

Appendix C

Multiple Indications Study Questionnaire

DHHS research authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a) (4)). Confidentiality protected by 5 U.S.C. 552(a) and (b) and 21 CFR part 20.

OMB Control #xxxxx Expires xxxxx

[Insert audio check question]

[Participants will be required to pass the audio check—indicating they are able to play videos and hear audio on their device/computer before proceeding]

[PROGRAMMER: Question piping is in green font]

[PROGRAMMER: SCREEN 1]

ADVERTISEMENT INSTRUCTIONS

On the next screen, you will see a television advertisement for a new product. The ad may take 15-30 seconds to start playing.

Make sure you are comfortable and can read the screen from where you sit. Do your best to remember details about the ad.

Once you finish viewing the ad, please click the Continue button.

[DISPLAY ASSIGNED AD] [SUPPRESS "CONTINUE" BUTTON UNTIL AD FINISHES PLAYING]

[PROGRAMMER: NEXT SCREEN]

We would like you to watch the ad a second time. Please click the Continue button to view the ad again.

[DISPLAY ASSIGNED AD AGAIN] [SUPPRESS "CONTINUE" BUTTON UNTIL AD FINISHES PLAYING]

[PROGRAMMER: NEXT SCREEN]

Q1. Were you able to see and hear the ad from start to finish both times?

Yes

No [Terminate]

Not sure [Terminate]

[PROGRAMMER: For remaining questions, if respondent does not provide response, prompt with, "Are you sure you don't want to provide a response?" before allowing to continue.]

Now, please answer the following questions based on the ad you saw.

[PROGRAMMER: NEXT SCREEN]

[BENEFIT RECALL]

Q2. What are the benefits of [DRUG X/DRUG Y]? Please list as many benefits as you can remember.

[Open Field]

[Study 1 codes: diabetic neuropathy/diabetes pain, nerve pain, burning pain/sensation, pins and needles, shooting pain, widespread pain, overactive nerves, chronic pain, fibromyalgia, anxiety; other codes to be determined based on cognitive interviews and pretesting]

[Study 2 codes: rheumatoid arthritis/RA, psoriatic arthritis, osteoarthritis, arthritis, joint pain, ulcerative colitis, pain and swelling, helps stop progression of joint damage, clearer skin, stomach/bowel/abdominal pain/problems, diarrhea; other codes to be determined based on cognitive interviews and pretesting]

[PROGRAMMER: NEXT SCREEN]**[INDICATION RECOGNITION]**

Q3. Please read each statement below. Based on the information in the ad you saw, select whether you think the statement is true, false, or you don't know.

[PROGRAMMER: SHOW FOR STUDY 1]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

[DRUG X] is for adults with...	True	False	Don't Know
a. Diabetes-related nerve pain			
b. Fibromyalgia			
c. Generalized anxiety disorder			
d. Type 1 diabetes			
e. Chronic pain			
f. Depression			
g. Asthma			
h. High cholesterol			

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

[DRUG Y] is for adults with...	True	False	Don't Know
a. Rheumatoid arthritis			
b. Psoriatic arthritis			

c. Ulcerative colitis			
d. Osteoarthritis			
e. Joint pain			
f. Lymphoma			
g. Acne			
h. High cholesterol			

[PROGRAMMER: NEXT SCREEN]

[GENERAL INDICATION COMPREHENSION]

Based strictly on the information presented in the ad you saw, please answer the following questions.

[PROGRAMMER: Keep the sentence above on the screen for Q4-Q12]

Q4. In addition to treating [diabetes-related nerve pain/rheumatoid arthritis], [DRUG X/DRUG Y] can treat other health conditions.

- True
- False
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q5. [DRUG X/DRUG Y] can treat any type of [chronic pain/joint pain].

- True
- False
- Don't know

[PROGRAMMER: NEXT SCREEN: NEW SCREEN FOR EACH QUESTION Q6D-Q9D]

[PROGRAMMER: SHOW FOR STUDY 1]

[PROGRAMMER: RANDOMIZE Q6D-Q9D]

[INDICATION OVERGENERALIZATION]

Q6D. Ryan has chronic back pain and needs a prescription drug to manage his symptoms. Is he a good candidate for [DRUG X]?

- Yes
- No
- Don't know

[FIRST INDICATION COMPREHENSION]

Q7D. Mark has pain in his feet. His doctor says the pain is caused by nerve damage related to his diabetes. Is he a good candidate for [DRUG X]?

- Yes
- No
- Don't know

[SECOND INDICATION COMPREHENSION]

Q8D. Michelle experiences widespread pain and fatigue. Her doctor recently told her she has fibromyalgia. Is she a good candidate for [DRUG X]?

- Yes
- No
- Don't know

Q9D. Kate is experiencing persistent worry and anxiety. Her doctor diagnosed her with generalized anxiety disorder. Is she a good candidate for [DRUG X]?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN NEW SCREEN FOR EACH QUESTION Q6RA-Q9RA]

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: RANDOMIZE Q6RA-Q9RA]

[INDICATION OVERGENERALIZATION]

Q6RA. Ryan is experiencing joint pain. His doctor told him the pain is caused by torn cartilage. Is he a good candidate for [DRUG Y]?

- Yes
- No
- Don't know

[FIRST INDICATION COMPREHENSION]

Q7RA. Mark is experiencing joint redness and swelling. His doctor says this is caused by his rheumatoid arthritis. Is he a good candidate for [DRUG Y]?

- Yes
- No
- Don't know

[SECOND INDICATION COMPREHENSION]

Q8RA. Michelle experiences swollen fingers and toes. Her doctor recently told her she has psoriatic arthritis. Is she a good candidate for [DRUG Y]?

- Yes
- No
- Don't know

Q9RA. Kate was recently diagnosed with ulcerative colitis. She experiences abdominal pain and diarrhea. Is she a good candidate for [DRUG Y]?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

[MISCONCEPTION ABOUT INDICATION INFORMATION]

[PROGRAMMER: SHOW FOR STUDY 1]

[PROGRAMMER: Notes for Q10D.

Study 1:

- Main indication condition: randomize the combination of indications shown to respondents: diabetes-related nerve pain and fibromyalgia OR diabetes-related nerve pain and generalized anxiety disorder,
- Main indication + similar indication condition show diabetes-related nerve pain and fibromyalgia,
- Main indication + dissimilar indication condition show diabetes-related nerve pain and generalized anxiety disorder.

Q10D. Only people who suffer from both [diabetes-related nerve pain AND fibromyalgia/diabetes-related nerve pain AND generalized anxiety disorder] should take [DRUG X/DRUG Y].

- True
- False
- Don't know

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: Notes for Q10RA. Study 2

- Main indication condition: randomize the combination of indications shown to respondents: rheumatoid arthritis and psoriatic arthritis OR rheumatoid arthritis and ulcerative colitis,
- Main indication + similar indication condition show rheumatoid arthritis and psoriatic arthritis,
- Main indication + dissimilar indication condition show rheumatoid arthritis and ulcerative colitis.]

Q10RA. Only people who suffer from both [rheumatoid arthritis AND psoriatic arthritis/ rheumatoid arthritis AND ulcerative colitis] should take [DRUG X/DRUG Y].

- True
- False
- Don't know

[PROGRAMMER: NEXT SCREEN]

[PERCEIVED RISK OF OTHER CONDITIONS]

[PROGRAMMER: SHOW FOR STUDY 1]

[PROGRAMMER: RANDOMIZE ORDER Q11D-Q12D]

Q11D. People with diabetes-related nerve pain are at greater risk for developing fibromyalgia.

- True
- False
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q12D. People with diabetes-related nerve pain are at greater risk for developing generalized anxiety disorder.

- True
- False
- Don't know

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: RANDOMIZE ORDER OF Q11RA-Q12RA]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMSQ11RA-Q12RA]

Q11RA. People with rheumatoid arthritis are at greater risk for developing psoriatic arthritis.

- True
- False
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q12RA. People with rheumatoid arthritis are at greater risk for developing ulcerative colitis.

- True
- False
- Don't know

[PROGRAMMER: NEXT SCREEN]

[RISK RECALL]

Q13. What are the risks or side effects of taking [DRUG X/DRUG Y]? Please list as many side effects as you can remember being mentioned in the ad.

[Open Field]

[Study 1 codes: serious allergic reactions, swelling of lips/tongue/throat, suicidal thoughts/actions, new/worsening depression, changes to mood/behavior, trouble breathing, rash/hives, muscle pain with fever, tired feeling/fatigue/sleepy, blurry vision/vision problems, life-threatening drug interaction; other codes to be determined based on cognitive interviews and pretesting]

[Study 2 codes: serious sometimes fatal infections, death, tears in stomach, tears in intestine, nervous system problems, serious allergic reactions, swelling of lips/tongue/throat, lower ability to fight infections; other codes to be determined based on cognitive interviews and pretesting]

[PROGRAMMER: NEXT SCREEN]

[RISK RECOGNITION]

Q14. Please check which of the following were mentioned in the ad as risks or side effects of taking [DRUG X/DRUG Y]. Even if you think a statement is true, please select it only if it was mentioned in the ad.

2. Rarely
3. Sometimes
4. Often
5. Always

[PROGRAMMER: NEXT SCREEN]

[PAST EXPERIENCE WITH DISEASE TREATMENT]

[PROGRAMMER: SHOW FOR STUDY 1]

Q29D. How familiar are you with prescription drugs for...

	1					6
	Very					Very
	unfamiliar	2	3	4	5	familiar
[randomize order of items]						
diabetes-related						
nerve pain						
fibromyalgia						
generalized						
anxiety disorder						

[PROGRAMMER: SHOW FOR STUDY 2]

Q29RA. How familiar are you with treatments for...

	1					6
	Very					Very
	unfamiliar	2	3	4	5	familiar
[randomize order of items]						
rheumatoid						
arthritis						
psoriatic						
arthritis						
ulcerative colitis						

[PROGRAMMER: NEXT SCREEN]

[PROGRAMMER: SHOW Q30D-Q32D FOR STUDY 1]

Q30D. Have you ever experienced diabetes-related nerve pain?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q31D. Have you ever been diagnosed with diabetes-related nerve pain?

- Yes
- No [PROGRAMMER NOTE: GO TO Q32D]
- Don't know [PROGRAMMER NOTE: GO TO Q32D]

[PROGRAMMER: NEXT SCREEN]

Q32D. Have you ever taken a prescription drug for diabetes-related nerve pain?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

[PROGRAMMER: SHOW FOR STUDY 2]

Q32RA. Have you ever taken a prescription drug for rheumatoid arthritis?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q33. Have you ever heard of [DRUG X/DRUG Y] before today?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

[PRETEST FOLLOW-UP]

Q34. Please share any additional thoughts you had about the ad or this survey.

[Open Field]

[PROGRAMMER: NEXT SCREEN]

[DEBRIEF]

[DRUG X/DRUG Y] is not a real product and is not available for sale. The purpose of this study is to learn about reactions to prescription drug information. To get a real-life reaction, we used a pretend product in this study. Please see your health care provider for questions about [diabetes-related nerve-pain/rheumatoid arthritis].

You have been very helpful. Thank you very much for your participation!