

## Appendix II

### Moderator's Guide Consumer Perceptions of Warnings for Medications That May Cause Sedation

---

Opening Remarks – Introductions and Rules

---

#### Ice Breaker (5 minutes)

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

---

#### 1. OTC and Rx Introduction (5 minutes) (10 min.)

Tonight's discussion is going to be about OTC medications and prescription medications.

- What is the main difference between over-the-counter (OTC) medications and prescription medications?

(IF NEEDED) There is one major difference between over-the-counter (OTC) medications and prescription medications. OTC medications are those medications that you can get without a prescription, while prescription medications are those medications that you need a written order from a prescriber to get the medication from a pharmacy.

- What comes to mind when you think about taking an OTC medication versus a prescription medication? (Probe for: is one stronger, safer, and more effective. Be sure to ask why they say what they say).

#### 2. OTC medications (40 minutes)

For the next 40 minutes we are going to focus on OTC medications

Let's first think about those situations when you have seen or used OTC medications:

- What written information do you look at on the OTC package or container before you purchase a product?
- Do you look at the written information on the OTC package or container just before you take a dose?
  - If yes, do you only look at the information the first time you use the product or each time you use the product?
  - What information do you look for? Do you always look for the same information? (Probe to find out if it varies with different products?)
  - If no, why not? (Probe for: already know how to take the product from previous OTC or prescription product experience)

I'm now going to show you some OTC medication packages. (Moderator pass out examples of diphenhydramine and chlorpheniramine products). Look at the back of the box where you will find the Drug Facts. Look under the heading "When using this product." As you can see there is a list of information (moderator read list):

- o marked drowsiness may occur
  - o avoid alcoholic drinks
  - o alcohol, sedatives, and tranquilizers may increase drowsiness
  - o excitability may occur, especially in children
  - o be careful when driving a motor vehicle or operating machinery
- When you read this information what does it mean to you?
  - Would you drive after taking this medication? If yes, why, if no, why not?
  - What is it telling you to do about driving? What does “be careful when driving” mean to you? Why does this information say to be “careful” when driving?
  - Is there anything confusing about this information? If yes, what?
  - If the warning clearly stated do not drive or operate machinery when taking this medication, would you take the medication? If no, why not? If yes, would you drive or operate machinery after taking it? If yes, why, if no, why not?

Most of the information you just read under “When using this product” is written to warn you about driving or operating machinery because this medication may cause drowsiness.

- Is there another way the information can be written that would be more helpful? If yes, what information? Would a picture be helpful? If yes, what should the picture look like? Would anything else be helpful (probe, highlighting, changing the location of the information on the package etc.)

### 3. **Prescription medications (30 minutes)**

Now for the next 30 minutes we are going to focus on Prescription medications.

#### **Prescription warning statements**

Some prescription medications have this information in their patient information material (Moderator pass out the two examples).

Let’s first look at this warning: (Moderator read the warning)

TRADENAME can cause sleepiness and may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate machinery, or do other dangerous activities until you know how TRADENAME affects you.

- When you read this information what does it mean to you?
- What is it telling you to do about driving?
- Is there anything confusing about this information? If yes, what?
- If you read this warning would you drive after taking this medication? If yes, why, if no, why not?

Now let’s look at this warning (Moderator read the warning)

TRADENAME can cause dizziness and drowsiness. Avoid drinking alcohol, operating machinery, and driving a car when taking TRADENAME. Avoid taking other medicines that may cause drowsiness without talking to your healthcare provider first.

- When you read this information what does it mean to you?
- What is it telling you to do about driving?
- Is there anything confusing about this information? If yes, what?
- If you read this warning would you drive after taking this medication? If yes, why, if no, why not?

Out of the 2 examples which one do you do you prefer and why? Is there another way the information can be written that would be more helpful?

### **Prescription Label Stickers**

Your prescription bottle often has stickers on them. These also contain information and warnings about the medication. These are examples of some of the stickers (show prescription bottles with examples of the stickers on them).

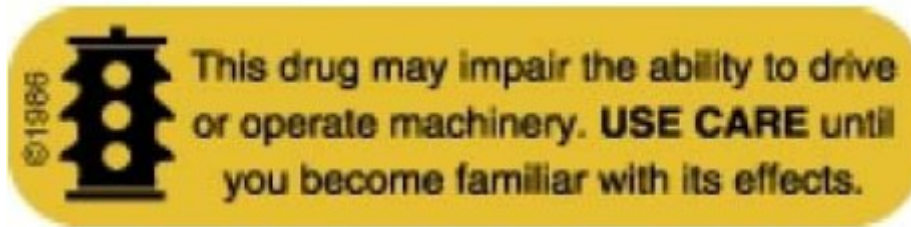
- Have you ever taken a prescription medication that had these stickers on the bottle? If yes, did you look at them? Why or why not?
- When you see these stickers are they important to you? Why or why not?

Here is an example of one of these stickers (moderator pass around the example of the sticker without driving referenced and read warning)



- What is this warning mean to you?
- If you saw this sticker on one of your medication bottles would you drive after taking the medication? If yes, why, if no, why not?

Here are examples of other stickers (moderator pass around the example of stickers with driving referenced and read warnings)



- What do these warnings mean to you?
- If you saw one of these stickers on your medication bottle would you drive after taking the medication? If yes, why, if no, why not?

If these stickers are intended to warn you about driving or operating machinery because a medication may cause drowsiness, is there a better way these stickers should be written? How about the pictures on the stickers? Are they clear? Are any of them confusing? Is there a better picture that could be used to warn not to drive or operate machinery while taking a medication that may cause drowsiness? If yes, what would it look like?

#### 4. **Additional thoughts about OTC labels (15 minutes)**

Since we have a few more minutes we would like to get some additional information from you about OTC labels. We are going to be discussing a few messages that may be found on OTC medication packages.

##### Claims on the OTC package:

Have you seen message such as “#1 Pharmacist Recommended” on the front of an OTC medication package (show them an example; Rogaine)? What comes to mind when you see a message like this one?

##### Talk to a doctor before use if you have not been diagnosed with (a certain problem, e.g. asthma):

Some OTC medication packages have a statement to ask a doctor before use if you have never been diagnosed with the problem the OTC medication is suppose to treat such as asthma. (Show the example of this statement; “Talk to a doctor before use if you have not been diagnosed with asthma” on flip chart). If you saw this statement on an OTC drug that you were thinking of taking but you were never diagnosed by a doctor with asthma, would you talk to your doctor before taking the medication? If no, why not?