

FDA Opioid Study

Online Focus Group with Consumers: General Population

Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications

Overview: [This section for moderator only and will not be shared with participants]

1. Welcome & Ground Rules (5 minutes)

The moderator will welcome the participants and explain the purpose of the focus group. The moderator will go over the ground rules.

2. Consent Form (5 minutes)

Verify participants received and returned a signed copy of the consent form. Review highlights, address their questions, and confirm their continued consent.

3. Discussion (75 minutes)

- Knowledge about Opioids
- Attitudes and Behaviors Related to Opioids
- Sources of Information
- Role of FDA
- Concept Testing

4. Closing (5 minutes): Thank you and incentives.

I. Welcome and Ground Rules

INTERVIEWER: Welcome, and thank you for participating in today's discussion. My name is _____ from RTI International. RTI is a non-profit research institute that works with various agencies of the federal government. The Food and Drug Administration has contracted with RTI to conduct focus groups as part of a research study about prescription pain medications.

My role is to guide our discussion and to encourage everyone to share their thoughts and experiences on the topics we will discuss. Please keep in mind that there are no right or wrong views or answers. Everyone's opinion is important, so we encourage you to speak up regardless of whether you agree with what others have said or if you want to add your perspective to theirs. In fact, if you have a different idea or feeling, we especially want to hear from you so we can better understand the different perspectives that people have.

Before we begin, I would like to review a few items:

Did everyone receive and return a signed copy of the consent form for today's group? Does anyone have any questions/concerns? Just a few highlights...

- o **Participation.** Your participation is voluntary and you can stop participating at any time. If at any time you are uncomfortable with any question, you can choose not to answer.
- o **Honest Opinions.** Most importantly, there are no right or wrong answers today. We'd like to hear everyone's opinions.
- o **Privacy.** Your name and contact information, which the RTI project team knows, will not be given to anyone else and no one will contact you after this session is over. We ask that participants not share anything that is discussed today with anyone outside of the group, and if you are speaking about someone else, that you do not share their name or other identifying information.
- o **Speaking.** Please try to **speak one at a time**. I may occasionally interrupt if two or more people are talking and to give everyone a chance to talk. Please only use your first name when speaking to protect your privacy.
- o **Recording.** To make sure that we capture everything people say today, we will be audio and video recording today's group and someone will be taking notes while we talk. This recording will also be transcribed. We will provide the FDA with the transcription and recording of our discussion. However, your name or any identifying information about you will not be included nor associated with the project or the report in any way.
- o **Reporting.** As part of this study, we will write a report for the FDA summarizing what we learned from these interviews. The report will not identify individuals or what a specific person said by name.
- o **Cell Phones.** As a courtesy, please silence or turn off your cell phones and other electronics, and be sure you are in a quiet place where you won't be interrupted.

Do you have any questions before we begin?

[Confirm consent to continue]

II. Introduction

The topic of today's group is opioid pain medications. Some of you may have taken them yourself, know of a family member or friend who has been prescribed opioids, and some of you may not have had any experience with opioids, which is fine too. We're interested in everyone's thoughts.

I'd like to start by asking everyone to introduce yourself with your first name only or a nickname that you'd like to use for the group and tell us what general part of the country you are from.

III. Discussion

Knowledge about Opioids

1. What words come to your mind when you hear the term opioids?

What kinds of drugs do you think about when you hear the term "prescription pain medicines" or "prescription pain relievers"? Have you heard the term "opioids" used to refer to any of these drugs (which ones)? What about the term "narcotics"?

- o **Probe:** What other words have you heard people use to refer to prescription pain medicines/relievers? Opioids?
- o **Probe:** What types of problems have you heard people being treated for with prescription pain medicines or opioids?
- o **Probe:** What are the benefits of taking a prescription pain medicine or opioid?
- o **Probe:** What are the side effects or risks of taking a prescription pain medicine or opioid?

MODERATOR: Read definition of "opioids"

Opioids are strong prescription medicines that can be used to relieve pain when it is unlikely that other pain medications such as acetaminophen (Tylenol) or ibuprofen (Motrin or Advil) will be able to control a person's pain. For example, after some surgeries. Examples of opioid medications include hydrocodone (Vicodin or Zohydro ER), oxycodone (OxyContin and Percocet), morphine, fentanyl and codeine.

For the rest of today's discussion I will use the term "opioids" to talk about these medications.

Attitudes and Behaviors Related to Opioids

2. Now I would like each of you to talk in general about any time you may have taken opioids.

Have you ever used an opioid and can you remember the name of it? When did you last use opioids and for how long? Why are/were you taking them?

Now I'd like to talk about any family members or friends that either currently use opioids or have used opioids in the past.

[ASK WHETHER PARTICIPANTS HAVE A FAMILY MEMBER OR FRIEND WHO HAS USED OPIOIDS. IF YES, CONTINUE WITH FOLLOW-UP QUESTIONS]. Can you remember the names of the opioid(s) they are taking or have taken in the past? How long have they/or did they take opioids? Do you know why they are or were taking them (what was the reason)?

OK, now I want to ask those of you who have been prescribed an opioid by a healthcare provider about your experience.

3. Can you walk me through the conversation you had with your health care provider when you were prescribed the opioid?
- What were you told about how well the opioid would work for your pain?
 - What were you told about any downsides or risks of taking the opioid?
 - Moderator should wait to hear how participants respond. When any of the following terms are mentioned, the follow-up questions should be: What does [that term] mean to you? Any term that is not spontaneously raised by participants will be asked about as part of Q6.
 - o Misuse
 - o Abuse
 - o Addiction
 - o Tolerance
 - o Dependence
 - o Withdrawal
 - o Overdose
 - What written information about the opioid did your provider give you? How did you use this information?
 - What questions did you ask your provider?

- o **Probe:** How did you decide whether to take the opioid?
 - o What information did you get verbally from the pharmacy when the opioid prescription(s) were filled? **Probe:** What questions did you ask the pharmacist?
 - o **Probe:** Can you describe any written information the pharmacy gave you about the opioid? How did you use this information?
 - o Did you look for any other information about the opioid, and if so, what and where?
 - o What additional information would you have liked to have known **before** starting the opioid for the first time? Who should have provided this information to you?
4. Besides what you've been told or received from a health care provider or pharmacist, where else have you seen or heard information related to opioids (if needed—probe, on television, radio, in newspapers/magazines, websites or on social media?)
- o **Probe:** Can you describe the information? Was any of the information that you saw new to you (if yes, what was new information)? What was confusing or hard to understand?

5. What have you heard or read about related to an 'opioid epidemic' in the United States? [MODERATOR NOTE: if some of the terms from Q3 above come up spontaneously here that weren't asked about previously in Q3, ask the follow-up question: What does [that term] mean to you?]

What is your understanding of why this is happening?

Probe: What do you think could be done about this, and by whom?

- **Probe:** What are some ways we can make sure patients in significant pain don't lose access to treatment and are treated effectively?

6. How has the information that you've read or heard about opioids affected the way you view taking them?

Next I'd like to ask you about some terms that are sometimes used when people talk about opioids. MODERATOR: Ask participants what they know about any of the following terms that they did not raise above either as part of harms in Q3 or Q5

- What does the term "misuse" mean to you?
- What does the term Abuse mean to you?

- What does the term Addiction mean to you?
 - What does the term Tolerance mean to you?
 - What does the term Dependence mean to you?
 - What does the term Withdrawal mean to you?
 - What does the term Overdose mean to you?
- **Probe:** Why do you think some people misuse opioids? Abuse opioids? Become addicted to opioids?
 - **Probe:** What are some factors that might make someone more likely to misuse opioids? To abuse opioids? To become addicted to opioids?
 - **Probe:** Do you know anyone who has become addicted to opioids? If so, can you talk about their experience? What problems did they experience as a result of becoming addicted to opioids?
 - **Probe:** What do you think can be done to help prevent people from misusing opioids? From abusing opioids? From becoming addicted to them? [Specific actions that can be taken] By whom? [Ask about health care providers if not mentioned].
 - How do you feel about people who misuse opioids? Abuse opioids? Are addicted to opioids?

General Questions

- What do you know about abuse deterrent opioids?
- What do you know about certain opioids called extended-release and long acting (ER/LA) opioids? (e.g. OxyContin, fentanyl, and morphine)
- What do you know about medicines that can help reverse an overdose of opioids? (e.g. Narcan, Evzio, and naloxone) What have you seen, read or heard about them? Where? What personal experience do you have with these medicines?
- What do you know about **medications** to help treat those who are addicted to opioids? (e.g. methadone, buprenorphine, and naltrexone)

Role of the FDA

Next we're going to talk about the U.S. Food and Drug Administration. FDA is the government agency that protects the public health by conducting an independent review of new medicines to make sure they work and are safe before they are approved and can be prescribed by health care providers and used by patients.

What do you think the FDA's role is in addressing problems related to opioids? How do you think they're doing in meeting that responsibility?

- o **Probe:** How do you think the FDA could protect patients from the harmful effects of opioids?

7. What information do you want to know about opioids from the FDA?

Concept testing

Now I'm going to show you some information about opioids from the FDA. Please read the sentences on the screen while I read them out loud and then we will discuss them.

Concept #1

We recognize how serious the problem of opioid misuse is. We also understand the need for patients living with chronic pain to have access to these medicines.

8. What is your reaction to this piece of information?

- o **Probe:** What do you like about it and why? What don't you like and why?

9. Is there any information/language that is confusing or hard to understand? Are there any terms that need to be defined? How could it be explained better, or what better words could FDA use?

10. What questions do you have after reading this?

Next I'll show you another piece of information from FDA:

Concept #2

We are taking several steps to address these issues. These include consulting with outside experts such as the National Academy of Medicine, better addressing the risk of abuse in labels and other information, encouraging development of opioids that have less chance of being misused, and considering ways to make medicines that can reverse opioid overdoses more widely available.

11. What is your reaction to this second piece of information?

- o **Probe:** What do you like about it and why? What don't you like and why?

12. Is there any information/language that is confusing or hard to understand? Are there any terms that need to be defined? How could it be explained better, or what better words could FDA use?

13. What questions do you have after reading this?

Now I'm going to show you one more piece of information from FDA:

Concept #3

To combat this epidemic, we need help from the public, health care professionals, other federal agencies, Congress and others.

14. What is your reaction to this information?

- o **Probe:** What do you like about it and why? What don't you like and why?

15. Is there any information/language that is confusing or hard to understand? Are there any terms that need to be defined? How could it be explained better, or what better words could FDA use?

16. What questions do you have after reading this?

MODERATOR NOTE: Add the bulleted list to screen only if there is discussion of how people can help.

The final piece of information that I'm going to show you is a second part of the last piece that we looked at (will show a screen that has the bullets below added)

People can help by::

- **Knowing the dangers of opioid abuse and talking to others about them.**
- **Recognizing that misuse of opioids is illicit drug use.**
- **Locking up all medicines safely and disposing of them properly.**
- **Knowing where to go to get help.**

17. What is your reaction to this information?

- o **Probe:** What do you like about it and why? What don't you like and why?

18. Is there any information/language that is confusing or hard to understand? Are there any terms that need to be defined? How could it be explained better, or what better words could FDA use?

19. What questions do you have after reading this?

Now after seeing all of this information,

20. What additional questions do you have? What other information do you think should be included? What information is included that doesn't need to be?

21. What would you do as a result of reading/hearing this information, if anything? Why/why not?

22. How does this information make you feel about the FDA? What else do you think they could they be doing?

23. After all of our discussions today, have your views about opioids changed, and if so, why?

Conclusion

These are all of my questions. Does anyone have any final questions or thoughts before we wrap up? I want to thank everyone for participating. [REVIEW INCENTIVE INFORMATION AND SHOW SCREEN WITH FDA INFORMATION]

If you would like more information or have any questions here are the web address for the FDA website, their phone number and email address, and a web address for a web page on opioid medications.

<http://www.fda.gov/Drugs>

(855) 543-3784

druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm>

Finally, if you'd like more information about substance use you can contact SAMHSA's National Helpline at 1-800-662-HELP (4357).