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BeSafeRx Cognitive Interview Guide

Color Key: Purple – Section headings and titles Black –Text for interviewer to read Red – Interviewer instructions (not to be read aloud) Green – Research questions (for interviewer's information, not to be read aloud)

Introduction

Hello, my name is **INTERVIEWER NAME**. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is working with the U.S. Food and Drug Administration, or FDA, to see what people think about information related to online pharmacies. The FDA is interested in getting opinions about the information I am about to discuss with you. You should have gotten a package in the mail for this study.

Do you have the package we mailed to you with you right now?

IF YES, CONTINUE IF NO BUT FORM IS NEARBY, ALLOW PARTICIPANT TIME TO GET IT IF NO AND NOT NEARBY, CONTINUE USING ON-SCREEN VERSION OR ASK IF IT'S OKAY TO EMAIL THE DOCUMENT TO R

Please wait to open the packet until I tell you it is time to start. After you look at the material inside, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

Informed Consent

Before we get started, there are a few things I need to tell you. This is a research project, and this interview is voluntary. That means that if you do not want to answer a specific question just tell me and I'll go to the next one. It is okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means that we will not share your name or information. Also, we will not link any information to your answers to figure out who you are. The interview will take about 45 minutes and you will receive a \$50 gift card as a token of appreciation. We would like to record this conversation if you are okay with that. The recording helps us make sure we hear everything you say correctly. Only the people who work on this research project will be able to listen to the recording and see our notes. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

IF FDA STAFF ARE ON THE PHONE: I also want you to know that a couple other people from the FDA who work on this research project are listening to this interview to take notes as we talk.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay with you if I record the interview?

TURN ON RECORDER. The date and time is _____. Now that I am recording, I want to ask again, is it okay if I record this interview?

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Background Questions and Information Review

Before we talk about the information I mailed to you, I have a few questions.

You told us when you volunteered for this interview that you [HAVE or DO NOT HAVE] experience ordering prescription medicine from an online pharmacy.

- IF HAVE, How often do you buy prescription medicine from online pharmacies?
 - o Which online pharmacy or pharmacies have you used? How did you choose which online pharmacy to use?
 - How likely are you to buy a prescription medicine from an online pharmacy again? Please respond on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely. What makes you say {PARTICIPANT'S SCALE NUMBER}?
- IF HAVE NOT, How likely are you to buy a prescription medicine from an online pharmacy? Please respond on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely. What makes you say {PARTICIPANT'S SCALE NUMBER}?
 - o IF AT ALL LIKELY, How would you choose which online pharmacy to use?

What concerns do you have, if any, about using an online pharmacy to buy prescription medicines?

Randomly assign participants to the following conditions to vary the order in which webpages are presented.

Number of Interviews	1st webpage	Followed 2 nd by	Followed 3 rd by
3	Know the signs	Recognize rogue	Know the health risks
2	Know the signs	Know the health risks	Recognize rogue
3	Recognize rogue	Know the signs	Know the health risks
2	Recognize rogue	Know the health risks	Know the signs
3	Know the health risks	Recognize rogue	Know the signs
2	Know the health risks	Know the signs	Recognize rogue

Now please open the envelop we sent you in the mail. Do you see a piece of paper that says "[INSERT 1st WEBPAGE]"? Please take a few minutes to look at it now. Please do not look at the other envelopes in the package just yet. When you are done, I have some questions for you about the information.

CHECK IN AFTER 2 MINUTES. ALLOW 2-3 MORE MINUTES IF NEEDED.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.

NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:

- Any verbal reaction to images or statements in the information.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which images or statements evoked any of these reactions.

RETROSPECTIVE GENERAL PROBES

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW. SHOW WEBPAGES ON SCREEN AS NEEDED TO AID DISCUSSION.

RESEARCH QUESTIONS

Is the BeSafeRx content clear and understandable?

What are the key messages that participants get from the content?

Does the content increase participants' overall understanding of the importance of buying medicines from safe online pharmacies?

Does the content provide participants with useful information about choosing an online pharmacy?

Do participants indicate that any of the content's information is new to them?

Do participants recognize the call to action of checking their online pharmacy?

Thank you for reading the material. Now I'm going to ask you some questions about it. I want you to know that I did not develop this material, so please give me your honest opinion about it—you will not hurt my feelings.

ASK SEPARATELY ABOUT EACH PAGE

First, just tell me your overall thoughts about what you've just read.

What do you like about it?

What don't you like?

How easy or difficult is it to understand this information? Is there anything confusing or unclear?

- [ASK FOR 1ST PAGE ONLY] In your own words, what is a rogue online pharmacy? Can you think of a better term to describe these types of pharmacies?
- [ASK FOR KNOW THE SIGNS ONLY] Again, in your own words, what is a brickand-mortar pharmacy? Can you think of a better phrase to describe these types of pharmacies?

After looking at this page, what new information, if any, have you learned about using online pharmacies?

What do you think of the way the information is set up?

- Is it easy to read?
- Does the order of the information make sense?

Would you say the amount of information on this page is too little, just right, or too much? What makes you say that?

How well does the title of this page describe the information it provides?

Do you have any other suggestions for improving this page?

- Is there anything that is NOT needed or can be removed? IF YES, What?
- Is there anything that could be added? IF YES, What?
- Is there anything that could be stated more clearly? IF YES, What could be stated more clearly?

REPEAT QUESTIONS ABOVE FOR 2ND AND 3RD WEBPAGES

ASK AFTER VIEWING ALL 3 PAGES

In your own words, what is the overall, main message that these pages are trying to tell you?

• What, if anything, is it asking you to do?

- What is the most important message?
- Is the most important information easy to find?
- What order would you prefer to read these pages so that the most important information is in the place where it should be?

Do these pages clearly explain the importance of buying medicines from safe online pharmacies?

- IF YES, Can you tell me what about these pages makes you say it is important?
- IF NO, Can you say more about what wasn't clear?

After reading these pages, do you have any questions about buying prescription medicines online? IF YES, What are they?

IMPACT

Now that you've read these pages, how likely are you to buy a prescription medicine from an online pharmacy? Please respond on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely. What makes you say {PARTICIPANT'S SCALE NUMBER}?

[IF LIKELIHOOD > 1] How likely are you to check your with your state to see if an online pharmacy is licensed? Please respond on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- [ASK IF <5] What could be done to make you more likely to check with your state to see if an online pharmacy is licensed?

If a friend or family member told you they found a new online pharmacy offering low prices on prescription medicines, how likely are you to recommend that this person visit FDA's BeSafeRx webpage to learn about rogue pharmacies? Please respond on a scale of 1 to 5 where 1 is not at all likely and 5 is extremely likely.

• What makes you say {PARTICIPANT'S SCALE NUMBER}?

WRAP-UP

Does the campaign title "BeSafeRx" make sense to you? Why?

Do you have any other suggestions for improving this material?

- Is there any information that is NOT needed or can be removed? IF YES, What information?
- Is there any information that could be added? IF YES, What information?
- Is there anything that could be stated more clearly? IF YES, What could be stated more clearly?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT R SEEMED CONFUSED ABOUT).

Closing

IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.

Those are all the questions I have for you. Is there anything we haven't talked about that you would like to tell me? **DISCUSS ANY RESPONDENT COMMENTS.**

Thank you for your time. **STOP TAPE RECORDER.**