Composite Scores Study
Phase 1 Questionnaire

INTRODUCTION

Thank you for participating in this study about prescription drug ads that appear in magazines and newspapers.

The study has two parts. First, we'll ask you some general questions about prescription drugs. Second, we'll show you an example ad and ask you some questions about it.

Your responses are very important to us. The U.S. Department of Health and Human Services is sponsoring this study and will use the results to better understand prescription drug ads.

GENERAL PRESCRIPTION DRUG QUESTIONS

Q1. [Understanding of "Safe and Effective" Paradigm]

When the FDA approves a prescription drug as being "safe and effective," it means that…

Select one answer from each row in the grid.

[RANDOMIZE ORDER]	TRUE	FALSE
a. The drug has no life-threatening side effects.	☐	☐
b. The drug has only minor side effects, such as dry mouth or tiredness.	☐	☐
c. The drug has no side effects.	☐	☐
d. The drug offers benefits that are greater than the risks.	☐	☐
e. The drug will help everyone who uses it.	☐	☐
f. The drug will help most people who use it.	☐	☐
g. The drug will cure the condition for which it is prescribed.	☐	☐

Q2. [Understanding of FDA Approval Requirements]

What does it mean when the FDA "approves" a prescription drug?

(open-ended)

Q3. [Understanding of FDA Approval Requirements]

Would you say the following statements are true or false?
Select one answer from each row in the grid.

	TRUE	FALSE
A. The FDA only approves prescription drugs that have been found to be extremely effective.	☐	☑
B. The FDA approves prescription drugs only if they do not have serious side effects.	☐	☑
C. Only prescription drugs that have been found to be extremely effective can be <u>advertised</u> to consumers.	☐	☑
D. Prescription drugs that have serious side effects cannot be <u>advertised</u> to consumers.	☐	☑

[COUNTERBALANCE Q4 AND Q5]

Q4. [Attitudes about Side Effect Information]

<u>Advertisements</u> for prescription drugs include too much information about side effects.

     ☐ Strongly agree

     ☐ Agree

     ☐ Neither agree nor disagree

     ☐ Disagree

     ☐ Strongly disagree

Q5. [Attitudes about Drug Side Effects]

The <u>prescription drugs</u> that are advertised on TV and in magazines have too many side effects.

     ☐ Strongly agree

     ☐ Agree

     ☐ Neither agree nor disagree

     ☐ Disagree

     ☐ Strongly disagree

Q6. [Understanding of Clinical Trials]

Who manages the studies to find out if a prescription drug works? (Select One)

❑ The FDA

❑ The pharmaceutical companies that make the drug

❑ The drugs are not tested

❑ Don't know

Q7. [Understanding of FDA Authority]

Which of the following products does FDA approve before they are sold to consumers? (Check all that apply)

❑ Prescription drugs

❑ Over-the-counter (OTC) drugs

❑ Herbal remedies

❑ Vitamins

❑ None of these products

Q8 – Option A. [Understanding of FDA Authority]

What percentage of <u>new</u> prescription drugs are approved by the FDA before they are sold to consumers?

❑ All of them (100%)

❑ Most of them (50-99%)

❑ Some of them (1-49%)

❑ None of them (0%)

❑ Don't know

Q8 – Option B. [Understanding of FDA Authority]

What percentage of <u>new</u> prescription drugs are approved by the FDA before they are sold to consumers?

❑ 100%

❑ 50-99%

❑ 1-49%

❑ 0%

❑ Don't know

Q8-A. [Understanding of FDA Authority]

[IF NOT 100% TO Q8] **Under what circumstances could a prescription drug be sold without FDA approval?**

    (open-ended)

Q9. [Understanding of FDA Authority]

FDA must approve all prescription drug <u>advertisements</u> before they appear in magazines or on TV.

    ❑ True
    ❑ False
    ❑ Don't know

INSTRUCTIONS

Next we will show you a magazine ad. Even though it is on a computer screen, please read this ad as if it were in a magazine. Please pay close attention to the ad as we will ask you questions about it afterwards.

The ad has two pages. You can enlarge and flip between the pages by clicking on the "Next" and "Back" buttons at the bottom of each page. Once you finish reading, please click "Next" to move to the next part of the study.

[SHOW AD]

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

Q10. [Ad Viewing]

Were you able to view the ad for [DRUG NAME]?

- ❑ Yes
- ❑ No ➔ [Skip to Q30]
- ❑ Not sure ➔ [Skip to Q30]

Q11. [Benefit Recall]

According to the ad, what are the benefits of [DRUG NAME]?

(open-ended)

Q12. [Clarity of Advertisement]

The ad clearly presented the benefits of [DRUG NAME].

- ❑ Strongly agree
- ❑ Agree
- ❑ Neither agree nor disagree
- ❑ Disagree
- ❑ Strongly disagree

[DISPLAY Q13 AND Q14 ON SAME SCREEN]

When considering a new drug, most people ask themselves two questions about its benefits:

    (1) Will this drug work?
    (2) If it does work, will it help a little or help a lot?

The questions below ask about these two ideas.

Q13 – Option A. [Perceived Efficacy - Likelihood of Benefit]

If you had to guess, if 100 people take [DRUG NAME], for how many will the drug work?

0	20	40	60	80	100
people	people	people	people	people	people

Q13 – Option B. [Perceived Efficacy - Likelihood of Benefit]

If you had to guess, if 100 people take [DRUG NAME], for how many will the drug work? Please enter a number in the box below.

      ____ people

Q14. [Perceived Efficacy - Magnitude of Benefit]

If you had to guess if [DRUG NAME] did help reduce bone fractures, how effective would [DRUG NAME] be?

1	2	3	4	5	6
Not at all effective					Extremely Effective

Q15. [Risk Recall]

According to the ad, what are the side effects of [DRUG NAME]?

      (open ended)

[DISPLAY Q16 AND Q17 ON SAME SCREEN]

When considering a new drug, most people ask themselves two questions about its risks:

    (1) Will this drug cause any side effects?

    (2) If it does cause side effects, how serious will the side effects be?

The questions below ask about these two ideas.

Q16 – Option A. [Perceived Risk - Likelihood of Risk]

If you had to guess, if 100 people take [DRUG NAME], how many will have any side effects?

0	20	40	60	80	100
people	people	people	people	people	people

Q16 – Option B. [Perceived Risk - Likelihood of Risk]

If you had to guess, if 100 people take [DRUG NAME], how many will have any side effects? Please enter a number in the box below.

      ____ people

Q17. [Perceived Risk- Magnitude of Risk]

If you had to guess, if [DRUG NAME] did cause side effects, how serious would they be?

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

Q18. [Attention Filter]

Please click on the box at the bottom of the screen. Do not choose an answer on the scale below. This is to eliminate random clicking of answer choices.

1	2	3	4	5	6	7
Not at all likely					Extremely likely	

    ☐ Box

Q19. [Trust in information]

How likely is it that the benefits of the drug presented in this ad are true?

1	2	3	4	5	6	7
Not at all likely						Extremely likely

Q20. [Source Credibility]

Please mark your agreement or disagreement with each of the following statements. The <u>sponsor</u> of this advertisement is:

Select one answer from each row in the grid.

[DO NOT RANDOMIZE]	Very Strongly Disagree 1	2	3	4	5	6	Very Strongly Agree 7
a. Sincere							
b. Honest							
c. Dependable							
d. Trust worthy							
e. Credible							

Q21. [Attitudes Toward the Brand]

Based on the information in the ad, rate [DRUG NAME].

	❑	❑	❑	❑	❑	❑	❑	
Bad product	1	2	3	4	5	6	7	Good product

	❑	❑	❑	❑	❑	❑	❑	
Disliked a lot	1	2	3	4	5	6	7	Liked a lot

	❑	❑	❑	❑	❑	❑	❑	
Unpleasant	1	2	3	4	5	6	7	Pleasant

	❑	❑	❑	❑	❑	❑	❑	
Poor quality	1	2	3	4	5	6	7	Good quality

Q22. [Unaided Composite Score Comprehension]

The next question asks about prescription drugs <u>in general</u>, not about the ad for [DRUG NAME].

What does the term "composite score" mean as related to prescription drugs?

      (open-ended)

[NEW SCREEN]

A composite score is an overall score that results from adding two or more scores together. For prescription drugs, a composite score can measure how well a drug works on two or more outcomes. Here are a few examples:

Example 1
There are different symptoms of seasonal allergies, such as stuffy nose, runny nose, headache, cough, and watery eyes. When Drug A was tested, it relieved some of these symptoms but didn't relieve others. Drug A received a score for how well it relieved each symptom. These scores were then added together to create a composite score.

Because Drug A had a high composite score, scientists agreed that it was effective in treating seasonal allergies. This is true even though Drug A doesn't help every seasonal allergy symptom.

Example 2
Drug B is a pain medication. To test whether Drug B works, scientists asked people if they had less pain after taking Drug B. However, people experience pain in different parts of the body. Drug B reduced pain in some body parts but not in other body parts. Drug B received a score for each body part. These scores were averaged together to create a composite score.

Because Drug B reduced pain in most body parts, scientists agreed that it was effective in treating pain. This is true even though Drug B didn't reduce pain in all body parts.

Q23. [Aided Composite Score Comprehension]

Which of the following is an example of a composite score?

❑ **Chess.** Chess is a board game where each player has 16 pieces. During the game, players capture each other's pieces by landing on the same spot of the board with one of their pieces. The player who captures the other player's king wins the game, even if he or she captured fewer pieces overall.

❑ **The SAT.** The SAT is a test with 3 sections—math, reading, and writing. A person's SAT score is calculated by adding the scores for each section. A person might have a low score on one section, but still have a high overall score because they did better on the other two sections.

❑ **Pregnancy Test.** Home pregnancy tests analyze urine to see if the HCG hormone is present. Some tests provide a cup for collecting urine; others provide a test strip to hold under a stream of urine. Some tests use a line to indicate pregnancy, and other tests use a plus sign to indicate pregnancy.

INSTRUCTIONS

Please view the [DRUG NAME] ad again. When you finish, we will ask you some questions about the ad.

The ad has two pages. You can enlarge and flip between the pages by clicking on the "Next" and "Back" buttons at the bottom of each page. Once you finish reading, please click "Next" to move to the next part of the study.

[SHOW AD AGAIN]

Now please answer the following questions based on the ad you saw. You may have answered some of these questions before, but please answer them again.

Q24. [Manipulation Check / Composite Score Recall]

A composite score appeared on which page of the [DRUG NAME] ad?

- ❑ First page
- ❑ Second page
- ❑ There was no composite score in the ad

Q25. [Clarity / Perceived Clarity of Ad]

Please mark how much you agree or disagree with each of the following statements.

[RANDOMIZE ORDER]	Strongly Disagree 1	2	3	4	5	6	Strongly Agree 7
a. The ad presented the benefits of [DRUG NAME] in a way that was easy to understand.							
b. This ad included a lot of detail about [DRUG NAME]'s specific benefits.							
c. I understand how [DRUG NAME]'s effectiveness was measured.							
d. I know the specific benefits of [DRUG NAME].							
e. I feel like I know what [DRUG NAME] will and will not do for me.							
f. The explanation of [DRUG NAME]'s benefits in this ad was confusing.							
g. I could easily explain the benefits of [DRUG NAME] to a friend or family member.							

h. The ad included too much information about [DRUG NAME]'s benefits.							

Q26. [Clarity of Composite Score Information]

Please mark whether the following statements are true or false.

[RANDOMIZE ORDER]	True	False
a. [DRUG NAME] prevents all bone fractures.		X
b. [DRUG NAME] might not prevent all bone fractures but is more effective than no treatment at all.	X	
c. [DRUG NAME] might not prevent all bone fractures equally.	X	

Q27. [Clarity of Composite Score Information]

Please mark how much you agree or disagree with the following statement.

[DRUG NAME] is worse than other prescription drugs at preventing bone fractures.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

Q28. [Perceived Influence of Composite Score]

How much does the information about composite scores presented earlier change the way you think about the [DRUG NAME] ad?

1	2	3	4	5	6	7
Not at all						A lot

Q29. Please provide a brief explanation for your response.

(Open-ended)

Q12-R. [Clarity of Advertisement]

The ad clearly presented the benefits of [DRUG NAME].

❑ Strongly agree
❑ Agree
❑ Neither agree nor disagree
❑ Disagree

❑ Strongly disagree

[DISPLAY Q13 AND Q14 ON SAME SCREEN]

When considering a new drug, most people ask themselves two questions its benefits:

(1) Will this drug work?
(2) If it does work, will it help a little or help a lot?

The questions below ask about these two ideas.

Q13-R – Option A. [Perceived Efficacy - Likelihood of Benefit]

If you had to guess, if 100 people take [DRUG NAME], for how many will the drug work?

0	20	40	60	80	100
people	people	people	people	people	people

Q13-R – Option B. [Perceived Efficacy - Likelihood of Benefit]

If you had to guess, if 100 people take [DRUG NAME], for how many will the drug work? Please enter a number in the box below.

____ people

Q14-R. [Perceived Efficacy - Magnitude of Benefit]

If you had to guess, if [DRUG NAME] did help reduce bone fractures, how effective would [DRUG NAME] be?

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

[DISPLAY Q16 AND Q17 ON SAME SCREEN]

When considering a new drug, most people ask themselves two questions about its risks:

(1) Will this drug cause any side effects?
(2) If it does cause side effects, how serious will the side effects be?

The questions below ask about these two ideas.

Q16-R – Option A. [Perceived Risk - Likelihood of Risk]

If you had to guess, if 100 people take [DRUG NAME], how many will have any side effects?

0	20	40	60	80	100
people	people	people	people	people	people

Q16-R – Option B. [Perceived Risk - Likelihood of Risk]

If you had to guess, if 100 people take [DRUG NAME], how many will have any side effects? Please enter a number in the box below.

_____ people

Q17-R. [Perceived Risk- Magnitude of Risk]

If you had to guess, if [DRUG NAME] did cause side effects, how serious would they be?

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

Q19-R. [Trust in information]

How likely is it that the benefits of the drug presented in this ad are true?

1	2	3	4	5	6	7
Not at all likely					Extremely likely	

Q20-R. [Source Credibility]

Please mark your agreement or disagreement with each of the following statements. The sponsor of this advertisement is:

Select one answer from each row in the grid.

[DO NOT RANDOMIZE]	Very Strongly Disagree 1	2	3	4	5	6	Very Strongly Agree 7
a. Sincere							
b. Honest							
c. Dependable							
d. Trust worthy							
e. Credible							

Q21-R. [Attitudes Toward the Brand]

Based on the information in the ad, rate [DRUG NAME].

	1	2	3	4	5	6	7	
	❑	❑	❑	❑	❑	❑	❑	
Bad product	1	2	3	4	5	6	7	Good product
	❑	❑	❑	❑	❑	❑	❑	
Disliked a lot	1	2	3	4	5	6	7	Liked a lot
	❑	❑	❑	❑	❑	❑	❑	
Unpleasant	1	2	3	4	5	6	7	Pleasant
	❑	❑	❑	❑	❑	❑	❑	
Poor quality	1	2	3	4	5	6	7	Good quality

Q30. [Medication Usage]

Have you ever taken any prescription drugs?

❑ Currently taking one or more prescription drugs

❑ Not taking any prescription drugs right now, but did before

❑ Never took any prescription drug

Q31. [Osteoporosis Diagnosis]

Have you ever been diagnosed with osteoporosis?

❑ Yes

❑ No

❑ Not sure

Q32. [Health Literacy]

How confident are you filling out medical forms by yourself?

❑ Not at all confident

❑ A little confident

❑ Somewhat confident

❑ Quite a bit confident

❑ Extremely confident

Q33. [Ethnicity]

Are you Hispanic or Latino?

❑ Yes
❑ No

Q34. [Race]

What is your race? You may select one or more races.

❑ American Indian or Alaska Native
❑ Asian
❑ Black or African-American
❑ Native Hawaiian or Other Pacific Islander
❑ White
❑ Some Other Race

Q35. [Gender]

Gender

❑ Male
❑ Female

Q36. [Education]

What is the highest level of school you have completed or the highest degree you have received?

❑ Less than high school
❑ High school graduate (high school diploma or GED)
❑ Some college, but no degree
❑ Associate's degree (2-year)
❑ Bachelor's degree (4-year) (example: BA, BS)
❑ Advanced or postgraduate degree (example: MA, MD, DDS, JD, PhD, EdD)

Q37. [Household Income]

Of these income groups, which category best represents your total combined family income during [FIELD YEAR]?

❑ Less than $20,000
❑ $20,000 - $29,999
❑ $30,000 - $39,999
❑ $40,000 - $49,999
❑ $50,000 - $74,999
❑ $75,000 - $99,999
❑ $100,000 or more

Q38. [Age]

What is your date of birth?

Month (drop down menu)

Year (drop down menu)

The purpose of this study is to learn about reactions to advertising for prescription drugs. In order to get a real-life reaction, we used a pretend product in this study. [DRUG NAME] is not a real product and is not available for sale, although there may be other prescription drugs available that are similar. Please see your healthcare provider for questions about osteoporosis.

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