

APPENDIX 2

Screener and Questionnaires

Screener

Recruiting Goals

- Participants must be age 18 and over.
- For Study 1, participants must have had been diagnosed with insomnia or have experienced the symptoms of insomnia in the past month.
- For Study 2, participants must have been diagnosed with high blood pressure.
- Participants must be able to read, understand, and speak English.
- Participants must not be healthcare professionals.
- Participants must not work for a pharmaceutical company, an advertising agency, or a market research company.
- An attempt should be made to have an equal number of males and females.
- The sample should have some range of education and race/ethnicity represented.
- Each interview will last approximately 20 minutes.
- Obtain participant's consent.

SCREENING QUESTIONS

S1. Are you at least 18 years old?

- Yes → continue
- No → eliminate [thank respondent politely]

S2. In what year were you born? _____

	If Year is > 1994	eliminate [thank respondent politely]
DO NOT READ	Don't Know 8	eliminate [thank respondent politely]
DO NOT READ	Refused 9	eliminate [thank respondent politely]

[INTERVIEWER: Recruit range of ages]

S3. Has a doctor or other healthcare provider ever said you have any of the following health problems?

- | | | | |
|------------------------|-----------|----------|----------|
| a. Asthma | _____ Yes | _____ No | [filler] |
| b. Diabetes | _____ Yes | _____ No | [filler] |
| c. Insomnia | _____ Yes | _____ No | |
| d. High blood pressure | _____ Yes | _____ No | |
| e. Acid reflux or GERD | _____ Yes | _____ No | [filler] |

[STUDY 1: INTERVIEWER: If "no" to S3c, ask S4]

[STUDY 2: INTERVIEWER: If "no" to S3d, eliminate and thank respondent politely]

S4. Have you had any of the following health symptoms in the past month:
[randomize]

- | | | | |
|----|-------------------------------------|----------|------------------|
| a. | Trouble falling asleep | _____Yes | _____No |
| b. | Dizziness | _____Yes | _____No [filler] |
| c. | Trouble staying asleep | _____Yes | _____No |
| d. | Not feeling rested when you wake up | _____Yes | _____No |
| e. | Numbness or tingling in your legs | _____Yes | _____No [filler] |
| f. | Frequent heartburn | _____Yes | _____No [filler] |

[STUDY 1: INTERVIEWER: If “no” to S4a, S4c **or** S4d, eliminate and thank respondent politely]

S5. Are you trained or employed as a health care professional?

- Yes → eliminate [thank respondent politely]
- No → continue

S6. Do you work for a pharmaceutical company, an advertising agency, or a market research company?

- Yes → eliminate [thank respondent politely]
- No → continue

S7. Can you read, understand, and speak English?

- Yes → eliminate [thank respondent politely]
- No → continue

S8a. Do you usually wear glasses or contact lenses for reading or watching television?

- Yes → ask S9b
- No → continue

S9b. Do you have your glasses or contact lenses with you today?

- Yes → eliminate [thank respondent politely]
- No → continue

DEMOGRAPHICS

S10. Gender

- Male
- Female

S11. How many years of education have you had? [QUOTA: AT LEAST 20% HIGH SCHOOL OR LESS]

- Completed grade school
- Completed middle school

- Completed high school or GED
- Some college
- Associate's degree (2-year)
- Bachelor's degree (4-year)
- Some postgraduate work
- Postgraduate degree (M.A., Ph.D., M.D., J.D., etc.)

S12. Are you:

- Hispanic or Latino
- Not Hispanic of Latino

S13. Which of these best represents your ethnic group? You may choose one or more.
Would you say that you are:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Other
- Prefer not to answer

Thank you. I would like to invite you to participate in this study.

Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print
Advertisements on Consumer Product Perceptions

DRAFT Questionnaire: PRETEST 1

Programming instructions are indicated in blue font and should be removed prior to fielding.

[PROGRAMMER:

- The viewing time of each page of the ad must be timed separately in milliseconds.
- Program progresses to the questioning in a “one-way” manner.
- Record time in milliseconds spent on each screen (including questions) throughout protocol.]

Interview Protocol

(Present Informed Consent Form. Participants will be blind to FDA’s sponsorship.)

[PROGRAMMER: Screen 1. TIME SPENT ON SCREEN IN MILLISECONDS]

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 advertising for a new product. We will show you an ad for a new product then ask you some questions about it. Your answers are private and will not be connected with your name. Your input is extremely valuable.

[PROGRAMMER: Screen 2. TIME SPENT ON SCREEN IN MILLISECONDS]

[RANDOMLY ASSIGN TO ONE VERSION OF SCREEN 2]

[VERSION 1: CONTROL]

The ad has two pages. We will ask you some questions about the ad after you have finished reading it.

[VERSION 2: INCREASED ATTENTION]

The ad has two pages. We will ask you some questions about the ad after you have finished reading it. Do your best to remember details about the ad. We will ask you to explain your answers.

[VERSION 3: TIME LIMIT]

The ad has two pages. We will ask you some questions about the ad after you have finished reading it. You will have up to 4 minutes to read the ad. The program will

automatically move on to the next part of the study after that time.

[VERSION 4: INCREASED ATTENTION + TIME LIMIT]

The ad has two pages. We will ask you some questions about the ad after you have finished reading it. Do your best to remember details about the ad. We will ask you to explain your answers. You will have up to 4 minutes to read the ad. The program will automatically move on to the next part of the study after that time.

[SCREEN 3]

If you want to see a bigger image of the page, you can enlarge the page by clicking on it, and you can flip between the pages by clicking the "Next" and "Back" buttons at the bottom of the screen. Once you finish reading the ad, please click "Start Next Part of Study" to move to the next part of the study. You may begin when you are ready.

[PROGRAMMER: Record time in milliseconds spent on each page of the print ad.]

[PROGRAMMER: Show stimuli. TIME SPENT ON EACH PAGE IN MILLISECONDS]

[PROGRAMMER: UNLESS OTHERWISE NOTED, RECORD TIME SPENT ON EACH QUESTION IN MILLISECONDS]

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

Q1. Were you able to view the ad for DRUG X?

Yes

No → [Terminate]

Not sure → [Terminate]

Q1b. Please list the thoughts that were going through your mind as you viewed the ad for DRUG X and list them below. Use one line for each thought.

[PROGRAMMER: Five separate text boxes]

--

Q2. What type of product is DRUG X? [PROGRAMMER: randomize responses]

- Over the counter drug
- Prescription drug
- Herbal supplement
- Lens cleaner
- Don't know or uncertain

Q3. What condition does DRUG X treat? [PROGRAMMER: randomize responses]

- High blood pressure
- Insomnia
- Migraine headaches
- Seasonal allergies
- Diabetes
- Acid Reflux/GERD
- Don't know or uncertain

[PROGRAMMER: Benefit question series = Q4 through Q7. Risk question series = Q8 through Q12. Randomize order of benefit question series versus risk question series]

Q4. In your own words, what are the benefits of DRUG X?
[PROGRAMMER: Four separate text boxes]

[PROGRAMMER: Randomize order of Q5-Q6]

(Perceived Benefit)

Q5. Based on the information in the ad, how effective would DRUG X be for you?

- | | | | | | |
|------------|---|---|---|------------|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | | | | | |
| Not at all | | | | Moderately | |

[PROGRAMMER: Randomize order of Q9-Q10]

(Perceived Risk)

Q9. Based on the information in the ad, how safe would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
Safe			safe		
safe					

Q10. Based on the information in the ad, how risky would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
risky			risky		
risky					

Q11. Based on the information in this ad, how likely is it that you would have a side effect from DRUG X?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
likely			likely		
likely					

[PROGRAMMER: Randomize order of Q12a-i. Record time spent on series.]

(Recall of Risks)

Q12. Based on the information in the ad, please check which of the following are risks of taking DRUG X.

	Yes	No	Don't Know
a. TTP is a risk when you take DRUG X		x	
b. You need blood tests when taking DRUG X.		x	
c. People with liver problems should not take DRUG X.	x		
d. A common side effect of DRUG X is ringing in the ears.	x		
e. A common side effect of DRUG X is blurred vision.	x		
f. People with a history of migraine headaches should not take DRUG X.	x		
g. A common side effect of DRUG X is dizziness.	x		
h. People with kidney problems should not take DRUG X.		x	
i. A common side effect of DRUG X is joint pain.		x	
j. DRUG X may cause hallucinations.	x		

[PROGRAMMER: Rotate order of Q13-Q14]

(Perceived Comparative Benefit and Risk)

Q13. Compared to other treatments you could take for insomnia, how well do you think DRUG X works?

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

Q14. Compared to other treatments you could take for insomnia, how safe or risky do you think DRUG X is?

- Much safer
- Somewhat safer
- About the same

Somewhat riskier
Much riskier

[PROGRAMMER: If Q13 = much better (1) or Q13 = somewhat better (2), ask Q15]

Q15. You said DRUG X works better than other treatments for insomnia. What in the ad made you say DRUG X works better?

[PROGRAMMER: Four separate text boxes]

Codes to be determined through pretesting

[PROGRAMMER: If Q14 = somewhat riskier (4) or Q14 = much riskier (5), ask Q16]

Q16. You said DRUG X was more risky than other treatments for insomnia. What in the ad made you say DRUG X was more risky?

[PROGRAMMER: Four separate text boxes]

Codes to be determined through pretesting

Q17. Thinking overall about the risks and benefits of DRUG X, would you say it has:

1	2	3	4	5	6	7
More risks benefits than benefits risks			Equal risks and benefits			More than

[PROGRAMMER: Randomize order of Q18a-d. Record time spent on series.]

(Risk/Benefit Tradeoff)

Q18. Please rate your agreement or disagreement with each of the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. The ad clearly communicated the <i>benefits</i> of DRUG X.					
b. The ad clearly communicated the <i>risks</i> of DRUG X.					
c. The ad evenly balanced the <i>risks and benefits</i> of DRUG X.					

(Behavioral Intention)

Q19a. How likely or not likely are you to look for more information about DRUG X?

- Not at all likely
- Somewhat likely
- Very likely
- Extremely likely

Q19b. How likely or not likely are you to switch to DRUG X?

- Not at all likely
- Somewhat likely
- Very likely
- Extremely likely

(Perceived Quality)

Q20. How would you rate the quality of DRUG X?

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

[PROGRAMMER: Randomize order of Q21a-c]

(Attitude toward Ad. From Bhutada et al., 2009, Shen & Chen, 2007, and MacKenzie & Lutz, 1989)

next few questions, please think only about the **coupon or offer** mentioned in the ad.

Q22b. What did the coupon or offer say? Please choose one. [PROGRAMMER: Randomize response choices]

- “Money-Back Guarantee”
- “Free 7-day Trial”
- “Free 30-day Trial”
- “\$20 off cost of your prescription”
- “#1 prescribed”
- “Buy one, get one free”
- “Buy two, get one free”
- “\$20 off the cost of your co-pay”
- Don't know or uncertain

[Programmer: If OFFER=NONE, skip Q23 and Q24]
[PROGRAMMER: SHOW AD AGAIN]

(Inferences about Offer)

Q23a. In your own words, list all your thoughts, reactions and ideas that went through your mind while you were looking at the **coupon or offer** in the ad for DRUG X. Please use a separate line for each thought.

[PROGRAMMER: Five separate text boxes]

Q23b. For each of the thoughts, reactions and ideas you listed, indicate whether the thought was positive, negative or neutral.

[PROGRAMMER: Display responses from Q23a. For each response, include a drop-down choice box or other appropriate choice box with the choices POSITIVE, NEGATIVE, NEUTRAL]

You said...	Is it...
[insert each response from Q24a above in a separate box]	POSITIVE NEGATIVE NEUTRAL

(Peripheral Cue)

Q24a. To what extent do you agree or disagree that the **coupon or offer** was:

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. Noticeable					
b. Believable					
c. Distracting					

Q24b. How likely would you be to use this coupon or offer for DRUG X?

1 2 3 4 5 6 7
 Definitely use Definitely not
 the offer use the offer

[PROGRAMMER: Randomize order of Q25a-d]
 (Skepticism)

Q25a. How likely is it that the benefits of the drug presented in this ad are true?

1 2 3 4 5 6 7 8 9
 Not at all Extremely
 Likely Likely

Q25b. How skeptical are you about the truth of the benefits of the drug presented in this ad?

1 2 3 4 5 6 7 8 9
 Not at all Extremely
 Skeptical Skeptical

Q25c. How likely is it that the risks of the drug presented in this ad is true?

1 2 3 4 5 6 7 8 9
 Not at all Extremely
 Likely Likely

Q25d. How skeptical are you about the truth of the risks of the drug presented in this ad?

generally true.					
h. The price of the product is a good indicator of its quality.					
i. You always have to pay a bit more for the best.					

(Subjective Health Literacy)

Q28. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Rarely
- Sometimes
- Often
- Always

(Objective numeracy)

Q29. Now here are some questions that require you to use numbers to solve the problem. Some are easy, and others are more difficult. Please don't use a calculator: We'd like you to answer on your own. Remember, almost everyone will have trouble with these questions, so don't be upset if some are difficult—just do your best!

[PROGRAMMER: DO NOT randomize Q29a-e]

a. What is the correct answer:

$$17 - 8 + 4 = ?$$

- a. 11
- b. 13
- c. 21
- d. 23
- e. 29
- f. Don't know

b. What is the correct answer:

$$100 \times 15 \times 20 = ?$$

- a. 1,500
- b. 15,000
- c. 30,000

- d. 150,000
- e. 300,000
- f. Don't know

c. 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?

___ times out of 1,000 [PROGRAMMER: set acceptable range from 0 to 1,000]

d. 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 BIG BUCKS LOTTERY?

_____ people [PROGRAMMER: set acceptable range from 0 to 1,000]

e. In ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME PUBLISHING SWEEPSTAKES will win a car?

___ percent [PROGRAMMER: set acceptable range from .001 to 100]

[Q30-Q31 BLANK]

Now a few questions to help us describe our sample of participants.

Q32. Do you have sleep problems, such as trouble falling asleep, staying asleep, or insomnia?

Yes

No

Don't know or uncertain

Q33. In general, how much do you feel you know about sleep problems?

A lot

A good bit

Some

Only a slight amount

Nothing at all

Q34. In general, how much do you feel you know about **treatments** for sleep problems?

A lot

- A good bit
- Some
- Only a slight amount
- Nothing at all

Q35. What type of product are you using to treat your sleep problems? You may select more than one.

- Prescription drug
- Over the counter drug
- Herbal supplement
- Some other product
- Behavior changes
- Nothing/I am not treating my sleep problems [{skip to Q37}](#)

Q36. How satisfied or dissatisfied are you with the treatment for your sleep problems that you are using now?

- Very satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Very dissatisfied

(Likelihood of Switching)

Q37. Based on what you read in the ad for DRUG X, how likely are you to switch from your current treatment to DRUG X?

- | | | | | | |
|------------|---|---|------------|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | | | | | |
| Not at all | | | Moderately | | |
| Very | | | likely | | |
| likely | | | | | |
| likely | | | | | |

[Q38, Q39 BLANK]

Q40. What did you use to complete today's survey?

- Laptop computer / Netbook computer
- Desktop computer
- Handheld phone (iPhone, Blackberry, Droid)
- Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
- Other: _____

Q41. Did you receive any help on the questions that had numbers in them from anything or anyone (e.g., calculator, other person, website)? It's okay if you did—we just want an honest answer.

Yes (write source _____)

No

Q42. 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 Q43)

Don't Know

Q43. Does your current insurance plan help pay for prescription drugs?

Yes

No

Don't Know

QP1. Did you read the instructions at the beginning of the study?

Yes

No

[End time: _____]

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

The purpose of this research is to learn about consumer reactions to medical advertising. In order to get a real-life reaction to this information, we created a brand to use in this study. DRUG X is not a real product and it is not available for sale. Please see your healthcare professional for questions about insomnia.

END

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Advertisements on Consumer Product Perceptions

DRAFT Questionnaire: PRETEST 2

Programming instructions are indicated in blue font.

[PROGRAMMER:

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Interview Protocol

(Present Informed Consent Form. Participants will be blind to FDA’s sponsorship.)

[PROGRAMMER: Screen 1. TIME SPENT ON SCREEN IN MILLISECONDS]

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 advertising for a new product. We will show you an ad for a new product then ask you some questions about it. Your answers are private and will not be connected with your name. Your input is extremely valuable.

[PROGRAMMER: Screen 2. TIME SPENT ON SCREEN IN MILLISECONDS]

The ad has two pages. We will ask you some questions about the ad after you have finished reading it.

[PROGRAMMER: SCREEN 3]

If you want to see a bigger image of the page, you can enlarge the page by clicking on it, and you can flip between the pages by clicking the “Next” and “Back” buttons at the bottom of the screen. Once you finish reading the ad, please click “Start Next Part of Study” to move to the next part of the study. You may begin when you are ready.

[PROGRAMMER: Record time in milliseconds spent on each page of the print ad.]

[PROGRAMMER: Show stimuli. TIME SPENT ON EACH PAGE IN MILLISECONDS]

[PROGRAMMER: UNLESS OTHERWISE NOTED, RECORD TIME SPENT ON

EACH QUESTION IN MILLISECONDS]

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

Q1. Were you able to view the ad for DRUG X?

Yes

No → [Terminate]

Not sure → [Terminate]

Q2. What type of product is DRUG X? [PROGRAMMER: randomize responses]

Over the counter drug

Prescription drug

Herbal supplement

Lens cleaner

Don't know or uncertain

Q3. What condition does DRUG X treat? [PROGRAMMER: randomize responses]

High blood pressure

Insomnia

Migraine headaches

Seasonal allergies

Diabetes

Acid Reflux/GERD

Don't know or uncertain

[PROGRAMMER: Benefit question series = Q4 through Q7. Risk question series = Q8 through Q12. Randomize order of benefit question series versus risk question series]

Q4. In your own words, what are the benefits of DRUG X?

[PROGRAMMER: Four separate text boxes]

[PROGRAMMER: Randomize order of Q5-Q6]

(Perceived Benefit)

Q5. Based on the information in the ad, how effective would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very			effective		
effective					

Q6. Based on the information in the ad, how well would DRUG X work for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very			well		
well					

[PROGRAMMER: randomize order of Q7a-h. Record time spent on series]

(Recall of Benefits)

Q7. Based on the information in the ad, please check which of the following are benefits of taking DRUG X.

	Yes	No	Don't Know
a. DRUG X is taken twice a day.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. DRUG X can be used for up to 3 months.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. DRUG X can help you stay asleep for up to 8 hours.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. DRUG X is safe for people with kidney problems.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. DRUG X treats insomnia in adults and children ages 10 and up.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. DRUG X is the #1 prescribed medication for insomnia.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g. DRUG X combines two ingredients.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. DRUG X can be habit-forming.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
i. DRUG X leaves your system within 4 hours.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Q8. In your own words, what are the risks of DRUG X?

[PROGRAMMER: Four separate text boxes]

[PROGRAMMER: Randomize order of Q9-Q10]

(Perceived Risk)

Q9. Based on the information in the ad, how safe would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
Safe			safe		
safe					

Q10. Based on the information in the ad, how risky would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
risky			risky		
risky					

Q11. Based on the information in this ad, how likely is it that you would have a side effect from DRUG X?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
likely			likely		
likely					

[PROGRAMMER: Randomize order of Q12a-i. Record time spent on series.]

(Recall of Risks)

Q12. Based on the information in the ad, please check which of the following are risks of taking DRUG X.

	Yes	No	Don't Know
a. TTP is a risk when you take DRUG X		x	
b. You need blood tests when taking DRUG X.		x	
c. People with liver problems should not take DRUG X.	x		
d. A common side effect of DRUG X is ringing in the ears.	x		
e. A common side effect of DRUG X is blurred vision.	x		
f. People with a history of depression should not take DRUG X.	x		
g. A common side effect of DRUG X is dizziness.	x		
h. People with kidney problems should not take DRUG X.		x	
i. A common side effect of DRUG X is joint pain.		x	
j. DRUG X may cause hallucinations.	x		

[PROGRAMMER: Rotate order of Q13-Q14]

(Perceived Comparative Benefit and Risk)

Q13. Compared to other treatments you could take for insomnia, how well do you think DRUG X works?

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

Q14. Compared to other treatments you could take for insomnia, how safe or risky do you think DRUG X is?

Much safer
 Somewhat safer
 About the same
 Somewhat riskier
 Much riskier

Q17. Thinking overall about the risks and benefits of DRUG X, would you say it has:

1 2 3 4 5 6 7
 More risks Equal risks More
 benefits and benefits than
 than benefits risks than
 risks

[PROGRAMMER: Randomize order of Q18a-c. Record time spent on series.]

(Risk/Benefit Tradeoff)

Q18. Please rate your agreement or disagreement with each of the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
d. The ad clearly communicated the <i>benefits</i> of DRUG X.					
e. The ad clearly communicated the <i>risks</i> of DRUG X.					
f. The ad evenly balanced the <i>risks and benefits</i> of DRUG X.					

(Behavioral intention)

Q19a. How likely or not likely are you to look for more information about DRUG X?

Not at all likely
 Somewhat likely
 Very likely
 Extremely likely

Q19b. How likely or not likely are you to switch to DRUG X?

Not at all likely
 Somewhat likely

Very likely
Extremely likely

(Perceived Quality)

Q20. How would you rate the quality of DRUG X?

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

[Q21 BLANK]

(Manipulation Checks)

Q22a. Do you remember seeing a coupon or other type of offer in the ad for DRUG X?

Yes
No
Not sure

[If OFFER=NONE, skip to Q25a]

Q22b. What did the coupon or offer say? Please choose one. [PROGRAMMER:
Randomize response choices]

“Money-Back Guarantee”
“Free 7-day Trial”
“Free 30-day Trial”
“Free refill”
“\$20 off cost of your prescription”
“#1 prescribed”
“Buy one, get the next one free”
“Buy two, get the next one free”
“\$20 off the cost of your co-pay”
Don't know or uncertain [always last]

[PROGRAMMER: SHOW AD AGAIN]

(Inferences about Offer)

Q23a. In your own words, list all your thoughts, reactions and ideas that went through your mind while you were looking at the coupon or offer in the ad for DRUG X. Please use a separate line for each thought.

[PROGRAMMER: Five separate text boxes]

Definitely use
the offer

Definitely not
use the offer

(Peripheral Cue)

Q24a. To what extent do you agree or disagree that the **coupon or offer** was:

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
d. Noticeable					
e. Believable					
f. Distracting					

Q24b. How likely would you be to use this coupon or offer for DRUG X?

1 2 3 4 5 6 7
Definitely use Definitely not
the offer use the offer

[PROGRAMMER: Randomize order of Q25a-d]
(Skepticism)

Q25a. How likely is it that the benefits of the drug presented in this ad are true?

1 2 3 4 5 6 7 8 9
Not at all Extremely
Likely Likely

Q25b. How skeptical are you about the truth of the benefits of the drug presented in this ad?

1 2 3 4 5 6 7 8 9
Not at all Extremely
Skeptical Skeptical

Q25c. How likely is it that the risks of the drug presented in this ad is true?

1 2 3 4 5 6 7 8 9
Not at all Extremely
Likely Likely

Q25d. How skeptical are you about the truth of the risks of the drug presented in this ad?

generally true.					
q. The price of the product is a good indicator of its quality.					
r. You always have to pay a bit more for the best.					

(Subjective Health Literacy)

Q28. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Rarely
- Sometimes
- Often
- Always

(Objective numeracy)

Q29. Now here are some questions that require you to use numbers to solve the problem. Some are easy, and others are more difficult. Please don't use a calculator: We'd like you to answer on your own. Remember, almost everyone will have trouble with these questions, so don't be upset if some are difficult—just do your best!

[PROGRAMMER: DO NOT randomize Q29a-e]

f. What is the correct answer:

$$17 - 8 + 4 = ?$$

- g. 11
- h. 13
- i. 21
- j. 23
- k. 29
- l. Don't know

g. What is the correct answer:

$$100 \times 15 \times 20 = ?$$

- a. 1,500
- b. 15,000
- c. 30,000

- d. 150,000
- e. 300,000
- f. Don't know

h. 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?

___ times out of 1,000 [PROGRAMMER: set acceptable range from 0 to 1,000]

i. 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 BIG BUCKS LOTTERY?

_____ people [PROGRAMMER: set acceptable range from 0 to 1,000]

j. In ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME PUBLISHING SWEEPSTAKES will win a car?

___ percent [PROGRAMMER: set acceptable range from .001 to 100]

[Q30 AND Q31 BLANK]

Now a few questions to help us describe our sample of participants.

Q32. Do you have sleep problems, such as trouble falling asleep, staying asleep, or insomnia?

- Yes
- No
- Don't know or uncertain

Q33. In general, how much do you feel you know about sleep problems?

- A lot
- A good bit
- Some
- Only a slight amount
- Nothing at all

Q34. In general, how much do you feel you know about **treatments** for sleep problems?

- A lot

- A good bit
- Some
- Only a slight amount
- Nothing at all

Q35. What type of product are you using to treat your sleep problems? You may select more than one.

- Prescription drug
- Over the counter drug
- Herbal supplement
- Some other product
- Behavior changes
- Nothing/I am not treating my sleep problems [{skip to Q37}](#)

Q36. How satisfied or dissatisfied are you with the treatment for your sleep problems that you are using now?

- Very satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Very dissatisfied

(Likelihood of Switching)

Q37. Based on what you read in the ad for DRUG X, how likely are you to switch from your current treatment to DRUG X?

- | | | | | | |
|------------|---|---|------------|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | | | | | |
| Not at all | | | Moderately | | |
| Very | | | likely | | |
| likely | | | | | |
| likely | | | | | |

[Q38, Q39 BLANK]

Q40. What did you use to complete today's survey?

- Laptop computer / Netbook computer
- Desktop computer
- Handheld phone (iPhone, Blackberry, Droid)
- Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
- Other: _____

Q41. Did you receive any help on the questions that had numbers in them from anything or anyone (e.g., calculator, other person, website)? It's okay if you did—we just want an honest answer.

Yes (write source _____)
No

Q42. 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 Q43)
Don't Know

Q43. Does your current insurance plan help pay for prescription drugs?

Yes
No
Don't Know

QP1. Did you read the instructions at the beginning of the study?

Yes
No

[End time: _____]

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

The purpose of this research is to learn about consumer reactions to medical advertising. In order to get a real-life reaction to this information, we created a brand to use in this study. DRUG X is not a real product and it is not available for sale. Please see your healthcare professional for questions about insomnia.

END

Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print
Advertisements on Consumer Product Perceptions

DRAFT Questionnaire: PRETEST 3 AND MAIN STUDIES

Programming instructions are indicated in blue font.

Questions specific to PRETEST 3 / STUDY 1 are in GREEN.

Questions specific to STUDY 2 are in RED.

[PROGRAMMER:

- The viewing time of each page of the ad must be timed separately in milliseconds.
- Program progresses to the questioning in a “one-way” manner
- Record time in milliseconds spent on each screen (including questions) throughout protocol.]

Interview Protocol

(Present Informed Consent Form. Participants will be blind to FDA’s sponsorship.)

[PROGRAMMER: Screen 1. TIME SPENT ON SCREEN IN MILLISECONDS]

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 advertising for a new product. We will show you an ad for a new product then ask you some questions about it. Your answers are private and will not be connected with your name. Your input is extremely valuable.

[PROGRAMMER: Screen 2. TIME SPENT ON SCREEN IN MILLISECONDS]

Some ads have two pages, others have only one. We will ask you some questions about the ad after you have finished reading it.

[PROGRAMMER: Screen 3. TIME SPENT ON SCREEN IN MILLISECONDS]

If you want to see a bigger image of the page, you can enlarge the page by clicking on it, and for two page ads you can flip between the pages by clicking the “Next” and “Back” buttons at the bottom of the screen. Once you finish reading the ad, please click “Start Next Part of Study” to move to the next part of the study. You may begin when you are ready.

[PROGRAMMER: Record time in milliseconds spent on each page of each print ad.]

[PROGRAMMER: Show stimuli. TIME SPENT ON EACH PAGE IN MILLISECONDS]

[PROGRAMMER: UNLESS OTHERWISE NOTED, RECORD TIME SPENT ON EACH QUESTION IN MILLISECONDS]

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

Q1. Were you able to view the ad for DRUG X?

Yes

No → [Terminate]

Not sure → [Terminate]

Q1b. Please list the thoughts that were going through your mind as you viewed the ad for DRUG X and list them below. Use one line for each thought.

[PROGRAMMER: Five separate text boxes]

[PRETEST 3 GROUP 1: Provide link on screen to view ad. PRETEST 3 GROUP 2: Do not show ad.]

Q2. What type of product is DRUG X? [PROGRAMMER: randomize responses]

Over the counter drug

Prescription drug

Herbal supplement

Lens cleaner

Not sure

Q3. What condition does DRUG X treat? [PROGRAMMER: randomize responses]

High blood pressure

Insomnia

Migraine headaches

Seasonal allergies

Diabetes

Acid Reflux/GERD
Not sure/Don't know

[PROGRAMMER: Benefit question series = Q4 through Q7. Risk question series = Q8 through Q12. Randomize order of benefit question series versus risk question series]

Q4. In your own words, what are the benefits of DRUG X?
[PROGRAMMER: Four separate text boxes]

[PROGRAMMER: Randomize order of Q5-Q6]

(Perceived Benefit)

Q5. Based on the information in the ad, how effective would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very			effective		
effective					

Q6. Based on the information in the ad, how well would DRUG X work for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very			well		
well					

[PROGRAMMER: randomize order of Q7a-h. Record time spent on series]

(Recall of Benefits)

[PRETEST 3 AND STUDY 1 ONLY]

Q7. Based on the information in the ad, please check which of the following are benefits of taking DRUG X.

	Yes	No	Don't Know
a. DRUG X is taken twice a day.		x	
b. DRUG X can be used for up to 3 months.	x		
c. DRUG X can help you stay asleep for up to 8 hours.	x		
d. DRUG X is safe for people with kidney problems.	x		
e. DRUG X treats insomnia in adults and children ages 10 and up.		x	
f. DRUG X is the #1 prescribed medication for insomnia.		x	
g. DRUG X combines two ingredients.	x		
h. DRUG X can be habit-forming.		x	
i. DRUG X leaves your system within 4 hours.		x	

[STUDY 2 ONLY]

Q7. Based on the information in the ad, please check which of the following are benefits of taking DRUG X.

	Yes	No	Don't Know
a. You take DRUG X once a day.		X	
b. DRUG X helps lower your blood pressure.	X		
c. You take DRUG X only once a month.	X		
d. DRUG X can reduce your bad cholesterol levels.		X	
e. DRUG X can reduce your risk of having a stroke.	X		
f. DRUG X is the only high blood pressure medication approved to treat children.		X	
g. DRUG X can help prevent heart attacks.	X		

Q8. In your own words, what are the risks of DRUG X?

[PROGRAMMER: Four separate text boxes]

[PROGRAMMER: Randomize order of Q9-Q10]

(Perceived Risk)

Q9. Based on the information in the ad, how safe would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
Safe			safe		
safe					

Q10. Based on the information in the ad, how risky would DRUG X be for you?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
risky			risky		
risky					

Q11. Based on the information in this ad, how likely is it that you would have a side effect from DRUG X?

1	2	3	4	5	6
7					
Not at all			Moderately		
Very					
likely			likely		
likely					

[PROGRAMMER: Randomize order of Q12a-i. Record time spent on series.]

(Recall of Risks)

[PRETEST 3 AND STUDY 1 ONLY]

Q12. Based on the information in the ad, please check which of the following are risks of taking DRUG X.

	Yes	No	Don't Know
a. TTP is a risk when you take DRUG X		x	
b. You need blood tests when taking DRUG X.		x	
c. People with liver problems should not take DRUG X.	x		
d. A common side effect of DRUG X is ringing in the ears.	x		
e. A common side effect of DRUG X is blurred vision.	x		
f. People with a history of depression should not take DRUG X.	x		
g. A common side effect of DRUG X is dizziness.	x		
h. People with kidney problems should not take DRUG X.		x	
i. A common side effect of DRUG X is joint pain.		x	
j. DRUG X may cause hallucinations.	x		

[STUDY 2 ONLY]

Q12. Based on the information in the ad, please check which of the following are risks of taking DRUG X.

	Yes	No	Don't Know
a. Taking some kinds of over-the-counter cough medicines at the same time as taking DRUG X increases your risk of having a heart attack.		X	
b. DRUG X may cause excitability.		X	
c. If you have a very slow heart rate, you should not take DRUG X.	X		
d. DRUG X may cause you to have blurry vision.	X		

e. One of the most common side effects is tiredness.	X		
f. Antibiotics may not work as well if you use DRUG X at the same time.		X	
g. You should have regular eye exams when you take DRUG X.	X		
h. One of the most common side effects is nausea.		X	

[PROGRAMMER: Rotate order of Q13-Q14]

(Perceived Comparative Benefit and Risk)

Q13. Compared to other treatments you could take for insomnia, how well do you think DRUG X works?

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

Q14. Compared to other treatments you could take for insomnia, how safe or risky do you think DRUG X is?

- Much safer
- Somewhat safer
- About the same
- Somewhat riskier
- Much riskier

[PROGRAMMER: If Q13 = much better (1) or Q13 = somewhat better (2), ask Q15]

Q15. You said DRUG X works better than other treatments for insomnia. What in the ad made you say DRUG X works better?

[PROGRAMMER: Four separate text boxes]

--

Codes to be determined through pretesting

[PROGRAMMER: If Q14 = somewhat riskier (4) or Q14 = much riskier (5), ask Q16]

Q16. You said DRUG X was more risky than other treatments for insomnia. What in the ad made you say DRUG X was more risky?

[PROGRAMMER: Four separate text boxes]

Codes to be determined through pretesting

Q17. Thinking overall about the risks and benefits of DRUG X, would you say it has:

1	2	3	4	5	6	7
More risks benefits than benefits risks			Equal risks and benefits			More than

[PROGRAMMER: Randomize order of Q18a-d. Record time spent on series.]

(Risk/Benefit Tradeoff)

Q18. Please rate your agreement or disagreement with each of the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
g. The ad clearly communicated the <i>benefits</i> of DRUG X.					
h. The ad clearly communicated the <i>risks</i> of DRUG X.					
i. The ad evenly					

balanced the <i>risks and benefits</i> of DRUG X.					
---	--	--	--	--	--

(Behavioral Intention)

Q19a. How likely or not likely are you to look for more information about DRUG X?

- Not at all likely
- Somewhat likely
- Very likely
- Extremely likely

Q19b. How likely or not likely are you to switch to DRUG X?

- Not at all likely
- Somewhat likely
- Very likely
- Extremely likely

(Perceived Quality)

Q20. How would you rate the quality of DRUG X?

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

[PROGRAMMER: Randomize order of Q21a-c]

(Attitude toward Ad. From Bhutada et al., 2009, Shen & Chen, 2007, and MacKenzie & Lutz, 1989)

Q21. In your opinion, was the ad for DRUG X:

- a. 1 2 3 4 5 6
 7
 Good
 Bad

- b. 1 2 3 4 5 6
 7
 Pleasant
 Unpleasant

- c. 1 2 3 4 5 6
 7
 Favorable

Unfavorable

(Manipulation Checks)

Q22a. Do you remember seeing a **coupon or other type of offer** in the ad for DRUG X?

Yes

No

Not sure

[If OFFER=NONE, skip to Q25a]

[PROGRAMMER: SHOW AD AGAIN]

This ad had information about a **coupon or offer** for DRUG X. When answering the next few questions, please think only about the **coupon or offer** mentioned in the ad.

Q22b. What did the coupon or offer say? Please choose one. [PROGRAMMER: Randomize response choices]

- “Money-Back Guarantee”
- “Free 7-day Trial”
- “Free 30-day Trial”
- “\$20 off cost of your prescription”
- “#1 prescribed”
- “Buy one, get one free”
- “Buy two, get one free”
- “\$20 off the cost of your co-pay”
- Don't know or uncertain

[Programmer: If OFFER=NONE, skip Q23 and Q24]

[PROGRAMMER: SHOW AD AGAIN]

(Inferences about Offer)

Q23a. In your own words, list all your thoughts, reactions and ideas that went through your mind while you were looking at the **coupon or offer** in the ad for DRUG X. Please use a separate line for each thought.

[PROGRAMMER: Five separate text boxes]

so.					
w. Beyond the money I save, redeeming coupons gives me a sense of joy.					
x. Generally speaking, the higher the price of a product, the higher the quality.					
y. The old saying “you get what you pay for” is generally true.					
z. The price of the product is a good indicator of its quality.					
aa. You always have to pay a bit more for the best.					

(Subjective Health Literacy)

Q28. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Rarely
- Sometimes
- Often
- Always

(Objective numeracy)

Q29. Now here are some questions that require you to use numbers to solve the problem. Some are easy, and others are more difficult. Please don't use a calculator: We'd like you to answer on your own. Remember, almost everyone will have trouble with these questions, so don't be upset if some are difficult—just do your best!

[PROGRAMMER: DO NOT randomize Q29a-e]

- k. What is the correct answer:

$$17 - 8 + 4 = ?$$

- m. 11
- n. 13
- o. 21
- p. 23
- q. 29
- r. Don't know

- l. What is the correct answer:

$$100 \times 15 \times 20 = ?$$

- a. 1,500
- b. 15,000
- c. 30,000
- d. 150,000
- e. 300,000
- f. Don't know

- m. 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?

___ times out of 1,000 [PROGRAMMER: set acceptable range from 0 to 1,000]

- n. 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 BIG BUCKS LOTTERY?

_____ people [PROGRAMMER: set acceptable range from 0 to 1,000]

- o. In ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME PUBLISHING SWEEPSTAKES will win a car?

___ percent [PROGRAMMER: set acceptable range from .001 to 100]

(Subjective Numeracy 1st part)

Q30. For each of the following questions, please check the box that best reflects how good you are at doing the following things:

- a. How good are you at working with fractions?

Q36. How satisfied or dissatisfied are you with the treatment for your sleep problems that you are using now?

- Very satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Very dissatisfied

[STUDY 2 ONLY]

Q32. Do you have high blood pressure?

- Yes
- No
- Don't know or uncertain

Q33. In general, how much do you feel you know about high blood pressure?

- A lot
- A good bit
- Some
- Only a slight amount
- Nothing at all

Q34. In general, how much do you feel you know about **treatments** for high blood pressure?

- A lot
- A good bit
- Some
- Only a slight amount
- Nothing at all

Q35. What type of product are you using to treat your high blood pressure? You may select more than one.

- Prescription drug
- Over the counter drug
- Herbal supplement
- Something other product
- Behavior changes
- Nothing/I am not treating my sleep problems {skip to Q37}

Q36. How satisfied or dissatisfied are you with the treatment for your high blood pressure that you are using now?

- Very satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Very dissatisfied

(Likelihood of Switching)

Q37. Based on what you read in the ad for DRUG X, how likely are you to switch from your current treatment to DRUG X?

- | | | | | | |
|------------|---|---|------------|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | | | | | |
| Not at all | | | Moderately | | |
| Very | | | | | |
| likely | | | likely | | |
| likely | | | | | |

[Q38 BLANK]

Q39a. In your opinion, how risky are prescription drugs compared to over-the-counter drugs?

- | | | | | | | |
|-----------------|---|---|----------|---|---|-----------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Much less risky | | | About | | | Much more risky |
| | | | the same | | | |

Q39b. In your opinion, how effective are prescription drugs compared to over-the-counter drugs?

- | | | | | | | |
|-----------|---|---|----------|---|---|-----------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Much less | | | About | | | Much more |
| effective | | | the same | | | effective |

Q40. What did you use to complete today's survey?

- Laptop computer / Netbook computer
- Desktop computer
- Handheld phone (iPhone, Blackberry, Droid)
- Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
- Other: _____

Q41. Did you receive any help on the questions that had numbers in them from anything or anyone (e.g., calculator, other person, website)? It's okay if you did—we just want an honest answer.

Yes (write source _____)

No

Q42. 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 Q43)

Don't Know

Q43. Does your current insurance plan help pay for prescription drugs?

Yes

No

Don't Know

QP1. Did you read the instructions at the beginning of the study?

Yes

No

[End time: _____]

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

The purpose of this research is to learn about consumer reactions to medical advertising. In order to get a real-life reaction to this information, we created a brand to use in this study. DRUG X is not a real product and it is not available for sale. Please see your healthcare professional for questions about insomnia.

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