

Misuse and Abuse of Over-the-Counter Medications

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 [INSERT 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 conducting this study, which is sponsored by the U.S. Food and Drug Administration (or FDA), to see what people think about health information related to medicines.

You should have gotten an email for this study. Do you have the email we sent you available right now?

IF YES, CONTINUE

IF NO BUT EMAIL IS NEARBY, ALLOW PARTICIPANT TIME TO GET IT

IF NO AND NOT NEARBY, ASK IF IT'S OKAY TO RESEND THE EMAIL TO RESPONDENTS. IF PARTICIPANT IS NOT ABLE TO RECEIVE OR SCREENSHARE AND VIEW THE DOCUMENTS RESCHEDULE INTERVIEW.

Please wait to open the email attachment until I tell you it is time to start. After you look at the material inside the attachment, 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. Your participation in this interview is voluntary and you don't have to answer any questions you prefer not to. It is also 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 contact information. The interview will take about 45 minutes and you will receive \$50 as a token of appreciation. We would like to record this conversation to make sure we hear everything you say correctly. Only the research team working on this 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 members of the FDA research team are listening to this interview so they can hear directly from you.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay if I record the interview? **IF NO, TAKE NOTES THAT ARE MORE DETAILED THAN WHEN RELYING ON THE AUDIO RECORDING.**

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?

Background Questions

To start, I have a few questions.

You told us when you volunteered for this interview that you've used [a prescription drug **OR** a medicine purchased over-the-counter without a prescription **OR** both a prescription drug and a medicine purchased over-the-counter without a prescription] just to get high or for fun. Which medicines have you used in this way? **IF SCREENER Q4=YES AND NOT MENTIONED**, Have you ever used Benadryl in this way? Imodium? Nasal decongestant sprays?

- **IF BENADRYL, IMODIUM, OR NASAL DECONGESTANT SPRAYS, ASK QUESTIONS BELOW ABOUT EACH.**
- **IF NONE OF THESE BUT ANOTHER MEDICINE, ASK QUESTIONS ABOUT IT.**
- **IF NONE OF THESE BUT MULTIPLE OTHER MEDICINES**, Which two of these medicines have you used just to get high or for fun most often? **REPEAT QUESTIONS BELOW FOR BOTH MEDICINES.**
 - o How did **[INSERT MEDICINE]** make you feel when you took it? **IF NEEDED, PROBE ON SHORT RESPONSES (E.G., HIGH, GOOD, RELAXED)**, Can you tell me more about that? How would you describe the sensation? How would you compare the feeling to any other substances you have taken to get high or for fun?
 - o How did you first hear about taking **[INSERT MEDICINE]** just to get high or for fun? **IF NEEDED**, Did someone recommend it to you, or did you see it on social media, in the news, on television, or somewhere else?
 - What did you hear about it? **IF NEEDED**, What risks or negative effects did you hear about it?
 - Did you look for any additional information about **[INSERT MEDICINE]** before you started using it?
 - **IF YES**, What additional information were you looking for and why?
 - Where did you look for it?
 - Did you find the information you wanted? **IF YES**, Where?
- **IF MULTIPLE MEDICINES**, Tell me about how you've used **[INSERT MEDICINES MENTIONED]**. **IF NEEDED**:
 - o Did you start with using just one of these medicines first? **IF YES**, Which one and why?
 - o Did you use any of these medicines at the same time?
 - **IF YES**, Which ones and why?
 - **IF NO**, How did you move from one medicine to another and why? Which medicine did you start with and why, and then which medicine did you add to it or use as a replacement or substitute and why?

- o How long did you use each medicine just to get high or for fun?
- Now let's talk about medicines that you haven't used just to get high or for fun yourself, but that you have heard about other people using this way.
 - o What medicines that can be bought over-the-counter without a prescription have you heard others are taking just to get high or for fun? **IF NOT MENTIONED**, Have you heard anything about using allergy medicines this way? About anti-diarrhea medicines? About nasal decongestant sprays?
 - Why are people using them this way? **IF NEEDED**, To feel good, to party, to substitute or help withdraw from another drug, to deal with depression or stress, or some other reason?
 - What risks or negative effects have you heard about them?
 - How did you first hear about people using these over-the-counter medicines this way? **IF NEEDED**, Was it in the news, on television, on social media, or something someone told you?
 - Where else have you read, seen, or heard this information?
 - o What prescription medicines have you heard of others taking just to get high or for fun?
 - Why are people using them this way? **IF NEEDED**, To feel good, to party, to substitute or help with withdrawal from another drug, to deal with depression or stress, or some other reason?
 - What risks or negative effects have you heard about them?
 - How did you first hear about people using these prescription medicines this way? **IF NEEDED**, Was it in the news, on television, on social media, or something someone told you?
 - Where else have you read, seen, or heard this information?
 - o Have you ever been curious about or considered trying any of these medicines just to get high or for fun? **IF YES**, Which ones, and why?
 - Have you ever looked for information about these medicines?
 - **IF YES**, What information were you looking for and why?
 - Where did you look for it?
 - Did you find the information you wanted? If so, where?

Each participant will see two of the three communications. Randomly assign participants to the following conditions to vary the order in which communications are presented. Show the 1st communication and ask questions, and then show the 2nd communication and ask questions.

Number of Interviews	1st communication	Followed 2nd by
1	Benadryl	Imodium
2	Benadryl	Nasadrine
2	Imodium	Benadryl
1	Imodium	Nasadrine
2	Nasadrine	Imodium
1	Nasadrine	Benadryl

BEGIN DISCUSSION OF FIRST COMMUNICATION.

Now please open the attachment labeled [Benadryl/Imodium/Nasadrine] in the email I just sent you. Do you see a document with [Benadryl/Imodium/Nasadrine] in the title? Please take a few minutes to look at it now. When you finish, I will ask you some questions about the information.

CHECK IN AFTER 2 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.

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

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

RETROSPECTIVE GENERAL PROBES

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.

RESEARCH QUESTIONS

What have participants read, seen or heard about non-medical/recreational use (misuse/abuse) of OTC medications?

From what source(s) have participants read, seen, or heard this information?

Have participants ever sought out information, considered using, or used any OTC or prescription medications for non-medical/recreational use? If so, which ones and why?

What are participants' initial overarching thoughts about FDA's communications about the misuse/abuse of Benadryl? Imodium? Nasal decongestants?

Why do participants think FDA is communicating about each of these products/issues?

Do participants indicate that any of the FDA information is new to them?

What is the main message that participants get from each communication?

How do each of these communications make participants feel (e.g., concerned about using these products generally, even with indicated use/dosages; unconcerned because they wouldn't misuse/abuse these products; curious and/or encouraged about non-medical use) and why?

How likely do participants feel these FDA communications would encourage recreational use and why?

What was it in the communications that caused participants to be curious or encouraged?

What would participants think or do after reading each of these communications, and why?

What information is missing or would be helpful to add to address the potential to encourage non-medical use? Why would this information be helpful?

Is there anything else participants suggest FDA think about when communicating about these kinds of safety issues?

ASK SEPARATELY ABOUT BOTH COMMUNICATIONS

What are your initial thoughts about what you've just read?

- Is this a product that you have ever used?

In your own words, what is the overall, main message that this communication is trying to tell you?

- Why do you think FDA is telling you this information?

After looking at this communication, what new information have you learned about [Benadryl OR Imodium OR Nasadrine]?

- **IF VIEWING BENDARYL**, Had you heard of the “Benadryl Challenge” or people using Benadryl this way before reading this? What had you heard? **IF NEEDED**, What risks or negative effects had you heard about?
- **IF VIEWING IMODIUM**, Had you heard of people taking Imodium to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria before reading this? What had you heard? **IF NEEDED**, What risks or negative effects had you heard about?
- **IF VIEWING NASADRINE**, Had you heard of people taking high doses of Nasadrine before reading this? What had you heard? **IF NEEDED**, What risks or negative effects had you heard about?

How does this message make you feel? **ALLOW TIME TO RESPOND TO THIS OPEN-ENDED QUESTION BEFORE PROBING.**

- Does anything you've read in this communication make you feel concerned or alarmed?
 - o **IF YES**: What was it about this communication that caused you to be concerned?
 - Are you concerned for yourself or someone else using this medicine? Why?
 - How does this communication make you feel about using [Benadryl OR Imodium OR Nasadrine] as directed and why? **IF NEEDED**, Are you generally concerned about using this medicine even with the indicated use and dosage on the label? Why?
 - How does this communication make you feel about using other medicines for [allergies OR diarrhea OR nasal congestion]? Why?
 - o **IF NO**: Why doesn't this information concern you? **IF NEEDED**, Are you unconcerned because you don't use this product or products like it, because you wouldn't misuse this product, because you don't have children or others in the home that would misuse it, or some other reason?
- Will you think any differently about [Benadryl OR Imodium OR Nasadrine] as a result of reading this information? **IF NEEDED**, For example, that caution is needed when using this medicine, or some other thoughts? Why, or why not?

- What will you do as a result of reading this information? **IF NEEDED**, For example, will you share the information with family or friends, or something else? Why, or why not?
- Does anything you've read in this communication make you feel curious or encouraged to try using this medicine this way?
 - o **IF YES**: What was it about this communication that caused you to be curious or encouraged?
- How likely do you think it is that this communication would encourage others to use this medicine this way? Why is that?
- What information is missing or would be helpful to add to discourage using this medicine this way? Why would this information be helpful?

What additional questions do you have about [Benadryl OR Imodium OR Nasadrine] after reading this information?

Do you have any other suggestions for improving this communication?

- Is there any information that is NOT needed or can be removed? **IF YES**, What information and why do you think it is unnecessary?
- Is there any information that could be stated more clearly? **IF YES**, What could be stated more clearly?
 - o **IF VIEWING IMODIUM**, The communication states that some individuals have taken Imodium to achieve a feeling of euphoria. What does “euphoria” mean to you? How could this be stated more clearly?
 - o **IF VIEWING NASADRINE**, The communication states that taking high doses of Nasadrine can lead to serious mental health problems. What does “mental health problems” mean to you? How could this be stated more clearly?

Now please open the attachment labeled [Benadryl/Imodium/Nasadrine] in the email I sent. Do you see a document with [Benadryl/Imodium/Nasadrine] in the title? Please take a few minutes to look at it now. When you finish, I will ask you some questions about the information. **[ASK QUESTIONS ABOUT 2ND COMMUNICATION, BEGINNING AT THE TOP OF PAGE 7]**

WRAP-UP

Next I'd like to ask you what a few different phrases mean to you.

- The first phrase is “using medicine for recreational purposes.” What does this mean to you?
- What does the phrase “using medicine for non-medical purposes” mean to you?
- During this interview, I used the phrase “just to get high or for fun” several times.

- o Does using medicine “for recreational purposes” mean the same thing to you as “just to get high or for fun?” **IF NO**, How is it different?
 - o Does the phrase “for non-medical purposes” mean the same thing to you as “just to get high or for fun?” **IF NO**, How is it different?
- Would you use any of these phrases to describe what you’ve read in these communications about the ways that some people are using these medicines, or would you describe this behavior in some other way? **IF NEEDED**, What words would you use?

Now that you’ve read both communications, how do you feel about FDA communicating about the harms associated with medicines that are being used just to get high or for fun? Is there anything else you would suggest FDA think about when communicating about these kinds of safety issues?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT RESPONDENT 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 else you would like the FDA to know about these communications or people taking medicines just to get high or for fun?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.
STOP TAPE RECORDER.