Testimony of Kim Hoffman
Patient Representative Regarding Breast Implants
Submitted to
Senate Health, Education, Labor & Pensions Committee
Public Health Subcommittee

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Mr. Chairman, my name is Kim Hoffman. I am a breast implant recipient from Missouri.

As the watchdog of public safety for food, drugs and medical devices, the FDA has failed specifically in its duties, by allowing a medical device with high complication rates to be marketed to American women by companies with dubious manufacturing practices.

Like thousands of other women, I experienced numerous debilitating problems immediately after receiving my textured, silicone breast implants, manufactured by Mentor Corporation, in 1995. To receive silicone implants after the moratorium in 1992, I was required to participate in a clinical study. Because data collected in this study could effect FDA's decision as to whether the agency should approve the wide spread availability of the product, I recognized the importance of accurately documenting my problems and including them in the study.

I reported my problems to my surgeon. He ignored me. I obtained a copy of the study protocol and realized a number of study rules had been violated. I reported the violations, *and* my physical problems to the manufacturer, who was the sponsor of the study *and* to the FDA; again, I was ignored. *After* numerous attempts to report my complications as a study participant, I received a form from my file at the manufacturer; it read, "patient has no complaint."

Astonished by the apathetic responses I'd received, and being from the show me state, I began my own investigation. I interviewed several other study participants and found problems with their cases as well. I was able to talk to people who worked for the manufacturers and even a couple of industry whistle-blowers. From them I learned that not only were there problems with the study and the documentation of problems experienced by patients, but the companies were having major problems with quality control issues and were violating good manufacturing practices. These problems had gone on for years.

These individuals alleged that there were problems with the implant design and gel suppliers; there were defects with the implants, valves, and outer shell; and there were inconsistencies in the gel used to fill implants. It appeared many of these problems had been concealed from the FDA. I reported this information to the FDA, *several people* at the FDA, but there was no apparent action.

Disturbed by the lack of responsiveness at the FDA, in the summer of 1998 I put all of the information together, information about the clinical trials and the manufacturing problems alleged by industry employees, and gave it to Congressman Green, the FDA, the House Energy and Commerce Committee, and eventually to Congressman Blunt.

The FDA's copy was given to James Austin Templer, a FDA compliance officer who oversaw Mentor Corporation, the manufacturer I had gathered the most data about. Mr. Templer referred the information to the FDA's Office of Criminal Investigations, and in 1998 a criminal investigation was opened.

Throughout 1999, I continued to receive alarming information, which was given to Mr. Templer and then forwarded to the FDA's criminal investigators. Unfortunately, little was done, in spite of the shocking information that was uncovered *and* Mr. Templer's efforts to push the investigation forward. It became obvious to both of us that there were significant problems with the medical devices and the integrity of the manufacturing process. Furthermore, it appeared internal problems at the FDA were undermining consumer protection.

The situation became critical in 2000. The FDA had announced that saline breast implants would be considered for market approval in the spring, and Mentor Corporation would be submitting a pre-market application (PMA) for approval of their products. The criminal investigation had gone nowhere and regulatory actions had been put on hold because of the criminal investigation. In January 2000, in frustration and out of a concern for American consumers, Mr. Templer tendered his resignation from a *twelve-year career at the FDA*. He hoped his resignation would get the attention of the agency. In his resignation letter to the commissioner, he, among other things, urged the agency to conduct a thorough investigation of the allegations, which had been made about the manufacturer and the study, *prior* to the agency's approval of saline breast implants. Unfortunately, the FDA again chose to look the other way.

In May 2000, the FDA approved saline breast implants. The approval came in spite of Mr. Templer's recommendation, in spite of complications rates as high as 43% for cosmetic patients and complication rates of over 70% for reconstruction patients (in the first 3 years), and in spite of an ongoing open criminal investigation into one of the manufacturers, which remains open even today.

Sadly, consumers believe "FDA approval" of a product means that the product has been adequately studied and has been found to be safe and effective for it's intended use. I'm not sure this should be concluded with this device. Unfortunately, the average consumer who might purchase this product will not have access to the information the FDA has ignored during the approval process, resulting in an inappropriate assumption of safety and effectiveness.

It is my fear that by ignoring the regulatory problems, the criminal allegations, the high complication rates and the recommendation of the FDA's own staff, the agency has *lowered the bar* for what is considered a safe and effective medical device. Additionally,

the ramifications of the FDA's decision could be widespread and ultimately effect other products and many American consumers.

It was this concept which disturbed Mr. Templer and me so deeply. Mr. Templer couldn't be here today, however, he asked me to advise the committee of *his* professional opinion regarding this topic.

Mr. Templer writes, "Based upon information I was aware of as an FDA official it does not surprise me that breast implant recipients are experiencing significant health consequences. I was aware of many quality control issues as well as situations where FDA employees illegally assisted an implant manufacturer. I reported these issues, but the FDA wanted to sweep the matter under the rug. In my opinion, the FDA has not adequately monitored or investigated the safety of breast implants, and in fact, they have looked the other way when credible allegations of criminal conduct have been made. I urge the committee to take the actions necessary to protect the public health, because the FDA has clearly failed to do so."

I agree with Mr. Templer: it will take an act of Congress to get to the bottom of the breast implant debacle. However, Congress must insist that our country's watchdogs are doing their jobs. The passing of this bill is a great first step. S. 961, the Breast Implant Research and Information Act, will ensure the FDA has full oversight and will provide accountability. The passing of this bill will ultimately benefit women's health and could also impact FDA's oversight of all medical devices.

I want to thank Senator Barbara Boxer and Senator John Edwards their leadership on this issue.

I urge you to make it a goal to pass this bill in *this* Congress. Breast implants have been put in women's bodies for over 30 years; it's high time we understand the long-term effects of this product and insist that they be manufactured with integrity and in accordance with good manufacturing practices.

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