

**Allen, Samie Niver**

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**From:** JoAnn Kuhne [joann.kuhne@inamed.com]  
**Sent:** Tuesday, August 05, 2003 11:35 AM  
**To:** Allen, Samie Niver  
**Subject:** RE: P020056 Shelf Life Summary Table and Revised Focus Group Protocol

Hi Samie,

I apologize; this was inadvertent. Attached is the corrected protocol with the term "charts" replaced by "safety data tables". We did change the protocol before to reflect this in our initial response to you. But ... I guess that particular change didn't save for some reason when we converted from "edit mode" in the final document. Sorry, I should have caught that in proofing.

Regards,

JoAnn

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-----Original Message-----

**From:** Allen, Samie Niver [mailto: SXN@CDRH.FDA.GOV]  
**Sent:** Monday, August 04, 2003 11:59 AM  
**To:** kuhne  
**Subject:** FW: P020056 Shelf Life Summary Table and Revised Focus Group Protocol

JoAnn,  
The shelf life table looks fine. As for the protocol, you stated that you replaced "charts." However, I still see it. What that just an oversight? If so, please email me the corrected protocol.

Thanks  
Samie

-----Original Message-----

**From:** JoAnn Kuhne [mailto:joann.kuhne@inamed.com]  
**Sent:** Wednesday, July 30, 2003 9:29 PM  
**To:** Allen, Samie Niver  
**Subject:** P020056 Shelf Life Summary Table and Revised Focus Group Protocol

Samie,

Attached is the completed Shelf Life Summary Table and revised Focus Group Protocol. Per your request we have filled in the missing blanks of the Shelf Life Table that you drafted and also included the changes that we discussed during our TC on Monday. Also as you requested, we modified the Focus Group Study Protocol to reflect the addition of one revision conference, which results in a total of five focus group conferences. Furthermore, page 12 of the protocol was modified to replace the term "charts"

with "safety data tables", per your additional request.

Regards,

JoAnn

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**Inamed Corporation Proposed Protocol for the Focus Group Testing  
of  
*MAKING AN INFORMED DECISION:  
SILICONE-FILLED BREAST IMPLANTS***

**GENERAL OBJECTIVES**

To ensure that the consumer information for McGhan Silicone-Filled Breast Implants meets patient needs as well as FDA requirements, research will be conducted to evaluate the patient informed decision brochure in development. The overall goals of the research will be to understand:

- What questions and concerns women have when considering breast augmentation, breast reconstruction and breast implant revision;
- To what degree the current literature addresses these questions;
- What additional information should be provided;
- If the language is understandable to the lay audience;
- If the language is clear and well organized; and
- What, if any, improvements can be made to the current literature.

**METHODOLOGY**

The focus groups will be conducted in person, rather than on the telephone, since the brochure is extensive and quite detailed, and it might be confusing for some consumers/patients to unravel without a moderator in the room. An experienced professional will be contracted to conduct the focus groups and summarize the results.

Five in-person focus groups will be conducted (minimum eight respondents per conference):

Augmentation

- 1 conference with women who *have had breast augmentation*
- 1 conference with women who *have considered or are considering breast augmentation*

Reconstruction

- 1 conference with women who *have had breast reconstruction*
- 1 conference with women who *have considered or are considering breast reconstruction*

Revision

- 1 conference with women who *currently have breast implants and are considering or may have considered revision surgery to replace one or both of their implants*

Specific screening criteria were developed at the inception of the project (Appendix A). Inamed Corporation and the contractor will finalize an appropriate list of screening questions to be asked of potential respondents in order to identify the target audience and ensure testing of the right individuals. A preliminary interview guide was developed at the inception of the project (Appendix B), but the final interview guide will be prepared by the contractor.

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A professional recruiter will use the questions to interview potential respondents who have been drawn from their database. The conferences will be approximately 90 minutes to two hours in duration.

**QUESTIONS TO BE ASKED OF THE FOCUS GROUPS**

1. What did you think about the layout (format) of the brochure?
2. What would you say are the main messages you got from reading this booklet?
3. What new things did you learn from this booklet that you did not know before reading it?
4. What did you like about this booklet?
5. What did you dislike about this booklet? (Probe: anything offensive)
6. What information will be most useful to you in helping you make an informed decision about whether or not to have silicone-filled breast implants? Not useful?
7. What did you think about the illustrations in the booklet?
8. What sections of the brochure or any terms used in the brochure did you find confusing or difficult to understand?
9. What did you learn about the potential risks and benefits of breast implants?
10. What did you learn from the clinical studies section (e.g., complication rates, additional surgical treatments, reasons for removals, etc.)? Explain how these clinical studies relate to you.
11. What questions do you have about silicone-filled breast implants that this brochure did not answer?
12. What additional comments or feedback do you have regarding this brochure, including suggestions for improving it?

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#### **EVALUATION AND FINAL REPORT**

A report of the focus group findings will be prepared by the contractor. The contractor has proposed a Topline final report consisting of 8-15 pages, which will include the findings as bullet points combined with short prose, followed by conclusions and recommendations. This report will summarize the responses to the 12 questions asked and provide an evaluation of the significance of the findings. Transcripts of the focus group testing could also be made available.

#### **ACTIONS IN RESPONSE TO FOCUS GROUP FINDINGS**

Inamed Corporation will target the timing of the focus groups for completion of the final report by ***(Date TBD)***. Inamed Corporation will review the results and develop proposed modifications to the patient brochure based on the focus group reports and then discuss any recommended changes with FDA. It is therefore anticipated that the final version of the *Making an Informed Decision: Silicone-Filled Breast Implants* will be ready for dissemination by ***(Date TBD)***.

**APPENDIX A**

**FOCUS GROUP SCREENING**

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## SCREENING

### INAMED FOCUS GROUP TESTING

#### *MAKING AN INFORMED DECISION: SILICONE-FILLED BREAST IMPLANTS*

#### **APPROACH:**

We would like to invite you to participate in a focus group for women. The sponsor of this research is a manufacturer of breast implant products, and they are developing literature for women who are interested in breast implantation or reconstruction, or who have had breast implants, or who currently have breast implants and may be considering revision surgery to replace one or both implants. They would like to hear your opinions about the patient literature they are developing in order to be sure it answers all the questions you have/have had about this subject.

This conference is being held for research purposes only. No attempt will be made to sell you any products.

#### **METHODOLOGY**

Five in-person focus groups; 90-120 minutes

#### **SEGMENTS:**

##### Augmentation

- 1 conference with women who *have had breast augmentation*
- 1 conference with women who *have considered or are considering breast augmentation*

##### Reconstruction

- 1 conference with women who *have had breast reconstruction*
- 1 conference with women who *have considered or are considering breast reconstruction*

##### Revision

- 1 conference with women who *currently have breast implants and are considering or may have considered revision surgery to replace one or both of their implants*

**DATES/TIMES:** *TBD*

**LOCATION:** *TBD*

**INCENTIVE:** \$75 – 100

#### **SCREENING INSTRUMENTS:**

- 1 Screener for participants who have or *have had breast implants*
- 1 Screener for participants who *have considered or are considering breast implants*

#### **NOTE:**

Age requirements differ between Augmentation and Reconstruction or Revision participants in both screeners. For Augmentation participants, at least 50% of the participants must be 25 – 35 year. There are no age requirements for Reconstruction and Revision participants.

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**FOR PARTICIPANTS WHO HAVE or HAVE HAD BREAST IMPLANTS**

1. **Have you ever had breast reconstruction/or breast augmentation?**

**MUST ANSWER YES.**

2. **Have you ever or are you currently considering breast implant revision?**

3. **What is your level of education?**

Some High School \_\_\_\_\_

Finished High School \_\_\_\_\_

Some College \_\_\_\_\_

Graduated College \_\_\_\_\_

Post Graduate Studies \_\_\_\_\_

**MUST HAVE CROSS-SECTION OF ALL EDUCATION LEVELS.**

4. **What age group do you fit into?**

18 – 24 \_\_\_\_\_ (must be at least 18 to participate)

25- 35 \_\_\_\_\_

36 - 45 years of age \_\_\_\_\_

50 – 60 years of age \_\_\_\_\_

61 or older \_\_\_\_\_

**PLEASE GET CROSS-SECTION OF AGES.**

**NOTE: FOR AUGMENTATION GROUPS, AT LEAST 50% OF PARTICIPANTS MUST BE 25-35.**

5. **Have you ever read literature on any medical procedure, for example, something you might have received from a physician or seen in his/her office?**

**MUST ANSWER YES.**

6. **When was the last time you participated in any type of product test, marketing research study or focus group?**

**WITHIN SIX MONTHS, TERMINATE  
MORE THAN SIX MONTHS AGO, CONTINUE**

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FOR PARTICIPANTS WHO HAVE or HAVE HAD BREAST IMPLANTS  
(Continued)

7. Are you, or is any member of your immediate family, employed or under contract with any research company or any company that manufactures or sells breast reconstruction or augmentation products?

MUST ANSWER NO

8. Are you or any member of your immediate family employed in marketing, advertising, public relations, *or are you employed in a health-related profession?*

MUST ANSWER NO

9. What is your employment status?

MUST HAVE A CROSS-SECTION OF OCCUPATIONS AS WELL AS HOUSEWIFE OR UNEMPLOYED

10. What is your ethnicity?

Caucasian \_\_\_\_\_

African-American \_\_\_\_\_

Other \_\_\_\_\_

CROSS-SECTION SHOULD BE PREDOMINANTLY CAUCASIAN

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-- END --

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**FOR PARTICIPANTS WHO ARE CONSIDERING/HAVE CONSIDERED IMPLANTS**

1. Are you considering, or have you ever considered having breast reconstruction/or breast augmentation?

**MUST ANSWER YES.**

2. Have you discussed the possibility of breast reconstruction or breast augmentation with:

Friends \_\_\_\_\_

Family \_\_\_\_\_

Physician \_\_\_\_\_

Other advisor \_\_\_\_\_

(such as social worker, nurse, clergy, therapist, etc.)

**RECORD ANSWERS. MUST HAVE DISCUSSED IT WITH AT LEAST ONE OF THE ABOVE**

3. What is your level of education?

Some High School \_\_\_\_\_

Finished High School \_\_\_\_\_

Some College \_\_\_\_\_

Graduated College \_\_\_\_\_

Post Graduate Studies \_\_\_\_\_

**MUST HAVE CROSS-SECTION OF ALL EDUCATION LEVELS.**

4. What age group do you fit into?

18 - 25 \_\_\_\_\_ (must be at least 18 to participate)

25- 35 \_\_\_\_\_

36 - 45 years of age \_\_\_\_\_

50 - 60 years of age \_\_\_\_\_

61 or older \_\_\_\_\_

**PLEASE GET CROSS-SECTION OF AGES.**

**NOTE: FOR AUGMENTATION GROUPS, AT LEAST 50% OF PARTICIPANTS MUST BE 25-35**

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FOR PARTICIPANTS WHO ARE CONSIDERING/HAVE CONSIDERED IMPLANTS  
(Continued)

5. Have you ever read literature on any medical procedure, for example, something you might have received from a physician or seen in his/her office?

MUST ANSWER YES.

6. When was the last time you participated in any type of product test, marketing research study or focus group?

WITHIN SIX MONTHS, TERMINATE  
MORE THAN SIX MONTHS AGO, CONTINUE

7. Are you, or is any member of your immediate family, employed or under contract with any research company or any company that manufactures or sells breast reconstruction or augmentation products?

MUST ANSWER NO

8. Are you or any member of your immediate family employed in marketing, advertising, public relations, or are you employed in a health-related profession?

MUST ANSWER NO

9. What is your employment status?

MUST HAVE A CROSS-SECTION OF OCCUPATIONS AS WELL AS HOUSEWIFE OR UNEMPLOYED

10. What is your ethnicity?

Caucasian \_\_\_\_\_

African-American \_\_\_\_\_

Other \_\_\_\_\_

CROSS-SECTION SHOULD BE PREDOMINANTLY CAUCASIAN

-- END --

## APPENDIX B

### FOCUS GROUP INTERVIEW GUIDE

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## INTERVIEW GUIDE

### INAMED FOCUS GROUP TESTING *MAKING AN INFORMED DECISION: SILICONE-FILLED BREAST IMPLANTS*

#### INTRODUCTIONS (10- 15 min.)

##### Moderator Introductions

We're going to discuss patient literature about silicone-filled breast implants, which are used for breast augmentation, breast reconstruction and breast implant revision. Our objective is to understand what you like and need in patient educational materials. And we will evaluate a specific piece of literature, which is being developed.

#### **One-way mirror/taping/confidentiality/no right or wrong responses**

##### Participant Introductions

*Name*

What patient literature do you remember reading in the past, (for example, inserts which come with drugs, materials from pharmacist, pamphlets seen in physician offices, or anything specific to a procedure you had)?

Make one suggestion to the companies that make medical literature for patients. You can say something they should do or should not do, but each participant must suggest something different.

#### KEY INFORMATION REQUESTS: UNAIDED (10- 15 min.)

**Think about when you were considering breast implantation/reconstruction/revision. (Moderator records on flip charts.)**

- What questions did you have? Or what questions do you have now?

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**PARTICIPANTS READ MATERIALS (30 min.)**

Moderator instructs participants to read literature as if they were considering having an implant. It is not a test.

- **Circle any words/phrases that you don't understand or have questions about.**
- **Check sections you think are particularly useful.**
- **Write any other comments in the margins.**

**EVALUATION OF INAMED LITERATURE (30 - 45 min.)**

- **What is your overall reaction to this piece?**
  - What do you like about it? What does it do well?**
  - What do you not like about it? How can it be improved?**
  - Was there anything offensive?**
- **What are some of the main messages you get from reading this piece?**
  - What did you learn about the potential risks of implants?**
  - What did you learn about the benefits of implants?**
- **Did you learn anything new from reading it, or not? Explain.**
- **What questions do you still have, if any?**
- **How would you evaluate the ease or difficulty of understanding this piece?**
- **Do you have any comments on how the piece is organized?**
- **What is your opinion about the design or format?**
- **Did you find the safety data tables useful or not? Explain.**
- **What are your thoughts about the photographs and drawings?**
- **What did you learn, if anything, from the clinical studies information?**

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**CLOSE** (5 - 10 min.)

- **Of all the information in the piece, what information is the most useful in helping you make an informed decision about breast implants? Why?**
- **What information is the least useful? Why?**

**END** (5 - 10 min.)

Moderator collects literature.