

Moderator's Guide
DTC: Truthful and Fairly Balanced?

Focus Group preparation notes:

Objective and Task

Objective: To explore consumers' perceptions and ideas about how fairly balanced and truthful DTC advertising of prescription drugs is.

Task Purpose: To conduct qualitative testing with consumers to explore the contextual factors (i.e., reactions, usefulness, preferences, and understanding) related to print and television DTC advertising of prescription drugs.

Data Collection

Setting: Eight (4 high education, 4 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 need for this group:

- NyQuil print ad
- Toviaz print ad
- Tylenol TV ad
- Orencia TV ad
- Cymbalta TV ad
- Cymbalta full list of risks

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 direct-to-consumer advertising of prescription drugs.
- Your **identity and anything you personally say here will remain confidential**. 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 advertising for prescription drugs that you may see on television, in magazines and newspapers, and on the internet. As part of our discussion today, we will be talking about what you like and don't like about the advertising as well as how you might make it more useful. Your feedback is very important to us and may ultimately be used to help the Department of Health and Human Services. 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 concert you saw live

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 the 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 Orencia TV ad (DTC)]

1. Have you ever asked your doctor about a drug that you've seen advertised?

- a. Where was the drug advertised?
- b. How did your doctor respond to your question?

IV. Questions/Discussion

A. Preliminary Questions.

1. What are some examples of prescription drug ads that you like? What do you like about them?
2. What are some examples of prescription drug ads that you do not like? What do you not like about them?

(*Moderator:* The two previous questions could turn into a rant. Please be aware of this possibility and redirect if this occurs.)

3. By law, prescription drug ads have some special requirements. This is why they seem a bit different from the other ads you see. The law says that these ads in particular are not allowed to be “false or misleading.” Something that is false is something that is not true. Something that is misleading is a little harder to define. In general, it means that if the ad makes people think something that is not true, even if the ad does not come out and say it, then it is misleading.

- a. What do you think would be a misleading drug ad?
 - b. What part of the ad would make it misleading?
4. What makes a good prescription drug ad?

(*Moderator:* Please follow-up on the ideas presented here. As we do not know what to expect, we do not have any pre-determined prompts at this time.)

B. Activity 1: What would the ideal prescription drug ad look like?

Moderator: Split into groups of three (up to three groups). Give each group paper, pencils, pens. They can draw or write in words what they think the ideal prescription drug ad would look like.

When the larger group has reconvened, go over each group’s ideas briefly.

1. Given that you’ve had time to think about this now, what are some ways you would improve prescription drug ads?

(*Moderator:* The following are possible prompts)

- a. How would that change the ads?
- b. How do you think people would respond to these new ads?

C. Activity 2: Come up with 10 “rules” for prescription drug ads.

Moderator: As whole group, please have the group arrive at a list of rules they would like these ads to follow.

- Use flipchart.
- Write down ideas as they are said and then have group rank them and pick the 10 “rules.”

D. Additional Questions

1. Another way that these ads are regulated is that the ad must be “fairly balanced” between the benefits and the risks of the drug. What do you think this means?

[Show Cymbalta TV ad.]

- 2. What do you think about the “fair balance” in this ad? [Probe: Why? What about that? Etc.]
- 3. Although it seems like these ads have a lot of risks, the risks you heard in the ad are not all the risks of the drug. Here is a list of all of the risks of this product.

[Show Cymbalta full risk list].

- a. How does this change the way you feel about the fair balance of the ad, if at all?
- b. What is the best way to provide a fair balance of risk and benefit information in these ads?
- 4. Do you have any other comments about prescription drug advertising?

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.