

PARE Claims Test Discussion Guide (Round 2)

Round 2 Objectives:

- Second round of focus groups among current and former smokers to understand ad/pack messaging perception and understanding focused on continuing to refine language options to improve message clarity, understanding and effectiveness.
- This round will seek to further explore and refine the best set(s) of messages.

Research Logistics:

The focus groups will be held in a focus group facility and facilitated by an experienced moderator. All groups will be conducted in English, and will be audio-recorded.

Upon entering the focus group room for the literacy testing, study participants will be asked to give to the research staff their mobile phone, PDA, tablet, and any other electronic device that could be used to either record or photograph the research materials, or assist in any way during the literacy assessment. These devices will be secured during the research and returned to the study participants as they are leaving the focus group room upon the completion of the research.

Prior to the start of the group discussions, all potential study participants will complete a brief survey to capture additional demographic information, as well as a standard literacy assessment.

The room in which the discussions will be held will be set up to contain the following:

1. Pens for each study participant
2. Flip charts placed where all study participants can view

The following study materials will be prepared and available:

1. Product concept description, for each participant, of PARE product.
2. Sample PARE Cigarette boxes printed with the claims, along with print outs, for each participant, of the product claims.
3. Poster-sized scales, adhered to the walls, to measure perceptions of:
 - a. Risk of exposure to harmful compounds
 - b. Risk of developing smoking-related diseases
 - c. Intent to use

I. INTRODUCTION (5 Minutes)

- Moderator introduction
- Confirm receipt of “informed Consent Form” from all participants
- Explain confidentiality
- Discuss ground rules
- Observers behind the glass
- Interview is being recorded for internal research purposes only
- Length: 2 hours

Hello, and thank you for joining our discussion today. My name is _____, and I am the moderator for today’s group discussion.

FOR THE AUDIO RECORDING: Before we begin, I’d like to go around the table and confirm that you have all signed the “Informed Consent Form.” As I call your name, please confirm that you have signed it. CALL NAMES ONE AT A TIME FOR CONFIRMATION. IF ANYONE HAS NOT SIGNED, HAVE THEM ESCORTED OUT OF THE ROOM TO BE ASKED WHETHER THEY WANT TO SIGN OR NOT. IF NOT, EXCUSE THEM FROM THE GROUP.

FOR AUDIO RECORDING: I would now ask for your verbal consent to participate in this group discussion. As I call your name, please state out loud whether “yes” you are a willing participant, or “no” you do not want to participate. CALL NAMES ONE AT A TIME FOR CONFIRMATION. IF ANYONE SAYS “NO,” HAVE THEM ESCORTED OUT OF THE ROOM TO BE ASKED WHY THEY HAVE CHANGED THEIR MIND. IF, AFTER DISCUSSION, PARTICIPANT STILL DECLINES, EXCUSE THEM FROM THE GROUP.

WITH ENTIRE GROUP:

Thank you again for participating in this discussion, which will take no longer than [ROUND 1: 2 hours; ROUND 2: 90 minutes; ROUND 3: 60 minutes]. I want to assure you that all your response will be kept completely anonymous and confidential, and we do not keep any personal information from the session.

We are conducting this research today on behalf of 22nd Century Group, and we will be talking about attitudes toward smoking and different types of tobacco products. Specifically, we will discuss risk perception and intent to use regarding current and new tobacco products.

IF GROUP/RESPONDENT IS “SMOKERS WITH INTENT TO QUIT,” “FORMER SMOKERS,” OR “NON-SMOKERS”:

This research is intended to gain an understanding from the overall population, which is why you, as (SMOKERS WITH AN INTENT TO QUIT, FORMER SMOKERS, NON-SMOKERS) have been included in the research. Please be assured we are not trying to market or sell a tobacco product to you. Rather, we are interested in understanding from a public health perspective, your assessment and reactions if certain new tobacco products were introduced to the general public.

Ground Rules

Now, before we get started, I have a few ground rules for us to keep in mind:

- IF GROUP: This is an open, group discussion. I encourage everyone to participate, and feel free to voice your opinion, even if, and especially if, it differs from opinions already expressed by others. As a discussion, not only do I want you to answer my questions, but please feel free to engage in discussion with others around the table. I'm here to make sure we hear from everyone, so I may, from time to time, call on you to make sure I understand your opinion.
- IF IDI: We bring people such as yourself to talk with to hear different opinions and perceptions. So please feel comfortable providing honest answers to the questions. There are no right or wrong answers.
- The session is being audio-recorded for internal purposes, to help me with my review of what we discussed. IF GROUP: So please try to speak one at a time, and speak up and clearly. IF IDI: So if you tend to be a quiet talker, please speak up and speak clearly.
- I have colleagues who are observing from behind the mirror and helping me by taking notes during our discussion.
- IF GROUP: Please feel free to excuse yourself to use the restroom at any time, but I ask that only one person at a time be out of the room so that we can continue our discussion. If you do excuse yourself, please return just as quickly as possible so you don't miss too much of the discussion.

Are there any questions about any of this before we get started?

II. BASELINE OF RISK PERCEPTION AND INTENT TO USE (10 Minutes)

We are first going to talk about various tobacco-related product types. I'm going to read a brief description of each to you.

READ IN DETERMINED RANDOMIZED ORDER:

| | | |
|--------|------------------------------------|--|
| Type 1 | Traditional Cigarettes | A cigarette is a narrow cylinder of finely cut tobacco leaves that are rolled into thin paper for smoking. The cigarette is ignited at one end, causing the cigarette to smolder and allowing smoke to be inhaled from the other end. Most modern manufactured cigarettes are filtered. Examples of traditional cigarettes are on the table. |
| Type 2 | 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 3 | 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 4 | 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. |

AFTER READING EACH ONE, ASK:

- Are you familiar with this product type?

OK, great. Now that we've reviewed these different product types, we're going to do a couple of rating exercises for each of them. In addition, we'll also be rating quitting tobacco smoking altogether.

I have a few statements that we are going to look at, and for each product type and quitting smoking, we will evaluate that statement. Two of the statements are with regards to personal risk and one is about your interest in the product type.

As we consider the two statements about risk, I would like you to keep in mind the following:

FOR CURRENT SMOKERS (WITH NO INTENTION TO QUIT AND THOSE INTENDING TO QUIT): When thinking about the product types, please think about:

FOR CIGARETTE TYPES: *"your personal risk of using the product."*

FOR OTHER TOBACCO PRODUCTS AND NRT: *"your personal risk if you were to stop smoking cigarettes and start using this product."*

FOR CESSATION: *"your personal risk if you were to completely stop smoking cigarettes."*

FOR FORMER SMOKERS OR NON-SMOKERS: When thinking about the product types, please think about:

FOR CIGARETTE, OTHER TOBACCO PRODUCTS AND NRT: *"your personal risk if you were to [resume/start using] the product."*

FOR CESSATION: *"your personal risk currently, as a past or non-smoker of cigarettes."*

Now, let me explain the scale to you. [On the wall/In front of you] is a scale, with numbers from 1 to 4, where 1 means "no risk," 2 means "low risk," 3 means "moderate risk," and 4 means "high risk."

After I read the first statement to you, [IF GROUP: as a group] we're going to place, on the chart on the wall, each of the product types, with respect to the level of risk you associate with each. POINT OUT THE SCALE AND EXPLAIN: So if you feel the product type is low risk, you'll place it here (point on example chart). If you feel it is high risk, you'll place it here (point on example chart). You can also use any point along the line between these end points.

Does anyone have any questions before we begin?

Great.

Statement 1: "Likelihood of Exposure to Harmful and Potentially Harmful Compounds"

The first statement is: *"When a tobacco product is consumed, there is a risk of exposure to harmful and potentially harmful compounds that are produced and transferred either through smoke (in a combustion-based product) or saliva (in an oral product). As you consume the product, you are exposed to these compounds through inhalation as you smoke a cigarette or via the GI tract as you use an oral product."*

As you listened to this statement, tell me:

- Specifically, what harmful compounds or substances came to mind as you were thinking of the product types we just discussed. LISTEN AND CAPTURE, IF DIFFERENT, FOR EACH PRODUCT TYPE. Any others?

Now, let's place each product type and quitting smoking on the chart based on its risk. MODERATOR, FACILITATE GROUP PLACEMENT OF EACH PRODUCT TYPE. BE SURE ALL PRODUCT TYPES ARE PLACED ON THE CHART.

CAPTURE ANY COMMENTS OFFERED REGARDING PLACEMENT OF THE PRODUCT TYPES ON THE CHARTS.

Now we're going to do the same exercise for the second statement.

Statement 2: "Risk of developing smoking/tobacco related diseases"

This next statement is: *"The risk of developing smoking or tobacco-related diseases means the chance of developing a disease, depending on the product, such as heart disease, lung cancer, and emphysema when using a combustion based product, and heart disease, gum disease or lesions, oral cancer, throat cancer and pancreatic cancer, when using an oral product."*

As you listened to this statement, tell me:

- Specifically, what smoking or tobacco-related diseases came to mind as you were thinking of the product types we just discussed. LISTEN AND CAPTURE, IF DIFFERENT, FOR EACH PRODUCT TYPE. Any others?

Now, let's place each product type and smoking cessation on the chart based on its risk. MODERATOR, FACILITATE GROUP PLACEMENT OF EACH PRODUCT TYPE. BE SURE ALL PRODUCT TYPES ARE PLACED ON THE CHART.

CAPTURE ANY COMMENTS OFFERED REGARDING PLACEMENT OF THE PRODUCT TYPES ON THE CHARTS.

Now we're going to look at the last rating for these product types. (DO NOT INCLUDE QUITTING SMOKING)

Statement 3: "Intent to Use"

The last statement is about your intent to use the product: *"By intent to use, we mean you intend to use the product on a regular, ongoing basis."*

Let's place each product type on the chart based on your intent to use the product. MODERATOR, FACILITATE GROUP PLACEMENT OF EACH PRODUCT TYPE. BE SURE ALL PRODUCT TYPES ARE PLACED ON THE CHART.

Thanks so much for your help with these initial exercises. I appreciate everyone's contribution.

We're now going to move on to the next part of our discussion.

III. PARE PRODUCT CONCEPT EVALUATION (5 MINUTES)

For this next section of our discussion, I have a description of a product that is currently under development, that we will call PARE. Let's start by reading a description of PARE and getting your reactions to it.

HAND OUT PRODUCT CONCEPT DESCRIPTION AND READ OUT LOUD TO THE GROUP.

- What do you think about PARE? What are the first thoughts that came to mind as we were reading the product description?

IV. PARE CLAIMS EVALUATION (60 MINUTES)

We are now going to discuss several statements that could appear on the package for PARE. As we look at and discuss these messages, I'll be interested in understanding your reactions to the statements and what they mean to you.

Some of the statements we're going to review would appear at the top of the front of the package, some at the bottom of the front, and some on the back of the pack.

I'm going to show you on a sample pack where these messages appear, and you'll also receive a sheet of paper with the messages. As you read the messages, on the sheet of paper, please use your pen to circle anything you like about PARE, underline anything that is confusing, and cross out anything that you do not find interesting or relevant. [SHOW THESE EXAMPLES/INSTRUCTIONS ON FLIP CHART.]

Let's begin with the first set of statements.

START

RANDOMIZE BETWEEN BEGINNING WITH REDUCED EXPOSURE VS. REDUCED RISK. WITHIN TOPIC, RANDOMIZE CLAIM SHOWN BASED ON ROTATION GRID.

PROVIDE FIRST/NEXT CLAIM TO RESPONDENTS, AND LET THEM READ ON THEIR OWN, MAKING MARKS ON THE PAGE. THEN READ OUT LOUD TO THEM.

FOR EACH, ASK:

- What comes to mind as you read these messages? What makes you say that?
- What is the main message or main points these statements communicate to you about PARE? What makes you say that? What words or phrases make you say that?
- Is there anything unclear or confusing in any of the statements? Are there any words or phrases that you are not sure of? How would you change those to make them more clear?
- If you saw this on a pack for PARE, what would you think about the product? What makes you say that?
- Based on these statements, again, if you saw them on a pack of PARE, what would you do? IF NEEDED, PROBE FOR ACTION: Would you try PARE? Why would you do that?
- FOR FIRST ONE: If you were in a store and saw these statements on a pack of PARE, how likely would you be to read them? All of them? Some of them?

REPEAT ABOVE FOR ALL 5 SETS WITHIN THE FIRST TOPIC.

Best of the Claims

Now, please spread the pages out in front of you, so that you can see all the statements on all the pages.

Which of the 5 sets do you prefer? Which is most clear in communicating to you about PARE? Why do you say that?

Let's take the set that is most preferred (IDENTIFY FOR THE RECORDING), and, if these statements were on the pack of PARE, where would you place PARE on our charts on the wall?

Let's look at (RANDOMIZE THE 2 RISK STATEMENTS, KEEPING INTENT TO USE ALWAYS LAST):

- Risk of exposure
- Risk of developing related diseases
- Intent to use

FOR EACH PLACEMENT, ASK:

Why do you say that?

Build Your Own

We want to make sure the statements that go on this package are the most clear for customers such as you.

What we're going to do now is put together the best message about PARE to best communicate the risks associated with PARE.

GIVE A FEW MINUTES FOR THEM TO ORGANIZE THEIR IDEAL.

- Someone tell me, what statement should we put on the top, front of the pack? Why?
- And what goes on the bottom, front of the pack? Why?
- And finally, what does on the back of the pack? Why?

SHOW CLAIM AS BUILT, AND ASK:

- Is there anything unclear or confusing in any of the statements? Are there any words or phrases that you are not sure of? How would you change those to make them more clear?
- If you saw this on a pack for PARE, what would you think about the product? What makes you say that?
- Based on these statements, again, if you saw them on a pack of PARE, what would you do? IF NEEDED, PROBE FOR ACTION: Would you try PARE? Why would you do that?
- With this set of statements that we pieced together, would you place PARE differently on the scales on the wall? IF YES, Where? Why?
- FOR INTENT TO USE: Is your intent to use PARE based on these messages, or something else about the product? Please explain.

END

REPEAT THE ABOVE, FROM "START" TO "END" FOR THE NEXT CLAIMS TOPIC.

V. FINAL ASSESSMENT (3-5 MINUTES)

- After all you've read and reviewed today about PARE cigarettes, who do you see this cigarette being intended for? Anyone else? Why do you say that?
- If you learned that the FDA was considering a rule that, in the next year and a half to 2 years, would reduce the nicotine in all cigarettes to a level that is not addictive, how, if at all, would that change your understanding and perception of PARE?
 - And how, if at all, would that change your intent to use PARE?

VI. WRAP-UP (2 MINUTES)

We've gone through all the materials and messages and have addressed everything we needed to cover. Thank you again for your time and participation. Before you leave, let me remind you of what was noted in the informed consent:

- Smoking causes serious and fatal diseases such as lung cancer, heart disease and emphysema in smokers. Smokers are far more likely to develop serious diseases like lung cancer than non-smokers.
- Cigarette smoking during pregnancy is associated with increased risk of pregnancy complications, spontaneous abortion, low birth weight infants and stillbirth.
- Cigarette smoking is addictive. It can be very difficult to quit smoking, but this should not deter adult smokers who want to quit from trying to do so.
- There is no such thing as a safe cigarette. Using MRTPs has not been shown to be safer than smoking conventional cigarettes and in addition MRTPs should not be viewed as an alternative to quitting smoking.
- Anything communicated during this research is not in any way intended to promote smoking, a particular MRTP or MRTPs in general.

Thank you again for your time and contribution to our research!