

OC Risk Information
Last updated 10/22/10

DRAFT
Moderator's Guide

I. Introduction of Moderator

- A. Independent consultant hired to moderate these discussions
- B. No vested interest in receiving any particular point of view

II. Ground Rules

- A. You have been asked here to offer your views and opinions; everyone's participation is important
- B. Audio/observers
- C. Speak one at a time
- D. No side conversations
- E. No right or wrong answers
- F. It's OK to be critical. If you dislike something or disagree with something that's said, I want to hear about it.
- G. All answers will be kept private to the extent provided by law, so feel free to speak your mind.

III. Brief Explanation of the Focus Group Purpose/Introduction of Topic

We have brought you here today to talk about women-only birth control. This includes methods such as oral contraceptive pills ("the pill"), birth control patches, vaginal rings, injections, and implants. The Food and Drug Administration is taking a look at the messages in different advertising for these methods and they would like to get a sense from you of what you are taking away from the ads. There are no right or wrong answers so please feel free to speak your mind. It is okay if there is disagreement—that will provide us with important information too.

IV. Participant Introductions

To begin, I'd like to have you go around the table and introduce yourselves. Please give me:

- a. your first name only
- b. hometown
- c. hobbies

V. Preliminary Questions

1. What do you think about when I say the pill?

2. How effective do you think the pill is? (compared to other birth-control products?)
3. What are some of the drawbacks to taking the pill?
4. Does the pill have any risks? What are they?
5. Have you ever seen any advertising for the pill?
 1. Where? (on TV, radio, magazines, internet)
 2. Did you watch/read the ad or did you ignore it?

VI. Response to DTC Ads

Moderator: Show DTC ad or ads

1. Does this ad do a good job of explaining the risks as you know them?
2. Based on this ad, what are the risks of the pill?
3. How do you think the benefits and the risks compare?
4. Would you be likely to try this product or another version of the pill after seeing this ad? (Have you ever tried it or used it?)

VII. Response to Risk List

Hand participants the list of contraindications and risks (see attached).

1. This is a list of all of the people who should not take the pill and a list of all of the serious but not so common warnings about the pill. What is your reaction to this list?
2. Do you think the TV ad captures these risks? Why or why not?
3. Are there any risks here you think the average woman would not understand?
4. How would you react if all of these warnings were spoken in the ad?

Moderator: Please note that these are rare risks and that participants should talk to their doctors before making any decisions about stopping use.

VIII. False Close

Moderator checks with observers to see if they have additional questions or clarifications.

IX. Close

Thank you for spending your time with us tonight. Your comments are very helpful.

Who should NOT take the pill?

Women:

- with weak kidneys
- with a poorly working liver
- with adrenal gland problems
- who've had thrombophlebitis
- with a history of Deep Vein Thrombosis
- with heart diseases
- with high blood pressure
- with certain kinds of diabetes
- with certain kinds of headaches
- who have had major surgery who have to stay still for a long time
- with breast cancer
- with endometrial cancer
- with unexplained abnormal bleeding from the vagina
- who are jaundiced
- who are or might be pregnant
- who have a liver tumor or active liver disease
- who smoke heavily and are over 35 years of age

What are the major warnings?

- Chance of death increases greatly if heavy smoker and over age 35
- Risks of stroke, liver tumors, gallbladder disease, and high blood pressure increase in women with the following conditions:
 - high blood pressure
 - high cholesterol
 - obesity
 - diabetes
- heart attack (mostly over age 35)
- stroke
- heart disease
- breast, ovarian, cervical, and endometrial cancer
- liver tumors
- partial or complete loss of vision
- gallbladder disease
- carbohydrate and fat effects—diabetic women should be careful
- high blood pressure
- migraine headaches
- bleeding irregularities