ARE FDA AND NIH IGNORING THE DANGERS OF TMJ (JAW) IMPLANTS?

HEARING

BEFORE THE

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

SECOND SESSION

JUNE 4, 1992

Printed for the use of the Committee on Government Operations

U.S. GOVERNMENT PRINTING OFFICE

68-349 CC WASHINGTON : 1993

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-041398-2

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ARE FDA AND NIH IGNORING THE DANGERS OF TMJ (JAW) IMPLANTS?

THURSDAY, JUNE 4, 1992

HOUSE OF REPRESENTATIVES,
HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2154, Rayburn House Office Building, Hon. Ted Weiss (chairman of the subcommittee) presiding.

Present: Representatives Ted Weiss, Donald M. Payne, David L. Hobson, and Bernard Sanders.

Also present: James R. Gottlieb, staff director; Diana M. Zuckerman, professional staff member; Elinor P. Tucker, clerk; and Stephen D. McMillan, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN WEISS

Mr. WEISS. Good morning. The Human Resources and Intergovernmental Relations Subcommittee is now in session. Because there is other heavy business on the floor, members of the subcommittee will be coming in and departing as their schedules permit and we will recognize them accordingly. Let me make a brief opening statement; then we will proceed to our first panel of witnesses.

Millions of Americans suffer from a vaguely defined syndrome called temporomandibular disorder, TMD for easier pronunciation. Every year between 500,000 and 1 million new patients seek treatment for TMD pain, dizziness, and other symptoms. Almost 80 percent 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 couldn't be more wrong. The FDA has never required that the manufacturers of the implants prove that they are safe or effective, and the NIH, with logic lifted right out of Alice in Wonderland, has not funded research on the

safety or effectiveness of implants or grafts because they believe them to be inadvisable.

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 Amendment. The 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 the manufacturer claimed that its new device was similar to a pre-1976 device, the 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 the 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 percent 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:

One: Why has FDA failed to regulate TMJ implants?

Two: 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?

And, three, and 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 the 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 the FDA's responsibility?

Before introducing our first panel, let me enter into the record, without objection, the statement prepared for delivery by our distinguished ranking minority member, Mr. Craig Thomas.

[The prepared statement of Mr. Thomas follows:]

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Congress of the United States
House of Representatives
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**Opening Statement for Congressman Craig Thomas (WY-AL)
Ranking Republican Member, Subcommittee on Human Resources and Intergovernmental Relations**

June 4, 1992

Hearing to review FDA and NIH Policies Towards TMJ and Jaw Implants

MR. CHAIRMAN, let me begin by thanking you for holding this hearing today.

When the Chairman announced the subject of this hearing, I like many folks, knew little of the disease temporomandibular joint dysfunction -- TMJ. Yet as my staff and I prepared background materials, we were surprised to find that it is a well known disease. Not only that, but many individuals we know either have it themselves or have family or friends afflicted with the disorder.

TMJ is a stress disorder. These days it is not unexpected that more and more individuals are affected by it. It is a disorder that primarily affects women, and it can be as debilitating as any disease we encounter. We will hear testimony today from individuals who have been affected by TMJ and know first-hand some of the problems with jaw implants. We will also hear from experts in the field who will detail exactly how complex this issue is for all the parties.

The purpose of this hearing is to evaluate FDA's and NIH's responses to this problem. The jaw implants were pre-1976 devices, meaning they did not have to go through the pre-market approval process that current applications must encounter. Implants were seldom used during the 1960's and 1970's, so the available data base on patients was not helpful. It was when jaw implant procedures increased dramatically in the 1980's that the problems became evident. It is clear that FDA did step in and issue warnings to physicians and dentists, and required the creation of a patient directory.

But we have to move beyond this issue and determine what courses of treatment are currently available to TMJ sufferers, and the options they may have in the future. At present, the only course of treatment for the most severe cases is extensive surgery requiring bone grafts. Given the advances made in medicine, we

can hope that more alternatives will become available in the near future.

Once again, Mr. Chairman, thank you for holding this hearing today. I look forward to hearing the testimony from all of our witnesses.

Mr. WEISS. Let me at this point call on our distinguished member from New Jersey, Mr. Payne, for any comment he would care to make.

Mr. PAYNE. Thank you very much, Mr. Chairman. Good morning. I would like to take this opportunity to recognize our chairman of this subcommittee for his leadership in calling the hearing on this very important topic today. I would also like to extend my regards to the panel of witnesses who have agreed to provide us with testimony this morning.

This past year, the safety and efficacy of silicone-based products have been the subject of increased scrutiny because they have been linked to cancer and autoimmune diseases such as rheumatoid arthritis. Concerns over the possible links, possible risks, associated with long-term usage and leakage into the body because of ruptured implants have also been expressed.

As a result of mounting public concern and new questions of product safety, the FDA placed a moratorium on the use of silicone gel breast implants, pending further investigation. Three months later, the FDA removed its ban on the manufacture and use of gel implants, stating there is no evidence to establish a causal link to cancer and autoimmune diseases, despite the remaining concerns regarding the product's safety.

Today we are here to examine new questions related to the safety of jaw implants used to treat patients with temporomandibular joint syndrome. The composite coating called Proplast used in some implants is reported to break apart, which may then cause the bone to deteriorate.

Although some patients with failing implants often suffer from noticeable side effects like pain, limited jaw movement, and joint noise, in others there were no symptoms, even while the implant was breaking down. Additionally, out of the 26,000 devices that were manufactured, it is unknown exactly how many of these implants have been distributed.

Public health organizations like the Food and Drug Administration and the National Institutes of Health were established and mandated to protect the public by ensuring that products recommended for approval are indeed safe for their approved use. Doctors have a responsibility to make their patients aware of the known risks associated with prescribed use and to explore all the available alternatives for treatment prescribed.

As public officials, when questions of public safety arise, it is our obligation to investigate and examine the evidence in the testimony presented before us and to render a conclusion with that objective in mind.

Again, Mr. Chairman, thank you for calling this hearing and I look forward to hearing the testimony of our witnesses.

Mr. WEISS. Thank you very much, Mr. Payne.

As is the custom of the Committee on Government Operations, all witnesses before the committee will be sworn in. From time to time during the hearing, we will be inserting into the record, without objection, documents relevant to this matter.

Before we begin, let me say to all of our witnesses that the full text of your written statements will be inserted in the hearing record and indeed, whatever final recommendations that we make,

will be based not just on your testimony, but on the basis of your prepared statements.

We have asked each of you to summarize your testimony in 4 minutes so that there will be time for questions after each panel presentation.

Let me now welcome our first panel of witnesses and ask you to take your places behind your nameplates on the witness table.

Our first panel includes Terrie Cowley, from Milwaukee, WI; Amy Marks, from New Orleans; and Paula Beaulieu from Tualatin, OR.

Would you each please raise your right hand.

[Witnesses sworn.]

Mr. WEISS. Let the record indicate all the witnesses have answered in the affirmative.

Before we start, I want to thank each of you for your willingness to participate in today's hearing. We will ask each of you to testify and we will have questions when all of you have completed your prepared testimony.

Ms. Cowley, we will begin with you.

We can't hear you when you stand. Please sit down, and face the subcommittee.

Ms. COWLEY [holding up a model skull]. This is the part of the anatomy we are discussing today, the jaw joint, the condyle with a Silastic implant or any other we will be speaking about.

Mr. WEISS. Ms. Cowley, please move the microphone closer to you.

STATEMENT OF TERRIE COWLEY, COFOUNDER, TMJ ASSOCIATION, LTD., A SUPPORT AND ADVOCACY ORGANIZATION, MILWAUKEE, WI

Ms. COWLEY. I am Terrie Cowley, cofounder of the TMJ Association of Milwaukee, WI, 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 dentists that the frequent headaches I was experiencing were due to my jaw joints. It was found that the discs which normally cushion the movement of the jaw joint in 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 3 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 constant 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, 4 years after my surgery, I met another jaw joint patient and we formed the TMJ Association. It has been our goal to obtain as much information as possible about this disorder from patients and professionals, to provide a way so other patients could meet and support each other, and to promote awareness of this disorder in the community.

Toward that end, 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 1 of nearly 12 to 28 percent of the population—30 to 50 million people—that annually seeks treatment for this disorder. Nearly 90 percent of these are female, and although it has not yet been 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. 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 insurance coverage or 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."

Although my own symptoms have gradually lessened, I am left with the same dilemma that many other patients now face. My implants have fractured and fragmented, and I have pieces of silicone in my joints which are causing constant inflammatory responses with facial swelling and pain. The other symptoms wax and wane.

So why don't I simply have the implants removed? Daily I weigh the benefits and risks of having the implants taken out: An uncertain surgical outcome, with no viable options for an implant replacement, and on the other hand, knowing that the implants continue to break and cause my jawbones to degenerate.

I have gone to the National Institute of Dental Research, the National Institutes of Health Office of Research on Women's Health, the FDA, the Agency for Health Care Policy and Research, the Congressional Women's Caucus, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, and other professional and congressional leaders, seeking their attention to this problem.

I am most grateful that this congressional hearing, Mr. Chairman, represents a serious effort to examine the disastrous state of the art of diagnosis and treatment of this disorder and the lack of serious efforts to deal with it. Thank you very much.

[The prepared statement of Ms. Cowley follows:]

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 basics 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

implants have fractured and fragmented and I have pieces of silicone in my joints which are causing constant inflammatory responses with facial swelling and pain. The other symptoms wax and wane. So why don't I simply have the implants removed? Daily I weigh the benefits and risks of having the implants taken out: an uncertain surgical outcome, with no viable options for an implant replacement, and on the other hand knowing that the implants continue to break and cause my jaw bones to degenerate.

I have gone to the National Institute of Dental Research, the NIH Office of Research on Women's Health, the FDA, the Agency for Health Care Policy and Research, the Congressional Women's Caucus, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, and other professional and congressional leaders, seeking their attention to this problem. I am most grateful that this congressional hearing, Mr. Chairman, represents a serious effort to examine the disastrous state of the art of diagnosis and treatment of this disorder and the lack of serious efforts to deal with it.

What can be done? It is my hope that recognition of these problems will lead to:

First, a public health notice of recall on Proplast/Teflon (Vitek, Houston, TX) implants should be widely publicized in both print and on TV. A national center should be established to develop a database based on a registry of patients who have received any type of alloplastic TMJ implant. The FDA, the Arthritis Institute, and the National Institute of Dental Research, must collaborate to conduct controlled, coordinated studies of patients who have received Proplast/Teflon, Silastic implants, or other TMJ implants, to determine the extent of damage to the jaw and skull and systemic pathology. Collaborative efforts between federal agencies and the device and materials industry is necessary to address the needs of the large number of TMJ implant patients.

Second, a serious effort to educate patients and professional providers as to the realities of this disorder and current treatments.

Third, initiation of federally funded research to better characterize the nature and causes of this disorder, as well as the development of methods of treatment based on solid scientific research.

Thank you.

Mr. WEISS. Thank you very much, Ms. Cowley. I know this is difficult testimony to give for each of you. I appreciate your participation.

Ms. Marks.

Please bring the microphone really close to you.

STATEMENT OF AMY MARKS, NEW ORLEANS, LA

Ms. MARKS. My name is Amy Marks, and the pain is so bad it is hard for me to know where to begin. Tuesday, I was released from the hospital, where I was being treated for pain control. I feel useless, just like I am taking up space.

I developed TMJ problems in 1978 after an automobile accident. I have had 19 surgeries to date, and still I have to fill my body up with pain pills, anti-inflammatories and muscle relaxers just to get through the day—which is still no more than lying in bed in agony.

The surgeries I had in 1983, 1984, and 1986 changed my life forever. The hour or hour and a half it took to place a Proplast Teflon in my head has proven to be irreversible. My life has come to a halt. The implants shattered, and today, tiny particles of Teflon are floating around in my head causing severe, constant pain.

Once the implants failed, everything after that was doomed. The Teflon made my jaw joint fail, and the doctors kept trying to rebuild it with two of my ribs and a collarbone. It took a lot of energy, strength, and courage to face each surgery. I thought each would be my last, and would give me back my life, so I kept agreeing to them. This is the point when suicide first entered my mind.

Every graft dissolved—a reaction which I have learned is common in Proplast survivors. A Christensen joint, made by TMJ Implants, failed so badly that the end of it stuck out of the side of my head. Before receiving my Techmedica joints, I lived without a jaw at all, which was extremely painful and disfiguring. I have scars and aching bones all over my body where bone and skin grafts were taken, as reminders of all these failures.

At one point, the pain and medication affected my body so much that my husband and I were told that I had AIDS. Of course, AIDS is not an issue. These symptoms were caused by the pain, the jaw problems, and the medical treatment.

Because this is an unseen illness, I have been shamed and degraded by doctors and nurses who didn't believe me. They said I was just a drug addict, or told me what I needed was a psychiatrist because the pain was in my head. After one surgery, my pain pump was mistakenly set at one-tenth of the medication I was prescribed. The nurses kept telling me to stop complaining, that I had developed a tolerance to the medication and they were giving me all they could.

I don't know what's worse—the pain itself, or the emotional pain of being trapped in a body that can't function. It takes a lot of energy to manage the pain, and it leaves me feeling very vulnerable, with no resources for me to fall back on. I have easily bought into the accusations and wondered, what is wrong with me? Why can't I just snap out of it? Why am I letting pain control my life—as if I have a choice in it. I start discounting myself.

Having children is a decision that has been taken away from me. With the amount of medication I am on, I couldn't safely carry a

child. I am beyond anger. I'm devastated, all because of a small piece of plastic.

My face is partially paralyzed and deformed because some of my jaw muscles are permanently severed. But the worst part is the swelling on both sides of my face. It is the constant, painful inflammation of a jaw that does not heal.

My life hasn't changed. It is gone. I feel like I have burning-hot screws constantly twisting into my skullbone in front of my ears. This pain never goes away. I can't concentrate enough to read a book, balance a checkbook, or write more than a few sentences. Suicidal thoughts are not from an occasional depression; that's how I start every day. I pray for the emotional strength to get out of bed and not be so angry. I miss the freedom that healthy people take for granted.

Before I entered this hell on earth, I was a dynamic, very productive person. I was a fashion model. I kept the books for several showrooms in the World Trade Center in Dallas. I ran a successful greenhouse and plant store. I managed a trendy upscale restaurant in Dallas, where I worked 20-hour days. I was an artist, a jewelry designer, and an interior decorator. I could be anyone—your wife or your daughter. I didn't ask for this.

The financial burden has been almost as devastating as the pain. I have creditors calling daily to collect on bills the insurance doesn't cover. I am 36 years old and I have been unable to work for years. My parents are using up their retirement money. My family loves me and the money could be tolerated if we didn't feel we were throwing it into a black hole of empty lies and broken promises.

Even with these problems, I checked out of the hospital against my doctor's wishes and paid my own way here today. Even though I have been only given 5 minutes to speak, I feel it is the most important 5 minutes of my life. I came because those who suffer TMJ and Proplast Teflon poisoning need help and deserve answers. My hope and my final prayer is you will make the money available for the research to neutralize the effects on my body from Proplast.

Doctors, hospitals, the Federal Government, and the FDA, the NIH, all have failed me and thousands of others who suffer because of a little piece of plastic. I hope this testimony isn't in vain. What is my purpose in living if I can't do anything to make my life worthwhile. This cannot wait. We must have action—and I must have hope—now.

Thank you very much.

[The prepared statement of Ms. Marks follows:]

My name is Amy Marks. The pain is so bad it is hard for me to know where to begin. Tuesday, I was released from the hospital, where I was being treated for pain control. I feel useless, like I'm just taking up space.

I developed TMJ problems in 1979 after an automobile accident. I have had 19 surgeries to date, and still I have to fill my body up with pain pills, anti-inflammatories and muscle relaxers just to get through the day—which is still no more than lying in bed in agony. The surgeries I had in 1983, 1984 and 1986 changed my life forever. The hour or hour and a half it took to place the Proplast Teflon in my head have proven to be irreversable. My life has come to a halt. The implants shattered, and today, tiny particles of Teflon are floating around in my head causing severe, constant pain.

Once the implants failed, everything after that was doomed. The Teflon made my jaw joint fail, and the doctors kept trying to rebuild it with two of my ribs and a collar bone. It took a lot of energy, strength and courage to face each surgery. I thought each would be my last, and would give me back my life, so I kept agreeing to them. This is the point when suicide first entered my mind.

Every graft dissolved—a reaction which I have learned is common among Proplast survivors. A Christianson joint, made by TMJ Implants, failed so badly that the end of it stuck out of the side of my head. Before receiving my TechMedica joints, I lived without a jaw at all, which was extremely painful and disfiguring. I have scars and aching bones all over my body where bone and skin grafts were taken, as reminders of all these failures.

If Vitek, Methodist Hospital, Dupont, LSU Medical School, Dr. John Kent or the FDA had come out a few years ago and admitted these problems, I could have avoided several failed surgeries.

Jaw surgery is major surgery, and it is extremely difficult and painful. Recovery takes weeks, followed by very painful physical therapy. I have been so weak and depressed, and at 5'8" have gotten down to 69 pounds, that I had to crawl to get to the bathroom because I was too weak to walk.

At one point, the pain and medication affected my body so much that my

husband and I were told that I had AIDS. Of course, AIDS is not an issue. These symptoms were caused by the pain, the jaw problems and the medical treatment.

Because this is an unseen illness, I have been shamed and degraded by doctors and nurses who didn't believe me. They said I was just a drug addict, or told me what I needed was a psychiatrist because the pain was in my head. After one surgery, my pain pump was mistakenly set at 1/10th of the medication I was prescribed. The nurses kept telling me to stop complaining, that I had developed a tolerance to the medication and they were giving me all they could.

I don't know what's worse–the pain itself, or the emotional pain of being trapped in a body that can't function. It takes a lot of energy to manage the pain, and it leaves me feeling very vulnerable with no resources for me to fall back on. I have easily bought into the accusations and wondered, What is wrong with me? Why can't I just snap out of it? Why am I letting pain control my life–as if I have a choice in it. I start discounting myself.

Having children is a decision that has been taken away from me. With the amount of medication I am on I couldn't safely carry a child. I am beyond anger. I'm devastated, all because of a small piece of plastic.

I have tried many other treatments besides surgery, including acupuncture; biofeedback; cortisone shots; splint therapy; and physical therapy. In one series of shots, local anesthetics were injected into ten or twelve points my head every week. I've been hospitalized for up to three weeks at a time for pain control. I've been given life-threatening levels of narcotics until I could barely talk, but there was still pain.

Today, I have TechMedica metal jaw joints on both sides of my head. Although the joints seem fine, the inflammation and scarring in the surrounding tissue severely limit my mouth opening and cause constant, agonizing pain. I can eat only mush, and even that increases my pain so much that I'm often confined to bed after a meal.

As a result of the surgeries, my face is partially paralyzed. It is also somewhat deformed because some of my jaw muscles are permanently severed. But the worst part is the swelling on both sides of my face. It is the constant, painful inflammation of a jaw that does not heal.

My life hasn't changed. It's gone. I feel like a big blob of pain, with big, burning-hot screws constantly twisting into my skull bone in front of my ears. This pain never goes away. Sometimes I also get sudden, sharp, stabbing pain that causes me to drop whatever is in my hands, shut my eyes and hold on to something to keep from falling. The pain and medication have reduced my blood pressure so much that I pass out and fall down. It hurts so much I can't drive, read, or do anything that requires thought or concentration for more than a few minutes. It hurts to walk, it hurts to talk for too long a time. Sometimes it hurts just to see. And it never stops.

I didn't ask for this. It could be anyone. Your wife, or your daughter. Before I entered this hell on earth, I was a dynamic, very productive person. I was a fashion model. I kept the books for several showrooms in the World Trade Center in Dallas. I ran a successful greenhouse and plant store. I managed a trendy upscale restaurant in Dallas, where I worked 20-hour days. I was an artist, a jewelry designer and an interior decorator.

Now, I can't concentrate enough to read a book, balance a checkbook, or write more than a few sentences. I can only eat mush, and even that is agony. I depend on others for my most basic needs. Suicidal thoughts are not from an occasional depression. That's how I start every day. I pray for the emotional strength to get out of bed, and not be so angry.

In addition, my life is lonely. I used to have so many friends, but now I am trapped in my bedroom. I miss seeing and talking to other people. I miss giving my husband passionate kisses. I miss the freedom of getting out of bed whenever I want to, the freedom of driving a car, the freedom of going wherever I want to, of going anywhere alone. Basically, I miss the freedom that healthy people take for granted. Everything I do, I must plan and prepare so the medicine is working at just the right time. And then it always wears off before I'm ready. Watching a movie is even difficult because it's hard for me to concentrate.

I am trying to find the money and a doctor to have a pain pump implanted in my stomach. It will constantly infuse morphine into my spine. One anesthesiologist thinks this temporary measure will reduce the pain enough for me to leave my house on my own. Otherwise, I honestly don't believe I can stand this pain much longer. Unfortunately,

no doctor wants the responsibility of treating me. They all seem scared of my complex case and unwilling to accept what little insurance I have left.

The financial burden has been almost as devastating as the pain. I have creditors calling daily to collect on bills the insurance doesn't cover. I am 36 years old, and I've been unable to work for years. My parents are using up their retirement money. My family loves me and the money could be tolerated if we didn't feel we were throwing it into a black hole of empty lies and broken promises.

Even with these problems, I checked out of the hospital against my doctor's wishes and paid my own way here today. I feel like the years since 1983 have left me feeling useless, completely unproductive and trapped in my body of pain. This testimony gives my life purpose. Even though I've only been given five minutes to speak, I feel it is the most important five minutes of my life. I came because those of us who suffer TMJ and Proplast Teflon poisoning need help and deserve answers.

- We want to know why these implants were allowed on the market.
- Why weren't they properly tested?
- Why were they just taken off the market a year ago, when there was so much evidence against them earlier?
- Why aren't the designers, manufacturers and marketers of these implants, and those in government who approved them, being held accountable for destroying my life and thousands of other lives?
- Why is it that neither the FDA nor the National Institutes of Health have funded research into TMJ and implants?
- Why aren't there funds available to help me and thousands like me who are suffering?

But mostly, my hope and my final prayer is that you will make the money available for the research to neutralize the effects on my body from Proplast.

Doctors, hospitals, the federal government, the FDA and the NIH all have failed me and thousands of others who suffer because of a little piece of plastic. I hope this testimony isn't in vain. What's my purpose in living if I can't do anything to make my life worthwhile? This cannot wait. We must have action—I must have hope—NOW.

Mr. WEISS. Thank you very much.
Ms. Beaulieu.

STATEMENT OF PAULA BEAULIEU, TUALATIN, OR

Ms. BEAULIEU. Mr. Chairman and members of the subcommittee: My name is Paula Beaulieu and I live in Tualatin, OR. I would like to thank you for this opportunity to relate to you the tragedy of my life in regards to Vitek Proplast Teflon and Dow Corning Silastic TMJ implants.

I have experienced chronic and debilitating pain since 1985, when my Proplast implant was placed. Chronic pain dictates my life and affects every aspect of my daily living. I have pain with every movement of my jaw.

I have undergone 17 TMJ surgeries since 1981; 15 of those surgeries are directly related to the placement of Vitek's Proplast/Teflon implant in 1985 and Dow Corning's Silastic implant in 1988. Multiple surgeries have changed me from a happy, funloving person to someone who is consumed with catastrophic health problems.

As a result of retained Teflon fragments which could not be completely removed surgically, my body has reacted by destroying the top of my jawbone and some of my skull. Over the years, I developed a receded chin and a gross open-bite and was unable to close my mouth. I lost the ability to chew solid food and my speech became severely impaired.

Besides looking like a freak, I became totally dysfunctional. Doctors have utilized muscles from my skull and cartilage from my ears, trying to restore the function of my jaw. I have sustained nerve injury to my face as a result of multiple surgeries.

Every surgery was a failure and my pain continued. Sometimes my pain would be so bad that I couldn't get up except to vomit. I have always been an active person and enjoyed working in the medical and dental field. Because of my problems with these implants, I have lost the ability to obtain or maintain full-time employment.

In August 1990, a radical form of surgery was proposed to me. The oral surgeon wanted to cut two ribs out of my chest and graft them into my jaw. He told me that my jawbone was continuing to erode due to the retained materials from the previous implants. I shuddered at the thought of having my ribs cut out of my chest, and I couldn't bring myself to consent to this radical procedure.

In desperation, I went to the local university medical library and began researching prosthetic joints, where I found an article about a company named "TMJ Implants" founded by Dr. Bob Christensen. "TMJ Implants" manufactures a prosthetic joint replacement for the jaw.

After consulting with Dr. James Curry in Colorado, I decided to have the TMJ joint replacement surgery. In December 1990, I underwent 8 hours of intense reconstructive surgery to replace my TMJ joints. I now have 24 screws and four metal plates in my skull.

The surgery was partially successful in that it restored my face by giving me back my chin and allowing me to close my mouth. I

still continue to have chronic and sometimes debilitating pain, but because I look fairly normal, it makes my burden easier to bear.

As I speak to you today, I am in need of additional surgery due to bone growth in and around my prosthetic joints. I have to pry my mouth open with my fingers many times throughout the day. I literally rip and tear bony tissue as I manipulate my jaw and it is very painful.

My TMJ prosthetic joints are functioning properly. In my opinion, my continuing problems are a direct result of the original injuries caused by the Vitek Proplast/Teflon implant.

My family has had to sacrifice their lives for mine, both physically and financially, and without their support and encouragement, I may well have ended my life.

Since the placement of the Vitek implant in 1985, my medical expenses have exceeded $172,000 and my out-of-pocket expenses have exceeded $40,000. My medical expenses will continue for the balance of my life, and I expect my future medical expenses will be over $1 million.

There are thousands of us who have had the Vitek Proplast/Teflon and/or Dow Corning Silastic implants. We are facing a lifetime of surgery, medical expenses, and pain. I am scared, but I will prevail.

Thank you.

[The prepared statement of Ms. Beaulieu follows:]

June 4, 1992

Mr. Chairman and members of the subcommittee; My name is Paula Beaulieu and I live in Tualatin, Oregon. I would like to thank you for this opportunity to relate to you the tragedy of my life in regards to Vitek Proplast/Teflon and Dow Corning Silastic TMJ implants.

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Besides looking like a freak, I became totally dysfunctional. Doctors have utilized muscles from my skull and cartilage from my ears, trying to restore the function of my jaw. I have sustained nerve injury to my face, as a result of multiple surgeries.

Every surgery was a failure, and my pain continued. Sometimes my pain would be so bad, that I couldn't get up, except to vomit. I have always been an active person and enjoyed working in the medical and dental field. Because of my problems with these implants, I have lost the ability to obtain or maintain full time employment.

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There are thousands of us who have had the Vitek Proplast/Teflon and/or Dow Corning Silastic implants. We are facing a lifetime of surgery, medical expenses and pain. I am scared, but I will prevail.

Thank you.

Paula Beaulieu
Tualatin, Oregon

Mr. WEISS. Thank you very much, Ms. Beaulieu.

You have each mentioned, in addition to the physical and mental burdens, that you carry an enormous financial burden. And Ms. Beaulieu, you quantified the total cost. What does the original operation cost?

Ms. BEAULIEU. The original implant surgery with the Vitek?

Mr. WEISS. Right.

Ms. BEAULIEU. I believe my surgeon's fee was $1,800 per side. That was in 1985. That did not include hospital or anesthesia or any of the other costs. That was strictly for the surgeon.

Mr. WEISS. Ms. Cowley.

Ms. COWLEY. Back in 1982, I believe the total came to something like $8,000—in that ballpark.

Mr. WEISS. Ms. Marks.

Ms. MARKS. I am sorry to tell you that the whole financial burden has been so devastating, having 19 surgeries, I cannot at this point break it down. I could get the records for you, but I don't know right now.

Mr. WEISS. Thank you.

[The information follows:]

The original surgeon fee was $8,500. This did not include the cost of the implant.

Mr. WEISS. Ms. Cowley, the FDA has published a warning about the dangers of Vitek Teflon TMJ implants and encouraged all patients to enroll in a registry so they can be kept informed of any additional information. Have these actions been effective?

Ms. COWLEY. I would say that as of yesterday when I checked, 153 people had been put on the implant registry out of approximately 26,000 implants that we think have been sold. So you have 153 people who have paid $20 to be on a registry. You have another approximately 3,000 patients—and you will have to get the figures from Medic Alert—but approximately another 3,000 who have requested information. Of those, about 700 were not even Vitek Proplast patients.

So I think probably the figures you are talking about are in the range of 2,000 people who have answered FDA's request to do something about getting information.

Mr. WEISS. Why do you think that so few have enrolled in the registry?

Ms. COWLEY. I think the dentists who have implanted these devices have not tried to notify their patients. Obviously, this is the case. There has been absolutely no media attention concerning these implants. People who pick up a newspaper, who may be asymptomatic, who never hear about this, are going along quite naturally without knowing they have time bombs in their heads.

So there has been no decent exposure, no media alerts to the patients. And the people who have implanted these devices apparently have not taken their responsibility seriously enough to bring these patients back in.

Mr. WEISS. Ms. Marks, you currently have the Techmedica TMJ implant. There is some promising data about its short-term safety, but nothing for longer than 2 or 3 years. How do you feel about that lack of long-term safety information?

Ms. MARKS. I am real concerned, but right now, as unrealistic as this might sound, my life is really 1 day at a time. If I can get through each day and make it through that day, that is what I look at. I am not happy with the fact there is not long-term research on Techmedica, but I got to the point I had no choice.

My bone grafts were failing. The Christensen joint did not work for me and I was not going to a Vitek joint. I had no options. This is the only option I had. I hope—I really hope for right now it is just each day at a time.

Mr. WEISS. Ms. Beaulieu, you currently have a total joint replacement made by TMJ Implants, Inc. There is very little published safety information, although several surgeons believe it to be safe and effective for long-term use. Do you think the FDA should require safety studies be submitted to them to make sure implants are safe for future patients?

Ms. BEAULIEU. Yes, sir, I do. I feel long-term studies and case histories should be submitted to the FDA regarding the Christensen implant, as well as any and all implants on the market today.

Mr. WEISS. I will ask each of you to respond to this question if you care to.

How would you respond to someone who says you are exaggerating the pain and suffering that you describe today? Ms. Cowley.

Ms. COWLEY. In regards to my testimony and my presentation on my symptoms and what I went through, I would only say I was most gracious in sparing this committee more gross details, OK?

Mr. WEISS. Ms. Marks.

Ms. MARKS. I get asked that question all the time, because most people don't even know what a TMJ joint is and how complicated it is. I certainly never had heard of it until this tragedy entered my life. Every action I take, talking, walking, breathing, turning over in bed, taking a shower, the water hitting my head, everything hurts. There isn't anything I can do—I don't know how to describe it to you. There is nothing I can do that doesn't hurt. And I wouldn't wish this pain on anyone.

But for somebody so callous that chose not to believe me, I would like to give this pain to them for about 5 minutes and see how long they lasted with it. It is totally and completely debilitating.

Mr. WEISS. Ms. Beaulieu.

Ms. BEAULIEU. First of all, I would tell them that I am not exaggerating and I would say to them that if I had only had one surgery since the placement of the Vitek implant and was claiming the type of pain and suffering that I have claimed here today, then I would say that I might be exaggerating. But I have had 15 surgeries in a 6-year period and I am sure anyone would agree with me, the type of pain and suffering associated with that is not exaggeration.

I do have some photographs if you would care to look at them. They are not the blood and the guts, but they are just some pictures that show the type of pain we have been through.

Mr. WEISS. I will take them for the record.

[Copies of photos are in subcommittee files.]

Ms. BEAULIEU. Thank you.

Mr. WEISS. How would you respond to someone who says everything in life has risks?

Ms. COWLEY. I would respond that they are absolutely right. However, in contemplating a risk, we usually weigh the costs and benefits of that risk. And in that pattern of contemplating those costs and benefits, we usually want to have as much information, accurate information—and in the case of implants, scientifically valid accurate information—on which we can base our decisions.

When we have no information, or when it is presumed that the implants that your dentist is putting in you are safe, and you take their word for it, you have assumed a risk based on faulty data and apparently that is what we did.

We assumed risks without knowing costs or the benefits.

Mr. WEISS. What kind of information were you given at the time when it was first suggested to you, when you first complained about your pain? Ms. Beaulieu.

Ms. BEAULIEU. I would like to respond to that. I remember the day specifically. My oral surgeon told me this Vitek implant was going to revolutionize TMJ surgery and I would never have to have another surgery, that this was a total fix.

Ms. MARKS. I, of course, experienced the same thing. Everything in life does have a risk. And if someone told me there was a 90 percent chance when I walked across the street I would be killed, I wouldn't take that risk, and I don't think you would either. But that is basically what happened to me.

I was not told—I was told this was going to be a fix. This was going to be the answer. This was going to give me back my life. And what it really did is I believe at least 90 percent, maybe 100 percent of these implants have failed and that is a risk that I would not willingly have taken.

Ms. COWLEY. May I respond to that, too?

Mr. WEISS. Go ahead.

Ms. COWLEY. The two sentences that go through my head every day are: You will never ever know that you had a problem. This is the next best thing to sex. I was told that by a dentist. I didn't ask what kind of sex he meant, unfortunately.

Mr. WEISS. Well, I thank you all very, very much for your willingness, in spite of your pain, to come to Washington and participate in these hearings. And before I call on Mr. Payne, I just want to say to you that I hope that your willingness to add additional burdens to your life by this participation will in fact have a beneficial result.

Ms. COWLEY. Thank you.

Mr. WEISS. Thank you.

Mr. Payne.

Mr. PAYNE. Thank you. At the time when your illness was diagnosed, was there any national center, hospital, medical center—I see the three of you are from three totally different locations. Was there anyplace that was noted for their expertise in this area?

For example, when open heart surgery began, I think there was a hospital in Texas that was supposed to be the center of the research efforts at that time. Was there anybody recommending that you go to have further diagnosis at a national center?

Ms. MARKS. Not really. I sought many, many, many opinions and did travel around the country seeking opinions, and basically there weren't that many options available. There were just, you want to function, this is what you have to do, this is the answer.

I was brought up believing your doctor tells you something and I am the one in pain. My doctor is the one with the knowledge and I am going to believe him. It took an unbelievable amount of courage to face each surgery and I did seek a lot of opinions before I did this.

Mr. PAYNE. Were the operations encouraged? In other words, were you presented with no other options, that this is the only way to go, or were your physicians anxious to have you submit to this procedure?

Ms. MARKS. I don't believe my physician was using me as a guinea pig. I don't believe that at all. I believe he sympathized greatly with my pain and saw this Proplast as a way to relieve it. And, in all honesty, I think he thought, as Paula said, it was going to revolutionize TMJ and it would make it possible for me to have my life back. There weren't many options.

I, of course, thought—I didn't think anything would be allowed to be put in my body that had not been thoroughly tested, thoroughly investigated. That never entered my mind, that risk. The risk, of course, that something could happen during surgery, due to the surgeon's fault or something happening to me when I am anesthetized, but something going wrong because it wasn't investigated never entered my mind. I took for granted that the Government is out to protect us and isn't going to put something on the market that is not safe. So that never entered my mind.

Mr. PAYNE. Ms. Beaulieu.

Ms. BEAULIEU. I, too, sought many doctors, dentists, psychiatrists, biofeedback specialists, in trying to find an end to my pain. And when I had my implant put in, after I felt like I knew that it had failed, I went to my doctor and he told me not to worry about it, that it was just healing pain. And I went around with this "healing pain" for 18 months.

And when I did just basically beg him to take me back to the operating room, I remember when he came to my room and he was shaking his head and he said, "Paula, I am so sorry I didn't believe you." He said, "Your implant was broken up in three pieces and the Proplast that was laminated to it was no longer there." He assured me he got all the particles and everything would be fine.

That same surgeon told me a year later he didn't want to operate on me anymore because he didn't want to fail. I moved on to the next doctor. I found another doctor in San Francisco who had a surgery that was in his words "radical" but used in his hands was very beneficial. That is when they opened me from the bottom of my ear to the back of the middle of my head and they took part of my muscle off my skull and they pulled it down into the joint.

Unfortunately, we were transferred to Portland and you get an attachment with these doctors, just like a marriage, and it is very, very, very difficult to change doctors. So we were living in Portland and I was still having great, great pain. And I doctored over the phone. I would call my doctor and I would say, "I am in so much pain I can't open my mouth, I am vomiting every day."

And he would say to me, "Paula, on a scale of one to ten, if your left joint could feel as good as your right joint, how would you feel about having that done." Of course, I said "yes." We scheduled surgery over the telephone. I did that five times in 18 months.

Mr. PAYNE. Thank you, Mr. Chairman. I have no further questions. Thank you all.

Mr. WEISS. Thank you, Mr. Payne. Again, our gratitude and appreciation to you.

Mr. WEISS. Let me now welcome our next panel of witnesses: Dr. Mark Fontenot from Louisiana State University School of Dentistry; Dr. Larry Wolford from Baylor University Medical Center; Dr. Daniel Laskin, Editor of the Journal of Oral and Maxillofacial Surgery; Dr. Marc Lappé, Professor, Health Policy and Ethics, University of Illinois College of Medicine; and Dr. Joseph Marbach, Columbia University School of Public Health. I am going to have to ask you to stand if you would, please.

Raise your right hand.

[Witnesses sworn.]

Mr. WEISS. Let the record indicate each of the witnesses has responded in the affirmative.

I want to thank all of you for taking time from your very busy and complicated schedules to be with us here today. Because of the large number of witnesses, I ask each of you to try to summarize your prepared statement in 5 minutes so there will be plenty of time for questions. Your entire statement, of course, will be inserted into the hearing record.

Dr. Fontenot, we will begin with you.

STATEMENT OF MARK G. FONTENOT, D.D.S., M. ENG., LOUISIANA STATE UNIVERSITY SCHOOL OF DENTISTRY, NEW ORLEANS, LA, AND THE DEPARTMENT OF MECHANICAL ENGINEERING, UNIVERSITY OF SOUTHWESTERN LOUISIANA, LAFAYETTE, LA

Dr. FONTENOT. Good morning, Mr. Chairman, members of the subcommittee. My name is Mark Fontenot.

Currently there are two major players in the artificial TMJ device market: Dow Corning and TMJ Implants, Inc. Dow Corning currently recommends three products for use in the TMJ: Silastic Medical Grade Sheeting, Silastic HP Sheeting, and the Silastic HP Temporomandibular Joint Implant.

One of the first commercial recommendations for the use of a Silastic product in the TMJ was contained in a 1965 data sheet for Silastic Medical Grade Sheeting. Specifically, Dow Corning recommended the use of Dacron-reinforced Silastic Medical Grade Sheeting to surgically correct limited jaw opening. Silastic Medical Grade Sheeting has been on the market for over 25 years and is considered a preamendment device.

Silastic HP Sheeting was introduced into the stream of commerce in or about 1985 by Dow Corning. According to data sheets for Silastic HP Sheeting, this product is recommended for use as either a temporary or permanent artificial TMJ device.

Also in or about 1985, Dow Corning introduced Silastic HP Temporomandibular Joint Implant. Dow Corning received FDA ap-

proval for this product in 1984. According to the package insert, this product is recommended only as a temporary device.

Since 1965, thousands of Silastic devices in the form of Silastic HP Sheeting, Silastic Medical Grade Sheeting, and Silastic HP Temporomandibular Joint Implant have been placed in the TMJ. Some of these Silastic products have had and continue to have clinical success. On the other hand, large numbers of Silastic products in the form of Silastic HP Sheeting and Silastic Medical Grade Sheeting have failed because of TMJ functional loads resulting in Silastic wear debris and tissue reaction.

The second major player in the market is TMJ Implants, Inc., formed in or about 1988. TMJ Implants, Inc., distributes TMJ Fossa-Eminence Prosthesis and the TMJ Condylar Prosthesis, which according to the firm are preamendment devices. Approximately 3,500 devices have been sold since 1988. Devices offered by TMJ Implants have had years of success, although some devices have failed because of TMJ functional loads resulting in wear debris and tissue reaction.

Before its bankruptcy, Vitek was the third major player in the TMJ device market. Vitek notified the FDA in 1982 of their intent to commercialize Proplast sheeting material as the Proplast TMJ Interpositional Implant. Approval from the FDA was granted in 1983.

At the 1986 annual meeting of the American Association of Oral and Maxillofacial Surgeons, several clinicians reported biomechanical failure of the Proplast TMJ Interpositional Implants in which device wear debris incited a cellular reaction such as a giant cell response. Between 1983 to 1988, Vitek sold approximately 25,000 Proplast TMJ Interpositional Implants.

A summary of all reports in the literature from 1986 to 1991 concerning Proplast TMJ Interpositional Implants reveals failure rates ranging between 10 and 25 percent per year. Subsequently, in 1991, the FDA rescinded their approval for these devices.

Vitek also developed a TMJ device to replace the entire TMJ in the early 1980's and marketed this device as the V–K TMJ Replacement System. The first generation V–K device was labeled as the V–K I which had an articular surface fabricated from Teflon FEP polymer.

In 1986, Vitek replaced the Teflon FEP with polyethylene. Justification for this change was based on wear-testing performed by Vitek to be more wear-resistant than Teflon FEP. Performance of the V–K I Fossa Prosthesis over an 8-year period was poor, resulting in over 50 percent removal of these devices. However, the V–K II has performed well to date. Both V–K I and V–K II devices are no longer available.

Byron Medical, OsteoMed, and Techmedica are minor players in the TMJ device market. Patients receiving TMJ devices from these companies number in the hundreds. These devices have enjoyed short-term success. However, the long-term prognosis or fate of these devices is unknown at this time.

Artificial TMJ device design is a delicate interaction between engineering considerations and principles, surgical techniques and requirements, TMJ functional demand, anatomical boundary limitations, and biocompatibility. Unfortunately, artificial TMJ device design and material component selection have been based more on intuition than on engineering principles and scientific data.

Accordingly, a variety of artificial TMJ device design solutions have evolved, leading to controversial results and, in some cases, widespread TMJ device failures. I would like to point out that device failures are now related to design as opposed to material selection.

The continued absence of documentation and research regarding the biomechanics of the TMJ and biomechanics of artificially reconstructed TMJ will prohibit effective treatment solutions for the population of patients suffering from TMJ disorders requiring surgery with or without artificial TMJ devices.

I sincerely appreciate the opportunity you have extended to me today. However, before leaving, I would like to give Congress the following take-home message: One, there is an absolute need to further expand our biomechanical understanding of the TMJ as evidenced by the information just given. Two, there is a critical need for adequately designed artificial TMJ devices.

[The prepared statement of Dr. Fontenot follows:]

Statement of

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Before the

Human Resources and
Intergovernmental Relations Subcommittee
of the
Committee on Government Operations

June 4, 1992

Mr. Chairman, Members of the Sub-Committee, my name is Mark Fontenot. I have a dental degree from the Louisiana State University School of Dentistry. I expect to receive a Doctor of Engineering in biomedical engineering from Tulane University in August of this year. In 1986, I received a 5 year grant from the National Institutes for Dental Research (NIDR) to investigate the biomechanics of normal and artificially restored temporomandibular joints. This NIDR sponsored research is the topic of my dissertation. Currently, I am moving to the Department of Mechanical Engineering at the University of Southwestern Louisiana in Lafayette, Louisiana. I hold an adjunct appointment in the Department of Oral and Maxillofacial Surgery at the Louisiana State University School of Dentistry in New Orleans.

Statement of Need

There is an urgent need to understand the temporomandibular joint (TMJ), increase the depth of knowledge into the biomechanics of the TMJ as well as diseases and disorders affecting this joint, and uncover safety and effectiveness of various modalities for TMJ treatment.

In the following paragraphs, data is presented which underscores and attempts to quantify the presence and persistence of TMJ disease in the general population. In particular, the scope of this statement focuses on the performance of current and past artificial (also called alloplastic) TMJ devices used in the surgical reconstruction of damaged temporomandibular joints. This information is derived from 8 years of basic and clinical science research, analyses of various retrieved artificial TMJ devices, engineering analyses of various artificial TMJ devices, contacts within the biomedical industry, information available from the FDA through the Freedom of Information Act, and the medical and dental literature.

Greater than 500,000, and perhaps as many as 1,000,000 new patients seek some form of conservative management for their TMJ problems each year from approximately 140,000 dental professionals. In other words, up to .4% of the U.S. population may seek some form of professional attention for their jaw joint problem this year. Patients suffering from TMJ pathology and dysfunction commonly present with facial pain and limited range of jaw motion which can affect chewing, swallowing, and speech. Conservative management of these patients include splint therapy, physical therapy, orthodontic therapy, adjustment of the teeth and occlusion (which is the way the upper and lower jaw come together), biofeedback, and drug therapy such as pain medication. If conservative management has been exhausted with limited results, such as failing to alleviate pain and/or limited range of motion, then surgical intervention with or without artificial TMJ devices may be considered.

Who are candidates for TMJ surgery with artificial TMJ devices? They are usually female, ranging in ages from 20 to 40. In general, these patients suffer from various forms of arthritis; facial pain and limited jaw opening resulting from dysfunctional temporomandibular joints; facial pain and limited jaw opening resulting from previously reconstructed joints with and without artificial TMJ devices; fusion of the bones in the temporomandibular joint causing pain and limited jaw opening; and trauma to the temporomandibular joints.

In 1988, as many as 42,000 TMJ arthroscopies and 35,000 open joint TMJ surgeries were performed in the U.S. In 1991, approximately 45,000 open joint procedures and as many as 100,000 arthroscopies were performed. Since 1965, it is estimated that at least 600,000 patients in the U.S. have had at least one TMJ surgery (this figure includes arthroscopy). Of these patients, 60,000 to 80,000 in the U.S. have received artificial TMJ devices such as implants developed and sold by Dow Corning, Vitek, and TMJ Implants, Inc.

History of Artificial TMJ Devices

The modern era surrounding the commercialization of artificial TMJ devices in the United States began in the mid 1960s when Dow Corning (Midland, MI) labelled Silastic® Medical Grade Sheeting for use in the TMJ to surgically correct limited jaw opening. Since 1965, the popularity of artificial TMJ devices has escalated from a few in the 1960s to thousands by 1986 when Vitek, Inc. (Houston, TX) developed and sold various TMJ devices such as the Proplast® TMJ Interpositional Implant and the V-K® Total TMJ System. In the late 1980's, other TMJ device manufacturers such as TMJ Implants, Inc. (Golden, CO) and Techmedica, Inc. (Camarillo, CA) commercially offered either production or custom TMJ devices, respectively. Although TMJ Implants, Inc. was formed in or about 1988, its founder (a surgeon) claims to have 30 years of success using the Fossa-Eminence™ Prosthesis as an artificial TMJ device. Then in 1990, Vitek filed for voluntary bankruptcy. Later in 1990, the Food and Drug Administration (FDA) issued a safety alert and device recall directly affecting approximately 25,000 Proplast® TMJ Interpositional Implants and 2,000 V-K® prosthesis. To date, approximately 3,000 "Proof of Claims" have been filed with the Vitek estate. Currently, there are two major players in the artificial TMJ device market, Dow Corning and TMJ Implants, Inc.

Artificial TMJ Device Market

The first major player in the market, Dow Corning, currently recommends three products for use in the TMJ: Silastic® Medical Grade Sheeting, Silastic® HP Sheeting, and the Silastic® HP Temporomandibular Joint Implant (Wilkes Design). One of the first commercial recommendations for the use of a Silastic® product in the TMJ was contained in a 1965 data sheet for Silastic® Medical Grade Sheeting. Specifically, Dow Corning

recommended the use of Dacron® reinforced Silastic® Medical Grade Sheeting to surgically correct limited jaw opening after Beekhuis and Harrington reported on the use of Silastic sheeting to surgically correct limited jaw opening in one patient with Paget's disease. Silastic® Medical Grade Sheeting has been on the market for over 25 years and is considered a pre-Amendment device.

Silastic® HP Sheeting was introduced into the stream of commerce in or about 1985 by Dow Corning. According to data sheets for Silastic® HP Sheeting, this product is recommended for use in the TMJ. However, these recommendations are different when compared to recommendations given in data sheets for Silastic® Medical Grade Sheeting. Generally, Silastic® HP Sheeting is recommended for use as either a temporary or permanent artificial TMJ device.

Also, in or about 1985, Dow Corning introduced the Silastic® HP Temporomandibular Joint Implant (Wilkes Design). Dow Corning received FDA approval for this product in 1984. In particular, the FDA found this product to be similar to Dacron® reinforced Silastic® Medical Grade Sheeting as described in a 1973 data sheet for Silastic® Medical Grade Sheeting. According to the package insert, this product is recommended only as a temporary device.

Data sheets and package inserts are similar in that these documents contain product information such as indications for use, instructions for use, sterilization procedures, and surgical techniques for placement. However, unlike data sheets for Silastic® Medical Grade Sheeting and Silastic® HP Sheeting, package inserts for the Silastic® HP Temporomandibular Joint Implant (Wilkes Design) are included with each and every device. Since data sheets for Silastic® Medical Grade Sheeting and Silastic® HP Sheeting are not placed in the packing, the surgeon or hospital must contact Dow Corning to obtain a data sheet regarding these products.

Since 1965, thousands of Silastic® devices in the form of Silastic® HP Sheeting, Silastic® Medical Grade Sheeting, and the Silastic® Temporomandibular Joint Implant (Wilkes Design) have been placed in the TMJ. The medical and dental literature contains reports on the use of Silastic® Medical Grade Sheeting, Silastic® HP Sheeting, and the Silastic® HP Temporomandibular Joint Implant (Wilkes Design) as well as other Silastic® products such as Silastic® tubing to artificially reconstruct the TMJ. However, Dow Corning only recommends the use of Silastic® Medical Grade Sheeting, Silastic® HP Sheeting, and the Silastic® HP Temporomandibular Joint Implant (Wilkes Design) in the surgical reconstruction of the TMJ. Large numbers of Silastic® products in the form of Silastic® HP Sheeting and Silastic Medical Grade Sheeting have failed because of TMJ loads resulting in Silastic® wear debris and tissue reaction.

The second major player in the market is TMJ Implants, Inc., which was formed in or about 1988. TMJ Implants, Inc. distributes the TMJ Fossa-Eminence™ Prosthesis and TMJ Condylar Prosthesis™, which are claimed by the firm to be pre-Amendment devices. First use of the Fossa-Eminence® Prosthesis was reported in 1961 by the founder of TMJ Implants, Inc. Approximately 3,500 devices, both TMJ Fossa-Eminence™ Prosthesis and TMJ Condylar Prostheais™, have been sold since 1988.

Before its bankruptcy, Vitek was the third major player in the TMJ device market. In the early 1970's, Vitek developed and sold Proplast® Sheeting (Teflon® FEP film laminated to a porous composite material fabricated from polytetrafluoroethylene (PTFE) and carbon). Then, in the early 1980's, Vitek developed and sold Proplast® II Sheeting (Teflon® FEP film laminated to a porous composite material fabricated from PTFE and aluminum oxide). Several oral and maxillofacial surgeons reported short term success using different types of Proplast® Sheeting in the TMJ. Based on these early successes from 1974-82 and a favorable response by numerous other clinicians, Vitek notified the FDA in 1982 of their intent to commercialize this sheeting material as Proplast® TMJ Interpositional Implants under section 510(k) of the Food, Drug and Cosmetic Act of 1976 by submitting a Premarket Notification entitled "Proplast® TMJ Interpositional Implant." Approval from the FDA was granted in 1983. At the 1986 Annual Meeting of the American Association of Oral and Maxillofacial Surgeons (AAOMS), several clinicians reported biomechanical failure of the Proplast® TMJ Interpositional Implants in which device wear debris incited a cellular reaction (such as a giant cell response) leading to pain and bone resorption. In mid 1988, Vitek withdrew the Proplast TMJ Interpositional Implants from the market, citing escalating cost of litigation and product liability coverage. A summary of all the reports in the literature from 1986 to 1991 concerning Proplast® TMJ Interpositional Implants reveals failure rates ranging between 10 and 25 percent per year. In 1991, the FDA notified Vitek of new information which showed that the Proplast TMJ Interpositional Implants could fragment, delaminate, or otherwise be damaged. For these reasons, the FDA rescinded their approval for these devices.

Vitek also developed a TMJ device to replace the entire TMJ in the early 1980's and marketed this device as the V-K® TMJ System. The first generation V-K® device was labelled as the V-K® I which had an articular surface fabricated from Teflon® FEP polymer. In 1986, Vitek replaced the Teflon FEP wear surface with polyethylene. Justification for this change was based on wear testing performed by Vitek which found polyethylene to be more wear resistant than Teflon® FEP. Performance of the V-K® I Fossa Prosthesis over an 8 year period was poor resulting in over 50% removal of these devices because of wear and tissue reaction. The V-K® II however has performed well to date. Both the V-K® I and the V-K® II are no longer available.

Comments

Based on the recommended use of the device by the manufacturer in conjunction with the surgical technique for placement of the device into the temporomandibular joint, the aforementioned TMJ devices are divided into the following three categories.

Category 1 devices are placed, either permanently or temporarily, after surgical removal of the TMJ disc. Silastic® Medical Grade Sheeting, Silastic® HP Sheeting, or Silastic® Temporomandibular Joint Implant (Wilkes Design) are used as Category 1 devices. At one time, the Proplast® TMJ Interpositional Implant was used as a Category 1 device. Category 1 devices are secured to the fossa of the TMJ with either sutures, wires, or screws. Currently, the profession rarely uses any permanent category 1 artificial TMJ devices. Although, the use of Silastic® Medical Grade Sheeting, Silastic® HP Sheeting, and the Silastic® HP Temporomandibular Joint Implant (Wilkes Design) as a temporary category 1 device is commonly practiced.

Category 2 devices are used to artificially resurface either the natural condyle or natural fossa. The TMJ Fossa-Eminence™ Prosthesis System offered by TMJ Implants, Inc. has been indicated to resurface the natural fossa since 1961. This device is secured to the natural fossa with screws. Silastic® Medical Grade Sheeting and Silastic® HP Sheeting sold by Dow Corning are also indicated for use as a category 2 device. For example, following the removal of the disc and the top portion of the natural condyle, Silastic® Medical Grade Sheeting can be fixed to the top of the condyle as a resurfacing device. At one time, Vitek indicated the use of the V-K® I TMJ Fossa Prosthesis as a category 2 device to resurface the fossa. Currently, the majority of category 2 device currently being placed are Fossa-Eminence™ Prostheses.

Category 3 devices are used to completely replace the condyle and fossa, which are the bones making up the temporomandibular joint. TMJ Implants, Inc. markets the only production TMJ device, which consists of a TMJ Fossa-Eminence™ Prosthesis System and a TMJ Condylar Prosthesis™. The TMJ Fossa-Eminence™ Prosthesis is fabricated from metal. The TMJ Condylar Prosthesis™ is fabricated from acrylic and metal. Both, the TMJ Condylar Prosthesis™ and the TMJ Fossa-Eminence™ Prosthesis are secured to the bones in the TMJ with screws.

Byron Medical (Tucson, AZ), OsteoMed (Glendale, CA), and Techmedica (Camarillo, CA) are minor players in the TMJ device market offering category 3 TMJ device. However, these companies only offer devices to a few select surgeons since these manufacturers consider their TMJ devices as custom devices which fabricated for the specific needs of each patient. Patients receiving TMJ devices from these three companies number in the hundreds. Byron Medical has offered custom TMJ devices

since 1991. Byron Medical's devices consist of an acrylic and metal condyle which is fastened to the natural condyle with screws. The corresponding fossa is fabricated of metal which is also fastened to the natural fossa with screws. OsteoMed has offered custom TMJ devices since 1991. OsteoMed's devices consist of a plastic fossa which is fastened to the natural fossa with screws and cemented with acrylic. The corresponding condylar prosthesis is fabricated from metal and attached to the jaw with screws. Techmedica has offered custom TMJ devices since 1989. Techmedica's devices consist of a fossa prosthesis fabricated from metal and plastic polymer and a condylar prosthesis fabricated from metal. The fossa and condylar prosthesis are secured to the bones in the joint with screws.

Knowledge of surgical techniques using artificial TMJ devices and the need for artificial TMJ devices preceded an understanding of the biomechanical aspects of the TMJ. In particular, controversy stills exists in the surgical and scientific community regarding the biomechanics of the normal, pathologic, and artificially reconstructed TMJ. For example, is the TMJ a load bearing joint and if it is, how much is it loaded and under what circumstances is the joint loaded? Based on the literature, it is apparent that researchers and clinicians have little understanding concerning the biomechanics of normal and especially artificially reconstructed temporomandibular joints. Of particular importance, is the lack of research and information reporting on the safety and effectiveness of artificial devices. Artificial TMJ device design is a delicate interaction between engineering considerations and principles, surgical technique and requirements, functional demand, anatomical boundary limitations, and biocompatibility. The continued absence of documentation and research regarding the biomechanics of the TMJ and artificially reconstructed TMJ will prohibit effective treatment solutions for the population of patients suffering from TMJ disorders and failed or failing TMJ devices.

Summary

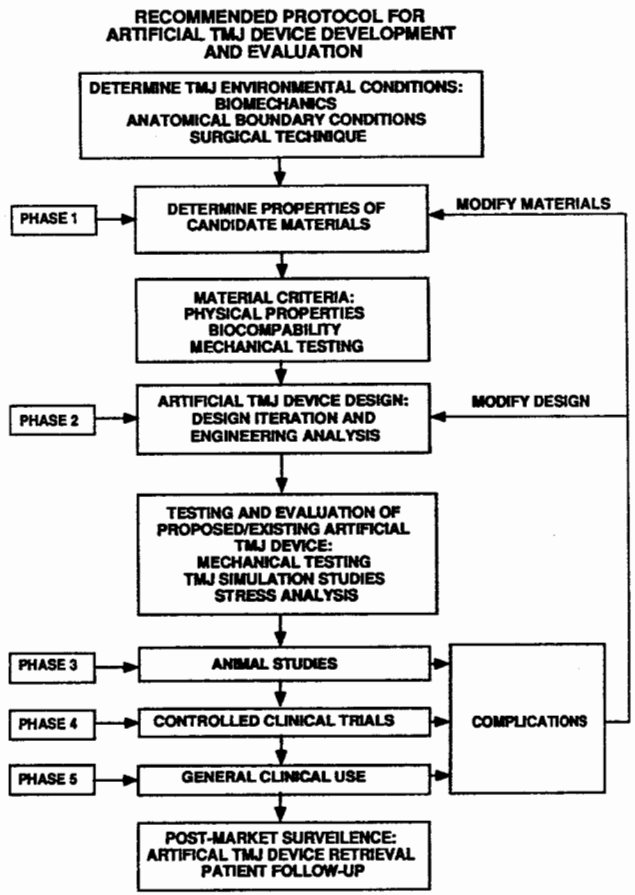
A large and growing TMJ patient population is challenging the dental community and demanding effective and documented care from the dental professionals for their TMJ related problems. Unfortunately, dentists and dental specialties are often left treating these patients with techniques and technologies having unknown clinical safety and/or efficacy, i.e. artificial TMJ devices. Furthermore, commercial availability of TMJ devices has increased over the past three decades, spurring their use by the surgical community. However, commercial development of TMJ devices and material component selection have been based more on intuition than on engineering principles and scientific data. Accordingly, a variety of artificial TMJ device design solutions have evolved, leading to controversial results and, in some cases, widespread TMJ device failures. Published information is either sparse or absent regarding the biomechanics of this complex and complicated joint, performance and biomechanics of TMJ devices,

prospective clinical trials surrounding various treatment modalities, biomechanical testing of devices, animal trials, and the post-operative management of patients with and without artificial TMJ devices.

Recommendations

I appreciate the opportunity you have extended to me today. However, before leaving, I would like to testify that Congress consider the following goals regarding the temporomandibular joint which are outlined below and illustrated in the flow chart on page 8.

1. An improved understanding of the TMJ;
2. Improved diagnostic technologies and techniques for TMJ related problems;
3. An improved understanding of the biomechanics of TMJ devices in the laboratory, and most importantly, in patients;
4. An evaluation of the performance of TMJ devices in animals;
5. Studies into the safety and effectiveness of TMJ devices;
6. Studies into the post-operative management of TMJ patients; and
7. Nationwide TMJ device retrieval program to better understand currently used devices.



Mr. WEISS. Thank you very much.
Dr. Wolford.

STATEMENT OF LARRY M. WOLFORD, D.D.S., BAYLOR UNIVERSITY MEDICAL CENTER, DALLAS, TX

Dr. WOLFORD. Thank you, Mr. Chairman. My name is Larry Wolford. I am from Baylor University Medical Center in Dallas, TX. I am a clinical professor at Baylor College of Dentistry. I have had quite a number of years' experience with Proplast Teflon products, as well as Silastic.

It is unfortunate, but we don't know how many patients are affected by this material. We do not know how many Silastic implants are in and how many Proplast Teflon type implants are in. Early reports in the mideighties were quite encouraging for Proplast Teflon implants. However, problems did begin to develop with a number of these patients. In fact, very devastating problems developed.

The complications seemed to rise from function on these materials that then break down and they cause significant types of responses for the body. One type of response is called a foreign body giant cell reaction. This is where the body's blood cells move into the area and try to digest the products, the fragmentations of the implant materials.

Unfortunately, because of the nature of the chemicals used in the Proplast Teflon and Silastic implants, the body is unable to digest these products. Consequently, what happens is these cells sit there around these particles trying to digest them. They release chemicals into the area and finally the cells die and release more enzymes and chemicals into the area that are destructive and can destroy bones and soft tissues in the area.

So what happens is bone resorbs away from the lower jaw, which then can cause changing in the position of the jaw structures. It can cause severe facial deformities. If the facial deformity occurs to such a degree, it can cause airway obstruction as well. This material can also penetrate into the brain cavity, creating a direct communication to foreign body reaction to the brain, as well as into the middle ear. This can cause such problems as ringing in the ear, dizziness, hearing loss, et cetera.

Probably one of the most devastating problems that these patients have, however, deals with pain. They may have severe headaches, jaw pain, face pain, neck, head, back, ears, jaw joint pain. It may be debilitating and very, very difficult to manage.

The nature of the giant cell reaction is not yet clearly understood. We are doing some significant research in that area. Recently, in fact, within the last couple of weeks, we have confirmed that these patients also have an immunological response to these materials as well.

With Proplast Teflon implants in the number of patients that I am following, about 40 percent of the patients still have the Proplast Teflon implants in and are doing OK. Interestingly, though, from an immunological standpoint, these patients also have problems, but not quite to the magnitude as the patients that have the more severe reactions.

The other concern we have is that this subgroup of patients who are severely reactive to the implant material may develop such an immune response that anything else put into their bodies to reconstruct the joint may have adverse reactions against it, also. So we do have both the immunological problem and the giant cell problem to work with.

In the number of patients that I have dealt with, we have found that even after the implant material is removed and after repeated surgical interventions to try to clear the joint area out and reconstruct the joint, if we go back in 4 years later, we still find foreign body giant cell reaction occurring there. The patients also still continue to have an immunological response to the materials.

I think the question we have to ask is: What can we do to help these patients? I think there are two basic avenues we need to explore: One is to deal and manage with these patients. The second is to do research to try and figure out precisely what the problems are and deal with those problems. One thing we need to do is be sure the public gets FDA public health notification about this problem and the magnitude of it.

We need to use the news media, all avenues of it, to get word out to patients and to doctors and physicians who are treating these patients, to make sure all patients are notified. If we had a mandatory, comprehensive, active enrollment into this registry it would allow us to really assess the effectiveness of the Proplast Teflon on our public. We would be able to do epidemiological studies to determine outcomes of treatment, as well, with these patients.

The big area we are having difficulty with is funding of these patients. Most of it comes with our third-party carriers where we have difficulties. Many health insurance companies will write out coverage for TMJ problems. Many patients—if an insurance company finds out a patient does have a TMJ problem—will write an exclusionary clause specifically to eliminate management of that disease process. Patients will have to sign that in order to get other health benefits.

More recently, there seems to be in the conduction of business for some insurance companies that they will routinely decline benefits for patients across the board. Some patients have to actually seek legal counsel in order to get their benefits.

Coverage provided by Medicaid, Medicare, and other Social Security programs is presently grossly inadequate. The amount of payment to treat a TMJ patient does not even cover the prosthesis—one prosthesis to put into a patient. The cost to a hospital to assume these patients is just incredible.

There are some areas of research that we really need to investigate further. My research fellow, Dr. Charles Henry, has been helping tremendously in evaluating both the giant cell reaction areas and also the immunological areas involved in these patients.

Our immunological department at Baylor University Medical Center has been working very closely with us in trying to determine what specific blood cells are involved in these reactions. We feel there are medications available and treatment regimens that may be available to turn off some of the reactive processes that are

going on with the foreign body giant cell reaction, as well as the immunological processes.

But we need further funding in order to further assess these areas. We feel these are the primary areas that need to be addressed in order to be able to turn this situation around and help these patients.

The other major area of concern is the management of pain for these individuals. Some of these patients have debilitating pain and we don't have very good methods yet to take care of it. All we can use are narcotics, anti-inflammatory medicines, muscle relaxers, et cetera. This, for some patients, is not adequate.

We do feel there are other medications that may be regarded as experimental at this time that may be helpful in turning off the immunological processes and the giant cell reaction that we feel is the predominant factor creating the pain.

The last section that I think needs to be addressed is to develop a national referral clinic or clinics where we could have people who are experts in this area deal specifically with these patients who cannot receive treatment elsewhere, because their doctors either don't know how to manage the problems or are unwilling to treat them.

Thank you very much.

[The prepared statement of Dr. Wolford follows:]

THE PROPLAST/TEFLON TEMPOROMANDIBULAR JOINT IMPLANT PROBLEM

Larry M. Wolford, D.D.S.
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Prepared for: Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee

Introduction

Alloplastic (synthetic) implant materials have been used to serve as interpositional implants in the temporomandibular joint (TMJ). One type of implant material used in TMJ reconstruction was Proplast/Teflon (Vitek, Houston, Texas). Although the exact number of patients exposed to Proplast/Teflon implants has not been established, over 26,000 interpositional implants were distributed by Vitek. This number does not include the Vitek total joint prostheses that were distributed (number distributed unknown) which were coated with Proplast/Teflon. Reconstruction of the TMJ with a Proplast/Teflon implant initially gave many patients acceptable function and satisfaction. Early reports on Proplast/Teflon implants were very promising with 91% of 6,182 reported procedures to have had satisfactory results. However, reports began to appear in the literature describing disintegration of the condyle, severe pain, malocclusion, foreign-body giant cell reaction, and headaches associated with Proplast/Teflon implants. Localized tissue damage occurs as a result of inflammatory cells secreting destructive enzymes.

Numerous complications have occurred with Proplast/Teflon TMJ implants, including loss of implant integrity, implant fragmentation and perforation, and a

foreign-body giant cell tissue reaction that continues to worsen with time. Clinically, patients may demonstrate unstable bite, difficulty eating and speaking due to limited jaw function, significant facial deformity, lymphadenopathy, and severe resorptive osteoarthritis. The bones of the jaw and skull can disintegrate allowing perforation into the brain and middle ear. Many patients develop symptoms of moderate to severe pain which affects daily activity that can render the patient non-functional in society; vertigo (dizziness); tinnitus (ringing in the ear); hearing loss; headaches; jaw, face, head, ear, neck, back and shoulder pain; and airway obstruction. The destructive effects of these materials in the TMJ are a result of the foreign-body giant cell reaction and are not yet clearly understood. Indications for the removal of failed Proplast/Teflon implants includes pain that affects daily activity, decreased range of motion, changes in occlusion and condylar morphology.

The foreign-body giant cell reaction associated with previously placed Proplast/Teflon implants, however, continues after removal of the implant, despite repeated meticulous surgical debridements. The most popular accepted methods for TMJ reconstruction after Proplast/Teflon implant failure involves the use of autologous (using the patient's own tissue) tissues. The placement of autologous tissues into an environment in which the foreign-body giant cell reaction is occurring results in a significant high failure rate that may require further surgery.

The orthopedic literature from the 1960's reported on the failure of teflon implants for hip prostheses. The early results were favorable, but with continued follow-up the implants demonstrated biomechanical failure with resultant fragmentation, foreign-body giant cell reaction and subsequent osseous changes. The orthopedic experience could have predicted the long term results described in the oral and maxillofacial surgery literature.

Patients with malocclusion/facial deformity, condylar resorption, pain, or any of the other previously mentioned symptoms as a result of Proplast/Teflon implantation into the TMJ are difficult to help because standard methods of treatment are often ineffective.

HOW CAN WE HELP PATIENTS WITH PROPLAST/TEFLON TEMPOROMANDIBULAR JOINT IMPLANTS?

1. Patient registry and development of data base
2. Provide funding for evaluation and treatment of patients
3. Continue present research and initiate new research to determine the consequences of failed Proplast/Teflon implants
4. Identify, through research and controlled studies, predictable methods of managing patients with Proplast/Teflon implants

MEDIC ALERT REGISTRY

1. The FDA Public health notice of the recall on Proplast/Teflon implants (Vitek, Houston, Tx) that were previously used for reconstruction of the temporomandibular joint (TMJ), should be widely publicized through all avenues of the news media. Patients who have previously received Proplast/Teflon TMJ implants must be encouraged through the news media and the medical/dental fields, to enroll in the Medic Alert Registry. Only by mandatory comprehensive active enrollment of patients into the Registry will the extent of the public exposure to Proplast/Teflon be identified. Enrollment of patients into the registry will allow epidemiological studies to be performed to determine the incidence and consequences of implant failure. The Registry can be an important source of information for affected patients as the possible health effects of these implants becomes available. Long-term consequences of Proplast/Teflon implant failure at this time is unknown. The Registry will ensure continuation of information to the patient in the event that the original treating doctor is no longer available to the patient.

2. *EVALUATION AND TREATMENT OF PATIENTS WITH PROPLAST/TEFLON IMPLANTS*

Publicize and educate patients who have received Vitek Proplast/Teflon TMJ implants of the need for periodic, follow-up examination, even in the absence of symptoms. Many medical insurance companies have excluded coverage for temporomandibular joint (TMJ) surgery. Patients may be forced to sign exclusionary clauses to maintain medical coverage if the insurance company learns that a patient has a

TMJ problem. Patients debilitated by their TMJ dysfunction secondary to failed Proplast/Teflon implants to the extent that they are unable to work, are often ineligible for medical insurance coverage. Reimbursement provided by Medicaid/Medicare and Social Security programs is presently so grossly inadequate that hospitals simply cannot afford the expensive long-term treatment these patients often require. Many patients may not receive treatment because they do not have medical insurance coverage for TMJ problems, are no longer able to afford treatment, or are not able to work due to disability secondary to pain and dysfunction associated with their TMJ. There is presently no financial support available for these patients to have necessary diagnostic tests, medical management, or surgical removal of the Proplast/Teflon implants and reconstruction of the TMJ.

3. *CURRENT TREATMENT RECOMMENDATIONS BY FDA MAY BE INADEQUATE*

Our recent study (Henry CH, Wolford LM, submitted for publication to the Journal of Oral and Maxillofacial Surgery) has shown low overall rate of success when using a patient's own tissue (autologous), bone and/or soft tissue, for reconstruction of the TMJ after Proplast/Teflon implant failure. Our study and a previously published study has suggested the foreign-body giant cell reaction as the most likely cause for failure of autologous tissue.

TREATMENT OUTCOMES AFTER PROPLAST/TEFLON IMPLANT FAILURE

	Temporalis	Dermis	Cartilage	Costochondral	Sternoclavicular	TJ
Number of subjects	35	9	4	16	14	26
Duration of P/T implant (months)	35.8	38.1	32.5	35.9	26.1	46.0
Avg. Age	33.8	36.1	36.6	32.1	32.1	41.9
Follow-up period (months)	42.0	57.0	27.0	47.8	62.6	14.0
Failure rate (%)	69	92	75	88	79	12

Current treatment recommendations by the FDA for reconstruction of the TMJ after Proplast/Teflon implant failure includes 1) using the patient's own tissue for reconstruction, 2) removal of implant and no reconstruction, or 3) use a non-Proplast coated implant. Based on our current research and experience, treatment options 1) and 2) are likely to be unsuccessful. Further research is necessary to determine predictable treatment protocols for these unfortunate patients. In an ongoing study (Wolford LM, Henry CH), reconstruction of the TMJ with specific (using known compatible materials) total joint prosthesis has shown good stability of the jaws and joints with acceptable function for the first year, but less than 50% of the patients have substantial relief of pain.

4. AREAS TO CONCENTRATE RESEARCH EFFORTS AND FUNDING

A) National Referral Clinic

Establish a national Center to develop a database based on a Registry of patients who have received Vitek Proplast/Teflon TMJ implants. The database will be designed to allow for an evaluation of various treatment outcomes and to provide long-term monitoring of patients who have received Proplast/Teflon implants. In addition, the Center will function as a national referral clinic for the evaluation, management and follow-up of patients who continue to exhibit signs and/or symptoms of dysfunction associated with Proplast/Teflon implants.

B) Foreign-body giant cell inflammatory reaction:

Our recent study, not published yet, demonstrates continuation of the foreign-body giant cell reaction even after implant removal. Our study demonstrated the presence of the foreign-body giant cell reaction as long as 4 years after implant removal, even after an average of 4.5 reconstructive surgeries. The long-term effects of the foreign-body giant cell reaction in these patients is presently unknown and must be investigated.

C) Immunological response to Proplast/Teflon implants:

Investigation of possible immunological responses to Proplast/Teflon implants and residual Proplast/Teflon particles within the TMJ must be conducted. Our preliminary

studies indicate that an immunological response may be a contributing factor in this disease process. Currently no studies have been published concerning the possible immunological response in humans to failed Proplast/Teflon implants.

D) Pain:

Investigation of severe intractable pain often associated with failed Proplast/Teflon implants should be a priority. Pain may be a result of the continuation of the foreign-body giant cell reaction with secondary release of inflammatory mediators. Understanding the body's response to failed Proplast/Teflon implants may permit development of treatment regimens that would alleviate pain.

Mr. WEISS. Thank you Dr. Wolford.
Dr. Laskin.

STATEMENT OF DANIEL M. LASKIN, D.D.S., PROFESSOR, MEDICAL COLLEGE OF VIRGINIA; EDITOR, JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY

Dr. LASKIN. Thank you, Mr. Chairman.

Mr. Chairman, I am Dr. Daniel M. Laskin, professor of oral and maxillofacial surgery in the Schools of Dentistry and Medicine of the Medical College of Virginia, Virginia Commonwealth University. I have also been editor-in-chief of the Journal of Oral and Maxillofacial Surgery since 1972.

I appear before this committee today for two purposes. First, is to express my concern over the serious situation that has occurred in many patients who have had synthetic materials placed for the treatment of temporomandibular joint disorders by oral and maxillofacial surgeons who were led to believe that these materials were safe and effective.

Second, is to attempt to explain to you how this situation arose and to encourage you to find ways in which such situations can be avoided in the future.

It has been estimated that over 10 million Americans suffer from TMJ disorders, and about 15 to 20 percent ultimately require surgery. The two most common categories of surgical patients are those with various forms of arthritis, particularly degenerative and rheumatoid arthritis, and those with problems involving the disc that is located between the jawbone—condyle—and the socket—glenoid fossa—of the TMJ. These conditions produce intense, debilitating pain, and difficulty with eating and speaking.

The surgical treatment of both arthritis and disc pathology generally involves removal of the affected tissues and their replacement with substitute materials. An ideal replacement would, of course, be tissue taken from another part of the patient's own body. However, this requires a second surgical site and increases the complexity of the procedure as well as the potential for additional complications.

Therefore, the use of biocompatible synthetic materials appeared to offer a reasonable alternative. Since there was little research available that directly involved the temporomandibular joint, the oral and maxillofacial surgeon turned to the medical literature for a solution.

The development of a total replacement for the temporomandibular joint was based on what had previously been done in the hip joint, and has involved either a metal socket and a plastic condyle, or a plastic socket—Proplast Teflon—and a metal condyle.

In the instance of the metal socket and plastic condyle, there has been insufficient data available up to the present time to determine long-term success. In the case of the plastic socket and metal condyle, despite the fact that Proplast Teflon is used, the long-term data do not show significant adverse reactions, as have occurred when this material is used in opposition to the natural jawbone.

Whereas there have been no significant problems with the total joint replacement reported in the literature, the same situation

does not exist with synthetic TMJ disc replacement. The use of silicone rubber—Silastic—to replace the TMJ disc was first described in 1969. The apparent safety of this material was initially confirmed by reports of minimal tissue reaction in long-term studies of silicone implants used in other small joints.

A Proplast Teflon laminate as a TMJ disc replacement was introduced on the market in 1983. As with the use of silicone rubber, the first reports noted a high degree of clinical success with this material. Starting in 1986, however, reports began to appear regarding adverse effects developing in patients who had received either silicone rubber or Proplast Teflon implants. These changes involved extensive resorption of bone and marked tissue inflammation.

There were also reports of fragments of material and a foreign body reaction being found in adjacent lymph nodes. Although in some patients the TMJ changes were not associated with symptoms, in others there were intense pain, jaw dysfunction, and occasional changes in the bite. And as a result of these and subsequent reports of adverse reactions, the oral and maxillofacial surgeon began to abandon the use of synthetic materials and seek more biocompatible natural tissues as substitutes.

Currently, the oral and maxillofacial surgeon is not only faced with the problem of finding better substitutes for joint tissue replacement, but also with the dilemma of what to do with those asymptomatic TMJ patients who have synthetic materials in the joint and show x-ray changes, or those who are currently both clinically and radiographically asymptomatic.

The American Association of Oral and Maxillofacial Surgeons, which represents almost 6,000 oral and maxillofacial surgeons in the United States, has taken a leadership role in bringing this problem to the attention of its membership through the pages of its journal and via its other media. It has also independently supported TMJ research as well as urged the National Institute of Dental Research to provide more funding for investigations in the TMJ area.

In addition to the need for putting more dollars into TMJ research in order to establish the efficacy of current and future treatments before they become widely disseminated, there is also a need for improvements in the regulatory mechanisms so devices and materials are not placed on the market before being proved safe and efficacious. Had adequate premarket research and clinical testing been done, perhaps the current disaster of the use of Proplast Teflon could have been avoided.

Practicing clinicians are not in a position to make properly informed judgments in regard to materials and devices, and must rely on Federal oversight to safeguard their patients. I urge the committee to do whatever is necessary to see that increased research and improved governmental regulations in this area are initiated and funded so the public can be adequately protected and problems such as we are discussing today can be avoided in the future.

I thank you for the opportunity to appear before this committee.

[The prepared statement of Dr. Laskin follows:]

Testimony of Dr. Daniel M. Laskin

Mister Chairman, I am Dr. Daniel M. Laskin, Professor of Oral and Maxillofacial Surgery in the Schools of Dentistry and Medicine of the Medical College of Virginia, Virginia Commonwealth University. I have also been Editor-in-Chief of the Journal of Oral and Maxillofacial Surgery since 1972. I appear before this committee today for two purposes. First, is to express my concern over the serious situation that has occurred in many patients who have had synthetic materials placed for the treatment of temporomandibular joint (TMJ) disorders by oral and maxillofacial surgeons who were led to believe that these materials were safe and effective. Second, is to attempt to explain to you how this situation arose and to encourage you to find ways in which such situations can be avoided in the future.

It has been estimated that over 10 million Americans suffer from TMJ disorders, and about 15 to 20% ultimately require surgery. The two most common categories of surgical patients are those with various forms of arthritis, particularly degenerative and rheumatoid arthritis, and those with problems involving the disc that is located between the jawbone (condyle) and the socket (glenoid fossa) of the TMJ. These conditions produce intense, debilitating pain, and difficulty with eating and speaking.

The surgical treatment of both arthritis and disc pathology generally involves removal of the affected tissues. Until the early 1960's, however, replacement of these tissues was usually not done. Although reports prior to that time claimed that TMJ tissue removal without replacement produced relief of pain and dysfunction in many patients[1-3], other patients continued to have problems requiring further surgical intervention.[4,5] As a result, oral and maxillofacial surgeons were encouraged to seek substitute materials to replace the tissues being removed in order to produce a more natural situation.

An ideal replacement would, of course, be tissue taken from another part of the patient's own body. However, this would require a second surgical site and would increase the complexity of the procedure as well as the potential for additional complications. Therefore, the use of biocompatible synthetic materials appeared to offer a reasonable alternative. Since there was little research available that directly involved the temporomandibular joint, the oral and maxillofacial surgeon turned to the medical literature for a solution.

The development of a total replacement for the temporomandibular joint was based on what had previously been done in the hip joint, and has involved either a metal socket and a plastic replacement (acrylic; methylmethacrylate) for the functioning component of the jawbone (condyle), or a plastic socket (Proplast-Teflon) and a metal condyle. In the instance of the metal socket and plastic condyle, there has been insufficient data available up to the present time to determine long-term success. In the case of the plastic socket and metal condyle, despite the fact that Proplast-Teflon is used, the long-term data do not show significant adverse reactions, as have occurred when this material is used in opposition to the natural jawbone.[6,7] Problems with both types of total joint prostheses do exist with regard to accurately fitting every patient, however, and research is currently being done on the development of a custom-made prosthesis based on CT scanning and the construction of a three-dimensional model of the actual patient's TMJ.

Whereas, there have been no significant problems with total joint replacement reported in the literature, the same situation does not exist with synthetic TMJ disc replacement. The use of silicone rubber (Silastic) to replace the TMJ disc was first described by Hansen and Deshazo in 1969[8], and this technique was subsequently adopted by the oral and maxillofacial surgeon. The apparent safety of this material was confirmed by Nalbandian et al in 1983[9], when they reported minimal tissue reaction in a long-term study (10-12 years) of silicone implants used in other small joints. Similar results were also presented in 1983 by Herndon[10], who noted that silicone had become the standard for comparison of joint implants. In the same year, Bessette reported significant improvement in 97% of his patients treated with silicone implants following TMJ disc removal.[11]

A Proplast-Teflon laminate as a TMJ disc replacement was introduced on the market in 1983, but there are earlier reports of its use for this purpose.[12] As with the use of silicone rubber, the first reports noted a high degree of clinical success with this material[13], despite earlier warnings by Charmley[14] that abraded particles of Teflon gave rise to an intense foreign body reaction in the hip joint. In 1984, Kiersch reported a 93% success rate in 250 TMJ patients in whom Proplast-Teflon was used to repair or replace TMJ discs.[15]

Starting in 1986, however, reports began to appear regarding adverse effects developing in patients who had received either silicone rubber or Proplast-Teflon implants.[16-20] These changes involved extensive resorption of bone and marked tissue inflammation. There were also reports of fragments of material and a foreign body reaction being found in adjacent lymph nodes.[21,22] Although in some patients the TMJ changes were not associated with symptoms, in others there was intense pain, jaw dysfunction, and occasional changes in the bite. As a result of these and subsequent reports of adverse reactions[23], the oral and maxillofacial surgeon began to abandon the use of synthetic materials and to seek more biocompatible natural tissues. These have included the use of the patient's ear cartilage, dermis (the deep layer of the skin) or a muscle flap from the side of the head.

Currently, the oral and maxillofacial surgeon is not only faced with the problem of finding better substitutes for joint tissue replacement, but also with the dilemma of what to do for those asymptomatic TMJ patients who have synthetic materials in the joint and show x-ray changes, or for those who are currently both clinically and radiographically asymptomatic. The American Association of Oral and Maxillofacial Surgeons, which represents the almost 6,000 oral and maxillofacial surgeons in the United States, has taken a leadership role in bringing this problem to the attention of its membership through the pages of its Journal and via its other media. It has also independently supported TMJ research as well as urged the National Institute for Dental Research to provide more funding for investigations in the TMJ area.

In addition to the need for putting more dollars into TMJ research in order to establish the efficacy of current and future treatments before they become widely disseminated, there is also a need for improvements in the regulatory mechanisms so that devices and materials are not placed on the market before being proved safe and efficacious. Had adequate premarketing research and clinical testing be done, perhaps the current disaster with the use of Proplast-Teflon could have been avoided. Practicing clinicians are not in a position to make properly informed judgements in this regard, and must rely on federal oversight to safeguard their patients. I urge you, ladies and gentlemen of the Committee, to do whatever is necessary to see that increased research and improved governmental regulations in this area are initiated and funded so that the public can be adequately protected and problems such as we are discussing today can be avoided in the future.

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Mr. WEISS. Thank you very much, Dr. Laskin.

Dr. Lappé, before we proceed with your testimony, I want to ask you a few questions for the record.

Is it correct that you appear today at my direction as chairman of this subcommittee?

Dr. LAPPÉ. Yes.

Mr. WEISS. Is it correct your testimony is based on your personal knowledge of this subject?

Dr. LAPPÉ. Yes, it is.

Mr. WEISS. Is it correct that in 1992 the Dow Corning Corp. secured an order of the Federal court which seeks to prohibit you from disseminating certain documents and information concerning safety tests and studies?

Dr. LAPPÉ. Correct.

Mr. WEISS. Pursuant to that order, you have heretofore not provided the subcommittee with any document that may be the subject of that order; is that correct?

Dr. LAPPÉ. Yes.

Mr. WEISS. Of course, you have had conversations with our staff in preparation for today's hearing; is that right?

Dr. LAPPÉ. That is right.

Mr. WEISS. Dr. Lappé, the subcommittee directs, pursuant to my letter of invitation and applicable statutes, including 2 U.S.C. 192, that you appear and testify on the subject matter of this hearing and provide such documents as may be requested.

Please proceed with your testimony.

STATEMENT OF MARC LAPPÉ, Ph.D., PROFESSOR, HEALTH POLICY AND ETHICS, UNIVERSITY OF ILLINOIS COLLEGE OF MEDICINE, CHICAGO, IL

Dr. LAPPÉ. Thank you, Mr. Chairman and members of the subcommittee.

I will attempt to provide a historical lattice work against which to place what could have been known by the medical community had there been more disclosure from the corporate sector—what type of information is available to physicians and surgeons who perform these interventions and what kind of remedies might be available to preclude the disasters that you heard described.

I think you can trace the origin of attempting to put in synthetic materials to the TMJ to approximately 1965, when two researchers used Silastic sheeting as a jaw insertion material.

That single report, which actually reported a less than fully successful application, was taken as the impetus by the corporate sector to begin to market the product that had absolutely no prior testing for its safety and efficacy for that application.

More particularly, the researchers thought they were seeing fibrosis, that is, a proliferation of fibroblasts around their implant, immobilizing the jaw of the patient that had this first implant.

It is the case that Dow Corning researchers knew that fibrosis was a predictable consequence of the type of elastomer used in Silastic sheeting. And hence, this would be a predictable complication of Silastic implanted material.

Further, Dow Corning knew that their sheeting simply could not hold up to the types of stress pressures that are exerted at the particular interface of the TMJ; the jaw can exert 200 to 300 pounds of pressure at that point.

Third, the corporation knew and the studies were freely available that showed that, when Silastic was used in other applications, it would lose strength and deteriorate over time.

Various silicone elastomers were known to break down and generate silicone wear particles when subjected to pressure and friction.

More importantly, Dow Corning knew as early as 1968–69 that degradation or the presence of Silastic elastomer would generate significant fibrosis, chronic inflammation, and giant cell formation.

Despite this data, Dow Corning knowingly allowed their silicone sheeting to continue to be used to repair the damaged TMJ joint, even though it is highly likely the sheeting could not stand up to the stresses of the joint and would generate precisely the problem that in many instances led to the need for replacement in the first place. That is, to be very clear, the Silastic sheeting itself has the capacity to cause fibrosis and ankylosis as a consequence of the inflammation it induces.

Now, the medical community only belatedly became aware of these capacities as a result of unfortunate patient experiences. In the early 1970's it is true, short-term studies seemed to support the use of Silastic material.

Studies that then came out in the 1980's began to document direct formation of ankylosis from wear particles. And a representative study published in 1982 warned the medical community that the discovery of the migration of silicone particles meant, "Physicians should be alert to the possibility of systemic reactions to the silicone polymer in susceptible patients."

These systemic reactions had already been seen from silicone polymers in breast implant patients, and as this report discloses, in TMJ patients. The researchers went on to warn of the possible contribution of silicone rubber foreign-body synovitis in hastening the clinical failure of prostheses manufactured from these materials.

Other researchers documented the perforation, fragmentation, and deterioration of this material, and still it remained and remains to this day on the market.

By the mid-1980's, researchers were finding silicone-induced foreign body reactions and lymph node swellings after TMJ arthroplasty using Silastic routinely. One study belatedly concluded, "Silicone may not be a totally inert material and its biomechanical properties are not ideal for use in TMJ."

I think the medical community could understandably have reached that conclusion. The package sheet inserts that came with Silastic stated in 1965 and 1966 this was an inert material. In 1967 and 1968 it was called highly inert. In 1969 to 1972 it was minimally reactive, and in 1973 through 1984 it was essentially nonreactive.

In 1985 on this report saying this material doesn't look like it is inert or biocompatible, the Dow Corning insert said it has excellent biocompatibility.

Now, for a physician to see the full instruction sheet on what risks and benefits exist for a patient, the physician would have to

write to Dow Corning Corp. to get it. It did not come as a package insert for any device that I am familiar with, except the Wilkes device.

And there is a long catalog of adverse effects that could occur from the use of the Wilkes material, but it is the same material that continued to be marketed in 1991 in Silastic sheeting for the same application.

Finally, I want to emphasize there was absolutely no animal pretesting of this material through 1989. And when the work did come forward that provided a useful model, it found that the effects in the sheet model that was developed were devastating. This material did not hold up over the long run in these animals.

To conclude, the development of Silastic sheeting in particular and other implant materials for the TMJ, which is one of the most critical joints in the body, is marked by a pattern of haphazard development, entrepreneurialism, unverified assertions in the absence of animal testing, and frankly, a silent FDA.

In 1992, we were left with no truly suitable implant material because the most commonly used one—Silastic brand reinforced sheeting—was only belatedly subjected to testing. Then it was found to be insufficient for just the properties known to its manufacturer 20 years earlier.

[The prepared statement of Dr. Lappé follows:]

TESTIMONY BEFORE THE HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE OF THE COMMITTEE ON GOVERNMENTAL OPERATIONS HOUSE OF REPRESENTATIVES
June 4, 1992

Marc Lappé, PhD
Professor of Health Policy & Ethics
University of Illinois at Chicago
College of Medicine

The urge to intervene in the repair of a debilitating illness is an age-old impulse. This has proven especially true for trismus, from the Greek "trismos" meaning "gnashing", where the rigid locking of the jaw is almost always debilitating to some degree. Persons with this condition experience pain, difficulty in speaking, eating, and difficulties in keeping their dental hygiene. While trismus is usually short-lived and reversible because of its dependence on muscular spasm, its bony counterpart, ankylosis, is not. Ankylosis refers to the build-up of caclifications in a joint, leading to limitation in movement. When this occurs in the temporomandibular joint (TMJ), one of the most critical joints in the body, movement of the jaw is greatly limited by either the fusion of bone or fibrous tissue. Ankylosis can result from infection, congenital problems, or trauma.

Attempts to repair this condition date to the middle 1800s, when surgeons first devised crude techniques for freeing the TMJ from its fused or bound state. Modern treatment dates from 1934, when an American physician named Risdon first reported success in placing gold foil in the joint cavity to prevent re-ankylosis of fused TMJs. Modern joint replacement or repair that relies on synthetic materials began in earnest in about 1965, when Drs. Beekhuis and Harrington in Detroit, Michigan first reported using a Silastic® sheet to provide a new interface for the damaged TMJ (See attached bibliography).

According to sworn testimony from a Dow Corning employee, this

single report served as the principal impetus to encourage the marketing of Silastic® sheeting for this new, and untested purpose. Remarkably, this marketing went forward in spite of the fact that the original authors had correctly surmised that the lack of success of their implant was due to further immobilization of their patient's jaw through fibrosis. Dow Corning researchers knew that fibrosis was a predictable consequence of placement of silicone-based sheeting, and hence that this would be a predictable complication of Silastic® implanted material.

A. Corporate Knowledge

Dow Corning's cooperation in marketing and endorsing an unapproved use of Silastic® sheeting as a medical device for TMJ repair was remarkable for three reasons:

1) Dow Corning knew or had reason to know that their sheeting was intrinsically flawed for any stress-bearing joint subject to pressure and repetitive flexing (the jaw can exert 200-300 pounds of pressure);

2) By anology with silicone-based heart valve poppets, Dow Corning knew that Silastic® would not hold its physical properties over time because of its propensity to absorb serum-borne lipids and lose strength.

3) Various silicone elastomers were known to break down and generate silicone wear particles when subjected to pressure and friction.

4) Dow Corning knew that such degradation would generate significant fibrosis, chronic inflammation and giant cell formation; and

Despite this data, Dow Corning knowingly allowed their silicone sheeting to be used for repairing the damaged TMJ even though it was highly likely that the sheeting, even when reinforced, could not stand up to the stresses typical of a major pressure-bearing, inflammation-damaged joint. Silastic® was known to have the selfsame properties that surgeons hoped to mitigate from its use: Silastic® itself, as well as related silicone rubbers, can cause fibrosis and ankylosis, and ultimately the arthritic changes in the jaw that it is intended to cure.

B. What the Medical Community Knew

The medical community's knowledge of possible adverse effects from the use of Silastic® necessarily lagged behind that of the manufacturer and the FDA.

In the early 1970s, short-term studies appeared to support the use of silicone rubber-type products for repair of the TMJ. Patients with newly implanted Silastic® did quite well for periods usually limited to a few months. This result is likely the result of the limited nature of the initial fibrosis provoked by silicone sheeting. (In fact, many surgeons learned to capitalize on this property by allowing the silicone to remain in the TMJ only long enough to produce a smooth fibrous capsule--and then removing the piece of silicone sheeting).

Mid-range studies where follow-up proceeded for 1-5 years or more revealed substantial problems with Silastic® replacements for the meniscus in the TMJ: patients who initially did well experienced late pain and further limitations of jaw mobility.

Research reports and clinical studies of humans published at the end of the 1970s and early 1980s documented the direct formation of ankylosis from wear particles from both TMJ and other Silastic® and silicone-based implants. A representative study published in 1982 warned the medical community that the discovery of the migration of particles of silicone meant that "physicians should be alert to the possibility of systemic reactions to the silicone polymer in susceptible patients". They went on to warn of "the possible contribution of silicone-rubber foreign-body synovitis in hastening the clinical failure of prostheses that were manufactured from these materials" (Gordon et al, J Bone and Joint Surgery 64-A: 574, 1982). By the mid-1980s, two Swedish researchers reported the fragmentation, perforation and deterioration of the (silastic) material" (Eriksson and Westesson, Oral Surgery, Oral medicine and Oral Path 62: 2, 1986).

By the mid-1980s, researchers were finding silicone-induced foreign body reactions and lymph node swelling after TMJ arthroplasty using Silastic®. One such study belatedly concluded that "silicone may not be a totally inert material and that its biomechanical properties are not ideal for use in the TMJ" (Dolwick et al, Oral Surgery, Oral Medicine and Oral Path 59: 449, 1985).

During this same period, reports appeared that showed that inflammation of the synovial lining of the joint (synovitis)--a condition which often preceded joint damage in the first place--could be produced by particulate Silastic®. Only at the end of the 1980s, had enough failures occurred with these other joint applications of Silastic®--including the production of a destructive arthritis--to lead some researchers to call for strict limits on its use, in replacing joint surfaces in the arm of wrist as well as in the temperomandibular joint.

C. Pathologic Findings

Noteworthy in all of these studies that documented adverse findings was the ubiquitous presence of the so-called giant cell. This cell is a characteristic histologic marker of chronic inflammation that can flag the presence of an immune response. Such chronic inflammation was observed in breast implant recipients, patients who had received Silastic® implants for joint replacement in the hand or foot, and among those with TMJ replacements.

The most percipient researchers noted a close correlation between silicone's ability to produce such granulomas and its destructive potential. Similar findings made by internal Dow Corning studies were unknown to the medical community because they were concealed by incomplete pathology reports in published documents by Dow Corning researchers (See Silas Braley and Gordon Robertson, Medical Instrumentation, 1973).

D. Problems of Disclosure

Even though Dow Corning had found granulomatous responses,

fibrosis, and calcification in their own studies years earlier @1968-1970 (this data was made public via the FDA's review of breast implants), they neither acknowledged this reaction as one characteristic of their own product nor warned of the likelihood of its occurrence in its package data for Silastic® sheeting or for the Wilkes' device--a pre-cut form of reinforced sheeting especially designed for use in the TMJ..

More importantly, the full product description for the sheeting was only available to surgeons who asked for it: it did not come as a package insert. If they received the product description, the surgeon was still not assured of accurate information.

The product information sheet developed by Dow Corning is notably deficient in warning about hazards and the importance of limiting any use of its device. Warnings that only short term use would be appropriate for TMJ applications only appeared in the most recent product descriptions.

D. Pre-testing

Even as these clinical reports were being amassed, only a handful of animal studies were done attempt to validate the long-term efficacy or safety of the Silastic® TMJ implant. None were made available to the medical community. As late as 1989, researchers were able to state that "No animal studies are currently available to document the effects of temporary silastic implantation following TMJ discectomy" (Tucker and Burkes, J Oral Maxillofac Surg 47: 1290, 1989).

One researcher went further and noted that "Of particular significance to the surgeon is the fact that there are now commercially available several types of implant material for the TMJ without one single long-term study of its use in an animal model or human subjects available for critical analysis" (Acton et al, Australian Dental Journal 34: 228, 1989).

When a suitable animal model was finally developed in 1991, its conclusions were hardly reassuring. Researchers found that the jaws of sheep implanted with Silastic® TMJ sheeting underwent severe bony destruction accompanied by a foreign body giant cell reaction. These

findings were sufficiently grave to lead the researchers to conclude--twenty years after the first uses of Silastic® for TMJ arthroplasty--that "(silastic's) physical properties are not appropriate for its long-term use in the TMJ." Even the short-term use of Silastic® to induce the formation of a fibrous capsule was clearly still (in 1991) highly experimental in these authors' view, because the capsule could be "of poor quality and contain multinucleated giant cells" (Bosanquet et al, J Oral Maxiollofac Surg 49: 1204, 1991).

E. Comment

From having read all of the documents made public by Dow Corning, and from the review of the open literature, it is clear that Dow Corning knew decades earlier what Dolwick and Audemorte finally realized in 1985: their material was intrinsically flawed as a biomaterial for long-term implantation into the human body. In the 1960s, they saw foreign body cell reactions, and knew that silicone induced fibrosis and calcification. In the late 1970s and early 1980s they had access to published data confirming the adverse effects of wear particles, and failed to incorporate these consequenes into an adequate warning. They continued marketing nonetheless.

The development of Silastic® sheeting in particular and other implant materials for the TMJ, one of the most critical joints of the body, is marked by a pattern of haphazard development, entrepeneurialism, unverified assertions in the absence of animal testing, and a silent FDA. In 1992, we are left with no truly suitable implant material, in part because the most commonly used one--Silastic® brand reinforced sheeting--was only belatedly subjected to testing. And then, it was found to be deficient for just the properties which were known to its manufacturer fully twenty years earlier.

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Mr. WEISS. Dr. Marbach.

STATEMENT OF JOSEPH J. MARBACH, D.D.S., COLUMBIA UNIVERSITY SCHOOL OF PUBLIC HEALTH, NEW YORK, NY

Dr. MARBACH. Mr. Chairman, members of the subcommittee, my name is Joseph Marbach. I am on the faculty of Columbia University in the city of New York, where I hold the title of clinical professor of public health.

As my contribution to these hearings, I wish to take a long step back from the operating table, all the way to the consultation room, and share my clinical and research experience with you. Of the thousands of TMJ patients I have examined, I have personally referred none for surgery.

There are two central points I would like to make. My first point is that the data show that conservative, nonsurgical treatments for TMJ disorders are associated with little risk and with moderately high rates of success. While I know of no systematic long-term followup studies for surgery, my clinical experience is that surgery is associated with considerable risk and, at best, short-term success. Since we know that TMJ pain varies considerably over time, even those limited reports of short-term surgical successes have to be questioned.

A more pressing consideration is the disability resulting from the surgery. While disability following surgery can rank from negligible to considerable, the worst postsurgical cases are far worse than the worst cases in the natural presurgical state. Here I define disability as increased pain, impaired speech and chewing, and facial disfigurement.

My second point is illustrated right here in this room. The panel of patients are all women. We experts are all men. About 80 percent of those who seek care for TMJ are women. Yet women make up virtually 100 percent of the surgical cases. In the 4,000 TMJ cases that have consulted me, I personally only met one male that has undergone surgery, but I have been consulted by a steady stream of women. I have a strong impression there are a disproportionate number of women relative to men who have undergone this surgery.

Were I in a position to influence research funding in the field, I would suggest that funding for treatment outcome of surgery be but part of a more comprehensive outcome study of all methods for treatment of TMJ problems. This should be conducted within a framework of a general study of the health of these women. Our NIDR-funded projects during the last decade have shown these women have far more illnesses, fewer children, fewer accidental pregnancies, more premenstrual symptoms, and that even their children are sicker and have more illnesses than a control group of women that are their demographic counterparts. This issue of surgery is clearly but the tip of the iceberg for these women.

Thank you.

[The prepared statement of Dr. Marbach follows:]

Columbia University in the City of New York | *New York, N.Y. 10032*

SCHOOL OF PUBLIC HEALTH
Division of Sociomedical Sciences

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Testimony Before the
Subcommittee on Human Resources and Intergovernmental Relations

June 4, 1992

Joseph J. Marbach, D.D.S.
Clinical Professor of Public Health

Mr. Chairman, members of the subcommittee, my name is Dr. Joseph Marbach. I am on the faculty of Columbia University in the city of New York, where I hold the title of Clinical Professor of Public Health. I have been in private practice limited to facial pain and temporomandibular joint disorders for 29 years and was the director of the TMJ clinic at Columbia University for 14 years and later founded the TMJ clinic at Harvard University in Boston, Mass. I am both a clinician and researcher.

I understand that the purpose of this hearing is to explore issues surrounding the safety and efficacy of temporomandibular joint implants.

As my contribution to these hearings I wish to take a long step back from the operating room table all the way to the consultation room and share my clinical and research experience with you. Of the thousands of TMJ patients I have examined, I have personally referred none for surgery.

There are two central points I'd like to make.

My first point is that the data show that conservative <u>non-surgical</u> treatments are associated with little risk and moderately high rates of success. While I know of no systematic long-term follow-up study of surgery, my extensive clinical experience is that surgery is associated with considerable risk and, at best, short-term success in a minority of cases. However, a forthcoming paper from our research group at Columbia shows that TMJ pain intensity varies considerably over time, so that even those limited reports of short-term surgical successes have to be questioned.

An even more pressing consideration is the disability resulting from the surgery. While disability following surgery can range from negligible to considerable, the worst post-surgical cases are far worse than the worst cases in their natural, pre-surgical states. Here, I define disability as increased pain, impaired speech and chewing, and disfigurement. I believe that there are certain situations in which surgery is indicated; in the case of tumors and frozen joints that are the result of trauma, but these are exceedingly rare situations.

My second point is illustrated right here in this room. The panel of patients are all women. Epidemiologic data suggest that the signs and symptoms of TMJ are equally distributed between the sexes, even though women are more likely to seek care. About 80% of those seeking care for TMJ are women and 20% are men. Yet women make up virtually 100% of the surgical cases and men closer to 0%. In the 4,000-odd TMJ cases who have consulted with me, I have personally only met <u>one</u> male who has undergone TMJ surgery, but I am consulted by a steady stream of such women. I have yet to conduct a systematic review of my entire clinical practice records, but I have a strong impression that a disproportionate number of women relative to men have undergone surgery. (I suppose it's possible that I see only the surgical failures and that men who undergo TMJ surgery are all treatment successes.) Although I have thought about it a great deal, I have no satisfactory explanation for the probable disproportionate sex ratio among those in my clinical practice who have received TMJ surgery.

Were I in a position to influence research funding in this field, I would suggest that funding for treatment outcome of surgery be but a part of more comprehensive outcome studies of all methods for treatment of TMJ problems. This should be conducted within the framework of a general study of these women's health. Our NIDR-funded projects during the last decade have shown that these women have far more illness, fewer children, fewer accidental pregnancies, more premenstrual symptoms and that even their children have more illnesses than a control group than women who are their demographic counterparts. This issue of surgery is clearly but the tip of the iceberg for these women.

I will provide an elaboration of my comments to the subcommittee within the required time.

Mr. WEISS. Thank you very much, Dr. Marbach.

I am going to ask questions of you individually at this point, but if any of the others want to comment in response, please feel free to do so.

Dr. Fontenot, you testified that in the 1980's, silicone sheeting was used for permanent TMJ implants, but it is now recommended by the manufacturer only for temporary use. Does temporary use avoid the immune responses, bone deterioration, and other problems that were found with the so-called permanent implants?

Dr. FONTENOT. I think the response is time dependent. In terms of comparing temporary versus permanent, temporary devices fabricated from Silastic sheeting have much less reaction or little reaction when compared to permanent devices.

Mr. WEISS. Does research show that Dow's temporary TMJ implant is effective in creating a tissue capsule to replace the disc?

Dr. FONTENOT. There is a body of information that gives good clinical outcome, or positive results with implantation of Silastic as a temporary device, and also there is another body of information which gives results that aren't favorable.

Mr. WEISS. In the mid-1980's, there were many articles in dental journals praising Vitek's Teflon Proplast implants. When did the evidence start to indicate serious problems with its implants?

Dr. FONTENOT. About in the mid-1980's. Sometime in 1985 or 1986 was when the first reports came out. I think there were about 15 or 20 reports since the mid-1980's.

Mr. WEISS. Dr. Wolford, you describe relatively good results with a new total TMJ replacement device made by Techmedica. However, you have only followed these patients for an average of 12 months thus far. It is my understanding that there are no studies that follow the patients for more than 2 or 3 years; is that correct?

Dr. WOLFORD. That is correct.

Mr. WEISS. One clear lesson from Teflon implants is that short-term results can be deceiving. In fact, your own preliminary study showing better short-term results for Teflon TMJ implants compared to silicone implants was used by Vitek to get approval to sell implants in 1984. In the case of Teflon implants, most problems did not become apparent until the implants were in for about 3 years; is that correct?

Dr. WOLFORD. That is correct. Some individuals develop problems within a few months after placements of Proplast Teflon. There are other patients that have implants, and I have some patients that have had them in for 14 years, and are still functioning. I believe some of the work Dr. Fontenot has done has illustrated that the life expectancy of Proplast Teflon implants is about 3 years now. Is that correct, Mark?

Dr. FONTENOT. Yes.

I might add also—and I forgot to mention that we have done some extensive research in using autogenous tissues after Proplast Teflon implants had been in the joint. The best success rate we have is only about 30 percent success using a patient's own tissues to reconstruct a joint after Proplast Teflon has been there.

Mr. WEISS. You found foreign body response to Teflon implants continued more than 4 years after the implants were removed. That is perhaps the most frightening thought, because this response can cause continued bone degeneration and other problems; isn't that correct?

Dr. WOLFORD. That is correct. What happens, the implant material fragments and gets embedded into the bony and soft tissue structures around the joint and migrates to other areas in the head and neck as well. We cannot remove it surgically. When we use the patient's own tissues to rebuild the joint, it tends to pull this material back out of the adjacent tissues and causes a breakdown of the implant materials.

Mr. WEISS. Do you have concerns about other TMJ implants on the market today?

Dr. WOLFORD. Yes, sir. There are only a couple of the implant devices I think currently available that are using materials that have been fairly well proven in orthopedics. There are some devices out there now that are using materials that orthopedics abandoned a number of years ago.

Mr. WEISS. Can you be more specific on that?

Dr. WOLFORD. One specific concern we have is with acrylic used in the TMJ joint, which one current device does use. I don't know of any research on the long-term outcome of using that kind of material. But we know that orthopedics discontinued using that a number of years ago. In fact, if our manufacturers in the TMJ area would review the orthopedic literature, they may have avoided the problems that have occurred with Proplast Teflon because that was used back in the 1960's in orthopedics and was a dismal failure then.

Mr. WEISS. One of your patients, Ms. Marks, testified earlier this morning. She obviously has terrible problems with pain. I received a letter from a Tucson, AZ, dentist who knows of three Teflon TMJ patients who killed themselves because they don't want to live with the pain.

How typical is this with TMJ patients?

Dr. WOLFORD. This is a very difficult problem with some patients. We think it occurs in a subgroup of individuals who just have a very hypersensitive response to implant materials and the pain is so devastating for them that they don't want to live. If the health professional people don't know how to deal with it, know how to intercept it, it could be a devastating problem.

Mr. WEISS. What are the implications of your research for other implants?

Dr. WOLFORD. I think some of the work we are conducting at this time where we are able to identify specific blood cells responsible for the immunological response, sort of like the allergic response to the materials, and what we are doing in evaluating and trying to figure out how we can turn off the giant cell reactions—we may be able to identify and be able to destroy the specific cells that are causing these kinds of responses.

Relative to other implants, evaluating them in the same research methods, that which are with the Proplast Teflon patients, we may be able to identify specific cells for those materials as well; through immunological research and treatments, we may be able to eliminate those highly reactive cells to the foreign body materials.

This could involve such things as breast implants and any other kind of metal or implant devices used in the body.

Mr. WEISS. Dr. Laskin, you are a member of the FDA advisory panel that reviewed TMJ implants in 1989. At that meeting, you quoted Scandinavian research from many years earlier that suggested it might not be necessary to remove or replace discs with anything at all.

Has anyone followed up on that by examining whether implants are worse than nothing?

Dr. LASKIN. There have been several studies that have looked at the results when the disc has not been replaced, and you have heard a lot of testimony about what happens when you do replace the disc, but no single study either retrospectively or prospectively has compared a group of patients with and without disc replacement.

The answer to the question: There really is not adequate information to arrive at any conclusions.

Mr. WEISS. You mentioned in your testimony that the American Association of Oral and Maxillofacial Surgeons has supported TMJ research. Has it financially supported research on TMJ implants?

Dr. LASKIN. Yes, it has.

Mr. WEISS. I have a letter from 1984 in which Dr. John Kent, a well-respected TMJ researcher, told the president of Vitek that he was concerned about the safety of the Teflon implants they had developed together. One patient had to have the implant removed after 1½ years because of pain and swelling. When he performed surgery, he found that the implant was badly worn and the capsule was covered in a "heavy black pigment."

Dr. Kent expressed concern that they might have "a calamity of unbelievable proportions on our hands." Despite this concern, Dr. Kent and Dr. Homsy continued to aggressively promote these Teflon implants during the next few years; isn't that correct?

Dr. LASKIN. Following 1984, we published a number of articles in our journal that related to the outcomes of the use of these various implants. Our journal is a peer-reviewed journal and everything is subjected to scientific review. Therefore, those articles couldn't be considered as promotion.

Mr. WEISS. Right. But I am not asking about what your journal did, but what Dr. Kent and Dr. Homsy did.

Dr. LASKIN. I am not aware of what Dr. Homsy did. I am familiar with things Dr. Kent has written. These things I would not consider as promotional.

Mr. WEISS. Were his comments favorable toward continued utilization of these products?

Dr. LASKIN. Yes, they were.

Mr. WEISS. We have documents indicating Dr. John Kent had 21,000 shares of stock in Vitek at the same time that he was publishing articles praising Vitek's Teflon TMJ implants. Of course, everyone now agrees those early studies resulted in a lot of implant surgery that harmed patients.

As the editor of the major journal for TMJ, do you have any disclosure policies for conflicts of interest?

[The documents regarding Dr. Kent follow:]

EXHIBIT NO. 13
J. CARROUM

SCHOOL OF DENTISTRY
Louisiana State University
Medical Center
1100 Florida Avenue
New Orleans, LA 70119-2799
Telephone: (504) 948-8565

Department of Oral and Maxillofacial Surgery

February 14, 1984

Dr. Charles Homsey
President
Vitek, Inc.
3143 Yellowstone Road
Houston, TX 77054

Dear Charlie:

We have just recovered from Hawaii, the flu, and I understand that you are away at the orthopedic meeting in Atlanta. Briefly let me share some of my concerns concerning our past and future relationships.

The business of modifications of the preformed facial implants is of concern to me since I believe that the development of these implants to eliminate carving from a block of material occurred through our combined efforts. The concept itself, I believe, is one which is a product of efforts to include all possible modifications thereof whether its through changes that I make personally to you or we arrive at changes as a result of suggestions by others in the fields of oral plastic or ENT surgery. Let's face it, in the history of facial implants I do not believe there has been any effort to develop a preformed zygomatic, periorbital, or chin impant with the exception of the Dow Corning silcone rubber chin implant. The recent changes by Dr. Bromely Freeman and Dr. L. Whitaker represent nothing more than minor modifications of the concept of preformed chin and zygomatic implants. If this concept is one which Vitek and myself enjoy then I feel that benefits should be shared equally since these modifications in all honesty would not develop had we not come on to the scene with preformed facial implants.

The Freeman Chin, conceptually, was very upseting because it represented an extremely minor variation of the chin form which I developed for Vitek. I chose to ignore that problem because of some sentimental values which seem to be important to you. From a pure fair and creditable business logic, all royalties from the sale of the Freeman Chin should have been credited towards me since his implant is basically the form that I have developed. Again I chose not to pursue this anymore because of some sentimental reasons which you have with Dr. Freeman and because I do respect Dr. Freeman.

Dr. Charles Homsey
February 14, 1984
Page 2

Good sense, however, tells me not to ignor the Whitaker situation. There would be no preformed modification by Whitaker were it not for my design of zygomatic implants which I developed.

Therefore I must insist that minor modifications such as both of these and any future modifications of our existing preformed periorbital zygomatic, and chin implants must be shared equally by Vitek and myself at the current 3% royalty to myself.

On another matter, I have recently redone a right total joint prosthesis for Willowdean Wilson with absolutely devasting results from the first procedure which was a Syncar fossa articulating against a box type condyle. You may recall she is the one that is opening and closing in the movie and was done approximately 18 months ago. Because of recurrent pain and swelling, we reoperated her last Friday and found a significant 2 mm thick encapsulation with heavy black pigament over the right zygomatic arch. The metallic condyle had dug its way into the fossa to the nomex layer. You will be receiving the condyle fossa, and considerable tissue within a few days to evaluate this concern of mine about potential fossa wear after such a short period of time. If this represents a result after a couple of years of several hundred patients with total joint prosthesis, we have a calamity of unbelievable proportions on our hands. I think we need to discuss this and consider some laboratory studies to give some creditability to where we are going with this system. I'll be giving you a call to discuss this later in the week.

Sincerely yours,

John N. Kent, D.D.S.
Boyd Professor and Head
Department of Oral and Maxillofacial Surgery

cd:860

CAUSE NO. 87-332-B

FRANCES DE LUNA AND HUSBAND, RODRIGO DE LUNA	*	IN THE DISTRICT COURT
VS.	*	117TH JUDICIAL DISTRICT
ROGER P. BYRNE AND VITEK, INC.	*	NUECES COUNTY, TEXAS

DEFENDANT VITEK, INC.'S RESPONSES TO PLAINTIFFS' SECOND SET OF INTERROGATORIES, REQUEST FOR PRODUCTION, AND REQUEST FOR ADMISSIONS

NOW COMES Defendant Vitek, Inc. and, subject to the provisions of Rules 166b, 167, 168, and 169, Tex. R. Civ. P., files these, its Responses to Plaintiffs' Second Set of Interrogatories, Request for Production, and Request for Admissions. Defendant makes its answers under oath fully and separately to each interrogatory except to those to which objection may be made, reserving the right to supplement such interrogatories based on additional information that may become available through discovery in this case.

Respectfully submitted,

WHITE, HUSEMAN, PLETCHER & POWERS
2100 The 600 Building
Post Office Drawer 2707
Corpus Christi, Texas 78403-1695
(512) 883-3563

By
MARGERY HUSTON
State Bar No. 10329500

PTIPI inserts contained information as it became known regarding problems that can occur with implant surgery in general, including the PTIPI. Things listed in the inserts included squeaking noises in the joint, shortened life expectancy of the implant from a rough condyle surface resulting from irregular resorption, that the implant may fail from abnormal joint loading or failure to trim the implant properly.

Excessive thickness of the implant could cause above normal loading of the joint. Overloading of the joint may result in significant wear of the Teflon surface, displacement, or fragmentation of the material with foreign body giant cell reaction, and/or granulation response and condyle resorption. Since the described health problems related to underlying disease, such as degenerative disease and loads in the joint which are greater than normal, Vitek cannot control these factors and the factors may not be controllable by the surgeon or patient, both of whom are very important in the success of the procedure. Because of the need for conformability, the strength and stiffness of the PTIPI can only be so great. If conformability is insufficient because of increased strength and stiffness of the PTIPI, then the implant will not function correctly.

There are many patients with PTIPI's which have been in place for four to five years, and which are functioning well.

INTERROGATORY NO. 13: Please describe in full and complete detail any and all interests (financial, professional, or otherwise) that John S. Kent, D.D.S., has in Vitek, Inc., or any product manufactured by Vitek, Inc.

ANSWER: Dr. Kent owns 21,000 shares of Vitek stock. Vitek has approximately 1,500,000 share which have been issued to shareholders. Dr. Kent owns less than 2% of the stock of Vitek. The stock was originally issued to Dr. Kent during the first four months of 1982, and then by a stock split (two for one) in March 1983. Dr. Kent receives a portion of royalties on some Vitek products he collaborated with Dr. Homsy in designing.

REQUEST FOR PRODUCTION NO. 9: All memos and communications of any kind and nature between Vitek, Inc., (and/or Charles Homsy) and John Kent in any way concerning any of the devices in question.

ANSWER: Defendant objects to Request for Production No. 9 for the reason that it is overbroad, unduly burdensome, harassing in nature, and not reasonably calculated to lead to the discovery of admissible evidence. Defendant objects to the interrogatory further as requiring information concerning implants which are not the implants which are the subject of this suit. Information regarding any implants not involved in this suit is irrelevant and immaterial to any matter at issue in this litigation. Without waiving the foregoing objections, as to the PTIPI, which is the implant made the basis of this lawsuit, Vitek will produce such documents at a time and place convenient to all parties.

INTERROGATORY NO. 14: Describe in full and complete detail the relationship between Charles Homsy (and/or Vitek, Inc.) and Louisiana State University Medical Center or any of its schools, departments, agents, and/or employees, concerning the research, design, testing, manufacture, and/or sale of any of the devices in question.

SCHOOL OF DENTISTRY
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Department of Oral and Maxillofacial Surgery

March 30, 1982

Charles A. Homsy, Sc.D., Director
Prosthesis Research Laboratory
Fondren Orthopedic Center
The Methodist Hospital F-109
6560 Fannin St.
Suite 2080
Houston, TX 77030

Dear Charlie:

Have been on the road this past week and will be going out again the next week and the following week. In Philadelphia this past week there was a considerable interest shown in the Temporomandibular Joint Clinical Congress, particularly the discussion period in which it was brought out that the use of Proplast teflon laminate sheeting may be effective in the management of degenerative joint disease and repair of perforated meniscus. Our article on this is nearly ready and we will, of course, get as much exposure as we can from this course and from the publication. A question comes to mind regarding the 3% royalty for this sheeting. I assume that it has been coming in but has been very small because there has not been a lot of this kind of surgery done in the past. However we anticipate numbers of procedures to rise to 10,000 or more annually easily within the next year. This is based on statistics from accrediting programs, etc. I am wondering if we should not make this available in a ovoid shape for the oral and maxillofacial surgeons. Please give me your thoughts on this.

There is also tremendous interest with the glenoid fossa device. Our abstract for the Atlanta meeting has gone in today and we are including in two articles, one that is nearly complete and one to be sent in the near future.

Finally, when the American Board of Oral and Maxillofacial Surgery meets San Diego on June 25 through June 30, at that meeting there will also be a Continuing Education Course that I will be one of the principal speakers on the use of biomaterials in the TMJ facial and dental areas.

As you can see educationally this is a very, very exciting time with an exponential increase in potential number of patients who are in need of Proplast biomaterials.

Best wishes.

John N. Kent, D.D.S., Professor and Head
Department of Oral & Maxillofacial Surgery

Dr. LASKIN. We have had a disclosure policy since 1987.

Mr. WEISS. Thank you.

Dr. Lappé, in your testimony, you say there was clear evidence from years ago that the silicone TMJ implants would fail. Is the main problem that it is a joint that is frequently used or are other kinds of silicone implants also likely to fail?

Dr. LAPPÉ. From my own reading of the open literature, I think it has become clear that there are many uses of silicone that have also led to comparable reactions, adverse reactions to those in the TMJ.

Mr. WEISS. The FDA relies on the accuracy of the information it receives from the industry. In the case of Dow Corning silicone breast implants, that information was not accurate or complete. Are there similar problems involving the information Dow provided to the FDA regarding TMJ implants?

Dr. LAPPÉ. I don't have a roster of the exact materials they have submitted, but I can say that I think it would be equally revealing to look at the full panoply of studies they did or didn't do on sheeting.

Mr. WEISS. As you know, there was important information about breast implants contained in documents that the FDA could not see because they were under a court seal. When Dr. Kessler finally read those documents, he declared a moratorium on breast implants. You examined some court documents regarding Dow silicone TMJ implants.

Are there documents you believe would provide valuable information to the FDA?

Dr. LAPPÉ. Without breaching my promise of confidentiality, which I had to sign before seeing the documents, I can only say they would be equally revealing.

Mr. WEISS. Dr. Marbach, have you ever received a research grant to compare the treatment and outcome of TMJ patients whose faulty implants were replaced with those whose implants were removed but not replaced?

Dr. MARBACH. No, but I would like to.

Mr. WEISS. Can you briefly describe the data that supports your view that TMJ patients are better off without implants, even if part of their TMJ is missing?

Dr. MARBACH. It is a big question, but briefly speaking, probably the most devastating natural disease that occurs in the temporomandibular joint would be rheumatoid arthritis, in which most of the joint structures are destroyed. Most of these people have no pain. They speak satisfactorily, they can get nourishment satisfactorily, so in a natural state, one doesn't really need the joint. At this hearing we are talking about something that is virtually unnecessary—temporomandibular joint surgery.

Mr. WEISS. Again, I thank each of you very, very much for your participation. We know how complicated your schedules are, and your willingness to find the time to come indicates your genuine concern and commitment to dealing with the problems related to this hearing.

Let me recognize the distinguished Member from Vermont, Mr. Sanders.

Mr. SANDERS. Thank you, Mr. Chairman. I have no questions at this time.

Mr. WEISS. Thank you very much.

Well, those bells indicate the House will be going into session in about 15 minutes. Thank you again very, very much. Hopefully, on the basis of your testimony, we will have some more favorable response to some grant applications.

Let me ask, before I excuse you, have there been any recent developments from NIH in regard to grant applications for any of you?

Dr. MARBACH. I am the recipient of a $1½ million grant application as of last year. They have been quite progressive. They are funding research on conservative treatment, diagnosis, and outcome, of which I am the recipient. I think they have put their best foot forward. I mean that, not just because they give me money, they are doing the right thing.

Mr. WEISS. Dr. Laskin.

Dr. LASKIN. I was funded for 23 consecutive years by NIDR for TMJ research and running a TMJ research center.

Dr. FONTENOT. I have completed a 5-year NIDR grant back from 1986 to 1991 that has looked at the biomechanics of this joint as well as the artificially reconstructed joints.

Dr. WOLFORD. All the research I have done has been self-funded by my private practice.

Mr. WEISS. Thank you. Thank you all very, very much.

Our third panel consists of Mr. Jim Benson, Director, Center for Devices and Radiological Health, Food and Drug Administration; Dr. Harald Löe, Director, National Institute of Dental Research; and Dr. Vivian Pinn, Director, NIH Office of Research on Women's Health.

As I explained earlier, it is our custom to swear in all our witnesses.

[Witness sworn.]

Mr. WEISS. Let the record indicate each witness has answered in the affirmative.

I should indicate before we start, I have another committee on which I serve, where I have amendments to offer. When that committee notifies me, we will take a break for lunch. That will be sometime within the course of the next 15 minutes to a half-hour.

Again I want to thank each of you for joining us today.

Mr. Benson and Dr. Löe, we will ask you each to try to limit your testimony to a 5 minute summary, so we will have enough time for questions. Your written statements will be entered into the record, and they will be utilized in the subcommittee's determination of its final report and recommendations.

STATEMENT OF JAMES S. BENSON, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

Mr. BENSON. Thank you, Mr. Chairman. I am here today to update you on the activities of the FDA pertaining to the regulation of the temporomandibular joint implants; the evaluation of our preamendments class III devices; and our overall strategy for eval-

uating the safety and effectiveness of devices which contain silicone.

Before I move to the substance of my testimony, I would like to begin by discussing an overall theme which I believe ties these issues together—that is, that we are significantly increasing our vigilance over the safety of marketed products. This shift in program emphasis is one of the cornerstones of the Safe Medical Devices Act, SMDA, of 1990.

With our enhanced surveillance over marketed products, we are particularly enthusiastic about our new authority under SMDA to require companies to undertake postmarket surveillance studies on their products. Data gleaned from these studies will enable us to make a science-based risk assessment and thereby take appropriate regulatory action, or notify patients if appropriate.

Let me turn to the specific issues beginning with Vitek's interpositional implant.

Our decision to allow this product onto the market was based on the scientific knowledge available to us at the time. When reviewing Vitek's 510(k) submission in 1983, the reviewers of that demonstrated that the Proplast implants performed as well, if not better, than the equivalent product made out of silicone.

Would we have made a finding of substantial equivalence if the 510(k) were submitted today? Probably not, but now we have a much better understanding about the relationship between materials and their biological environment. In addition, as the medical device program has matured, we have strengthened our knowledge of materials and of issues of biocompatibility.

When we first became aware of problems associated with the use of the interpositional implant in March 1988, we promptly issued a request for a directed inspection of Vitek. This started the chain of events which ultimately led to seizure in October 1990 of all TMJ implants manufactured by Vitek and the successor corporation, Oral Surgery Marketing Inc. On August 30, 1991, we rescinded the 510(k) premarket notification for Vitek's interpositional implant and on October 2, 1991, we implemented the patient notification program ourselves.

The FDA took responsibility for notifying patients with these implants because Vitek is now bankrupt and cannot follow up appropriately. I might add that action was a precedent-setting action on the part of the agency. It had never been done before.

This centerpiece of our patient notification program aims at publicizing an 800 telephone number and that number is 1–800–554–5297, which physicians and patients can call to receive information about the problems associated with Vitek's implants.

Although more effort to find patients clearly needs to be undertaken, I am proud of the initiatives taken by the agency on this issue.

Let me turn to another important matter you asked me to address this morning—the evaluation of preamendment devices. Our recent experience calling for premarket approval applications for silicone gel-filled breast implants taught us an important lesson. We need to be more aggressive in moving to require premarket approval of those class III preamendment devices that need to undergo approval.

In the coming year we will issue Federal Register proposals to call for PMA's for five more products. We also are preparing to initiate the three-step process contained in the 1990 law which is designed to reassess which of the current list of preamendment class III products, if any, should be reclassified.

I would like to emphasize that FDA has a number of ways to help guard against safety problems on these devices in the interim. These include careful premarket evaluation of new versions under the 510(k) process, use of postmarket surveillance authority, utilization of MDR and user reports, ensuring compliance with GMP's [general manufacturing practices] before approval, and mandatory recall for products found to have problems.

We will use all available authorities to assure the safety of these devices.

Finally, let me address FDA's strategy for reviewing the safety and effectiveness of devices which contain silicone.

Silicone is a very useful material with properties that make it desirable for many medical applications. In fact, silicone has been considered by the medical and engineering communities to be one of the more inert biomaterials available for use in and around the human body.

Our current strategy has four parts.

First, as Dr. Kessler testified before this committee last summer, we have taken strong enforcement actions against the continued use of liquid injectable silicone.

Second, the FDA has committed to a scientific reevaluation of each device which contains silicone gel, which we have started with breast implants. In addition, we will require tracking of all gel products under the SMDA.

Third, FDA has a research program which focuses on the uses of silicone liquid in syringes.

Finally, with respect to devices with solid silicone, we will direct our attention to those devices where the silicone is used in a load bearing or articulating setting. The potential concern for these devices may be the effects of breakdown or wear particles.

In closing, I want to stress that no biomaterial, including silicone, is completely safe when used in the human body. The key is to understand what the risks are and then to make risk/benefit judgments accordingly.

This concludes my statement and we would be happy to answer questions.

[The prepared statement of Mr. Benson follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

JAMES S. BENSON

DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES AND

INTERGOVERNMENTAL RELATIONS

COMMITTEE ON GOVERNMENT OPERATIONS

U.S. HOUSE OF REPRESENTATIVES

JUNE 4, 1992

FOR RELEASE ONLY UPON DELIVERY

Good Morning Mr. Chairman and Members of the Subcommittee:

I am here today to update you on the activities of the Food and Drug Administration (FDA) pertaining to the regulation of temporomandibular joint (TMJ) implants; the evaluation of pre-Amendments class III devices; and our overall strategy for evaluating the safety and effectiveness of devices which contain silicone.

Before I move to the substance of my testimony, I would like to begin by discussing an overall theme which I believe ties these issues together -- that is, that we are significantly increasing our vigilance over the safety of marketed products. Keeping watch on devices as they are used for many years, or experience unanticipated failure, enables us to identify and correct problems and thus, avoid human tragedy. This shift in program emphasis is one of the cornerstones of the Safe Medical Devices Act (SMDA) of 1990.

SMDA provided the agency with new postmarketing authorities such as temporary suspension of a premarket approval application (PMA), cessation of distribution and issuance of a mandatory recall order, and the ability to track certain devices if patient notification or recalls are required. SMDA also gave us authority to require that manufacturers conduct postmarket surveillance studies of certain products. To fully utilize these new as well as pre-existing authorities, we are

looking more carefully at those marketed products that appear to have a weak safety foundation. Although we can not perform a retrospective review of all marketed devices, we have put into place a strategy to evaluate products where new information indicates a potential safety problem. Let me cite a recent example of this intensified focus:

--Through our medical device reporting (MDR) system, we discovered evidence that certain small bore catheters were associated with an increased incidence of "cauda equina syndrome," a prolonged and possibly permanent neurological disorder. This information was communicated by our MDR staff to scientific and clinical staff in the Office of Device Evaluation. The resultant action was threefold: first, we rescinded all § 510(k) premarket notifications for these catheters; second, we held direct discussions with representatives of national anesthesiology organizations to alert them to the danger of this practice; and third, in concert with the Center for Drug Evaluation and Research, we developed a "safety alert" for dissemination to anesthesia care providers around the country.

In the context of enhanced surveillance over marketed products, we are particularly enthusiastic about our new authority under SMDA to require companies to undertake postmarket surveillance studies on their products. We have begun utilizing this

authority, having identified 23 initial product categories for which study protocols must be submitted. Nineteen of these are permanently implantable devices, the failure of which may cause serious adverse health consequences or death. Under our discretionary authority, we have required postmarket surveillance of injectable collagen, pyrolytic carbon heart valves, polyurethane-coated breast implants, and most recently, pacemaker leads. Data gleaned from these studies will enable us to make a science-based risk assessment and thereby take appropriate regulatory action, or patient notification, if appropriate.

It is against this background that we have taken and are taking action against Vitek's interpositional implant and related products; that we are stepping up our efforts to call for premarket approval applications for pre-Amendments class III products; and that we are developing a strategy to address products containing silicone.

Vitek's Interpositional Implant (IPI)

The situation with this particular implant is clearly one where our decision to allow the product onto the market was based on the scientific knowledge which was available to us at the time. When reviewing Vitek's 510(k) submission in 1983, the reviewers had data from a case study which demonstrated that the Proplast implants performed as well as, if not better than, the

equivalent product which was made out of Silastic material. In addition, we had information from the medical literature reporting surgeons' successful experiences with use of the product. Would we have made a finding of substantial equivalence if the 510(k) were submitted today? Probably not -- but now we have the advantage of another decade worth of information on long-term use of the product in patients. In addition, as the medical device program has matured, we have strengthened our knowledge of materials and of issues of biocompatibility. For example, we now have a much better understanding about the relationship between materials and their biological environment. Unlike drugs, where it is only important to examine the effect of the drug on the body, with medical devices one must also consider how biological systems in the body can affect various properties of a material -- and, in turn, how those changes affect the long-term performance of the device. Consequently, when clearing products for market, particularly those which are permanently implantable, we now ask a myriad of new questions on issues pertaining to biocompatibility. Problems such as those which occur as a result of materials toxicity or degradation underscore the need for a strong postmarket surveillance system -- these problems can not always be foreseen during the premarket review process.

When we first became aware of problems associated with use of

the interpositional implant in March 1988, we promptly issued a request for a directed inspection of Vitek Incorporated. This started the chain of events which ultimately led to seizure in October 1990 of all TMJ implants manufactured by Vitek and a successor corporation, Oral Surgery Marketing Inc.

During our persistent discussions with Vitek which occurred following our awareness of problems in 1988, FDA issued two § 518(a) letters requesting Vitek, or the bankruptcy trustee, to initiate a patient notification program. In response to the first letter, Dr. Charles Homsy, head of the then-bankrupt Vitek, responded that he would notify the 44 physician members of a professional society but was unable to do more. Mr. Ben Floyd, Vitek's bankruptcy trustee, refused to comply with any part of either order. Two months after issuance of the second § 518 (a) notification, on August 30, 1991, we rescinded the 510(k) premarket notification for Vitek's interpositional implant -- and on October 2, 1991, we implemented the patient notification program ourselves.

As you know, FDA's patient notification program aims to contact patients who received the Vitek Interpositional Implant (IPI) and Vitek's total joint replacements. FDA took on responsibility for notifying patients with these implants because Vitek is now bankrupt and cannot follow-up appropriately. There is a major obstacle, however, to informing patients about the problems associated with these

implants: finding them. The identities and locations of the patients with these implants are unknown. Although Vitek records contain lists of hospitals and some individual physicians who purchased the device, these records are incomplete and very outdated; furthermore, most patients are no longer being treated by the same physicians.

For this reason, the centerpiece of our patient notification program aims at publicizing an 800 telephone number which physicians and patients can call to receive information about the problems associated with Vitek's implants. Callers also receive information on how to enroll in a special international patient registry operated by Medic Alert. Enrollment in the registry will enable FDA to contact patients in the future if new information develops about this type of implant. To augment the effort, FDA is currently in the process of implementing additional mechanisms and strategies for publicizing the problems associated with these implants, including a mass mailing to approximately 170,000 licensed dentists and updated press packages for distribution to professional and consumer journals and related organizations.

In addition to the patient notification program, I would like to highlight several additional actions we are taking on this and other related issues.

-- First, we are issuing a § 518(e) notification to Novamed and Oral Surgery Marketing Inc., Vitek's successor companies, requiring a recall of their total joint prostheses, and sheets and blocks of Proplast which are used in the temporomandibular joint.

-- Second, we have issued a warning letter to Novamed and Oral Surgery Marketing Inc., citing their lack of applicable 510(k)s for all Proplast devices including preformed facial implants, custom implants, TMJ implants, and blocks and sheets of Proplast which are used for facial and other reconstructive purposes. This letter also directs Novamed and Oral Surgery Marketing to recall these devices.

-- Third, we have issued warning letters to several other manufacturers of TMJ implants who have been identified recently and have not received appropriate clearance to market these devices.

-- Fourth, we are retrospectively looking at the performance characteristics of load-bearing products which are made of both Proplast and the predicate material, Silastic.

-- And finally, because Dr. Homsy has sought refuge in

Switzerland, we have issued an import alert to ensure that all Proplast products manufactured can not enter the United States. We have also notified officials of the European Community and Switzerland of our concerns relating to the use of Proplast containing products and about potential manufacturing sites in Switzerland.

Pre-Amendment Class III Products

Now let me turn to another important matter which you asked me to address this morning -- the evaluation of pre-Amendment devices.

Our recent experience calling for Premarket Approval Applications (PMAs) for silicone gel-filled breast implants taught us an important lesson -- we need to be more aggressive in moving to require premarket approval of those class III pre-Amendments devices that need to undergo approval. We began with approximately 140 generic types of pre-Amendments class III devices. Final § 515(b) regulations calling for the submission of PMAs have been promulgated for eight of these devices.

In the coming year, we will issue Federal Register proposals to call for PMAs for five more products: saline-filled breast implants; testicular silicone gel-filled implants; penile implants; certain cardiovascular bypass devices; and cranial electrotherapy stimulators. These devices were selected

because of our concerns about their safety and/or effectiveness.

In addition to these actions on particular devices, as you may know, the SMDA requires the Agency to review -- through a 3-step process -- the classification of all pre-Amendments class III devices which are not yet the subject of a final § 515(b) regulation. As a first step, FDA is to publish a notice requiring companies to submit a summary of information on their devices, including sources of the data, and any outstanding reports on device problems. Second, we are to issue a proposed regulation for each device, either retaining the device in class III or reclassifying it. Third, the SMDA directs us to publish a final regulation on the classification of each device. Under SMDA, this review process is to be completed by December 1, 1995. Finally, for all devices remaining in class III, within a year of final classification, FDA must establish a schedule for promulgating regulations requiring the submission of PMAs.

We should note that, once the process is completed, sufficient data may be available to justify reclassifying a significant portion of the pre-Amendments class III devices into class II. This is based, in part, on the availability of new information generated since the original classification decisions were finalized in the early to mid-1980's, as well as on the

additional controls available for class II devices under the 1990 Act. Additional resources would need to be committed to review the resulting PMAs, and the length of time it will take for FDA to complete the review of these PMAs will be dependent upon the resources allocated.

I would emphasize that FDA has a number of ways to help guard against safety problems with these devices in the interim.

-- First, no new version of a pre-Amendments class III device can be marketed until it is reviewed by the Agency under the premarket notification process; and, during the review process, we will require, for the majority of submissions, clinical data to address safety and effectiveness questions.

-- Second, we are now requiring the submission of postmarket surveillance protocols for some categories of pre-Amendments class III products entering the market. These devices include cardiovascular intravascular filters; permanent pacemaker electrodes and pulse generators; and intravascular occluding catheters.

-- Third, adverse experiences must be reported to us under the Medical Device Reporting (MDR) and User Facility Reporting provisions of the law.

-- Fourth, like virtually all devices, these products are subject to our good manufacturing practice (GMP) regulation to ensure the devices are produced properly. On this issue, I might add that we are currently finalizing a program to require pre-clearance GMP inspections for class III pre-Amendments devices.

-- Finally, SMDA provides FDA with authority to order a manufacturer to "cease distribution" under specified conditions, and we can then order the mandatory recall of devices that meet the Statute's standard for risk.

While these authorities by no means negate the need to call for pre-Amendments PMAs in a systematic way, we will use all available resources to assure the safety of these devices.

Products Containing Silicone

Finally, let me address FDA's strategy for reviewing the safety and effectiveness of devices which contain silicone.

Silicone is a very useful material, with properties that make it desirable for many medical applications. In fact, silicone has been considered by the medical and engineering communities to be one of the more inert biomaterials available for use in and around the human body. There are literally hundreds of

products which contain silicone in various forms and chemical compositions. There are many marketed products which contain silicone gel, liquid, and solid elastomers. Certain breast implants and testicular implants contain silicone gel. Liquid silicone, for example, is used as a lubricant for plastic syringes and metal instruments to be inserted into the body. And many orthopedic implants (such as finger joint prostheses) and ophthalmic devices (such as intraocular lenses) are made of solid silicone.

Given the widespread use of silicone in medical devices and the concerns that have been raised about potential adverse effects, we considered it important that the Agency be aware of all available research data on silicone safety. To this end, FDA convened a Conference on Silicone in Medical Devices in February 1991. I am proud of the effort FDA staff put into this conference. The conference provided a unique forum for the exchange of scientific information and views on the applications of silicone in medical devices by bringing together a group of nationally recognized experts from a wide range of fields, including individuals known to be currently conducting studies. In addition to offering an opportunity to exchange data, the conference helped to focus attention on the data needs, that is, gaps in our knowledge base -- which I hope will influence the research decisions of scientists so that we will be able to fill these gaps.

While many of the engineering and chemical properties of biomaterials, including silicone, can be measured, the long-term biological response is more difficult to predict or characterize in routine laboratory tests. Any biological response to silicone would be dependent on factors such as the form of silicone used (i.e., gel, liquid, or solid); volume used; length of exposure; and site of usage -- whether the device is in a load-bearing or articulating (i.e., jointed) site in the body. Silicone gel-filled breast implants, for example, were of greater concern to FDA than other products made of silicone because of the form -- silicone gel -- the relatively large volume of silicone that could be released if the shell ruptured or leaks, and the expectation of many, many years of exposure.

It is important to note that thus far, there is no clear evidence to establish a health risk caused by the use of medical devices which contain silicone. An epidemiological study is underway to investigate the possibility of a link between silicone gel-filled breast implants and immune-related disorders; but at this time, I must emphasize that no clear link has been demonstrated. That is not to say that we are not concerned about the possibility. Health risks related to silicone would be most likely to occur with devices that contain silicone liquid or gel, rather than the solid material. This is because the more liquid the silicone, the more likely

it is that chemical components could leach into the body. For this reason, FDA is focusing its activities primarily on devices that contain silicone liquid or gel. Whether or not an investigation of solid silicone is warranted depends on the results of our evaluation of silicone liquid and gel. Our current strategy has four parts.

First, when Dr. Kessler addressed this committee last summer, the focus of his testimony was on the use of unapproved drugs and devices -- he specifically addressed the use of liquid silicone injections and stated that FDA would take strong enforcement actions against continued use of this unapproved device. FDA has recently taken action against physicians who inject liquid silicone into patients to correct wrinkles and acne scars and to enlarge lips. This past February, a consent decree was signed by a group of New York physicians which prohibits the physicians, and anyone working in their clinic, from using or promoting injectable silicone until such time as the product is approved by FDA either for marketing or for investigational studies. Additional investigations are ongoing for similar activities by other physicians.

Second, FDA is committed to a scientific re-evaluation of each device which contains silicone gel, as we have started with breast implants. As I already mentioned, as part of this effort, FDA has announced that it will initiate the process of

requiring manufacturers to submit safety and effectiveness data for silicone gel-filled testicular implants. We are currently re-evaluating the premarket submission that was the basis for the approval of the angel chik device to determine if marketing of that product is still appropriate. We also plan to review the marketing submission for a chin implant that contains silicone gel; however, review of this product, which contains a small volume of silicone gel, will be deferred until we have more data from the breast implants manufacturers on characterization of silicone gel.

In conjunction with these re-reviews, FDA recently announced that it will require the tracking of any permanently implantable device that has silicone gel as a primary constituent of the finished product. This requirement applies to silicone gel-filled breast prosthesis; silicone gel-filled testicular prosthesis; silicone gel-filled chin prosthesis; and silicone gel-filled angel chik reflux valve. In addition, the silicone inflatable breast prosthesis will also be required to be tracked.

As the third part of our silicone strategy, FDA currently has a research program which focuses on uses of silicone liquid. One study, for example, is designed to identify the components, and quantify the amount of silicone liquid that is injected into the body by the use of syringes lubricated with silicone

liquid. This information will be used to estimate the amount of silicone that a diabetic patient might receive during repeated injections. Additional studies are underway on silicone liquid used investigationally as an intraocular fluid to treat retinal detachments. These studies will compare the components and purity of silicone oils from different manufacturers. Lastly, FDA is working with other government agencies to complete a literature survey of the approximately 50 low molecular weight silicone derivatives found in or used in the manufacture of silicone gel-filled breast implants. This information will be useful in assessing the risk to the patient of exposure to components of silicone released into the body from implant bleed or rupture. The result of these studies, taken together, is that we will know the components of silicone, we'll be able to determine the toxicity of those components, and then assess the risk to the patient according to the form, volume, exposure, and site of use.

Finally, with respect to devices with solid silicone, we will direct our attention to those devices where the silicone is used in a load-bearing or articulating setting. The potential concern with these devices may be effects of breakdown or wear particles, including migration to distant sites, granuloma formation, and chronic foreign body response.

In closing, I want to stress that it is important to keep in

mind that no biomaterial, including silicone, is completely safe for use in the human body. When selected and used appropriately, silicone is still one of the most compatible biomaterials for use in medical devices.

This concludes my formal remarks. My colleagues and I will try to answer any questions.

Mr. SANDERS [presiding]. Thank you very much.
Dr. Löe.

STATEMENT OF HARALD LÖE, M.D., DIRECTOR, NATIONAL INSTITUTE OF DENTAL RESEARCH, ACCOMPANIED BY VIVIAN PINN, M.D., DIRECTOR, NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH; DUSHANKA KLEINMAN, DEPUTY DIRECTOR, NATIONAL INSTITUTE OF DENTAL RESEARCH; JOSEPH LEVITT, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA; STEVE NIEDELMAN, DEPUTY DIRECTOR, DIVISION OF COMPLIANCE OPERATIONS, OFFICE OF COMPLIANCE AND SURVEILLANCE; AND BARRY SANDS, BIOMEDICAL ENGINEER, OFFICE OF DEVICE EVALUATION

Dr. LÖE. Mr. Chairman, my name is Harald Löe and I am the Director of the National Institute of Dental Research. With me today is Dr. Vivian Pinn, Director of the Office of Research on Women's Health at NIH, and Dr. Dushanka Kleinman, Deputy Director of the NIDR.

We are pleased to be here. We share the committee's concerns for the many patients who have had TMJ implant surgery.

When NIDR was established 44 years ago, it was charged with the overall mission of improving the oral health of the American people. At that time tooth decay and periodontal diseases were rampant. Oral health research paved the way for their prevention and the result has been a dramatic decline in the prevalence and severity of these diseases and a significant improvement in the oral health of Americans.

As NIDR made headway into controlling the most common oral diseases, our research effort expanded to other oral health concerns, including women's health problems such as rheumatoid arthritis, osteoporosis, and the TMD's. From 1980 to 1992 we invested $24 million in TMD research.

In addition, NIDR funds $13 million a year in biomaterials research. We emphasize the importance of sound bioengineering principles as well as biocompatibility issues in studies of materials proposed for use in repairing oral hard and soft tissues. In the case of dental implants—devices inserted into the jawbone to replace permanent tooth replacements—we have seen an orderly progression of research from in vitro tests to animal studies to clinical studies and clinical trials, including education and dissemination information to the dental community and to the public. Today dental implants represent a viable, functional, and widely accepted alternative treatment for people who are toothless.

Research on TMJ implants is in the early stages of development. In part this is because the scientific rationale indicating under what circumstances TMJ implants should be used has not been established. For these reasons, NIDR has consistently advocated conservative approaches to treatment of these diseases. These include the use of splints, physical therapy, exercises, techniques to reduce muscle tension, biofeedback, and pain medication. These therapies continue to be employed by many practitioners because they help most patients.

We funded our first TMJ research project in the 1960's. Since then, investigators have made steady progress in understanding

the normal and abnormal function of this very complex part of our facial anatomy. We have sponsored workshops and symposia, issued program announcements and requests for applications and proposals, funded research training programs, and distributed information to the public and the profession as it became available.

I have here a chronology of these activities I would like to submit in due course for the record.

[The chronology follows:]