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OPENING STATEMENT OF THE HONORABLE TED WEISS

AT A HEARING ON JAW IMPLANTS

Thursday, June 4, 1992

Millions of Americans suffer from a vaguely defined syndrome called temporomandibular disorder (TMD). Every year, between 500,000 and one million new patients seek treatment for TMD pain, dizziness, and other symptoms. Almost 80% of the patients are women between the ages of 20 and 40.

In some cases, TMD goes away by itself. In other cases, pain medication, physical therapy, biofeedback, and other treatments are successful. However, if these treatments do not work, thousands of patients choose surgery every year; and if less radical surgeries are not effective, they are likely to get implants or bone grafts.

Most people would assume that these surgical treatments are carefully evaluated by the Food and Drug Administration or the National Institutes of Health. They would be wrong. The FDA has never required that the manufacturers of the implants prove that they are safe or effective, and the NIH has not funded research on the safety or effectiveness of implants or grafts.

We have heard this story before. Most medical devices were not required to be proven safe or effective until 1976, when Congress enacted the Medical Device Amendments. That law treated devices that were already on the market before 1976, like breast implants, more favorably than devices that were not yet in use. And, if a manufacturer claimed that their new device was similar to a pre-1976 device, FDA was likely to agree without asking for much evidence to prove that was true.

That is how most jaw implants were allowed to be sold. And as a result of that carelessness on the part of FDA, thousands of patients have suffered terribly from implants that never should have been allowed to be sold in the first place. Not only did the implants not work, not only did they cause unrelenting debilitating pain, they sometimes cause serious permanent damage that continues long after the implants are removed.

We will hear today about one implant that apparently failed 100% of the time, and others that failed most of the time. There is evidence that the overwhelming majority of the grafts and implants that have been used so far will eventually fail, if they haven't already.

Not all patients have had pain and suffering because of their implants, but it may be that most eventually will. Most frightening of all, some of these implants are causing permanent damage to the skull, and the patients are not even aware that they are in danger.

We will hear testimony today from women who suffer from indescribable pain as a result of their implants. We will also hear testimony from surgeons and other experts who will explain why this has happened.

At today's hearing, we will attempt to answer the following questions:

1. Why has FDA failed to regulate TMJ implants?
2. Why has NIH failed to fund research on the safety of TMJ grafts or implants, or to determine the best possible treatment for the thousands of TMJ patients who have been damaged by their implants?
3. Most important, are millions of patients with many different kinds of implants put at risk while two federal health agencies pass the buck or drop it altogether? How often does FDA fail to require manufacturers to conduct research on their products, while NIH refuses to fund research on those same products because they believe it is FDA's responsibility?

Good morning. I am Terrie Cowley, co-founder of the TMJ Association, Ltd. (6418 W. Washington Blvd., Milwaukee, WI 53213), and I am here to testify about my experiences with silicone jaw joint implants and the experiences of other people with other types of jaw joint implants.

Nearly 15 years ago, I was told by my physicians that the frequent headaches that I was experiencing were due to my jaw joints. It was found that the discs which normally cushion the movement of the jaw joint into my skull were perforated and that degenerative arthritis had developed in both joints. After 5 years of continuing discomfort, I underwent a surgical procedure in 1982 in which both of the discs were removed and replaced with Dow Corning silicone jaw joint implants.

From the day of surgery, my condition worsened. For nearly three years, I experienced excruciating headaches, neck and back pain and extreme fatigue. My vision and hearing were distorted. I developed problems of balance and equilibrium. I encountered memory lapses and a reduction of my ability to articulate. I could no longer function well enough to maintain a full-time job and lived in a state of terror, not knowing how long I could live in a continually worsening physical state. I was passed from one professional to another, none of whom could offer any help.

In 1986, four years after my surgery, I met another jaw joint patient and we formed the TMJ Association, Ltd. It has been our goal to obtain as much information as possible about this disorder from patients and professionals. We also want to provide a way so other patients could meet and support each other. Finally, we want to promote awareness of this disorder in the community.

In the past 6 years I have been from one end of the country to the other, talking with patients and professionals to learn about the causes and treatments and life experiences of people suffering from this disorder. I learned that jaw joint disorders are quite common and that I was one of nearly 12 to 28% of the population (30 to 50 million people) that annually seeks treatment for this disorder. Nearly 90% of these are female and, although it has not been yet determined how many have undergone surgery and/or disc replacement, it is clear that they number in the hundreds of thousands.

Yet, despite the pervasiveness of this disorder, it remains ill defined by the dental and medical professions and there are raging controversies over diagnosis and treatment.

In the last few years I have talked to many patients with jaw joint disorders. I constantly hear what scientists call anecdotes and what I call horror stories. I talk daily to patients with stories similar to those of patients you will hear testify today. They tell of broken marriages because their spouses cannot cope with the unending pain and disability.

They tell of the financial burden placed on them and their family members to the point of bankruptcy. In a recent conversation with a lawyer, I was told that 57 of her 60 temporomandibular joint implant clients were either bankrupt or so financially compromised that they were close to bankruptcy. They tell of constant pain so severe that every day is a battle against suicide.

They tell of the inability of even their physicians to relate to their pain, such as the patient who was told to "go home, have a few drinks, make love and forget you have pain." And they tell me that they live in terror because their symptoms indicate that the implant material has worked its way into the brain and they do not have the money to have it removed. These are the people who have begged me to find a way to tell other victims about this disaster "before they get like I am."

I found that people who have this disorder become isolated. They become isolated from their children, because the children have learned to go to others for their basic needs. They become isolated in the marital sense from their husbands, for intimacy many times takes second place to pain and even the simple act of hugging is painful. They become isolated from society, never being able to plan on such simple things like going to a movie or taking a trip because they never know if they will be physically well enough. They become isolated from the professional providers. A pain management specialist once told me that the TMJ patients are the most tragic of all. When I asked why, he said that "everybody treats them, they rarely get better and there is no one professional who assumes responsibility for the treatment."

Because there is no known etiology for jaw joint disorders, it is not uncommon to identify this disorder as psychogenic in origin and suggest the sufferer may be responsible for the cause and/or maintenance of his or her pain. In fact, at a recent meeting, I heard a speaker state that all his patients get psychological evaluations, but of course we call it pain management.

The stigma is apparent. Last year at an NIH workshop on Women's Research in cardiovascular disease that I attended with my husband, breakfast conversation focused on jaw joint disorders. The scientists easily discussed what they thought were reasons for the disorder, while the only woman at the table remained silent. Later, she took me aside and told me she had the disorder but she would never let her peers know because they would think she was crazy. And, I also hear from the minority with this disorder -- the men. The men who are afflicted are suffering in silence. They hesitate to attend a meeting or to ask for help.

Although my own symptoms have gradually lessened, I am left with the same dilemma that many other patients now face. My

