

Draft Interview Protocol.

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Study 1

Docket Number 2005N-0016

Questions will be administered by professional interviewers; all items will be read aloud to the participant. Answers to open-ended questions to be audio recorded.

Section I. Interview.

Thank you for agreeing to participate in this study today.

(Present and explain Informed Consent Form).

Today we will show you a print ad for a new prescription medication. Read it as you normally would if you saw an advertisement for a new medicine in a magazine. Take as much time as you want to look over this material. Tell me when you are finished.

[Interviewer: Record reading times for each page: page 1 of ad (front) and page 2 (brief summary)]

[Participant views designated advertisement]

[After participant has completed reading the ad]

1a. What condition does this product treat?

Terminate if answer other than (insert list of acceptable descriptors)

2a. Which of the following best describes how MUCH you read of the first page of the ad?

- I read all of it
- I read most of it
- I read some of it
- I read very little of it
- I read none of it

2b. Which of the following best describes how THOROUGHLY you read the first page of the ad?

- I read it all pretty thoroughly

- I looked for certain key points
- I just skimmed it
- I didn't read any of it

2c. Which of the following best describes how MUCH of the second page of the ad you read?

- I read all of it
- I read most of it
- I read some of it
- I read very little of it
- I read none of it

2d. Which of the following best describes how THOROUGHLY you read the second page of the ad?

- I read it all pretty thoroughly
- I looked for certain key points
- I just skimmed it
- I didn't read any of it

3a. What were you thinking about as you read this advertisement?

(tape record answers; pre-code categories to be determined)

3b. Did you have any specific questions in mind as you read this advertisement?

- Yes (if YES) What were they?

(record verbatim)

3c. Did you have any other specific questions in mind as you read this advertisement?

(continue probing until NE)

- No (if NO)

[PROBE to clarify _____]

[Terminate if 3b = no AND probe indicates that the subject did not think about ad.]

4a.i. I am going to read a series of phrases that might describe what a person might have in mind as they read this advertisement. For each one, tell me whether you Strongly Agree, Agree, Disagree, Strongly Disagree that the phrase describes you as you read the advertisement.

As I read the advertisement, I was ...

(Randomize i through x)

(Items to be tailored to Caregiver or Diagnosed)

- i. Trying to understand what Oncor does
- ii. Trying to understand who should take Oncor

- iii. Comparing Oncor to other brands of (*insert condition*) medicines
- iv. Comparing Oncor with non prescription, over-the-counter medicines
- v. Comparing Oncor with herbal and dietary supplements

- vi. Thinking about whether Oncor might be appropriate for me
- vii. Thinking about whether Oncor might be appropriate for a friend or relative

- viii. Thinking about whether to talk with my doctor about Oncor
- ix. Thinking about questions I might ask my doctor

- x. Thinking about looking for more information about Oncor
- xi. Thinking about how I could get more information about the product

- xii. Thinking about the company that makes Oncor
- xiii. Thinking about what is research might be about
- xiv. Thinking about the room I'm sitting in

[Ask ONLY IF participant did not “agree” or “strongly agree” to any items in Q4a]

4a.ii. How would you describe your thinking as you read the advertisement?

RECORD VERBATIM _____

[Skip IF Disagree or Strongly Disagree to all items in Q4a.i]

4b. Now, look back at this list (Q4a.i) and tell me which ONE is the single best description of you as you were reading the ad?

5a. Now, please think about the different pieces of information presented in pages one and two of this ad. Tell me which, if any, of the various pieces of information you would describe as being “most useful” to you. You may choose as few or as many pieces as you want.

[Use this pen to circle the parts of the ad that were most useful (or use the computer touch screen)

[If participant circles an entire page: “Within this page, what parts would you describe as most useful?”]

5b. Now, looking just at the second page, which, if any, pieces of information would you describe as the most useful parts of this page?"

5b.i. Which five parts are the most useful to you?

5b.ii. After these five parts, what part is the next most useful to you?

[Designate with "6"]

[Repeat "next most useful" probe sequence to determine "7" – "10"]

5c.i. Tell me what, if any, **topics** are missing from this second page of the ad that would be useful to you.

RECORD VERBATIM _____

Probe: Anything else?

5c.ii. Tell me what, if any, **details** are missing from this second page of the ad that would be useful to you.

RECORD VERBATIM _____

Probe: Anything else?

6. I am going to read a series of statements. For each of these statements, tell me whether you strongly agree, agree, disagree, strongly disagree, or have no opinion.

[Randomize order of "first" and "second" page.]

For this part, think just about the (first /second) page of this advertisement,

[Randomize a and b]

- a. This page helps me understand the risks associated with this product.
- b. This page helps me understand the benefits associated with this product.

[c is always third]

- c. This page helps me understand the tradeoff between the risks and benefits of using this drug.

[Randomize d – h, and m or s]

- d. This page helps me decide whether to talk to a doctor about this drug

- e. The information on this page is credible.
- f. The information on this page is not trustworthy.
- g. The information on this page is believable.
- h. The information on this page makes me want to look for more information about this product.

(items to be asked only for page 1)

- m. The information on this page makes me want to read the information on page 2.

(items to be asked only for page 2)

- s. This page helps me answer questions I had about information presented on the first page.

(items to be asked after all the above)

[Randomize x-z]

- x. This type of drug is relevant to me personally.
- y. This type of drug is relevant to someone close to me.
- z. This ad makes me want to try this drug.

[Randomize 7a 7b]

7. a. Based on this ad, how favorable or unfavorable is your impression of Oncor ? Would you say it is: [READ ALL]

- 5 Very favorable,
- 4 Moderately favorable,
- 3 Neither favorable nor unfavorable,
- 2 Moderately unfavorable, or
- 1 Very unfavorable?

b. Based on this ad, how positive or negative is your impression of Oncor? Would you say it is: [READ ALL]

- 5 Very positive,
- 4 Moderately positive,
- 3 Neither positive nor negative,
- 2 Moderately negative, or
- 1 Very negative?

[Randomize 7c 7d]

c. Compared to other prescription medicines for (... *insert condition* ...), how positive or negative is your impression of Oncor? Would you say your impression of Oncor is: [READ ALL]

- 5 Much more positive than other prescription medicines,
- 4 Somewhat more positive than other prescription medicines,
- 3 About the same as other prescription medicines,
- 2 Somewhat more negative than other prescription medicines, or
- 1 Much more negative than other prescription medicines?

d. Compared to other prescription medications for (... *insert condition* ...), would you say Oncor is: [READ ALL]

- 5 A much better product,
- 4 A little better product,
- 3 About the same,
- 2 A little worse product, or
- 1 A much worse product?

[Ask for caregiver]

e.i. If you had a friend, relative or family member who was suffering from (... *insert condition* ...), how likely would you be to recommend that they ask their doctor about Oncor? Would you: [READ ALL]

- 5 *Definitely recommend* that they ask their doctor,
- 4 *Probably recommend* that they ask their doctor,
- 3 *Maybe or maybe not recommend*,
- 2 *Probably not recommend*, or
- 1 *Definitely not recommend* that they ask their doctor

[Ask for diagnosed]

e.ii. How likely are you to ask your doctor about Oncor? Are you: [READ ALL]

- 6 *Definitely* ask my doctor,
- 5 *Probably* ask my doctor,
- 4 *Maybe or maybe not* ask my doctor
- 3 *Probably not*, ask my doctor, or
- 2 *Definitely not* ask my doctor

[Rotate 7f 7g 7h]

f. Based on this ad, how risky overall would you say it is to use Oncor? Would you say it is: [READ ALL]

- 5 Very risky to use,
- 4 Moderately risky to use,
- 3 Risky,
- 2 Only slightly risky, or
- 1 Not risky at all?

g. Based on this ad, how dangerous overall would you say it is to use Oncor? Would you say it is: [READ ALL]

- 5 Very dangerous to use,
- 4 Moderately dangerous to use,
- 3 Dangerous,
- 2 Only slightly dangerous, or
- 1 Not dangerous at all?

h. Based on this ad, how safe overall would you say it is to use Oncor? Would you say it is: [READ ALL]

- 5 Very safe to use,
- 4 Moderately safe to use ,
- 3 Safe,
- 2 Only slightly safe, or
- 1 Not safe at all?

[Take back advertisement]

8a. Tell me whether this EXACT phrase appeared in the advertisement for Oncor.

Did the phrase [read item] appear in the ad? [remind if necessary, “exact” phrase]

- | | | | |
|-----------------------------------|-------|------|------------|
| i. Oncor may cause lung damage | 1 Yes | 2 No | 3 Not sure |
| ii. Oncor may cause swelling | 1 Yes | 2 No | 3 Not sure |
| iii. Oncor may cause heart damage | 1 Yes | 2 No | 3 Not sure |
| iv. Oncor may cause dry mouth | 1 Yes | 2 No | 3 Not sure |
| v. Oncor may cause liver damage | 1 Yes | 2 No | 3 Not sure |

[Rotate 8b and 8c]

8b. Think about this warning and tell me how risky you think it is, [... *insert appropriate risk level warning (Oncor may cause dry mouth / Oncor may cause heart damage)*]. Would you say it is: [READ ALL]

- 5 Very risky,
- 4 Moderately risky,
- 3 Risky,
- 2 Only slightly risky, or
- 1 Not risky at all?

8c. Think about this warning and tell me how serious you think it is, [... *insert appropriate risk level warning (Oncor may cause dry mouth / Oncor may cause heart damage)*]. Would you say it is: [READ ALL]

- 5 Very serious,
- 4 Moderately serious,
- 3 Serious,
- 2 Only slightly serious, or
- 1 Not serious at all?

9. Has an advertisement for a prescription drug ever caused you to look for more information, for example, about the drug or about your health? [INTERVIEWER: If asked, “we mean broadcast or print ads.”]

- | | |
|-------------|------------|
| Yes | 1 |
| No | 2 |
| DO NOT READ | Don't Know |
| DO NOT READ | Refused |

Section II. Background demographics and health characteristics (to be gathered during recruitment or during interview)

I'd like to ask just a few more questions for classification purposes. Remember, we are not keeping any record of your identity, so this information, as well as the rest of your answers, is anonymous.

[Ask Q10 ONLY if Caregiver]

[Prescreen information will provide gender of the person receiving care-giving. Use to preset the appropriate gender pronoun for this sequence (“he” or “she”).]

10a. Do you provide care-giving help to a person who has been diagnosed with (*insert condition*)?

- Yes
- No

If “No”, PROBE: _____ (Ask how participant was recruited / screened)

10b. What is your relationship with the person you help?

- _ I am the parent
- _ I am the spouse
- _ I am the son/daughter
- _ I am a relative
- _ I am a friend

10c. Tell me which, if any, of the following care-giving activities do you regularly perform:

- _ Make sure they eat properly
- _ Make sure they take their medications
- _ Get to/from dr. visits and other important appointments
- _ Get prescriptions filled
- _ Look for information about their health condition
- _ Interact or communicate with the healthcare system, insurance providers, or government agencies
- _ Help them decide whether to use a prescription medicine
- _ Help them exercise

10d. About how long have you been doing these activities?

(approx) ____ years and ____ months

10e. Overall, how would you describe the health of this person. Would you say:

- | | | |
|-------------|---|------------|
| | 1 | Excellent, |
| | 2 | Very good, |
| | 3 | Good, |
| | 4 | Fair, or |
| | 5 | Poor |
| DO NOT READ | 8 | Don't Know |
| DO NOT READ | 9 | Refused |

10f. In general, how much do you feel you know about health and medicines? Would you say you know:

	A lot	1
	A good bit	2
	Some	3
	Only a slight amount	4
	Nothing at all	5
DO NOT READ	Don't Know	8
DO NOT READ	Refused	9

10g. Have you ever heard of Oncor, before today? *[[false positive]]*

- 1 Yes
- 2 No

10h. Have you ever seen any ads or promotions for Oncor before today? *[[false positive]]*

- 1 Yes
- 2 No

The next few questions refer to the person you assist with their *(insert condition)*

[SKIP OTC questions IF Cholesterol]

10i. Have s/he ever taken an over-the-counter medicine for *(insert condition)*?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

10j.i. Is s/he currently taking an over-the-counter medicine for *(insert condition)*?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

[Ask if “yes”]

10j.ii. Which one of these phrases best describes how satisfied or dissatisfied you are with the current over-the-counter medicine s/he is taking. Would you say you are:

- 5 Very satisfied,
- 4 Somewhat satisfied,
- 3 Neither satisfied nor dissatisfied,
- 2 Somewhat dissatisfied, or
- 1 Very dissatisfied?

10k. Has s/he ever taken a prescription medicine for (*insert condition*)?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

10 l.i. Is s/he currently taking a prescription medicine for (*insert condition*)?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

[Ask if “yes”]

10 l.ii. Which one of these phrases best describes how satisfied or dissatisfied you are with the current prescription medicine s/he is taking. Would you say you are:

- 5 Very satisfied,
- 4 Somewhat satisfied,
- 3 Neither satisfied nor dissatisfied,
- 2 Somewhat dissatisfied, or
- 1 Very dissatisfied?

10m. In the last six months, about how many **different** prescription drugs has s/he used (for women: including birth control pills)? _____

DO NOT READ	Don't Know	98
DO NOT READ	Refused	99

10n. In the last six months, about how many **different** over-the-counter drugs has s/he used, including vitamins or nutritional supplements? _____

DO NOT READ	Don't Know	98
DO NOT READ	Refused	99

Now we switch the focus for a couple of questions about you.

10 o. In the last six months, about how many **different** prescription drugs have you used (for women: including birth control pills)? _____

DO NOT READ	Don't Know	98
DO NOT READ	Refused	99

10p. In the last six months, about how many **different** over-the-counter drugs have you used, including vitamins or nutritional supplements? _____

DO NOT READ	Don't Know	98
DO NOT READ	Refused	99

[If Caregiver, go to Q12]

[Ask Q11 ONLY for Diagnosed]

11a. Overall, would you say your health is:

	Excellent	1
	Very good	2
	Good	3
	Fair	4
	Poor	5
DO NOT READ	Don't Know	8
DO NOT READ	Refused	9

11b. In general, how much do you feel you know about health and medicines? Would you say you know:

	A lot	1
	A good bit	2
	Some	3
	Only a slight amount	4
	Nothing at all	5
DO NOT READ	Don't Know	8
DO NOT READ	Refused	9

11c. Have you ever heard of Oncor, before today? *[[false positive]]*

1	Yes
2	No

11d. Have you ever seen any ads or promotions for Oncor before today? *[[false positive]]*

- 1 Yes
- 2 No

[SKIP OTC items IF Cholesterol]

11e. Have you or anyone in your family ever taken an over-the-counter medicine for *(insert condition)*?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

11f.i. Are you or anyone in your family currently taking an over-the-counter medicine for *(insert condition)*?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

[Ask if “yes”]

11f.ii. Which one of these phrases best describes how satisfied or dissatisfied you are with your current over-the-counter medicine. Would you say you are:

- 5 Very satisfied,
- 4 Somewhat satisfied,
- 3 Neither satisfied nor dissatisfied,
- 2 Somewhat dissatisfied, or
- 1 Very dissatisfied?

11g. Have you or anyone in your family ever taken a prescription medicine for *(insert condition)*?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

11g.i. Are you or anyone in your family currently taking a prescription medicine for *(insert condition)*?

- 1 Yes
- 2 No
- 3 Don't Know or uncertain

[Ask if “yes”]

11g.ii. Which one of these phrases best describes how satisfied or dissatisfied you are with your current prescription medicine. Would you say you are:

- 5 Very satisfied,
- 4 Somewhat satisfied,
- 3 Neither satisfied nor dissatisfied,
- 2 Somewhat dissatisfied, or
- 1 Very dissatisfied?

11h. In the last six months, about how many **different** prescription drugs have you used (for women: including birth control pills)? _____

DO NOT READ Don't Know 98
DO NOT READ Refused 99

11i. In the last six months, about how many **different** over-the-counter drugs have you used, including vitamins or nutritional supplements? _____

DO NOT READ Don't Know 98
DO NOT READ Refused 99

[Ask both Caregivers and Diagnosed]

12. What is your marital status? Are you: (READ CODES)

Married 1
Single 2
Widowed 3
Divorced 4
Separated 5
DO NOT READ Don't Know 8
DO NOT READ Refused 9

13. What was the last grade of school that you completed? (READ CODES IF NECESSARY)

- 1 Grade school or less
- 2 Some high school
- 3 Completed high school
- 4 Some college
- 5 Completed college
- 6 Graduate school or more
- 7 Other education beyond high school (business, technical, etc)
- 8 Refused

14. Which of these best represents your ethnic group? You may say yes to more than one.
Would you say that you are:

- 1 American Indian or Alaska Native
- 2 Asian
- 3 Black or African-American
- 4 Hispanic or Latino
- 5 Native Hawaiian or Pacific Islander
- 6 White
- 7. Other
- 9. (Don't Read) Ref / DK /NA

15. In what year were you born? _____

16. For classification purposes only, please tell me which category represents your total household income last year before taxes. Please tell me when I reach the category that describes your income. Was it:

- | | | |
|-------------|--------------------------------|---|
| | Less than \$10,000 | 1 |
| | \$10,000 to less than \$20,000 | 2 |
| | \$20,000 to less than \$35,000 | 3 |
| | \$35,000 to less than \$50,000 | 4 |
| | \$50,000 to less than \$75,000 | 5 |
| | \$75,000 or over | 6 |
| DO NOT READ | Don't Know | 8 |
| DO NOT READ | Refused | 9 |

17. Gender (Record; **do not read**)

- 1 Male 2 Female

[End time: _____]