

FDA Principal Investigator: Gwen Zornberg

Date: October 3, 2014

NEW METHODS FOR EVALUATION OF IMPACT OF FDA DRUG SAFETY COMMUNICATIONS

APPENDIX I. Interview script for Patients/Consumers

I. INTRODUCTION/BACKGROUND (5 minutes)

Good morning/afternoon/evening. My name is _____ and I am calling as part of a study being conducted by physicians at Harvard Medical School and Brigham and Women's Hospital. I'm calling about the Drug Safety Information study that you agreed to participate in. If you complete this interview, we will send you or a charity of your choice \$50 in recognition of your time and effort. Is this still a good time for us to talk? [IF NO, ARRANGE A TIME TO CALL BACK.]

As a reminder, this interview is about information you get about prescription drugs. We will be focusing on drugs used to help with sleep. First, let me confirm that you recall receiving at least one prescription for *[depending on patient]* **Ambien (also called zolpidem)/Lunesta (also called eszopiclone)**. Is that right? *If no, thank the potential respondent for his/her time and end the interview. If yes, continue.*

Just to clarify, I am not a medical doctor and am not qualified to offer medical advice, so if any questions come up about your own treatment plans, you should discuss them with your health care provider. If there is a question that you would rather not answer, we can skip it. This interview is being recorded so that our team can faithfully capture your responses.

We are interested in patients' knowledge about the safety of their medications. We hope to use your responses to make information about drug safety as helpful to patients as possible in the future. Let's begin.

II. PRESCRIPTION DRUG SAFETY (10 minutes)

1. First, can you tell me about the sources of information that you use to get drug safety information about the prescription drugs you take? By "drug safety information", we mean information about the side effects of prescription drugs, including how to recognize those side effects or how to avoid side effects with changes in dosing.

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PROMPT: If not mentioned please prompt for each of these four sources: A health care provider, any written material given with the drug, media, friends/family.

- 1a. *(If yes to **provider** follow-up with)* What type of provider – doctor, pharmacist, nurse? And what types of drug safety information does s/he, they tell you about?

- 1b. *(If yes to **any written material** follow-up with)* What material are you referring to specifically? Where did you get this material? ? Can you tell me about the sorts of drug safety information you learn from this material?

- 1c. *(If yes to **media** follow-up with)* Can you tell me what types of media you use to learn about drug safety information? Do you get drug safety information from companies' television or magazine advertisements? Are there specific websites you use? Have you ever worried about the quality of information from the media?

- 1d. *(If yes to **friends/family** follow-up with)* Can you tell me about the sort of drug safety information these people provide?

2. Of the sources you mentioned, which do you use most often and why?

III. PRESCRIPTION SLEEPING PILLS (10 minutes)

Next, I'd like to ask you about prescription medications that you take to help you sleep.

3. In the last two years, can you tell me what, if anything, your health care provider has told you about *(depending on patient)* **Ambien/Lunesta**?

PROMPT, IF NEEDED:

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- i. Did she/he ever give you handouts or other informational materials to read at home?
- ii. Did you discuss the advantages of taking that sleeping pill?
- iii. Do you recall hearing about any side effects or disadvantages?

4. Can you tell me about any useful information you received about the safety of (*depending on patient*) **Ambien/Lunesta** in the last two years that didn't come from your health care provider?

PROMPT, IF NEEDED:

- i. What was the source of the information?
- ii. What made you trust the accuracy of the information?

5. Can you tell me how any of the drug safety information you received from any source affected the way you take (*depending on patient*) **Ambien/Lunesta**? What action did you take/what did you do?

IV. SAFETY INFORMATION AND SLEEPING PILLS (10 minutes)

Now, I'd like to present you with some safety information related to your sleeping pill and get your reaction to it.

For Ambien users only: Ambien can be an effective sleep aid, but also has risks. People might feel drowsy and have trouble staying alert for several hours in the morning after they took it. During that time, patients' safety might be at risk when taking part in activities requiring alertness, like driving or operating heavy machinery. Next-morning drowsiness is most likely with the long-acting forms of Ambien. Women appear to be more prone to drowsiness the next morning after taking Ambien. Because of this, the company was required to lower the recommended dose.

For Lunesta users only: Lunesta can be an effective sleep aid, but also has risks. People might feel drowsy and have trouble staying alert for several hours in the morning after they took it. During

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that time, patients' safety might be at risk when taking part in activities requiring alertness, like driving or operating heavy machinery. Men and women appear to be equally prone to drowsiness the next morning after taking Lunesta. Because of this, the company was required to lower the recommended dose.

6. Did you know about this safety-related information prior to our conversation today? *If NO, skip to 7. IF YES...*

6a. When did you hear about it? From what source? *If not mentioned please PROMPT for whether any of these sources are relevant: A health care provider, the drug label, media, friends/family.*

6b. After you heard this information what, if anything, did you do in response? *SKIP TO END.*

7. Now that you have heard about this information, what might you do in response? Will you go back to your health care provider to discuss it?

8. In the future, how would you like to get updated drug safety information about (*depending on patient*) **Ambien/Lunesta**?

That's all of the questions I have for you. Is there anything I haven't asked about that you would like to discuss? Thank you for your time and your insights. I appreciate your speaking with me.