

Premarket Consumer Perception Study

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Statutory language on labeling of tobacco products

- “A tobacco product shall be deemed to be misbranded if its labeling is false or misleading in any particular....” (FDCA § 903(a)(1))
- Currently mandated four warning statements:
 - WARNING: This product can cause mouth cancer
 - WARNING: This product can cause gum disease and tooth loss
 - WARNING: This product is not a safe alternative to cigarettes
 - WARNING: Smokeless tobacco is addictive

The scientific evidence included in the MRTPAs indicate that the current label statements cause the snus products to be misbranded!

Consumer Perception Study

- Quantitative, randomized, controlled study of 13,200 subjects aged 18-64 years (6,600 current users of tobacco products, 6,600 non-users)
- Protocol with defined study hypotheses, end-points, and statistical methods
- Done by research contractor with extensive experience of consumer research and online data acquisition
- Subjects sourced from consumer panels and via advertising
- Online questionnaire
- Methods build on those routinely used for industry-sponsored consumer research but procedures enhanced to comply with FDA guidance
- IRB review
- Input from SM's Advisory Panel and from CTP

FDA Guidance Document: general principles for scientific studies

- Well-designed study that allow for critical analysis and replication by other investigators
- Clear objectives, hypotheses
- Protocol with standardized, validated methods for analysis
- Adequate sample size
- Appropriate control groups
- Procedures to minimize bias and permit generalization to the U.S. population
- Analyses that adequately address the effects of study measures
- Appropriate methods for assigning subjects
- Oversight by an IRB

Study objectives

- Assess consumer understanding, tobacco use behavior, and perceptions of health risks among subjects exposed to one out of the four existing warning statements, and two test statements
- Overall, according to current tobacco use, and in demographic subgroups
 - WARNING: This product can cause mouth cancer
 - WARNING: This product can cause gum disease and tooth loss
 - WARNING: This product is not a safe alternative to cigarettes
 - WARNING: Smokeless tobacco is addictive
 -
 - No tobacco product is safe but this product presents a lower risk to health than cigarettes
 - No tobacco product is safe but this product presents a substantially lower risk to health than cigarettes

Linguistics of tested statements

Simple assertions

- WARNING: This product can cause mouth cancer
- WARNING: This product can cause gum disease and tooth loss
- WARNING: This product is not a safe alternative to cigarettes
- WARNING: Smokeless tobacco is addictive

Simple assertion plus summary of the concept tobacco harm reduction, continuum of risk in one sentence

- No tobacco product is safe but this product presents a lower risk to health than cigarettes
- No tobacco product is safe but this product presents a substantially lower risk to health than cigarettes

Study design: random allocation

Randomly allocated statement	Tobacco users (N=6,600)	Non-users (N=6,600)
"Oral cancer"	1,100	1,100
"Gum disease"	1,100	1,100
"Not safe alternative"	1,100	1,100
"Addictive"	1,100	1,100
"Lower risk"	1,100	1,100
"Substantially lower risk"	1,100	1,100

Example of research stimuli:

Color photographs shown to participants allocated to "No tobacco product is safe but this product presents lower risk to health than cigarettes"



Sample demographics

		Current users (%)	Non-users (%)
Gender	Male	58	57
	Female	42	43
Age (years)	18-24	24	31
	25-44	44	37
	45+	32	32
Region	Northeast	24	26
	Midwest	27	24
	South	27	24
	West	22	26
Ethnicity	Minorities	29	30
	Non-Minorities	71	70
Annual income	<45 K	51	49
	45K+	49	51

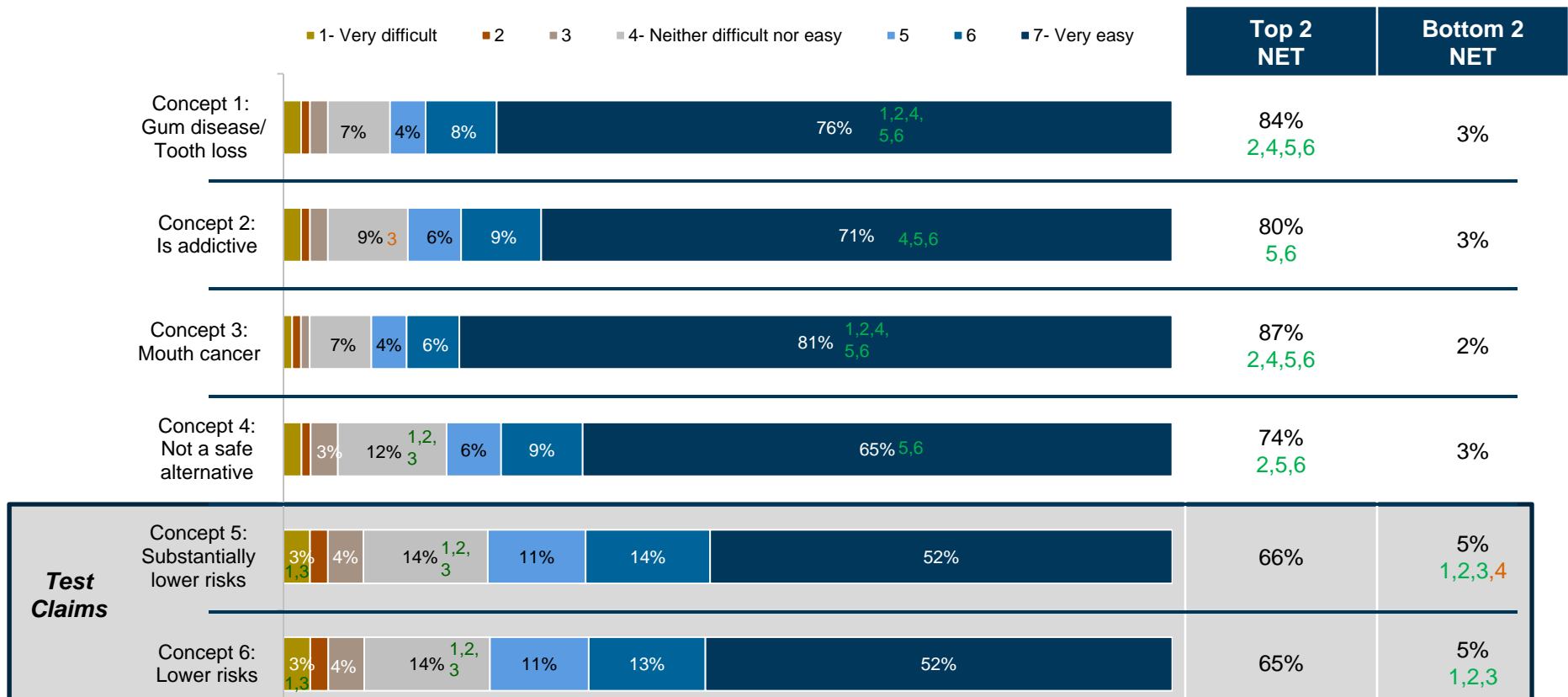
Sample balanced for gender, age, geography, income according to CDC's Morbidity and Mortality Weekly Report 60: 35

Results

- Ease of understanding
 - Q51. “Having seen the warning label on the snus package, using the scale below, please indicate how easy or difficult is it to understand the meaning of the warning label on the package you just viewed”
- Believability
 - Q59. “How believable is the warning label on this package of snus?”
- Risk perception of snus vs cigarettes
 - Q61. “How does the information you saw on the warning label directly influence your perception of the personal health risks associated with using snus compared to the personal health risks posed by cigarettes?”
- Motivation to buy snus
 - Q58. “How does the information you saw on the warning label directly impact how motivated you are to buy snus?”
- Likelihood to use snus
 - Q53. “After viewing the information in the warning label, how does the information you saw on the warning label directly influence your likelihood to use snus?”

Ease of Understanding Warning Claim

While two-thirds of those who evaluated the test warning labels found the claims to be easy to understand, this is a significantly lower proportion than those who evaluated any of the current label claims. The claims easiest to understand specifically mention gum disease/tooth loss and mouth cancer.

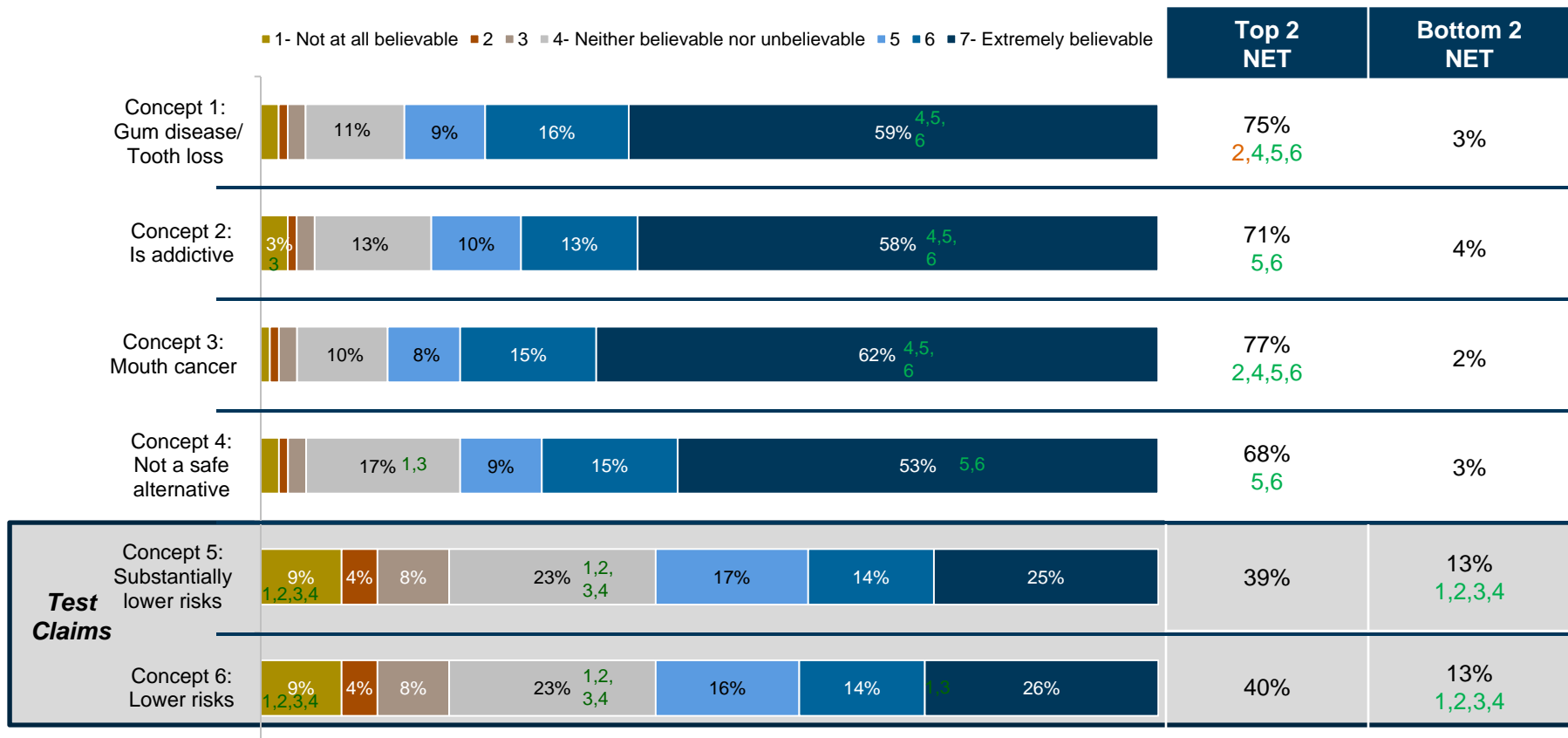


Q51. Having seen the warning label on the snus package, using the scale below, please indicate how easy or difficult is it to understand the meaning of the warning label on the package you just viewed.

Base: Concept 1: n=2201; Concept 2: n=2211; Concept 3: n=2202; Concept 4: n=2201; Concept 5: n=2202; Concept 6: n=2186

Believability of Warning Claim

Respondents overall were significantly less likely to find the two test claims to be believable compared to all current claims.

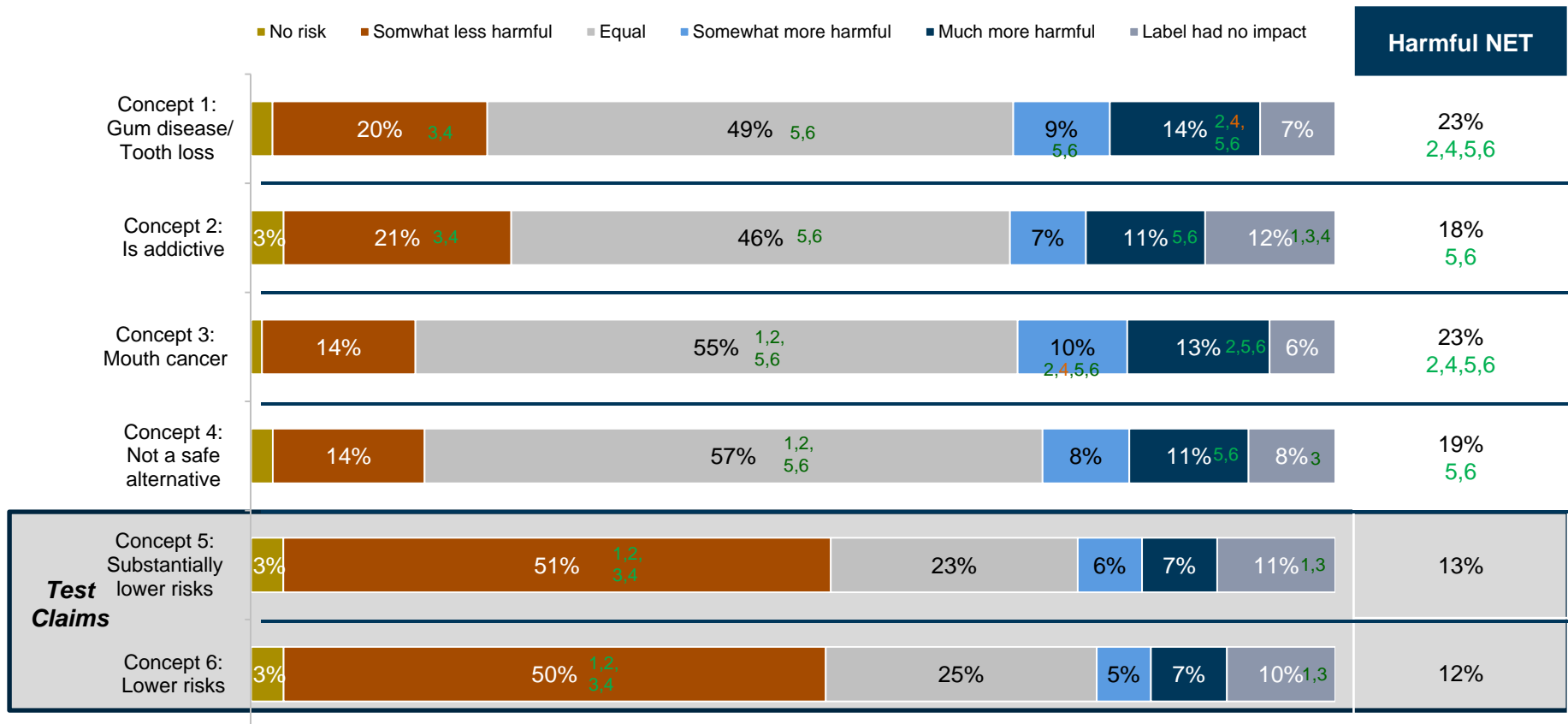


Q59. How believable is the warning label on this package of snus?

Base: Concept 1: n=2201; Concept 2: n=2211; Concept 3: n=2202; Concept 4: n=2201; Concept 5: n=2202; Concept 6: n=2186

Risk Perception of Snus vs. Cigarettes Based on Warning Claim

Respondents largely internalized the message of the test warning claims. Half exposed to either test claim felt snus would be 'somewhat less harmful' than cigarettes, which is significantly higher than any of the current claims.

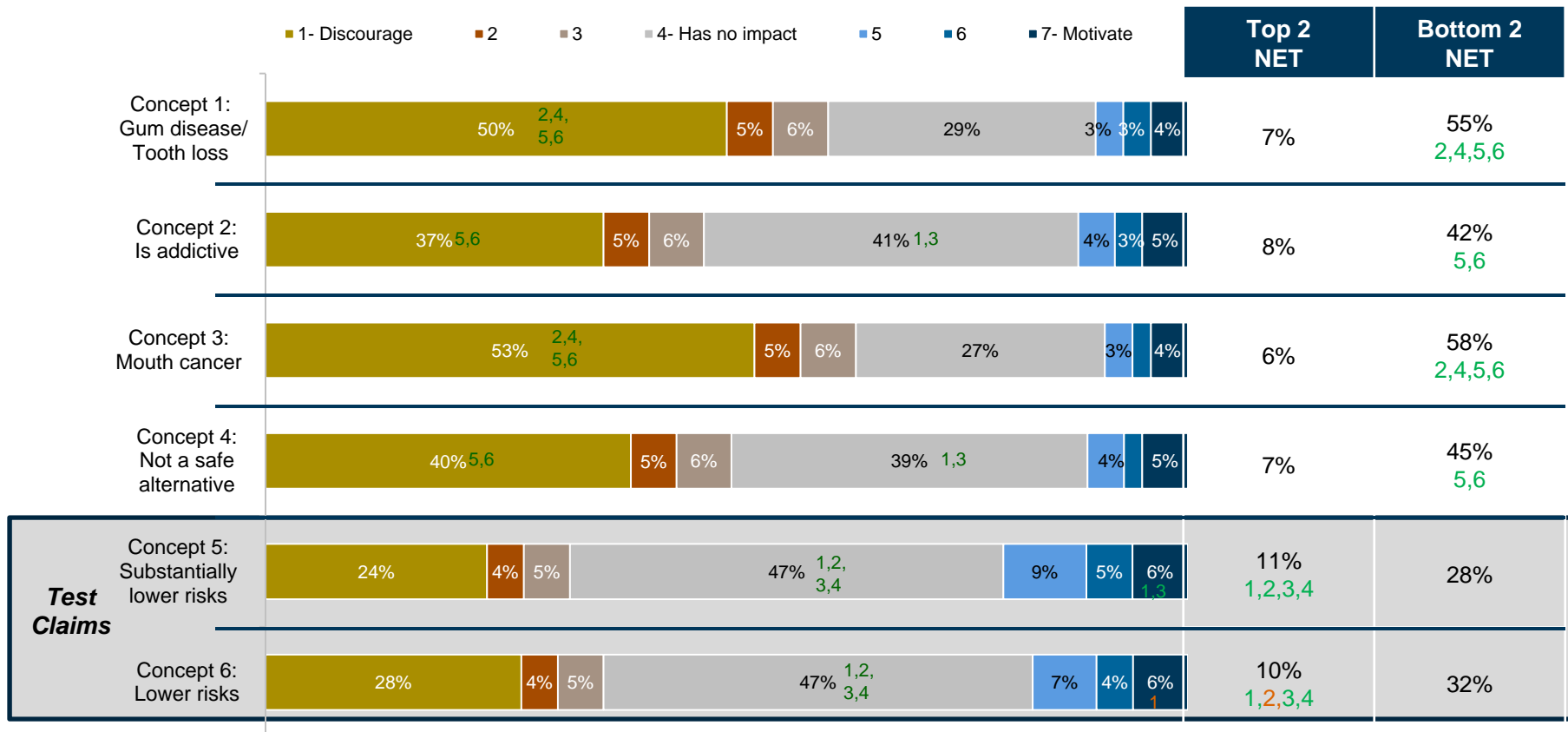


Q61. How does the information you saw on the warning label directly influence your perception of the personal health risks associated with using snus compared to the personal health risks posed by the tobacco products below?

Base: Concept 1: n=1833; Concept 2: n=1888; Concept 3: n=1883; Concept 4: n=1858; Concept 5: n=1866; Concept 6: n=1832

Motivation to Buy Snus Based on Warning Claim

Though small proportions (11% and 10% respectively), both test claims would be significantly more likely to motivate overall respondents to buy snus compared to all current labels.

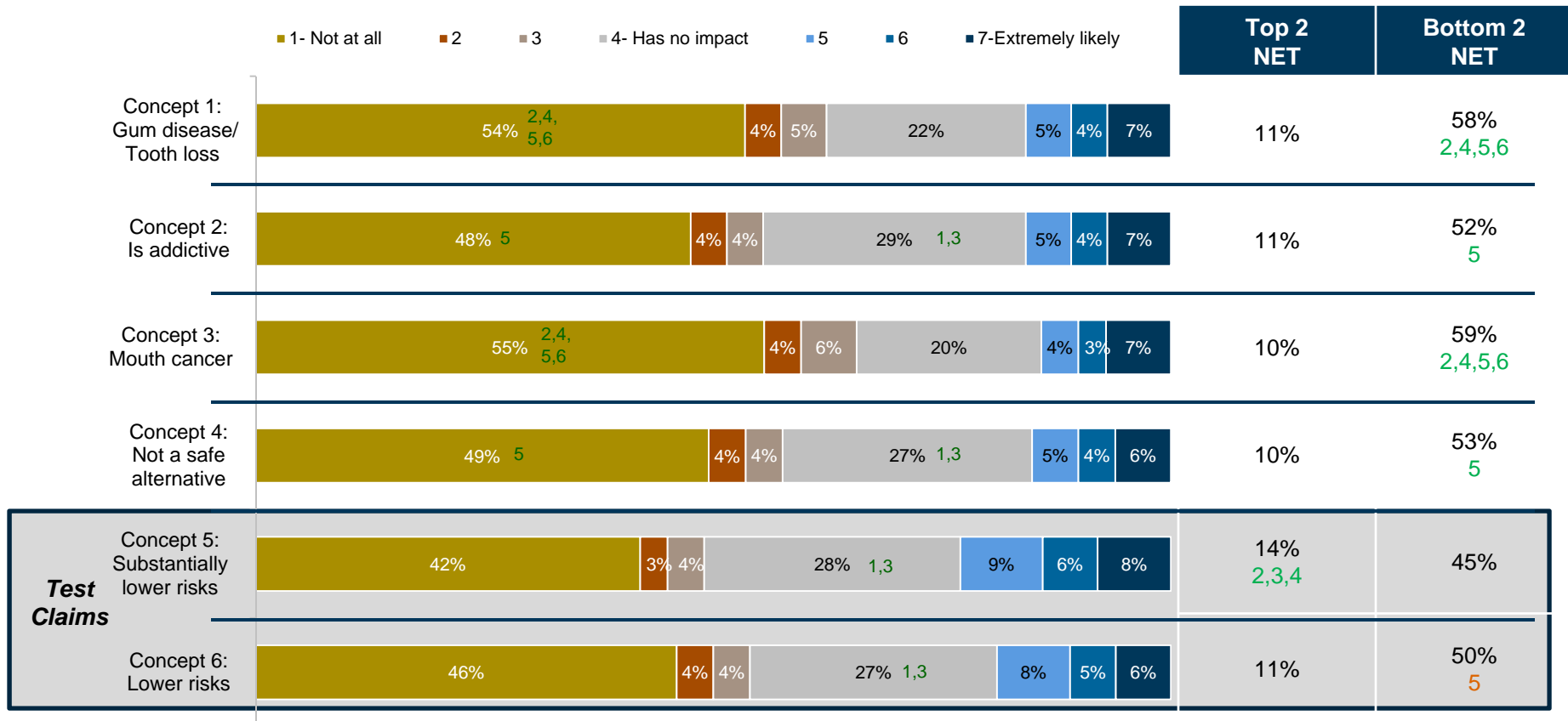


Q58. How does the information you saw on the warning label directly impact how motivated you are to buy snus?
 Base: Concept 1: n=2201; Concept 2: n=2211; Concept 3: n=2202; Concept 4: n=2201; Concept 5: n=2202; Concept 6: n=2186

Likelihood To Use Snus Based On Warning Claim

While it is a small proportion (14%), the test claim of 'a substantially lower risk than cigarettes' is significantly more likely to influence snus usage among overall respondents than claims about being addictive, causing mouth cancer or not being a safe alternative to cigarettes.

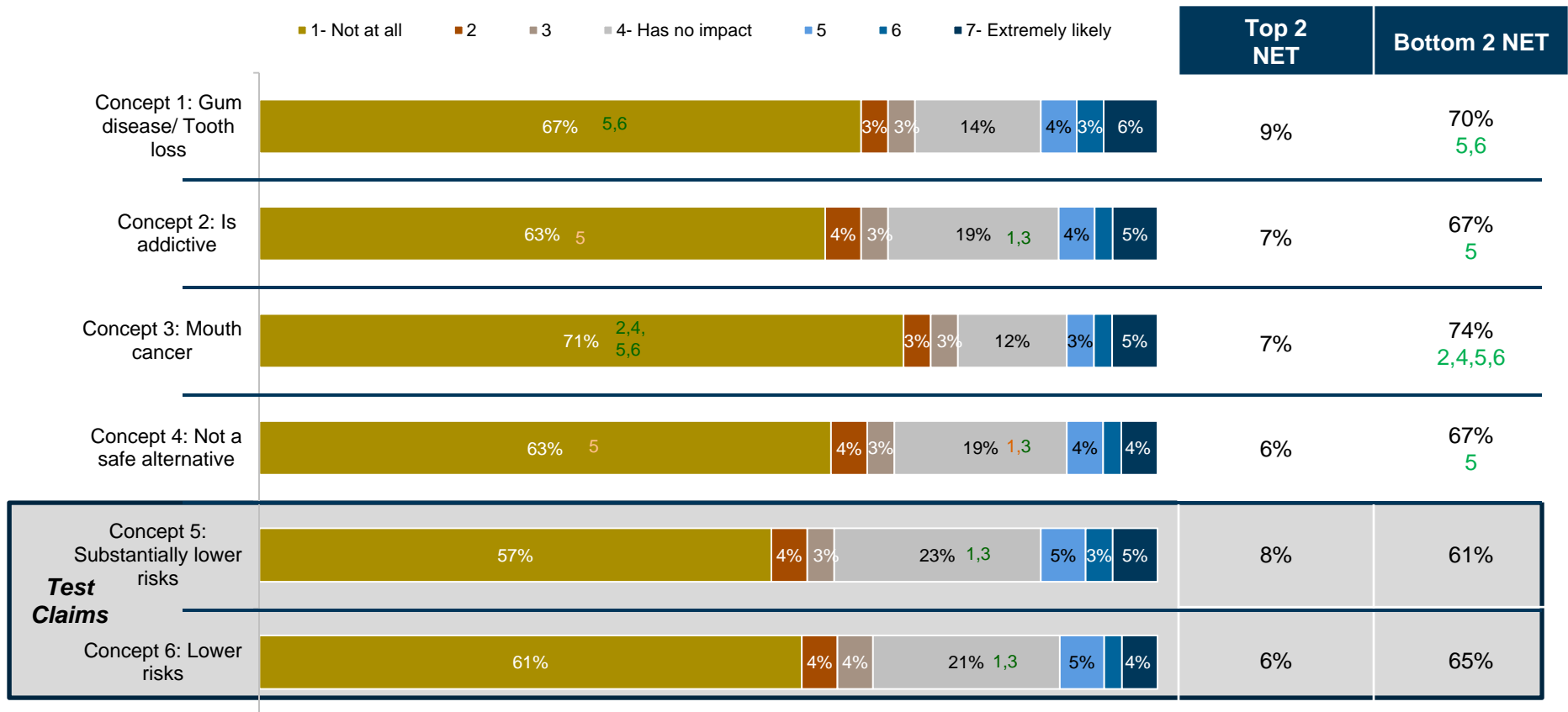
However, the claim simply stating 'a lower risk than cigarettes' performs on par with current claims.



Q53. After viewing the information in the warning label, how does the information you saw on the warning label directly influence your likelihood to use snus?
 Base: Concept 1: n=2201; Concept 2: n=2211; Concept 3: n=2202; Concept 4: n=2201; Concept 5: n=2202; Concept 6: n=2186

Likelihood To Use Snus Based On Warning Claim

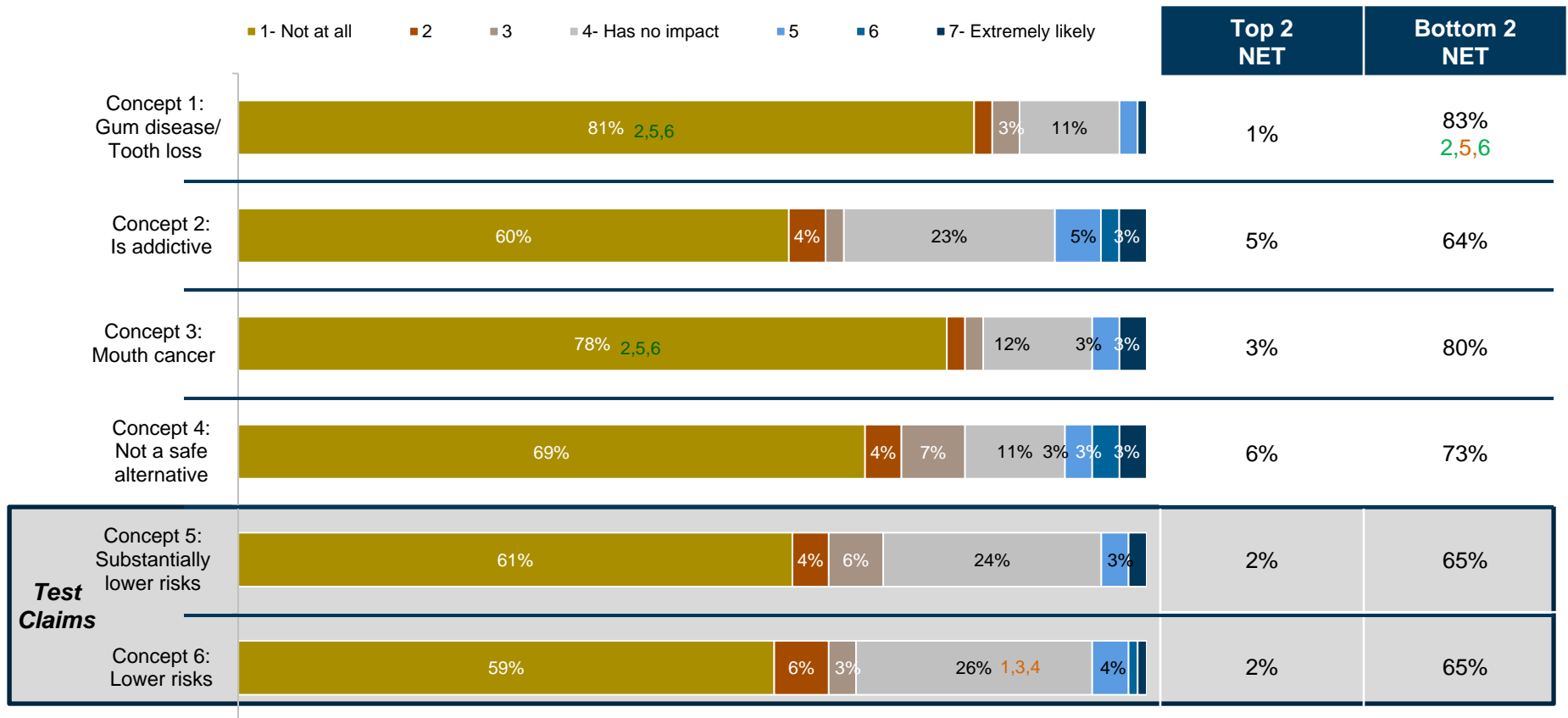
No claims stand out as one that would influence non-users to use snus.



Q53. After viewing the information in the warning label, how does the information you saw on the warning label directly influence your likelihood to use snus?
 Base: Concept 1: n=1101; Concept 2: n=1110; Concept 3: n=1100; Concept 4: n=1101; Concept 5: n=1104; Concept 6: n=1094

Likelihood To Use Snus Based On Warning Claim

None of the claims tested are likely to influence former users to use snus, with a significant proportion of those exposed to the test claims citing the claims 'had no impact' on their likelihood to use snus.



Q53. After viewing the information in the warning label, how does the information you saw on the warning label directly influence your likelihood to use snus?

Base: Concept 1: n=108; Concept 2: n=135; Concept 3: n=126; Concept 4: n=115; Concept 5: n=116; Concept 6: n=99

Group: Non-Users of Tobacco: Former Users (Regular or Occasional)

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Conclusions

- The two tested new statements resulted in respondents being better informed about the relative risk of snus versus cigarettes
- Impact on motivation to buy and likelihood to use snus restricted to current users of tobacco products
- No adverse impact on current non-users of tobacco product from the tested new statements

Conclusions, cont'd

- Findings among young adults (18-24 years), minorities, and respondents from low income households
 - Results were similar to those for the total populations of current users and non-users of tobacco products
 - Study findings thus do not raise unique issues or concerns for these demographic subsets
- Premarket data indicate that the tested two new statements are unlikely to produce unintended consequences

Independent analysis

- Advisory Panel much involved in the development of the protocol for the premarket study
- Two panel members together with others have conducted their own, independent analysis
- Publication of results is underway
- Findings do not contradict the analyses and conclusions included in the MRTPAs
- Raw data from the study made available

Premarket data and behavioral intentions

- There will always be an element of uncertainty in premarket studies
- In real life humans may not act the way we say we will in a research setting, we may be influenced by unexpected situational or subconscious stimuli
- Postmarket data concern actual behaviors
 - Final protocol not required until after an MRTP order has been issued

Relationship to MRTP Order

MRTPA Areas of Evidence	FDCA Statutory Standard for MRTP Order	Proposed MRTPA Warning Labels
Swedish Human Health Evidence	-Individual Risk Reduction -Public Health Benefit	-deletion of mouth cancer warning -deletion of gum disease and tooth loss warning
Norwegian Behavior Evidence	-Public Health Benefit	
Swedish Match-funded Clinical Trials on Smoking Cessation Potential and Nicotine PK and PD	-Individual Risk Reduction -Public Health Benefit	
Premarket Consumer Perception Study	-Public Health Benefit	-inclusion of “substantially lower risks to health” warning
Dynamic Population Modeler	-Public Health Benefit	