

FDA Opioid Study

Online Focus Group with Consumers: Opioid Users

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

Overview [This information is for moderator 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 noted below, address participant questions, and confirm 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. To further protect your privacy we are using audio only for this group so you will not be able to see anyone else and they won't be able to see you.
- 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 recording today's group and someone will be taking notes while we talk. This audio 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 the 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. You've all been selected for this group because you indicated that you are currently taking an opioid to treat non-cancer pain daily or on most days and have been for the **past three (or more) months**? Is that correct for everyone?

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 kinds of drugs do you think about when you hear the term "prescription pain medicines" or "prescription pain relievers"? Which prescription pain relievers have you heard referred to as "opioids"? What about the term "narcotics"? What other words come to your mind when you hear the term opioids?
 - o **Probe:** What other words have you heard people use to refer to prescription pain medicines/relievers? Opioids?
 - o **Probe:** What else do you know about opioids specifically?

MODERATOR: Read definition of "opioids"

For the purposes of our discussion today, opioids are strong prescription medicines that can be used to relieve pain when other therapies or pain medications such as acetaminophen (Tylenol) or ibuprofen (Motrin or Advil) have not successfully controlled a person's pain. 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 we're going to talk more about people's thoughts about opioids.
 - o **Probe:** When do you think taking an opioid is a good idea?

- o **Probe:** What are some of the risks you see of taking opioids?

3. Next I want to talk about personal experiences that you have had with opioids.

What are the names of the opioids you are currently taking or took in the past? How long have you been taking/took these opioids? For which conditions or problems are/were you using opioids? Did you try non-opioid medications before starting the opioids? If yes, what were they? What other treatments or therapies (e.g. mediation, massage, biofeedback, etc.) did your provider prescribe or recommend and when during your treatment for pain?

4. 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 the pain? Beyond, relieving your pain, what was your long-term goal in taking an opioid, e.g. did you want to be able to start playing a sport again or go back to working a certain job? What discussion did you have with your health care provider about taking opioids, including how your health care provider would assess if the opioid was working? What were the outcomes related to your goal(s) (e.g. were they able to achieve them?). If so, what happened with respect to the opioids? If not, what happened?
- What were you told about any downsides or risks of taking opioids?
 - *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 subsequently.*
 - Misuse
 - Abuse
 - Addiction
 - Tolerance
 - Dependence
 - Withdrawal
 - Overdose

Moderator note: Any term that is not spontaneously raised by participants above should be specifically asked about using the same the same question: What does the term opioid [term] mean to you?

- What written information about the opioid did your provider give you? How did you use this information?
 - What kinds of conditions or requirements did your provider require before prescribing the opioids (e.g. contracts, drug tests, other requirements?)
 - **Probe:** How did you decide whether to take the opioid? Can you walk me through your decision process? Was there information you wished you would have received from the prescriber before making the decision to take an opioid, and if so, what and how do you think having that information would have affected your decision? Did you ever wish you would never have taken the opioid? If so, why?
5. What information have you gotten verbally from the pharmacy when the opioid prescription(s) were filled and how often have you received this information?
- **Probe:** What questions did you ask the pharmacist? What additional information would you have liked to know **before** starting the opioid for the first time? Who should have provided this information to you?
 - **Probe:** Can you describe any written information the pharmacy gave you about the opioid? If so, please describe the information you were given. How did you use this information?
6. Next I'd like to talk about more non-traditional uses of opioids. What are some factors that might make someone more likely to misuse or abuse opioids? To become addicted to opioids?
- **Probe:** What do you think health care providers are doing now to decrease the risks of their patients misusing or abusing opioids when they are prescribed? To decrease the risks of becoming addicted to opioids?
 - **Probe:** What other things do you think health care providers should do to decrease the risk of someone misusing or abusing opioids when prescribed? To decrease the risk of addiction?
 - **Probe:** What did **your** healthcare provider do to decrease the risk of misuse, abuse, or addiction when they prescribed opioids to you? How effective do you think that was? What other things do you think your prescriber should have done?
 - **Probe:** What things do you think others (e.g. Congress, state or federal governments, law enforcement, etc.) could/should do to decrease the risk of misuse, abuse, and addiction to opioids?
7. Have you ever used an opioid differently than how it was prescribed (e.g. take it more often, decrease your dose, double up on doses, or take it through a different route than prescribed,)? If so, how did you use it differently, why, and how frequently did this occur?

- o **Probe:** Did you talk with the health care provider who prescribed the opioid about taking it differently than it was prescribed and if so, what was the discussion? Did you talk to any health care provider about changing how you took the opioid and if so, what was the discussion?
 - o **Probe:** What do you know about the risks of taking an opioid differently from how it was prescribed (If not raised by participants, ask about increased risk of addiction and overdose)? How do you know this information (from health care provider, family/friends, etc.)?
 - FOR THOSE WHO SAID THEY HAVE TAKEN DIFFERENTLY THAN HOW PRESCRIBED: Did you know this information before you took the opioid differently than how it was prescribed? How did knowing that information affect your decision??
 - o **Probe:** Did changing how you took the opioid result in any injury or harm to you? If so, what happened? What was/were the outcome(s)?
 - **If not mentioned ask about:**
 - Overdose
 - o **Probe:** What do you think could have helped prevent you from using the opioid differently than it was prescribed? [Specific actions that could be taken] By whom?
 - o **Probe:** What information would have helped to prevent this?
8. Have you ever become addicted to opioids? If so, can you talk about your experience?
- o **Probe:** What problems did you experience as a result of becoming addicted to opioids?
 - If not mentioned, ask about withdrawal from opioids
 - o **Probe:** Was your prescriber aware and if so, what did they do?
 - o **Probe:** What was the result of your addiction?
 - **If not mentioned ask about:** problems at school or work, problems with family and/or friends, financial problems, etc.
 - o **Probe:** Have you ever received treatment for your addiction? If yes, what kind (medical detox, inpatient, outpatient, medication assisted therapy)? If not, why not?
 - o **Probe:** What do you think could have been done to help prevent you from becoming addicted? [Specific actions that could be taken] By whom?
 - o **Probe:** What information would have helped to prevent this?
9. How have your **experiences** with using opioids affected the way you view them?

Sources of Information and Message Communication

10. Besides what you've been told or received from your health care provider or pharmacist, where 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 content of 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?
11. What kind of information did you look for about the opioid(s) you were prescribed beyond what was provided by your prescriber or pharmacist? Where did you look for this information (ask about specific searches and websites)? Why did you want this information?
12. Thinking about the information that you've seen or heard about opioids, what did it say about the potential harms of taking opioids?
- o **Probe:** How useful was the way this information was conveyed? How can information on the potential harms of opioids be communicated better?
13. What have you read or heard about related to an 'opioid epidemic' in the United States? What is your understanding of why this is happening? What do you think could be done about this, and by whom?
- **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?
14. How has the **information that you've seen or heard** about opioids affected the way you view taking opioids?

General Questions

- What do you know about abuse-deterrent opioids? [After asking, provide definition: What personal experience do you have with these medicines?
- What do you know about 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) Can you talk about any 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)
- What personal experience do you have with these medications?

- What are your thoughts about stigma or shame associated with taking opioids? What personal experience do you have with this? How did it affect you? Can you talk about any specific people that you were concerned about knowing you were taking an opioid (we don't need to know their names)? What were your concerns?

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 better protect patients from the harmful effects of opioids?

15. 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.

MODERATOR TO READ EACH CONCEPT ALOUD BEFORE DISCUSSION

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.

16. 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?

17. 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?

18. 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 medicine 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.

19. 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?

20. 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?

21. 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.

22. What is your reaction to this information?

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

23. 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?

24. What questions do you have after reading this?

MODERATOR NOTE: If participants ask how people can help, then ask about the below bullets.

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.**

25. What is your reaction to this information?

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

26. 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?

27. What questions do you have after reading this?

Now after seeing all of this information,

28. 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?

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

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

31. 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).