Attachment A

Evaluation of How Best to Communicate to Healthcare Providers about the Risks & Benefits of Prescription Drug Use for Pregnant and Nursing Women

Mental Models Protocol

Introduction

Hello, this is <*name*> with Decision Partners. We are conducting research on behalf of the Food and Drug Administration into the decisions healthcare providers face when treating pregnant or nursing women. As part of this project, we're speaking with healthcare providers to better understand how they make these treatment decisions and how they use information when treating patients. Thank you for agreeing to participate in this research. Our conversation will take about 45 minutes.

I have a list of questions to help guide our discussion, but please feel free to raise anything that comes to mind as we go along. In this kind of an interview, there are no right or wrong answers. All of your comments will add value to this initiative. I also want to assure you that this interview is confidential. We will not identify you as the specific source of any comments in our report. Instead, our report of the interviews will consolidate the responses of everyone we interview. You will not be identified anywhere in the report.

Before we start, in order to ensure that my notes of our conversation are accurate and complete, I'd like to ask your permission to record our conversation, but I would like to stress again that your responses will be kept confidential. Again, you will not be able to be identified through the recording. Is it alright with you if I record this conversation?

Opening

[*Note to interviewer: please say this next sentence very slowly and deliberately*]

Our focus is particularly on treatment decisions for pregnant or nursing women who have a chronic condition that generally requires medication:

- By chronic condition, we mean a disease or other condition that generally involves long-term (that is, more than one month) use of prescription drugs. Examples of chronic conditions include asthma, depression, epilepsy, hypertension and cancer treatment.
- By treatment decisions, we mean your decision whether to prescribe a drug, how and what information to communicate to the patient, and any other ways that you may manage risks to the mother or child. Treatment decisions also include the decisions you face upon learning of inadvertent exposure: that is, providing advice when you learn a woman has become pregnant while taking a prescription drug.
- We are focusing on the use of prescription drugs and not on the use of non-prescription drugs at this time.

Interviewer Note: *If the interviewee seems hesitant or uncomfortable with an open-ended question, remind him or her, as appropriate, that you are interested in understanding what first comes to his or her mind about this topic.*

Part 1: Influences on Decision Making

Let's begin by talking generally about the decisions you face regarding making treatment decisions for women with chronic conditions who are pregnant or nursing. The next few questions will be about these decisions generally.

1. Before we begin, can you briefly describe your practice and specifically, your experience treating pregnant or nursing women with chronic conditions?

2. Thank you. Now, could you describe the typical decisions you face as you care for a pregnant or nursing woman with a chronic condition?

    - Prompt [*if not already answered*]:
        - What types of conditions or situations would require additional information on treatment risks and benefits?
        - What specific information do you look for?
        - Where are you most likely to find the information you are looking for?
            - Prompt for quality of the source(s) of information they mention. (*Interviewer note*: By quality, we mean the scientific quality of the information and the degree to which they believe it is unbiased.)
        - How do you involve patients in the decision-making process?
        - Are there other things that you keep in mind while making recommendations in these cases?

3. Are there specific things you do or consider in a case where the fetus was exposed to a prescription drug before the woman knew she was pregnant?

    - Prompt [*if not already answered*]:
        - What specific information would you look for?
        - Where are you most likely to find the information you are looking for?
            - Prompt for quality of the source(s) of information they mention.
        - How do you involve patients in the decision-making process?
        - Are there other things that you keep in mind while making recommendations about a pregnant or nursing woman starting, continuing, or stopping using a specific prescription drug?

4. Thank you. I'm now going to offer you some factors that physicians may say influence their decisions for treating chronic conditions in pregnant or nursing women. Some of these you may have already mentioned, some of them you haven't raised. Please rate each of these factors as having a very high, high, medium, low, or no influence on your decisions.

    - First, your personal comfort with treating pregnant or nursing women. Would you rate that a very high, high, medium low or no influence on your decisions?
    - Next the availability of information regarding treatment risks? Would you rate that as a very high, high, medium, low or no influence?
    - What about the scientific quality of information regarding treatment risks - a very high, high, medium, low or no influence?

- What about the patient's history with particular treatments - a very high, high, medium, low or no influence?
- How about your interaction and relationship with your patient - a very high, high, medium, low or no influence?
- What about your understanding of your patient's understanding of the treatment risks - very high, high, medium, low or no influence?
- What about your understanding of your patient's preferences - very high, high, medium, low or no influence?
- How about your patient's ability to manage or monitor her condition - very high, high, medium, low or no influence?
- How about your own personal attitude toward risk - very high, high, medium, low or no influence?
- How about any liability concerns that you may have - very high, high, medium, low or no influence?
- Are there any other pressures that you face when making prescribing decisions?
    - Would you rate this as very high, high, medium or low influence? [*If more than one, rate them one at a time.*]

[Note to interviewer: if all are very high, ask which one is the most important.]

Part 2: Role of Prescribing Information in Decision Making

Now I am interested in hearing about the role of prescribing information in the types of decisions we have been discussing. By prescribing information, I mean the information you may find in the drug package itself and in the PDR. I'm going to refer to this as the *package insert*. You may also know this as the "PI," as product information, or as the drug label. The package insert also usually accompanies manufacturers' other promotional material.

[Note to interviewer: Technically, the package insert is "FDA-approved" prescribing information, that is, information that is reviewed and approved by FDA.]

5. First, what can you tell me about how you use the package insert in treatment decisions generally?

6. Thank you. Now, what can you tell me about how you use the package insert when facing decisions about the use of prescription drugs for treating chronic conditions in pregnant or nursing women?

> *[Interviewer Note: Interviewee may spontaneously mention pregnancy categories or animal and human evidence. If so, note these ideas, but save prompts for Q8, Q9 and Q10]*

7. About how often do you refer to the package insert when making treatment decisions for pregnant or nursing women with chronic conditions? Would you say very often, somewhat often or not often?

- Under what conditions would you be more likely to look at the package insert information?
- Under what conditions would you be less likely to look at this information?

8. Can you talk a bit {*if already mentioned*, more} about the package insert's pregnancy categories? Can you walk me through the categories and say what each of them mean to you?

Follow up if not mentioned, or if an example is needed.

- What does category A mean to you?
- What does category B mean to you?
- What does category C mean to you?
- What does category D mean to you?
- What does category X mean to you?

- Would you say you rely on the categories when making treatment decisions to a very high, high, medium or low degree? Why?
- **[*High Priority Question*]** What would your reaction be if the categories were no longer in the package insert?
- **[*High Priority Question*]** How do you think your decision making would change if the categories were removed completely?

9. Thank you. Now, can you talk a bit {*if already mentioned:* more} about how any human data in the package insert influence your decision making?

- How do you use animal data in the package insert in your decision making?

10. Ok, I'd now like discuss two scenarios:

a. First, when the package insert says that there are animal data that show an effect but that there are no human data available, how confident would you say you are in your understanding of the risk?

Note to interviewer: Do not prompt. Record response in their own words.

- How does this scenario influence how you typically make treatment decisions about pregnant or nursing women with chronic conditions?

b. Second, when the package insert indicates that animal data show a negative effect and available human data show no effect, how confident would you say you are you in your understanding of the risk?

Note to interviewer: Do not prompt. Record response in their own words.

- How does this scenario influence how you typically make treatment decisions about pregnant or nursing women with chronic conditions?

Part 3: Determining Usefulness and Value of Current Prescribing Information

Thank you. Now I am interested in your thoughts on the usefulness or value of current prescribing information in package inserts in terms of helping you with your prescribing decision.

10. Thank you. First of all, what is your overall perception of the usefulness of available information in package inserts? Would you say it is very useful, somewhat useful or not very useful?

- Why do you say that?
- What specific information in the package insert is most useful in helping you to make treatment decisions?
- What about the available package insert information is least useful?

11. To what degree—very high, high, medium or low— is the currently available prescribing information in package inserts adequate in informing your treatment decisions for women with chronic conditions who are pregnant or nursing?

12. Thank you. Now, I want to focus on how one might evaluate the usefulness of package insert information. What would you be looking for when judging the usefulness of this information for decisions about treatment for pregnant and nursing women with chronic conditions?

- Why?

[Interviewer Note: Do not prompt in too much detail here, unless time is no issue]

13. Now I'd like to offer you some criteria that some may say are important to consider when evaluating information used to inform treatment decisions for chronic conditions in women who are pregnant or nursing. Some of these you may have already mentioned, some of them you haven't raised. We are going to go through these one at a time. I'll first ask you to rate each criterion as being of very high, high, medium or low importance to consider when evaluating the usefulness of the prescribing information in package inserts. I will then ask you to think about current prescription drug package inserts, in general, and rate its quality (high, medium or low) against that criterion.

- First, what about the completeness of the prescribing information? Would you rate that very high, high, medium or low importance?
    - Would you rate the current prescribing information very high, high, medium or low quality in terms of its completeness? *If medium or low:* why?
- What about the timeliness, or how up-to-date the prescribing information is - very high, high, medium or low importance?
    - Would you rate the current prescribing information very high, high, medium or low quality in terms of its timeliness? *If medium or low:* why?
- What about understandability of the prescribing information? Would you rate that very high, high, medium or low importance? Why?
    - Would you rate the current prescribing information very high, high, medium or low quality in terms of its understandability? *If medium or low:* why?
- Next, what about how accessible the format or structure of the information is? Would you rate that very high, high, medium or low importance?
    - Would you rate the current prescribing information very high, high, medium or low quality in terms of its accessibility? *If medium or low:* why?
- What about reducing the need to search for necessary information - very high, high, medium or low importance?

        - Would you rate the current prescribing information very high, high, medium or low quality in terms of reducing the need to search for necessary information? *If medium or low:* why?
    - How about the level of detail regarding human or animal evidence - for example, study design, number of subjects. Would you rate this factor very high, high, medium or low importance?
        - Would you rate the current prescribing information very high, high, medium or low quality in terms of the level of detail regarding human and animal evidence? *If medium or low:* why?
    - How about the clinical relevance of the evidence - very high, high, medium or low importance? Why? What does clinical relevance mean to you?
        - Would you rate the current prescribing information very high, high, medium or low quality in terms of its clinical relevance? *If medium or low:* why?
    - What about the usefulness of guidance on decision making and managing risks - very high, high, medium or low importance?
        - Would you rate the current prescribing information very high, high, medium or low quality in terms of its guidance on decision making? *If medium or low:* why?
    - Are there any others? Would you rate [*name factor*] very high, high, medium or low importance?
        - Would you rate the current prescribing information very high, high, medium or low quality for this factor? *If medium or low:* why?

[*Note to interviewer: if all are rated very high, ask which one is the most important*.]

Part 4: Wrap Up

Thank you. We are almost finished. I have just a few more questions.

14. Are there any topics that you think are important to discuss regarding treating pregnant and nursing women with chronic conditions that we have not yet addressed?

15. And finally, if you could give FDA one piece of advice regarding information in package inserts related to treatment decisions for pregnant and nursing women, what would that advice be?

That concludes our interview. Your comments will be very useful in this research. Your insight also guides our thinking about the type of insight we may expect from physicians like you. If you have any questions or comments in the days to come, please feel free to contact Sarah Thorne at Decision Partners [1-877-588-9106]. You may also direct any questions to Nancy Ostrove, the FDA Project Investigator for this project. She can be reached at (301) 827-9279. Thank you very much for your time today.