

Moderator's Guide

Quantitative Concepts/Composite Scores

Focus Group preparation notes:

Objective and Task

Objective: To explore consumers' understanding of how the effectiveness of drugs is measured, what composite scores are, and how consumers understand the presentation of composite scores in DTC advertising.

Task Purpose: To conduct qualitative testing with consumers to explore the contextual factors (i.e., reactions, usefulness, preferences, and understanding) that relate to the understanding of composite scores in DTC advertising of prescription drugs.

Data Collection

Setting: Four (2 high education [but without MDs or PhDs in sciences], 2 low education) in-person focus groups will take place in focus group facilities in the metropolitan Washington, DC area as well as other cities across the country to be determined. Focus groups will last approximately 90 minutes. A trained moderator will lead the discussion. Interviews will be audio taped and transcribed.

Consenting: Written consent will be obtained from each participant at the beginning of each focus group.

Process: The focus group will comprise the following steps.

1. Welcome:

- a. **Informed consent**—facility personnel will briefly review the consent form and obtain each participant's written consent.
- b. **Welcome**—the moderator will thank the participants for taking the time to participate and explain further the purpose of the focus group.
- c. **Warm-Up**—the moderator will establish some ground rules and ask participant a few questions about their current medication use.

2. **Focus Group Discussion.** The moderator will use examples of print, television, and internet DTC advertising to engage participants in the current topic and to spark discussion.

3. **Closing.** The moderator will summarize the findings with the participant and ask for final thoughts.

Stimuli needed for this group:

- NyQuil print ad
- Toviax print ad
- Tylenol TV ad
- Orenzia TV ad
- Lipitor print ad
- Nasonex print ad
- Actonel print ad

Informed Consent Procedure

[Give participant informed consent form.] Here are two copies of an informed consent form. Please take a moment to review it and if you agree to it, please sign one copy. The other copy is for you to keep for your records. It contains a telephone number you can call if you have any questions after our interview is over.

- The consent form states that you agreed to participate in a group discussion about the presentation of information about prescription drugs.
- Your **identity and anything you personally say here will remain confidential to the extent allowed by law**. Your name, address, and phone number will not be given to anyone, and no one will contact you after this group discussion is completed. When I write my report, I will not refer to you by name. We will look at the results of the discussions as a group, not individually.
- Your decision to take part in this research study is completely voluntary. You can refuse to answer any question during the study and you can stop participating at any time. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.
- Most importantly, there are **no right or wrong answers**. We want to know your opinions and what you think about the materials.
- I would like to **audio record** our discussion to ensure accuracy. I am going to take notes during our conversation, but I would like to go back and review our discussion to make sure that I have everything correct. Do I have your permission to audio record our discussion today?
- Finally, do you have any questions before we begin?

WELCOME

Thank you for taking the time to join us today. Your participation is very important. I am _____ from Harvrey Marketing/ICF Macro, a marketing research organization. The purpose of this group is to get your feedback on how you decide how well a drug works from advertising for prescription drugs that you may see on television, in magazines and newspapers, and on the internet. As part of our discussion today, you will see some examples of advertising and answer some questions about them. Your feedback is very important to us and may ultimately be used to help the Department of Health and Human Services make the ads more user-friendly. Our discussion will last about two hours.

I am an independent consultant hired to moderate these discussions. As such, I do not have a vested interest in receiving any particular point of view. I simply want to have an active and lively discussion with all of you.

I. Ground Rules

- A. You have been asked here to offer your views and opinions; everyone's participation is important
- B. Audio/observers
- C. Speak one at a time
- D. No side conversations
- E. No right or wrong answers
- F. It is OK to be critical. If you dislike something or disagree with something that is said, I want to hear about it.
- G. All answers will be kept private to the extent provided by law, so feel free to speak your mind.

II. Participant Introductions

To begin, I would like to have you go around the table and introduce yourselves. Please give me:

- a. your first name only
- b. hobbies
- c. last live concert attended

III. Introduction to DTC Advertising

We all see a lot of advertising—on television, in magazines and newspapers, on the internet. We see a lot of advertising for medical products, including over-the-counter and prescription drugs, dietary supplements, medical devices, and health foods. What we are going to talk about today are ads for prescription drugs. These ads look a bit different from any other ads you see, even over-the-counter drugs, because they always include information about the risks of using the product and tell you to ask your doctor for more information.

[Show NyQuil print ad (OTC) and Toviaz print ad (DTC)]

Also, in television ads, these ads have an audio announcer who lists side effects that may come from the using the product and they tell you to ask your doctor for more information.

[Show Tylenol TV ad (OTC) and Orenca TV ad (DTC)]

Have you ever asked your doctor about a prescription drug you saw advertised?

IV. Composite Scores in DTC Ads

I'd like to show you some prescription drug ads now and ask you some questions about them.

1. Show Lipitor print ad (single score endpoint).
 - a. What do you think this drug treats?
 - b. How well will this drug work against high cholesterol?
 - c. How well will it work to lower bad cholesterol?
 - d. How well will it work to raise good cholesterol?
 - e. What did you learn about high cholesterol from this ad?
 - f. [*if not mentioned, ask*] Did you learn anything about the different parts or components of high cholesterol?
 - g. What do you think of this presentation of how well the drug works?
 - i. How understandable is it?
 - ii. Is there a way the presentation could be improved?
2. Show Nasonex_face print ad.
 - a. What do you think this drug treats?
 - b. How well will this drug work against nasal congestion?
 - c. How well will it work to stop a runny nose?
 - d. How well will it work to stop sneezing?
 - e. What did you learn about congestion from this ad?
 - f. [*if not mentioned, ask*] Did you learn anything about the different parts or components of congestion?
 - g. What do you think of this presentation of how well the drug works?
 - i. How understandable is it?

- ii. Is there a way the presentation could be improved?
3. Show Actonel print ad.
 - a. What do you think this drug treats?
 - b. How well do you think this drug will work against osteoporosis?
 - c. How well will it work against bone fractures of the hip?
 - d. How well will it work against bone fractures in the wrist?
 - e. What did you learn about osteoporosis from this ad?
 - f. [*if not mentioned, ask*] Did you learn anything about the different bones that can be affected by osteoporosis?
 - g. What do you think of this presentation of how well the drug works?
 - i. How understandable is it?
 - ii. Is there a way the presentation could be improved?

III. Preliminary Questions

Now I would like to talk a bit about prescription drugs in general.

1. What does it mean to say a prescription drug works or is effective?
2. Who does the tests to find out if a prescription drug works?
3. How do they do this?
 - a. What kind of measures do you think they use?
 - b. Tell me about a time they might use more than one measure.
4. Has anyone heard the term “composite score” before?
 - a. Where have you seen this term used? (sports, SATS, ACT, army promotion)
 - b. Have you have heard it used in medicine?
5. For the purposes of our discussion today, let’s use this definition of composite score: a single measure of how well a drug works from a combined set of different measures.

Here are three different examples of how composite scores are used in medicine:

- a. Some medical conditions, like diabetes and high cholesterol, have physical markers, like blood glucose levels or cholesterol levels. Others do not have objective measures and are more subjective, like pain, depression, ADHD, or nasal congestion. In these

cases, sometimes they will measure how bad a condition is by several different questions.

- b. Some medical conditions like osteoporosis involve multiple parts of the body and measurements at each location are combined into one overall score or result, such as bone loss measurements at the spine, in the hip, shoulder, wrist, and other areas.
- c. Sometimes the drug maker wants to report how the drug made you feel or what effect it has on your life, such as your ability to work or exercise. They may ask a number of questions and average the answers to get a score. These are called patient reported outcomes.

Does anyone have questions about these examples before we go on?

After a drug is approved for sale, the drug company can advertise it to doctors or to patients and consumers. When they do that, they must find a way to explain to you, the consumer, what these measures mean. That's what we are going to talk about next.

Let's look at one of the ads you saw earlier again. (show Nasonex_face print ad).

1. The ad lists a number of symptoms of nasal congestion. When it was measured, the drug was shown to work on all of the symptoms combined, but it was not shown to work on any one of the symptoms. In other words, it worked on "congestion," which included runny nose, but not necessarily on "runny nose."
 - a. What does this mean to you?
 - b. Does this change the way you think about the drug? In what way or why not?
 - c. How does this affect how effective you think the drug is? Why or why not?
 - d. How does this affect how safe you think the drug is? Why or why not?

Let's look at another ad you saw earlier (show Actonel print ad).

1. This drug was shown to work overall by measuring the seven areas shown in the ad. Overall, it was shown to reduce bone fractures, but not at specific locations.
 - a. What does this mean to you?
 - b. Does this change the way you think about the drug? In what way or why not?
 - c. How does this affect how effective you think the drug is? Why or why not?
 - d. How does this affect how safe you think the drug is? Why or why not?

V. False Close

Moderator checks with observers to see if they have additional questions or clarifications.

VI. Close

Thank you for spending your time with us tonight. Your comments are very helpful.