April 20, 1999

The Commissioner of the FDA
Dockets Management Branch
Food and Drug Administration
Dept. of HHS, Rm. 1-23
12421 Parklawn Drive
Rockville, MD 20857

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Dear Commissioner,

In the best interest of American women, please do not bend to the pressure of the breast implant manufacturers to allow silicone gel breast implants to return to the market, either in a restricted or unrestricted way.

My board certified rheumatologist believes my connective tissue disease was most likely caused by my (ruptured) silicone breast implants that were in from 1978 to 1995. There is no autoimmunity in my family. In 1995, blood tests showed me to have an ANA titer of 1:320. The rheumatologist told me he thought one of my implants was ruptured. Two weeks later when a plastic surgeon removed the implants, the rheumatologist was proven correct.

Due to the deterioration of my physical health the rheumatologist strongly recommended I quit work. It was one of the most difficult things I ever faced to leave my life's work and my career. Though I had some severe joint problems before 1995, I was still able to work. January 1997 was the last day I was employed. Doctors have told me they do not anticipate that I will be able to return to work.

If the FDA had followed its mission, long ago it would have made silicone gel implant manufacturers prove the safety of their product. From the 1976 "grandfather" clause to 1992 when former FDA Commissioner David Kessler put a temporary ban on silicone gel implants, is an inexcusably long time for the FDA remain silent.

In August 1998, at Oregon Health Sciences University library, when looking under the heading 'silicone breast implants', there were 654 citations on MEDLINE 1995 to Aug. 1998. 349 of those were listed under the subheading Adverse Effects. That is more than 50% of the articles. The studies cited as showing no relationship between silicone breast implants and disease were funded by the manufacturers and were looking chiefly for classic connective tissue diseases. Having read extensively, I note that atypical diseases are ones identified with silicone exposure. I personally exhibit features of lupus, scleroderma and also have Sjogrens.

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Many women who had mastectomies rail at the thought of not being able to have implants to replace a breast lost to cancer. But women who had silicone breast implants after mastectomy who became ill with atypical connective tissue diseases have to again undergo surgery to have the silicone removed once they became ill. Some of them have expressed the felt as though they lost their breast twice.

In a published article, my rheumatologist, Dr. Kip Kemple of Portland, OR made an estimate of the number of persons becoming ill have silicone implantation. Having seen more than 1,000 silicone patients, he estimates that somewhere between 10 and 20% of exposed persons become ill due to silicone exposure. It is with great sadness for my life's losses that I live with the aftermath of silicone.

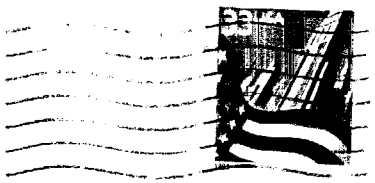
I entreat you to continue the ban on silicone gel breast implants. Women who desire implants after mastectomy could opt for the saline filled silicone bag implants. Their total exposure to silicone would, at least, be that much less.

Sincerely yours,

Nancy Korb

Mrs. Nancy Korb
13221 SE Forest St.
Vancouver, WA 98683

Mr. & Mrs. Norman Korb
13221 SE Forest St.
Vancouver, WA 98683-6531



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