TO: Donna Crawford, Mentor Corporation
FROM: Larry L. Bye, Field Research Corporation
RE: Protocol For Testing of Patient Informed Consent Brochure For Gel Breast Implants
DATE: May 5, 2004

This memorandum presents our recommended protocol for conducting focus group testing of the gel breast implant informed decision brochure. This protocol parallels the approach used in 2000 for the testing of the brochure for saline breast implants. The FDA reviewed and approved this protocol at that time.

BACKGROUND/OBJECTIVES

The objective of this effort is to determine if the patient informed decision brochure that Mentor and FDA have developed concerning the gel breast implants successfully communicates the risks and benefits associated with implants to patients considering the procedure.

The specific information goals targeted by the study are as follow:

- To determine whether the brochure, as currently designed, achieves its educational and informed decision objectives and, if not, how it should be revised in order to achieve them,
- To assess whether information contained in the brochure is clearly understood,
- To identify unintended effects associated with brochure exposure, e.g. inaccurate perceptions or problematic attitudes and beliefs,
- To assess the brochure's effectiveness in conveying the risks and benefits of implant use,
- To obtain patient suggestions for improvements in the brochure, and,
- To identify additional information needed by patients after they have read the brochure.

PROPOSED PROTOCOL

Our approach to accomplishing these objectives is summarized below.

Overview

We propose conducting conduct four focus group interviews, two with patients interested in breast augmentation and two with patients interested in breast reconstruction. We believe that segregating these two types of respondents into different groups is desirable given the very different psychology and circumstances surrounding reconstruction versus augmentation. We understand that the FDA has recommended use of focus group methods in order to gather the needed information. We concur that this is a reasonable way to proceed, although we recommend the gathering of some individual-level data in addition to group discussion data. This is explained more fully below.

Group Size, Interview Length and Sites

As is customary with focus group research, each group will be composed of 8-10 respondents. Interviews will last approximately two hours. In return for their time, respondents will be paid an honorarium of $75 each. The interviews will be conducted in professionally designed focus group facilities, facilities that allow for comfortable observation and audio/video recording.

We propose to conduct the interviews in two different locations: the San Francisco Bay Area and the Dallas area. These city recommendations are tentative and can be changed if it will be easier to recruit respondents in other settings. Since focus group studies involve a very small number of respondents non-randomly selected, it is not appropriate to think of them as scientific samples. Hence, it makes little difference where we conduct the interviews, especially given the nature of this project. It is very unlikely that geography will impact study conclusions.

Group Composition Specifications

Respondents will be women aged 18 plus who are interested in breast augmentation or reconstruction, the primary target audience for the patient education brochure. Participants will be selected and assigned to groups so that each group will have a representation of different ages (about one-third 18-35, one-third 36-49, and one-third age 50 plus), employment status (about half employed versus half unemployed), and level of educational attainment (about one-third high school, one-third some college, and one-third college graduates). In addition, about two-thirds will be Caucasian and one third will be of African-American, Latino, or Asian/Pacific Islander backgrounds.

None of the women will be employed as health professionals or trained in the health professions. Also, none will be employed in marketing, advertising, public relations, communications or related fields. None will have been in a focus group interview in the last year. In addition, none will have ever used breast implants of any type or be breast health activists or advocates. Further, none will have ever initiated litigation for any reason.

Respondent Recruitment Plan

Our most successful approach to recruitment in the earlier study was to gain the cooperation and support of one or more high-volume physicians identified by Mentor Corporation in each study city. We suggest primarily relying on this method for the upcoming project. Over a number of weeks, support staff in these medical practices will be asked to preliminarily screen interested potential respondents and refer them to us for further screening. If qualified they will be recruited for the interviews. Field will provide recommendations to the practice office staff on how to effectively approach and screen potential respondents. In addition, we will provide any materials that they need. We will also stay in close communication as the work unfolds so that we can promptly identify and solve any problems that develop.

We suggest discussions with Mentor personnel about whether to also use some of the other recruitment methods used on the previous project: networking with breast cancer awareness groups, Mentor mailing lists and classified advertising. As indicated above, these methods did not work very well last time. However, it is possible that changes over the last few years might make some of these approaches more effective.

Interview Content/Discussion Guide

Because of the length of the brochure, and the complexity of the information, we propose to mail it to respondents a few days prior to the interview. This will allow them to read it prior to the interview in a manner that more closely approximates real world use of the brochure. The interview itself will be conducted as follows:

- Explanation of focus group process, ground rules, and introductions. (10 min.)

- Self-administered survey completion. (15 min.)

Respondents will complete a brief self-administered questionnaire designed to yield individual-level data on a number of critical questions prior to group discussion of the brochure. The questionnaire will primarily focus on comprehension of brochure information: what respondents thought the main messages were and what was learned on the risks and benefits of implants and other important topics. Use of the questionnaire will allow us to collect these data unpolluted by group social influences. Respondents will be allowed to refer to the brochure during survey completion.

- Discussion of brochure, section-by-section. (65 min.)

The moderator will go through the brochure, section by section, and probe for detailed information about main messages and unclear or confusing content. As part of this discussion, the moderator will be alert to unintended effects of exposure to the brochure, especially perceptions and beliefs that are inconsistent with the facts presented in the document. In addition the moderator will probe for reactions to the sequencing of information, brochure layout and format, and the effectiveness of data displays and other visual aides.

The section-by-section discussion will be guided by the following questions:

1. What would you say are the main messages being communicated in this part of the brochure? (Probe for details and multiple responses.)

2. What did you learn that you did not know before reading it? (Probe for details and multiple responses.)

3. (For sections bearing on risks/benefits:) What did you learn about the potential risks and benefits of breast implants? What did you learn from the clinical studies section? How do these studies relate to you?

4. Is there anything unclear or confusing in this part of the brochure? (Probe for details and multiple responses.)

5. What did you think about the illustrations and data displays in this section? (Probe for any possible problems.)

- Overall assessment of brochure (10 min.)

At the end of the section-by-section discussion, respondents will be asked to respond to four additional questions:

1. What did you think about the sequencing of topics and layout of the brochure? (Probe for details.)

2. What did you like the most about this brochure? (Probe for specifics and multiple responses.)

3. What did you like the least? (Probe for specifics and multiple responses.)

4. What information in here will be most useful to you...in making an informed decision about whether or not to have breast implants? What was least useful?

- Identify specific suggestions for improvement. (10 min.)

Respondents will be asked to identify suggested improvements in the brochure, suggestions that have not already been identified in the discussion.

- Identify Additional Information Respondents Need. (10 min.)

Near the end of the interview, respondents will be asked to identify what additional information they would like in order to make a fully informed decision about whether or not to have a breast implant.

Data Analysis and Reporting of Findings

We will analyze both the questionnaire-derived data as well as data from the group discussions. The group discussion data will be analyzed based on verbatim written transcriptions of the interviews. We will content analyze these transcript data using standard content analytical methods. After data analysis is completed, we will prepare a formal written report outlining findings and recommendations bearing on each of the major study topics and objectives.

PROPOSED TIMELINE

We suggest the following timeline for this project:

Week 1 Finalize study design, Field Research Corporation work scope, and contract

Week 2 Select interview sites, facilities and schedule interviews

Weeks 3-4 Finalize respondent recruitment plans, group composition specifications, screening questionnaires, and other recruitment materials

Weeks 4-6 Arrange for assistance from Mentor personnel, physicians, consumer groups, and other recruitment partners/resources; brief and train everyone who will be involved in screening potential respondents

Weeks 7-10 Screen and invite eligible respondents to be in focus group interviews; finalize discussion guide, self-administered questionnaire, and necessary discussion stimuli.

Week 11 Conduct group interviews

Week 12 Present top-line report

Weeks 12-14 Analyze data and present final report

The Proposed Project Team

We propose that Field Research Corporation (Field) serve as the prime contractor. Field will assume responsibility for project planning and co-ordination and be the principal point of contact for Mentor Corporation. Field will be responsible for final study design,

development of the interview guide and any necessary discussion stimuli, moderation of the group interviews, data analysis, and preparation of a final report of study findings/recommendations. Field will also be responsible for respondent recruitment, interviewing site and logistical arrangements, audio taping of interviews, and transcription.