

Block 1:

• Against what background is the decision made in your country to place or keep an implant on the market?

Response

- **Background:** The United States has a risk-based classification system for medical devices. Medical devices are classified into class I, II, or III, each with increasing level of regulatory oversight. Breast implants have been classified into class III. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with class III devices, FDA has determined that these devices require a premarket approval (PMA) application.
- PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device.
- The regulations governing PMA applications are located in 21 CFR Part 814. The specific sections dealing with denial, withdrawal and temporary suspension of approval are located in sections 21 CFR sections 814.45, 814.46 and 814.47. The highlights of the regulations relevant to your questions are provided below.
- **Approval:** PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is reasonably safe and effective for its intended use, which FDA determines by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. There are specific grounds for denying a premarket approval application. Among those grounds, the two most critical are:
 - a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;
 - a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;
- **Withdrawal:** There are statutory grounds for withdrawal of approval of a device approval.
 - **Among the grounds in the statute, the following are the most relevant:**
 - that the device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;
 - on the basis of new information before FDA with respect to the device, evaluated together with the evidence available when the application was approved, that there is a lack of a showing of reasonable assurance that the

device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

- **The regulations:** provide for the following procedures: the first step is a temporary suspension of PMA approval, and the second step is a formal withdrawal of PMA approval.
 - Temporary suspension would occur when FDA determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.
 - Once a temporary suspension order is issued, FDA conducts a hearing to determine whether the device approval should be permanently withdrawn.

- **In your opinion, what are the consequences of whether or not to prohibit an implant, how is this viewed in your country?**

Response

An approved medical device can be removed from the market when new information demonstrates there is no longer a reasonable assurance of safety or effectiveness. The consequences of withdrawing the approval of an approved medical device include potential impacts on patient care and on the medical community. In reaching such a conclusion, FDA evaluates the benefit-risk profile of the medical device while considering all newly available benefit and risk information. As part of the benefit-risk evaluation, FDA considers all types of available information including patient preference information to help evaluate the consequences of withdrawal of approval on patient care.