



Postapproval Conditions

37. On p.4503, you provided a list of proposed postapproval conditions, should your PMA be approved. However, you did not provide any details for any of them. Additional information is necessary for each of them.

- a. You stated that you will develop a model surgical informed consent form and/or other media based on input from the FDA General and Plastic Surgery Devices Advisory Panel and FDA. The purpose of this form, as compared to the patient informed decision labeling, is not clear. Please provide your draft form and your plan for this form, including a clear description of its purpose and distribution.**

Response 37a:

Mentor has further evaluated the need for a separate surgical informed consent. Based on our review of the existing patient labeling, along with our understanding that some hospitals require their own surgical informed consent, Mentor believes that an additional informed consent is redundant. Furthermore, we believe that an additional consent will be confusing to the patient. Therefore, based on this information, Mentor is not planning on developing a model surgical informed consent form and/or other media at this time.

- b. Please provide your focus group study protocol that has the purpose of improving the patient informed decision labeling.**

Response 37b:

Mentor has prepared a focus group study protocol for the patient informed decision labeling. The protocol is virtually identical to the protocol utilized for the saline patient labeling. A copy of the focus group study protocol is located in Appendix 35.

- c. You stated that you will continue to follow Core Study patients for 10 years. You also stated that you will continue the Core Study MRI cohort for 10 years, with the MRIs performed every 2 years. Although noted as separate conditions of approval, these should be two elements in a single postapproval study for the Core Study. Please provide a detailed postapproval study protocol for your Core Study, including your MRI cohort, which requires continued physician follow-up visits through 10 years. In addition, please describe the specific steps that you will take to maintain an adequate level of follow-up at each timepoint.**

Response 37c:

Mentor submitted the protocols and Informed Consents for both the Core Study and Core Study MRI cohort as part of IDE G000088. The protocols and informed consents specified that all patients participating in the long-term study will be seen by a physician annually for a total of 10 years. Those patients selected to participate in the MRI substudy will not only be seen annually for 10 years, but will also have MRI scans on a biannual basis, i.e., 2, 4, 6, 8, and 10 years post implantation. As the 10-year duration studies were specified in the original protocol and informed consent form approved by FDA, Mentor does not believe that separate post approval study protocols are required.

Mentor is planning on maintaining the excellent follow-up rates postapproval by continuing with the monetary incentive programs outlined in the Informed Consent that each patient signed upon inclusion in the study. If necessary, Mentor will present each patient with an additional consent form reminding them of their commitment to participate in the long-term 10 year study.

- d. There were several proposed conditions of approval that appeared to be related to physician education/training. These included:**
- **your “recommendation” that all patients implanted with breast implants be followed every year or two by a trained physician;**
 - **educational information for physicians on clinical recognition of rupture; and**
 - **development, with a third party, of surgeon education and training on the use of silicone gel-filled breast implants.**

FDA believes that these elements should be combined into a single education and certification program to train surgeons and physicians with regard to proper surgical technique, patient selection, patient monitoring, clinical recognition of rupture, recommendations for patient follow-up, management of complications, including suspicious and confirmed intracapsular/extracapsular rupture, etc. Please provide a detailed description of your education and certification plan for surgeons and physicians, including copies of any materials that you plan to distribute to surgeons and physicians either during the actual training program or afterwards. In addition, please incorporate completion of a training program (i.e., certification) as a requirement for obtaining access to your device.

37d Response:

Mentor is working cooperatively with the American Society of Plastic Surgeons (ASPS), the Plastic Surgery Education Foundation (PSEF) and the American Society of Aesthetic Plastic Surgeons (ASAPS) to develop a comprehensive physician training program. Each of these professional organizations has many years of experience in developing and implementing all aspects of physician

education programs, and has the necessary infrastructure to support their implementation. Their organizational expertise includes collaborative program planning, logistics implementation, program evaluation, and accreditation by the Accreditation Council on Graduate Medical Education (ACGME). ACGME accreditation enables them to grant physician Continuing Medical Education (CME) credits verifying attendance at an educational program. The faculty members that will participate in these educational programs are experienced clinicians and skilled educators.

The physician education program (Silicone Breast Implant Education Symposium) will focus on surgical techniques, patient selection and monitoring, methods for the detection of ruptures, and the overall risks and complications associated with silicone gel-filled breast implants. It will also cover how to improve patient communication and understanding in order to better manage patient expectations and reduce elective reoperations. For specific course topics, please refer to the attached agenda (Attachment 38). Mentor has been collaborating on the presentations to ensure that the program content is comprehensive and will work on an on-going basis to update the slides as relevant. A DRAFT of the slides is included as Attachment 38. Mentor will also provide support materials for this training, such as product labeling and relevant literature.

The educational programs will be conducted five times annually in conjunction with regularly scheduled society meetings, and will also be available on DVD and as an internet-based CME educational program for those physicians that may be unable to travel to these symposia. The societies also recognize that some physicians that may not currently be members will be seeking training options. The symposia will be open and available for all interested physicians. Mentor's corporate website will also list the names and contact information for surgeons who have completed a Silicone Breast Implant Education Symposium.

Mentor continues to believe that physician education on breast implants can be safely implemented post market approval, and agrees with FDA that it will be a requirement to gain access to these devices. Mentor proposes taking a tiered approach in implementing this requirement to ensure an orderly and effective outcome for both patients and physicians. Upon approval, any physician who is not currently enrolled in Mentor's Adjunct Study will be required to verify that they have obtained a "Certificate of Participation" from the educational symposium prior to receiving any product shipments. Mentor will allow physicians who are currently enrolled in the Adjunct Study to receive gels for a period of 90 days post approval while these physicians work to gain their certifications. Upon conclusion of that 90 day period, Mentor will require all physicians to provide verification of their participation in an educational symposium prior to receiving product shipments.

During the last decade many physicians have had significant experience with the implantation of silicone gel breast implants because of their ability to continually access the product through Mentor's Adjunct Study. These physicians, through use over the years, have become well trained in the surgical techniques of implanting gel devices. At the time of approval, many patients will be scheduled to undergo the completion of their reconstruction or their revision surgery. Mentor believes it will create a hardship for those patients whose surgeries would have to be rescheduled if their physician is required to complete the education program in advance of receiving the products to complete their procedure.

In addition to participation in Mentor's Adjunct Study, physicians have had access to professional education initiatives to augment their training and experience. For example, the American Society of Plastic Surgeons ("ASPS") has sponsored instructional courses and has held annual symposia to provide ongoing in-depth reviews of safety and outcomes data related to breast reconstruction and breast augmentation. In addition, ASPS has developed a web-based, outcomes data-collection tool, allowing for national benchmarking and comparison of an individual surgeon's outcomes against that benchmark. The society is also funding breast implant research to educate its membership, to ensure patient safety, and to improve patient outcomes. All of these initiatives have been significant tools in training and maintaining surgical education.

- e. **You proposed to develop, with a third party, a lifetime patient registry. At a recent meeting of the General and Plastic Surgery Devices Advisory Panel, the Panel recommended the inclusion of certain elements, such as data on CTD, rupture, offspring, and patients after explantation, as well as other clinical endpoints in a breast implant registry. Please provide the detailed plan for your registry. IN addition, please provide the specific steps you will take to assure that you will meet the goals of the registry, in terms of data collection and follow-up.**

37e Response:

Voluntary Patient Registry:

Mentor agrees with the concept of a voluntary breast implant patient registry, and will provide patients access to a registry that will be a secured database and has been developed and administered by an independent unbiased third party. Data from the registry will be accessible for analysis (redacted of patient identification) and periodic reports will be published discussing implant trends.

During the October 2003 panel hearing, FDA was introduced to a registry developed by ASPS/PSEF. The Tracking Outcomes in Plastic Surgery (referred to as "TOPS") registry, which collects plastic surgery procedural data, and clinical outcomes, is also capable of collecting satisfaction data from patients themselves. A breast implant registry is embedded within the Internet data-

collection tool of TOPS. This registry (National Breast Implant Registry or "NaBIR") can track information, such as the number of implants placed or removed, clinical indications, type of facility, anesthesia administered, and short-term complications. The registry was designed to allow physicians to track implanted devices of their highly mobile patients.

NaBIR's advantages are that it is a secure, internet-based, HIPPA-compliant program designed to collect breast implant data across manufacturers and implant types. Patient and surgeon confidentiality is assured and data collection and analysis is real-time. NaBIR has been sufficiently successful in its design that it has attracted international interest. It has served as the template for IBIR, the International Breast Implant Registry, which is poised to become the standard for the European community, Australia, and South America.

Mentor has made a decision to contract with NaBIR. In collaboration with PSEF, Mentor will edit the currently available registry forms to ensure that the information FDA requires as a condition of approval is being gathered in a timely and effective manner. A DRAFT of the enrollment form and an example of a summary report are attached (Attachment 36). This implant registry will be implemented post-approval and will be funded by using a patient pass-through fee to NaBIR.

Mentor believes that TOPS and NaBIR data collection efforts will be the registry of choice to trace implant-related data and outcomes.