DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0007]

Silicone Inflatable Breast Prostheses; Information for Women Considering Saline-Filled Breast Implants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a patient risk information sheet entitled ''Information for Women Considering Saline-filled Breast Implants.'' The purpose of this information sheet is to provide prospective patients with information about the possible risks involved with silicone inflatable breast prostheses (saline-filled breast implants).

ADDRESSES: Submit written requests for single copies of the information sheet entitled ''Information for Women Considering Saline-filled Breast Implants'' to the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. ''Information for Women Considering Saline-filled Breast Implants'' is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ–84), 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION: Saline-filled breast implants were already on the market when FDA was given the authority to regulate medical devices. After passage of the Medical Device Amendments of 1976, FDA classified this device into class III (premarket approval). Under a ''grandfather'' clause, manufacturers were permitted to continue marketing class III devices already on the market, with the understanding that at some time in the future FDA would require them to submit preclinical and clinical data showing that their devices are both safe and effective. FDA believes that it is important for prospective recipients of saline-filled breast implants to know that FDA has not yet seen or evaluated preclinical information and clinical trials on these devices. The agency believes that patients should receive information about the possible risks involved before surgery so that they have an opportunity to review the material and discuss it with their doctor. Each woman must decide with her doctor whether she is willing to accept the risks in order to achieve the expected benefits. FDA believes that this decision should be an informed one.

FDA issued a notice to promote the dissemination of information on risks associated with saline-filled breast implants in the **Federal Register** of September 26, 1991 (56 FR 49098). FDA stated in that notice that it would regard saline implants as misbranded under the Federal Food, Drug, and Cosmetic Act (the act) if their labeling does not provide adequate written information to patients on the risks associated with these devices. Included in the **Federal Register** notice was a suggested patient risk information sheet.

Subsequently, in December 1994, FDA solicited comments from health professional groups, consumer organizations, and manufacturers on updating the patient risk information sheet. FDA has sent the updated risk information sheet to the two manufacturers of saline-filled breast implants, Mentor H/S and McGhan Medical, so they can provide it to physicians who perform breast implant surgery. It is the responsibility of these physicians to provide the information sheet to prospective patients before they have decided on surgery so they can read, consider, and discuss the current information before deciding whether to have the surgery.

To ensure that patients receive the revised patient information, these two manufacturers have agreed to send a ''Dear Doctor'' letter to their physician customers, including a copy of the revised patient risk information sheet, to remind them of the importance of providing this information to all prospective patients. Written confirmation from the physicians that they agree to disseminate the revised patient information will be requested. The manufacturers also agreed to ask the American Society for Plastic and Reconstructive Surgeons to include in their next newsletter an article advising their members of the updated patient information, and reminding them of their responsibility to provide this information to all prospective patients. Lastly, the manufacturers are to ensure that all saline breast implants shipped include the revised patient risk information sheet.

The saline-filled breast implant is currently the only device legally available for breast augmentation. For breast reconstruction, the current legal restrictions on the use of silicone gel-filled implants limit their use to those cases where the saline breast prosthesis is considered medically unsatisfactory.

Because FDA believes it is important that the information in the patient risk information sheet is available to consumers and the general public, FDA is providing the text of this sheet below and will provide single copies on request to the Division of Small Manufacturers Assistance (address above).

Information for Women Considering Saline-filled Breast Implants

Saline-filled breast implants (silicone envelopes filled with salt water) were already in use in 1976 when the Food and Drug Administration (FDA) began regulating medical devices. Under this 1976 law, manufacturers could continue selling devices already on the market (''grandfathered''). But the 1976 law made it clear that at some time in the future, FDA would require manufacturers to submit their research data showing that these products are safe and effective. Women need to know that until this call for research data occurs, laboratory, animal, and human tests on some of these ''grandfathered'' products—including saline breast implants—may not have been completed by the manufacturer or reviewed by FDA.

Women considering saline-filled breast implants for breast enlargement or reconstruction should receive the following information about implants (and, when appropriate, other options for reconstruction) before surgery is scheduled. This will allow them time to review the material and discuss possible risks and benefits with her doctor. For some women, breast implants can improve their quality of life. Some breast cancer survivors believe that getting implants has been an important part of their recovery. However, other women find external breast forms to be satisfactory. Reconstruction options include breast implants or surgery using tissue from a patient's own abdomen, back, or buttocks to form a new breast. This surgery requires sufficient fat tissue and a longer operation, and like any other procedure, it is not always successful. For each woman, whether her goal is augmentation or reconstruction, the benefits may be different. With her doctor's advice, each woman must decide whether or not she wishes to accept the possible risks in order to achieve the expected results.

Breast implant surgery presents the same general risks associated with anesthesia and any other surgery. After the surgery, there are other special risks related to saline-filled breast implants. (The manufacturer's package

insert for these devices gives additional, more detailed information. Your surgeon has a copy and can provide it to you.)

Most Common Risks

Deflation. Breast implants cannot be expected to last forever. Some implants deflate (or rupture) in the first few months after being implanted and some deflate after several years; yet some seem to be intact 10 or more years after the surgery. It is not known when deflation is most likely to happen. The implant can break due to injury to the breast or through normal wear over time, releasing the saline (salt water) filling. Researchers are doing studies to determine rupture rates over time. Whenever a saline-filled implant does deflate, it usually happens quickly and requires surgery to remove and, if desired, replace the ruptured implant. Since salt water is naturally present in the body, the leaked saline from the implant will be absorbed by the body instead of being treated as foreign matter.

Making breast cancer harder to find. The implant could interfere with finding breast cancer during mammography. It can ''hide'' suspicious-looking patches of tissue in the breast, making it difficult to interpret results. The implant may also make it difficult to perform mammography. Since the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. It is essential that every woman who has a breast implant tell her mammography technologist before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because more x-ray views are necessary with these special techniques, women with breast implants will receive more radiation than women without implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

Capsular contracture. The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant. This is called capsular contracture. Over several months to years, some women have changes in breast shape, hardness, or pain as a result of this contraction. No good data are available on how often this happens. If these conditions are severe, more surgery may be needed to correct or remove the implants.

Other Known Risks

Calcium deposits in the tissue around the implant. When calcium deposits, which are not harmful, occur, they can be seen on mammograms. These deposits must be identified as different from the calcium that is often a sign of breast cancer. Occasionally, it is necessary to surgically remove and examine a small amount of tissue to see whether or not it is cancer. This can frequently be done without removing the implant.

Additional surgeries. Women should understand there is a fairly high chance they will need to have additional surgery at some point to replace or remove the implant when and if it wears out. Also, problems such as deflation, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Discuss the risk of these additional surgeries with your physician. Many women decide to have the implants replaced, but some women do not.

Infection. Infection can occur with any surgery. The frequency of infection with implant surgery is not known, but a prospective patient should ask her surgeon what his or her experience has been. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with foreign bodies present (such as implants) are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed. After the infection is treated, a new breast implant can usually be put in.

Hematoma. A hematoma is a collection of blood inside the body (in this case, around the implant or around the incision). Swelling, pain, and bruising may result. The chance of getting a hematoma is not known, but a woman thinking about breast implants should ask her surgeon about his or her experience. If a hematoma occurs, it will usually be soon after surgery. (It can also occur at any time after injury to the breast.) Small hematomas are absorbed by the body, but large ones may have to be drained surgically for proper healing. Surgical draining causes scarring, which is minimal in most women.

Delayed wound healing. In rare instances, the implant stretches the skin abnormally, depriving it of blood supply and allowing the implant to push out through the skin. This complication usually requires additional surgery.

Changes in feeling in the nipple and breast. Feeling in the nipple and breast can increase or decrease after implant surgery. Changes in feeling can be temporary or permanent and may affect sexual response or the ability to nurse a baby. (See the paragraph on breast-feeding below.)

Shifting of the implant. Sometimes an implant may shift from its initial placement, giving the breasts an unnatural look. An implant may become visible at the surface of the breast as a result of the device pushing through the layers of skin. Further surgery is needed to correct this problem. If the implant shifts, it may become possible to feel the implant through the skin. (Placing the implant beneath the muscle may help to minimize this problem.) Other problems with appearance could include incorrect implant size, visible scars, uneven appearance, and wrinkling of the implant.

Unknown Risks

In addition to these known risks, there are unanswered questions about saline-filled breast implants. For example, can the implants bring on symptoms of autoimmune diseases such as lupus, scleroderma, and rheumatoid arthritis? Can they bring on neurological symptoms similar to multiple sclerosis in some women? Can the implants increase the risk of cancer? (Because saline-filled implants contain only salt water, any risk that might be related to silicone gel would not occur with this type of product.) There is some concern, but little information, about possible risks from the silicone rubber material of the envelope. Also, questions have been raised about the potential for the saline to become contaminated with fungus or bacteria. If so, these organisms might be released into the woman's body if her implant deflated.

Autoimmune diseases. According to scientific studies, women with breast implants in general are not at an increased risk for autoimmune or connective tissue diseases. However, these studies are too small to detect whether there might be a slightly increased risk of any one of these rare diseases. Also, these current studies have looked only for the symptoms of known autoimmune diseases, rather than the variety of symptoms that some women report experiencing. Some of the reported symptoms include:

- Swelling and/or joint pain or arthritis-like pain;
- General aching
- Unusual hair loss
- Unexplained or unusual loss of energy
- Greater chance of getting colds, viruses, and flu
- Swollen glands or lymph nodes
- Rash
- Memory problems, headaches
- Muscle weakness or burning
- Nausea, vomiting
- Irritable bowel syndrome.

Breast-feeding and children. Questions have been raised about whether or not breast implants present safety concerns for nursing infants of women with breast implants. Some women with breast implants have reported health problems in their breast-fed children. Only very limited research has been conducted in this area, and at this time there is no scientific evidence that this is a problem. It is not known if

there are risks in nursing for a woman with breast implants or if the children of women with breast implants are more likely to have health problems.

Cancer. At this time, there is no scientific evidence that women with saline-filled breast implants are more susceptible to cancer than other women.

Dated: June 15, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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