

United States Food and Drug Administration
Testing Communications on Medical Devices and Radiation-Emitting Products (CDRH)
OMB Control Number 0910-0678
Gen IC Request for Approval

Title of Gen IC: CDRH Rapid Message Testing with Consumers and Caregivers— March 2023 Breast Implant Safety Communication

1. Statement of Need

Breast implants are medical devices implanted under the breast tissue or chest muscle to increase breast size (augmentation) or to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality (reconstruction). According to the American Society of Plastic Surgeons, approximately 400,000 women received breast implants in the United States in 2017 alone (Surgeons ASoP, 2018).

The FDA first identified a possible association between breast implants and the development of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in 2011. Since that time, the FDA has undertaken several steps to better understand this issue, including an in-depth review of post-approval study data, medical device reports, scientific literature and breast implant-specific registries, and public discussions. We have regularly communicated about the risks associated with breast implants and heard from patients who are concerned about their implants being connected to various health conditions. In March 2019, we discussed many important breast implants concerns in a [public advisory committee meeting](#). In July 2019, we issued a [Safety Communication](#) informing the public that the FDA requested Allergan to recall all BIOCELL textured breast implants and tissue expanders marketed in the U.S. based on Medical Device Reports (MDRs) of BIA-ALCL-related deaths associated with these devices.

More recently, in March 2023, we issued a [Safety Communication](#) (Attachment A) stating the FDA is also aware of 19 cases of squamous cell carcinoma (SCC) in the scar tissue (capsule) around breast implants, and there have been reports in the literature of deaths from progression of the disease. While the FDA continues to believe that occurrences of SCC in the capsule around the breast implant may be rare, the cause, incidence and risk factors remain unknown.

The purpose of this project is to obtain feedback on the March 2023 Safety Communication, testing in both English and Spanish, to help inform the agency's communications about reports of SCC in the capsule around breast implants and its recommendations for consumers and health care providers. Although the focus of this testing is the March 2023 Safety Communication, the findings will also be of help to the FDA more generally in informing communications about safety issues with other implantable devices where the FDA's recommendation for consumers is typically to discuss with the doctors the risk of removing the device compared to the risk of leaving it in place.

Communications science tells us that we must test messages with our intended audiences. Thus, the FDA plans to test these communications using individual in-depth interviews with a small sample of 18 U.S. adults drawn from diverse consumer and health care professional (HCP) panels. The sample will include 12 consumers and six HCPs.

This data collection is the fourth in a series of rapid message tests CDRH plans to submit to OMB under generic clearance 0910-0678. These projects are part of CDRH's effort to make target audience testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order (White House, 2015) to improve how information is

presented to consumers by applying behavioral science insights, and it meets repeated calls from the FDA's Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public.

2. Intended Use of the Information

The FDA is not seeking quantitative data or generalizable findings; it is only interested in having its contractor, Westat, test the communication with a small sample of target audience members for understandability to ensure the messages meet their objectives without causing unintended negative effects by being misunderstood or misinterpreted.

The FDA's Risk Communication and Advisory Committee includes renowned experts and researchers in social sciences, marketing, health literacy, and related fields. From its very first meeting in 2008, the Committee has consistently advised and reaffirmed that testing communications with the target audience is necessary for the FDA, and that using small samples is an effective approach for testing and communicating in a timely manner. In fact, research has shown that "saturation," or the point at which no new information or themes are observed, can occur with as few as 12 interviews, as described in Guest et al (2006).

The FDA will use the collected interview data to refine its messaging by improving the comprehensibility for a higher public health impact. Specifically, the FDA is asking Westat to gain insight to the following questions:

1. What are the main messages that participants get from the Safety Communication?
2. What do participants recognize as the call to action?
3. What information do participants indicate is new to them?
4. How clear and understandable is the text to participants? What words or phrases are confusing, and what suggestions do participants offer for improving them?
5. What information do participants find useful? Not useful?
6. How helpful do participants say the Safety Communication is for facilitating patient-provider discussions?
7. Is there information that is missing or would be helpful to add?
8. How well do participants think the content is organized?
9. What other suggestions do participants have to improve the information?

The data collected will not be statistically representative of the target audience population. Therefore, the data will not be used for making policy or regulatory decisions.

3. Description of Respondents

We will conduct 18 45-minute in-depth individual interviews with U.S. adults. Westat has partnered with PRC, a recruitment specialist, to recruit 12 consumers from its general population panel. Westat has also partnered with WebMD Professional/Medscape, a specialist in healthcare professional recruitment, to recruit six HCPs from its user database. Both PRC and WebMD Professional/Medscape track and store all database member activity and assign a unique ID number which stays with the member throughout their entire membership. These tracking records consist of profile information provided during enrollment, profile updates, and past focus group or in-depth interview involvement. PRC and WebMD Professional/Medscape monitor the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality

checks include individual vetting of contact information, and review of enrollment data, as well as review of screener questions, rescreening of participants before participation, and client feedback on past focus group and interview response.

We will use a participant screener (Attachment B) to recruit a mix of 12 consumers, half of whom currently have breast implants and half who are considering breast implants. We will primarily recruit lower education consumers for feedback on literacy and comprehension. Six consumer interviews will be conducted in Spanish with participants who speak Spanish as their first language. We will also use the participant screener to recruit a mix of health care professionals including three primary care physicians, three plastic surgeons, and three oncologists. To the extent possible, both participant pools will be diverse in terms of age, race, ethnicity, and geography.

Individuals who are interested and appear to qualify will be contacted by phone to schedule their participation in an interview. The recruiters will send scheduled participants a confirmation email (Attachment C) with the date/time of their interview, a Zoom link, and login instructions.

4. How the Information is Collected

We will conduct all interviews remotely using online software (e.g., ZoomGov) and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, tablets, or mobile phones. We will ensure that any materials viewed by the participants for the test are compatible with these devices.

For each 45-minute interview, a trained interviewer will lead the discussion using a semi-structured interview guide (Attachment D) that ensures consistency in major topics but allows flexibility in probing each participant on particular questions.

With the consent of participants, we will audio record each interview. We will produce a written transcript of the discussion and use the transcript for the analysis.

FDA staff will be able to observe unobtrusively and will not be visible on screen, and this will be made known to participants as part of the informed consent. This request for verbal informed consent is included in the interview guide introduction.

5. Confidentiality of Respondents

We will provide all respondents with informed consent language that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. As part of the consent procedure, respondents will be asked whether they allow audio recording of the interview. Recording will not begin before participants have had the opportunity to ask for any clarification and provide consent. Participants will be asked to again confirm their consent when recording begins. Participants who do not allow audio recording will not be invited to participate in the interview.

The recruiters, PRC and WebMD Professional/Medscape, will send regular recruitment updates to Westat via email. These updates will contain no personally identifiable information (PII), such as the recruits' last names or contact information. Therefore, the FDA and Westat will not have full names or contact information for any participants and there will be no link between the data collected and participants' identities. No participant's identifiable information such as name will be included in the transcripts. All interview materials will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. Transcripts will be zipped

electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to the FDA, Westat will destroy all personally identifying information to protect each participant's personal identity. Additionally, the transcripts and interpretive report delivered to the FDA after message testing will omit all information that could be used to identify respondents.

All electronic data storage media that contain confidential, private, or proprietary information will be maintained within secure areas.

The FDA's Institutional Review Board (IRB) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

6. Amount and Justification for Proposed Incentive

Both PRC and WebMD Professional/Medscape use a "by-invitation-only" recruitment methodology and incentivize panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time.

For this project, PRC will provide \$50 incentives to consumer participants at the end of each 45-minute interview in the form of a digital gift card. WebMD Professional/Medscape will provide \$100 incentives to primary care physicians and \$150 incentives to medical specialists (plastic surgeons and oncologists) at the end of each 45-minute interview in the form of a check. These incentives are consistent with the established thresholds specified in Supporting Statement A and approved by OMB for testing conducted under generic clearance 0910-0678.

7. Questions of a Sensitive Nature

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' reactions to the messages and materials.

Nevertheless, respondents will be told that they may skip any question that they do not want to answer or may stop participating at any time.

8. Description of Statistical Methods

We do not plan to use formal statistical methods in this study but rather qualitative analysis methods. Our analysis approach is based on the Framework method, as described in Spencer et al (2003). Framework is a matrix-based approach to data management, which facilitates both case and theme-based analysis. The Framework method allows for data reduction through summarization and synthesis yet retains links to original data, in this case the transcripts. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The software will allow us to import interview transcripts, create links between the transcripts and the Framework matrices, and develop new queries or matrices as needed.

The Framework method will allow us to recognize patterns within the data. Findings will be supported with verbatim participant quotes and grounded in accepted principles of health communications.

9. Burden

We estimate that participants will spend approximately 60 minutes of their time on this task, which includes time for screening via email (3 minutes), time for scheduling an interview and reviewing instructions (7 minutes), the time involved in logging in early to confirm the technology is operating correctly (5 minutes), and time to participate in the interview (45 minutes).

| Type/Category of Respondent | No. of Respondents | Participation Time (minutes) | Burden (hours) |
|--|--------------------|------------------------------|----------------|
| Screener | 450 | 3 | 23 |
| Scheduling an interview and reviewing instructions | 18 | 7 | 2 |
| Early login | 18 | 5 | 2 |
| Interview | 18 | 45 | 14 |
| Totals | 450 | 60 | 41 |

10. Date(s) to be Conducted

July 2023

11. Requested Approval Date

July 2023

12. FDA Contacts

| Program Office Contact | FDA PRA Contact |
|--|---|
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