

Appendix A

Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements: Consumer Screener, Consent Form, and Cognitive Interview Guide

Price Comparison Study

Cognitive Testing – Recruitment Screener **(CONSUMERS)**

[Ask to speak to an adult age 18 or older living in the household.]

Hello, my name is _____ and I'm from [name of company]. I'm calling on behalf of RTI International, a non-profit research organization, about a study being sponsored by a public health agency. We're calling to recruit people to take part in a research study about advertisements. We are not selling or promoting any product. The study involves reviewing a few advertisements on a computer and answering some questions about what you watched.

RTI will be conducting interviews with several people, and we would like to see if you are eligible. We have various time slots available and will work with you to find a time that fits your schedule. The interview will last up to one hour. In appreciation for your participation, you will be reimbursed for your time, effort, and travel expenses.

To see if you are eligible for this study, I need to ask you a few questions. All of your responses will be kept private. My questions will only take a few minutes. May I proceed?

Yes → CONTINUE

No → [Thank respondent and end call.]

1. Have you ever been told by a doctor that you have any of the following conditions?

Osteoporosis	<input type="checkbox"/>	→ TERMINATE
Allergies	<input type="checkbox"/>	→ TERMINATE
High Cholesterol	<input type="checkbox"/>	→ TERMINATE
Asthma	<input type="checkbox"/>	→ TERMINATE
Diabetes	<input type="checkbox"/>	→ CONTINUE

2. How old were you on your last birthday? _____

[ASSIGN RESPONSE TO AGE RANGE BELOW]

17 or younger	<input type="checkbox"/>	→ TERMINATE
18-20	<input type="checkbox"/>	→ CONTINUE
21-29	<input type="checkbox"/>	→ CONTINUE
30-39	<input type="checkbox"/>	→ CONTINUE
40-49	<input type="checkbox"/>	→ CONTINUE
50-59	<input type="checkbox"/>	→ CONTINUE
60 or older	<input type="checkbox"/>	→ CONTINUE

[ATTEMPT MIX]

3. What is the highest level of education you have completed?

_____ Degree

[ASSIGN RESPONSE TO EDUCATION LEVEL BELOW]

Less than high school	<input type="checkbox"/>	→ CONTINUE
High school graduate	<input type="checkbox"/>	→ CONTINUE
Some college	<input type="checkbox"/>	→ CONTINUE
College (2-year) degree	<input type="checkbox"/>	→ CONTINUE
College (4-year) degree	<input type="checkbox"/>	→ CONTINUE
Some post-college	<input type="checkbox"/>	→ CONTINUE
Post-college degree	<input type="checkbox"/>	→ CONTINUE

[AIM FOR AT LEAST ONE-THIRD OF TOTAL R'S WITH SOME COLLEGE OR LESS. NO MORE THAN 2 WITH A 4-YEAR COLLEGE DEGREE]

4. How would you describe your race?

American Indian / Alaskan Native	<input type="checkbox"/>	→ CONTINUE
Asian	<input type="checkbox"/>	→ CONTINUE
Black or African American	<input type="checkbox"/>	→ CONTINUE
Native Hawaiian / Pacific Islander	<input type="checkbox"/>	→ CONTINUE
White	<input type="checkbox"/>	→ CONTINUE
Other	<input type="checkbox"/>	→ CONTINUE

[NO MORE THAN FIVE PARTICIPANTS OF A SINGLE RACE]

5. What is your sex?

Male	<input type="checkbox"/>	→ CONTINUE
Female	<input type="checkbox"/>	→ CONTINUE

[ATTEMPT 5/4 SPLIT]

6. Do you currently work in or for...

Market research company	<input type="checkbox"/>	→ TERMINATE
Department of Health and Human Services	<input type="checkbox"/>	→ TERMINATE
Pharmaceutical company	<input type="checkbox"/>	→ TERMINATE
A job that involves direct patient care (e.g., doctor, nurse)	<input type="checkbox"/>	→ TERMINATE
RTI International	<input type="checkbox"/>	→ TERMINATE
None of the above	<input type="checkbox"/>	→ CONTINUE

Invitation for Eligible Participants:

Thank you for answering all of my questions. We would like to invite you to take part in an informal, personal interview. The interviews are being scheduled on [DATES].

The discussion will last up to one hour. No one will attempt to sell you anything, and no one will call you for other studies as a result of your participation in this study. In appreciation for your time, effort, and travel expenses, you will receive \$75 at the time of the interview. This is an important research effort, and we hope that you will be part of it. I also want to let you know that the interviews will be audio recorded. They will only be listened to by project staff and will be deleted at the end of the project.

Can we schedule your attendance?

Yes → CONTINUE

No → [Thank respondent and end call]

[IF ELIGIBLE AND AVAILABLE, SCHEDULE INTERVIEW]

During the interview, we will ask you to review some sample advertisements and read a survey about the advertisements. **If you wear reading glasses, please remember to bring them to the interview.**

Closing for Ineligible Participants:

Thank you for answering our questions. At this time, you are not eligible to be in this study. However, we appreciate your willingness to help us. Have a good day.

Price Comparison Study

Cognitive Testing – Consent Form

Introduction and Purpose:

You have been invited to take part in a research study. The purpose of the research is to get feedback on survey questions about prescription drug advertisements. RTI International, a non-profit research organization in North Carolina, is conducting the study. This study is sponsored by a public health agency.

Procedures:

During the interview, we will ask you to view one ad and complete a survey about the ad on a laptop computer. We will ask you to complete the survey and “think aloud” as you do so. This helps us to test the survey and ensure that it is understandable. The interview will take up to 60 minutes to complete.

We are conducting interviews with 9 individuals in Raleigh, NC, who have a certain medical condition.

Benefits:

There is no direct benefit to you for being in this interview. However, you may find the discussion interesting and informative. What we learn from the interview will be used to improve the survey for future participants.

Risks:

The questions we ask are not meant to be sensitive. Still, there is a chance that you may feel discomfort about some of the questions we ask. Your participation in this study is voluntary. You may choose not to answer any question that you do not want to answer, and you can stop participating at any time.

Confidentiality:

Your participation in this study will be kept confidential by RTI. The information that you give us will be combined with the responses of other participants in a summary report that will not identify you by name. All notes taken during the interview will be kept in a locked file cabinet or on a password protected computer. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. Only authorized project staff will be able to see them. You will not be contacted in the future about this study after your participation in this interview ends. We will also be audio recording our discussion. The audio files will be stored on a password protected computer and will be deleted at the end of the project.

Reimbursement:

In appreciation for your time, we will give you \$75 at the end of the interview.

Right to Refuse or Withdraw:

It is your choice to take part in this interview. You can choose not to talk about any topic. You can end the interview at any time. You can withdraw from the study for any reason at anytime.

Persons to Contact:

If you have questions about the interview, you can call Dr. Brian Southwell, the project director. He can be reached between 9 AM and 5 PM Eastern Standard Time Monday – Friday at 1-800-334-8571 ext. 8037. If you have questions about your rights as a participant, you can call RTI’s Office of Research Protection toll-free at 1-866-214-2043.

Your Consent:

I have read this consent form. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to be in the interview.

The above document describing the benefits, risks and procedures for this research study has been explained to me. I agree to participate.

Signature of participant _____ Date ____/____/____

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

Signature of Person Who Obtained Consent _____ Date
____/____/____

FDA PRICE COMPARISON STUDY

COGNITIVE INTERVIEW GUIDE – CONSUMERS: PHASE 2

INTRODUCTION

[PROGRAMMER: The line breaks used in this document indicate when questions should be on separate screens]

[PROGRAMMER: Informed consent to be recorded first.]

[PROGRAMMER: Use Quota assignment to assign the 9 participants evenly across the three study conditions]

[PROGRAMMER: Randomize the order of the presentation of the 3 ads—there will be two filler ads and one study ad]

SCRIPT:

Thank you for agreeing to participate in this study today.

Make sure you are comfortable and can read the screen from where you sit. This study is about advertisements (ads) that appear in magazines and newspapers. You will view one ad and then will be asked to answer the questions that follow. Your answers are private, and no one will ever connect your name with your answers. Your input is extremely valuable.

S1. Have you ever been diagnosed by a physician or other qualified medical professional with any of the following conditions? Select all that apply.

- Asthma
 - Cancer
 - Depression
 - Diabetes [Respondent needs to check Diabetes to Continue]
 - Heart attack
 - None of the above
-

SCRIPT: On the next screen, you will see some ads for new and existing products. Even though they are on a computer screen, please read the ads as if they were in a magazine.

Imagine that the ads are for products in which you might be interested.

Please pay close attention to the ads because we will ask you questions about it afterward.

[PROGRAMMER: Display ad correspondent to the participant's experimental condition. JUST for the cognitive interviews, allow participants to go back to previous screens.

We would now like to ask you some questions specifically about the prescription drug ad that you saw.

Q1. Were you able to view the prescription drug ad?

- Yes [Continue]
- No [Terminate; Link to screening responses and keep data, though]

Q2. What was the main message of the prescription drug ad you saw?

[OPEN-ENDED RESPONSE]

Q3. Which of the following drugs did you see advertised?

[PROGRAMMER: Randomize response options. Allow respondents to check more than one box]

- Veridan
- Lyrica
- Cymbalta
- Carmitet
- None of the above

[PROGRAMMER: Randomize Q4 and Q5. Include thirteen separate rows]

SCRIPT: The prescription drug ad you saw included messages about a prescription drug named Veridan.

Q4. Based on the prescription drug ad, what are the benefits of **Veridan**? Please list as many benefits as you can remember. Use one line for each benefit you list.

Q5. Based on the prescription drug ad, what are the risks and side effects of **Veridan**? Please list as many risks and side effects as you can remember. Use one line for each risk or side effect you list.

SCRIPT: This question asks about information that may or may not have been in the prescription drug ad.

Q6. Which of the following statements, if any, were in the prescription drug ad you saw?
Check all that apply.

[PROGRAMMER: RANDOMIZE ORDER]

- If you take Lyrica, switching to Veridan could save you up to \$560.00 a year.
- If you take Lyrica, switching to Veridan could cause you to spend \$210.00 more a year.
- Veridan is an FDA-approved treatment for your diabetes-related nerve pain.
- Only Veridan is designed to treat two of the most common types of nerve pain, diabetic nerve pain and pain after shingles.
- Taken once a day, it works by interfering with chemical processes in the brain that cause you to feel pain, providing significant relief.
- Veridan is the first and only pain reliever that is FDA-approved to treat some forms of pain caused by general inflammation
- The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison are not known to have the same efficacy or safety.
- None of the above.

[PROGRAMMER: Randomize Q7 and Q8]

Q7. Based on the prescription drug ad, please indicate whether each of the following was mentioned as a benefit of taking **Veridan**. Even if you think a statement is true, please select “Yes” only if it was mentioned in the ad.

[PROGRAMMER: RANDOMIZE ORDER]	Yes, claim is in the ad	No, claim is not in the ad
a. relieves diabetic nerve pain		
b. only needs to be taken once a day		
c. relieves problems with urination		
d. reduces indigestion, nausea, or vomiting		
e. works better than Lyrica		

Q8. Based on the prescription drug ad, please indicate whether each of the following was mentioned as a side effect or risk of taking **Veridan**. Even if you think a statement is true, please select “Yes” only if it was mentioned in the ad.

[PROGRAMMER: RANDOMIZE ORDER]	Yes, claim is in the ad	No, claim is <u>not</u> in the ad
a. blurred vision		
b. headache		
c. insomnia		
d. diarrhea		
e. skin sores		
f. dry mouth		
g. thoughts of suicide		
h. difficulty breathing		
i. paralysis		
j. hallucinations		

SCRIPT: For the following questions, we are interested in your initial impression and honest opinions. There are no right or wrong answers, and it is OK to have strong opinions. Please feel free to use the entire range of response options.

Q9. Based on the prescription drug ad, please rate how likely or unlikely you are to do each of the following behaviors.

	Not at all likely 1	2	3	4	5	Very likely 6
a. Look for information about Veridan .						
b. Talk with a friend or family member about Veridan .						
c. Ask your doctor for more information about Veridan .						
d. Ask your doctor to prescribe Veridan .						
e. Take Veridan if your doctor prescribed it.						

SCRIPT: Please answer the following questions to the best of your ability.

Q10. How accurate is the following statement?

“If you take Lyrica, switching to Veridan could save you up to \$560.00 a year.”

1	2	3	4	5	6
Not at all accurate					Very accurate

Q11. How important would the following statement be if you were deciding whether **Veridan** is a good option for you?

“If you take Lyrica, switching to Veridan could save you up to \$560.00 a year.”

1	2	3	4	5	6
Not at all important					Very important

SCRIPT: Please answer the following questions to the best of your ability.

Q12. How accurate is the following statement?

“The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison are not known to have the same efficacy or safety.”

1	2	3	4	5	6
Not at all accurate					Very accurate

Q13. How important would the following statement be if you were deciding whether **Veridan** is a good option for you?

“The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison are not known to have the same efficacy or safety.”

1	2	3	4	5	6
Not at all important					Very important

Q14. Imagine you wanted to explain to a friend what the statement displayed below means. Please explain the statement in your own words.

“The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison are not known to have the same efficacy or safety.”

[OPEN-ENDED RESPONSE]

SCRIPT: Next, we’d like to ask you a few questions about yourself.

Q15. How often do you have someone (like a family member or friend) help you read instructions, pamphlets, or other written material from your doctor or pharmacy?

1	2	3	4	5
Never	Rarely	Sometimes	Often	Always

Q16. How confident are you filling out medical forms by yourself?

1	2	3	4	5
Not at all confident	A little bit	Somewhat	Quite a bit	Very confident

Q17. In general, how much do you feel you know about diabetes? Would you say you know:

1	2	3	4	5
Nothing	Only a slight amount	Some	A good amount	A lot

Q18. How would you rate your familiarity with prescription drugs that treat diabetes?

1	2	3	4	5
Very unfamiliar				Very familiar

Q19. Please indicate your level of agreement with the following statements. Please note that these questions refer to *any product* and **not just prescription drugs**.

	1					5		6
	Strongly disagree		2	3	4			Strongly agree

Generally speaking, the higher the price of a product, the higher the quality.						
The old saying "you get what you pay for" is generally true.						
The price of the product is a good indicator of its quality.						
You always have to pay a bit more for the best.						

Q20. Please indicate your level of agreement with the following statements. Please note that these questions refer to *any product* and **not just prescription drugs**.

	1 Strongly disagree	2	3	4	5	6 Strongly agree
I generally shop around for lower prices on products, but they still must meet quality requirements before I buy them.						
When shopping, I compare the prices of different brands to be sure I get the best value for the money.						

Q21. Did you do any of the following in the past year to help ease the costs of prescription medication? Check all that apply.

- Skipped doses
- Cut pills in half
- Stopped taking the medication
- Switched to a generic
- Tried to get financial assistance
- Delayed filling a prescription
- Asked your doctor for a lower-priced medication
- Bought prescription drugs from another country
- Used alternative therapies
- None of the above [PROGRAMMER: If this is checked, do not allow other boxes to be checked off as well]

Q22. Are you currently taking, or have you ever taken, any prescription drug(s) for diabetes?

- Currently taking
 - Have taken in the past but not currently taking
 - Have never taken
-

Q23. How upsetting is having diabetes for you?

- Not at all
- Slightly upsetting
- Moderately upsetting
- Very upsetting
- Extremely upsetting

Q24. How much control over your diabetes do you have?

- None at all
- Slight amount
- Moderate amount
- Large amount
- Total amount

Q25. How much uncertainty do you currently experience in your life as a result of being diabetic?

- None at all
 - Slight amount
 - Moderate amount
 - Large amount
 - Extremely large amount
-

Q26. Please answer the following questions to the best of your ability.

a. Imagine that you flip a fair coin 1,000 times. What is your best guess about how many times the coin would come up heads in 1,000 flips?	_____ [PROGRAMMER: Allow only numbers or symbols]
b. In the BIG BUCKS LOTTERY, the chance of winning a \$10 prize is 1%. What is your best guess about how many people would win a \$10 prize if 1,000 people each buy a single ticket to the BIG BUCKS LOTTERY?	_____ [PROGRAMMER: Allow only numbers or symbols]
c. In ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME	_____ [PROGRAMMER: Allow only numbers or symbols]

PUBLISHING SWEEPSTAKES will win a car?	
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Q27. Are you now covered by any form of health insurance or health plan? This includes any private insurance plan through your employer or a plan that you purchased yourself, as well as a government program like Medicare or Medicaid.

Yes

No [Skip to Q29]

Don't know

Q28. Does your current insurance plan help pay for prescription drugs?

Yes

No

Don't know

Q29. Have you ever seen any advertising for **Lyrice** before today?

Yes

No

Unsure

Q30. Have you ever taken **Lyrice**?

Yes

No

Unsure

SCRIPT:

You have been very helpful. Thank you very much for taking part in this survey!

The purpose of this research is to learn about how people feel about information provided in direct-to-consumer prescription drug ads and to learn how people use this information to understand how well prescription drugs work. Veridan is not a product currently for sale. Please see your healthcare professional for questions about your health and your medical conditions. We used Lyrice in this study as an example comparison only. Use of the brand name does not imply endorsement of the product by FDA.