

Appendix H

**Generic Drug Devices Focus Group
Moderator Guide****Introduction and Ground Rules**

MODERATOR: 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 be part of tonight's discussion because you said that [you/your family member] use a [autoinjector/dry powder inhaler] prescription drug-device combination product. The Food and Drug Administration (FDA) is interested in hearing your opinions and experiences about the combination product that [you use/your family member] uses.

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 tonight, which will last about 90 minutes. Your participation is voluntary, and you have the right to not answer any question or withdraw from the study at any time.

- If at any time you are uncomfortable with my 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 secure to the extent permitted 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-recorded. The recordings will be transcribed and will help me write the final report summarizing the feedback from the various focus groups being conducted. The recordings and transcripts will be stored on password-protected computers at RTI and FDA. No names or identifying information will be included in the transcripts or mentioned in the final report created from these focus group discussions.
- Behind me is a one-way mirror. Behind that are some of my colleagues. We are also video streaming for colleagues who could not travel to be here. They're watching to make sure that I ask you all the questions I have for you. Near the end of our conversation, I'm going to go into the back and see if they have any last-minute questions for you.
- 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.
- **[FOR ADOLESCENTS]** None of the answers you give will be shared with your parent or guardian. I would like us to keep what's said here in the group private, so please don't talk to anyone outside of this group about what we've discussed.

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- Most importantly, there are no right or wrong answers. I want to know your opinions. I do not work for the people sponsoring this research, I'm not trying to sell anything, and I didn't write the questions we're going to look at, so don't hold back on giving me your honest opinions.
- Please silence your cell phones.
- Do you have any questions before we begin?

I. Warm Up.

First, I'd like to go around the room and introduce ourselves. When we get to you, please let us know your first name or your nick name and one thing you'd be doing if you weren't here tonight.

II. Experience with Current Drug Device

1. How long did it take before you were comfortable using [your/your family member's] [AI/DPI]? What were the hardest parts to learn?
 - **PROBE:** Which parts of using the [AI/DPI] did training most help you learn?
2. What do you wish someone had told you about the [AI/DPI] before using it for the first time?
3. If you hadn't gotten training on the [AI/DPI], where would you have looked for information?
4. What else would you have wanted to know?

III. Thoughts on generic drugs

You're all here tonight because you reported that [you use/you are a caregiver for someone who uses] some sort of an [\[Auto-injector \(AI\)/Dry Powder Inhaler \(DPI\)\]](#).

First, I'd like to hear your thoughts about generic drugs. We'll talk about it in a minute, but first, I'd like to start with an exercise to get us thinking about what these products are. I'd like you to look at the first question on page 1 of your workbook and take a few minutes to write down your thoughts.

[MODERATOR READ FIRST QUESTION]: What does "generic drug" mean to you?

[MODERATOR GIVE PARTICIPANTS TIME TO RESPOND IN THEIR WORKBOOKS]

5. Who would like to share what they wrote in their workbook?

[MODERATOR WRITE ANSWERS ON FLIP CHART]

Let's talk briefly about your responses.

[MODERATOR NOTE SIMILARITIES/DIFFERENCES ACROSS RESPONSES]

6. Why did these words come to mind?

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- PROBE: What experiences made you think about these words/phrases?
- PROBE: What have you seen or heard about generic drugs?
- PROBE: Now that you've seen other comments, are there any other words or phrases that you would add?

IV. Affinity Mapping

Next, we're going to move to a brief group activity.

To start, we're going to write a word on these white boards, and I'd like you to use the post it notes in front of you and take a few minutes to write down the first thoughts (words or phrases) that come to mind when you see or hear this word. Write one idea per sticky note. Any questions?

[LEAD MODERATOR PASS OUT POST-IT NOTES; USE WHITEBOARD TO CREATE AN AFFINITY MAP FOR EACH OF 2 GROUPS.]

[MODERATOR: WRITE WORDS APPROPRIATE FOR SPECIFIC SEGMENT: "Epi-Pen," "Auto-injector," "Inhaler," "Advair Diskus"]

[MODERATORS: GIVE PARTICIPANTS TIME TO RESPOND ON STICKY NOTES]

Now we're going to divide our group into two smaller groups for the next part of our activity.

[MODERATORS DIVIDE THE ROOM IN HALF].

[MODERATOR TAKE STICKY NOTES THE PARTICIPANTS HAVE WRITTEN ON AND PLACE EACH GROUP'S NOTES ALL OVER THE TWO WHITE BOARDS IN NO SPECIFIC ORDER]

Now I'd like to have each group work together *silently* to try to organize which ideas go together. As long as you do not talk, feel free to move any sticky note to any place. Move yours, move those of others, and feel free to move an idea that has been moved by someone else. Don't be offended if someone moves yours to a place that you don't think it belongs, just move it to where you think it belongs—but do this activity in silence.

[MODERATOR: ENCOURAGE GROUPS TO GET UP AND WALK AROUND. ONCE BOTH GROUPS HAVE SETTLED ON CATEGORIES, HAVE THEM PLACE POST IT NOTES ON CHART PAPER IN NEAT COLUMNS.]

Now that you have organized your thoughts, take a few minutes to talk about the categories you've created, and work together to come up with a name for each one.

[MODERATOR: GIVE GROUPS TIME TO WORK TO NAME GROUPS, AND THEN RECONVENE]

Now, let's look at both groups' sets of categories.

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7. What themes emerged? Were there any surprises?

- PROBE: What similarities do you see between the two groups? What differences are there?
- PROBE: What characteristics or other qualities helped you organize your notes?
- PROBE: Now that you've seen other comments, what other thoughts about [KEY WORD] might you add?

8. If I asked you to think about ideas surrounding *generic combination products* (specifically) would any of your categories change?

- PROBE: What ideas, if any, would you want to add to the board?

9. What do you think would be different if your AI/DPI was replaced by a generic version?

- PROBE: size, shape, color, auto or pushbutton injector, ease of use, number of steps to use
- PROBE: efficacy of medicine, performance of device, consistency of dose
- PROBE: handling, training

[REPEAT FOR ANY OTHER KEYWORDS]

V. Journey Mapping

For this next exercise, you're going to use page 2 of the worksheet in front of you and your imagination. You'll see that there are 3 boxes. I'm going to give you a scenario, and I'd like you to fill in the boxes with the steps that you'd take, the questions you might have, the emotions you might be feeling during that task, etc. [MODERATOR ensures that participants understand exercise] Any questions?

[MODERATOR: GO THROUGH STEPS WITH PARTICIPANTS, PROBING ON THOUGHTS, FEELINGS, AND BEHAVIORS (A-E BELOW), IF THEY AREN'T NATURALLY RAISED]

- Feelings: Anxiety, fear
- Trust: In healthcare providers, efficacy of medicine, performance of device, consistency of dose
- Confused: not sure how to use the drug device
- Self-efficacy
- Willingness to use generic device
- Actions to be taken: Contact healthcare provider, talk with pharmacist, ask for training

[STARTING POINT]

Ok, the first step says that it's time to get a refill on [your/your family member's] [AI/DPI]. Assume that you have a refill left, so you don't have to go to the doctor. Go ahead and fill out the boxes in the worksheet but stop after you complete the boxes under the first step.

[MODERATOR ALLOW TIME FOR PARTICIPANTS TO FILL IN]

10. What are you feeling when you get a refill for your prescription?

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OMB Control #0910-0695 Expires 02/28/2021

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11. What questions do you have?

- PROBE: What concerns do you have?

12. What actions do you need to take? How do you take action?

- PROBE: How difficult or easy are these tasks?

[SECOND POINT]

Take a look at the second column on your worksheet. At the second point, you get your [AI/DPI] from the pharmacy and, instead of the brand name, you get a generic version. I have examples of the generic version of the [AI/DPI] for you all to hold and look at while you are doing the exercise.

[MODERATOR HANDS OUT BRANDED AND GENERIC combination products. INFORM PARTICIPANTS THAT combination products ARE REAL, BUT THAT THEY **CANNOT** BE DISCHARGED. THE AUTOINJECTOR IS A TRAINER DEVICE. IT HAS **NO** NEEDLE AND **NO** MEDICINE. THE DRY POWDER INHALER DOES **NOT** CONTAIN MEDICINE]

[WHEN MODERATOR HANDS OUT THE DEVICE, GIVE THE PARTICIPANTS THE BOX WITH THE INSTRUCTIONS FOR USE (IFU).]

As you think about this step in the scenario, and review the devices, fill out the boxes for that step (column) in the process. Remember to stop after you complete the boxes under this step.

[MODERATOR ALLOW TIME FOR PARTICIPANTS TO FILL IN]

13. What is the first thing that comes to your mind if your [AI/DPI] was replaced with this generic device? [IF NEEDED] How would you feel if your [AI/DPI] was switched to a generic version?

- PROBE: trust, fear, anxiety, relief (cost), confusion
- PROBE: What might influence those feelings? (e.g., discussions with providers, research)

14. What questions would you have about a generic [AI/DPI]?

- PROBE: Who would you ask for an answer?
- PROBE: How difficult or easy would those questions be to get answered?
- PROBE: What concerns would you have?

15. What else did you write down for this step?

[THIRD POINT]

Ok, now you are going to use the generic [AI/DPI] device for the first time. Go ahead and fill out the column on the worksheet for this last step.

16. What information would you need to use the device?

- PROBE: How would you get the information you need?

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17. What would you expect to happen while using the device?

- PROBE: How do those expectations compare with what you'd expect with your regular device?

18. What feelings would you have while using the device?

- PROBE: How might these feelings be different than your experience with your regular device?

19. What else did you write for this step?

Now, looking across the map as a whole...

20. At what point in the journey would you have the most questions?

- PROBE: How would these questions make you feel?
- PROBE: How would you get answers to these questions

21. What are some of the challenges that would arise if your [AI/DPI] was replaced with a generic device?

- PROBE: What would be the hardest parts about switching to a generic device?
- PROBE: What might help to address these challenges?

22. What feelings arise at different points along the journey?

- PROBE: What positive emotions would you have? What negative emotions would you have?
- PROBE: How would you manage those feelings?
- PROBE: How might your feelings change as you progress?

VI. General Discussion of Generic Drug Devices

[MODERATOR CONFIRMS THAT PARTICIPANTS CAN REVIEW BRANDED AND GENERIC DEVICES]

23. Now that you've seen the branded and generic device, what are your initial thoughts on how the generic device is similar or different from the branded AI/DPI?

- PROBE: size, shape, color, auto or pushbutton injector, ease of use, number of steps to use
- PROBE: efficacy of medicine, performance of device, consistency of dose
- PROBE: handling, training

24. What kind of training, if any, would you want before you used the generic [AI/DPI]?

- PROBE: How would you get this training? [user-initiated or healthcare provider-initiated]?
- PROBE: What if you couldn't get any training? How would you feel?

[FALSE CLOSE] I'm going to step into the back and check with my colleagues to see if I forgot anything or if they have any last-minute questions before we finish up.

Closing

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I would like to thank you for coming here today and participating in this discussion. This research was sponsored by the Food and Drug Administration also known as the FDA. FDA would like to thank you for sharing your opinions as they will be very useful in helping them to understand people's reactions and thoughts about the devices we have talked about.