



Concept Testing: Focus Group Plan

Objectives for Focus Groups

FDA-CDER recognizes the need to improve communication to consumers on how to safely purchase prescription medicine online. Formative research recently completed by CDER provided guidance to develop concepts and themes that may help raise awareness of health risks associated with buying prescription medicine from illegal online pharmacies. This research plan describes testing of creative concepts and key messages for an FDA public outreach campaign. The objectives of the research are:

1. To assess the extent to which draft concepts and messages are understandable, relevant and appealing by current and potential consumers of independent online pharmacies
2. To elicit feedback to refine concepts, messages, and placement
3. To determine whether there are substantive sub-audiences that respond to different messaging

Method

FDA proposes conducting six (6) focus groups that will provide insight into consumers' reactions to the creative concepts and messages. The participants will be contacted and screened by a professional recruiter. The groups will be led by a trained facilitator, and a research assistant will take notes of each session. Recordings of the sessions will be transcribed, and the transcriptions, along with the notes and observations, will be used to develop a report.

The focus group participants will be adults residing in the U.S. who use Internet services to obtain prescription medicine for themselves or in a caregiver role. Twelve people will be recruited to seat 8-10 in each of six groups, for a total of 72 participants. Within each group:

- Forty (40) percent of participants will have purchased prescription medicine through Internet services connected with health insurance or "brick-and-mortar" national chain stores
- Sixty (60) percent will have purchased prescription medicine through independent online pharmacies. Examples of independent online pharmacies include legal sites such as Drugstore.com, as well as sites advertising discounts on medicines from Canada or another foreign country. By definition, these independent pharmacies will not be



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associated with U.S. health insurance or “brick-and-mortar” national chain stores.

- Participants will be mixed by gender, household income, race/ethnic origin, age

Dates and Locations

The focus groups will be conducted three weeks after OMB approval is granted, hopefully in mid-September, 2011. In order to meet our recruiting criteria, focus groups will be held both online and in large metropolitan areas. Chicago and Los Angeles are proposed because the large size and diverse populations will facilitate recruiting from a small universe of online pharmacy users. Online groups will have the advantage of recruiting from different regions of the country and from rural and urban areas. Each focus group will be 90 minutes long.

The proposed schedule is as follows:

Date*	Location	Number of Groups
Monday, September 19	Video conference	2 online groups
Tuesday, September 20	Chicago	1 in-person groups
Wednesday, September 21	Los Angeles	1 online group
Thursday, September 22	Los Angeles	2 in-person groups

*The actual dates will depend on OMB approval.

Collection Procedures

Participants will be recruited from existing lists of candidates with professional research facilities. They will be screened for eligibility using an FDA-approved script (see attached Participant Screener draft). Those successfully completing the requirements of the screening will be invited to join the focus group, and will be informed of their rights as a study participant. The recruiter will call or email participants two days before the event to remind them of the date, time, and location of the focus group. Participants will sign a release form describing the limited use of audio recordings of the sessions.

The sessions will take place in meeting facilities (courtesy of contractor Booz Allen Hamilton) or virtually via video conferencing. Per the Moderator Guide (see attached draft), after short introductions, the moderator will facilitate the discussion around the concepts and messages to be tested. There will be sufficient time during the sessions to address ideas and questions



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spontaneously generated from the discussion. At the conclusion of the sessions, participants will be thanked and directed to the FDA web site and toll-free number should they have questions on the topic. Participants will receive a check at the market rate (around \$75 - \$100) as a token of appreciation for their time.

A note taker will also be present during the sessions. All sessions will be audiotaped and transcribed.

Using the notes and transcripts, the moderator and note taker will prepare final interpretive reports for the six (6) groups. The raw data for these reports will be the words, phrases, sentences, and non-verbal responses of the participants. The final report will be based on the discursive data gathered from each group. The report will detail the characteristics of each group and will highlight variations and commonalities between the groups. Based on the findings, the report will provide recommendations for refining the messages. Since focus group research constitutes a qualitative methodology, quantitative results will not be reported.

Intended Use of Information

Findings from the research will be used to improve health communication messages. Specifically, the research will help to refine the core concepts and messages of the communications campaign. The data will not be used for the purposes of making policy or regulatory decisions.



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Online Pharmacies: Focus Groups for Concept Testing Participant Screener

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services,

Food and Drug Administration
Office of the Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

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Recruiting Grid: recruit 12 to seat 8-10 in each group for Chicago and Los Angeles; recruit 10 to seat 6-8 for online focus groups

Prescription Purchasing History	Chicago	Los Angeles	Online Focus Groups
Purchase from independent online pharmacies (60%) Purchase from online services connected to health insurance or national chain retail stores (40%)	1	2	3



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- Introduction Good day. I hope you are doing well. My name is _____ and I am calling today from XXX to see if you are interested in participating in a focus group we are conducting for the U.S. Food and Drug Administration. Participants will share opinions on a certain topic, in this case buying prescription drugs from online pharmacies. Would you mind answering a few questions to determine if you meet our criteria? All of the information you provide will remain private to the extent permitted by law.
- Question 1 Have you bought prescription medicines online? *Please consider prescription medicine any medicine requiring a doctor's prescription to treat an illness or chronic condition. Please do not include contact lenses, pet medications, or other medicines or herbal remedies that can be purchased over the counter. If they have never purchased prescription medicines online, go to not selected and end of call.*
- Question 2 Which of the following online prescription services have you used? Please state all that apply. *Read list. We wish to have 60% of our participants to have purchased from an independent online pharmacy. They do not need to be separated into different focus group sessions.*
- Online services connected to your health insurance.
 - Online services connected to a chain pharmacy (for example, CVS, RiteAid, Walgreens)
 - An independent online pharmacy
- Question 3 To the best of your knowledge, have you purchased from an online pharmacy based in a country outside the U.S.? *Please record for background purposes.*
- What is your gender? *Please include a good mix.*
- Demographic Questions How old are you? _____ years. *Please ensure that we have at least some representation across the spectrum, from some in their 20s to some in their 60s (possibly 70s) and everything in between.*
- What is your current household income? *[Record]*
- Less than \$30,000
 - \$30,000 to \$50,000
 - \$50,000 to \$75,000
 - \$75,000 to \$100,000
 - More than \$100,000



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What is the highest level of education that you have completed? *Read list. Please ensure some diversity of education across focus groups.*

- Less than a high school diploma
- High school graduate or GED
- Technical/vocational school
- Some college credit, but no degree
- Associate's degree (AA, AS)
- Bachelor's degree (BA, AB, BS)
- Master's, doctoral, or professional school degree (MA, MS, MEd, MEng, MBA, MSW, PhD, MD, JD, DVM, EdD)

Are you Hispanic or Latino? *Record.*

- Yes
- No

What is your ethnicity? Please select one or more. *Read list. We wish to have no more than 65% of our participants include white people.*

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Pacific Islander

Focus Group
Details/
Request for
Participation

Thank you very much for your time. You are a perfect candidate for our focus group. Each focus group will be approximately 90 minutes long, and will be held on <date/time> at <location>. You will be compensated \$75 for your time, and light refreshments will also be available. Also, so you are aware, the focus group session will be audio taped to ensure accuracy. However, your participation and everything you say during the discussion will be private to the extent permitted by law.

Would you be willing to participate in our focus group? *If yes, continue to Reminder Email/Phone Call. If no, go to End of Call.*

Reminder
Email/ Phone
Call

We will provide you a reminder two to three days in advance of the focus group, which will include the address of the facility and the day and time. Would you prefer we call you or send you an email with this information? *Email:* Would you please provide me your email address so I can send you the information? *Phone:* Is this the



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best number to reach you at or would you prefer we call a different number? What is that number? *Next go to End of Call*

- Not Selected Thank you for your willingness to participate; however, based on our criteria, we will not need your help in this set of focus groups.
- End of Call That is everything I have today. Thank you very much for your time. Have a great day.

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Online Pharmacies: Focus Groups for Concept Testing Moderator's Guide

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services,

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<p>Intro</p> <p>[5-10 minutes for Intro through Disclosures]</p>	<p>Good Afternoon. My name is XXX and I'm the moderator for today's 90 minute group discussion. This is my colleague XX, who will be observing and taking notes for us today.</p> <p>I am very pleased you could join us today. Thank you for fitting this session into your schedule. You're here today to take part in a focus group. It's a discussion to find out your opinions - like a survey, but with broad, general questions.</p> <p>We've asked you to be in this discussion to get your feedback on some materials that we will be developing related to your health and the health of others in your family and community.</p> <p>Over the course of our discussion today I will show you a few draft ideas that might appear on [website, TV, etc.]. After I show you each one, I will ask you a few questions to get your reactions.</p> <p>Based on what you tell us, the creative team will move forward with refining these ideas and eventually turning them into finished products.</p> <p>I personally had no part in designing the material, so feel free to tell me what you really think of them. All of your comments - whether positive or negative are welcome.</p>
<p>Moderator Information:</p>	<p>We work for Booz Allen Hamilton, a government contractor based in McLean, Virginia in the Washington, DC area. We conduct research like this with a wide range of people on a variety of subjects.</p>
<p>DISCLOSURES: ▶</p>	<p>The session is being recorded to make sure we capture everything you say. Likewise, as previously mentioned, XX will be taking notes as a backup. We are taping this session so we can accurately report your responses and opinions. We will not report who said what, but will focus exclusively on what was said.</p> <p><i>Check for questions about the informed consent forms signed earlier.</i></p>
<p>E. Permissions/ Logistics</p>	<p>[Bathroom location]. I just ask that only one person be up or out of the room at a time.</p>
<p>F. Guidelines</p> <p>[5-10 minutes]</p>	<p>And finally to make the best use of everyone's time, there are just a few guidelines:</p>



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with Group Introductions]	<ul style="list-style-type: none">○ Please talk one at a time - we want to accurately record and hear everyone's responses.○ Please aim toward equal "air time" so that no one talks too much or too little. I might ask you to hold your thoughts if there are others who have not gotten the chance to speak. If I do cut you off please understand that I have so many questions and so little time.○ Please give us your honest opinions. We care about what you believe, whether or not anyone else agrees with you - there really is no wrong answer.○ Please note that any information shared here is confidential, and we therefore ask you not to discuss anything shared here outside this room.
Group Introductions	<p>Just so we can get to know each other a little better. Let's start with some quick introductions.</p> <p>Let's go around the table starting on my right. Please tell us your name and what you like to do in your leisure time [or choose another ice-breaker as appropriate].</p>
Concept testing [30-45 minutes]	<p>Ok so now that we've gotten to know each other a little bit... I am going to show you some ideas regarding buying prescription drugs online. This is still very early in the process so these are just ideas. You will need to use your imagination to think about how they would look when finished. <i>[SHOW ONE PRODUCT. ROTATE PRODUCT ORDER ACROSS GROUPS. ASK THE FOLLOWING AFTER EACH SPOT.]</i></p> <ul style="list-style-type: none">○ What is your first impression?○ What is the main idea of this message? <i>Probe: What are they trying to say in this message?</i>○ Does seeing this idea make you interested in seeing more of it?○ If you were going about a typical day, how likely would this ad get your attention? Do you think you would notice it? What might help you notice it more?○ Is the idea believable?○ Is this idea relevant to you? <i>Probe: Why/why not?</i>



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	<ul style="list-style-type: none">o Who would you say they are trying to reach?o What, if anything, is it asking you to do?o Would you be likely to do anything after reading this ad? <i>Probe:</i> Look up the website?o Where would you expect to see this ad?o [If logo has not been discussed] Did you notice the logo? What do you think it means?<ul style="list-style-type: none">o Is there anything you find confusing about the logo?o Is there anything you dislike about the logo?o [If tagline is not discussed previously] What does this tagline mean to you?<ul style="list-style-type: none">o Is there anything confusing about the tagline?o Is there anything you dislike about the tagline? <p><i>[REPEAT QUESTIONS FOR OTHER PRODUCTS]</i></p> <p><i>[DISPLAY BOTH CONCEPTS SIDE BY SIDE]</i></p> <ul style="list-style-type: none">o Which of these concepts do you like best? Why?o FDA wants people to be aware of potential risks to their health if they buy prescription medicines from illegal online pharmacies. Which do you think does a better job of conveying that message?o Are there any other thoughts you have on how to get that message across?
Wrap Up [5-10 minutes]	<p>I am going to step out for a few minutes to check with my colleagues to see if there are additional questions they'd like asked. Meanwhile, I want you to think about:</p> <p>What one piece of advice would you give the people designing and distributing these messages?</p> <p><i>[STEP OUT AND RETURN].</i></p>
Closing [1 min]	<p>That concludes our questions. Thank you very much for your participation today. One of the outcomes of our work will be a campaign to consumers on how to safely purchase prescription drugs from online pharmacies, and your feedback will help tremendously as we refine these messages.</p>