

TAB 2 – DRAFT PANEL QUESTIONS

1. The primary rupture rate information came from Mentor's Core Study. Mentor has provided 2-year data and partial 3-year data. The partial 3-year data includes only physician follow-up. MRI cohort data were captured at the 1 and 2-year timepoints. The following information is currently known regarding the rupture rate for Mentor's Core Study data:
 - For the MRI Cohort (approximately one-third of the Core Study patients who had serial MRI at years 1 and 2 following implantation), the by-patient, total rupture rates (silent + symptomatic) through 3 years are 0.5% for augmentation, 0.8% for reconstruction, and 4.8% for revision.
 - There were no ruptures reported in the Non-MRI Cohort (approximately two-thirds of the Core Study patients who did not undergo MRI).

Mentor also provided rupture rate information from supplemental sources, such as the literature and the Adjunct Study.

To determine the rupture rate over the expected lifetime of the device, Mentor relied on a case series of augmentation patients with exclusively subglandular implants, who did not have capsular contracture or any additional surgical procedures, and who underwent a single MRI to screen for rupture.

Considering the rupture information in their submission, and given that majority of ruptures for silicone gel-filled breast implants are silent, please discuss whether Mentor has adequately characterized the rupture rate and how this rate changes over the expected lifetime of their device.

2. Considering the information presented on consequences of rupture from the Core Study and supplemental sources, please discuss whether Mentor has adequately characterized the consequences of rupture for their device with regard to:
 - a. the frequency of observed intracapsular gel, extracapsular gel, and migrated gel, as well as the destination of the migrated gel
 - b. the local health consequences of patients with ruptured implants
 - c. the incidence, prevalence, and timing of silent ruptures that progress to symptomatic ruptures
 - d. the incidence, prevalence, and timing of intracapsular ruptures that progress to extracapsular ruptures.
3. Mentor's proposed labeling includes recommendations for: (1) the method and frequency of screening for silent rupture; (2) clinical management of suspicious and confirmed intracapsular and extracapsular rupture; and (3) potential health consequences of extracapsular and migrated gel. Please discuss the appropriateness of these

recommendations and the extent to which the proposed labeling is supported by the available information.

4. In terms of postapproval plans, Mentor proposes continuation of their Core Study with yearly physician follow-up through 10 years, with MRIs continuing at years 4, 6, 8, and 10. The same safety and effectiveness data will be collected. Patients who are explanted without receiving replacement implants will be discontinued from the study. Their postapproval study will not collect data on children of women with breast implants. In addition, Mentor proposes using the existing ASPS/PSEF's TOPS and NaBIR registries, which involve participating physicians who voluntarily collect limited local complication data when patients return for a visit.

Please comment on the adequacy of Mentor's postapproval plans to address any postapproval concerns that you may have.

5. Based on your answers to the questions 1-4 above, as well as the other safety data/information and preclinical testing provided by Mentor, please discuss whether you believe that there is reasonable assurance that this device is safe¹ over its expected lifetime for the proposed indications of breast augmentation, reconstruction, and revision. With respect to rupture, you should consider that most ruptures are silent, and that there is difficulty in ensuring routine MRI examination for women with breast implants. You should also consider data from revision patients as a continuum for patients originally undergoing breast augmentation or reconstruction.
6. To evaluate device effectiveness, Mentor collected data in their Core Study on patient satisfaction and QoL (e.g., Tennessee Self-concept Scale, SF-36, Body Esteem Scale, Rosenberg Self-Esteem Scale). Mentor also provided a review of the available QoL literature. Based on these data/information, please discuss whether you believe that there is a reasonable assurance that their device is effective² for the proposed indications of breast augmentation, reconstruction, and revision.

¹ 21 CFR 860.7(d)(1) states that there is a reasonable assurance that a device is safe when it can be determined that the probable benefits to health from use of the device for its intended uses, when accompanied by adequate instructions for use and warnings against unsafe use, outweigh any probable risks.

² 21 CFR 860.7(e)(1) states that there is a reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warning against unsafe use, will provide clinically significant results.