

Section VIII. Scientific Studies and Analyses

E. Consumer Perception

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VIII. Scientific Studies and Analyses

E. Effect of Marketing on Consumer Understanding and Perceptions

1. Qualitative Study to Develop PARE / VLN™ Claims within the United States

Four qualitative studies (M/A/R/C Research 2018, "Qualitative..." [\[pg_53\]](#)) were performed on products branded as PARE® or VLN™. Initially the product was conceptualized under the brand name PARE®. The intent of the name was to imply to reduce or “pare” back. The Spanish translation of PARE® meaning “stop” was discovered in the second focus group. Since quitting or

stopping smoking is not a claim for the product, an alternative name was tested. The descriptive name VLN™ was tested in subsequent studies along with PARE®. The goals of the qualitative studies were to:

- Evaluate consumer perception of and understanding surrounding proposed pack messaging for VLN™ cigarettes.
- Understand perceptions of risk and communication of that risk through the statements on the pack.

The pack messaging was modified after each phase of the qualitative studies taking into account learnings from the previous phase. Based on the results of the qualitative studies, final pack messaging was developed and tested in a quantitative study. The overall intent of the messaging was to develop claims that smokers could understand, while not attracting non-smokers and former smokers. Also, it was important to develop statements to help the smoker understand that less nicotine does not mean a safer cigarette. Subjects were shown sample packs or pack wording and asked questions probing their understanding of the message, their impression of the relative health risks associated with the product and their intent to purchase. Reduced exposure and reduced risk claims were tested in Phases 1, 2, and 3. The decision was made to pursue only reduced exposure claims. Therefore, no discussion of reduced risk claims is included here. Only reduced exposure claims were tested in Phase IV.

The first two studies were focus groups (FG) and the last two were in depth interviews (IDI). The studies were conducted across the geographic regions of the United States. Research participants were categorized based on their smoking status according to self-report. The categories were defined as follows:

- “Adult smokers with no intention to quit”

- “Adult smokers with intention to quit”
- “Recent quitters”
- “Long-term quitters”
- “Never used”

There was a mix of menthol and non-menthol smokers in the studies.

i. Phase I

Phase I of the study evaluated reduced exposure and reduced risk claims. Subjects were shown written statements about the product. The study included 69 participants in 12 focus groups conducted across four cities:

Table VIII.E-1 Phase I Focus Group Segments

City	Focus Group Segment*	# of Participants
NYC March 14, 2018	Males 50+	8
	Current Smokers – Intend to Quit (MX)	
	Females 35-49	6
	Current Smokers – No Intent to Quit (MX)	
	Males 21-34	6
	Current Smokers – No Intent to Quit (MX)	
Atlanta March 15, 2018	Females 50+	6
	Current Smokers – No Intent to Quit (MX)	
	Males 35-49	6
	Current Smokers – No Intent to Quit (MX)	
	Females 18-34	7
	Current Smokers – Intend to Quit (MX)	
Detroit March 15, 2018	Males 50+	7
	Current Smokers – No Intent to Quit (MX)	
	Females 35-49	5
	Current Smokers – Intend to Quit (MX)	
	Males 21-34	6
	Current Smokers – Intend to Quit (MX)	
Los Angeles March 16, 2018	Females 50+	6
	Current Smokers – Intend to Quit (MX)	
	Males 36-50	6
	Current Smokers – Intend to Quit (MX)	
	Females 21-35	6
	Current Smokers – No Intent to Quit (MX)	

*Abbreviation: “(MX)” indicates a mix of Non-Menthol and Menthol users

In Phase I, respondents were, shown examples of different tobacco/nicotine-related products and given verbal descriptions of each. The focus was to establish participants’ familiarity of each product type.

Table VIII.E-2 Phase I Tobacco/Nicotine Product Cues

Type 1	Full Flavor Tasting Cigarettes	Full flavor tasting cigarettes have strong, sustained and extensive taste. Examples of full flavor brands are on the table.
Type 2	Light Tasting Cigarettes	Light tasting cigarettes have a lighter, less pronounced taste than full flavor cigarettes. Here are some examples of light tasting brands.
Type 3	Ultra-Light Tasting Cigarettes	Ultra-light tasting cigarettes have a very light taste compared to full flavor cigarettes. Here are some examples of ultra-light tasting cigarettes.
Type 4	e-cigarettes	Electronic cigarettes, also known as e-cigarettes, e-vaporizers, or electronic nicotine delivery systems, are battery-operated devices that people use to inhale an aerosol, which typically contains nicotine (though not always), flavorings, and other chemicals. Some examples of e-cigarettes are shown here.
Type 5	Moist Snuff	Moist snuff is a smokeless tobacco product that is consumed by placing it into your mouth between the lip and the gum. You don’t burn it, and users often spit when they use it. Here are some examples of moist snuff.
Type 5	SNUS	SNUS is a smokeless, moist powder tobacco pouch that you place under your top lip. It comes in flavors such as mint and wintergreen. You don’t burn it, and you don’t have to spit when you use it. You can see some examples of SNUS here on the table.
Type 7	Nicotine Replacement Therapy (NRT)	Nicotine Replacement Therapy are products that contain nicotine but no tobacco, and are used to help people quit cigarettes or other tobacco products. Nicotine Replacement Therapy products usually come in the form of gum, patches, inhalers, lozenges or tablets, as shown here on the table.

Visual aids were used as the basis for the discussion of the “risk” and “intention to use.” Respondents were asked to rate the relative risk (exposure to harmful compounds and risk of developing disease) associated with using the products listed above, plus their intent to personally use the products.

Table VIII.E-3 shows the consumer preferences for the various pack messages. A clear message from the participants was that simple wording was better. Based on the messaging, the subjects placed the VLNTM product about equal to e-cigarettes when asked about exposure to HPHCs (Figure VIII.E-1). The participants placed the product about equal to snus when considering the risks of developing tobacco related diseases (Figure VIII.E-2). The product as labeled had a low intent to use (Figure VIII.E-3).

Table VIII.E-3. Phase I - Consumer preference results.

REDUCED EXPOSURE CLAIMS – Phase 1 Preferences

<p>CLAIM 1 TOP OF FRONT PANEL VERY LOW NICOTINE PARE Cigarettes Contain 5% Less Nicotine Than Leading Brands* *Approximately 95% less nicotine in tobacco and smoke compared to the top 3 selling brands.</p> <p>BOTTOM OF FRONT PANEL The Tobacco Smoke From PARE Cigarettes is No Safer Than Smoke From Any Other Cigarette.</p> <p>BACK OF PACK PARE exposes you to significantly less nicotine, an addictive chemical.</p>	<p>CLAIM 3 TOP OF FRONT PANEL VERY LOW NICOTINE Made with PARE'S Patented Reduced-Nicotine Tobacco* *The tobacco in PARE Cigarettes Contains Less Than 5% of the nicotine of the three leading US cigarettes.</p> <p>BOTTOM OF FRONT PANEL No cigarette is safe. Very Low Nicotine does not mean a safer cigarette.</p> <p>BACK OF PACK This product contains much lower levels of nicotine, an addictive chemical. However, it is "tar," not nicotine, that causes smoking-related diseases. The "tar" produced by PARE is comparable to "tar" produced by other cigarettes.</p>	<p>CLAIM 5 TOP OF FRONT PANEL VERY LOW NICOTINE PARE Cigarettes Contain 95% Less Nicotine Than Leading Brands* *Approximately 95% less nicotine in tobacco and smoke compared to the top 3 selling brands.</p> <p>BOTTOM OF FRONT PANEL PARE Cigarettes Are No Safer Than Any Other Cigarette.</p> <p>BACK OF PACK All tobacco products contain nicotine, an addictive chemical. PARE cigarettes give you much less nicotine than competing brands. However, smoking PARE is no safer than smoking any other cigarette.</p>	<p>CLAIM 4 TOP OF FRONT PANEL VERY LOW NICOTINE This product is made with tobacco containing very low levels of nicotine, an addictive chemical* *The tobacco in PARE Cigarettes Contains Less Than 5% of the nicotine of the three leading US cigarettes.</p> <p>BOTTOM OF FRONT PANEL This cigarette is not a safe alternative to traditional cigarettes.</p> <p>BACK OF PACK This product contains significantly lower levels of nicotine than other cigarettes, which may help you better manage your smoking. However, it is "tar," not nicotine, that causes smoking-related diseases. The "tar" in PARE is comparable to "tar" produced by other cigarettes.</p>	<p>CLAIM 2 TOP OF FRONT PANEL VERY LOW NICOTINE Nicotine is an addictive chemical. PARE Cigarettes Contain Less Than 5% of the Nicotine of Leading Brands* *Compared to the top 10 best-selling brands.</p> <p>BOTTOM OF FRONT PANEL No Cigarette is Safe. PARE Cigarettes Present The Same Health Risks as Other Cigarettes.</p> <p>BACK OF PACK People smoke cigarettes to get nicotine, but it's the smoke or "tar" that kills smokers. Smoke from a PARE cigarette contains less nicotine than other cigarettes but it is no different from the smoke from other cigarettes. Smoking PARE cigarettes over the long-term will cause the same damage to your health as smoking any other cigarette.</p>

Most Descriptive Claim Reduced Exposure Claims



Most Descriptive Claim Per Pack Location in Build-Your-Own Scenario for Reduced Exposure Claims

Figure VIII.E-1. Phase I - Likelihood of exposure to harmful and potentially harmful compounds.

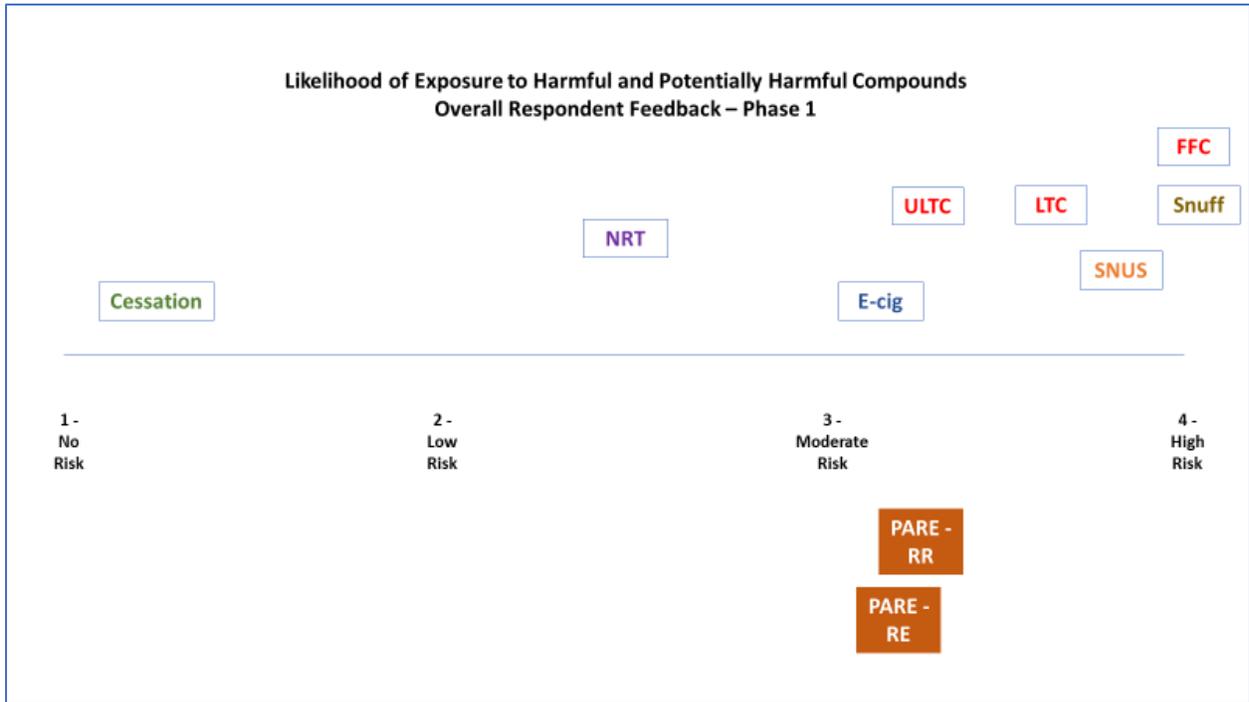


Figure VIII.E-2. Phase I - Risk of developing smoking/tobacco-related diseases.

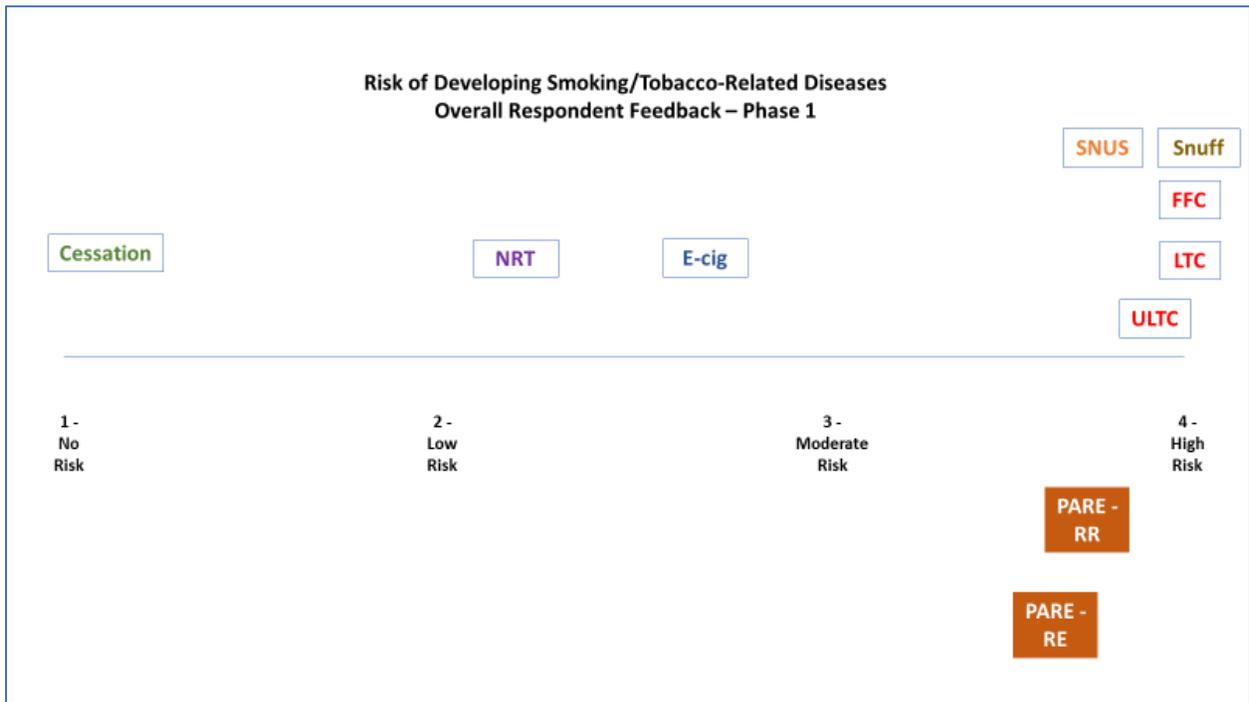
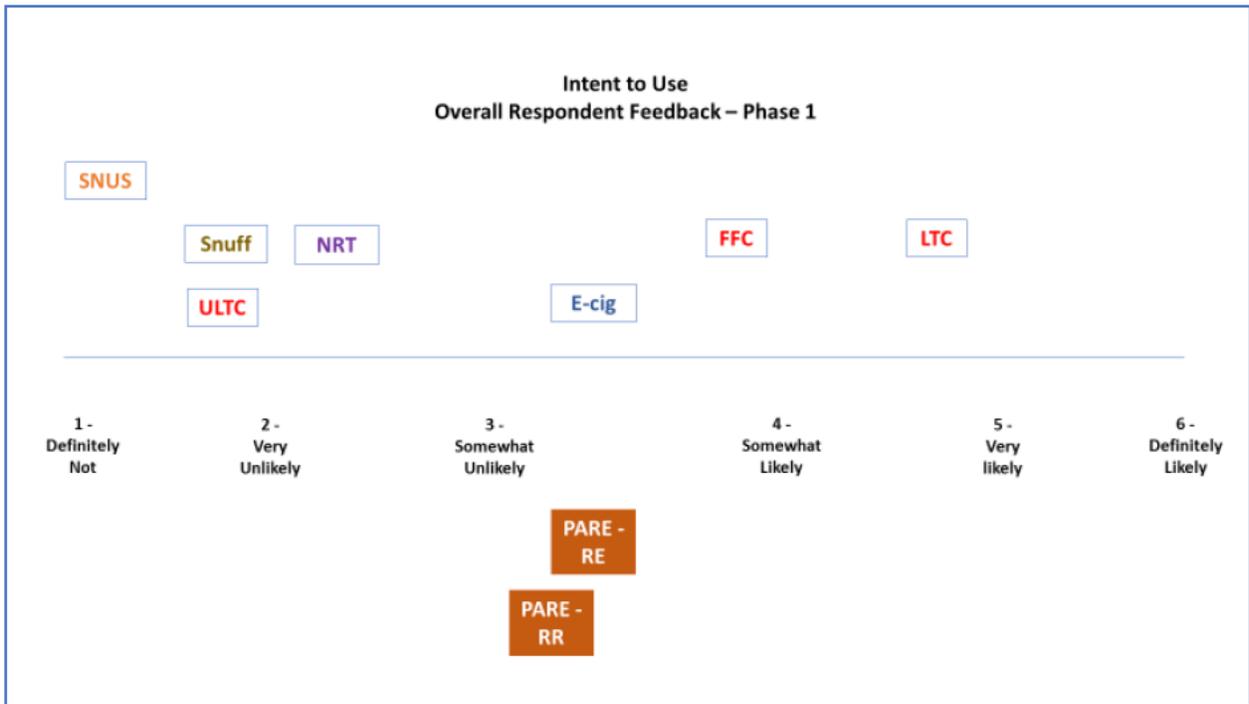


Figure VIII.E-3. Phase I - Intent to use.



ii. Phase II

In Phase II, participants were shown mock-ups of packs. Figure VIII.E-4. Sample mock-up of pack showing placement of various pack messages. shows a mock- up of the pack with the placement of various pack messages.

Figure VIII.E-4. Sample mock-up of pack showing placement of various pack messages.



Phase II included 177 participants in 30 focus groups from the following segments:

Table VIII.E-4 Phase II Focus Group Segments

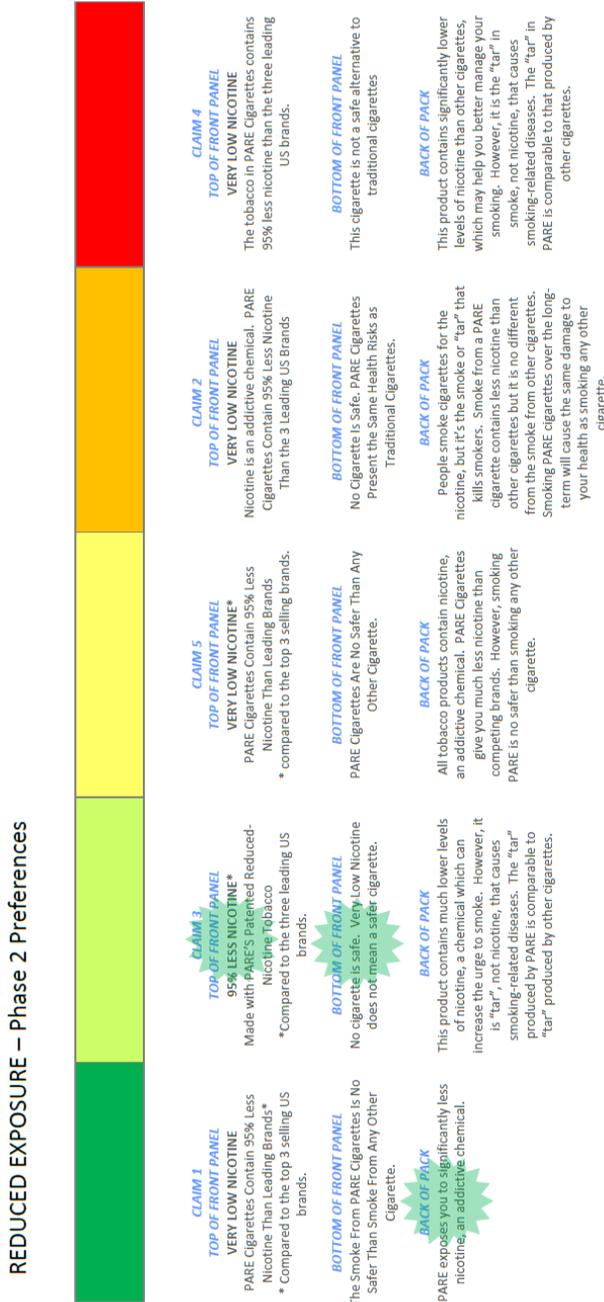
City	Focus Group Segment*	# of Participants
Chicago, IL March 22-23, 2018	Females 50+	7
	Current Smokers – No Intent to Quit (NM)	
	Males 50+	6
	Current Smokers – No Intent to Quit (NM)	
	Males 35-49	5
	Current Smokers – Intend to Quit (MX)	
	Females 21-34	6
	Current Smokers – No Intent to Quit (M)	
	Females 21-34	6
	Recent Quitters	
	Females 50+	7
	Current Smokers – Intend to Quit (MX)	
	Females 50+	6
Long-term Quitters		
Males 35-49	6	
Long-term Quitters		
Hartford, CT March 22-23, 2018	Females 50+	6
	Current Smokers – No Intent to Quit (M)	
	Males 35-49	6
	Current Smokers – No Intent to Quit (M)	
	Females 18-34	3
	Current Smokers – No Intent to Quit (M)	
	Females 18-34	6
	Current Smokers – Intend to Quit (MX)	
	Females 18-34	6
	Long-term Quitters	
	Females 50+	6
Recent Quitters		
Males 35-49	6	
Recent Quitters		
Dallas, TX March 26-27, 2018	Males 50+	6
	Current Smokers – No Intent to Quit (NM)	
	Males 50+	6
	Current Smokers – Intend to Quit (MX)	
	Females 35-49	6
	Current Smokers – No Intent to Quit (NM)	
	Males 18-34	6
Current Smokers – No Intent to Quit (NM)		
Males 18-34	6	
Current Smokers – Intend to Quit (MX)		

	Males 18-34	6	
	Recent Quitters		
	Males 50+	6	
	Long-term Quitters		
	Females 35-49	6	
	Recent Quitters		
	Male LA-34	6	
	Current Smokers – No Intent to Quit (NM)		
	Male LA-34	6	
	Long Term Quitters		
	Male 50+	6	
	Current Smokers – No Intent to Quit (M)		
Denver, CO March 28-29, 2018	Male 50+	5	
	Recent Quitters		
	Female 35-49	6	
	Current Smokers – No Intent to Quit (NM)		
	Female 35-49	6	
	Current Smokers – Intend to Quit (MX)		
	Female 35-49	6	
	Long Term Quitters		
	Total Participants		177

**Abbreviations: “(NM)” indicates smokers who use Non-Menthol cigarettes, “(M)” indicates those who use Menthol cigarettes and “(MX)” indicates a mix of Non-Menthol and Menthol users*

Table VIII.E-5 shows the consumer preference for the various pack messages. The “95% Less Nicotine” principal claim was preferred over “Very Low Nicotine.” Based on the messaging, the subjects again placed the product about equal to e-cigarettes when asked about exposure to HPHCs (compare Figure VIII.E-1 to Figure VIII.E-5). The participants placed the product about slightly less risky than traditional cigarettes when considering the risks of developing tobacco related diseases (Figure VIII.E-6). The product as labeled had a low intent to use (Figure VIII.E-7).

Table VIII.E-5. Phase II - Consumer Preference Results



Most Preferred Claim Per Pack Location in Build-Your-Own Scenario for Reduced Exposure Claims
 Total Base = 128 Respondents Across 3 Cities (Hartford, Dallas, Denver)

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Figure VIII.E-5. Phase II - Likelihood of Exposure to Harmful and Potentially Harmful Compounds

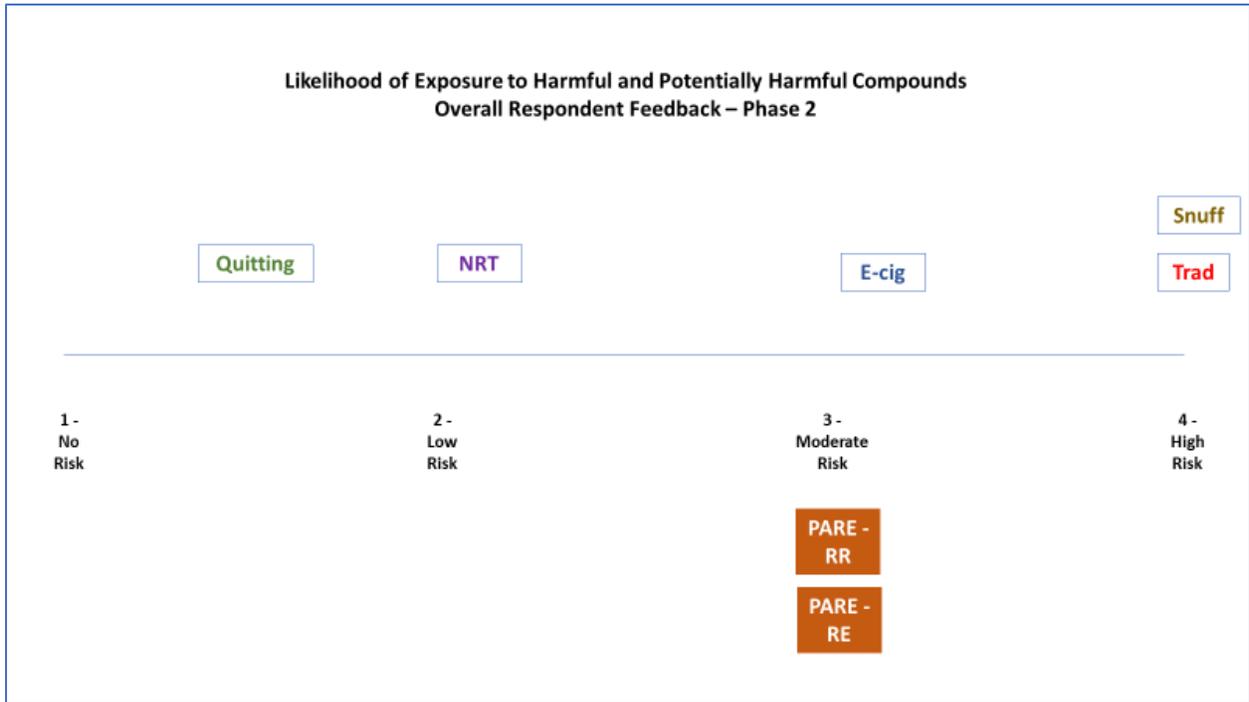


Figure VIII.E-6. Phase II - Risk of developing smoking/tobacco-related diseases.

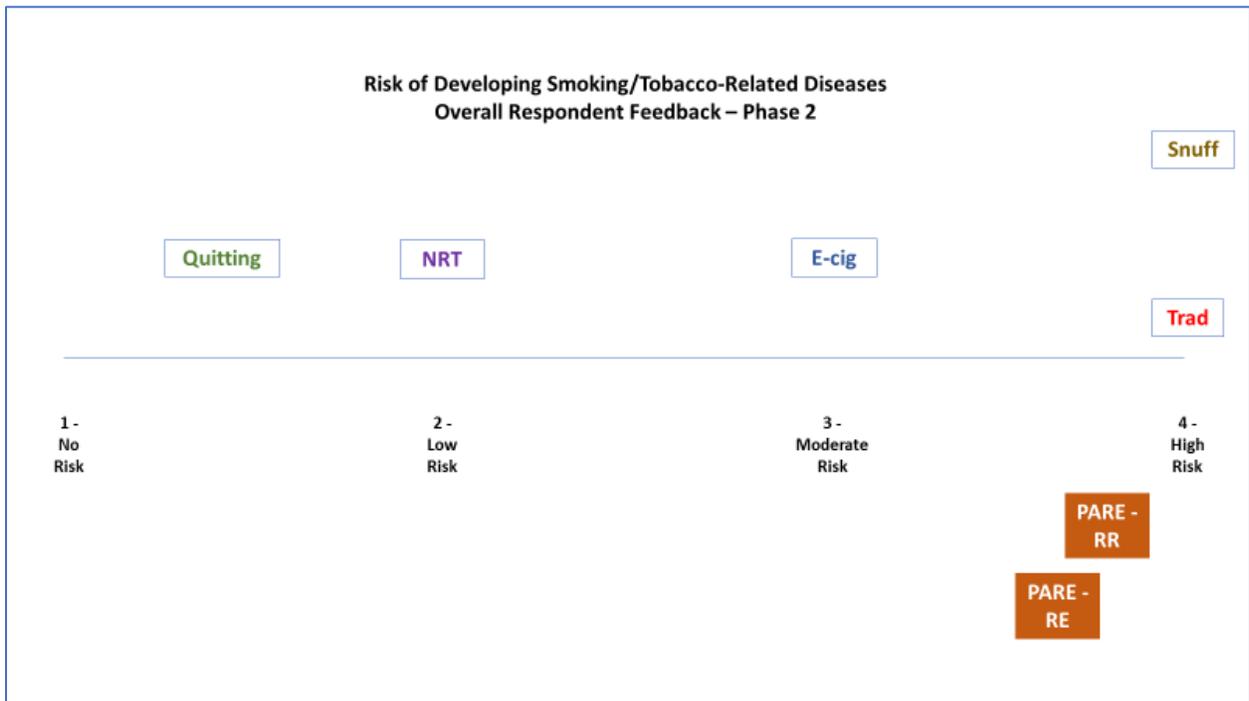
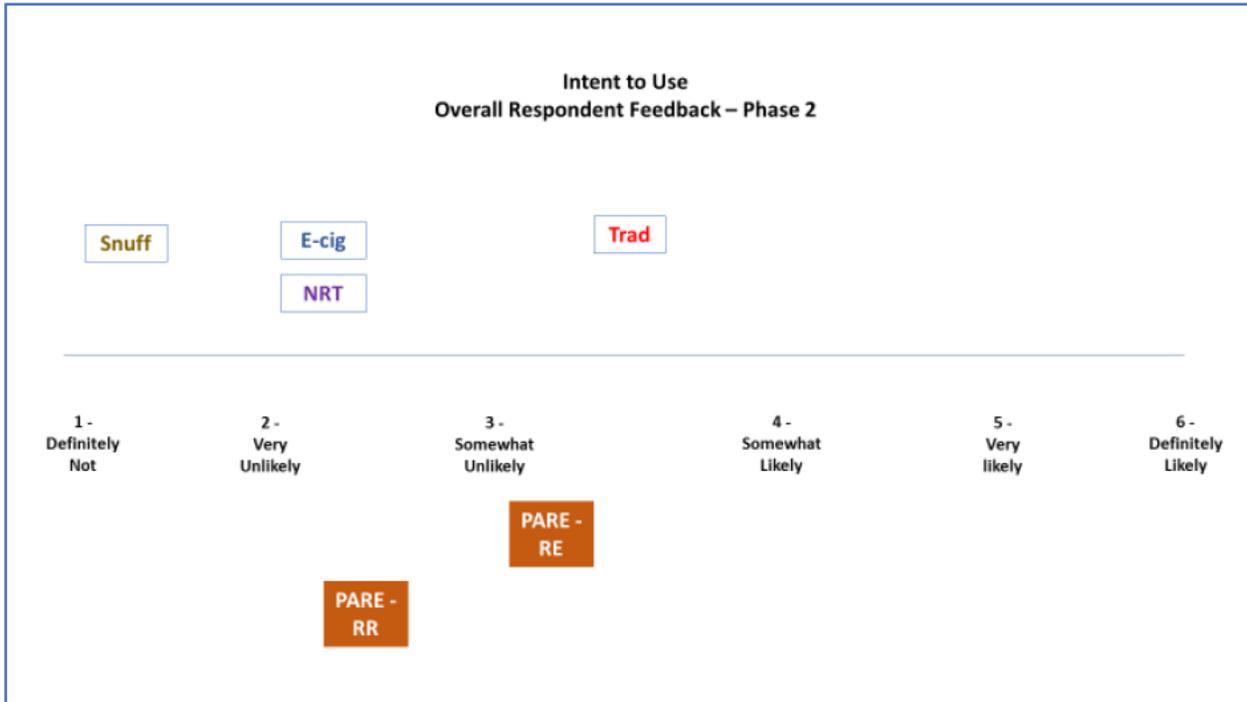


Figure VIII.E-7. Phase II - Intent to Use.



iii. Phase III

Phase III consisted of in-depth interviews conducted in Boston, Chattanooga, St. Louis, and Las Vegas. This phase included 50 participants from the following segments:

Table VIII.E-6 Focus Group Segments

Segment*	Males				Females			
	18-25	26-34	35-49	50+	18-25	26-34	35-49	50+
Never Used	1	1	1	1	1	2	1	1
Recent Quitter	-	2	1	1	-	4	1	1
Long-term Quitter	-	2	1	1	-	2	1	2
Current Smoker – Intend to Quit (MX)	-	2	1	1	-	2	1	1
Current Smoker – No Intent to Quit (M)	-	2	1	1	-	1	-	1
Current Smoker – No Intent to Quit (NM)	-	2	1	1	-	2	1	1
Total Participants								50

*Abbreviations: “(NM)” indicates smokers who use Non-Menthol cigarettes, “(M)” indicates those who use Menthol cigarettes and “(MX)” indicates a mix of Non-Menthol and Menthol users

Participants were shown PARE® packs with revised labeling. Figure VIII.E-8 shows the consumer preference for the various label statements. In these in-depth interviews there appeared to be a preference of “Very Low Nicotine” over “95% Less Nicotine.” Based on the messaging, the subjects again placed the product about equal to e-cigarettes when asked about exposure to HPHCs (Figure VIII.E-9). The participants again placed the product about slightly less risky than traditional cigarettes when considering the risks of developing tobacco related diseases (Figure VIII.E-10). The product as labeled had a low intent to use (Figure VIII.E-11).

Figure VIII.E-8. Phase III - Consumer Preference Results

REDUCED EXPOSURE – Phase 3 Preferences



Most Preferred Claim Per Pack Location in Build-Your-Own Scenario for Reduced Exposure Claims
 Total Base = 50 Respondents Across 4 Cities (Boston, St. Louis, Chattanooga, Las Vegas)

5180077 PARE Claims Development – Qualitative
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Figure VIII.E-9. Phase III - Likelihood of Exposure to Harmful and Potentially Harmful Compounds

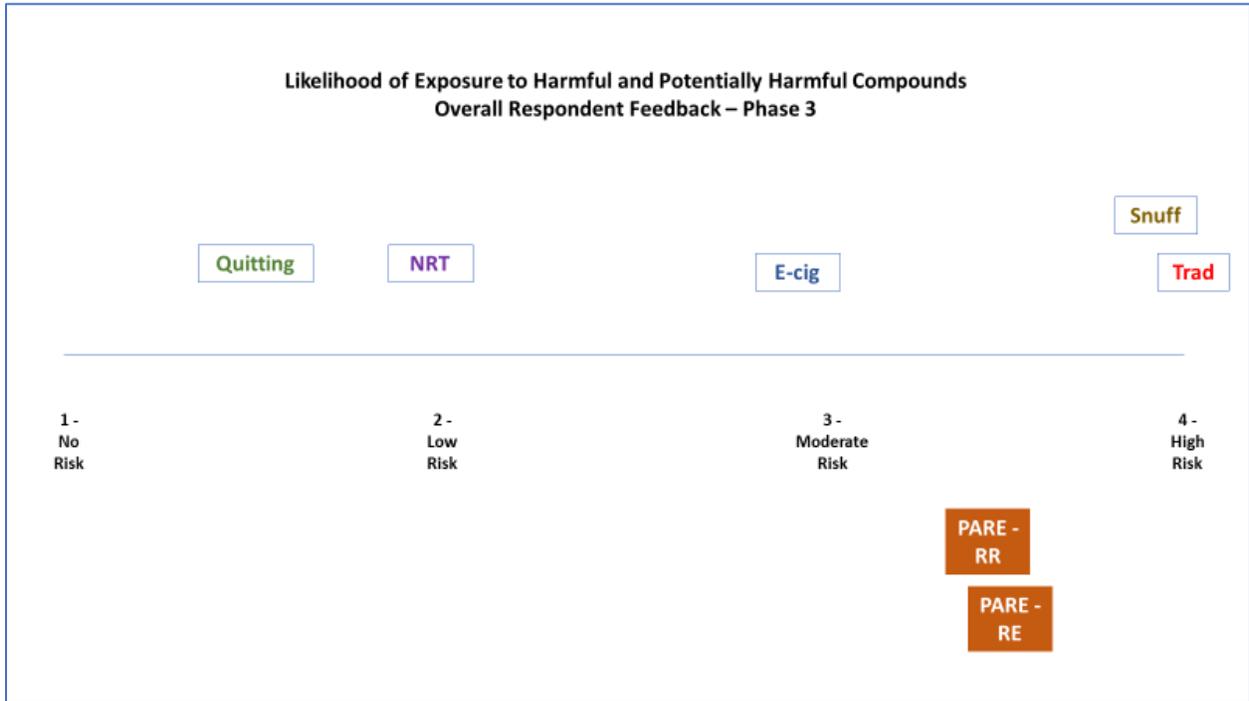


Figure VIII.E-10. Phase III - Risk of Developing Smoking/Tobacco-related Diseases

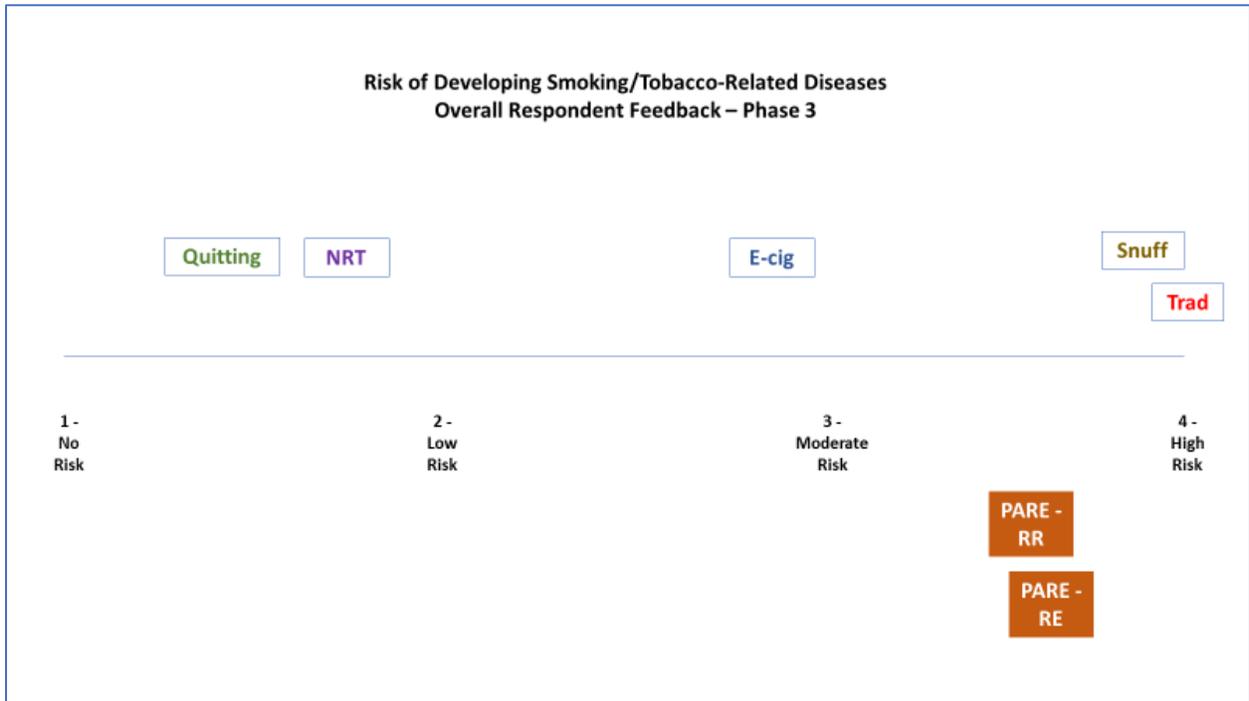
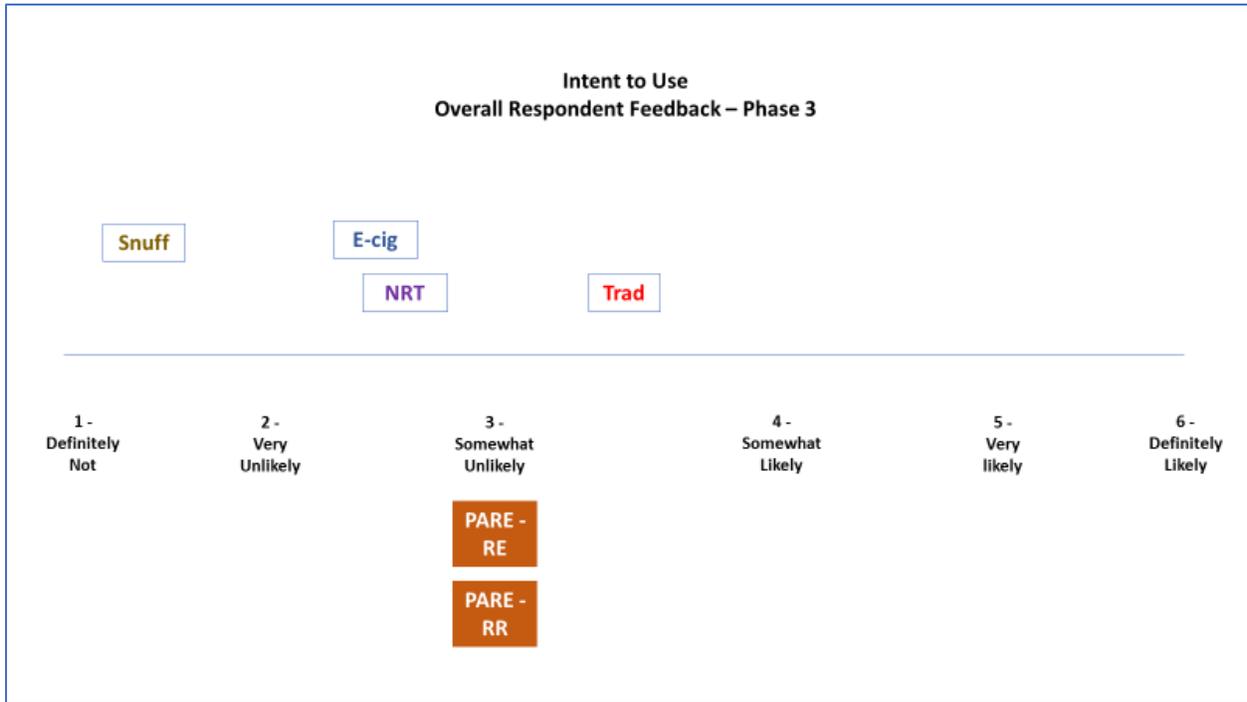


Figure VIII.E-11. Phase III - Intent to Use



iv. Phase IV

Phase IV participants were shown VLN™ packs with substantially simplified messaging (Figure VIII.E-12). Two different color schemes were shown. One was similar to the “PARE®” scheme shown in Figure VIII.E-4, the other was the traditional design shown in Figure VIII.E-12. Table VIII.E-7 shows the principal claim tested - “95% LESS NICOTINE” and supporting secondary claims.

Figure VIII.E-12. Mock-up of VLN™ Pack



Table VIII.E-7. Principle Claims Tested in Phase IV.

TOP OF PACK AND TOP SECONDARY STATEMENT
95% LESS NICOTINE
Helps reduce your nicotine consumption
95% LESS NICOTINE
(b) (4)
95% LESS NICOTINE
(b) (4)
95% LESS NICOTINE
(b) (4)

Phase IV was conducted in the suburbs of Newark, New Jersey and consisted of 56 in-depth interviews from the following segments:

Table VIII.E-8 Phase IV Group Segments

Segment*	Males				Females			
	18-25	26-34	35-49	50+	18-25	26-34	35-49	50+
Never Used	2	2	1	2	2	2	2	2
Recent Quitter	-	2	1	2	-	1	1	-
Long-Term Quitter	-	1	2	1	-	3	2	2
Current Smoker – Intend to Quit (MX)	-	1	1	2	-	2	1	-
Current smoker – No Intent to Quit (MX)	-	4	2	3	-	3	3	1
Total Participants								56

*Abbreviation: “(MX)” indicates a mix of Non-Menthol and Menthol users

Table VIII.E-9 shows the consumer preference results for the VLN™ packs. The secondary claim preferred by the consumers was (b) (4) Consumers interpreted the messaging to indicate that the a VLN™ user would be more likely to be exposed to harmful compounds than an e-cigarette user (Figure VIII.E-13). The product was considered riskier than e-cigarettes but less risky than traditional cigarettes (Figure VIII.E-14). The intent to use was about equal to e-cigarettes (Figure VIII.E-15). Concerning the different packaging concepts, respondents noted that the PARE package concept looked more like a natural product. Several noted a dislike of the yellow package color and were confused by the “tree” or mountain image. Participants noted that the VLN package was sleek or streamlined. They were confused by the VLN acronym. Some guessed its meaning – Very Low Nicotine.

Table VIII.E-9. Phase IV - Consumer preference results.

OVERALL PREFERENCES: All Claims – Phase 4

Claim 1	Claim 3	Claim 4	Claim 5	Claim 6	Claim 2	Claim 8
<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY Helps reduce your nicotine consumption</p>	<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY (b) (4)</p>	<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY (b) (4)</p>	<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY (b) (4)</p>	<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY (b) (4)</p>	<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY Helps reduce your nicotine consumption</p>	<p>TOP OF FRONT PANEL 95% LESS NICOTINE</p> <p>TOP SECONDARY (b) (4)</p>
<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>	<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>	<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>	<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>	<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>	<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>	<p>BOTTOM OF FRONT PANEL 95% less nicotine does NOT mean a safer cigarette. All cigarettes, including _____, can cause smoking-related diseases and death.</p> <p>BACK OF PACK ____ smells, burns, and tastes like a conventional cigarette, but greatly reduces your cigarette consumption.</p> <p>For more information, go to www.____cigarettes.com.</p>



Most Preferred Claim Per Pack Location in Build-Your-Own Scenario (comparison across all claims)

Total Base = 54 Respondents (Paramus, NJ)

5/18/2017 5:00:37 PM PAF Claims Development - Qualitative
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Figure VIII.E-13. Phase IV - Likelihood of Exposure to Harmful Compounds

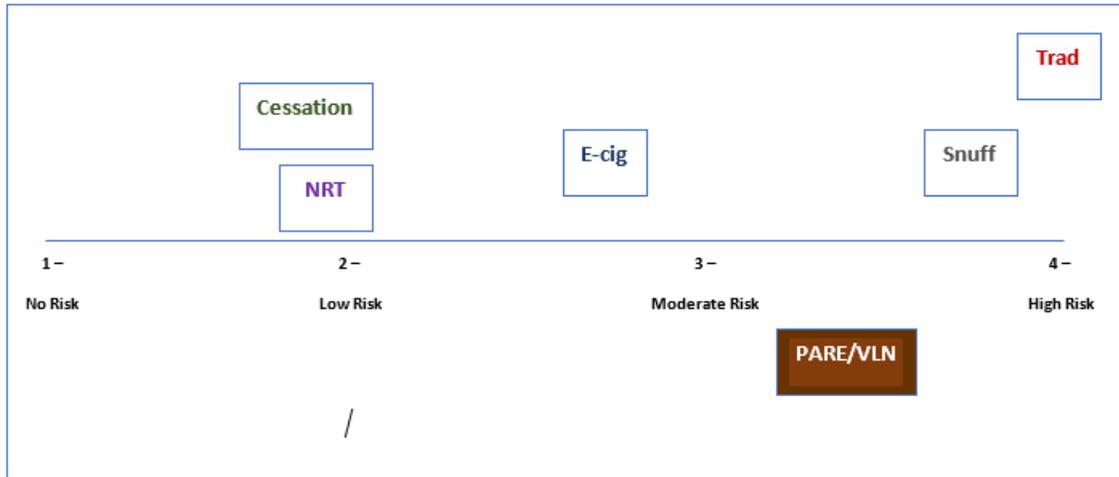


Figure VIII.E-14. Phase IV - Risk of Developing Smoking/Tobacco-Related Diseases

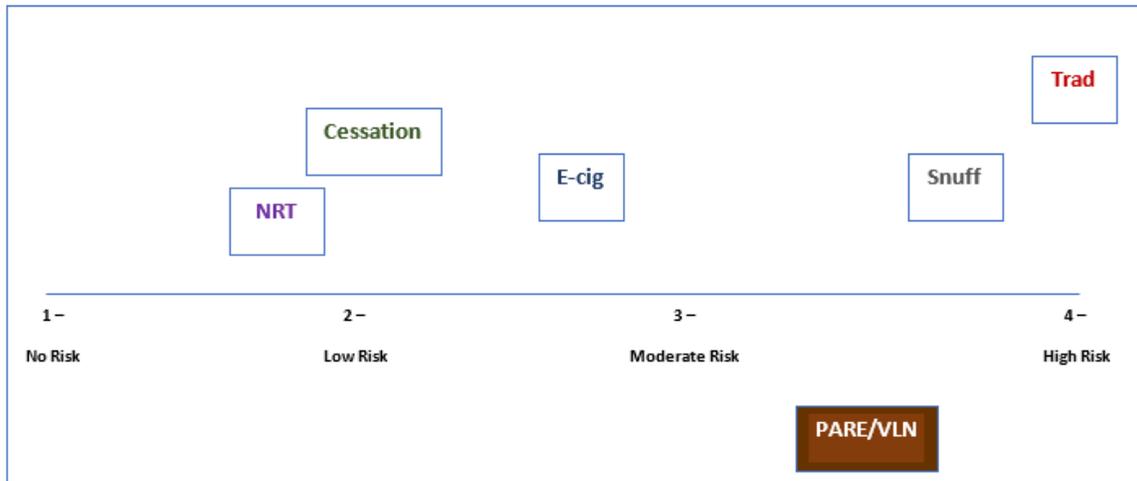
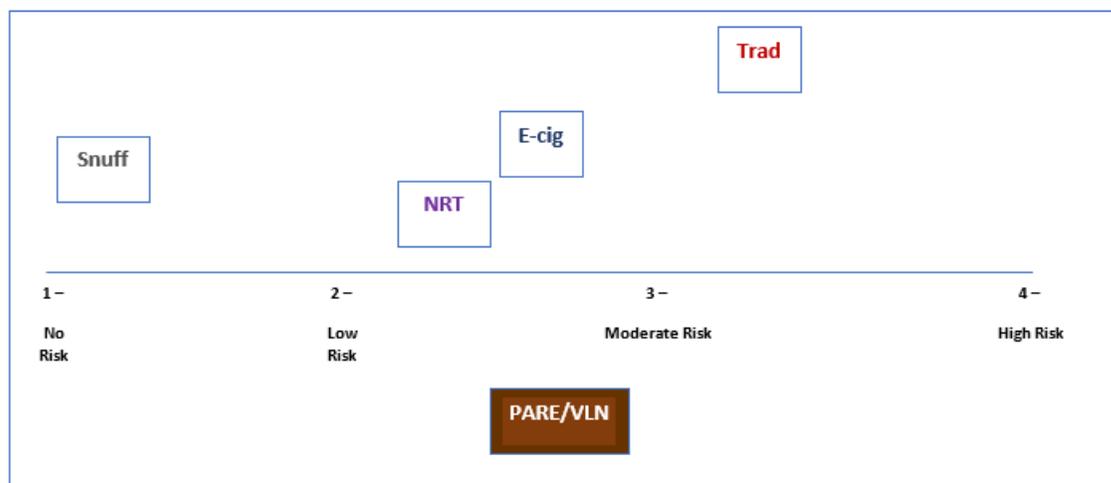


Figure VIII.E-15. Phase IV - Intent to Use



Conclusions of qualitative research studies

Overall, the participants in the studies were aware of the health risks of smoking and were able to place the various product types on a consistent risk continuum. Depending on pack wording, VLN™ was always perceived to have a risk slightly less than conventional cigarette products. Participants understood that there are harmful substances found in smoke, but most could not identify them. There were misconceptions about nicotine with many people believing

that nicotine was the chemical in smoke that was responsible for the harmful effects. The participants did know that nicotine was the addictive chemical in smoke. Concerning the concept of a very low nicotine product, many consumers could not connect low nicotine with low addiction. Some were confused by the concept as they did not understand why a cigarette manufacturer would try to help them quit. Many were confused about the products intended category: is it a cigarette or NRT?

Many different reduced exposure and reduced risk messages were evaluated. The decision was made to drop the reduced risk approach. At the time the studies were being conducted it was not clear what the specific supportable claims would be. As the studies progressed, clarity led to specific statements that corresponded with supportable claims. A clear message was that concise simple statements were preferred by consumers. Most consumers did not understand words like carcinogenic or even toxic¹. They were aware that smoking caused diseases but did not understand terms like emphysema. It was clear from the studies that the messages needed to be simple and clear.

There was generally low intent to purchase the product throughout all of the Phases. The consumers had a hard time understanding the positioning of the product. Most thought the product was intended for smokers who want to quit. There were key differences in the perceptions of the product by the different segments:

- There were no detectable differences in the different regions of the United States in their perceptions of the product.
- Female smokers expressed a higher likelihood of using VLN™ than males.

¹ All participants were screened to determine their literacy level using the Rapid Estimate of Adult Literacy in Medicine (REALM) scanner. Efforts were made to include respondents scoring less than 60 on the assessment, a score indicating a reading level at or below 8th grade.

- Younger smokers quickly picked up on the attributes of the product and indicated a strong interest in product trial.
- Older participants were more skeptical of the product and its ability to help them.
- Current smokers **with no intention** to quit were skeptical of the product’s ability to help them.
- Current smokers with an **intent to quit** expressed interest in the product.
- Recent quitters generally liked the concept but believed abstinence was a key in quitting. Some could see themselves using the product if they “needed a smoke”.
- Never smokers expressed **no interest** in using the product.

2. Quantitative Study to Develop VLN™ Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users

The purpose of this consumer perception study (M/A/R/C Research 2018, "Quantitative..." [\[pg 53\]](#)) was to measure responses to versions of VLN™ label and messaging within populations of (1) adult smokers with an intention to quit, (2) adult smokers without any intention to quit, (3) adult former smokers and (4) adult never smokers. Adult former smokers were subdivided into recent quitters (within the past year) and longer-term quitters (more than one year of cessation). There was an approximate equal number of males and females and the study covered all geographic areas of the U.S. as defined by the Census Bureau (Figure VIII.E-16). For each group there was an approximately equal number of subjects from each of the following age categories:

- 25 to 44 years
- 45 to 64 years
- 64+ years

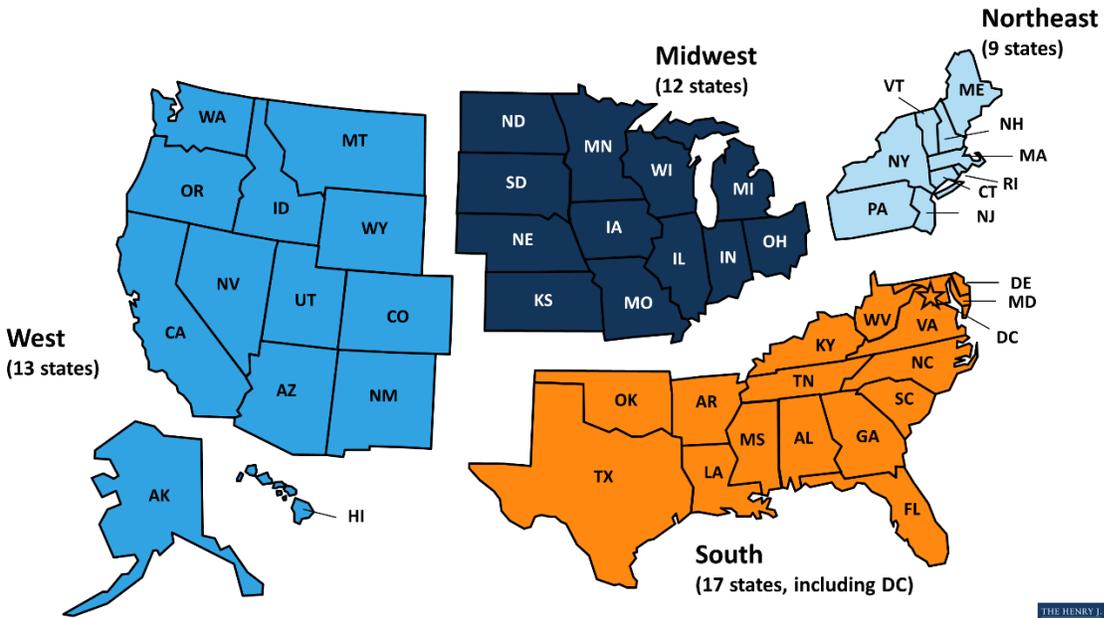
A group of legal age to 25 years-old was over sampled in an attempt to understand the

impact the product may have on young never smokers who might consider initiating with the product. Subjects for this study were recruited into the study from an online non-probability based opt-in panel. Potential participants were contacted via e-mail and asked to participate in an online study, with one reminder notice sent. Participants clicked on a link in their email or in a panel-specific app to access the study's online consent, which described the study and requested participation. Respondents provided informed consent when they agreed to participate in the survey. After screening for eligibility², subjects were assigned to a product concept following a randomized least-fill method to ensure representative distribution within each concept across tobacco usage and demographic criteria. Table VIII.E-10 shows the estimated representation per concept across all relevant groups.

² Exclusion criteria: Past 6-month participation in any tobacco-related research; Currently pregnant or breastfeeding or planning to become pregnant within the next 6 months; Employees of tobacco or vapor companies, news or media, advertising / marketing, marketing research, healthcare, or attorney or paralegal, or having a first degree relative that is employed by these types of companies.

Figure VIII.E-16. Census Regions Used in the Quantitative Study

Census Regions and Divisions of the United States



Source: http://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf



Figure VIII.E-17. Research Design Overview

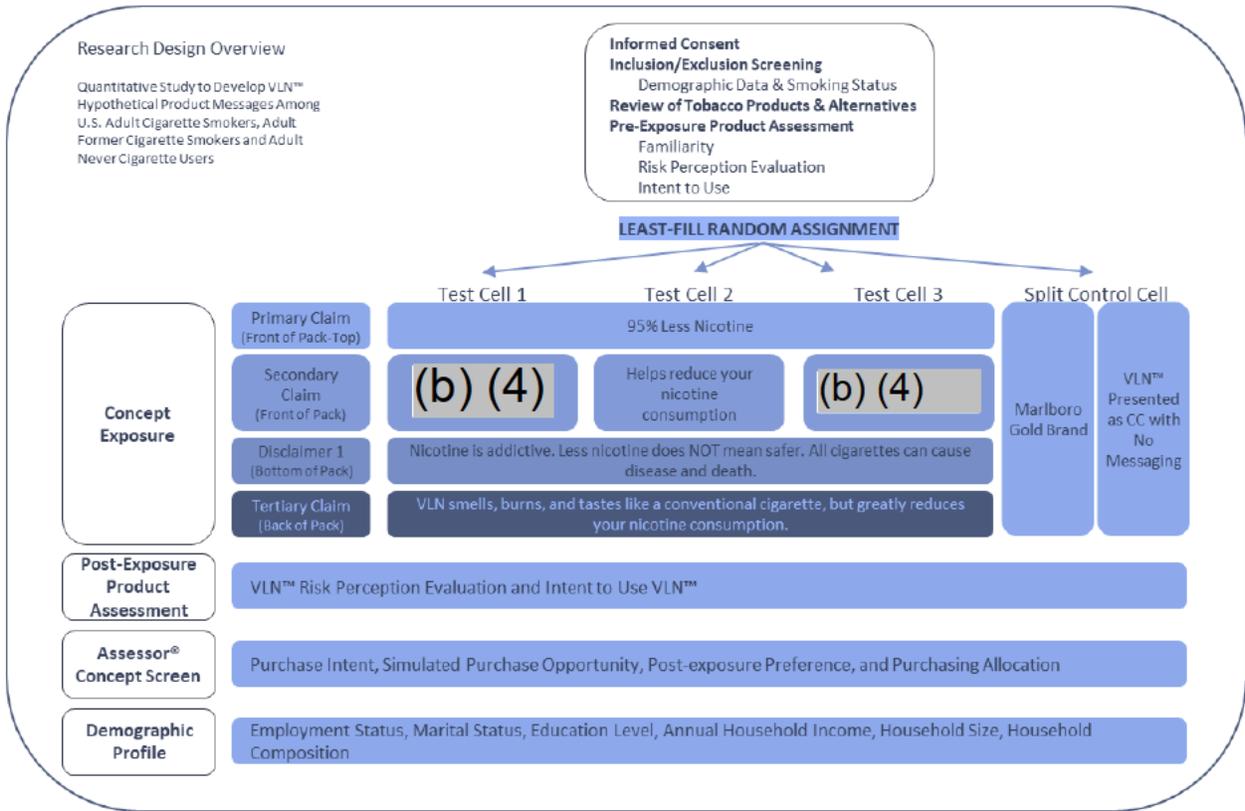


Table VIII.E-10. Sampling Plan By Tobacco Usage Group (per test concept)

	Sample Size	Margin of Error (at 95% Confidence Interval)
Never Users	2000	2.2%
Adult Consumers	1000	3.1%
Oversample of Legal Age to 25	1000	3.1%
Former Smokers	2000	2.2%
Recent Quitters	1000	3.1%
Long-Term Quitters	1000	3.1%
Current Smokers	3000	1.8%

With Intention to Quit	1500	2.5%
With No Intention to Quit	1500	2.5%

Table VIII.E-11 details the planned distribution of completers per concept and per analytic group for all Test Concept Cells assessed on a total of ~7,000 per concept and the distribution percentages across demographic subgroups. Two control concept groups were run for comparison purposes. One group was shown a Marlboro Gold pack and the other group was shown a VLN™ pack with no claims. Table VIII.E-12 shows the planned distribution of completers for the two control groups.

Table VIII.E-11. Planned demographic representation by tobacco usage for test concept cells (per concept).

		Never Users	Never Users Oversample - LA to 25	Long-Term Quitter	Recent Quitters	Current Smokers With Intention to Quit	Current Smokers With No Intention to Quit
Quotas		1000	1000	1000	1000	1500	1500
Gender	Male	41%	41%	52%	51%	49%	51%
	Female	59%	59%	48%	49%	51%	49%
Age (Oversample)	21-25***		100%				
Age	21-24	13%		1%	11%	10%	8%
	25-44	32%		27%	42%	43%	37%
	45-64	31%		5%	31%	45%	40%
	65+	24%		67%	15%	2%	16%
Race/Ethnicity	White, Non-Hispanic	66%	66%	82%	71%	71%	76%

	Black, Non-Hispanic	12%	12%	7%	11%	15%	12%
	Asian, Non-Hispanic	6%	6%	3%	4%	3%	2%
	American Indian/Alaska Native, Non-Hispanic	1%	1%	1%	***	2%	1%
	Hispanic	14%	14%	7%	13%	8%	8%
	Non-Hispanic Multi-race	1%	1%	1%	***	1%	1%
	US Census Regions	Northeast	17%	16%	20%	13%	16%
	Midwest	21%	21%	23%	28%	26%	28%
	South	36%	35%	31%	36%	37%	35%
	West	27%	27%	26%	24%	21%	22%

* Proportions estimated based on referencing NHIS 2015, NHIS 2016, BRFSS, and HINTS.

**Less than one-half of one percent.

***For the purposes of this study, Legal-Age was defined as 21 years of age.

Table VIII.E-12. Planned demographic representation by tobacco usage for split control concept cells (per concept).

	Never Users	Never Users Oversample - LA to 25	Long-Term Quitter	Recent Quitters	Current Smokers With Intention to Quit	Current Smokers With No Intention to Quit
Quotas	500	500	500	500	750	750
Gender	Male	41%	41%	52%	51%	49%
	Female	59%	59%	48%	49%	51%
Age (Oversample)	21-25***		100%			

Age	21-24	13%		1%	11%	10%	8%
	25-44	32%		27%	42%	43%	37%
	45-64	31%		5%	31%	45%	40%
	65+	24%		67%	15%	2%	16%
Race/ Ethnicity	White, Non- Hispanic	66%	66%	82%	71%	71%	76%
	Black, Non- Hispanic	12%	12%	7%	11%	15%	12%
	Asian, Non- Hispanic	6%	6%	3%	4%	3%	2%
	American Indian/ Alaska Native, Non- Hispanic	1%	1%	1%	**%	2%	1%
	Hispanic	14%	14%	7%	13%	8%	8%
	Non- Hispanic Multi- race	1%	1%	1%	**%	1%	1%
US Census Regions	Northeast	17%	16%	20%	13%	16%	15%
	Midwest	21%	21%	23%	28%	26%	28%
	South	36%	35%	31%	36%	37%	35%
	West	27%	27%	26%	24%	21%	22%

* Proportions estimated based on referencing NHIS 2015, NHIS 2016, BRFSS, and HINTS.

**Less than one-half of one percent.

***For the purposes of this study, Legal-Age will be defined as 21 years of age.

Figure VIII.E-17 shows an overview of the research design. Demographics were collected for each subject. The Perceived Risk Instrument (PRI) (Chrea *et al.* 2015 [pg 53]) was

used to assess the subject's perception of the risk of the product. The PRI was administered before and after exposure to the product concept. The Assessment of Intent to use tool was used to measure purchase and intent to use.

This perception study was divided up into stages. The first stage involved asking subjects their perceptions about the perceived health and addiction risks of nicotine containing products using the Perceived Risk Instrument tool and also intent to use using the Assessment of Intent to Use tool. The subjects were presented with the following conventional nicotine product packages:

- Conventional Cigarettes (CCs)
- E-cigarettes (e-cigs)
- Moist Snuff
- Nicotine Replacement Therapies (NRT)

In the second stage the subjects were shown one of the following product package concepts³:

- Marlboro Gold
- VLN™ with no claims on the packaging (VLN No Claims)
- VLN™ with the principal claim of 95% less nicotine and the supporting statement – Helps reduce your nicotine consumption (VLN Consumption)
- VLN™ with the principal claim of 95% less nicotine and the supporting statement – (b) (4) (b) (4) (VLN Use)
- VLN™ with the principal claim of 95% less nicotine and the supporting statement – (b) (4) (b) (4) (VLN Urge)

The subjects were then asked the same risk and health perception questions as well as intent to use using the perceived Risk Instrument and the Assessment of Intent to Use tool. These tools asked the subjects to rate their perception about health and addiction risks. The subject responses for each tool were averaged. The average provides an overall assessment of the

³ Initially, it was planned to propose to the FDA a series of secondary supporting statements that could be used along with the 95% Less Nicotine claim. (b) (4) . These results will not be discussed further in this application.

subject's perception⁴. These averages are for discussion purposes only and are not intended to replace the individual data in the report.

In the third stage the subjects were asked to look at all of the product packages including the range of conventional nicotine products and rate them again on their perceptions and intent to use.

In the first stage subjects were shown traditional tobacco and NRT packaging and asked their familiarity (Figure VIII.E-18). Everyone was very familiar with conventional cigarettes. There was low awareness of moist snuff among all groups except that current smokers were slightly familiar with the product. Current smokers (CS) were more familiar with e-cigarettes than former smokers (FS). Current smokers and former smokers were equally familiar with NRT. Never smokers (NS) were generally less familiar with all of the products except moist snuff where former smokers were less familiar than never smokers. As would be expected, never smokers were even less familiar with NRT than current or former smokers. The subjects were then asked to rate the products on their health risks (Figure VIII.E-19) and addiction risks (Figure VIII.E-20). All of the tobacco products were rated moderate to high risk. Current smokers consistently rated all of the products lower for health risks and risk of addiction. Non-smoking legal age to 25 (LA-25) years old consistently underestimated the health risks (Figure VIII.E-21) and risk of addiction of tobacco products (Figure VIII.E-22). Subjects with an intent to quit consistently rated the health risks (Figure VIII.E-23) and the risk of addiction (Figure VIII.E-24) higher than smokers with no intent

⁴ While the average provides an overall assessment, individual responses provide insight into the different perceptions of the sub-groups. As an example, in the health questions risk of oral cancer was rated high for moist snuff and lung cancer was rated high for conventional cigarettes. The averages were calculated as averages of the reported average response of the subjects.

to quit. Former smokers were well aware of the health and addiction risks associated with the products. Recent quitters rated the risks of conventional cigarettes and e-cigarettes slightly less than long term quitters (Figure VIII.E-25 and Figure VIII.E-26).

Figure VIII.E-18. Product Familiarity

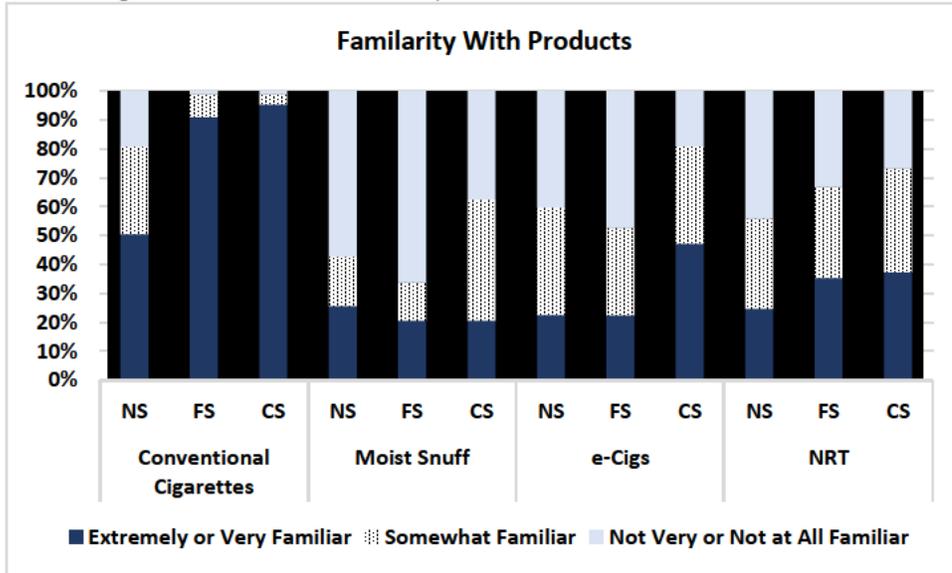


Figure VIII.E-19. Overall Health Perception of Products

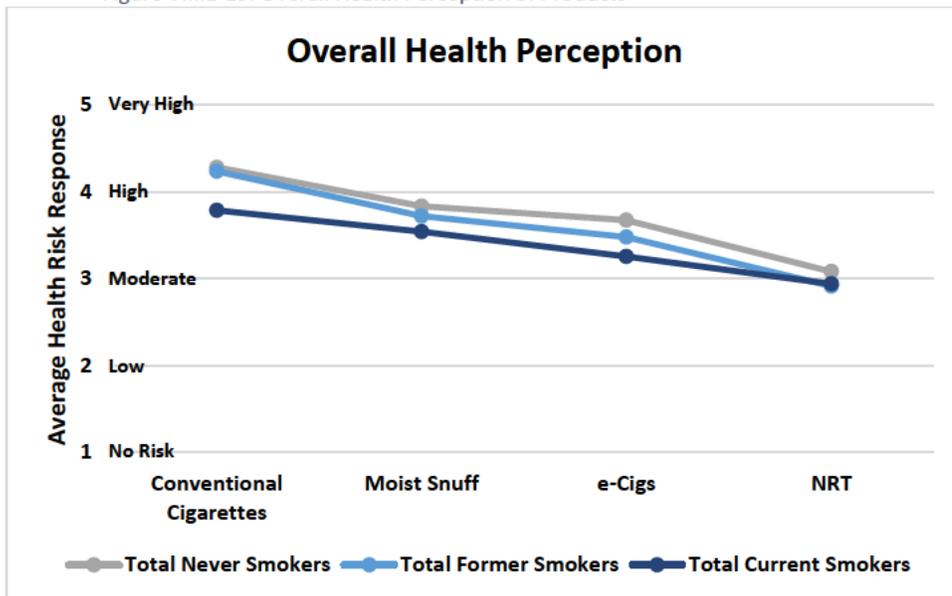


Figure VIII.E-20. Overall Addiction Perception of Products

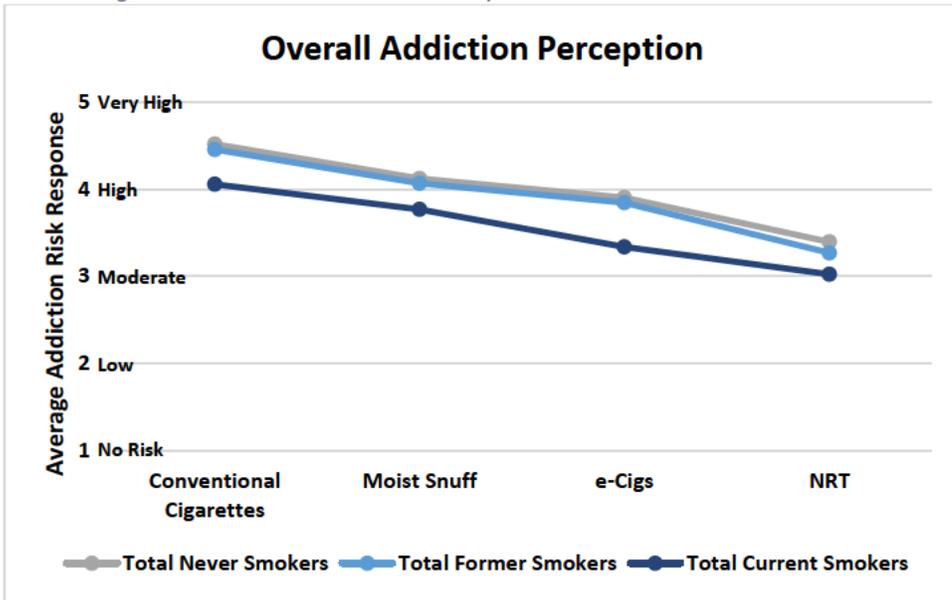


Figure VIII.E-21. Overall Health Perception of Never Smokers.

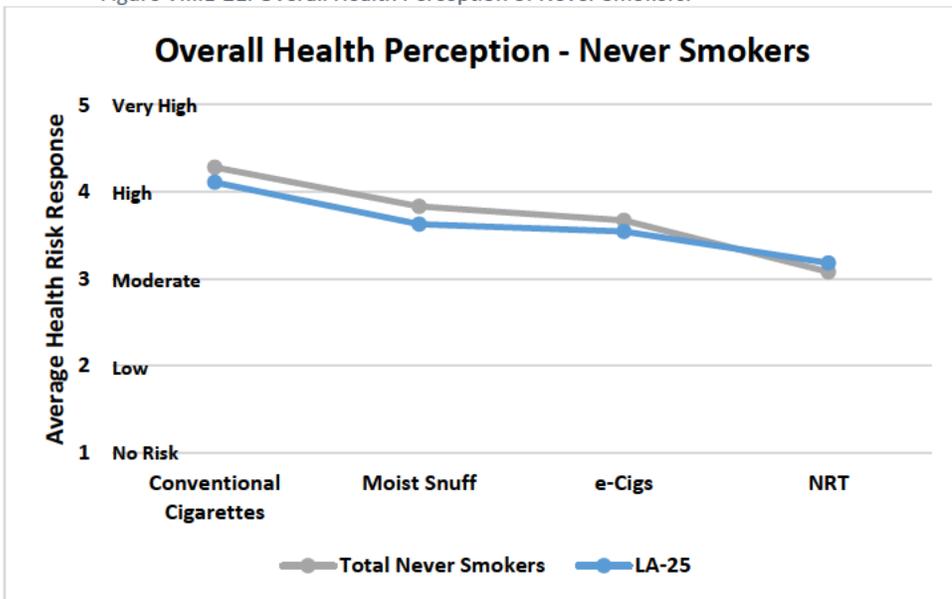


Figure VIII.E-22. Overall Risk of Addiction Perception of Never Smokers

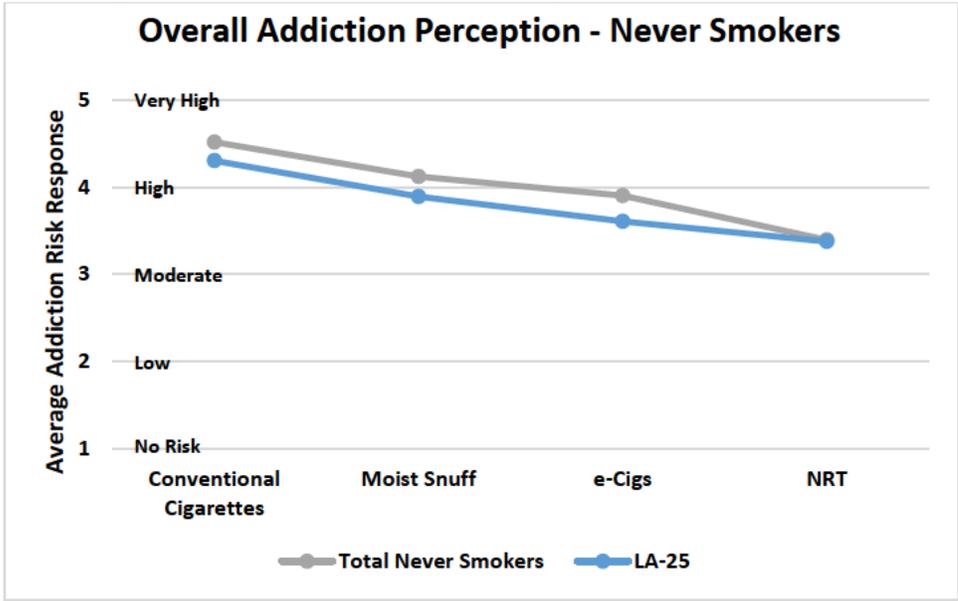


Figure VIII.E-23. Overall Health Perception of Current Smokers

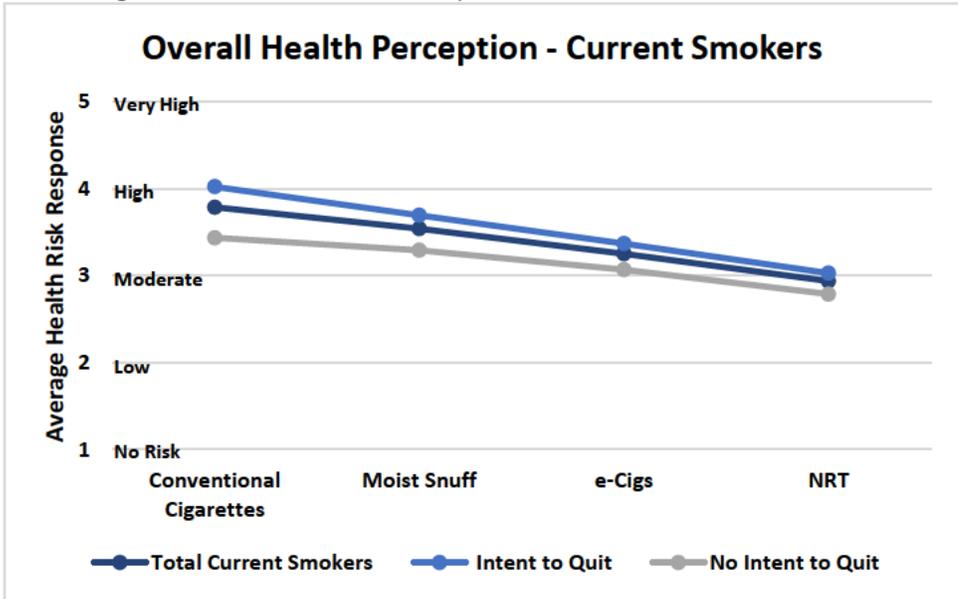


Figure VIII.E-24. Overall Risk of Addiction Perception of Current Smokers

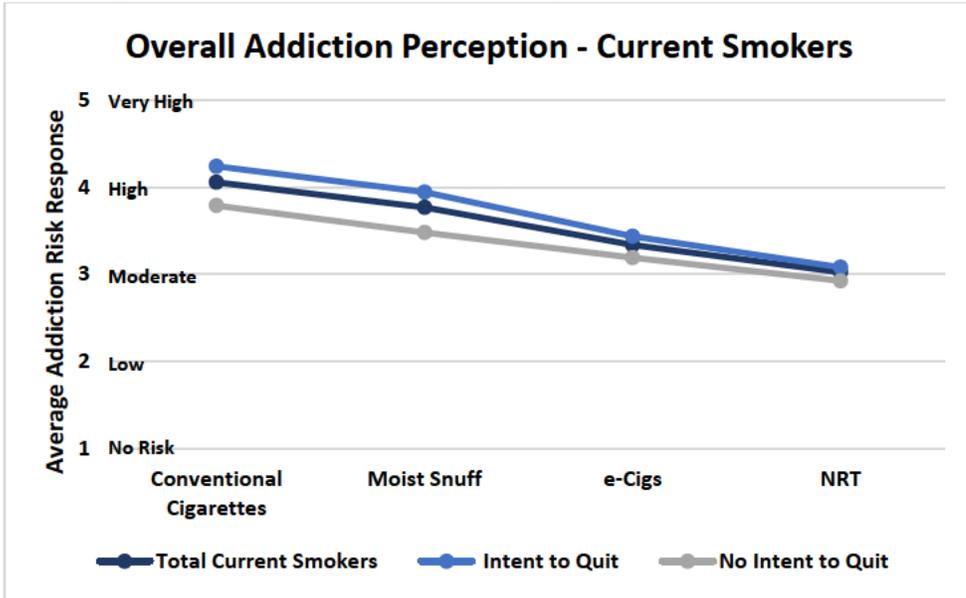


Figure VIII.E-25. Overall Health Perception of Former Smokers

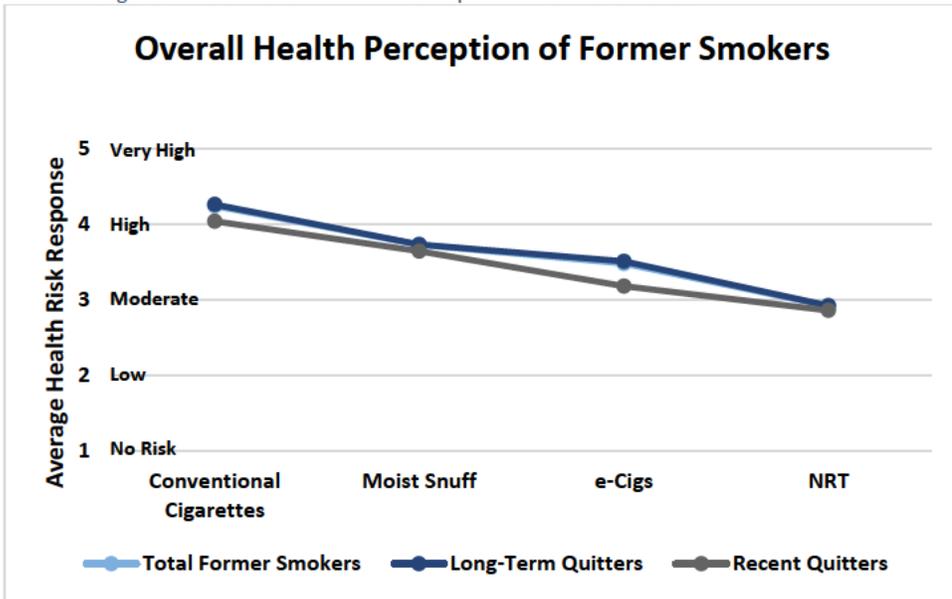
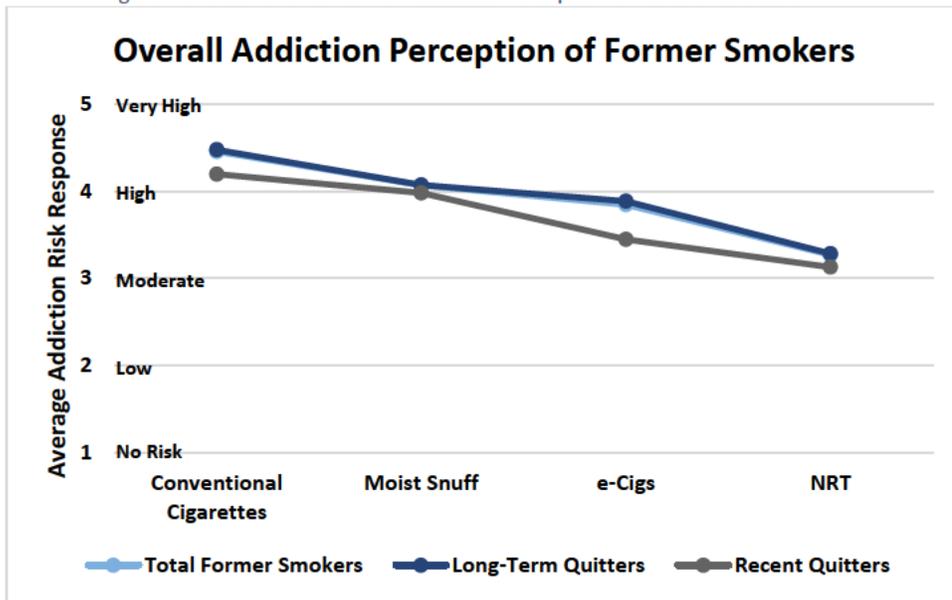


Figure VIII.E-26. Overall Risk of Addiction Perception of Former Smokers



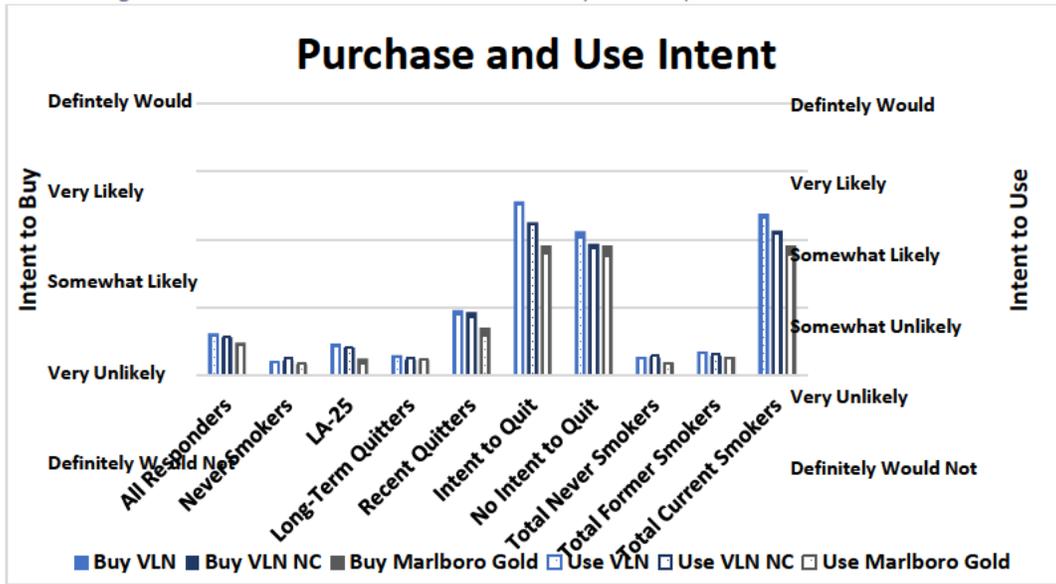
In the next stage of the study, subjects were shown three product concept packages:

- Marlboro Gold
- VLN™
- VLN™ package with no claims (NC)

They were asked to review the packages and then were asked questions about perceived risks, purchase, and use intent. There was little purchase or use intent by never smokers or former smokers in VLN™ or Marlboro Gold (Figure VIII.E-27)⁵ (1 = definitely would not). There was interest in VLN™ as indicated by purchase and use intent by current smokers who gave the products a somewhat likely rating for use. The purchase and use intent were higher for VLN™ than Marlboro Gold. Interestingly, the VLN™ No Claim pack seemed more interesting to current smokers than Marlboro Gold.

⁵ Participants were asked to rate the use of products on a 6-point scale ranging from “Definitely Would Not(1)” to “Definitely Would (6).” Intent to purchase was rated on a 5-point scale using the same terms.

Figure VIII.E-27. Purchase and Use Intent of VLN™, VLN™ NC, and Marlboro Gold



Subjects were asked the same perceived health and addiction risk questions after seeing the packs. The subjects perceived the health risks of Marlboro Gold, VLN™ No Claims and VLN™ consistent with conventional cigarettes with a high risk rating (Figure VIII.E-28) and more risky than moist snuff, e-cigarettes and nicotine replacement therapy. The subjects perceived the risk of addiction to be moderate for VLN™, between e-cigarettes and NRT (Figure VIII.E-29). That is, the consumers understood that VLN™ has reduced nicotine, that nicotine is the addictive chemical in cigarettes, and they perceived that the risk of addiction is reduced. Interestingly, the subjects perceived the VLN™ No Claim to have a lower addiction risk than moist snuff.

Figure VIII.E-28. Perceived Health Risks of Product Concepts and Comparators

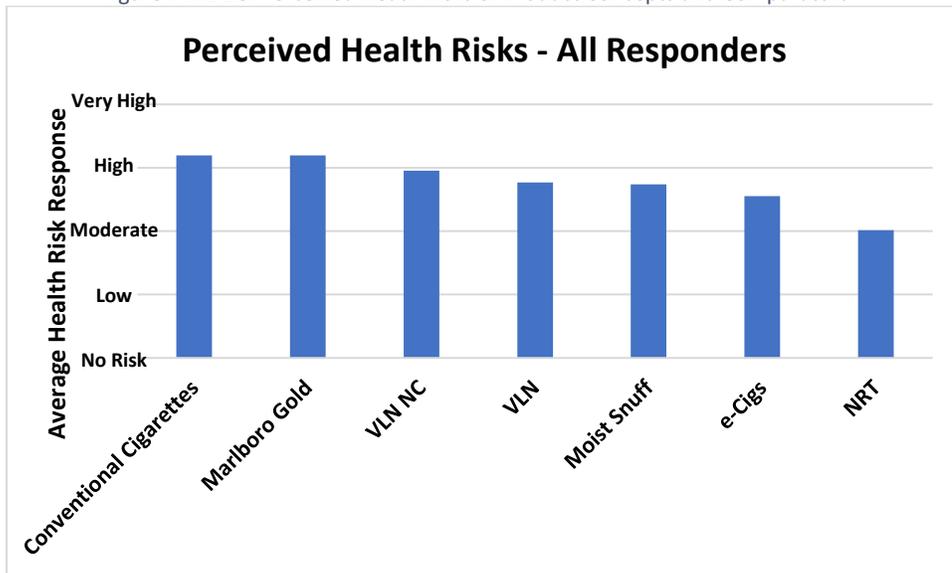
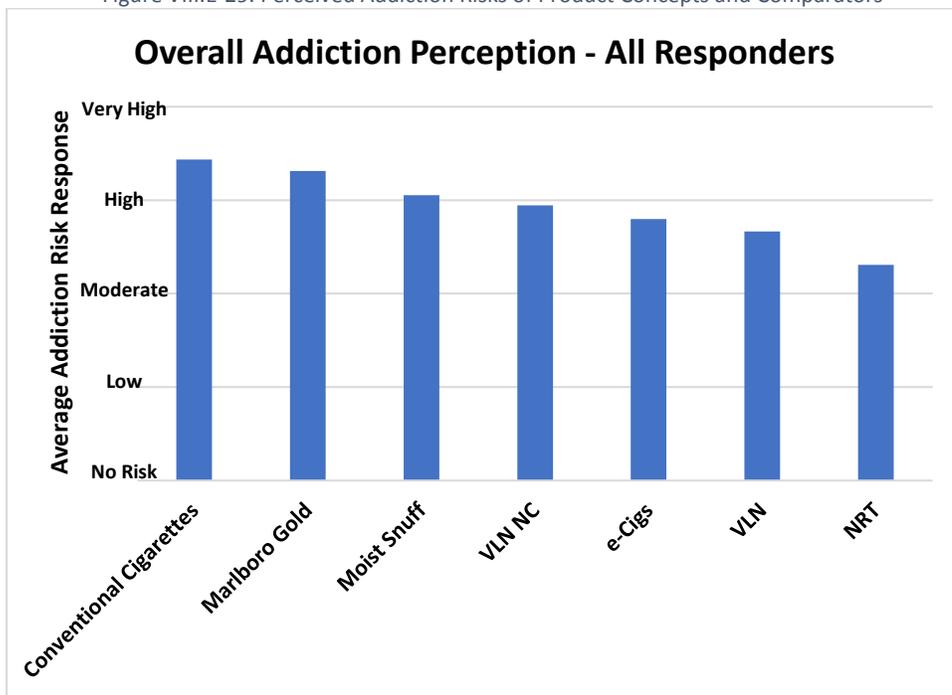


Figure VIII.E-29. Perceived Addiction Risks of Product Concepts and Comparators



The subjects consistently rated VLN™ No Claim pack slightly less risky than Marlboro Gold even though there were no claims on either pack (Figure VIII.E-30 and Figure VIII.E-31). VLN™ was perceived as slightly less risky than VLN™ No Claims pack. The differences between the responses for all products was small.

Figure VIII.E-30. Perceived Health Risks of VLN™, VLN™NC, and Marlboro Gold

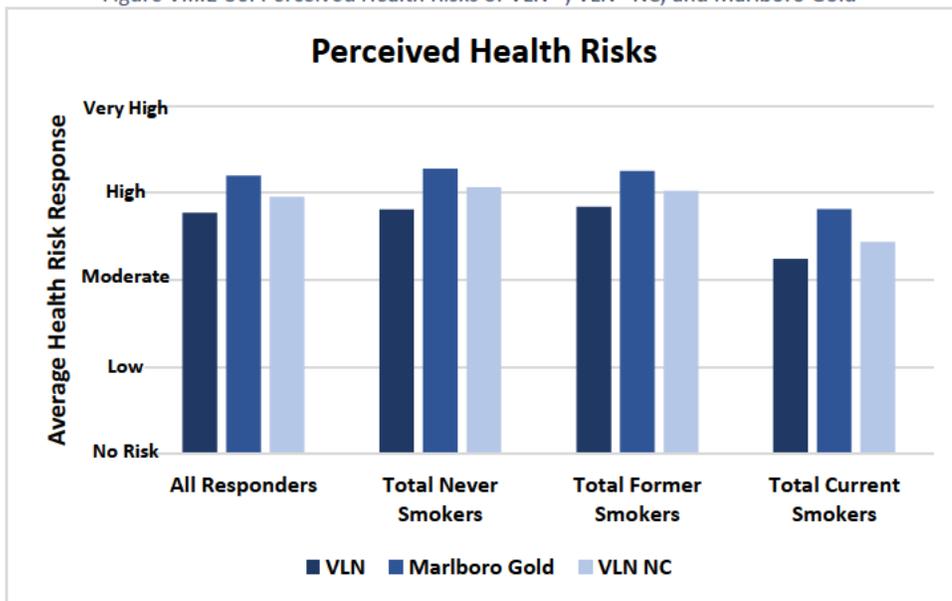
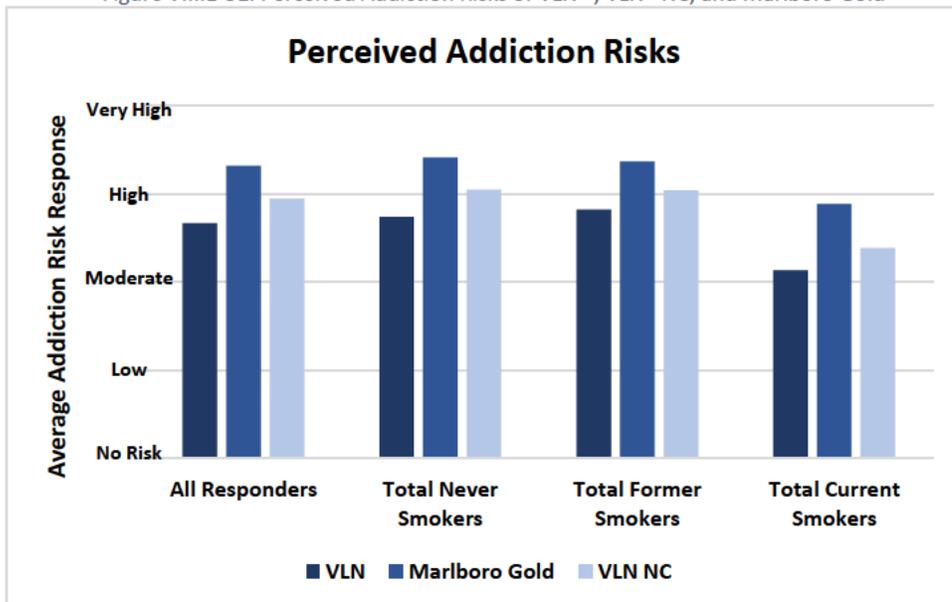


Figure VIII.E-31. Perceived Addiction Risks of VLN™, VLN™NC, and Marlboro Gold



When viewing all of the nicotine containing products, the younger segment (Legal Age to 25(LA-25)) underestimated the health and addiction risks (Figure VIII.E-19 and Figure VIII.E-20). When this group viewed the VLN™ and Marlboro Gold product concepts, they again

underestimated the health and addiction risks (Figure VIII.E-32 and Figure VIII.E-33). Comparing to VLN™ NC there was a small reduction in the perceived risk of VLN™ by the LA-25 group when compared to the general population.

Figure VIII.E-32. Perceived Health Risks of VLN™, VLN™NC, and Marlboro Gold in Never Smokers

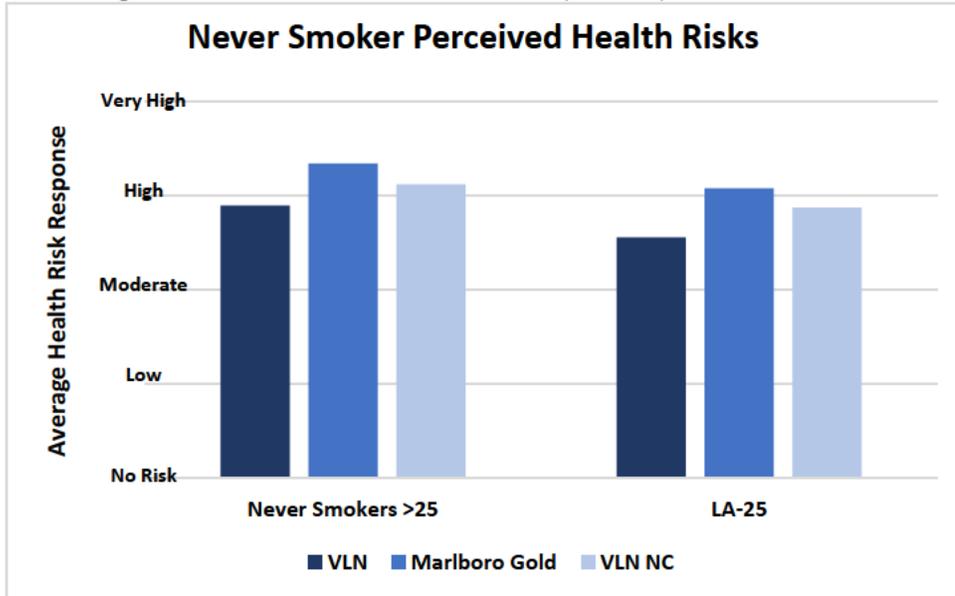
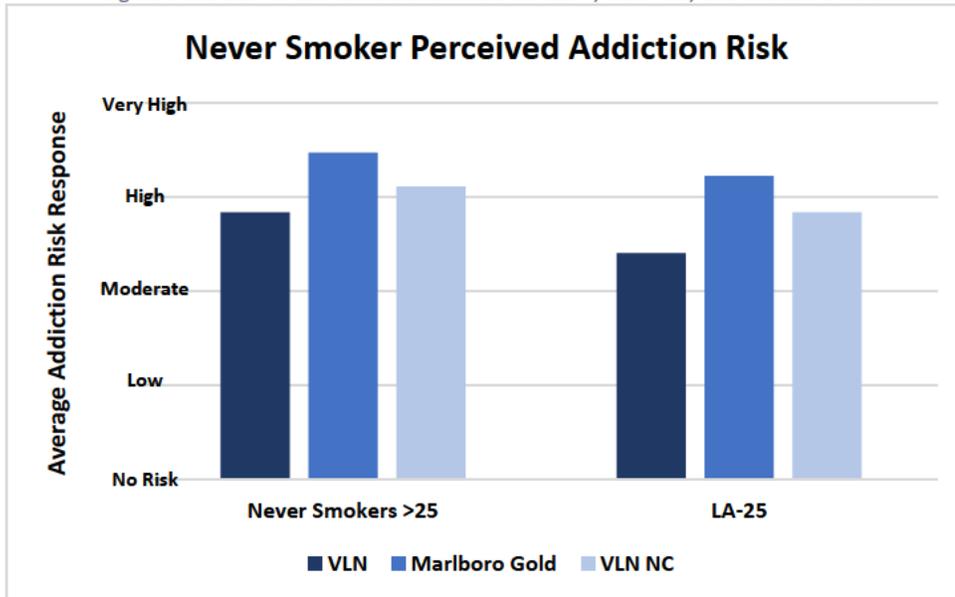


Figure VIII.E-33. Perceived Addiction Risks of VLN™, VLN™NC, and Marlboro Gold in Never Smokers.



Current smokers also underestimate the health and addiction risks associated with nicotine containing products (Figure VIII.E-19 and Figure VIII.E-20). When current smokers were

shown the new product concepts, they perceived the health and addiction risks to be less for VLN™ No Claims when compared to Marlboro Gold (Figure VIII.E-34 and Figure VIII.E-35). Comparing to VLN™ NC there was a small reduction in the perceived risk of VLN™ by the Current Smokers. Smokers with an intent to quit consistently rated the new product concepts as having a slightly higher health and addiction risk than smokers with no intent to quit.

Figure VIII.E-34. Perceived Health Risks of VLN™, VLN™NC, and Marlboro Gold in Current Smokers

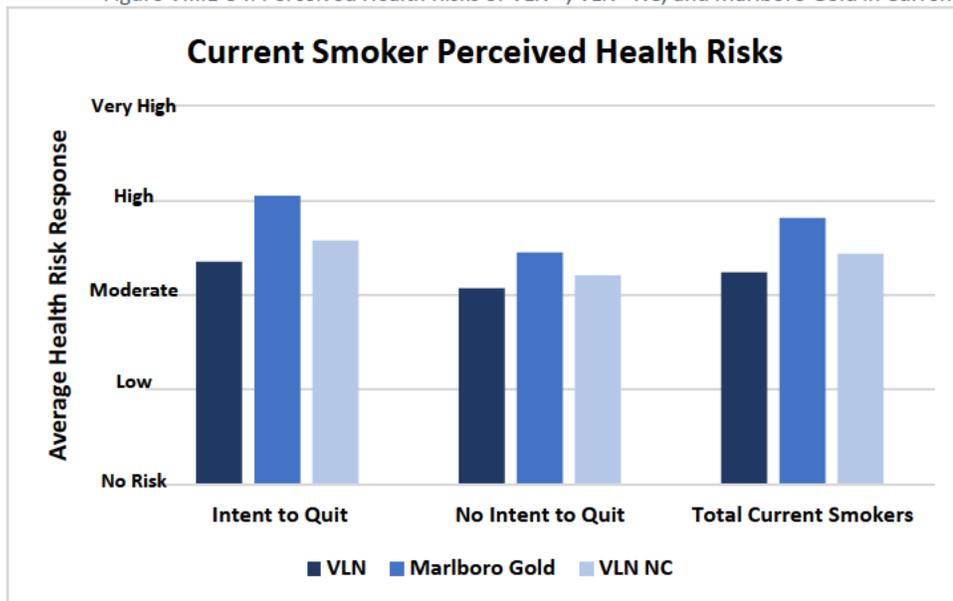
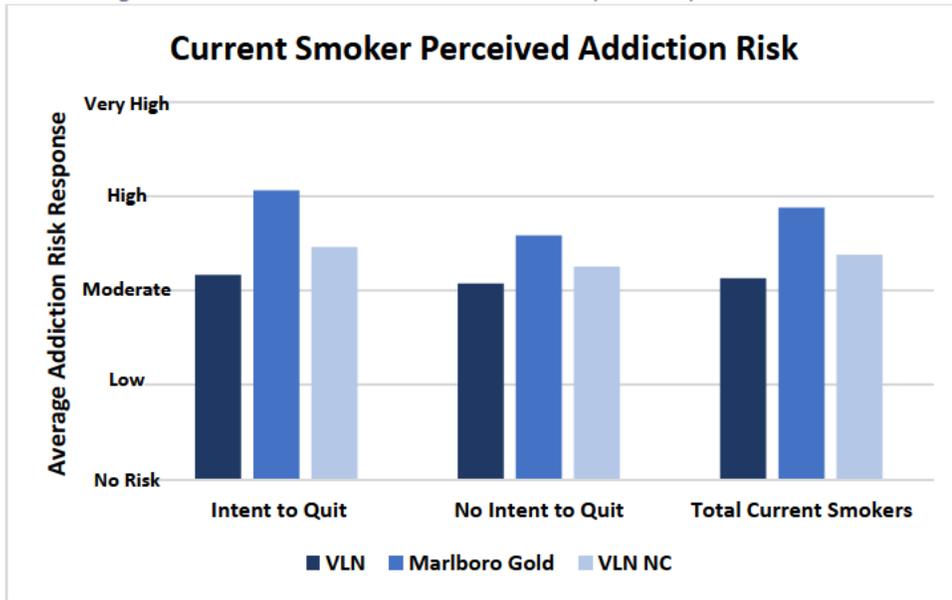


Figure VIII.E-35. Perceived Addiction Risks of VLN™, VLN™NC, and Marlboro Gold in Current Smokers



Before being shown the new product concepts, the subjects were asked their intent to use the group of nicotine products (Figure VIII.E-36). The subjects were then shown the packaging concepts and asked their use intent again (Figure VIII.E-37). Exposure to the product concept had no effect on intent to use by never smokers or former smokers. There was a small but measurable decrease in use intent of conventional cigarettes, e-cigarettes and NRT after viewing the VLN™ product concept (Figure VIII.E-38). In current smokers, those with an intent to quit indicated a higher intent to use VLN™ as compared to smokers with no intent to quit (Figure VIII.E-39). The intent to use the VLN™ cigarette was higher than Marlboro Gold in smokers with and intent to quit. There was minimal difference in the smokers with no intent to quit.

Figure VIII.E-36. Intent to Use Products Before Viewing New Product Concepts

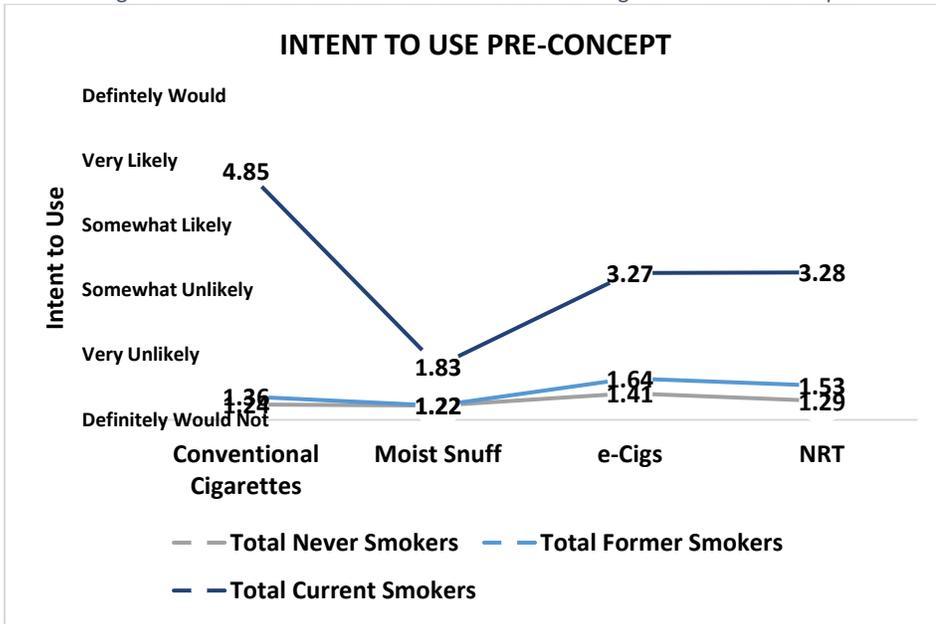


Figure VIII.E-37. Intent to Use Products After Viewing New Product Concepts

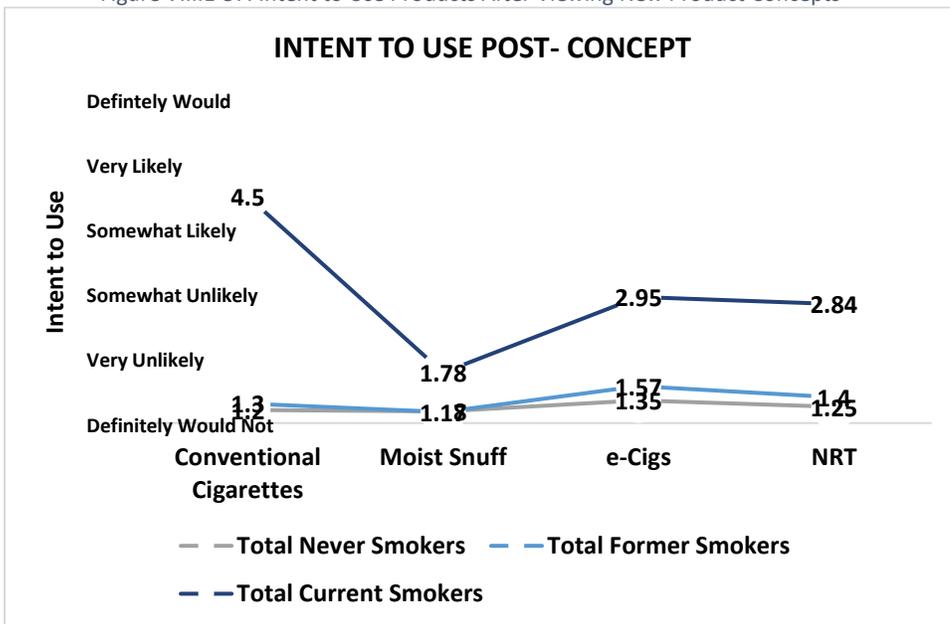


Figure VIII.E-38. Intent to Use Products Before and After Viewing New Product Concepts

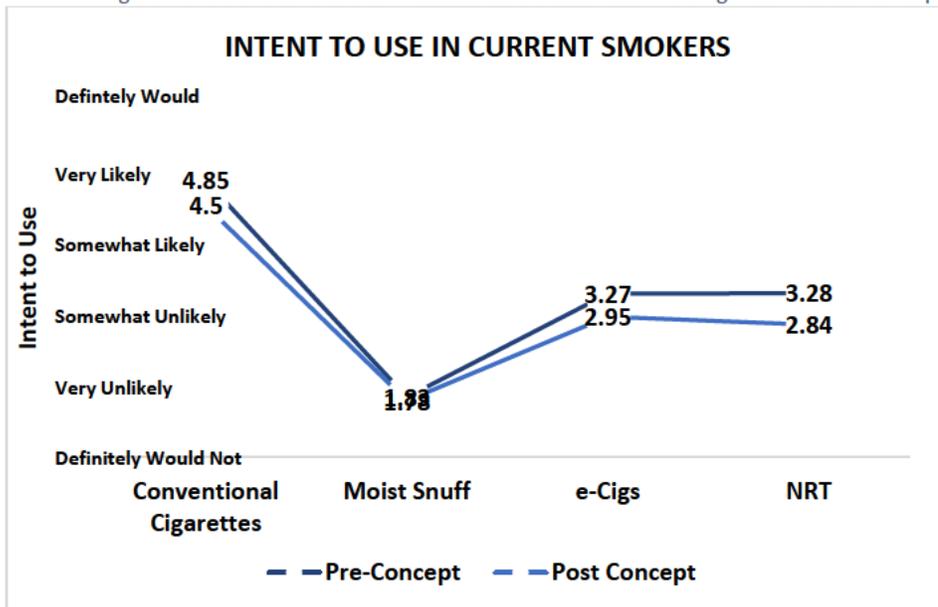
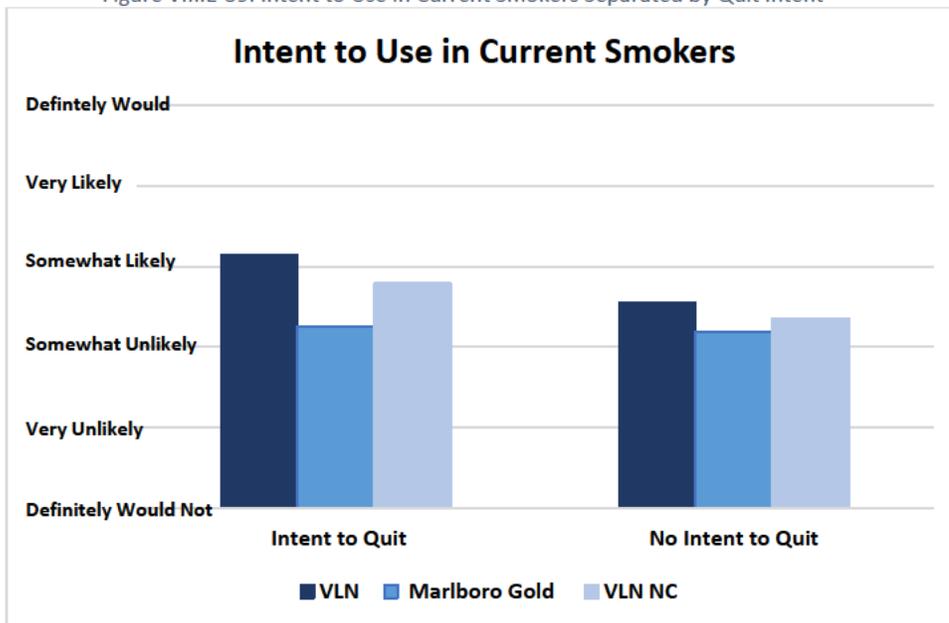


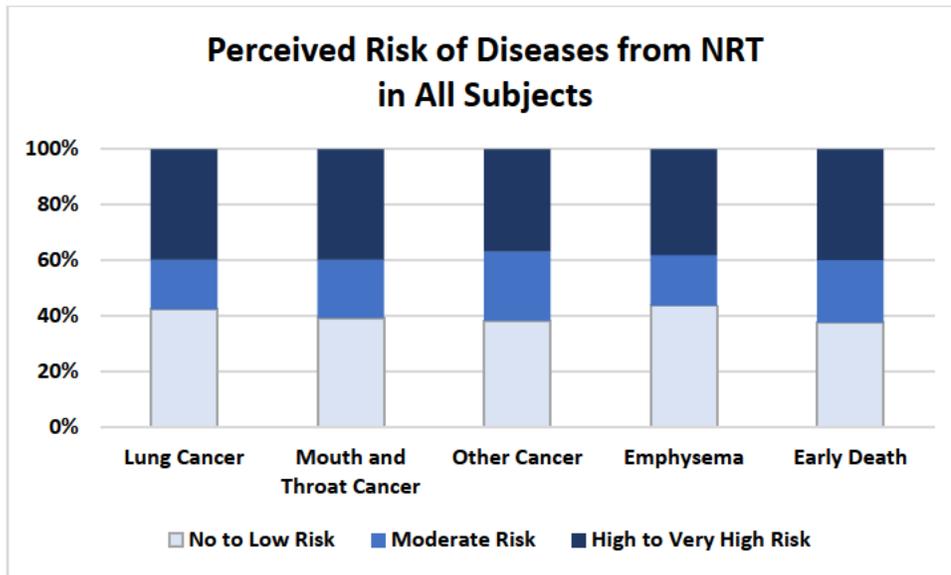
Figure VIII.E-39. Intent to Use in Current Smokers Separated by Quit Intent



It is well known that consumers believe low nicotine cigarettes are generally less harmful or lower risk for certain tobacco-related diseases. (Byron *et al.* 2018 [pg 53]; Cummings *et al.* 2004 [pg 53]; Denlinger-Apte *et al.* 2017 [pg 53]; Strasser *et al.* 2008 [pg 53]). Indeed, the FDA is aware of the issue having reviewed quantitative and conducted qualitative studies about what the public

knows about nicotine (Johnson 2016 [pg 53]). The FDA has also published (O'Brien *et al.* 2017 [pg 53]) a quantitative study investigating beliefs about nicotine and low nicotine cigarettes. This study used the 2015 nationally-representative Health Information National Trends Survey of 3738 subjects. About three quarters of people either were unsure of the relationship between nicotine and cancer or incorrectly believed that nicotine causes cancer. People who were non-White, less educated, age 65 +, and never established smokers were most likely to be unaware that nicotine is not a cause of cancer. More than a quarter of people held the potentially inaccurate beliefs that low nicotine cigarettes would be less harmful and addictive than typical cigarettes. Whites were more likely than Blacks to believe low nicotine cigarettes were less harmful than typical cigarettes, and never smokers were more likely to believe this than established quitters. Whites and people with at least a college degree were more likely to believe that low nicotine cigarettes would be less addictive than typical cigarettes. Overall, the authors found that many people, particularly the demographic subgroups identified here, held incorrect beliefs about nicotine and potentially inaccurate beliefs about low nicotine cigarettes. This work was done in the context of the proposed product standard to reduce nicotine. The study findings suggest that it would be important to educate consumers on the role of nicotine in tobacco related disease to prevent them from assuming that lower nicotine products are less harmful. From the results of the qualitative and quantitative studies it is clear that the participants were confused about nicotine, the role of nicotine in disease, and the overall implications of lowering nicotine in the product. In this quantitative study, over 30% of the subjects rated NRT as having a high or very high risk of lung cancer, mouth and throat cancer, other cancers, emphysema, and early death (Figure VIII.E-40).

Figure VIII.E-40. Perceived risk of diseases from NRT



The FDA has developed the concept of a continuum of risk as part of its comprehensive plan for regulating nicotine products. At the high end of the risk is conventional cigarettes and the low end NRTs. The FDA has not articulated where different products fall on the continuum but has stated that conventional cigarettes are on the high end and NRT's are on the low end. In this perception study, subjects rated the health risks of one of the comparator products (Conventional Cigarettes (CC), E-Cigarettes, Moist Snuff, Nicotine Replacement Therapies (NRT)) and VLN™. Two control groups were included. One was the market leading brand Marlboro Gold and the other was VLN™ pack with no claims. Subjects were also asked about their perception of the risk of addiction from the products. Purchase and use intent were also measured. The study had open ended questions that allowed subjects to describe their understanding of the products, risks and attributes. Based on the results of the perception study the subjects were able to adequately understand the role of nicotine and the implications of its reduction in VLN™ cigarettes.

i. Risk of Addiction

Nicotine is the chemical in tobacco products that is responsible for addiction. Consumers are constantly being told that nicotine is addictive. The FDA recently required all “covered tobacco products” to bear the following:

"WARNING: This product contains nicotine. Nicotine is an addictive chemical."

The VLN™ pack has the following statement on the front:

“Nicotine is addictive. Less nicotine does not mean a safer cigarette. All cigarettes can cause disease and death.”

In this perception study, subjects were able to place nicotine containing products on continuum of addiction risks with conventional cigarettes at the high end and NRT at the low end. The subjects perceived the addiction risk of Marlboro Gold to be like conventional cigarettes. The subjects rightly perceived the addiction risk of VLN™ to be less than conventional cigarettes and Marlboro Gold and to be in between the perceived addiction risks of e-cigarettes and NRT.

ii. The Effect of Marketing VLN™ with Modified Exposure Message on Consumer Perception of the Product

The results of the study suggest that participants understood the modified risk message and perceived that VLN™ poses some health and addiction risks. Furthermore, the results demonstrate that the VLN™ modified risk message did not mislead participants into believing that VLN™ is less harmful or that VLN™ poses less health risk as compared to other tobacco products. Study Subjects placed VLN™ on the continuum of risk in the same area as conventional cigarettes. Compared to Former Smokers and Never Smokers, Current Smokers tended to underestimate the risk of addiction and health effects of all tobacco products including VLN™.

Young Never Smokers (legal smoking age to 25-years old) also underestimated the health risks and risks of addiction of all tobacco products including VLN™.

iii. The Effect of Marketing VLN™ with Modified Exposure Message on Initiation among Never Smokers

There was very little purchase or use intent by Never Smokers. Compared to Current Smokers, Never Smokers had a higher perception of the health risks and risk of addiction of tobacco products including VLN™. Never Smokers adequately understood the health risks and risk of addiction of VLN™ and demonstrated no interest in the VLN™.

iv. The Effect of Marketing VLN™ with a Modified Exposure Message on Youth

There was very little purchase or use intent by subjects legal age to smoke to the age of 25 years old (LA-25). Compared to general population of Never Smokers, LA-25 had a lower perception of the health risks and risk of addiction of tobacco products including VLN™. Youth (LA-25) adequately understood the health risks and risk of addiction of VLN™ and demonstrated no interest in the VLN™.

v. The Effect of Marketing VLN™ with Modified Exposure Message on Initiation among Former Smokers

There was very little purchase or use intent by Former Smokers. Compared to Current smokers, Former Smokers had a higher perception of the health risks and risk of addiction of tobacco products and VLN™. Former Smokers who were long term quitters (> 1 year) tended to rate the tobacco products health and addiction risks slightly higher than recent quitters. Former Smokers adequately understood the health risks and risk of addiction of VLN™ and demonstrated no interest in the VLN™.

vi. The Effect of Marketing VLN™ with Modified Exposure Message among Current Smokers

Current Smokers expressed an intent to purchase and could see themselves using VLN™ cigarettes. The interest and intent were higher than Marlboro Gold, the Number 1 selling cigarette in the United States. Current smokers demonstrated that they understood the health risk of VLN™ by placing VLN™ on the continuum of risk next to conventional cigarettes. Current smokers perceived the risk of addiction of VLN to be between e-cigarettes and NRT, that is, they understood that VLN™ had less nicotine and could be potentially less addicting. Smokers with an intent to quit had a higher perception of the health risks and risk of addiction of tobacco products and VLN™ than Smokers with no intent to quit. Intent to use all nicotine products was asked before and after presentation of the VLN™ product concept. After presenting the VLN™ product concept, the intent to use conventional cigarettes, e-cigarettes and NRT decreased. This suggests that participants of this study showed an interest in shifting away from nicotine products to products having lower levels of nicotine.

vii. Conclusion

The overall results of the study suggest that participants understood the modified exposure message and perceived that VLN™ poses some health and addiction risks. Furthermore, the results demonstrate that the VLN™ modified exposure message did not mislead participants into believing that VLN™ is less harmful or that VLN™ poses less health risk as compared to other tobacco products.

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