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Focus Group Consumer Consent Form

Key Information

- Your participation is voluntary.
- You are being asked to be part of a focus group discussion about the process for approving prescription drugs and prescription drug promotions. As part of the discussion, we will ask you to talk about your experiences with prescription drug promotions, and we will ask you to give your opinion about some types of promotions.
- The focus group discussion will take about 90 minutes.
- To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

What is the purpose of this study?

- This study is designed to learn more about consumers' understanding and opinions of the prescription drug approval and drug promotion review process.
- If you take part in the study, you will be one of 60 consumers to do so. You are being invited to participate in this research study because you may have unique insights about how prescription drugs are approved and promoted.

Who is leading the study?

- The person in charge of this study is Sarah Parvanta of RTI International, a nonprofit research institute. This research is being conducted on behalf of the U.S. Food and Drug Administration (FDA).

Do I have to take part in this study?

- It is your choice to participate in this focus group discussion. No one will be upset if you choose not to participate.
- Even if you decide to be part of the study, you can stop participating at any time. You also do not have to answer any questions that you do not want to. You will receive a token of appreciation after you complete the study even if you choose not to answer some questions.

What will I be asked to do?

- We are asking you to participate in a focus group discussion (with about 9-12 people). During the discussion, we will ask you about your understanding and perceptions of the process for approving prescription drugs and reviewing prescription drug promotions.

- The focus group discussion will last about **90 minutes**.
- We will audio record the discussions, and the recordings will be used to create transcripts. Study staff may be viewing the focus groups in person (behind a one-way mirror) or remotely (via live video streaming). Only first names will be used in the focus group.
 - If you do not want to be audio recorded, or you do not consent to having the focus groups be live-streamed to remote staff, you will not be able to participate in the research.

What are the possible risks?

- The risks associated with participating in this focus group are the same as those you would experience talking in a group of people that you do not know.
- We do not expect that any of the topics discussed during the focus group will make you uncomfortable or upset you; however, if they do, you do not have to participate in that part of the discussion.
- RTI will take several steps to keep your participation secure to the extent provided by law. Even with these steps, there is still a small risk that your privacy could be breached.
 - RTI and FDA will not receive any record of your full name or contact information. This means that your personal information (name, address, phone number) will not be linked to any of your responses.
 - All data collected during the focus groups will be kept confidential to the extent provided by law. The study team will not disclose your name or any of your responses.
 - All data collected during the focus group will be stored in a locked file cabinet or on a password-protected computer for a period of three years and will only be accessible by RTI, after which they will be destroyed.

Will I benefit from taking part in this study?

- There are no direct benefits to you for participating in this study. However, we will use the experiences and thoughts you share to inform FDA guidance on promotions for prescription drugs.

Will I receive any payment for taking part in this study?

- You will receive \$100 for taking part in this study.

Who will see the information I give?

- The transcripts will be sent to FDA as part of a final report. When we analyze the results, your information will be separated from the information that identifies you and it will be combined with information from other people taking part in the study.
- We will write two reports about all the focus groups and may use quotes from you, but we will not use your name. You will not be identified in any published or presented materials. Nothing you say will be connected with your name.

Can my data be kept and used for other research studies?

- Your data will not be used for any future research after this study is complete.
- You will not be contacted in the future about this research after your participation in the focus group ends.
- We plan to will keep the audio recordings on a secure online server and destroy them at the end of the study. However, the transcripts will be sent to FDA as part of a final report.

What if I have questions?

- Before you decide whether or not to participate in the study, please ask any questions that come to mind. Later, if you have questions about the study, you can contact the investigator, Sarah Parvanta at 919-541-6045. She can be reached between 9:00 AM and 5:00 PM Eastern Time Monday to Friday.
- The (FDA) Institutional Review Board (IRB) is a group of people who are responsible for ensuring that the rights of participants in research are protected. The FDA IRB is not involved in this study but may review the records of your participation in this research to ensure that proper procedures were followed. If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact FDA IRB at 1-301-796-9605 or RIHSC@fda.hhs.gov or RTI's Office of Research Protection at 1-866-214-2043.

You will be given a copy of this consent form to keep and we will keep a copy with the study records.

Research Participant Statement and Signature

I understand what the study involves, and my questions so far have been answered. I understand that my participation in this research study is voluntary. I agree to take part in this focus group study.

Participant's signature

Date