

# SWEDISH MATCH USA, INC. MODIFIED RISK TOBACCO PRODUCT APPLICATION AMENDMENT

Presented by:

Benjamin J. Apelberg, PhD, MHS

Director, Division of Population Health Science

Office of Science

Center for Tobacco Products

U.S. Food and Drug Administration

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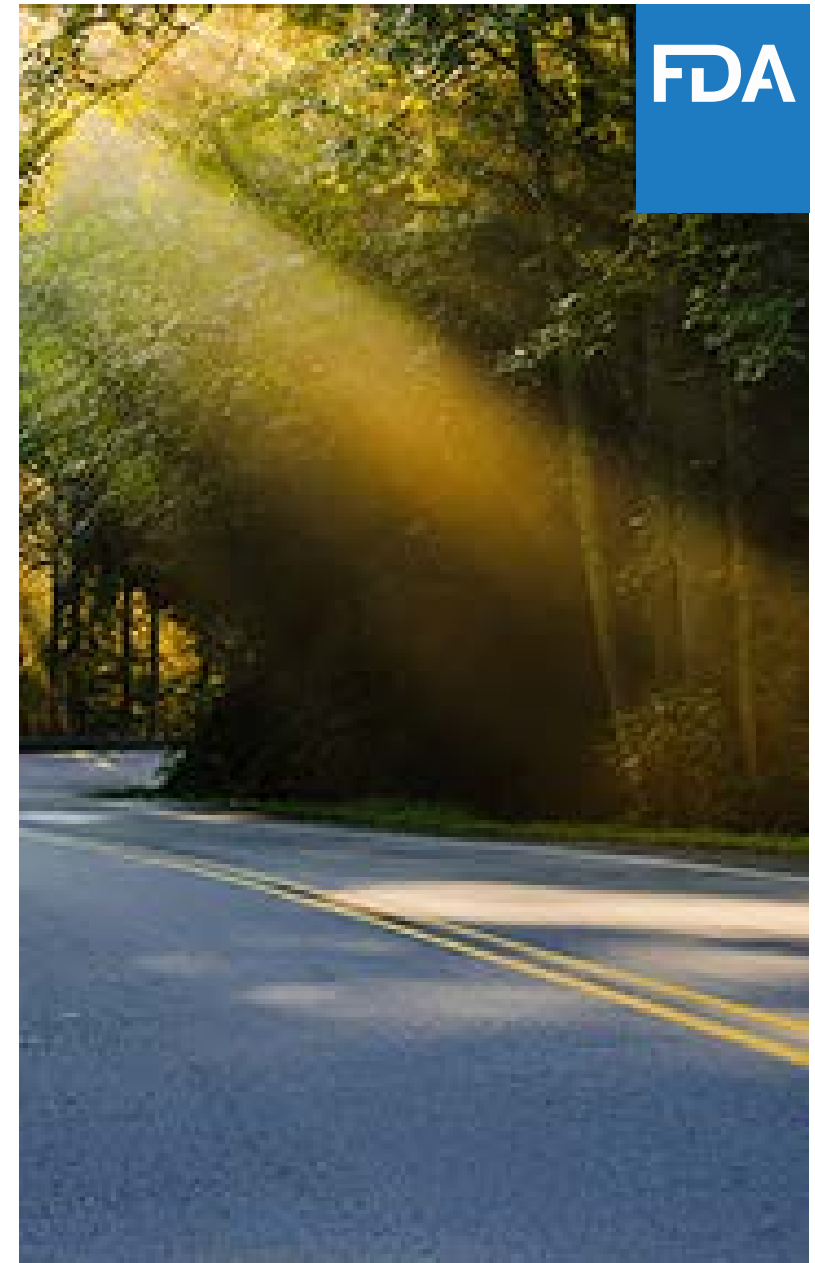
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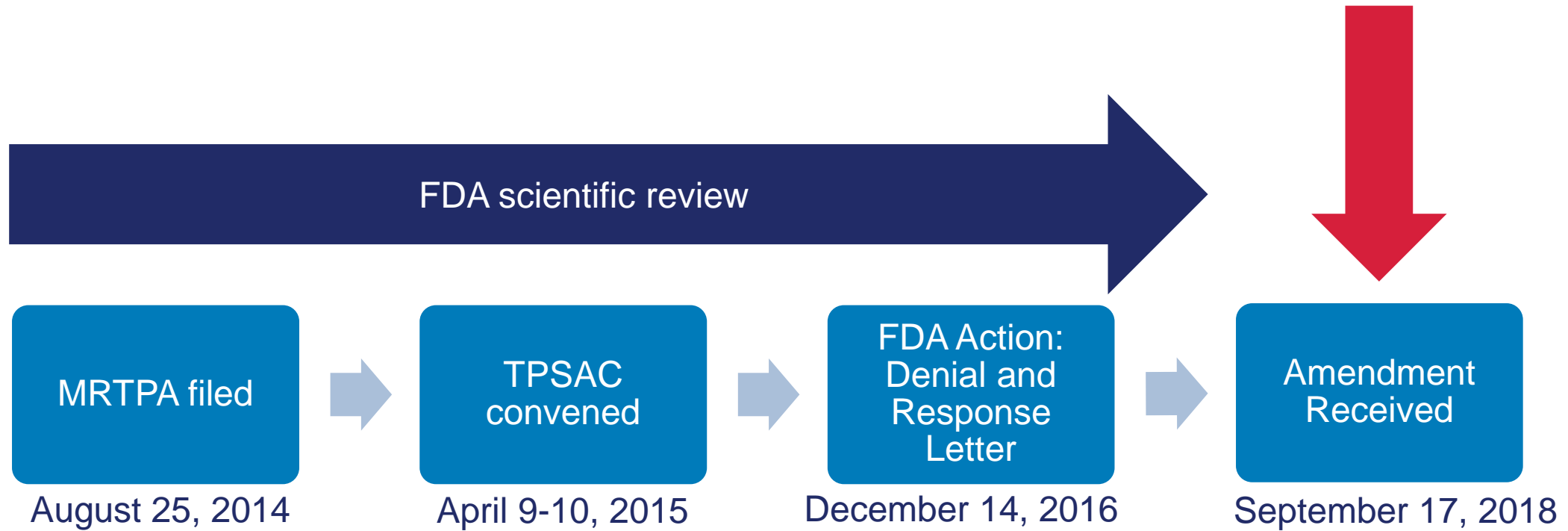
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- Summary of Swedish Match MRTPAs regulatory history and status
- Overview of amendment
- Question for the committee



# SWEDISH MATCH MRTPA SUBMISSION



# RISK MODIFICATION ORDER STANDARD - 911(g)(1)

The FD&C Act requires FDA to determine if a proposed MRTP, as it is actually used by consumers, will:

- (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and
- (2) benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products



# SWEDISH MATCH MRTPA PRODUCTS

The applicant is seeking an order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for:

## 8 General Snus products

General Loose

General Dry Mint Portion Original Mini

General Portion Original Large

General Classic Blend Portion White Large – 12 ct

General Mint Portion White Large

General Nordic Mint Portion White Large – 12 ct

General Portion White Large

General Wintergreen Portion White Large



- Swedish Match originally proposed marketing these products as modified risk through the removal and revision of certain health warnings currently required by the Comprehensive Smokeless Tobacco Health Education Act for smokeless tobacco products.
- TPSAC met on April 9-10, 2015 to discuss these applications and address the questions posed to the committee.
- FDA completed its review of the applications and issued a decision on these applications on December 14, 2016 with a denial of one request and a response letter describing deficiencies relevant to the other two requests.

- FDA **denied** the request to remove “WARNING: This product can cause gum disease and tooth loss.” because FDA determined that the applications did not contain sufficient evidence to satisfy the standards of 911(g)(1), including that the implicit claim was not substantiated.
- FDA **deferred final action** on the request to remove “WARNING: This product can cause mouth cancer.” and revise “not a safe alternative” to “WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes.”
  - In their present form, the applications do not contain sufficient evidence to satisfy the standards of 911(g)(1).
  - The applications could be amended in a way that could support an order, including by revising the proposed claims and conducting additional studies.



- Regarding the risks relative to cigarettes, FDA recommended that Swedish Match consider a revised claim that was more precisely tailored to the supporting science, e.g.:
  - an adequately tested explicit claim;
  - placed outside the health warning; and
  - communicates information on the differences in specific health risks between the eight General Snus products and cigarettes.
- FDA also recommended that if Swedish Match chose to conduct a new consumer perception study, it should address the deficiencies of its initial study, including:
  - Ensuring the study stimuli test the proposed modified risk information verbatim; and
  - If the proposed claim appears in the warning, then the study should examine the impact of that context on consumer perception and understanding.

- On September 17, 2018, FDA received an amendment to the MRTPAs, providing responses to the deficiencies outlined in the Response Letter.
  - Revised modified risk claim about the risks of General Snus relative to cigarettes
  - A new consumer perception study to evaluate the revised claim and address methodological problems in the original study

# REVISED MODIFIED RISK CLAIM



“Using General Snus instead of cigarettes puts you at lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

- In April 2015, TPSAC discussed the original applications, including the health risks of General Snus relative to cigarette smoking across a number of health endpoints.
- The applicant revised its proposed claim after receiving input from TPSAC and FDA and the revised claim appears responsive to FDA's recommendations.
- In addition, the applicant's amendment contains a new consumer perception study, addressing the revised claim and the methodological concerns previously identified by FDA.
- **The focus of this TPSAC meeting is on this new consumer perception study.**
- FDA's assessment of the new information contained in the amendment will be incorporated to update its review of the applications in regard to standards of 911(g)(1), including the likely impacts on behavior among different groups and population health impact.

# QUESTION FOR THE COMMITTEE

## TPSAC Discussion

**FDA's** preliminary assessment of the amendment finds that the applicant has addressed previous concerns by proposing a modified risk claim that is, for example, more specific and independent of the warning label; and by conducting a new consumer perception study that does not suffer from the methodological flaws of their original study.

**TPSAC** will be asked to discuss FDA's preliminary assessment, including whether the revised modified risk claim raises new or additional concerns regarding the potential impact on:

- (a) consumer understanding; and
- (b) population health.

# SWEDISH MATCH USA, INC. MODIFIED RISK TOBACCO PRODUCT APPLICATION AMENDMENT: CONSUMER UNDERSTANDING AND INTENTIONS

Presented by:  
Alexander Persoskie, PhD  
Social Scientist  
Office of Science  
Center for Tobacco Products  
U.S. Food and Drug Administration

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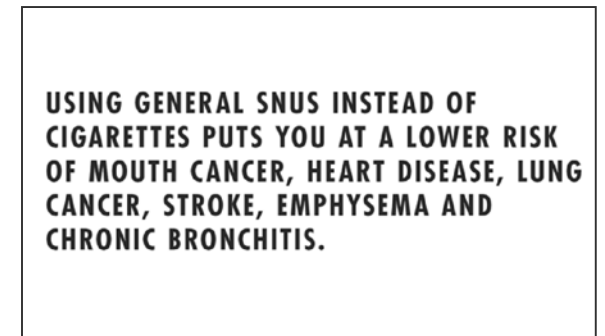
Swedish Match's modified risk marketing plan:

- Claim will not be added to product label or labeling.
- Claim will appear in ads: branded website, direct mail/email, social media, print/ online, consumer events.

Proposed ads:

- Introduce what snus is and how to use it;
- Describe features of *General Snus*: origin, ingredients, production; and
- Include the proposed claim and mandated smokeless tobacco warnings.

Screenshots from video ad:



# PERCEPTIONS AND BEHAVIORAL INTENTIONS (PBI) STUDY



## OBJECTIVE

Assess the claim's effects on consumer understanding and product use intentions.

## DESIGN

Between-subjects online experiment: Participants randomized to view the *General Snus* video ad with:

### Swedish Match's Proposed Claim

USING GENERAL SNUS INSTEAD OF CIGARETTES PUTS YOU AT A LOWER RISK OF MOUTH CANCER, HEART DISEASE, LUNG CANCER, STROKE, EMPHYSEMA AND CHRONIC BRONCHITIS.

or

### 1 of 2 Alternative Test Claims

USING GENERAL SNUS PRODUCTS INSTEAD OF CIGARETTES WOULD SIGNIFICANTLY REDUCE HARM AND THE RISK OF CERTAIN TOBACCO-RELATED DISEASES TO INDIVIDUAL TOBACCO USERS.

or

### No Test Claim

(CONTROL)

After viewing the video ad, participants reported their perceptions and product use intentions.

## SAMPLE

U.S. adults recruited from online panels to include:

Young adult cigarette smokers ( $n = 1,828$ )	Older adult cigarette smokers ( $n = 1,942$ )
Adult smokeless tobacco users ( $n = 970$ )	Adult former cigarette smokers ( $n = 1,942$ )
Young adult never tobacco users ( $n = 1,914$ )	Older adult never tobacco users ( $n = 1,936$ )

(Note: Young adult = legal age to 24. Older adult = age 25 or older. Adult = legal age or older.)

# PBI STUDY: SELECTED OUTCOMES



## UNDERSTANDING

Perceived health risks of using *General Snus* daily in absolute terms, for 8 health effects.

Very Low Chance	Low Chance	Moderate Chance	High Chance	Very High Chance	<i>Don't Know</i>
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Perceived health risks of using *General Snus* daily compared to (a) smoking cigarettes daily; (b) using moist snuff and other snus brands daily; and (c) dual using *General Snus* with cigarettes.

<u>much lower</u> chance	<u>lower</u> chance	<u>the same</u> chance	<u>higher</u> chance	<u>much higher</u> chance	<i>Don't Know</i>
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Number of cigarettes one can smoke a day while using *General Snus* to lower one's disease risk.

Zero (0) cigarettes	Up to 5 cigarettes	Up to 20 cigarettes	As many as you want	None of the above	<i>Don't Know</i>
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## INTENTIONS

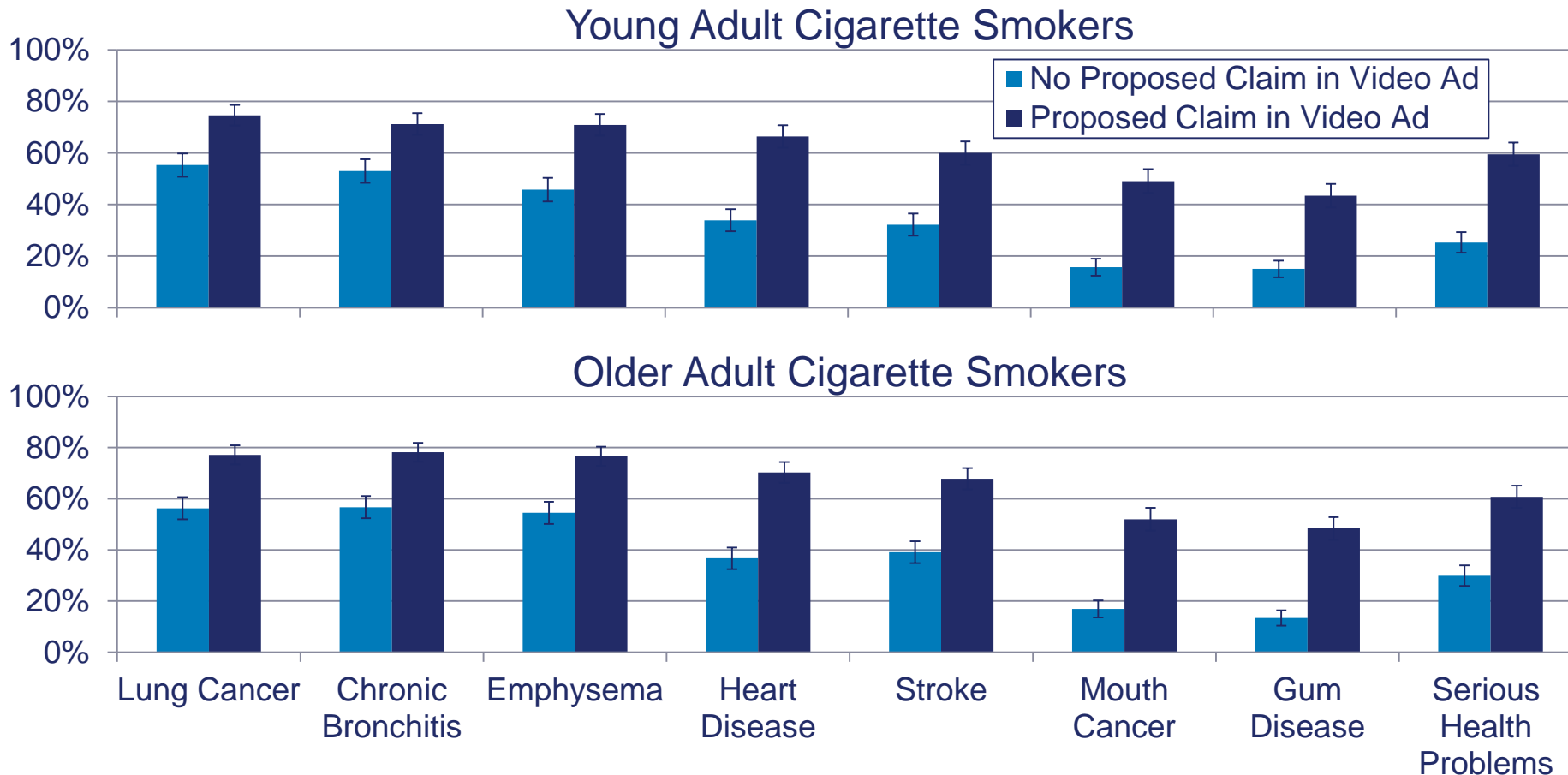
Self-reported likelihood of buying *General Snus* if sold in a store where one usually shops.

No chance, almost none	Very slight possibility	Slight possibility	Some possibility	Fair possibility	Fairly good possibility	Good possibility	Probable	Very probable	Almost sure	Certain, practically certain
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# CIGARETTE SMOKERS' PERCEIVED RISK COMPARED TO CIGARETTES



## Percentages of Cigarette Smokers Who Perceived Lower Health Risks from *General Snus* vs. Cigarettes



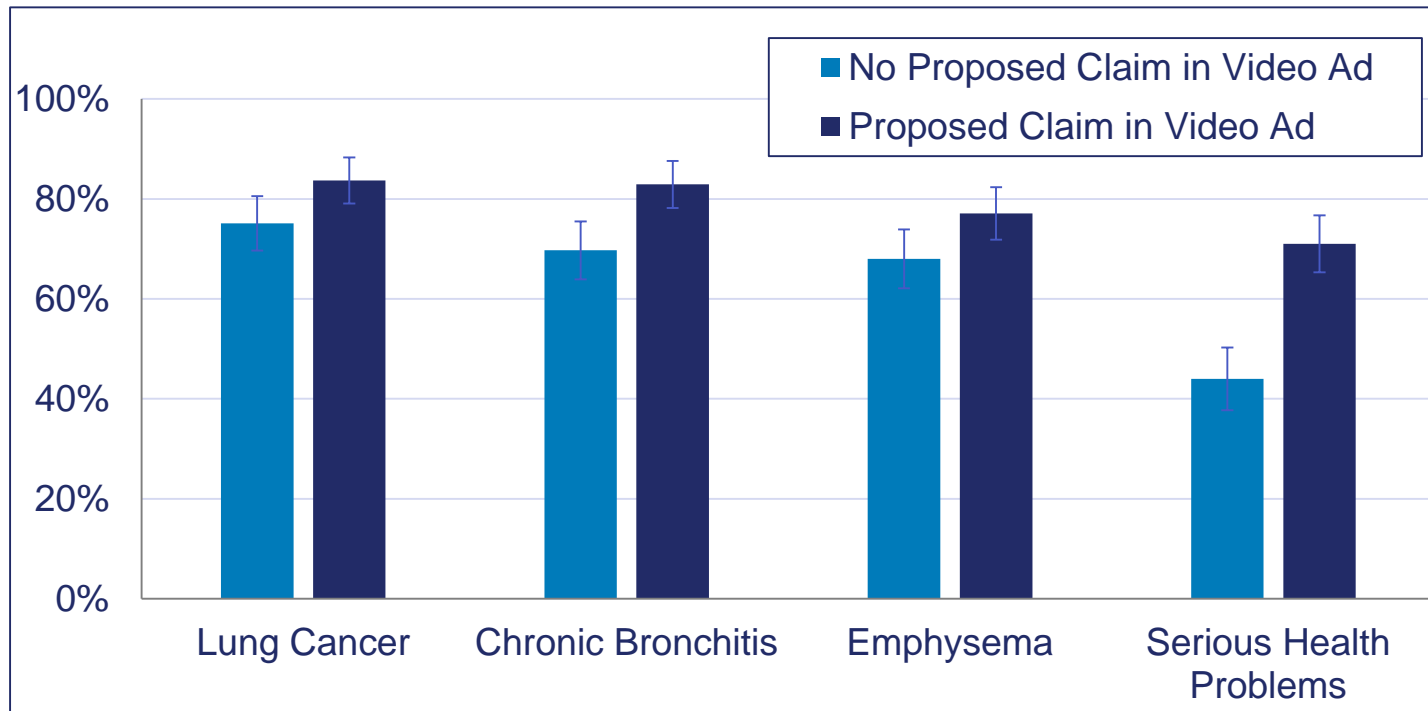
Swedish Match's proposed claim increased the percentage of smokers who perceived daily *General Snus* use as lower in health risks than daily cigarette smoking.

(Source: PBI Study Report, pp. 108-110; Nov. 26, 2018 Amendment, pp. 33-36. Error bars: 95% CIs)

# SMOKELESS USERS' PERCEIVED RISK COMPARED TO CIGARETTES



## Percentages of Adult Smokeless Tobacco Users Who Perceived Lower Health Risks from *General Snus* vs. Cigarettes



(PBI Study Report, p. 112. Error bars: 95% CIs)

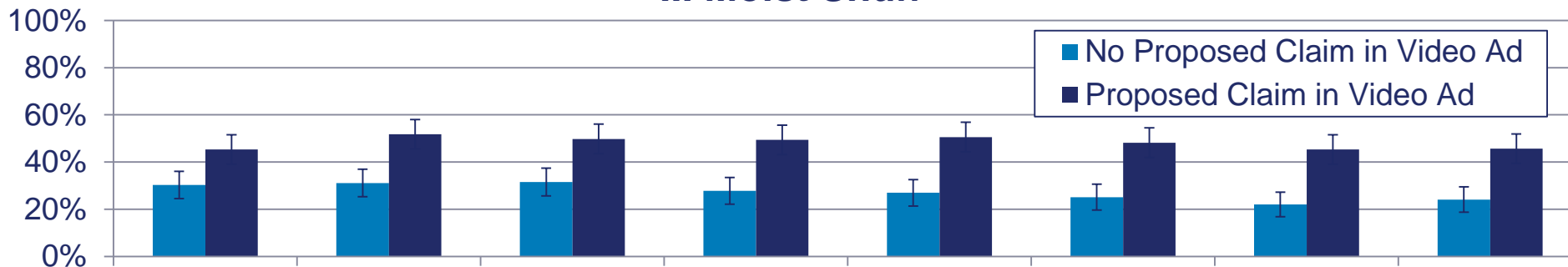
Swedish Match's proposed claim increased the percentage of smokeless users who perceived daily *General Snus* use as lower in health risks than daily cigarette smoking.

# PERCEIVED RISK COMPARED TO MOIST SNUFF AND OTHER SNUF

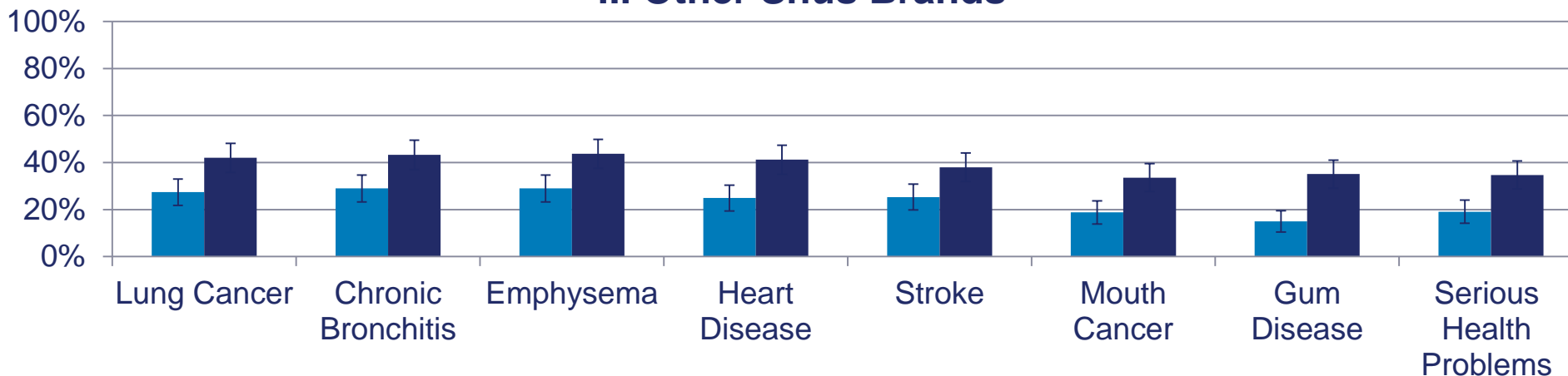


## Percentages of Smokeless Tobacco Users Who Perceived Lower Health Risks from *General Snus* compared to:

### ... Moist Snuff



### ... Other Snus Brands



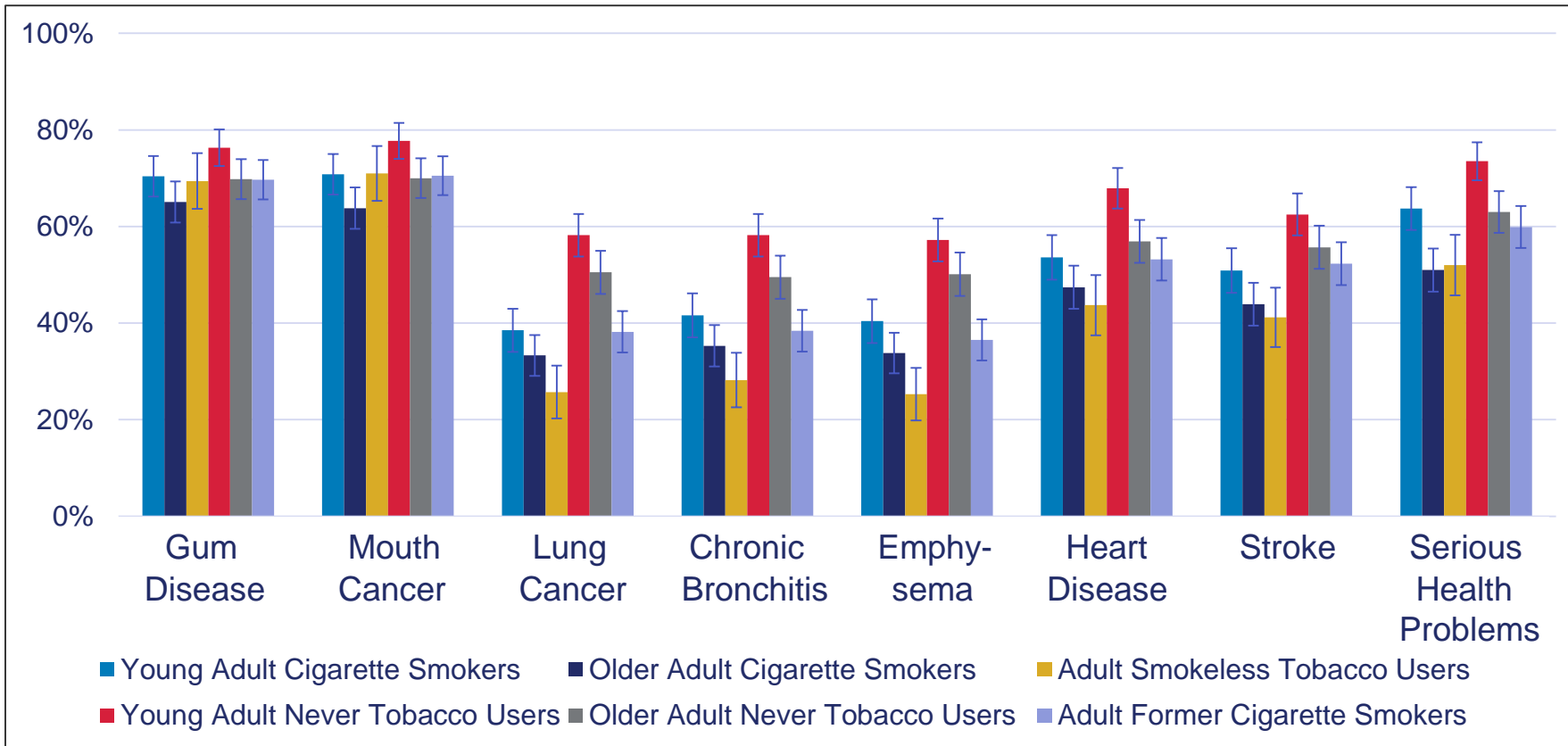
Swedish Match's proposed claim increased the percentage of smokeless users who perceived daily *General Snus* use as lower in health risks than daily use of moist snuff and other snus brands.

(Source: November 26, 2018 Amendment, pp. 26-31. Error bars: 95% CIs)

# PERCEPTIONS OF ABSOLUTE HEALTH RISKS



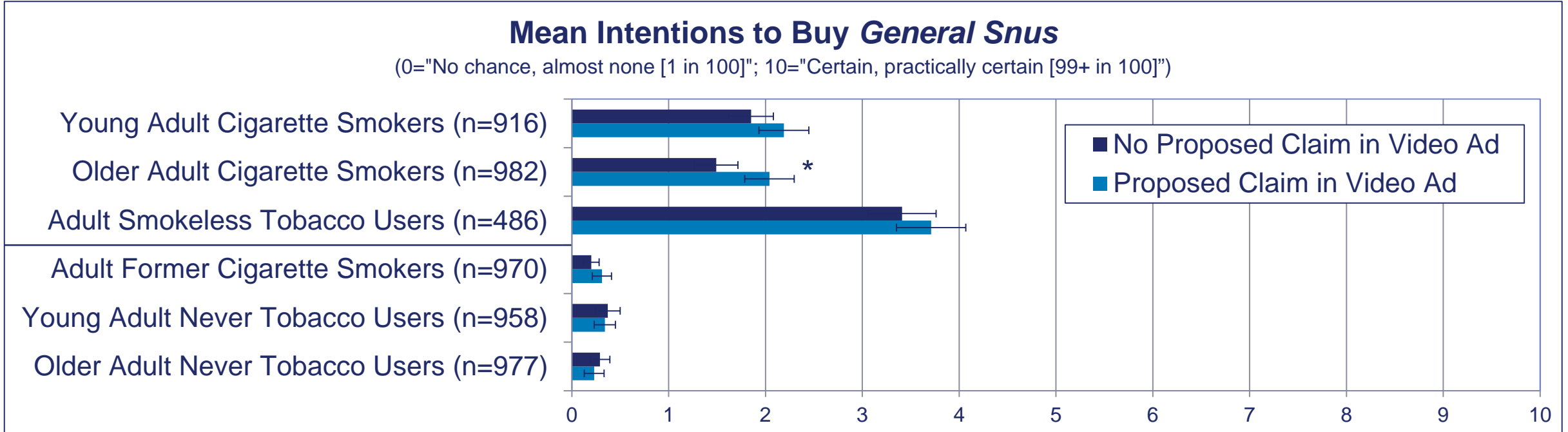
Percentages of Participants Who Perceived a “Moderate,” “High,” or “Very High” Chance of Health Effects from Using *General Snus*, after Viewing the Video Ad with Swedish Match’s Proposed Claim



After viewing the video ad with Swedish Match’s proposed claim, consumers perceived daily *General Snus* use as presenting substantial health risks, particularly for gum disease and mouth cancer.

(Source: PBI Study Report, pp. 87-98. Error bars: 95% CIs)

# CLAIM'S EFFECTS ON INTENTIONS



(Source: PBI Study Report, pp. 71-75. Error bars: 95% CIs) \*  $p=.001$

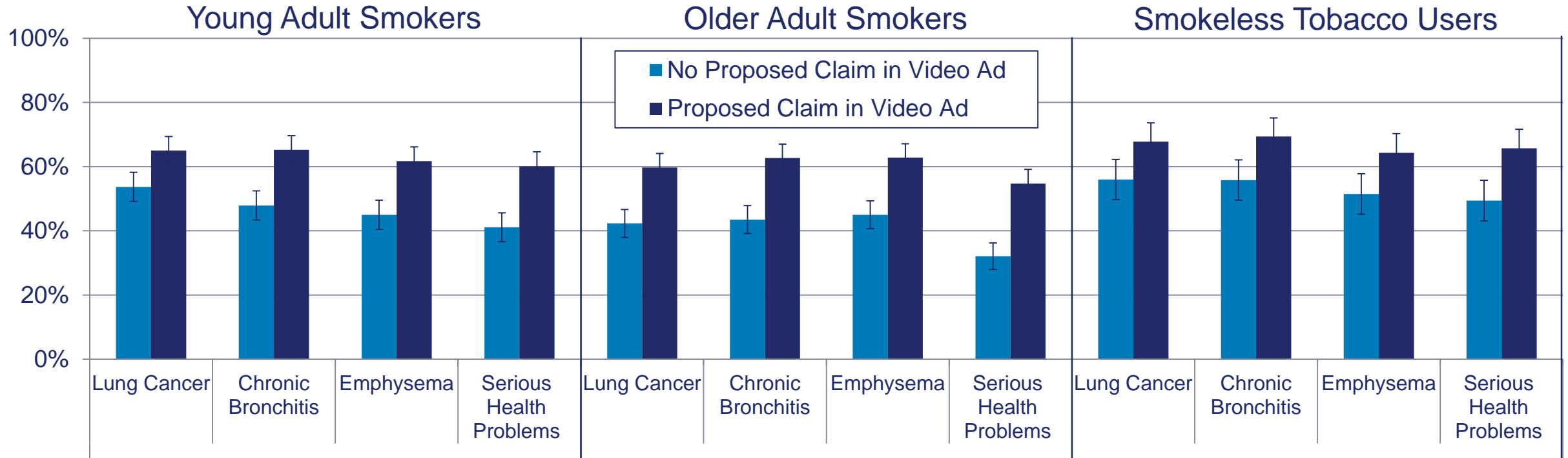
Swedish Match's proposed claim significantly increased older adult smokers' intentions to buy *General Snus*. Increases among young adult smokers and adult smokeless users did not reach significance.



# UNDERSTANDING OF HEALTH RISKS OF DUAL USE



## Percentages Who Perceived Lower Health Risks from Exclusive *General Snus* Use vs. Dual Use with Cigarettes



(Source: PBI Study Report, pp. 121-125. Error bars: 95% CIs)

Swedish Match's proposed claim improved consumers' understanding that dual using *General Snus* with cigarettes presents greater health risks than exclusively using *General Snus*.

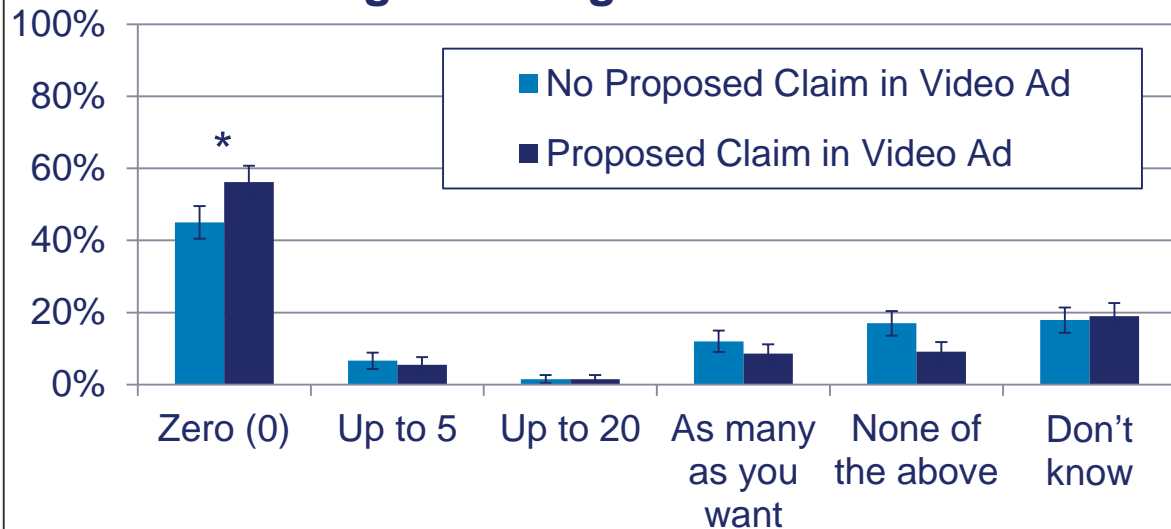
# UNDERSTANDING OF HEALTH RISKS OF PARTIAL SWITCHING



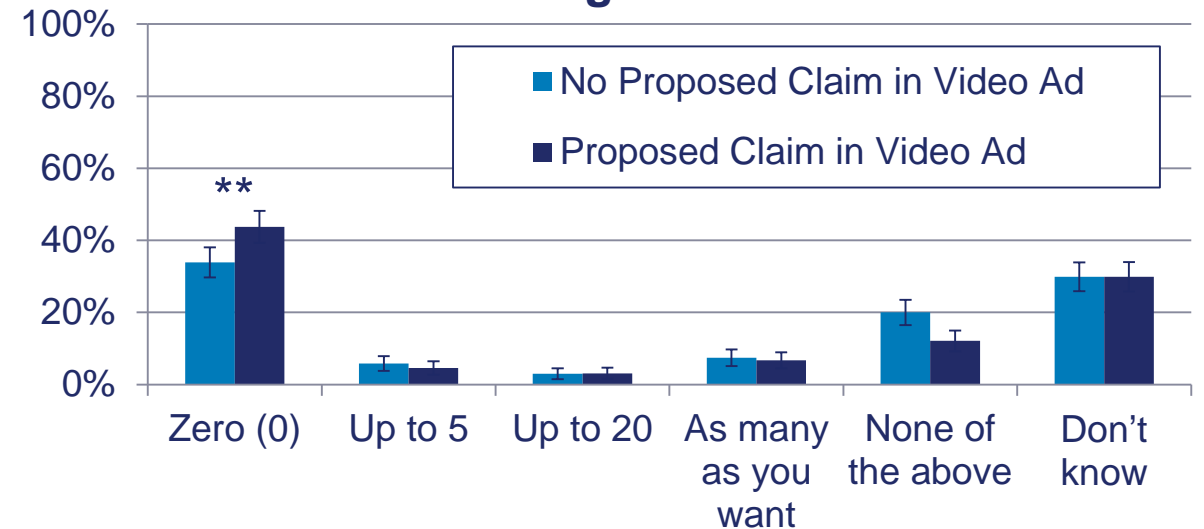
Swedish Match’s proposed claim did not appear to mislead smokers to believe that they could benefit their health by *partially* switching to *General Snus*.

“For *General Snus* to put you at a lower risk of disease, how many cigarettes can you smoke on a day when you also use *General Snus*?”

## Young Adult Cigarette Smokers



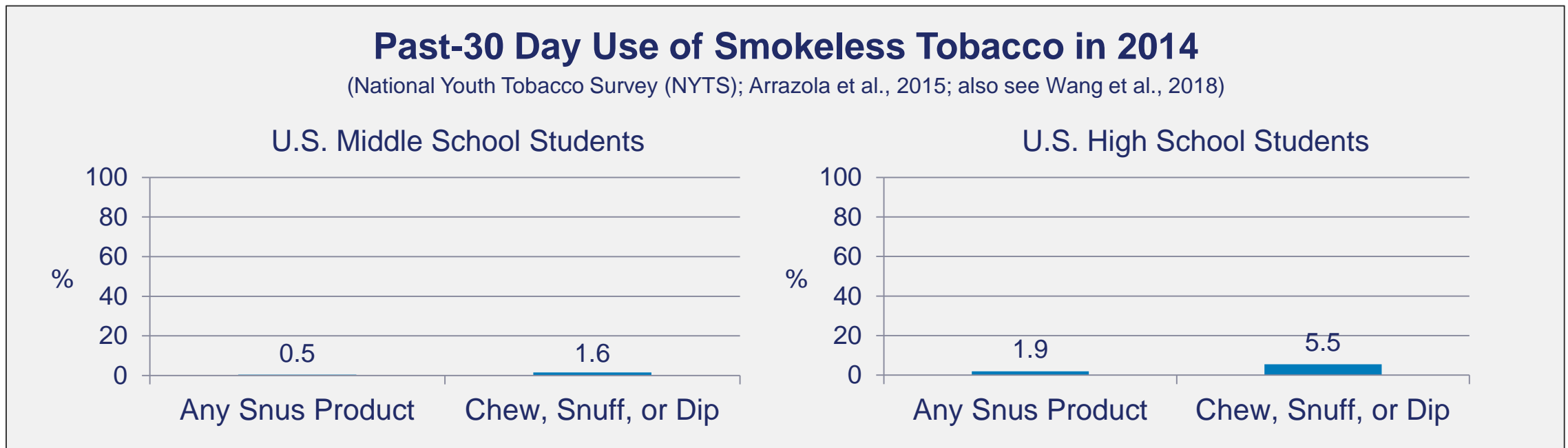
## Older Adult Cigarette Smokers



(Source: November 26, 2018 Amendment, pp. 38-39. Error bars: 95% CIs) \* $p=.001$  \*\* $p=.005$

# ASSESSMENT OF YOUTH AND YOUNG ADULTS

- PBI Study: Results were similar among young and older adult never tobacco users.
- Swedish Match's proposed advertising includes targeting information toward adults.
- Youth use is currently low.



# SUMMARY OF PBI STUDY FINDINGS



## Swedish Match's Proposal

- Market its 8 *General Snus* products using its claim in ad channels such as its website, direct mail, email, consumer events, social media, and print.

## Understanding of Product Risks

- Proposed claim increased smokers' and smokeless users' perception of *General Snus* as lower in health risks than cigarettes.
- Proposed claim increased smokeless users' perception of *General Snus* as lower in health risks than moist snuff and other snus brands.
- Consumers continued to perceive *General Snus* as causing substantial health risks, particularly for mouth cancer and gum disease.

## Use Intentions

- Proposed claim increased intentions to buy *General Snus* among consumers who could benefit their health by switching completely.

## Understanding of Risks of Dual Use

- Proposed claim increased smokers' and smokeless users' perception of exclusive *General Snus* use as lower in health risks than dual use with cigarettes.
- Proposed claim increased smokers' belief that they would have to smoke zero cigarettes to benefit.

## Limitations

- No data on claim's effects on dual use vs. complete switching (but see above on understanding). No data on claim's effects on youth.

# CONCLUSIONS: CONSUMER UNDERSTANDING AND INTENTIONS



- PBI Study addressed deficiencies in consumer research in Swedish Match’s 2014 submission.

Consumer Research in 2014 Submission	PBI Study
Proposed a claim in a warning label; did not test this context	Proposed a revised claim outside of the warning label
Did not test the claim verbatim (omitted key word “Warning”)	Tested the revised claim verbatim
Used study items with flaws that limited interpretability	Used improved measures to assess most outcomes

- PBI Study results provide supportive evidence for Swedish Match’s revised claim:

<b>Understanding</b>	The claim improved U.S. consumers’ understanding of the products’ health risks relative to cigarettes, smokeless tobacco, and dual use of the products with cigarettes.
<b>Intentions</b>	The claim increased intentions to buy <i>General Snus</i> among adult tobacco consumers who could benefit their health by completely switching, with no statistically significant increase among non-users of tobacco.

# REFERENCES



- Arrazola, R. A., Singh, T., Corey, C. G., Husten, C. G., Neff, L. J., Apelberg, B. J., et al. (2015). Tobacco use among middle and high school students – United States, 2011-2014. *MMWR*, 64, 381-385.
- Wang, T. W., Gentzke, A., Sharapova, S. Cullen, K. A., Ambrose, B. K., Jamal, A., et al. (2018). Tobacco product use among middle and high school students – United States, 2011-2017. *MMWR*, 67, 629-633.

# CLARIFYING QUESTIONS

