

**FDA OFFICE OF WOMEN'S HEALTH**  
**Medicine and Pregnancy**  
**Moderator Guide**

**Focus Group Purpose & Objectives**

The FDA Office of Women's Health (OWH) will conduct four focus groups with women of various races/ethnicities, ages and educational levels who have a variety of chronic health conditions and are currently pregnant, had a baby in the last 5 years, or are currently planning to get pregnant in order to examine knowledge and attitudes about medication use in pregnancy and pregnancy registries. The specific objectives are:

- 1) Solicit participant feedback on the layout, messaging, and usability of the 2012 OWH fact sheet 'Medicine and Pregnancy';
- 2) Identify common questions women have for health care professionals regarding medication use during pregnancy;
- 3) Learn more about what women know about weighing the risks and benefits of taking medicines during pregnancy;
- 4) Learn what women know about pregnancy registries and identify perceived barriers to participation in a pregnancy registry;
- 5) Solicit recommendations on the best ways to inform pregnant women about pregnancy registries.

**Road Map of Discussion**

<b>Discussion Categories</b>	<b>Approximate Allotted Time</b>
Welcome and Opening Remarks	2-3 minutes
Focus Group Process	5 minutes
Introductions and Icebreakers	5 minutes
Topic 1: Information Sources and General Attitudes about Medication Use in Pregnancy	20 minutes
Topic 2: Feedback and Understanding of 'Medicine and Pregnancy' Fact Sheet	25 minutes
Topic 3: Awareness and Attitudes Towards Pregnancy Registries	20 minutes
Closing	5 minutes
<b>Total Allotted Time</b>	<b>85 minutes</b>

**Welcome and Opening Remarks (1-2 minutes)**

Good evening and welcome. I want to thank you for taking the time to join us for this focus group. We do appreciate that you have taken time from your day to participate.

My name is \_\_\_\_\_, and my role is to guide the discussion. I'm going to tell you a little bit about what you can expect tonight--the purpose of this focus group discussion is to ask your

opinions about medication use during pregnancy. Our discussion is going to last about an hour and half. Once we get started, I am going to ask you questions and you are going to share your thoughts and opinions. We want to learn from you; I am here to listen to what you have to say. Your opinions are very important. You are representing women who are pregnant, recently gave birth or are actively trying to have a baby. We may use what we learn from you today and from other focus groups to create materials and resources that can help pregnant women.

The research team will keep what you say this evening in strict confidence. This research is not being conducted by a pharmaceutical or drug company or by any organization that profits from the sale of medications.

Participation in the discussion group is voluntary. You may choose to leave at any time without penalty.

### **Focus Group Process (5 minutes)**

Before we get started, there are just a few additional things I'd like to point out about the process. In order to make this session successful, there are few guidelines for everyone to follow:

- 1. No "Right" or "Wrong" Answers:** I want to assure you that there are no "right" or "wrong" answers. Please feel free to share your point of view, even if it is different from what others have said. In fact, it's really important for us to hear all the different points of view and participation from everyone is important. If you want to follow-up on something someone said, or if you want to agree or disagree, feel free to do that. I want you to speak your mind. Please speak one at a time, in a loud enough voice for all to hear and no side conversations.
- 2. Tape Recording and Observation:** I want to remind you that we will be tape recording the session because we don't want to miss any of your comments. As you may have noticed, there is a one-way mirror in this room. Behind the mirror are staff members who are observing and taking notes. They are not in the same room with us because they can be distracting. The session is being taped so I can write an accurate report, not of "who said what," but "what was said."
- 3. Confidentiality:** Although we will be on a first name basis today, we will not use your real names in any reports. We will keep the information you give us private and confidential. We ask that you do not talk about what other group members say to anyone outside this group.
- 4. Incentive and Timing:** We expect to be here until \_\_\_\_\_. We appreciate you taking this time with us so we want to make sure we end on time. I will be watching the clock and may need to break off the discussion at times to be sure we have time to discuss all topics. Then we will distribute to each of you \$75 in cash as a token of our appreciation for participation.

Lastly, I just want to say that your health is private. So, please do not feel that you need to share details about your health if you are not comfortable sharing them with the group.

### **Introductions and Icebreakers (5 minutes)**

Let's begin by going around the room and please tell us:

- Your first name or the name you would like to be called this evening?
- What you would be doing if you weren't here tonight?
- What is your favorite food to cook or eat?

I'll start.

### **Topic 1: Information Sources and General Attitudes about Medication Use in Pregnancy (20 minutes)**

#### **Warm up Question**

As you know, we are trying to get your feedback about medication use in pregnancy.

*What are some positive things about pregnancy you can think of?*

I'd like to begin our discussion by asking your opinions are using medicine during pregnancy.

1. *When pregnant, who do you (or will you) rely on for information about pregnancy, health, and babies?*
2. *Where have you gotten information about what medication is safe during pregnancy?*

**PROBE:** *Physician/Doctor, Midwife, Pharmacist, Books/Magazines, Nurse, Friends/Family, Nurse Practitioner, Internet (ask to name specific websites)*

3. *How do you prefer to get information about medication use and safety?*
4. *How can you tell if it's trustworthy?*

**PROBE:** *website, Doctor, friends, family, news media, etc.*

5. *How do you decide whether it's okay to take medication in pregnancy?*

### **Topic 2: Feedback and Understanding of 'Medicine and Pregnancy' Fact Sheet (25 minutes)**

Next I'd like to discuss what you think about this fact sheet 'Medicine and Pregnancy'. (*Distribute Fact Sheet*) Please take a few minutes to read it and then we will discuss what you think about it.

The first questions I have are based on the design of the fact sheet, not the content:

1. *What do you like about how the fact sheet is designed? What works for you? What does not work for you?*

**PROBE AS NECESSARY:**

- *Title*
- *Message*
- *Organization of the information*
- *Design and layout*
- *Colors*
- *Photos – are they appropriate/relevant?*
- *Type size (font size)*

2. *Was this fact sheet clear/easy to understand? (Ask participants to raise hand to indicate: easy, fair, or difficult to understand) If not, what part(s) was not clear to you?*

**PROBE:** *Reading level*

3. *What do the photos tell you?*
4. *Who should read this fact sheet?*
5. *What are some questions you have had for health care professionals about taking medication in pregnancy?*
6. *Where would you expect to find this fact sheet?*
7. *Is there anything missing that a pregnant woman might also want to know about finding out about using medication during pregnancy? How can the fact sheet be improved?*

Now I'd like to ask you about the information presented on the fact sheet:

*[PASS OUT FACT SHEET CHECK] Please use the pencil provided to answer the questions on this sheet and do NOT put your name on the paper. When everyone has finished the sheet, we will go over a few more questions.*

1. *What is one main point of the fact sheet you remember most? What are some other important points?*
2. *Is this information new to you? Raise your hand if you learned something new from the fact sheet. [RECORD THE NUMBER] What is new?*
3. *The fact sheet lists some questions pregnant women should ask their health care provider. What are some questions pregnant women may have about taking medication in pregnancy?*
4. *What is one way to find out if a medication is safe to take in pregnancy?*
5. *Do you want more information on about taking medication in pregnancy? If yes, what type of information in particular do you want?*

**Topic 3: Awareness and Attitudes Towards Pregnancy Registries (20 minutes)**

The fact sheet also talks about pregnancy registries. A Pregnancy Registry collects information from women who take prescription medicines or vaccines during pregnancy to help learn about how medicines affect pregnant women and their babies.

1. *How many of you have heard about pregnancy registries before reading the fact sheet? What do you think they are? What have you heard? How did you hear or learn about the pregnancy registry?*
2. *Have you ever participated or signed up for a pregnancy registry? If not, would you consider signing up? Why or why not?*
3. *What do you think are some benefits of a pregnancy registry are?*

**PROBE:** *more information about safety*

4. *What do you think some concerns might be about signing up for a pregnancy registry? Why?*

**PROBE:** *fear, concerns about time commitment, etc.*

5. *Have you ever gone to a government website to get information on pregnancy registries? If so, which one? [DO NOT ASK this question if they all say they learned about registries for the first time during focus group.]*
6. *What are some ways to better communicate the benefits of pregnancy registries to help women learn more about which prescription medicines are safe to take during pregnancy? What is the best way to encourage pregnant women to sign-up for pregnancy registries?*

**PROBE:** *Venues (churches, health providers), activities, events*

**Closing (5 minutes)**

Now for the last few questions:

1. *What is the most important point about taking medicine in pregnancy we discussed?*
2. *Is there anything we missed that you would like to talk about?*

Before we wrap things up, I am going to step into the observation room to see if there are any additional questions from them. I will back in just a couple minutes.

That wraps up the questions I have for you today. Do you have any final questions for me before we end?