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
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IV

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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
Huson, and Bernard Sanders.
Also present: James R. Gottlieb, staff director; Diana M
Zuckerman, professional staff member; Elinor F. 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 Intergov-
ernmental Relations Subcommittee is now in session. Because
there is other heavy business on the floor, members of the sub-
committee will be coming in and departing as their schedules per-
mit and we will recognize them accordingly. Let me make a brief
opening statement; then we will proceed to our first panel of wit-
nesses.

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 treat-
ment for TMD pain, dizziness, and other symptoms. Almost 80 per-
cent 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, thou-
sands of patients choose surgery every year; and if less radical sur-
geries 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 inescapable 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 devices 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.)"
Mr. WEISS. Let me at this point call on our distinguished mem-
ber 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 testi-
mony 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 ar-
thritis. Concerns over the possible links, possible risks, associated
with long-term usage and leakage into the body because of rup-
tured 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 safe-
ty 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 im-
plants have been distributed.

Public health organizations like the Food and Drug Administra-
tion and the National Institutes of Health were established and
mandated to protect the public by ensuring that products rec-
ommended for approval are indeed safe for their approved use. Doc-
tors 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, with-
out 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 presentation.

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

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

Would you each please raise your right hand.

[Witnesses raise hands]

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 disklike structure between it and the iliacus. We have been talking about the disability.

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 dentist 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 were damaged 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 implants.

From this point of surgery, my condition worsened. For nearly 3 years, I experienced exacerbating 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 as a full-time job and lived in 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 great 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 to patients 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 or disc replacement, it is clearly 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 losing their jobs, even their physicians to relate to their pain, such as the patient who was told "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, implantcontinue 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. Chair-

man, 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 Darre Cowley, co-founder of the TMJ Association, Ltd. (414 W. Washington Blvd., Milwaukee, WI 53211). 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 and unrelenting pain I was experiencing was due to my jaw joints. It was found that the discs which normally cushion the movement of the jaws were perforated and that degenerative arthritis had developed in both joints. After 5 years of continuous discomfort, I underwent a surgical procedure in 1992 in which both of the discs were removed and replaced with Dow coming silicone jaw joint implants.

From the day of my surgery, my condition worsened. For nearly three years, I experienced excruciating headaches, back and neck 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 1996, four years after my surgery, I met another jaw joint patient and we formed the TMJ Association, Ltd. It has been our goal to operate our association as possible this discomfort from patients and professionals. We also want to provide a way so other patients can come together. Finally, we want to promote awareness of this disorder in the community.

In the past 4 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 not rare, but very common. It is estimated that 10% 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 treatment, it is clear that they number in the hundreds of thousands.

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

In the last few years I have talked to patients with jaw joint disorders. I constantly hear what scientists call anecdotes and what I often call stories. I tell 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 families to the point of bankruptcy. In a recent conversation with a lawyer, I was told that 9 of my 40 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 and get some rest." And they tell us that they live in terror because their physicians indicate that the implant material has worked its way into the arterial system and they do not have the money to have it removed. There are the people who have begged me to find a way to talk 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 stay away. They become isolated in the marital sense from their husbands, for intimacy may cause further pain. They become isolated from society, never being able to go on social outings because of the single act of hopping is painful. They become isolated from society, never being able to go on social outings because of the single act of hopping is painful. 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 has a root canal, but they rarely get better and there is no 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 psychosomatic 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 have psychological evaluations, but of course he calls it pain management.

The stigma is apparent. Last year at an NIH workshop on Women's Heart and 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, 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.

In the last few years I have talked to patients with jaw joint disorders. I constantly hear what scientists call anecdotes and what I often call stories. I tell 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.
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 are also evident. So why don't I simply have the implants removed? I weigh the benefits and risks of having the implants taken out: 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 Public Health Association, 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 Proplasex/Teflon (Vitex, 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 various prostatic TMJ implants. The FDA, the Arthritis Institute, and the National Institute of Dental Research, most college state to created, would undertake studies of patients who have received various 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 many 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, imitation 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.
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 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 user shows 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 NHI, 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:]
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 medication treatment.

Because this is an unrelenting illness, I have been shamed and degraded by doctors and nurses who don’t believe me. They said I was just a drug addict, or told me what I needed was a psychobabitat 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 fallen into the deceptions 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 possibly carry a child. I am beyond anger, I am devastated, all because of a small piece of plastic.

I have tried many other treatments besides surgery, including acupuncture, biofeedback, cognitive therapy, 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 TecheMedica metal jaw joint 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 surprise, my feet is partially paralyzed. It’s 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, bulging-hot areas 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. I 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 poorly. 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 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, 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 former life. I sought for granted. Everything I do, I must plan and prepare so the medication 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 insurance that 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. I 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 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—no 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, fun-loving 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 opin-
ion, my continuing problems are a direct result of the original inj-
uries caused by the Vitrok Proplast/Teflon implant.

My family has had to sacrifice their lives for mine, both phys-
ically and financially, and without their support and encourage-
ment, I may well have ended my life.

Since the placement of the Vitrok implant in 1985, my medical ex-
penditure has exceeded $172,500 and my out-of-pocket expenses have
exceeded $40,000. My medical expenses will continue for the bal-
ance of my life, and I expect my future medical expenses will be
over $1 million.

There are thousands of us who have had the Vitrok Proplast/Tef-
lon and/or Dow Corning Silastic implants. We are facing a lifetime
of surgery, medical expenses, and pain. I am scared, but I will pre-
vail.

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 Vitrok 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 1985, 15 of those surgeries are directly related to
the placement of Vitrok's Proplast/Teflon implant in 1985, and Dow Corning's Silastic
implant in 1988. Multiple surgeries have changed me from a happy, fun loving 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 jaw bone and some of my skull. Over the
years, I developed a swollen cheek and a gross open-bit, 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 arm and earlobe from my neck, trying to restore the function of my jaw. I have
sustained severe 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 rills out of my cheek, and graft them into my jaw. He told me that my jaw bone
was contracting in a way due to the retained materials from the previous implants. I
shredded at the thought of having my rills cut out of my cheek, 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.

In short, I want you to know that if you had the opportunity, you would not have gone
through the same pain that I have. I am leaving this letter with you this day as a
warning to those who are considering this type of surgery. It is not worth the pain and
suffering that you are going to have to go through."

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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 Vittek.

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 surgery.

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 surgery fee was $8,000. This did not include the cost of the implant.

Mr. Weiss. Ms. Cowley, the FDA has published a warning about the dangers of Vittek 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 300 who have requested information. Of those, about 750 were not even Vittek 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 Technomed 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 no long-term research on Tecmedica, but I got to the point I had no choice. My knee is 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. Baurieu, you currently have a total joint replacement, Kendall 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. Baurieu. Yes, 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. Baurieu. 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 going this committee more gross details. [laughter]

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 illusious 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. Baurieu.

Ms. Baurieu. First of all, I would tell them I am not exaggerating and I would say to them 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. Baurieu. 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 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 explained about your pain? Ms. Baurieu.

Ms. Baurieu. 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 60 percent chance 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.

Mr. 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 best new thing to sex. I was told by that a dentist. I didn’t ask what kind of sex he meant, unfortunately.

Mr. WEISS. Well, I thank you all 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. Thank you. At the time when your illness was diagnosed, was there any national center, hospital, medical center—I don’t know the right name—where they were anywhere 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 opinions available. There were just, you want to function, this is what you do. This is the answer.

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

Mr. Payne. Were the operations encouraged? In other words, were you put through this 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 he followed this Proplant 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 anesthesia. I was wrong because it wasn't investigated and I went back. There weren't many options.

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 entered into the hearing record.

Dr. Fontenot, we will begin with you.


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 Sheet, Silastic HP Sheet, 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 Sheet. Specifically, Dow Corning recommended the use of Dacron-reinforced Silastic Medical Grade Sheet to surgically correct limited jaw opening. Silastic Medical has been on the market for over 25 years and is considered a prerequisite device.

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

Also in or about 1985, Dow Corning introduced Silastic HP Temporomandibular Joint Implant. Dow Corning received FDA approval, and it was marketed to surgeons as a device that could be used as an alternative to traditional surgical procedures for the treatment of TMJ dysfunction.
sign and material component selection have been based more on intuition than on engineering principles and scientific data.

Accordingly, a variety of artificial TMJ device designs 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 for further expansion of 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:)
Mr. Chairman, Members of the Subcommittee, 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 1988, I received a 5 year grant from the National Institute of Dental Research (NIDR) to investigate the biomechanics of normal and artificially rearticulated temporomandibular joints. This NIDR sponsored research is the topic of my dissertation. Currently, I am meeting in 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) and to increase the depth of knowledge into the limitations of the TMJ as well as disease and disorders affecting this joint, and uncover safer and effective means of various modalities for TMJ treatment.

In the following paragraphs, data is presented which underscores and encourages to quantify the presence and permanence of TMJ disease in the general population. In particular, the scope of this statement focuses on the performance of current and artificial (also called alloplastic) TMJ devices used in the medical treatment of damaged temporomandibular joints. This information is derived from 2 years of basic and clinical science research, analysis of various artificial TMJ devices, and contacts with 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 100,000 dental professionals. In other words, up to 8% 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 bite and occlusion (which is the way the upper and lower jaw come together), biofeedback, and drug therapy such as pain medications.

Conservative management has been evaluated with limited results, such as failing to alleviate pain and/or limited range of motion, thus surgical intervention with or without artificial TMJ devices may be considered.

Who are candidates for TMJ surgery with artificial TMJ devices? They are usually found, residing mostly from 30 to 60. In general, these patients suffer from various forms of pain in the head, neck, and facial areas resulting from dysfunction of temporomandibular joints: facial pain and limited jaw opening resulting from previously removed or non-functional TMJ devices, fusion of the bones in the temporomandibular joint causing pain and limited jaw opening; and trauma to the temporomandibular joint.

In 1988, as many as 65,000 TMJ arthroplasties and 55,000 open jaw TMJ surgeries were performed in the U.S. In 1991, approximately 45,000 open joint procedures and as many as 150,000 arthroplasties were performed. Since 1985, it is estimated that at least 600,000 patients in the U.S. have had at least one TMJ surgery (this figure includes arthroplasty). Of these patients, 40,000 to 80,000 in the U.S. have received artificial TMJ devices such as implants developed and sold by Dore Coing, 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 1980s when Dore Coing (Malvern, MD) labeled Silastic Medical Grade Steaming for use in the TMJ to surgically correct chronic TMJ pain. Since 1983, the popularity of artificial TMJ devices has increased from a few in the 1980s to thousands by 1995 when Vitek, Inc. (Illinois, USA) was the only major manufacturer of TMJ devices such as TMD implants and the Vitek TM System. In the late 1980s and early 1990s, manufacturers such as TMJ Implants, Inc. (Colorado, CO), TMD Technologies, Inc. (Consett, CA) commercially offered other brands (Golden, CO, Thumshiel Ltd, Toronto, Canada) commercially offered other brands (Golden, CO, Thumshiel Ltd, Toronto, Canada) commercially offered other brands (Golden, CO, Thumshiel Ltd, Toronto, Canada) commercially offered other brands. Although TMJ implants were produced or manufactured by about 1984, in founder a surgeon-clinician to have 25 years of success using failure or about 1984, in founder a surgeon-clinician to have 25 years of success using failure or about 1984, it is thought that the failure of the products in artificial TMJ devices. In 1989, Vitek filed for voluntary bankruptcy. Later in 1990, the Food and Drug Administration (FDA) approved a safety device and device sold directly affecting approximately 25,000 Prosthesis TMJ implants and 2,000 Vitek implants. To date, approximately 5,000 "Prosthesis" devices have been filed with the Vitek claim. Currently, there are two major players in the artificial TMJ device market, Dore Coing and Vitek Implants, Inc.

Artificial TMJ Device Market
Shunting. For years open in the market, Dore Coing, currently recommends three products for use in the TMJ: Silastic Medical Grade Steaming, Silastic HP Steaming, and the Silastic HP Implant (Vitek Design). One of the first commercial recommendations for the use of artificial TMJ product in the TMJ was contained in a 1982 data sheet for Silastic Medical Grade Steaming. Specifically, Dore Coing

Mark G. Fanan, D.D.S., M.D.  Page 3 31

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

Silastic HP Steaming was introduced into the stream of commerce in or about 1985 by Dore Coing. According to data sheets for Silastic HP Steaming, 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 Steaming. Generally, Silastic HP Steaming is recommended for use either as a temporary or permanent artificial TMJ device.

Also, in or about 1985, Dore Coing introduced the Silastic HP Temporomandibular Joint Implant (Willis Design). Dore Coing received FDA approval for this product in 1984. In particular, the FDA found this product to be similar to Dacron® reinforced Silastic Medical Grade Steaming as described in a 1975 data sheet for Silastic Medical Grade Steaming. 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 Steaming and Silastic HP Steaming, package inserts for the Silastic HP Temporomandibular Joint Implant (Willis Design) are included with each and every device. Data sheets for Silastic Medical Grade Steaming and Silastic HP Steaming are attached to the implant in the packaging, the surgeon or surgeon must contact Dore Coing to obtain a data sheet regarding these products.

Since 1985, thousands of Silastic devices in the form of Silastic HP Steaming, Silastic HP Temporomandibular Joint Implant (Willis Design) has been placed in the TMJ. The medical and dental literature contains reports on the use of Silastic HP Temporomandibular Joint Steaming, Silastic HP Steaming, and the Silastic HP Temporomandibular Joint Implant (Willis Design) as well as other Silastic medical devices. The data sheet for Silastic Medical Grade Steaming also has been placed in the TMJ. The medical and dental literature contains reports on the use of Silastic HP Temporomandibular Joint Steaming, Silastic HP Steaming, and the Silastic HP Temporomandibular Joint Implant (Willis Design) in the surgical reconstruction of the TMJ. Large numbers of Silastic products in the form of Silastic HP Steaming and Silastic Medical Grade Steaming have failed because of TMJ leads resulting in Silastic wear debris and tissue reaction.
The second major player in the market is TMI Implants Inc., which was formed in or about 1988. TMI Implants Inc., distributes the TMI Femur Enhance® Prosthesis and TMI Condylar Prosthesis® which are claimed by the firm to be pre-emptive devices. First use of the Femur Enhance® Prosthesis was reported in 1991 by the founder of TMI Implants Inc. Approximately 1,000 devices, about TMI Femur Enhance® Prosthesis and TMI Condylar Prosthesis® have been used since 1988.

Before its bankruptcy, Vink was the third major player in the TMI device market. In the early 1980's, Vink developed and sold ProShip® Sheathing (Teflon® PTFE film laminated to a porous composite material fabricated from polytetrafluoroethylene (PTFE) and carbon). Then, in the early 1980's, Vink developed and sold ProShip® II Sheathing (Teflon® PTFE film laminated to a porous composite material fabricated from PTFE and aluminum oxide). Several soft and multinational surgeons reported short term success using different types of ProShip® Sheathing in the TMI. Based on information obtained from 1974-82 and a favorable response by numerous other clinicians, Vink notified the FDA in 1982 of its intent to commercially distribute the ProShip® Sheathing. Vink submitted the ProShip® Sheathing for approval under section 510(k) of the Food, Drug and Cosmetic Act of 1938. Approval for the ProShip® TMI Interpositional Implant was granted by the FDA in 1990.

Vink also submitted a request to the FDA for approval of the ProShip® II Sheathing. Vink also reported that the TMI device had been implanted in 1,000 cases in hospitals in the United States and that it was estimated that 100 TMI devices had been implanted in the device. Vink indicated that the TMI device had been used in a patient who had undergone a knee replacement operation.

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since 1991. Byron Medico's device consists of an acrylic and metal crown which is bonded to the natural crown with screws. The corresponding fossa is fabricated of metal which is also bonded to the natural fossa with screws. Consilium has offered a TMI device since 1991. Consilium's device consists of a fossa fabricated from metal which is bonded to the natural fossa with screws and composites acrylic. The corresponding crown in the present case was fabricated from metal and attached to the TMJ. Technojo's device consists of a fossa fabricated from metal and plastic polymer and a composite prosthesis fabricated from metal. The fossa and condylar prosthesis are secured to the bone in the joint with screws.

Knowledge of surgical techniques using artificial TMJ devices and the need for artificial TMJ devices is not understood by the biomedical aspects of the TMJ. In particular, controversy still exists in the surgical and scientific community regarding the biomechanics of the normal, pathologic, and artificially reconstituted 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 reconstituted temporomandibular joints. Of particular importance, is the lack of research and information regarding the safety and effectiveness of artificial devices. Artificial TMJ device design is a delicate interaction between engineering considerations and principles, surgical techniques and requirements, functional demands, anatomical boundaries, and biocompatibility. The continued absence of documentation and research regarding the biomechanics of the TMJ and artificially reconstituted 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 for the dental professional for their TMJ related problems. Unfortunately, dentists and dental specialists are often left dealing with these patients with techniques and technology having unknown clinical efficacy. For example, in 1942, a TMJ device has been used over the past three decades, but is failure being used by the surgical device. The development of TMJ device and material requirements have been based upon little information on biological principles and scientific data. Accordingly, it is not uncommon for TMJ device design solutions to evolve, leading to continual results and, in some cases, widespread TMJ device failures. Published information in either space or space regarding the biomechanics of this complex and complicated joint, performance and biomechanics of TMJ devices.

Recommendations

I appreciate the opportunity you have extended to me today. However, before leaving, I would like to note that Congress should consider the following points regarding the temporomandibular joint which are outlined below and illustrated in the flow chart on page 5.

1. An improved understanding of the TMJ;
2. Improved diagnostic techniques and techniques for TMJ related problems;
3. A more improved understanding of the biomechanics of TMJ devices;
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. National TMJ device removal program to better determine currently used devices.

Mark C. Freeman, D.D.S., M.Spg.
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RECOMMENDED PROTOCOL FOR ARTIFICIAL TAJU DEVELOPMENT AND EVALUATION

DETERMINE TAJU ENVIRONMENTAL CONDITIONS: DURABILITY AND DISINTEGRATION SURGICAL TECHNIQUE

DETERMINE PROPERTIES OF CANIDATE MATERIALS

MATERIAL COMPOSITION: PHYSICAL PROPERTIES REPRODUCIBILITY

MATERIALS TESTING

MODYF DESIGN

ARTIFICIAL TAJU DESIGN: DURABILITY, DENTAL AND ENGINEERING ASSESSMENTS

TESTING AND EVALUATION OF PROPOSED TAJU DESIGN: SIMULATION TAJU DESIGN METAL, CERAMIC TESTING YIELD STRESS MEASUREMENTS STRESS ANALYSIS

COMPICATIONS

ANIMAL STRESS

CONTROLLED CLINICAL TRIALS

GENERAL CLINICAL USE

POST-MARKET SURVEILLANCE: ARTIFICIAL TAJU DEVICE RETRIEVAL, PATIENT FOLLOW-UP

Mr. Weiss, Thank you very much.
Dr. Wolfdorf

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

Dr. Wolfdorf, Thank you, Mr. Chairman. My name is Larry Wolfdorf. 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 mid-eighties 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 serious 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 resorb 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, etcetera.

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 puts them at risk for adverse reactions against the implant joint or even against the entire joint. So we do have both the immunological problem and the giant cell problem to deal 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 what we need 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, either in and of itself 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 Tenon on our public. We would be able to do epidemiological studies to determine outcomes of treatment, as well as 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 joint 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, etc. etc. 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 doctor either don’t know how to manage the problems or are unwilling to treat them.

Thank you very much.

[The prepared statement of Dr. Woldorf follows:]
THE PROPLAST/TEFLON TEMPOROMANDIBULAR JOINT IMPLANT PROBLEM

Larry M. Welford, M.D., D.D.S.
Charles H. Henry, D.D.S.
Baylor University Medical Center
Dallas, Texas

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 (Vitrek, Houston, Texas). Although the exact cause of failure has not been established, over 25,000 interpositional implants were distributed by Vitrek. This number does not include the Vitrek 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 5482 reported procedures to have had satisfactory results. However, recent articles in the literature describing disintegration of the condyle, severe pain, malocclusion, foreign-body giant cell reaction, and implant fragmentation have cast doubt in the minds of many TMJ practitioners. Numerous complications have occurred with Proplast/Teflon TMJ implants, including loss of implant integrity, implant fragmentation, pain, and decreased range of motion, changes in occlusion, and condylar morphology.

The foreign-body giant cell tissue reaction that continues to be a problem with all alloplastic materials is thought to be the cause of the pain and the difficulties in articulation. The pain is usually aching, constant, and affects daily activity.

The destractive affects of these materials in the TMJ are a result of the foreign-body giant cell reaction and fibrosis, a poorly understood phenomenon. Diseased implants include pain that affects daily activity.

The foreign-body giant cell reaction associated with previously reported alloplastic implants, however, continues after removal of the implant. Despite repeated methods for TMJ reconstruction after Proplast/Teflon implant failure, the use of autologous bone and the patient's own tissue to enhance TMJ function have not proven effective. The limitations in these techniques continue to occur in a significant high failure rate that may require further surgery.

The orthopedic literature from the 1950's reported on the failure of teflon implants for hip prostheses. The early results were favorable, but withdrawal of the implant demonstrated biodegradation of the implant materials. The foreign-body giant cell reaction and subsequent pseudotumoral response is associated with Proplast/Teflon implants. Localized tissue change occurs as a result of inflammatory cells secreting destractive enzymes.

Patients with malocclusion, facial deformity, pain, or any of the other previously mentioned symptoms as a result of Proplast/Teflon implants who require TMJ surgery 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 cause of failed Proplast/Teflon implants
4. Identify, through research and controlled studies, predictable methods of managing patients with Proplast/Teflon implants

MEDIC ALERT REGISTRY

The FDA Public Health notice of the recall on Proplast/Teflon implants (Vitek, Houston, Tex) 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 media alert registry (only by voluntary comprehensive active surveillance). The Vitek Registry will obtain the extent of the public's exposure to Proplast/Teflon by identifying, 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 become better understood in the literature. Registry staff must be trained on how to determine 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 debilitating by their TMJ dysfunction secondary to failed Proplast/Teflon implants to the extent that they are unable to work, are entitled to workers' compensation and disability benefits. Reimbursement provided by Medicare/Medicaid and Social Security in the present so grossly inadequate that hospitals simply cannot afford the expensive long-term treatment these patients often require. They do not have medical insurance coverage for TMJ problems, are no longer able to attend work, and are not able to work due to disability secondary to pain and dysfunction associated with their TMJ. There is presently no firm support available for these patients to have necessary diagnostic tests, medical management, or surgical removal of Proplast/Teflon implants and reconstruction of the TMJ.

3. CURRENT TREATMENT RECOMMENDATIONS BY FDA MAY BE INADEQUATE

Current treatment recommendations by FDA may be inadequate. Our recent study (Henry C. Wolford CM submitted for publication to the Journal of Oral and Maxillofacial Surgery) has shown the overall rate of success when using the patient's own tissue (autologous) bone and/or soft tissue. For TMJ reconstruction of the TMJ after Proplast/Teflon implant study and a previously published study has suggested that the foreign-body giant cell reaction as the most likely cause for failure of autologous tissue. TREATMENT OPTIONS AFTER PROPLAST/TEFLON IMPLANT FAILURE

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<td>Failure rate (%)</td>
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Current treatment recommendations for the FHN for reconstruction of the TMJ after Proplast/Teflon implant can be divided into 3 factors: 1) patient's own tissues for reconstruction, 2) removal of implant and no reconstruction, or 3) use of bio-prosthetic nasal 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 DW, Henry CW), reconstruction of the TMJ with specific (using known compatible materials) total joint prosthesis has shown good function and pain relief 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 Vitak Proplast/Teflon TMJ implants. The database will be designed to includes center's referral patterns 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 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 to 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. Wurz. 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, the School of Dentistry and Schools of Dentistry and Medicine of the Medical College of Virginia, Virginia Commonwealth University.

I have been asked to speak on behalf of the Journal of Oral and Maxillofacial Surgery since 1972.

I appeared before this committee today for two purposes. First, it 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 joint disorders by oral and maxillofacial surgeons who were led to believe that these materials were safe and effective.

Second, it is an 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 arising from the mandible that is located between the jawbone—condyle—and the socket—glenoid fossa—of the TMJ. These conditions produce intense, debilitating pain, and difficulty 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 a 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 bio-compatible synthetic materials appeared to offer a real 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 interest in 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 in 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 have 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 bio-compatible 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 TMJ patients who have synthetic materials in the joint and show x-ray changes, or those who are currently both clini-cally 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]
Mister Chairman, I am Dr. Daniel M. Lenkin, Professor of Oral and Maxillofacial Surgery at the University of Virginia. In my capacity as a consultant to the Veterans Administration, I have been very concerned about the problem of TMJ disc replacement.

Whereas, there have been no significant problems with total joint replacements reported in the literature, the same situation does not exist with prosthetic TMJ disc replacements.

The use of silicone rubber (Silastic) to replace the TMJ disc was first described by Hasson and Deschay in 1969, and this technique was subsequently adapted by the oral and maxillofacial surgeons. The apparent safety of this material was confirmed by Tahhan in 1980, when they reported minimal tissue reactions in long-term tests.

First, I would like to express my concern over the situation that has occurred in many patients who have silicone prosthetic materials in their TMJ. The treatment of temporomandibular joint disorders by oral and maxillofacial surgeons have been led to believe that these materials were safe and effective. Second, it is my intention to inform 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 (cuboid) and the socket (glenoid fossa) of the TMJ. These conditions produce interferences, producing pain, and difficulties with eating and speaking.

The surgical treatment of both arthritis and the pathology generally involves removal of the affected tissues. Until the early 1980s, replacement of these tissues was usually done by using a bone graft. However, this procedure is associated with pain, dysfunction, and a high degree of success. In recent years, oral and maxillofacial surgeons have encouraged the use of facial and parotid gland flaps to replace the affected tissues and to produce a more normal 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 offered a more 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 femoral head, or a plastic socket (Proplast-Teflon) and a metal head. In the instance of the metal acetabulum and plastic socket, there has been insufficient data available up to this point to determine long-term success. In the case of the plastic socket and metal head, despite the fact that Proplast-Teflon is used, the long-term data does not show significant adverse reactions, as have occurred when this material is used in the hip joint. Problems with this type of joint prostheses do exist, however, and are currently being done on the development of a custom-made joint based on CT scanning and the construction of a three-dimensional model of the actual patient's TMJ.

In addition to the need for paying dollars into TMJ research in order to establish the efficacy of current and future treatments, there is also a need for educating the public and the government on the issues of TMJ. As more and more people become aware of this problem, more research and funding will be necessary to study the problem and to develop new treatments.
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Mr. Weiss. Thank you very much, Dr. Laskin.

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

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

Dr. Lappe. Yes.

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

Dr. Lappe. Yes, it is.

Mr. Weiss. Is it correct that in 1963 the Dow Corning Corp. secured an order of the Federal court which seeks to prohibit you from disseminating any documents or information concerning safety tests and studies?

Dr. Lappe. Correct.

Mr. Weiss. Pursuant to that order, have you heretofore not provided the subcommittee with any documents that may be the subject of that order?

Dr. Lappe. Yes.

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

Dr. Lappe. That is right.

Mr. Weiss. Dr. Lappe, 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, ILL.

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

I will attempt to provide a historical backdrop 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 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 symbiotic materials to the TMJ to approximately 1960, when two researchers used 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 1965, it was emphatically inert, and 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 1983 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

Dricular 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 was 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 inflammatory 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 of 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 remained 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 1965, it was emphatically inert, and 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 1983 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 Wilkses device.

And there is a long catalog of adverse effects that could occur from the use of the Wilkses 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 pre-testing 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 devasting. 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 1962, 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:]
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 clearly 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 analogy 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 same 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” (Erkisson and Westesson, Oral Surgery, Oral Medicine and Oral Path 62: 2, 1985).
By the mid-1980s, researchers were finding silicone-induced foreign body reactions and lymph node swelling after TMJ arthroplasty using Silastic®. One such study boldly concluded that "silicone may not be a totally inert material and that its biomechanical properties are not ideal for use in the TMJ." (Gubinck et al, Oral Surgery, Oral Medicine and Oral Path 59: 445, 1985).

During this same period, reports appeared that showed (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 temporomandibular 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 persistent 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 Slas Brealy and Gordon Robertson, Medical Instrumentation, 1973).

D. Problems of Disclosure

Even though Dow Corning had found granulomatus 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 for 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 Burke, J Oral Maxilofac Surg 47: 1280, 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 SlaStic® for TMJ arthroplasty—that
"(SlaStic's) physical properties are not appropriate for its long-term use
in the TMJ." Even the short-term use of SlaStic® 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" (Bozanquet et al., J Oral Maxillofac

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 Dowick and Audemorte finally realized in
1985: their material was intrinsically flawed as a biomaterial for long-
term implantation into the human body. In the 1980s, 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 consequences into an adequate warning. They
continued marketing nonetheless.

The development of SlaStic® 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, entrepreneurialism,
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—SlaStic® 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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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 50% of those seeking care for TMJ are women and 25% are men. Yet women make up virtually 100% of the surgical cases and men closer to 0%. In the 4,000-sold TMJ cases who have consulted with me, I have personally only met one male who has undergone TMJ surgery, but I am consulted by a steady stream of adult 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. It supposes 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 of treatment of TMJ problems. This should be conducted within the framework of a panel study of these women's health. Our NIH-funded projects during the last decade have shown that these women have more illness, fewer children, fewer accidental pregnancies, more premenstrual symptoms and that even their children have more illnesses than a control group then 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 FDA 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.

I believe 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 some consideration to the clinical outcome, or positive results with implantation of Silastic as a temporary device, and also there is another body of information which is not favorable.

Mr. Weiss. In the mid-1980's, there were many articles in dental journals praising Vitak'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, the articles came out. I think there were about 15 or 20 reports since the mid-1980's.

Mr. Weiss. Dr. Woldorf, 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. Is it my understanding that there are no studies that follow the patients for more than 2 or 3 years; is that correct?

Dr. Woldorf. 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 Vitak to get approval to sell implants in the United States. Teflon implants; most problems did not become apparent until the implants were in for about 3 years; is that correct?

Dr. Woldorf. That is correct. Some individuals develop problems within a few months after placement of Proplast Teflon. There are other patients that have implants, and I have some patients that have had them for 15 years, and are still functioning. I believe some of the data we have done has illustrated this.

Mr. Weiss. 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 40 percent success using a patient's own tissue to immunologically match joint after Proplast Teflon has been there.

Mr. Weiss. You found foreign body response to Teflon implants continued for 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. Woldorf. 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. Woldorf. 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. Woldorf. 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.

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.

Mr. Weiss. How typical is this with TMJ patients?

Dr. Woldorf. This is an extremely difficult problem with some patients. We think it occurs in a subgroup of individuals who just have a 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 interpret it, it could be a devastating problem.

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

Dr. Woldorf. 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 reaction—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 Teflon 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 biomedical research is adequate or worse than adequate?

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 Teflon 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 Vitrek that he was concerned about the safety of the Teflon implants that 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. Hosmy 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 Vitrek and Dr. Hosmy did.

Dr. Laskin. I am not aware of what Dr. Hosmy did. I am familiar with their work and with what has been 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 Vitrek at the same time that he was publishing articles praising Vitrek'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 disposal policies for conflicts of interest?

[The documents regarding Dr. Kent follow.]
Good sense, however, tells me not to ignore the Whitsaker situation. There would be no performed modification by Whitsaker with it not for any design of symptomatic implants which I developed.

Therefore I must insist that where modifications such as both of these and any future modifications of our existing, preferred porcine total hip, symptomatic and thin implants must be shared equally by Vitek and myself at the current 50% ratio to myself.

On another matter, I have recently re-done a right total joint replacement for William Wilson with absolutely devastating results from the first procedure which was a Provisor femoral socket against a bus type cup. You may recall that it was the one that is appearing again in the movie and yes done approximately 15 months ago. Because of recurrent pain and swelling, we re-operated her last Friday and found a significant 5 cm thick encapsulation with heavy black pigment over the right symptomatic area. The metallic implants had dug its way into the fossa in the lower femur. You will be receiving the report next week. I have considerable reason to believe that this reaction may be a similar one to the one that occurred in Mrs. Wilson. If this represents a result after a couple of years of several hundred patients with total joint replacement, we have a plenty of relatively new patients on our hands. I think we need to discuss this and consider some laboratory studies to give some credibility to where we are going with this system. I'll be giving you a call to discuss this later in the week.

Sincerely yours,

[Signature]

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

RICE UNIVERSITY, HOUSTON, TEXAS
PIIF inserts contained information as it became known regarding problems that can occur with implant surgery in general, including the PIIF. Things that may go wrong include: periprosthetic fracture, loosening, either within the joint, shortened life expectancy of the implant from a rough ceramic surface resulting from irregular wear over the years, or from stress riser. It's important to trim the implant properly.

Excessive thickness of the implant could cause early normal loading of the joint. Overloading of the joint may result in significant wear of the femoral component, displacement, or fragmentation of the material with foreign body giant cell reaction, and/or precipitation of bone and cartilage. Although the described health problems related to implanting tissue, such as dislocations, and/or bone and cartilage. Severe problems such as these may be expected and should be reported to the implant manufacturer immediately. The implant manufacturer may be able to provide, if available, equipment changes that are important in the success of the procedure. Because of the need for conformity, the strength and stiffness of the PIIF can only be as great as conformity is beneficial because of increased strength and stiffness of the PIIF, then the implant will not function correctly.

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

SUBJECTIVE NO. 2: Please describe in full and complete detail any and all occurrences of fractures, protrusions, or other problems that occur in the bone, soft tissue, implant, etc.

ANSWER: Dr. East over 2,000,000 of Vitak stock. Vitak has approximately $1,000,000 share which has been issued to shareholders. Dr. East owns over 20% of the stock of Vitak. The stock was originally issued to Dr. East in November 1959, and then by a dividend split, (for one) in March 1959. Dr. East receives a portion of royalties on some Vitak stock, and we will be included in the agreement with the Smith, Nephew, the Otis, and others, royalty in designing.

REQUEST FOR PRODUCTION NO. 5: All names and communications of any kind and the estimated amount, stock, etc., and will not require any to any way conveying any of the devices in question.

ANSWER: Defendant objects to request for Production No. 5 for the reason that it is overbroad, uncertain, and irrelevant, and the party requesting the same has not shown and made reasonably calculable by some means or other that it is necessary or relevant. Defendant objects further as requiring information which is the subject of this suit and not the subject of any investigation, and is not the subject of any information regarding any implants not involved in this suit it is irrelevancy material to no matter at issue in this litigation. Without violating the foregoing objections, all as to the PIIF, which is the implant made by the Vitak Company, and not the Smith, Nephew, Otis, and others, will not require any conveying any of the devices in question.

SUBJECTIVE NO. 10: Describe in full and complete detail the relationship between Charles Heming (defendant, etc.) and Louisiana State University Medical Center or any of its schools, departments, agents, and employees, concerning the research, design, testing, manufacture, and/or sale of any of the devices in question.

- 10 -

SCHOOL OF DENTISTRY
Louisiana State University
Medical Center
1200 Florida Avenue
New Orleans, LA 70119
(504)448-4555

Department of Oral and Maxillofacial Surgery

March 20, 1983

Charles A. Poole, M.D., Ph.D.,* Chair

President Research Laboratory

To: The Faculty of the School of Dentistry

Relating to the above date, the above mentioned faculty members have been informed of the above date in order to follow up on the above date provided for the above date.

Finally, when the annual meeting of the American Dental Association was San Diego on June 27 through June 30, at that meeting please there will be a Continuing Education Course that I will be one of the principal speakers on the use of bone material in the TMJ and cranial area.

As you can see educationally this is a very, very fast-moving time with an exponential increase in potential number of patients who are in need of implant bimaterials.

Best wishes,

John H. Kent, D.D.S., President and Dean

School of Dentistry

University of Texas at Dallas

School of Dentistry
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 for at least 20 years ago that the silicone TMJ implants would fail. Is the main problem now that it is a joint that is a failure?

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. Marrbach, 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. Marrbach. No, but I would like to.

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

Dr. Marrbach. Most of the patients who have no TMJ structures are destroyed. Most of these patients 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 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 bills indicate the House will be going into session in about 10 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. Marrbach. I am the recipient of a $1.5 million grant application as of last year. They have been quite progressive. They are currently funding research on conservative treatment, diagnosis, and outcomes of which I am the recipient. I think they have put their best foot forward. I mean that, not just because they give us 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 Dr. Jim Benson, Director, Center for Devices and Radiological Health, Food and Drug Administration; Dr. Harold Lee, 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. Lee, we will ask you each to try to limit your testimony to a 5-minute summary, so 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 emphasizes the role 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 the data under 510(k), the reviewers of that document were not aware 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 of 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 procedure described above.

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 premendement 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 these class III premendement devices that need to undergo approval.

In the coming year we will issue Federal Register proposals to call for 510(k)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 premendement class III products, if any, should be recategorized.

I would like to emphasize that FDA has a number of ways to help us understand whether problems with these devices are 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 GMPs (general manufacturing practices) before approval, and mandatory recall for products found to have problems.

We will use all available authorities to ensure 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 material, including silicone, is completely safe when used in the human body. The key is to understand the risks and to then make risk/benefit judgments accordingly.

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

[The prepared statement of Mr. Benson follows]
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 -- 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 1992.

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 "cause equivale

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

reinstated 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 "flexible about our new authority under

Section 510(k) 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 lead. Data gleaned from these studies will enable

us to make a science-based witness 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 Vitak'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.

Vitak's Interpositional Implant (IFI)
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 Vitak'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 these 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 Vitak Incorporated. This
started the chain of events which ultimately led to seizure in
October 1990 of all TMI implants manufactured by Vitak and a
successor corporation, Oral Surgery Inc.

During our persistent discussions with Vitak which occurred
following our awareness of problems in 1988, FDA issued two
§ 510(k) letters requesting Vitak, or the bankruptcy trustee,
to initiate a patient notification program. In response to the
first letter, Dr. Charles Honey, head of the then-bankrupt
Vitak, responded that he would notify the 44 physician members
of a professional society but was unable to do more. Mr. Ben
Floyd, Vitak's bankruptcy trustee, refused to comply with any
part of either order. Two months after issuance of the second
§ 510(k) notification, on August 30, 1991, we rescinded the
510(k) premarket notification for Vitak'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 Vitak Interpositional Implant (IFI)
and Vitak's total joint replacements. FDA took on
responsibility for notifying patients with these implants
because Vitak 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 Medis-Arcert. 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 § 510(k) 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. Romay 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 FDA 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 II or reclassifying it. Third, the FDA directs us to publish a final regulation on the classification of each device. Under FDA, 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 1980 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, REMA 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 tendon 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 assessed, 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 leak 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 liquid silicone injections — 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 pre-market submission that was the basis for the approval of the Angel chik device to determine if marketing or use 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 implant 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 devices that has silicone gel as a primary constituent of the finished product. This requirement applies to silicone gel-filled breast prostheses; silicone gel-filled testicular prostheses; silicone gel-filled chin prostheses; and silicone gel-filled Angel chik reflex 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 intravascular 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 is 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.
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.

(Chronology follows.)