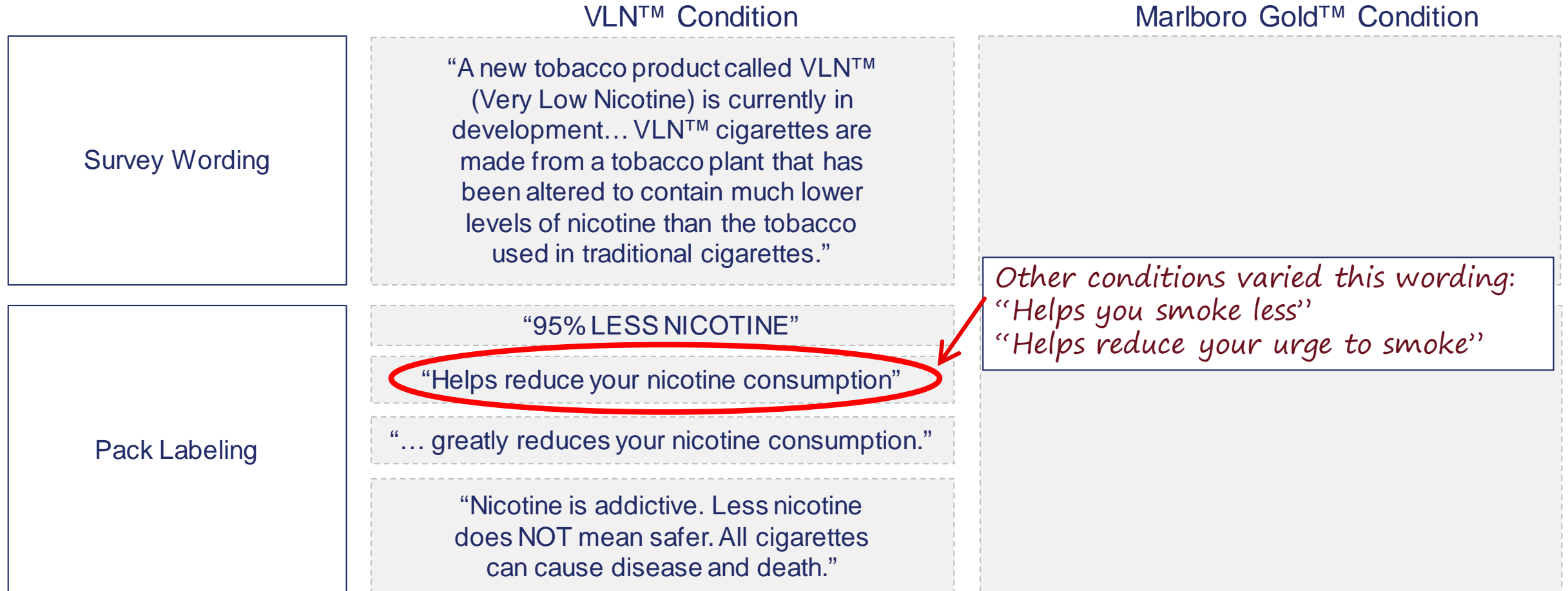
Never Smokers

- Young Adult (LA-25)
- Overall Adults

QUANTITATIVE RESEARCH ON UNDERSTANDING

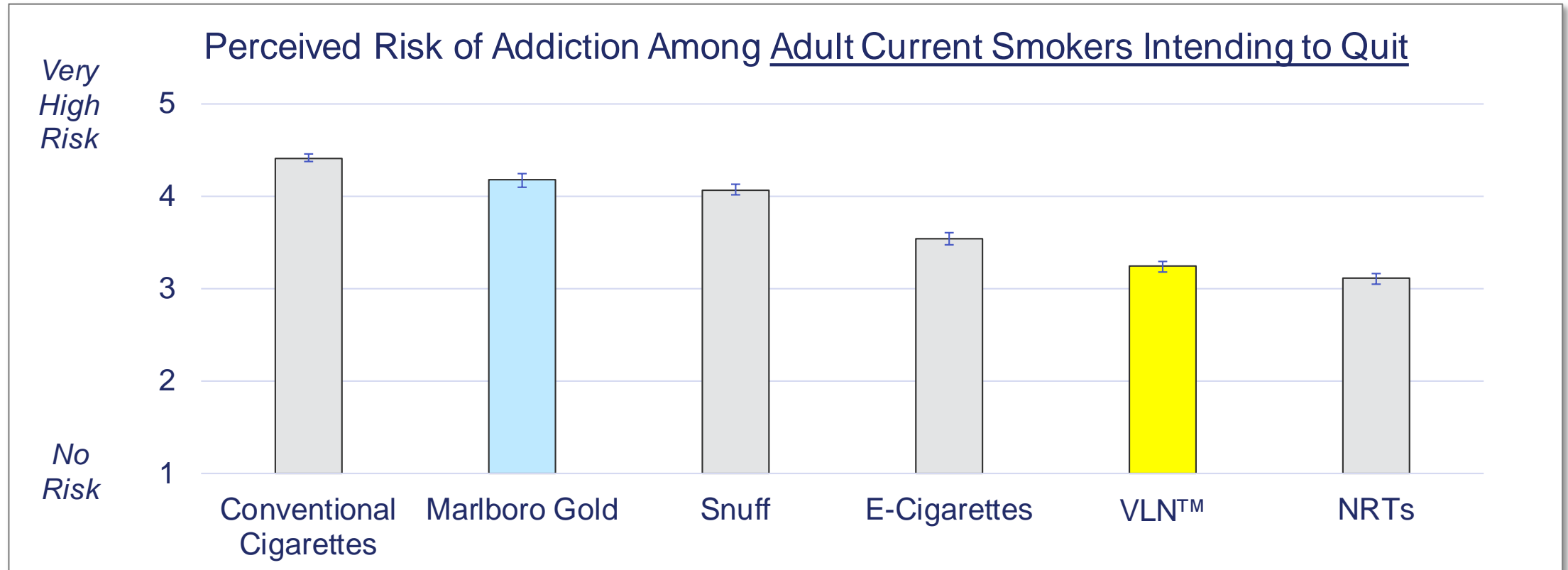


Modified risk information about VLN™ in online experiment:





PERCEIVED ADDICTION RISK

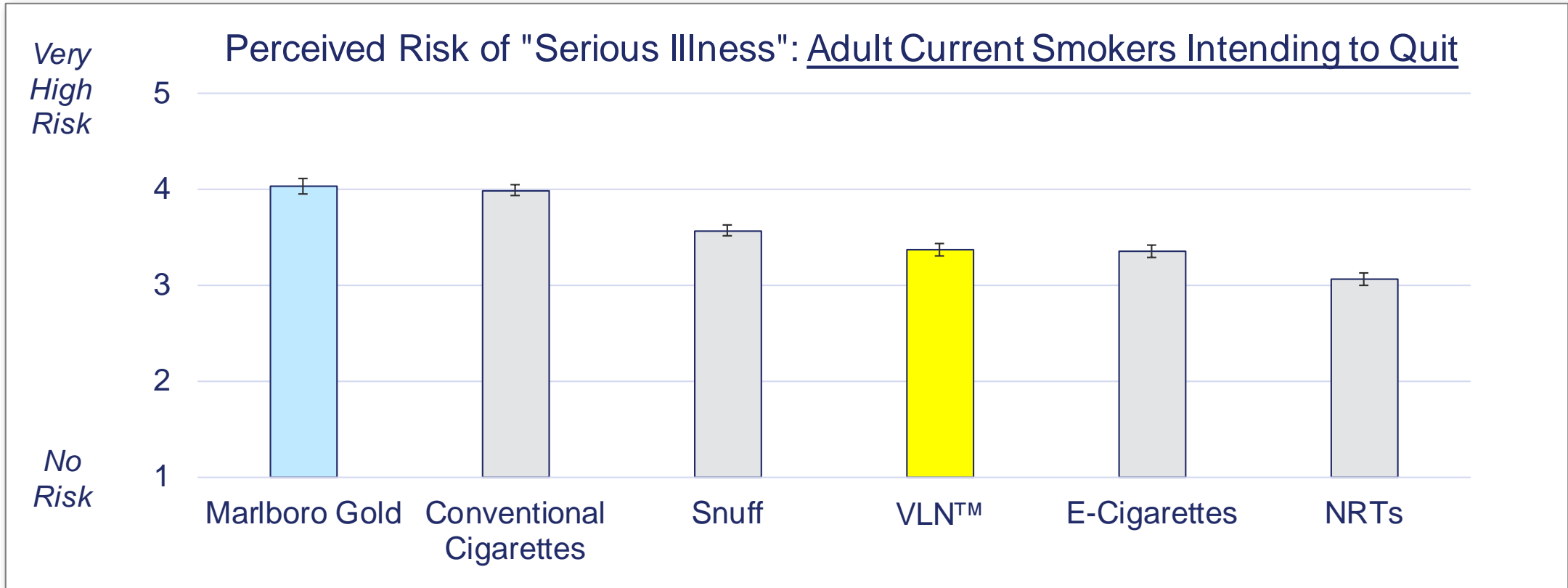


“Taking into consideration everything you know about [product], indicate what you believe is the risk of each of the following long-term or lifetime addiction-related issues because of [product]... being addicted to [product].”

Source: Based on the M/A/R/C Research Quantitative Report, p. 99. Error bars: 95% CIs.



PERCEIVED HEALTH RISKS

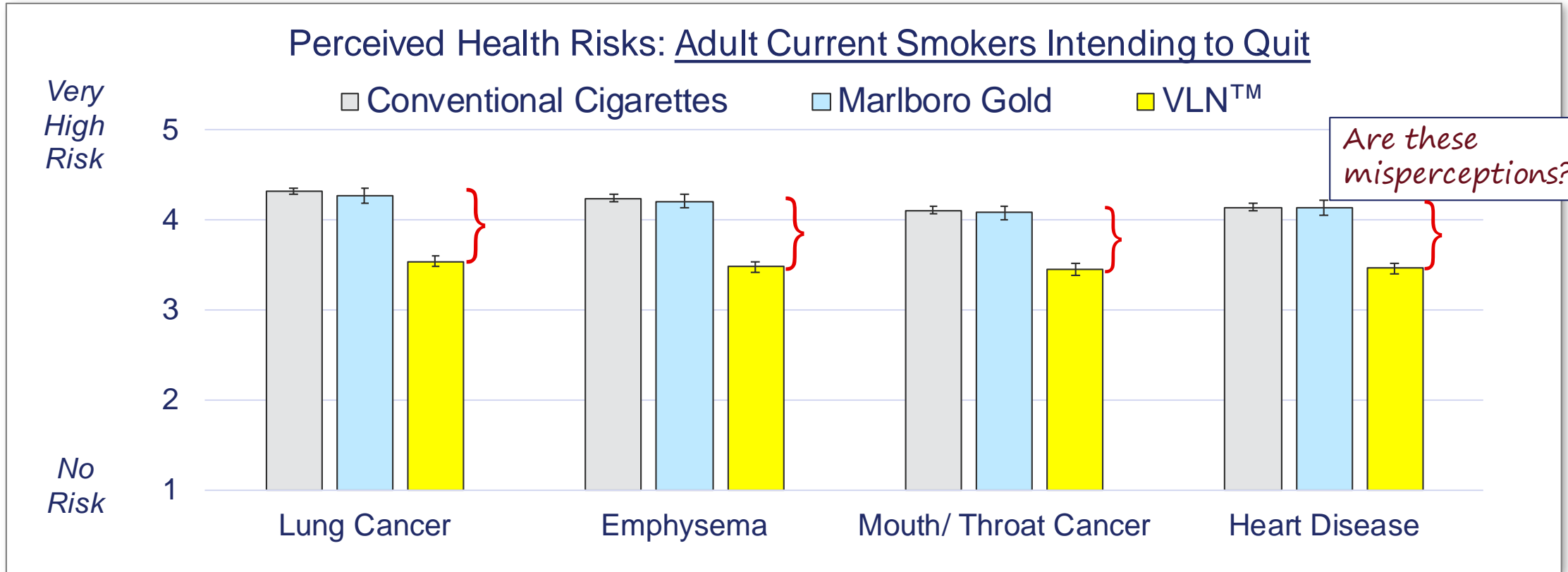


“Taking into consideration everything you know about [product], indicate what you believe is the risk of each of the following long-term or lifetime health-related issues because of [product].”

Source: Based on the M/A/R/C Research Quantitative Report, p. 64. Error bars: 95% CIs.



PERCEIVED HEALTH RISKS



“Taking into consideration everything you know about [product], indicate what you believe is the risk of each of the following long-term or lifetime health-related issues because of [product].”

Source: Based on the M/W/R/C Research Quantitative Report, p. 85. Error bars: 95% CIs.

ARE THE LOWER RISK RATINGS MISPERCEPTIONS?



- Possibility A: Participants assumed they would use VLN™ cigarettes the same amount as other cigarettes when rating the products. Their health risk ratings are inaccurate.
- Possibility B: Participants assumed they would use less of VLN™ cigarettes compared to other cigarettes when rating the products. Their health risk ratings are potentially accurate.



ARE THE LOWER RISK RATINGS MISPERCEPTIONS?



“If you were asked to describe VLN™ to a friend or family member, what would you say?”

Responses suggested a mix of **understanding**, **uncertainty**, and **confusion**; many were inconclusive.

Health risks remains the same but 95% less nicotine.

Low-nicotine cigarette. Like "regular" cigarettes with reduced nicotine levels. **NOT clear** whether risk levels are reduced at commensurate levels.

It's a cigarette with 95% less nicotine so it gives you the **same feeling as smoking without all of the harmful effects**. Many people are addicted to the action of smoking as much as they are to the chemicals so it might be a better solution to try.

It is a cigarette with less nicotine.

Source: Example responses obtained from W/A/R/C Research Quantitative Study raw data.



QUALITATIVE RESEARCH ON UNDERSTANDING



Four phases of qualitative consumer research also found mixed interpretations of VLN™'s health risks.

Example Quotes from Phase 4 in-depth interviews after viewing various claims and disclaimers

These are exactly the same minus the regular nicotine... You're still smoking and things like that, but if it's not as addicting, you're not smoking as much. You're probably reducing all of these health issues greatly...

... if you're seeing the message "95% LESS NICOTINE," you're going to want to continue to smoke more. Or not more, but more frequently, because you're not being as harmful as you would with something regular.

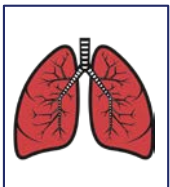
Some people understood the need to cut down or quit smoking to benefit from using VLN™. Others did not.

Source: Section VIII E Scientific Studies and Analyses – Consumer Perception, pp. 3-26; Example quotes obtained from M/A/R/C Qualitative Study Phase 4 Transcripts.



Adults accurately perceive VLN™ as less addictive than other cigarettes and similarly addictive as NRTs.

Adults perceive VLN™ as moderately to very likely to cause tobacco-related diseases.



Adults perceive VLN™ as less likely to cause diseases compared to other cigarettes.

It is unclear whether this is because they believe they will smoke fewer VLN™ cigarettes.



DISCUSSION QUESTION 4



4

UNDERSTANDING

Discuss whether the labeling enables consumers to accurately understand the following effects of using the products:

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- Disease risks

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DISCUSSION QUESTION 4



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UNDERSTANDING

Discuss whether the labeling enables consumers to accurately understand the following effects of using the products:

- Addiction risk
- Disease risks

THE END

