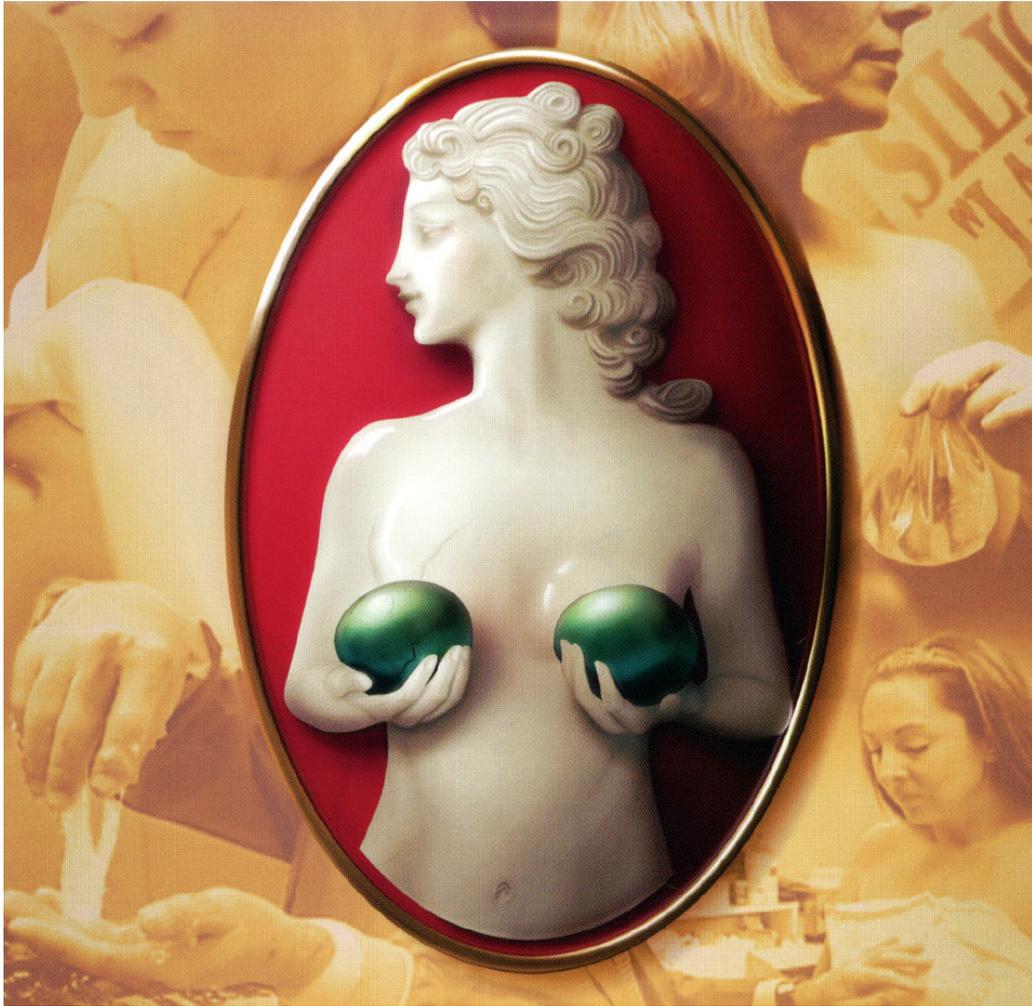


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# *Absolutely Safe* Discussion Guide



**OUR BODIES  
SELVES**  
information inspires action

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## Note to the Facilitator

This guide is designed to foster deep, discussion-based learning based on the complex issues raised in the film. These questions can be the basis of large and small group discussion or writing assignments.

## The Decision

In the film, we meet many women who discuss their decision to get implants, from Carol's mother Audrey who got them in the 1970's, to Deneé, who has recently decided to get them. We hear from them and from others about the factors that influence how women think about getting implants. We learn about the incredible popularity of breast implants, with up to 300,000 surgeries a year. Plastic surgeons Dr. Rose and Dr. Melmed discuss the high demand for the operation.

- What makes implants popular?
- What reasons do women in the film give about why they got (or will get) implants?
- What factors influenced their decision?
- What influence did family members have on their decision-making?
- How did the women in the film discuss family, social, or other pressures around their decision?
- How did these women express feeling empowered around their decision?
- For the women in the film, what role did concern about implant safety play in the decision?
- What do you think has changed over time about how women make the decision to get implants?
- What do you think are the differences or similarities between cis gender and transgender women's perspectives on implants?
- What role do breasts play in gender identity for women?
- In what ways do you think the decision to get implants is influenced by women's economic, ethnic/racial, cultural, gender identity, and sexual orientation or able-bodied status?
- What other factors influence how someone might feel about the appearance of their breasts?

In the film, Anne Stansell, a breast cancer survivor, talks about how she came to have implants:

*The doctor says you have breast cancer, you need a mastectomy, you need radiation, you need implants. Like part of the treatment. In reality, I didn't need implants to get clear of the cancer, but they made seem like it was a part of the recovery.*

- What might this perspective indicate about women's empowerment and control over their bodies in the context of their healthcare?
- Does your experience with doctors and the medical system align with hers or differ?
- What more should be done to assure patients' ability to make their own decisions about their bodies and medical treatment?

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## The Informed Decision

In the film, Audrey and others say that they had no information about how implants could impact their health. Today there is general acknowledgment that people should make informed decisions about implants including knowing about potential complications and rupture rates. The United States Food and Drug Administration (FDA) website provides both a booklet outlining issues for women to consider in making *informed decisions* about breast implants, and the device labels which also report device-specific complication rates and other considerations. Surgeons are not required to provide this information to patients, however and many women who have had implants say they never saw this information.

- What makes a decision to get implants “well-informed”?
- What information should be required to be provided and when should it be considered by the patient?
- What are the differences between making an “informed decision” and signing an “informed consent” form for surgery?
- What, or who, do you think are the best and most reliable information sources?
- What restrictions should be placed on teenagers with regard to implants?
- How would you make the decision for yourself?
- How would you help someone else make the decision?

## Thinking about Risk

In the film, Houston plastic surgeon Dr. Franklin Rose, says that he accepts that there is some miniscule risk of an adverse event associated with breast implants. He equates this to the risks we accept as part of everyday life. In the film, Dr. Susan Alpert, formerly of the FDA Office of Device Evaluation says:

*“It’s not that they are free of risk. Nothing is free of risk. There are no products that we regulate that are without risk and with 100% benefit. Nothing lasts forever, nothing is perfectly safe.”*

- How does Dr. Alpert’s statement align with how you think about medical device risks?
- What is your perspective on Dr. Rose’s explanation of risk in everyday life and how it relates to potential risks associated with breast implants?
- How might you expect your decisions about risks and rewards of your personal choices and behaviors to differ from a federal safety agency’s risk assessment process?
- How does Deneé think about the risks associated with breast implants?
  - In what ways does her perspective change after the operation?
  - How does her husband think about potential risks?
- How do you weigh the risks versus the benefits of products that you use?

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## Absolutely Safe

Early in the film we see footage of women protesting in Washington DC in 1995 to demand that the FDA require breast implants to be assessed for safety and effectiveness. They are chanting “We are the evidence.”

- Why do you think the film is titled “Absolutely Safe”?
- Who says/claims that breast implants are safe?
  - On what basis do they make this claim?
  - If there is any doubt, why would they dismiss it?
- What kinds of evidence do you think support the claim that breast implants are absolutely safe?
  - What kinds of evidence support the claim that they are not?
  - What is the meaning of the chant from the 1995 demonstration?

## What FDA Approval Means

The FDA is responsible for evaluating the evidence of the safety and effectiveness of medical devices. In the film, we watch several panels convened by the FDA consider approval of silicone breast implants. Ultimately, the FDA did approve the implants. To quote from their [website](#):

*Based on the totality of the evidence, the FDA believes that silicone gel-filled breast implants have a reasonable assurance of safety and effectiveness when used as labeled. Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make informed decisions about their use.*

- In what ways does this statement support or complicate the widely-held belief that FDA approval means that breast implants are safe?
- What do you think the FDA means by “reasonable assurance of safety”? Or “used as labeled”?
- In what ways do you agree or disagree with the FDA’s statement?

*“Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make informed decisions about their use.”*

- Based on what you saw in the film and your own knowledge, what are the arguments in favor of the statement that the *benefits and risks of breast implants are sufficiently well understood*?
  - What are the arguments against that conclusion?

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## Science and the FDA

In the car, Wendi makes an ironic observation about the lack of safety testing of silicone implants “We’re trying to get these bodies like Playboy Bunnies and we’re the bunnies being tested on.” In 2006, the FDA did require manufacturers to conduct short and long-term studies of large numbers of women as a condition of approval. They also required the manufacturers to fund studies of doctor’s attitudes and practices towards the provision of information about complications and about patient understanding of safety labeling.

- Do you agree or disagree with Wendi’s observation that women with implants are like animals used in laboratory testing?
- If the FDA believes that risks and benefits are sufficiently well understood, why do you think they required manufacturers to continue to study implant patients and the decision-making process?
- What actions should the FDA take if adverse effects continue to be documented by the mandated studies?

Dr. Virginia Ernster, co-chair of the Institute of Medicine panel that reviewed implant safety, says in the film:

*We could have said, the data are all so flawed, we have to study women for another 20 years. And it would have been a cop out because no one is going to be able to amass a large, large, large group of women in a single study and follow them over time....There are all sorts of issues that go into design the perfect, definitive study that it almost make it impossible to do.*

In the 2005 FDA approval hearings, we watch panel member Dr. Stephen Li say that although the data show evidence of clinical problems, he’d be “loathe to make them do a research project on each one of them as a condition for approval.” Both of these comments and Dr. Rose’s statement that “they’ve been studied and studied” appear to discourage further research on the basis that it’s not necessary, it would be burdensome, and more or less impossible to do in a satisfactory manner.

- How persuasive are these arguments to you?

Dr. Michael Harbut, the occupational and environmental medicine researcher interviewed in the film, specifically about his patient Dr. Joy Taylor, also says that scientific investigation into implant safety has been discouraged.

- Why would researchers want to discourage further research?

Dr. Diana Zuckerman, president of the non-profit National Center for Health Research, points out what she sees as fundamental flaws with the science that has been conducted and provides her view on better research approaches. She suggests that research conducted by the manufacturers themselves, or by the Mayo Clinic and Harvard “generously” funded by the manufacturers, may be biased. She also

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critiques most of the studies as too short term, too small in numbers of women, and lacking a physical exam and interview of individuals with implants.

- How compelling are her critiques?
- How do you think research studies on breast implant safety and effectiveness should be designed?

Dr. Ernest Lykissa, toxicologist, also describes the limitations of the science to date, specifically, the lack of study of explanted implants and of platinum-related toxicity. The FDA now includes information about the study of platinum on their Breast Implant webpage. They conclude that the studies are inconclusive but that they will continue to evaluate the issue.

- What is your level of confidence in the FDA to support and evaluate new scientific findings about implants and health?
- If you were on the FDA panel, how would you make a decision in the face of uncertainty and incomplete science?

## Doctors, Medicine and Women's Bodies

In several places in the film, we observe Drs. Rose and Melmed practicing medicine including interviewing patients, conducting surgery, and performing follow up care. Additionally, Carol and other women interact with these doctors.

- What did you observe about how Dr. Melmed and Dr. Franklin interacted with the women in the film, in particular, with their patients?

Several women in the film, including Wendi and Audrey, report that their doctors dismissed their concerns about their implants causing their health problems. Other women described feeling relieved to hear from a doctor that “No, it’s not all in your head.” The women’s health movement has long raised concerns that debilitating conditions such as premenstrual syndrome and postpartum depression and side effects from birth control pills and hormones used to treat menopause symptoms were being dismissed by doctors.

- For those women whose concerns were dismissed, how common do you think these women’s experiences with their doctors are?
- In what ways do you think women, men, and gender non-conforming individuals may be treated differently in medical care?
- What do you think are the influences on doctor’s behavior with their patients?
- How does the doctor’s authority discourage questions patients might have about implant safety?
- In what ways have patients gained power in the medical system?

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## Conflicts of Interest

Audrey begins her testimony to the FDA panel by saying that she is testifying on her own behalf and has no conflicts of interest.

- What do you think she meant by stating she had no conflicts of interest, and why do you think she makes that statement?

Later in the film, John Byrne, then an editor for *BusinessWeek*, notes that four of the nine FDA panelists were plastic surgeons, who he says “shouldn’t have even been sitting on the panel because of their obvious self-interest.” Dr. Zuckerman strongly suggests that the manufacturers’ funded research is biased in favor of the safety of their products. Finally, John Swanson, former Dow-Corning communications director flatly states that profit motives prevented the company from revealing what they knew about safety problems with implants.

- What role has money played in the science and regulation of breast implants?
- What’s the best way to prevent conflicts of interest contributing to biased research?
- How do conflicts of interest impact the doctor-patient relationship?
- If conflicts of interest create bias, what process might better assure unbiased information on breast implants?

## The Media

The “media” is almost a character in the film. Deneé discusses *US Weekly* magazine and MTV, and Dr. Melmed mentions Connie Chung’s reporting on the issue as a key factor in his reconsideration of implant safety. *The New York Times*, *Time Magazine* and NBC News coverage of hearings and reports flash on the screen, and a *BusinessWeek* editor is interviewed for the film.

- How does the media shape our perception of safety, science, and implants?
- How well does the media interpret complex health research issues for lay audiences?
- How do media images shape our own self-image or pressure people to look a certain way?
- What helps you be a critical consumer of media?
- How does the media influence what a woman is supposed to look like or what makes a person feminine?

## The Law

Legal issues are also featured in the film. We learn about a \$2.7 billion legal settlement resulting from a lawsuit of women made ill by implants against Dow-Corning, the original maker of silicone implants. Many women, however, received little or no compensation for their injuries. One of the

