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## Kathy Ferrell's Medical - Legal Consulting Newsletter

December 2005

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**Greetings! Merry Christmas and Happy New Year !**

This is my second e-newsletter which I hope you find useful and informative. I welcome your suggestions for future monthly newsletters, including topics you would like for me to address. I look forward to being of service to you.

### Are Mentor Corporation Breast Implants Safe?

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Mentor Corporation, which hopes to win FDA approval soon to sell its silicone-gel breast implants for general cosmetic use, faced a problem last year as it prepared to distribute to doctors the demonstrative or "sizer" models. These models which prospective customers would try on for size sometimes left behind an unsettling slick of silicone oil.

A former senior engineer with the company told the FDA last month that the implants tended to leak their contents due to a hole left by the manufacturing process. He and others developed a less permeable material for the one-inch patch. But despite urging from its staff, the company made these modifications to the demonstrative or sizer models only. The company never made the same modifications to the devices destined to be implanted in women who want to have their breasts restored after surgery or enlarged for cosmetic purposes. He further said that although low-bleed patches costs "a few pennies extra for each implant", the company decided not to modify the implants sold to women. He speculated that the company did not want to jeopardize its FDA application by having to test a modified patch. Mentor Corporation's position is that intense testing of the implants provided to clinical trials has shown their leakage to be "minute and negligible".

Possible health complications from silicone- gel 'bleeds' are among issues the FDA is addressing as it moves toward a decision to allow unrestricted sale of silicone implants for breast enlargement for the first time since 1992. During the April advisory panel hearing, an FDA staff report described three tests the company had undertaken to measure gel bleed. The review concluded that all were of limited value in determining what might happen in the body. The advisory pane ultimately recommended that the FDA approve Mentor's product. Daniel G. Shultz, directory of the FDA's Center for

Devices and Radiological Health, confirmed in December that the FDA is evaluating the allegations made by the former senior engineer.

In the U.S., an estimated 1-2 million patients or approximately 1% of the adult female population have breast implants. The most common adverse event for breast implants is "reaction". Much has been reported on the systemic conditions associated with silicone gel based implants. However, few reports in peer-reviewed literature support many of the associations.

Local morbidity does occur and can manifest as pain, paresthesia, capsule contractures, hardness or an unnatural feel of the breast, migration and siliconoma. Systemic immunologic reaction to silicone exposure also occurs, but the outcome of this exposure, if any, is unclear. Failure to accurately diagnose silicone gel breast implant bleed or rupture could lead to increased legal liability should there be physical or psychological injury from the decision not to explant the prosthesis based on findings described in relevant imaging (MRI, CT, ultrasound or mammography) examinations.

Resources:

- <http://www.fda.gov/cdrh/breastimplants/handbook2004/localcomplications.html>
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=593>
- <http://www.fda.gov/cdrh/breastimplants/resources.html>

### ***The LNC's Role in Product Liability Case Analysis***

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As a Legal Nurse Consultant (LNC), I use my unique medical skills to assist attorneys in product liability case analysis. My role includes the following:

- Examine the standards of care practiced by the medical practitioner who prescribed the drug or medical device
- Determine if liability rests with the practitioner or manufacturer
- Review the plaintiff's medical record to establish clear causation
- Develop the plaintiff's medical history to recognize drug or product induced illness in a person who has multiple co-existing illnesses
- Identify possible third-party counter claims
- Perform thorough medical literature searches concerning the product; e.g., product warnings, package inserts, language and content of advertisements
- Obtain adverse reaction and medical device reports from the FDA under the FOIA
- Evaluate all the evidence to prove or disprove the legal basis for the plaintiff's case
- Identify and obtain medical and technical testifying experts

[My experience with product liability cases includes PPA, Zyprexa, and Vioxx. Please contact me to discuss how my services may be of use to your firm.](#)

### **Contact Information**

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