

Safe Enough?

By Diana Zuckerman

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How safe need an implant be before the Food and Drug Administration decides it is "safe enough" for a surgeon to put it in your body? The answer may surprise you.

Congressional leaders from both parties continue their scathing criticism of FDA for failing to protect consumers from unsafe medical products. Vioxx is the most obvious example but far from the only one.

The problem is not just prescription drugs. In just the last few weeks, the FDA announced the potentially fatal risks of heart valves and defibrillators. And, the FDA now seems poised to make another blooper, recently announcing their intention to approve silicone gel breast implants for the first time.

Pundits have had a field day, castigating women's organizations for expressing concerns about a product that implant makers and plastic surgeons assure us is perfectly safe. They trot out flawed research and old reports to back up their claim, conveniently ignoring evidence that conflicts with their conclusions.

A cardinal rule of medical research is some products that seem safe at first may be found harmful years later. When the National Academy of Sciences first published a report on Agent Orange in 1974, for example, it concluded there was no clear evidence Agent Orange harmed Vietnam veterans. Years later, scientists concluded it causes birth defects and several types of cancer. Similarly, the first Institute of Medicine (IOM) reports of "Gulf War Syndrome" concluded war exposures had not caused health problems. Scientists now agree Gulf war veterans are at increased risk of ALS (Lou Gehrig's disease), and possibly other fatal diseases.

In 1999, the IOM concluded there was no evidence implants caused diseases. Instead, they were concerned implants could break or interfere with mammograms, cause pain, or require additional surgery. They reviewed all the studies published, but many were of animals or cells. There were very few clinical trials or epidemiological studies of women with implants, and almost all were funded by Dow Corning, the company that makes silicone and commissioned the studies to avoid losing billions of dollars in legal settlements with implant patients who became ill.

As an epidemiologist, I realized the Dow studies were scientifically flawed. Since most cancers or autoimmune diseases take many years to develop and be diagnosed, the studies should have focused only on women who had implants for at least seven to 10 years. Instead, they included many women who had implants for only a few months or years. The studies also included small numbers of women who had implants for 25 years or more -- but those "silly putty" breast implants were much thicker and more durable than the implants sold after 1980. It would not have mattered who paid for the research if it was well designed -- but it wasn't. That is why scientists wonder if the studies were designed to prove implants safe,

rather than determine if they were safe.

In contrast, in studies funded by the National Cancer Institute or the FDA rather than implant makers, findings were dramatically different. By studying women who had breast implants for at least seven years, they included many women whose implants were possibly leaking. The results showed statistically significant increases in several cancers and autoimmune diseases. They also found a doubling of deaths from brain cancer and a tripling of deaths from lung cancer when women with implants were compared to other plastic surgery patients, even though the two groups are very similar in access to health care, smoking and other health habits that could influence disease.

When symptoms are studied instead of diseases, even short-term research reveals implant problems. In 2003 and 2005, the FDA scrutinized two breast implant makers' research. A surprising number of patients were found to have pain, broken implants or other problems that required surgical removal of their implants within the first three years. Even more surprising, women were more likely to report autoimmune symptoms, such as joint pain and fatigue after having these implants for two years, compared to how they felt just before getting implants. Statisticians note these differences were not caused by aging.

In a recent rant in this newspaper, Steve Milloy accused me of frightening people about the risks of breast implants, and accused other women's organizations of ignoring scientific evidence of the safety of implants. I would be happy to sit down with him and together examine every single study. Unfortunately, accurately describing research results sometimes frightens people. But what really frightens people is learning too late they can't trust FDA-approved medical products, whether painkillers or implants.

Why are so many Americans harmed by FDA-approved products? It has been suggested companies sold products they knew were unsafe. In some cases, the FDA has been accused of ignoring the allegations or even actively helping to conceal them. For example, when the FDA closed its criminal investigation of Mentor, an implant maker, the agency compliance officer resigned in disgust and complained to the FDA commissioner. A congressional investigation continues into the matter, but FDA officials seem ready to approve breast implants before the ongoing congressional investigations are completed.

Are silicone breast implants safe enough for breast cancer patients? Are they safe enough for people you care about? Implant makers have flooded medical journals with articles claiming they are. The few government studies raise important, never-answered questions about long-term safety. The key question here is what does the FDA mean by "safe enough?"

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