

Invited Testimony of Diana Zuckerman, PhD Before the Standing Committee on Health Canadian Parliament Ottawa

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I am Dr. Diana Zuckerman, President of the National Research Center for Women & Families. Our independent, nonprofit organization is a think tank that gathers and explains research information and uses it to improve the health and safety of women, children, and families.

I am speaking from the perspective of someone trained in psychology and epidemiology, who was a university faculty member and researcher at Harvard and Yale and taught courses in research methods before moving to Washington, DC to work on health issues in the U.S. Congress, U.S. Department of Health and Human Services, White House, and for nonprofit organizations.

I have read every published epidemiological study on breast implants and will briefly discuss what is known and not known, based on those studies. I will also tell you about a criminal investigation of one of the implant manufacturers, Mentor, and the many calls and emails we have received from women in Canada who are finding it impossible to have their leaking silicone gel breast implants removed in a timely manner.

Who conducts research on breast implants?

Clinical trials are a major source of information on the short-term risks of silicone breast implants. In clinical trials, the goal is to follow women prospectively to determine what complications and health problems occur, and to compare that to a control group. Although silicone implants have been on the market for 40 years, the only well-designed clinical trials have data for only 2-3 years and they do not include a control group. The clinical trials have been conducted by the implant companies as part of their effort to obtain approval to market the implants in Canada and the US.

Epidemiological studies are the major source of information about what actually happens to women who have breast implants for at least five years. **Almost every published epidemiological study on breast implants has been paid for by companies that sell or sold breast implants.** In fact, one company in the U.S. has received many millions of dollars from Dow Corning to conduct most of these studies, almost all of them in Europe, and every one of those studies has concluded that implants are safe. However, careful scrutiny of the results in the peer-reviewed articles indicates serious health problems among women with those implants. For example, one recent study reported that women with breast implants were significantly more likely to report breast pain and take anti-depressants, but still concluded that breast implants were safe.

More importantly, a small number of studies have been conducted by independent researchers, not using implant company funds or funds from plastic surgeons. These include government-funded researchers in Canada and the U.S. Their findings almost always indicate problems with implants that are in direct contradiction to the findings of the studies funded by implant companies. I will focus on their findings today.

What do we know about the health effects of ruptured silicone gel implants?

The FDA funded, designed, and conducted the best study on the health of women with ruptured silicone implants. FDA scientists concluded that **most** women with implants for 11 years or more have at least one ruptured implant, even if they don't realize it. They also found that 21% of women with implants for at least 7 years have at least one implant that is leaking silicone outside the scar tissue, and that women with leaking implants were more likely to report fibromyalgia or several other painful and debilitating autoimmune diseases. The FDA study is superior to other studies because it focused on women who were basically happy with their implants, and who had implants for **at least 7 years**. That length of time is key. Other studies have included women who had implants for an average of 7 years -- but not at least 7 years.

Most women who have had problems with rupture had implants for a long time -- usually much longer than seven years.

Cosmetic Problems

More independently funded research is needed on the risks of ruptured silicone gel implants. Meanwhile, let's look at some of the **cosmetic** results of silicone gel implant problems.



Here is a 29-year old woman who had her implants removed after 7 years. Her capsular contracture was so painful that she apparently preferred getting her implants out to keeping them in. This photograph is from the FDA's website.



That is obviously not a good outcome, but [here](#) is a woman who wasn't so lucky -- Sharyn Noakes. Her ruptured implant had leaked into her healthy breasts. When the silicone was removed, this is all that was left of her breasts.



And [this](#) is Kathy Nye, a breast cancer survivor who suffered from necrosis and her implant extruded through her skin. Inamed reported a 6% necrosis rate among reconstruction patients in their Core study.

Signs and Symptoms

Now that you have seen some of the cosmetic problems, let's take a look at the women's symptoms. In data presented to the FDA, Inamed and Mentor both found that women with implants for only two years had a significant increase in autoimmune symptoms such as joint pain and nervous system symptoms. FDA asked a statistician to determine if this was due to aging. It wasn't. And, these findings are consistent with what we have heard from thousands of women with silicone breast implants. Most were happy with their implants for years and never suspected that their increasing problems with fatigue or aches and pains might be related to their implants. The women's personal experiences are not conclusive evidence, but they indicate a pattern that needs to be considered -- especially since they are consistent with Inamed and Mentor's own data showing an increase in autoimmune symptoms over a period of only two years on a cohort of young augmentation patients.

What do we know about the health risks of silicone gel implants more generally?

Aleina Tweed, an epidemiologist at the British Columbia Centre of Excellence for Research on Women, conducted a study of breast augmentation patients in Canada, most of whom had implants for 10 years or longer. She found that the women with implants visited doctors and specialists more often, and were four times as likely to be hospitalized, compared to other women the same age from the same communities.

Why has that important Canadian study received so little attention? Probably because no one was paid to do PR on the study. In contrast, studies funded by Dow Corning, the maker of silicone, have received enormous publicity. You may have heard that hundreds of studies, including studies at Harvard and the Mayo Clinic and a report of the U.S. Institute of Medicine, provide clear proof that breast implants are safe. However, the Institute of Medicine report is outdated -- completed in 1999 and based on studies conducted before that. And, it was based on the other studies that are so often quoted, such as the Mayo Clinic study and the Harvard study -- studies that were all funded by Dow Corning and other implant makers.

Almost all the studies included in the Institute of Medicine report suffered from the same shortcomings: they were too small, and they lacked statistical power because they included women who had implants for too short a period of time. For example, the Mayo Clinic study included only 749 women with breast implants, only 125 of whom were reconstruction patients. To be in the study, women had to have implants for at least one month. The average length of time was about 7.5 years, which means that only about 375 women had implants for more than 8 years. Since diseases like lupus, scleroderma, and rheumatoid arthritis are not very common among women in their 20's and 30's, this study doesn't have the power to detect most of the diseases it measured. The authors themselves acknowledged that major shortcoming.

So, while I agree with the Institute of Medicine that there is not sufficient evidence to conclude that implants cause

autoimmune disease, the report can't be considered conclusive proof that implants don't cause autoimmune disease.

The U.S. government has also funded some important studies of breast implants, and like the Canadian study, they tend to report serious health problems for women who have implants for a long period of time. The National Cancer Institute study found a doubling of brain cancer, lung cancer, and suicide. It is an exceptionally well-designed study, because all the women in the study had breast implants for at least 12 years. Another major strength of the study is that it compared women with silicone implants to women who underwent other kinds of plastic surgery, such as liposuction. This is important because all plastic surgery patients tend to be above average in health and income, but also tend to smoke more than other women.

How do the many implant studies funded by Dow Corning compare to the government funded studies in Canada and the U.S.? Many of the Dow Corning studies focused on women with implants for a short period of time, and at least one on women with ruptures for a short period of time. Many measured illness in terms of hospitalization rather than diagnosis. Remember that most women getting breast augmentation are in their 20's or 30s, with many in their teens. Think of how unlikely it is that a 30-year old woman will be hospitalized for rheumatoid arthritis.

Inamed and Mentor Research Quality and Integrity

Inamed and Mentor both started clinical trials to analyze the safety of silicone gel breast implants in 1990. Both companies lost track of almost all of their patients to follow -up within 5 years. If only they had done a good job on those studies, we would have great long-term data today. But they didn't, and so we don't.

The companies both were given the opportunity to test their silicone gel implants on thousands of patients in the Adjunct Studies that they conducted. They enrolled thousands of patients and then failed to follow -up on most of them, making those studies useless.

Last year, shortly after Inamed and Mentor silicone implants were considered by advisory committees in Canada and the U.S., I heard from several Mentor employees who expressed concerns about the accuracy of the data that Mentor provided to the FDA, and also informed me that the patch used on Mentor implants leaks silicone and should be fixed. I contacted the FDA and arranged for the Mentor employees to speak to FDA officials. As a result, the FDA started a criminal investigation, interviewing me and several former Mentor employees. I was told several weeks ago that the investigation is still underway. I would be glad to put those former Mentor employees in touch with officials at Health Canada as well.

What does approval matter?

Although there are restrictions on silicone gel breast implants in Canada and the U.S., tens of thousands of women have continued to get them. Many of those women were not breast cancer patients.

Even so, approval matters. If Health Canada approves silicone gel breast implants, it will send a clear message that it believes that the implants are safe, and more teenage girls and women will certainly choose silicone implants as a result.

The study by Aleina Tweed shows that in Canada, women with breast implants have more health problems and their efforts to get well are costly to the Canadian system. Most of the women had at least one surgery to fix an implant problem, and 17% had four or more additional surgeries. Tweed's findings are especially striking to us because our Center hears from many Canadian women with breast implants who tell us that they can't get help from most Canadian plastic surgeons. Many have discovered -- often after years of symptoms -- that their implants are leaking. They need a plastic surgeon to remove them, and often can't afford to pay for the surgery. But the waiting list is very long. We know a patient who contacted Dr. Mitchell Brown's office this spring, because she heard he is an excellent surgeon who knows how to remove leaking silicone implants. She was told she would need to wait until December 2006 just to see him for a consultation. She was told that if she needed surgery, that would have to wait until December 2007. My staff found that hard to believe, so we also contacted Dr. Brown's office more than a week later and we were told the exact same thing. My staff asked if there was a shorter wait if she could pay for the surgery, and we were told that the wait was much shorter.

We know several patients who tried to arrange surgery with other Canadian plastic surgeons. They were told that silicone would likely leak during the surgery and that they could be left looking deformed, They were discouraged from removing their implants, and told that at least they should replace them with new implants.

If Health Canada approves silicone gel breast implants, the number of teenagers and women needing to have leaking silicone implants removed will increase dramatically. To allow that to happen in a country where few plastic surgeons know how to remove leaking silicone gel breast implants, and those that do have very long waiting lists is not ethical or appropriate. And, according to Aleina Tweed's research, it will cost the Canadian healthcare system dearly.