

Moderator's Guide

Consumer Perceptions of Prescription Drug Communications

Opening Remarks – Introductions and Rules

Ice Breaker (5 min.)

Moderator: Let's go around the room and introduce ourselves. Please tell me your first name, how long you have lived in the area, and just a little bit about your household.

Tonight we're going to talk about prescription drugs or medicines (5 min).

- What does the term prescription drug mean to you? What are some examples of these types of drugs? How are prescription medicines different from other medicines? **[IF THEY HAVEN'T ALREADY MENTIONED IT, let them know that a prescription medicine is one that you can't get without a prescription from a prescribing healthcare provider.]**

FOR REMAINDER OF SESSION, use the term (drugs or medicines) they seem to use most, or explain that you'll be using the terms interchangeably.

1. Generic vs. Brand Name (15 min)

- What does the term generic drug mean to you? Can you name any examples?
- What does the term brand name drug mean to you? Can you name any examples?
- Are brand name prescription drugs and generic prescription drugs identical? **[IF NO, PROBE]:**
 - o How do they differ?
 - o Does how well a drug works depend on whether it is a brand name or generic? Is one stronger than the other? What gives you this impression?
 - o Are side effects more likely with a brand name or generic drug? Is one safer than the other? Why do you think that is?
 - o After a brand name drug has been available for a while, generic versions of the drug usually start to become available. How do you explain the time it takes for generic drugs to become available?
 - o Why do you think generic prescription drugs cost less than brand name prescription drugs?

[IF THEY HAVEN'T ALREADY MENTIONED IT, let them know that a generic drug is an equivalent version of a brand name drug. This differs from cases where different brand name drugs can be used to treat the same condition. When we discuss generic drugs today, we are talking about the equivalent version of a brand name drug rather than a competing brand name.]

- Now let's take a look at some specific messages about generic and brand name drugs.

DISPLAY MESSAGES one at a time using large foam-board posters. Read each message aloud as it is displayed. Provide each message printed on paper to each

participant. The sequence in which the messages are presented to participants should be determined before each focus group and balanced to limit order effects.

[PROBE for each message] What does this mean to you? How clear or confusing is it? How believable is it? How does this message compare to what your health care provider may have told you? Does it make sense to you? **[If not, PROBE]** Why not? Are you surprised by it? Can you re-phrase this message in your own words?

- o *A generic drug includes the same active ingredient that makes a brand name drug work. Your doctor or pharmacist can talk with you about other differences.*
- o *Their inactive ingredients may differ, but brand name and generic drugs work equally well.*
- o *A drug's cost does not reflect how well it works. Brand name drugs cost more to pay for drug research and development. Generic drugs cost less because they use existing research.*
- o *Generic drugs are as safe and work as well as brand name drugs. All drugs meet FDA's high standards – from quality and performance to manufacturing and labeling.*

2. Side Effects (15 min)

- Next, let's talk more about brand name prescription drugs. Specifically, let's discuss the ads for brand name prescription drugs you see on television, in magazines, or online. What reactions have you had to those types of ads? How do those ads usually make you feel about taking the advertised drug? **[IF OVER-THE-COUNTER DRUGS ARE MENTIONED, remind them we are only talking about drugs that require a prescription from a doctor or other prescribing healthcare provider.]**
 - o What are the positives and negatives to hearing the side effect information included in ads for brand name prescription drugs? **[List positives and negatives on a flip chart.]**
- Potential side effects are also in the written information you probably get with your prescription drugs. Think about the last time you got a new prescription filled for a drug you had never taken before.
 - o Did reading about the potential side effects affect how you felt about taking the drug? **[If yes, PROBE]** How did it affect how you felt?
- FDA says that the drugs it approves are safe. So, how can these drugs have side effects?
- Let's look at some messages now about prescription drug side effects.

[PROBE for each message] What does this mean to you? How clear or confusing is it? How believable is it? Does it make sense to you? **[If not, PROBE]** Why not? Are you surprised by it? Can you re-phrase this message in your own words?

- o *An advertisement can't tell you whether a drug is right for you, but your doctor can answer questions about your health and drugs that may help.*

- o *Don't let information about side effects scare you away from using a prescription drug. Instead, ask your doctor if the drug's benefit to your health is more important than the possible side effects.*
- o *No drug is 100% safe – if it has a good effect, there's at least a chance of an unwanted bad effect.*
- o *Like everything you put in your body, prescription drugs have risks. Many are minor and unlikely to happen, but some can be more serious. Your doctor can help you decide which risks are worth taking.*
- o *Discuss your personal situation with your doctor - does a drug's possible health benefits for you outweigh its possible risks?*

3. Research Needed for Drug Review (15 min)

- Now let's talk about the research needed to support whether a prescription drug should be approved. What is your understanding of how drugs are researched, reviewed, and approved? **[PROBE]:** For example, who conducts the research? How much and what kind of research do you think is needed for FDA to determine whether a drug should be approved? How many people do you think are studied?
- Now let's look at some more messages – this time about drug review.

[PROBE for each message] What does this mean to you? How clear or confusing is it? How believable is it? Does it make sense to you? **[If not, PROBE]** Why not? Are you surprised by it? Can you re-phrase this message in your own words?

- o *By the time you hear about a “new” drug, it isn't new to FDA. FDA bases its drug approval decisions on years of research, starting from drug makers' early safety tests in animals to later tests in hundreds or thousands of patients.*
- o *Drug approvals are never rushed. Years of research support FDA's decision to approve each new drug.*
- o *FDA does not speed drug approvals to help drug makers. In special cases, FDA speeds the approval process for promising drugs that treat serious conditions. This is to benefit patients who desperately need new therapies that work.*
- o *FDA responds to patients' needs, but it does not approve drugs on the basis of hope. Drug approvals require evidence of safety and effectiveness.*
- FDA continues to monitor prescription drugs even after they are approved. Why do you think that is? How is it that new risks are sometimes discovered for drugs that have been available for years?
 - o *New science can reveal new risks of approved drugs.*
 - o *Scientific knowledge about drug risks and benefits increases as drugs are taken by more and more people.*

4. Discussing Decisions with Healthcare Providers (15 min)

- We've discussed a few cases in which you might want to talk with your doctor about prescription drugs and the ads you see on television, in magazines, or online. Have you ever felt you should stop taking a prescription drug without first talking with your doctor? Tell me about the situation and the decision you made. **[PROBE]:**
- Again, let's take a look at some possible relevant messages around this issue.

[PROBE for each message] What does this mean to you? How clear or confusing is it? How believable is it? Does it make sense to you? **[If not, PROBE]** Why not? Are you surprised by it? Can you re-phrase this message in your own words?

- o *Doctors and nurses spend years learning about bodies and keeping them healthy. Talk to a health care professional before making important decisions about your medicines.*
- o *Don't stop taking a prescribed drug until you've checked with your doctor. Your doctor is a trained medical professional – are you?*
[PROBE] This message poses a question to you as the reader, whereas the other messages don't. What is your reaction to this question?
- o *You would call a doctor before stopping your child's prescription. Do the same before stopping yours.*
- o *Meet Jane – mother of two. She volunteers at school, drives the carpool to soccer practice, and always talks to her children's doctor about their health. But Jane was too busy to talk to her own doctor about the side effects she experienced from her own medicine. "I thought I knew enough after reading about my symptoms online, so I quit taking my prescription. That decision landed me in the hospital." Don't let this happen to you – talk with your doctor before stopping your prescriptions.*

5. Understanding FDA's Role (15 min)

- What do you think is the relationship between FDA and drug companies?
[PROBE]: In terms of making sure prescription drugs work and are safe, how do FDA and drug companies work together? Who is responsible for what? Do they influence each other in any way?
- Here are the last few messages that I'd like you to consider.

[PROBE for each message] What does this mean to you? Is it clear, or confusing? Is it consistent with how you think about the FDA, or is it different? What, if anything, does the message say to you about FDA as a source for health-related information? Do you believe it? Does it make sense to you? **[If not, PROBE]** Why not? Are you surprised by it? Can you re-phrase this message in your own words?

- o *FDA. Protecting and Promoting Your Health.*
- o *FDA. Making Science-Based Decisions to Protect Your Health.*
- o *FDA keeps watch on prescription drugs for your safety.*
- o *In the court of health, FDA weighs the evidence and judges in your favor.*

o FDA. The last word on drug safety.

ENDING:

Those are all the questions I have for you tonight. Are there any final thoughts about this topic that you want to share before we leave?

Thank you again for your help with these focus groups. Good night.