

## PLLR Moderator's Guide

### I. I n t r o d u c t i o n s

#### Rotation:

- Presentation of labeling examples will be rotated across groups. See Appendix A for proposed rotation schedule.

#### Timing:

- Online groups will be 75 minutes, with 5-6 participants.

### (5 minutes)

Hello everyone, this is \_\_\_\_\_, can everyone hear me clearly? I work for an independent research company called Westat and I am here today on behalf of the Food and Drug Administration (FDA). Thank you so much for taking time to talk to us today. I am here because FDA wants to understand your experiences with prescription labeling for pregnant women. Our discussion should last no longer than 75 minutes.

I need to cover a few things before we get started:

- Your participation today is totally voluntary; you can leave the discussion at any time.
- Everything you say will be kept secure to the extent permitted by law. Your name will not be linked to anything you have said today. Also, your name will not be included in any of the reports we write about our talk. We may use quotes from our conversation but these will not be used in a way that can identify you.
- With your permission, we'd like to record our conversation today. This will help make sure we accurately capture everything you've said. Before our discussion starts, I will ask each of you if you agree to participate in our discussion and if it's okay for us to record it.
- You will receive \$300 as a token of our appreciation for taking part today.
- I am joined on this call by my co-worker \_\_\_\_\_.S/he is listening in to take notes, just in case the recording is not clear. **[IF APPLICABLE:** We are also joined by people from FDA who are very interested in today's discussion. They will not participate in the discussion, they are just observing.]

Now, just a few tips to keep our discussion on time and on track:

- When you have something to say, jump right in as soon as the person before you is finished speaking; don't wait to be called on.
- Before you speak, please **say your name**, so people can respond to your comments.
- And please feel free to talk to each other, not just to me. That's why we're talking in a group: so you can react to each other's ideas. There aren't any right or wrong answers and it's okay to disagree with each other, let's just be polite about it.

- We'd like to hear from everyone, so please speak up and please let others do so as well. Also, if I haven't heard from you in a while, I may call on you, or if you're shaking your head in disagreement or you look anxious to say something. It's very important that we hear everyone's perspectives.
- Please do not take other calls during our time together. If you get interrupted or need to dial back in for some reason, please ask what we're talking about if you cannot figure out when you rejoin. It's important that we hear from everyone.
- We have a lot of topics to cover and not a lot of time. So if I interrupt you or move us along, please don't be offended. I just need to keep us on track and on time.
- Please silence your cell phones or turn them completely off.
- Any questions before we start? And does everyone agree to participate and be recorded? [MODERATOR: Obtain verbal consent from each participant for the recording.]

## II. PLLR Knowledge (5 minutes)

1. To begin, I would like to go around the group and have you each introduce yourselves. Please tell me your first name, and how long you have been practicing.
2. Now let's talk about some of your experiences in prescribing [pharmacists: counseling pregnant patients] prescription drugs for pregnant patients. Where do you get information on the safety of medications in pregnancy?
3. How often do you use the medication labeling to obtain prescribing and safety information for your pregnant patients? Why/why not? And if why not, what do you use instead?
4. Are you aware that the pregnancy letter categories A,B,C,D,X are no longer being used in prescription labeling? How have you adjusted to prescribing without a letter category? What are your thoughts on this change?

### **Background Information on Prescription Drug Labeling**

Before we start, I will share with you some background information on prescription drug labeling. The objective of drug product labeling is to communicate to healthcare providers a summary of the essential scientific information needed for the safe and effective use of the drug. It is important to keep in mind that when a drug is approved, it is also approved to use in pregnant women, except in the case of explicit contraindication. Additionally, labeling does not specify clinical practice guidelines, but rather, includes a concise summary of available information needed for the safe and effective use of drugs.

### III. Example 1. Case Reports and Animal Risk [Drug Labeling 3] (12 minutes)

I am going to display on the screen a sample excerpt from prescription labeling for a fictitious drug that has been approved for premenopausal women with acquired, generalized hypoactive sexual desire disorder. Please take a moment to review that material. When you are done reading through it, I have some questions for you all about it. [MODERATOR DISPLAY THAT MATERIAL ON THE SCREEN. ALLOW 2-3 MINUTES FOR PARTICIPANTS TO READ.]

1. How useful is this Pregnancy subsection of labeling to you? What about this subsection is helpful? What is unhelpful? [PROBE FOR LENGTH, WHETHER PARTICIPANTS WOULD REVIEW ALL THE INFORMATION PROVIDED IN REAL LIFE]

- What information, if any, would you add to this subsection? What information is not needed or could be removed?
- Based on the information in this subsection, would you prescribe this medication to a pregnant woman? Why or why not?

2. Now let's look closer at the infographic that is at the top of the labeling. What did you think of this infographic? What information do you think it is trying to convey? The intent is not for the infographic to replace the Risk Summary, however, do you think the infographic supplements the information in the Risk Summary?

- What is your opinion of how helpful this infographic is as a summary of the available risk information? What makes you say it helpful? What makes it not helpful?
- Is the infographic clear? If not, what is confusing about it? What is missing from this infographic?
- Do you think that the message conveyed by this infographic is consistent with the message you just read in the Risk Summary?
- Describe how you would use this infographic to make decisions about prescribing.
- How could the infographic be modified to be more informative?

3. Now let's talk about the information that is being conveyed in this labeling and the way that it is presented. What do you think of the way the information is set up? Is the most important information easy to find?

- How easy or difficult is it to understand this information? Is there anything confusing or unclear? What about the information on risks, keeping the potential benefits in mind? [PROBE ON INFORMATION ABOUT THE RISKS AND BENEFITS. IS THIS INFORMATION CLEAR, OR IS ANYTHING CONFUSING?]
- Based on the information that is presented here, what is your interpretation of the benefit vs. risk of prescribing this medication to a pregnant patient?
- How helpful is the statement on background risk of major birth defects and miscarriages in the U.S. population in interpreting the data on the drug presented in the Risk Summary?

4. Let's talk about how this labeling communicates risk and the uncertainty of risk. Based on the information that is presented here, what is your interpretation of the risk of prescribing this medication to a pregnant patient?

- In your opinion, how well is the quality of the data conveyed? What about the strength and relevance of the clinical data? What about the strength and relevance of the animal data?
- What are some suggestions for how the risk could be conveyed better?
- What is your interpretation of the animal data presented?

ONLINE: Now we will look at another way the infographic could be presented.

#### **IV. Example 2. Registry data and no animal risk [Drug Labeling 1] (12 minutes)**

Now we will look at the next labeling example of a fictitious prescription drug that has been approved for chronic inflammatory disease. Please take a moment to read over Example 2 on your screen. [MODERATOR WILL DISPLAY LABEL ON SCREEN. ALLOW 2-3 MINUTES FOR PARTICIPANTS TO READ.]

1. How useful is this Pregnancy subsection of labeling to you? What about this subsection is helpful? What is unhelpful? [PROBE FOR LENGTH, WHETHER PARTICIPANTS WOULD REVIEW ALL THE INFORMATION PROVIDED IN REAL LIFE]

- Based on the information in this subsection, would you prescribe this medication to a pregnant woman? Why or why not?

2. Now let's look closer at the infographic that is at the top of the labeling. What did you think of this infographic? What information do you think it is trying to convey? The intent is not for the infographic to replace the Risk Summary, however, do you think the infographic supplements the information in the Risk Summary?
  - What is your opinion of how helpful this infographic is as a summary of the available risk information? What makes you say it is helpful? What makes it not helpful?
  - Is the infographic clear? If not, what is confusing about it? What is missing from this infographic?
  
3. Now let's talk about the information that is being conveyed in this labeling and the way that it is presented. How easy or difficult is it to understand this information? Is there anything confusing or unclear? [PROBE ON INFORMATION ABOUT THE RISKS AND BENEFITS. IS THIS INFORMATION CLEAR, OR IS ANYTHING CONFUSING?]
  - How helpful is the Clinical Consideration? What do you think it is trying to communicate? Does it influence your decision whether or not to prescribe this drug to a pregnant patient?
  - Based on the information that is presented here, what is your interpretation of the benefit vs. risk of prescribing this medication to a pregnant patient?
  - How helpful is the statement on background risk of major birth defects and miscarriages in the U.S. population in interpreting the data on the drug presented in the Risk Summary?
  
4. Let's talk about how this labeling communicates risk and the uncertainty of risk. Based on the information that is presented here, what is your interpretation of the risk of prescribing this medication to a pregnant patient?
  - Does the statistical information provided help with your interpretation of the risk? Please describe why or why not.
  - What are some suggestions for how the risk could be conveyed better or is it clear?

## V. Example 3. Vaccine registry data and no animal risk [Vaccine labeling] (12 minutes)

Now we will look at the next labeling example of a fictitious prescription drug that has been approved for prevention of dengue disease in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas. Please take a couple minutes to review Example 3 on your screen. [MODERATOR WILL DISPLAY LABELING ON SCREEN. ALLOW 2-3 MINUTES FOR PARTICIPANTS TO READ.]

1. How useful is this Pregnancy subsection of labeling to you? What about this subsection is helpful? What is unhelpful? [PROBE FOR LENGTH, WHETHER PARTICIPANTS WOULD REVIEW ALL THE INFORMATION PROVIDED IN REAL LIFE]

- Based on the information in this subsection, would you prescribe this medication to a pregnant woman? Why or why not?

2. Now let's look closer at the infographic that is at the top of the labeling. What did you think of this infographic? What information do you think it is trying to convey? The intent is not for the infographic to replace the Risk Summary, however, do you think the infographic supplements the information in the Risk Summary?

- What is your opinion of how helpful this infographic is as a summary of the available risk information? What makes you say it helpful? What makes it not helpful?
- Is the infographic clear? If not, what is confusing about it? What is missing from this infographic?

3. Let's talk about the information that is being conveyed in this labeling and the way that it is presented. How easy or difficult is it to understand this information? Is there anything confusing or unclear? [PROBE ON INFORMATION ABOUT THE RISKS AND BENEFITS. IS THIS INFORMATION CLEAR, OR IS ANYTHING CONFUSING?]

- How helpful is the Clinical Consideration? What do you think it is trying to communicate? Does it influence your decision whether or not to prescribe this drug to a pregnant patient?
- Based on the information that is presented here, what is your interpretation of the benefit vs. risk of prescribing this medication to a pregnant patient?

- How helpful is the statement on background risk of major birth defects and miscarriages in the U.S. population in interpreting the data on the drug presented in the Risk Summary?
4. Let's talk about how this labeling communicates risk and the uncertainty of risk. Based on the information that is presented here, what is your interpretation of the risk of prescribing this medication to a pregnant patient?
- What are some suggestions for how the risk could be conveyed better or is it clear?
5. When there is a pregnancy registry or surveillance study for a medication, the contact information is being included in labeling so that you can refer your patients to enroll. What do you know about pregnancy registries or surveillance studies? Have you referred patients a registry? Would you refer patients to enroll if you saw this information in labeling? If you would not refer patients to enroll, is there additional information you would like to see before you consider enrolling a patient?

## VI. Example 4. Large epidemiological studies and no animal risk [Drug Labeling 2] (12 minutes)

Now we will look at the next labeling example of a fictitious prescription drug that has been approved for nausea and vomiting. Please take a couple minutes to read example 4 on your screen. MODERATOR WILL DISPLAY LABELING ON SCREEN. ALLOW 2-3 MINUTES FOR PARTICIPANTS TO READ.]

1. How useful is this Pregnancy subsection of labeling to you? What about this subsection is helpful? What is unhelpful? [PROBE FOR LENGTH, WHETHER PARTICIPANTS WOULD REVIEW ALL THE INFORMATION PROVIDED IN REAL LIFE]
  - Based on the information in this subsection, would you prescribe this medication to a pregnant woman? Why or why not?
2. Now let's look closer at the infographic that is at the top of the labeling. What did you think of this infographic? What information do you think it is trying to convey? The intent is not for the infographic to replace the Risk Summary, however, do you think the infographic supplements the information in the Risk Summary?
  - What is your opinion of how helpful this infographic is as a summary of the available risk information? What makes you say it helpful? What makes it not helpful?

- Is the infographic clear? If not, what is confusing about it? What is missing from this infographic?

3. Now let's talk about the information that is being conveyed in this labeling and the way that it is presented.

- How easy or difficult is it to understand this information? Is there anything confusing or unclear? [PROBE ON INFORMATION ABOUT THE RISKS AND BENEFITS. IS THIS INFORMATION CLEAR, OR IS ANYTHING CONFUSING?]
- Based on the information that is presented here, what is your interpretation of the benefit vs. risk of prescribing this medication to a pregnant patient?
- How helpful is the statement on background risk of major birth defects and miscarriages in the U.S. population in interpreting the data on the drug presented in the Risk Summary?

4. Let's talk about how this labeling communicates risk and the uncertainty of risk. Based on the information that is presented here, what is your interpretation of the risk of prescribing this medication to a pregnant patient?

- How does the statistical information provided help with your interpretation of the risk, if at all.
- How useful are the study limitations in explaining the uncertainty of risk with use of this drug during pregnancy?
- What are some suggestions for how the risk could be conveyed better, or is the risk clear?

## VII. Wrap-up (10 minutes)

1. If you could construct your own infographic for the labeling, what would you like to see? Why? And how would it differ from the infographic presented above?
2. Is there anything else you want to say on these topics beyond what we've already discussed? Any questions or recommendations?

Before we finish, I am going to check with our observers if they have any questions. [CHECK AND ASK ANY QUESTIONS.]

- Review payment logistics.
- THANK AND END



## Appendix A: Proposed Rotation Schedule

Rotating order of labeling examples. For each group, the order of sections within the guide will be arranged to match the assigned rotation.

**Table 1: Proposed Labeling Rotation Schedule**

Segment	Group	First	Second	Third	Fourth
<b>Segment 1: OB/GYN</b>	Group 1	V	L1	L2	L3
	Group 2	L1	L2	L3	V
	Group 3	L2	L3	V	L1
	Group 4	L3	L1	V	L2
	Group 5	V	L2	L1	L3
<b>Segment 2: Family Medicine</b>	Group 1	V	L1	L2	L3
	Group 2	L1	L2	L3	V
	Group 3	L2	L3	V	L1
	Group 4	L3	V	L1	L2
	Group 5	L3	V	L1	L2
<b>Segment 3: Other specialty physicians</b>	Group 1	V	L2	L1	L3
	Group 2	L1	L3	L2	V
	Group 3	L2	L3	V	L1
	Group 4	L3	V	L1	L2
	Group 5	L1	V	L3	L2

Note: This table assumes the maximum number of groups for Year 1; 5 for each segment, with 5-6 participants each for a total of 15 groups.

V = Vaccine

L1 = Labeling 1

L2 = Labeling 2

L3 = Labeling 3