February 11, 2019

ATTACHMENT C
Focus Group Moderator Guide
Health Care Providers' Understanding of Opioid Analgesic Abuse-Deterrent Formulations:
Focus Groups

I. Introduction

Welcome and thank you for participating in tonight's discussion. My name is _________________ and I work for RTI International, a non-profit research organization. You have been asked to participate in this discussion because you are a [healthcare provider/pharmacist] who [prescribes/dispenses] opioids medications for patients [For physicians, PAs, and NPS only: with non-cancer pain]. The Food and Drug Administration wants to understand healthcare professionals' perspectives about prescription opioid analgesics and has contracted with the research firm RTI to conduct this series of focus groups.

We're interested in hearing from you all today about your experiences and opinions. I'm not a medical professional or an expert on the topics we will discuss. My role is only to moderate today's focus group and ensure that everyone has the chance to express their ideas and opinions.

Before we begin, I want to go over a few ground rules for our discussion, which will last 90 minutes. Your participation is voluntary, and you have the right to withdraw at any time without penalty.

- If at any time you are uncomfortable with the questions, you can choose not to answer.
- If you are unclear about what I am asking, please do not hesitate to ask me to repeat the question or provide clarification.
- Everything we discuss today will be kept confidential and secure to the extent allowable by law. Use only your first name or a nickname in the group. Only the recruiters have your full name and contact information. It will not be given to anyone at RTI or to anyone at FDA, and no one will contact you after this discussion is over.
- Our discussion will be audio and video recorded. The audio recording will be transcribed and will help me write a final report summarizing the feedback from the focus groups being conducted. The recordings and transcripts will be stored on password-protected computers at RTI and FDA for five years after the conclusion of this research project. No names or identifying information will be included in the transcripts or mentioned in the final report created from these focus group discussions.
- Please try to speak one at a time]. I may occasionally interrupt when two or more people are talking in order to be sure everyone gets a chance to talk and that responses are accurately recorded.
- There are no right or wrong answers and we are not looking for consensus. We want to hear all of your opinions, so don't hold back on giving me your honest thoughts.
- Please silence your cell phones, PDAs, and pagers and minimize any distractions for the next 90 minutes.
- I am not selling anything and do not work for a company that sells any products. Some members of the research team from RTI and FDA are observing the discussion [remotely/from behind the one-way mirror].

- Do you have any questions before we begin?

[NOTE: MODERATOR WILL CHOOSE DISPENSE VS. PRESCRIBE THROUGHOUT BASED ON SEGMENT]

II. Warm Up

Let's go around and introduce ourselves. Please tell me your first name, what type of practice you work for, and how long you've been practicing.

1. [PRESCRIBERS] I'd like to start by asking you which opioid analgesics you prescribe and the conditions for which you prescribe them? How has your prescribing changed over the last couple of years?

   [PHARMACISTS] I'd like to start by asking you what trends you've noticed regarding the opioid analgesics you dispense? How has that changed over the last couple of years?

III. Terminology and Understanding

MODERATOR: Next, I'd like to get your feedback on some terminology that's used to describe prescription opioids and their characteristics.

2. Thinking about prescription opioids, what does "misuse" mean to you?
3. What does "abuse" mean to you in the context of prescription opioids?
4. What does "addiction" mean to you in the context of prescription opioids?
5. What are the differences between misuse and abuse?
6. What are the differences between abuse and addiction?

7. What is your understanding of how abuse is defined in the drug labeling for prescription opioids? [IF NEEDED: drug labeling is the official prescribing information.]

MODERATOR show PRESCRIPTION DRUG ABUSE definition on whiteboard: "*The intentional, non-therapeutic use of a prescription drug, even once, for its rewarding psychological or physiological effects.*"

8. Looking at this definition, how does it compare to your previous understanding of the term? [IF NEEDED: How is it different/the same? What about related to the inclusion of "even once"?] What changes would make it clearer?

9. What is your understanding of how "addiction" is defined in the drug labeling for prescription opioids?

MODERATOR show DRUG ADDICTION definition on whiteboard: "*Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and includes: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal.*"

10. Looking at this definition of “addiction”, how does it compare to your previous understanding of the term? [IF NEEDED: How is it different/the same?] What changes would make it clearer?
11. Describe the experiences you have had with a patient(s) misusing or abusing opioid analgesics prescribed for them. How did you respond to those issues?
12. Describe the experiences you have had with patients becoming addicted to opioid analgesics prescribed for them. How did you respond to that?
13. How would you describe the difference between “risk of abuse” and “risk of addiction” to a colleague? [MODERATOR LIST ON WHITEBOARD]
14. How would you describe the difference between “risk of abuse” and “risk of addiction” to a patient? [MODERATOR LIST]
15. What does the term “abuse deterrent” or “abuse deterrence” mean to you in the context of prescription opioids?
16. What does the term “abuse deterrent formulation” mean to you?
17. How would you describe abuse deterrent formulation opioid analgesics to a colleague who may not know what they are? How would you describe them to a patient for whom you were [prescribing/dispensing] them? [MODERATOR LIST]
    a. Are you aware that the labels for opioid ADF formulations include a definition of “abuse”?
18. The terms “abuse deterrence” and “abuse-deterrent formulation” have been used to describe some opioid-containing products. What do you think about the term “abuse deterrent formulation” or ADF?
    a. How well do you think the ADF term describes these opioids?
    b. Is there anything about the ADF term that you think might cause misunderstanding about these opioids? What specifically might cause that confusion and why?
19. What other terms have you heard used to describe these opioids?
    a. How does the ADF term compare with the other terms you’ve heard for these opioids?
20. What other terms do you think would better describe these opioids? Why do you think that term would better describe these opioids? Why would that term be better understood by providers? Why would that term be better understood by patients?
21. What terminology or language would help make it clear that that ADFs only attempt to reduce abuse through certain routes, for example, by making them more difficult to be crushed for snorting or IV injection? [MODERATOR LIST]
22. What terminology or language would help make it clear that that ADF opioids are still addictive? [MODERATOR LIST]
23. What terminology or language would make it clear that these opioids cannot prevent abuse by the most common oral route? [MODERATOR LIST]”?

MODERATOR: I'd like to show you a description of abuse deterrent formulation opioids developed by FDA.

[MODERATOR SHOW/PASS OUT COPIES OF DESCRIPTION]

The FDA encourages the development of prescription opioids with abuse-deterrent formulations (ADFs) to help combat the opioid crisis. The agency recognizes that abuse-deterrent opioids are not abuse- or addiction-proof but are a step toward products that may help reduce abuse. The FDA fully supports efforts to better understand the impact of these products in the real-world setting. The FDA also supports the development of innovative formulations that have the potential to make abuse of these products more difficult or less rewarding. This does not mean a product is impossible to abuse or that abuse-deterrent properties necessarily prevent addiction, overdose, and death. Notably, currently marketed technologies do not effectively deter one of the most common forms of opioid abuse -- swallowing the tablet or capsule. Because opioid medications must in the end be able to deliver the opioid to the patient, there may always be some potential for addiction and abuse of these products.

Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject, for the specific opioid drug substance. The science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are evolving. The FDA is working with drug makers to support advancements in this area and helping drug makers navigate the regulatory path to market as quickly as possible. In working with industry, the FDA is taking a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products.

24. What is your first reaction to this information?
25. What is unclear or confusing about this information?
26. What other information would be useful for providers? For patients? What would you like to see added?
27. Is there information from the definitions you were shown earlier (for abuse, addiction and misuse) that should be included in this information? If so what and why?

28. What issues can abuse-deterrent forms (ADFs) of opioid analgesics address? Why? What can they NOT help address? Why?
    a. [IF NEEDED] How do ADF opioid analgesics address the risk of abuse? What makes you say that?
    b. [IF NEEDED] How do ADF opioids address the risk of misuse? What makes you say that?
    c. [IF NEEDED] How do ADF opioid analgesics help address the risk of addiction? What makes you say that?
    d. [IF NEEDED] How do ADF opioid analgesics resist patient manipulation or tampering? What makes you say that?

29. How do ADFs affect patients?
    a. [IF NEEDED] How do they affect you and your practice?
    b. [IF NEEDED] How do they affect society more broadly?

IV. Experience with ADFs

MODERATOR: Next, I'd like to discuss your experience with [prescribing/dispensing] opioid analgesics more generally.

30. Which ones do you [prescribe/dispense] and for what purposes?
    a. Do you check information in a PDMP (prescription drug monitoring program) before [prescribing/dispensing] opioids? In what circumstances do you do this? When do you not do this?
31. What [assessment or screening/counseling] do you conduct before you [prescribe/dispense] opioids? Walk me through what you do and why.
32. If you have any concerns raised during [assessment or screening/counseling], or after consulting the PDMP, what do you do?

33. I'd like to talk specifically about your experiences [prescribing/dispensing] abuse-deterrent opioid analgesics. Examples of abuse-deterrent opioid analgesics include OxyContin, Hysingla ER, MorphaBond ER, Xtampza ER, Arymo ER, and RoxyBond.
    a. Which ones do you [prescribe/dispense]?
    b. How often do you [prescribe/dispense] them?
    c. [FOR PRESCRIBERS] Why do you prescribe them?
    d. [FOR PRESCRIBERS] Walk me through how you decide to prescribe ADF medication instead of non-ADF medication.
    e. [FOR PRESCRIBERS] What types of patients do you prescribe them for and why? What benefits do they provide to those patients? What are their down sides?
    f. What concerns do you have about [prescribing/dispensing] ADF opioid analgesics? What issues have you experienced when prescribing ADFs [IF NEEDED: For example, patient anger, high cost, lack of coverage by insurance]
    g. From what sources did you learn about ADF opioid analgesics? How, if at all, have you used the official prescribing information in the drug labeling or package inserts?

34. How do you talk with your patients about ADF opioid analgesics?
    a. Walk me through that conversation. What do you say? What do they say? What questions do they ask about ADFs?
    b. How are these discussions initiated (e.g., by you, by the patient, others)?
    c. What discussions do you have with patients' family members about ADF opioid analgesics? What questions do they ask about ADFs and how do they differ from the questions patients ask?
    d. What kinds of discussions do you have about ADF opioid analgesics with colleagues? PRESCIBERS: With pharmacists?

35. [FOR PHARMACISTS] What kinds of discussions do you have with prescribers about ADF opioid analgesics?
    a. How do you communicate with prescribers about ADF opioid analgesics? How do you educate them about the properties of ADF opioid analgesics? Walk me through that conversation.

V. Barriers and Facilitators to using ADFs

36. What do you think are the most common perceptions or attitudes that other prescribers have about ADF opioid analgesics? What about the patients you talk with/prescribe them to?

37. What misperceptions do you think prescribers have about ADF opioid analgesics? How would you suggest overcoming these misperceptions?

38. What important information do providers tend not to know about ADF opioid analgesics?

39. What misperceptions do you think patients have about ADF opioid analgesics? How would you suggest overcoming these misperceptions?

40. [FOR PRESCRIBERS] What would help encourage providers to prescribe an ADF opioid analgesic?

41. What issues can abuse-deterrent forms (ADFs) of opioid analgesics address? Why? What can they NOT help address? Why?
    a. [IF NEEDED] How do ADF opioid analgesics address the risk of abuse? What makes you say that?
    b. [IF NEEDED] How do ADF opioids address the risk of misuse? What makes you say that?
    c. [IF NEEDED] How do ADF opioid analgesics help address the risk of addiction? What makes you say that?
    d. [IF NEEDED] How do ADF opioid analgesics resist patient manipulation or tampering? What makes you say that?

42. How do ADFs affect patients?
    a. [IF NEEDED] How do they affect you and your practice?
    b. [IF NEEDED] How do they affect society more broadly?

VI. Provider Training and Education

43. Not including any training you may have received in [medical/pharmacy school] or residency or equivalent training, what training, education, or resources have you received related to ADF opioids? [FOR THOSE WHO SAY NONE, follow up on what they got in school/residency]
    a. Please share what was helpful and useful and what wasn't.
    b. Who sponsored or developed the training/education?

44. What kinds of resources should be used to educate providers like yourself about ADF opioid analgesics (e.g., fact sheets, brochures, web resources, consultation services, etc.)?
    a. What would make this resource helpful?
    b. Which types of providers would find this most helpful? Why?
    c. From what sources would you like to receive these resources?

45. What trainings should be used to educate providers about ADF opioid analgesics?
    a. What would make this training helpful?

b. Which types of providers would find this most helpful? Why?
c. [IF NOT MENTIONED] Tell me more about the format, channels, and sponsors.

46. Not including any training you may have had in [medical/pharmacy school] or residency or equivalent training, what training, education, or resources have you received related to opioids generally? [FOR THOSE WHO SAY NONE, follow up on what they got in school/residency]
    a. What topics were covered?
    b. Please share what was helpful and useful and what wasn't.

I'd like to check with the observers from the research team to see if they have any last questions or clarifications. [MODERATOR CHECKS WITH OBSERVERS]

Those are all of my questions. Is there anything else that you would like to add about the topics we discussed today? Is there anything else you would like FDA to know about abuse-deterrent formulation opioids?