THE *TMJ* Report

The Newsletter in Support of TMJ Sufferers Around the Country

The TMJ Association, Ltd. • 6418 W. Washington Blvd. • Milwaukee, Wisconsin 53213 **Spring/Summer 1994**

TMJ Implant Patient Support Network Joins with The TMJ Association

The Board of Directors of The TMJ Association was both proud and deeply humbled by the receipt of the following letter from Amy Marks and Barry Thistlethwaite, co-founders of the TMJ Implant Patient Support Network.

To Members of the TMJ Implant Patient Support Network and The TMJ Association

Dear Members:

The TMJ Implant Patient Support Network grew out of the need to educate and inform TMJ implant patients, work for research, and help implant victims find the resources to deal with medical challenges and financial burdens. While we have made great progress, we find that now, for health reasons, we must step back from this important work.

The TMJ Association, the largest and most credible TMD patient support organization, is an excellent source of information for TMD and implant patients. And we have been very grateful from the start for the remarkable work Terrie Cowley, president, has done in Congress, the NIH, FDA, and other agencies to get appropriate research underway. Her efforts most recently came to fruition in the April TMD research workshop, a major step in our struggle.

Today, more than ever, we need a unified front for all TMD patients to ensure that the research agenda from the workshop is fully funded, and to influence research priorities where needed.

After discussing the priorities and directions of both organizations, we at the Network are proud to join The TMJ Association. We thank Terrie, Jennifer Hutchinson, and the board of the Association for agreeing to combine our organizations and to accept our members as their own. As new TMJ Association members, former

(Continued on page 2)

First International Scientific Workshop on TMD Held

During April 17-20, 1994, approximately 100 professionals from around the world gathered together for the first time to identify and set priorities for research opportunities, and to establish the basis for a comprehensive research agenda for TMJ disorders. The National Institute of Dental Research (NIDR) provided leadership for the workshop, with co-sponsorship from the National Institute for Arthritis and Musculoskeletal Disorders (NIAMS), and the Agency for Health Care Policy and Research (AHCPR). Representatives from various branches of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) were present, as well as patient advocates Terrie Cowley and Jennifer Hutchinson.

The workshop featured poster exhibits, lectures, and panel discussions. Major working groups were formed that focused on the following issues: muscle disorders, joint disorders, assessment and diagnosis, treatment, epidemiology and health services, and basic science. Each group was instructed to make research recommendations in order of priority, and to address two "Dear Doctor" questions submitted by patients which will be included in an NIDR brochure and sent to people requesting information on TMJ disorders.

Dr. Patricia Bryant of the NIDR, in her statement at the workshop opening ceremonies, stressed the need for solid science to answer questions patients need answers to, and to "ensure that a disaster such as the implant one will never happen again." Dr. Harald Loe, Director of NIDR, expressed his pleasure with the international and interdisciplinary approach offered by the workshop, adding that it would be remembered as a "watershed in the history of TMJ research that would crystallize the knowledge of the world's foremost authorities, chart a course for the future, and put an end to the needless pain and suffering experienced by so many people." Dr. Barry Sessle, University of Toronto, encouraged workshop attendees to look at the latest scientific advances, learn from them, and apply them to TMJ disorders.

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TMJ IMPLANT... *(continued)*

Network members will now receive the Association's excellent newsletters, correspondence, and other services. We are also excited about the direction the Association is taking, and feel that you will be pleased with its continuing development.

We thank the members of the Network for their support — particularly those who have contributed time, efforts, and funds to making it a success. We ask you to continue to respond quickly and energetically to the needs of the Association. Most importantly, call your congressmen, senators, and federal agency representatives when asked, to inform them of our needs. And, if you have time or skills to contribute, contact Terrie at the Association to help where you can truly make a difference.

We will continue to be involved in this effort as much as possible, and look forward to returning to more active roles within The TMJ Association when health and circumstances allow. We hope that more of you will find time and energy to contribute to this vital, life-giving effort. Many lives depend on it.

Sincerely,

Barry Thistlethwaite
Amy Marks
Co-Founders

We thank Amy and Barry for their kind words and expression of confidence and support for The TMJ Association. They have worked incredibly hard to provide support for people with TMJ implants, and in bringing media attention to the plight of TMJ implant patients. However, at this time, Amy and Barry's attention is focused on "getting Amy better," and they in turn have our support and good wishes.

Their gesture makes us even more determined to do everything possible to improve the health care and human condition of every TMJ patient in this country. We look forward to Amy and Barry's help with the ongoing activities of The TMJ Association as their circumstances permit.

FIRST INTERNATIONAL... *(continued)*

There was agreement among workshop participants that little is known in the area of basic science and the biomechanics of the temporomandibular joint. It was also acknowledged that treating professionals have little scientific basis for, and lack consensus on, definition, cause, diagnosis, or treatment. A multi-disciplinary approach was encouraged to address the numerous problems faced by TMJ sufferers. Many participants emphasized the need for an agenda for research and professional/patient education.

The feature article of the next issue of ***The TMJ Report*** will be on the workshop presentations and recommendations.

RENEWAL REMINDER

Please check the Expiration Date on your mailing label. If your subscription has expired, you must renew in order to receive another newsletter. Annual membership is still $15. Make your check payable to The TMJ Association, and be sure to write "Renewal" on the check.

THE *TMJ* Report ...

Subscription Information

The purpose of ***The TMJ Report*** is to provide members with up-to-date information on important issues and the activities of The TMJ Association. Annual membership fee is $15.00. As a member, you will receive your subscription to ***The TMJ Report***. Back issues are available for $4.00 each.

Disclaimer

The TMJ Report is intended solely as an information guide and source of support for people with TMJ disorders. It does not constitute medical advice, nor is it a substitute for medical advice. Always consult with your doctor before starting any treatment. The TMJ Association does not provide physician referrals.

The Association does not endorse any particular medical professional or organization, nor do the opinions of a medical professional or organization referred to in ***The TMJ Report*** reflect the opinions of The TMJ Association.

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Biomaterials Meeting

The Society for Biomaterials held a planning conference on Management Requirements for a National Implant Data System, April 10-11, 1994, in Hyannis, Massachusetts. The planning conference served to accelerate the process of producing a unified approach to the study of biological host and implant response performances of various biomaterials and devices in human clinical use.

Researchers, practitioners, manufacturers, attorneys, treating institutions, insurers, regulatory agencies, and patient representative groups participated in this forum. Groups were formed to focus on a variety of issues, including manufacturing, consulting and testing, regulatory, professional, and international.

Terrie Cowley represented The TMJ Association and participated in the professional group. She raised the point that recent experience has demonstrated that implant recipients cannot depend on manufacturers, professionals, or the FDA to protect their interests. She further emphasized that patients need to be included in the decision-making processes of the database development and other factors affecting their well-being. As she stated, the implant patients have a stake in this process; in fact, they have the most to risk if an implant goes wrong — their quality of life and even their lives. It was unanimously decided to change the name of the group from "professionals" to "stakeholders." The recommendations listed the stakeholders in the following order: patients, researchers, manufacturers, regulators, clinicians, other health care professionals, third-party payers, and professional societies. Also, it was agreed that the database must be outcome focused — how to help the patient and how to deliver quality care.

Conference participants recommended several topics to be discussed at future meetings, such as defining the scope of the database, ownership, sponsorship, how to achieve compliance, who the user groups will be, and how the database will be audited and by whom.

When The TMJ Association has received the final draft of conference recommendations, we will provide you with a brief update in a later issue of the newsletter.

New Book on TMJ

***The Truth About TMJ: How to Help Yourself*, by Jennifer Hutchinson, was published in early March. We hope you received the order form from the publisher that we sent out. If not, you can get a copy of the book by sending a check or money order for $14.95, plus $1.05 shipping and handling, to Reinhardt & Still Publishers, 4250 Cedar Creek Grade, Winchester, VA 22602. You can also order by credit card by calling (800) 303-2244, or ask for the book at your local bookstore.**

World Health Organization Issues TMJ Implant Alert

Early this year, the World Health Organization (WHO) issued an alert entitled "Temporomandibular Implants (Proplast): Warning Concerning Implant Failure." The alert briefly summarized action taken by the FDA concerning the Vitek Proplast-Teflon TMJ implants, specifically listing each Vitek device and possible risks. Because the FDA is concerned that the products may be marketed in other countries, regulatory authorities are alerted to this possibility and to the adverse effects of these products.

"Implant Industry is Facing Cutback by Top Suppliers"

On April 25, 1994, an article entitled "Implant Industry is Facing Cutback by Top Suppliers," written by Barnaby Feder, appeared in the *New York Times*. A summary of the article follows.

Companies who make chemicals and materials, including Du Pont and Dow Chemical, are dropping the medical business for fear of being brought into the hundreds of lawsuits against manufacturers of jaw implants, silicone breast implants, and other devices. Industry executives and medical professionals fear this will eventually make life-saving implants hard to come by, and have a devastating effect on the development of new devices.

Consumer groups believe these cutbacks are part of industry's attempt to pressure Congress to limit the legal redress available for people injured by defective products. Senator Joseph Lieberman (D-CT) says, "This is a public health time bomb." Senator Lieberman supports legislation to overhaul product-liability rules, thereby reducing the materials suppliers' risk of lawsuits.

Du Pont has recently been named as a co-defendant in lawsuits filed against Vitek, manufacturer of the TMJ Proplast-Teflon implants. Du Pont states they had no part in either the design or sale of the product, and although their Teflon is manufactured for industrial and consumer use, they have made it available to medical companies along with warnings that they "had not been tested in any way" for medical use. Plaintiffs, on the other hand, argue that Du Pont knew or should have known Teflon was unsuited for Vitek's implants and should have refused to supply it. According to Du Pont, the company has had a 30-year policy of not withholding materials from the medical sector "because we didn't want to inhibit development." So far, Du Pont has won all but one case, but their legal costs are running into tens of millions of dollars.

Dow Corning is also dealing with their share of legal claims, totaling billions, involving silicone breast implants. They have stopped supplying silicone rubber to most equipment companies.

Dr. Sidney Wolfe of Public Citizen feels "the litigation is an inevitable result of misguided federal laws and policies that have allowed most medical implants to reach the public without extensive testing and specific approval from the FDA." According to Dr. Wolfe, "If you sell something, you are in the chain of responsibility." He believes both suppliers and equipment makers play a part in protecting consumers, and "eventually the lawsuits will lead to the use of better-quality materials in medical equipment."

Kristen Rand, Counsel to the Washington, DC, office of the Consumers Union, submitted a letter to the editor of the *New York Times* following the publication of this article. According to Ms. Rand, the article "does a disservice to hundreds of thousands of victims of untested, unsafe medical devices." She says "product liability actions are almost the consumer's only protection from dangerous, defective medical devices." Citing the Silastic TMJ implants as an example of her concern, she pointed out that "Dow's public documents hinted and medical literature confirmed that Dow had reason to know that the silicone rubber in the device was, according to one researcher in Congressional testimony, 'intrinsically flawed as a biomaterial for long-term implantation into the human body.' Dow did not include adequate warnings in the package inserts and continued to market the devices." And she concluded: "Virtually without exception, lawsuits the industry describes as frivolous turn out to be valid, and products alleged to be safe prove dangerous."

On May 20, 1994, the U.S. Senate Governmental Affairs Committee, Subcommittee on Regulation and Government Information, convened a hearing on the "Availability of Medical Devices." Kristen Rand provided testimony on behalf of the Consumers Union, Consumer Federation of America, and Public Citizen's Congress Watch.

The TMJ Association has been communicating with Ms. Rand on this subject. We have recently submitted written testimony to be entered into the congressional record, and encourage you to do the same by writing to Senator Lieberman at the following address:

Senator Joseph Lieberman
Governmental Affairs Committee
Subcommittee on Regulation and
Government Information
Hart Building, Room 605
U.S. Senate
Washington, DC 20510

As mentioned in the last issue of the newsletter, the U.S. Senate has been considering federal legislation that would substantially curtail the rights of injured consumers to sue corporations for defective products. On June 28 and 29, the Senate voted twice to defeat S.687, the Product Liability Fairness Act. The two votes mean that the legislation will not be considered again until 1995 at the earliest.

TMJ Implant Products Liability Litigation Update

The Judicial Panel on Multidistrict Litigation has granted a Transfer Order to all cases that were pending in Federal Court within their state to be transferred to Minneapolis, Minnesota, in front of Judge Paul Magnuson.

A Multidistrict Litigation (MDL) will allow law firms, on a national basis, to pool their resources and work together for discovery, depositions, and production of documents in the Federal Court in Minnesota. Attorneys around the country are now in the process of starting the examinations of Du Pont and Dow Corning employees and documents. They believe they will be able to show that these two manufacturers are responsible for injuries caused by the TMJ implants.

Du Pont has won close to 25 cases by utilizing the "bulk supplier defense." Their position is that they sold bulk Teflon and had nothing to do with it being used in a medical device, and that they are not responsible for any misuse by the Vitek Corporation. All of the cases that have been handled by the courts have resulted in either summary judgments or jury victories for Du Pont, with one exception. That case is now on appeal.

Despite this dismal record, some attorneys are confident that they have found information demonstrating that Du Pont did indeed know how the Teflon was to be used, and was in other ways more deeply involved with Vitek. They are proceeding with their cases on these theories.

Action has also been brought against Dow Corning for their involvement with Vitek but, more importantly, for the manufacturing and distribution of their own TMJ implant, Silastic. Attorneys hope to prove Dow Corning had knowledge of medical problems that existed as a result of their implants and knew they were marketing a faulty implant.

Unless the plaintiffs' attorneys are successful in establishing that Du Pont and Dow Corning are in fact legally liable, there will be no basis for recovery. The TMJ Association will keep you updated on this legal issue as important information becomes available.

Joint Resolution Passes in Illinois

The Senate and House of Representatives of the Eighty-eighth General Assembly of the State of Illinois has passed a Joint Resolution urging "the federal government to begin funding research to correct the problems resulting from faulty jaw implants," and "to initiate a victims' compensation fund to assist with expenses incurred as a result of faulty jaw implants." They further request that copies of the resolution be sent to the FDA as well as each member of the Illinois congressional delegation.

Joyce Zuercher, a Vitek implant recipient, contacted her senator regarding the implant problems, and was subsequently invited to present testimony to the Senate Executive Committee. In her testimony, she stated that her goal was to have immediate positive action taken to help implant survivors. An attempt was made by the Illinois Dental Society to "kill" the resolution and prevent Joyce from testifying. It was only through Joyce's tenacity and comprehensive knowledge of the implant issue that the resolution passed. Senator George Shadid's office is making arrangements for Ms. Zuercher to meet with Senator Paul Simon to discuss the needs of the implant patients The TMJ Association supported Joyce's efforts by providing information to members of the Senate Executive Committee.

New Support Group Forms in Canada

The TMJ Association recently received a letter from the TMJ Support Association of Alberta. Diane Hobbs, president, saw the article, "Jaw Pain," in the November issue of *American Health,* and wrote to tell us about her organization. With an ever-increasing number of patients in Canada, we feel it is important to pass this information on to our readers. The TMJ Support Association of Alberta is a provincial association with local chapters in their four major urban centers (Red Deer, Calgary, Lethbridge, and Edmonton). The organization publishes a quarterly newsletter and has an annual membership fee of $10. If you want to know more, you can write to the TMJ Support Association of Alberta, 3386 Breton Close NW, Calgary, AB, Canada, T2L 1X4.

Teen Wants to Hear from Other Sufferers

TMJ sufferer Michelle Nocera has written to The TMJ Association and expressed an interest in talking with other TMJ patients, particularly teenagers. Michelle, who is 17 years old, has had eight surgeries, including a Silastic implant. She is anxious to know if there are many teens out there with this disorder and, if so, how they are coping. You can contact Michelle by writing to her at 23 Alan Terrace, Jersey City, NJ 07306, or by calling her at home at (201) 792-2572. We have asked Michelle to keep us updated on the TMJ teen network, and we will share comments with you in future issues of the newsletter.

The TMJ Association Publishes New Brochures

The TMJ Association has two new brochures available — "Causes," and "Diagnosis." The cause brochure was taken from a previously published article, "Causes of TMD — Current Theories" (Nov. 1993). The diagnosis brochure is a reprint of "Diagnostic Imaging of the Temporomandibular Joint" that appeared in the May 1992 issue of ***The TMJ Report.*** You may order the brochures for $2.00 each.

FEATURE ARTICLE:

TEMPOROMANDIBULAR JOINT IMPLANTS

Introduction

Since many members of The TMJ Association are implant recipients, we feel compelled to provide them with pertinent information. For many of you, this may be old news. Others will find answers to questions they didn't know they had. And TMJ patients who have not had implants will understand the necessity of being as informed as possible about the safety and efficacy of the myriad of treatments presented to us by professionals.

Background

Since the mid-60s, professionals have been using various materials to replace all or part of the temporomandibular joint. Sometimes, surgeons replace the disc with what is now frequently called an **interpositional implant** (IPI). In other instances, the condyle (the head of the mandible, or lower jaw), fossa (the skull, or socket, of the jaw joint), or both, are replaced with **prosthetic devices.**

It may be safe to say that the total number of implant recipients is unknown. However, it is estimated that between 60,000 and 150,000 Americans have received **biomaterial** jaw joint parts. Many more have **autogenous** grafts that utilize parts of the body for reconstruction of the jaw joint. Such parts include rib, cartilage (usually femur or ear), temporalis muscle flap, or fat. Some surgeons use cadaver cartilage.

Most biomaterials for jaw joint reconstruction were introduced on the market before the 1976 Medical Devices Amendment Act was passed requiring

manufacturers to provide evidence that their devices were safe and effective. Because the TMJ implants were already on the market, no testing was required. They were simply "grandfathered" in under the Act or, in other words, were allowed to remain on the market. Manufacturers of new products only had to show that their devices were "substantially equivalent" to something already on the market.

TMJ Disc Implants. Two products that have been widely used as disc replacements for torn and/or displaced natural discs are **Dow Corning's Silastic** and **Vitek's Proplast-Teflon.**

Silastic implants appeared in several forms. The first, introduced in the mid-60s, was block Silastic, or silicone rubber, carved to shape. Another was Silastic HP Sheeting, which was reinforced with dacron. This was followed by the Wilkes Design, marketed in 1985. Designed for temporary use only, this implant was made with "tabs" to allow for easy removal after several months.

In the 70s, Vitek developed and sold Proplast Sheeting (Teflon FEP film laminated to a porous composite material made from polytetrafluoroethylene (PTFE) and carbon). The implant was modified in the early 80s, and Teflon film was then laminated to PTFE and aluminum oxide. These implants, usually no larger than a thumbnail, were manufactured individually, or custom cut from sheets in the operating room by the surgeon and then sutured to the fossa or condyle.

Many people with Silastic and Proplast-Teflon implants soon began experiencing problems. Simply put, when something artificial is implanted in the body, the immune system sends out giant white cells in an attempt to destroy it, or at least isolate it. Since TMJ implants are made of non-organic material, the giant white cells remain around the implant, pumping out irritating chemicals in an attempt to eliminate it. These chemicals dissolve tissue and bone, causing serious destruction. Additionally, as patients resume oral function, the movement of the joint causes friction on the material, resulting in fragmentation into microscopic particles. These particles migrate throughout the lymphatic system and cause systemic damage.

Because of an increasing number of reports of implant failure, Vitek's IPIs were recalled by the Food & Drug Administration (FDA) in March 1990, and several months later, Vitek declared bankruptcy as a result of rising litigation costs. Vitek continued to market their TMJ implants and surgeons still used them, until eventually the FDA seized all products from Vitek as well as its subsidiaries.

A subsequent "Safety Alert" was issued by the FDA to oral surgeons nationwide. Patients were advised to be examined every 6 months with an appropriate radiographic (imaging) exam, for as long as the implants remained in place. They were told that if the exam shows signs of deterioration, the implant should be removed as soon as possible. Then, in September, the FDA issued a "Public Health Advisory on Vitek Proplast TMJ Implants" to oral surgeons and, a month later, announced the establishment of Medic Alert's International Implant Registry.

As of January 1993, Dow Corning discontinued sales of all Silastic TMJ implants. The company has since instructed customers to inform patients with Silastic implants of the risks and benefits of removing the implant or leaving it in. If a patient decides to leave a Silastic disc in, he or she should be followed regularly with appropriate imaging and evaluation of symptoms. The company further states that the temporary Silastic implant (Wilkes Design) should have been removed, and patients with silicone sheeting used in custom TMJ devices should be monitored regularly. To date, although the FDA states they are receiving complaints about Silastic, they have not made a formal statement concerning the implants, nor have they recalled them.

TMJ Prosthetic Devices. The TMJ device market has seen the development of numerous prosthetic devices. They are generally made of a combination of various types of metal, acrylic, and plastic, and may be utilized to replace the condyle, fossa, or both. Among those that are no longer available, at least for now, are the ones manufactured by **Vitek**, **Techmedica**, **Osteomed**, and **TiMesh**. The two remaining on the market are the **Christensen** device (**TMJ Implants, Inc.**) and the **Morgan** implant (**The Temporomandibular Research Foundation**).

The TMJ Association has heard from people with different types of prosthetic devices. Although some of them seem to be doing fairly well, others are having tremendous problems, not unlike those with the Vitek and Dow Corning implants. For example, we have spoken to some people who are dealing with the third failure in a year, and severe systemic reactions. According to the FDA, **at present the safety and effectiveness of the devices on the market has not been determined.** In future issues of the newsletter, we will update you on the status of these devices.

Implant Problems and Symptoms of Failure

Over the last few years, The TMJ Association has heard from many people who have had, or still have, Proplast-Teflon and/or Silastic implants. Most of them are experiencing a wide range of symptoms — both craniofacially and systemically. It is important to understand that **an implant may be failing even if there are no symptoms**. Also, physical problems may be occurring that neither the patient nor the doctor attribute to the implant.

According to the FDA, problems seem to be related to length of time the implant is in place; however, from what we are hearing, problems are unpredictable and don't follow a distinct pattern. We talk with people who have had an implant for only 2-3 months and are having tremendous problems. On the other hand, we have heard from some who have had their implants as long as 10 years and are experiencing few symptoms.

We must state that our information is strictly anecdotal or, in other words, based on what patients have told us. If you are experiencing any of the symptoms below, they may be totally unrelated to TMJ implants, they may be a component part of the complex TMJ disorder, or they may reflect an entirely different disease ... we simply don't know. We cannot say you have these symptoms because of your implants. We hear from non-surgical TMJ patients who have some of these problems. All we can do is tell you what patients tell us.

Many people say they have felt worse physically and have had head pain since the day of implantation. Others have felt good for a period of time (6 months to a few years), or have been relatively asymptomatic and then gradually began noticing increasing head pain and systemic problems. What we are hearing is sufficiently alarming that we are enlisting the help of health care professionals and biostatisticians to develop a scientifically valid survey of The TMJ Association's database. We will be asking for your cooperation in this endeavor in the future.

The following is a list of some of the most frequently voiced diagnoses, complaints, or symptoms described to us by people with TMJ implants.

- Resorption or degeneration of the condyle and/or fossa; mandibular bone described as "melting" or "soft"; skull penetration (holes); disfigurement or deformity of the face
- Pain in joint area and head, from occasional discomfort to severe and intractable
- Joint sounds, e.g., cracking, grating, or crunching
- A change in the bite, movement of the jaw (laterally, forward and backward); limited opening or deviation of the jaw on opening
- Fibromyalgia, Myofascial Pain Dysfunction, muscle aches and pains, particularly in head, neck, and upper back; disruptive sleep patterns
- Chronic Fatigue Syndrome; flu-like symptoms — low-grade fever, malaise, fatigue
- Weakness and/or diminished muscle strength; lack of coordination
- Dizziness, lightheadedness, vertigo, nausea with/without vomiting
- Ringing in the ears, ear pain, hearing impairment, deafness, hyperacusis
- Visual disturbances — snowblindness, trouble focusing, blurred vision, blindness; dyslexia
- Memory loss, confusion, inability to think clearly
- Seizures and/or blackouts
- Swollen lymph nodes/glands in various parts of the body (e.g., neck, behind ears, under arms, groin)
- Abnormalities of the parotid gland
- Abnormal thyroid function
- Skin rashes, dry skin, itching, sensitivity to the sun
- Sjogren's Syndrome; dry eyes and dry mucous membranes
- Changes in skin color and texture, such as hardening, thickening, shining
- Allergies or sensitivities to chemicals and drugs
- Cold extremities
- Intolerance to heat and/or cold
- Asthma, pneumonia
- Dry, unproductive cough; chronic or episodic hoarseness
- Chronic respiratory, urinary tract, pelvic, or gastrointestinal infections
- Non-malignant tumors and/or granulomas in various parts of the body (e.g., breast tumors and/or fibrocystic breast disease, fibroid tumors)
- Radiographic tests indicating spots on the liver, lungs, brain, etc., without a definitive diagnosis
- Mitral Valve Prolapse
- Atypical Multiple Sclerosis
- Sarcoidosis
- Abnormal laboratory test results, e.g., low T cell count, elevated white count, low red count, slightly positive ANA

What to Do If You Have a TMJ Implant

1. If you have not already done so, **call your implanting surgeon and make an appointment to be seen as soon as possible.**
2. The FDA states that **"your surgeon will evaluate you clinically and order an appropriate radiographic examination."** An imaging technique that can provide information about the status of bony structures, degenerative changes, and inflammatory processes such as granulomas or fibrosis, is recommended.

   According to G.F. Carerra, MD, Chief of Diagnostic Radiology at the Medical College of Wisconsin, **Computed Tomography (CT, or CAT scan)** is probably the best way to look at the damage from post-implant degenerative changes. The exact location of the implant can be seen, even in patients with a considerable amount of metal in the joint.

   Magnetic Resonance Imaging (MRI) has some unique advantages and problems in post-op TMJ patients. Soft tissue abnormalities such as granulomas and inflammatory masses can be seen, along with the exact location of the implant materials. However, if metallic wires or pins have been used to hold the implant in place, these may

create enough artifact to significantly degrade the MRI. In such cases, a CAT scan would most likely be ordered.

Although there are other imaging techniques available, such as **plain x-rays, tomography,** or **arthrography**, these procedures each have drawbacks that make them unsuitable alternatives. At our request, Dr. Carerra has written an excellent article, "Imaging the Post-Implant TMJ." We plan to incorporate this information into our implant brochure in the near future.

3. According to the American Association of Oral & Maxillofacial Surgeons (AAOMS) guidelines, **your doctor should discuss with you the benefits and risks of leaving the implant in and having it removed, and what options are available to you regardless of what decision you make**. However, in these written guidelines, published in late 1993, benefits, risks, and options are not outlined.

Making a Decision

Since there is no standard of care for TMJ implant recipients, you ultimately must make the decisions about your health care. It is your responsibility to get as much information as possible before deciding whether to have the implant(s) explanted or left in, and what course of treatment you should follow in all instances.

Recommendations for implant patients are currently based on the professional provider's individual bias or anecdotal information, and what is available to him for implantation. Some doctors feel the implants should be removed regardless, because the failure rate is so high. Others feel they should be removed only if there is clinical evidence of implant failure, you are experiencing symptoms, or both.

If your MRI or CAT scan reveals minimal bone damage, and you are asymptomatic or have minimal symptoms, then you must weigh the risks of explantation, which involves another surgical procedure at this time and perhaps more reconstructive surgery in the future. If you decide against explantation, you should know that you may experience further damage to the joint that may undermine reconstructive surgery. For this reason, it is imperative that you be followed closely to detect signs of implant failure and/or further deterioration.

Most of the people we hear from whose imaging exams show moderate to severe damage and who are experiencing symptoms, decide to have their implants removed. Even after removal of the implant, tiny particles are left that can still cause foreign body reaction in the joint and migrate throughout the body. Since these microscopic particles are impossible to remove during surgery, it is important for you to be monitored after having an implant removed. The FDA's new Device Tracking Regulation stipulates that monitoring is to continue for the life of the device or the life of the patient.

Treatment Options

Unfortunately, there are no easy answers and very little consensus among professional providers regarding treatment for implant recipients. Generally, most implant patients must choose from one of the following options:

1. With minimal damage, surgeons may recommend **removal of the implant, debridement** (cleaning out the fragments and scar tissue), **and not replacing the implant**, hoping that function might be maintained or restored, and pain kept to a minimum without additional reconstructive surgery. If the joint is functioning fairly well and there is little or no pain, this may be the safest and most conservative option. However, some people develop bony or fibrous ankylosis (scar tissue), reactive tissue from the continuing foreign body giant cell reaction, and/or occlusal changes, which present a new set of problems. They may be manageable with conservative treatments, or the joint may fuse, making opening and moving the jaw more and more difficult.

   In some patients, surgeons remove the implant, debride the joint, and allow the joint to "rest" for several months before implantation of any material.

2. Some surgeons opt for **removal of the implant, debridement, and use of autogenous or cadaver tissue to replace the failed implant**. Treatments designed to replace an implant frequently fail. In the case of autogenous grafts such as a rib, the success rate is low — perhaps only 12 percent. This is because of the giant cell reaction, which can continue even after 4.5 surgical attempts to remove all the fragmented material (Larry Wolford, DDS. Testimony Before the Human Resources & Intergovernmental Relations Subcommittee, Committee on Government Operations, U.S. House of Representatives, 6/4/92).

3. Other surgeons are recommending **removal of the implant, debridement, and implantation of a total joint prosthetic device**. Two are currently available (the **Christensen** and the **Morgan**). Some of the people we hear from seem to be doing fairly well; others are experiencing severe problems with either the total joint itself or with continuing problems caused by the presence of a previous implant, or both. The FDA states they have no data from the manufacturers of these devices because these firms have not been required to submit data.

Many people go through a series of surgeries in attempts to reconstruct a joint that has been badly

damaged by an implant: removal of the implant, reconstruction with autogenous materials, and if that fails, a total joint prosthetic device, perhaps followed by other surgeries to clear out scar tissue or bony overgrowth which has formed. There is no scientific evidence that any of these surgical alternatives is safer or more effective than any other. **We cannot sufficiently stress the importance of getting as much information as you can and exploring all your options.**

Within the wake of the implant disaster, many people are justifiably skeptical of treatment options presented to them. They question the scientific validity of treatments, and they are hesitant to trust the recommendations of their professional providers. Many wonder if implant patients are once again being experimented upon.

It is unethical for professionals not to tell people they are participating in an experimental study. Before entering a study, patients must be informed of the reasons for the study, the procedure, length of time and costs, potential risks and complications, as well as the expected outcome. They should also be told who is funding the study and be asked to sign an informed consent paper detailing the above. If a professional is doing something new or different, this is simply trial and error — not a scientific experiment. Because of the lack of scientific protocols for treatment of implant patients, professionals are learning as they are treating us.

Problems Frequently Encountered by Implant Patients

As an advocacy group for TMJ patients, we constantly receive phone calls and letters from people who are desperate for help. Many implant victims we hear from can no longer work, function on a daily basis, or lead normal, productive lives. They are, in many cases, facing a lifetime of chronic pain and disability. Some cannot get treatment although they need surgery to remove failed implants and subsequent multiple revision surgeries. If they are able to get medical care, there are no FDA-proven, safe, effective implants on the market. Regardless of the options they choose, all are costly and without guarantee of success.

The majority of our phone calls from patients center primarily around two concerns: 1) I am getting worse and nobody knows what is wrong or will help me. What should I do? and 2) My doctor isn't talking to me and won't return my calls. How can I find another doctor?

Since we have not heard from every implant patient in the country, we are hesitant to say that what we are hearing about treatment and health care professionals is the norm. Some people are pleased with the care they are receiving. However, the overwhelming majority have never been informed of the implant alert by their implanting surgeons.

A most serious and tragic consequence of this situation is the subsequent breakdown of communication between patient and doctor. As one support group leader told us, "If we act intelligent, informed, and ask questions, we are told there is nothing wrong with us, nothing more they can do, and, by the way, find another doctor." Another woman said, "I get my information from The TMJ Association and other implant patients, and then go to the doctor and play dumb because if he abandons me, I have no one."

Another serious and all-too-common problem is that of pain management. Implant patients experience pain ranging from mild discomfort to severe and unrelenting. An obvious fact is that many people who need pain medication are not getting it. Others are being *under*medicated, and some people are on medications that require regular kidney or liver monitoring. In some cases, they are not being monitored and, as a result, are experiencing kidney and/or liver damage.

Pain medication preferences vary according to professionals. Many feel Nonsteroidal Anti-Inflammatory Drugs (NSAIDS) are the answer. However, they are often ineffective and can cause intestinal distress. Some professionals are trying other medications, even cancer drugs. At this time, there does not appear to be any specific drug to manage the implant patient's pain. It should be obvious to everyone concerned that there is an immediate need to investigate the cause and treatment of this pain.

Most implant recipients have very little, if any, insurance coverage for medical expenses. With treatment costs totaling thousands of dollars, it is not surprising that many are financially destitute. Some are in desperate need of implant removal, follow-up care, multiple future revision surgeries — which can cost as much as $50,000 per surgery — and drug therapy for chronic and debilitating pain as the result of failed implants.

Some insurance companies who wouldn't cover conservative therapies, yet paid for implant surgery, have refused to pay to have failed implants explanted, claiming it is "experimental." A few scattered surgeons across the country are removing implants without charge to the patient; however, hospitals rarely waive costs. Other surgeons may reduce their usual cost, and a few may intercede in trying to convince your insurance company that the consequences of leaving the implants in will result in much more major medical expense to the company in the future than if the insurance approved the removal now.

We are frequently asked if there will be any financial compensation from the government for the FDA's responsibility in overseeing the safety of devices. A major objective of The TMJ Association is to impress upon the government the importance of providing a reserve fund for implant recipients out of which future treatment and medical monitoring will be paid.

An increasing number of implant recipients are turning to the courts for compensation, as numerous lawsuits have been filed across the country against Du Pont and Dow Corning (see article, p. 4). Since Vitek is bankrupt, Vitek implant recipients are eligible for a portion of the designated settlement. However, only a few thousand dollars have been awarded to these claimants. We have recently been informed that, on May 16, the Vitek Bankruptcy Court ruled that the designated settlement fund could accept more claimants and, at this time, there is no bar date. For more information, call (713) 659-2817.

What the Authorities Recommend

TMJ implant patients are being advised to do many different things by many different people. As we have learned from talking with implant patients, many of these recommendations are ineffective.

The **National Institute of Dental Research (NIDR)** tells people with implants to contact clinicians who have been recipients of grants in the TMJ area. For some people we've talked to, these pursuits have been unsuccessful. A professional provider is not necessarily better equipped to handle the difficult problems of implant patients simply because he has received a grant.

The **FDA** advises implant patients to contact the nearest academic institution. We have heard from people who have gone to prestigious academic institutions for care, who were not successfully treated or were abandoned by their professional providers. The FDA further tells patients whose surgeons dismiss their complaints or refuse to treat them to contact their state dental association or AAOMS. Many people who have contacted AAOMS have only been given names of members in their state (who, incidentally, may not take on another surgeon's implant patient), or literature on dental implants.

Additionally, the FDA urges people who have Vitek TMJ implants, as well as those who have had them removed, to enroll in **Medic Alert's International Implant Registry**. Many patients who have done so have only received promotional material, and no updated information on their implants.

MedWatch, the FDA Medical Products Reporting Program introduced in June 1993, is specifically intended for **VOLUNTARY** professional reporting of adverse events and product defects. In a publication entitled "TMJ Implants: A Consumer Information Update" (August 1993), the FDA encourages patients to have their doctors complete the MedWatch reporting form. Then, in later communication with The TMJ Association, they state that the program is intended for both health professionals and the general public. The MedWatch form itself says it is for voluntary reporting **by health professionals.** With so many inconsistencies, it is not surprising that we are receiving reports from implant patients that their doctors will not fill out the forms, or do not believe their complaints and therefore will not report them to the FDA. Patients also have no way of knowing whether their doctors actually file the complaints or not.

Since the congressional hearing of June 1992, The TMJ Association has advised every TMJ implant recipient to contact the FDA to report problems they are experiencing. We are concerned that there is a possibility these complaints may not have been documented. Many people tell us they have left information on the FDA's answering machine, but have never received any information.

We feel the FDA problem reporting system is inadequate for the TMJ implant patients. In a letter to Commissioner Kessler dated 12/6/93, we requested a meeting to discuss TMJ implant issues, such as the establishment of a parallel reporting system (an 800 number) through which patients, manufacturers, and professionals can file complaints on a particular device directly with the FDA. To this date, our concerns and recommendations have been ignored.

How to Get Help

If you have a TMJ implant, there are several things you should do that may help not only yourself, but others as well.

1. **Contact The TMJ Association** and tell us what you are experiencing. Continue to keep us informed. The information you share with us is beneficial as we approach Congress, government agencies, and professional organizations. This helps *us* help *you.*
2. **Join a local support group.** Call us for the name and telephone number of a support group contact person in your area. One of the most important things you can do is talk to other people with TMJ implants.
3. To file a complaint about any type of TMJ implant, **call the FDA and request a MedWatch reporting form.** If you are experiencing problems and do not file a complaint, the FDA will presume your device is safe and effective. If you report problems, you will be helping to curtail problems for future implant patients. To receive a MedWatch form, call (800) FDA-1088. **Fill it out yourself (do not take it to your doctor), and return it to the FDA.**
4. If you wish to speak to someone at the FDA about a problem and/or receive information concerning TMJ implants, **call the Office of Consumer Affairs** at (301) 443-5006 .
5. If you are concerned or have a complaint regarding your professional medical/dental care

for your TMJ problem, **contact your state dental licensing board and your state health department**. Check your Yellow Pages or call Directory Assistance for telephone numbers.

6. **Register with Medic Alert's International Implant Registry.** In spite of complaints The TMJ Association receives regarding the Registry, a good reason for doing so is to receive any important information that may become available regarding your implants. You can register by calling (800) 344-3226, 24 hours a day, 7 days a week. You must pay an initial enrollment fee of $25 and then $10 annually to maintain your file.
7. **Write letters to the proper authorities.** Many people have already written to the FDA, AAOMS, and the ADA, and have been far less than satisfied with the results. However, because of your letters to the appropriate agencies and congressional committees, we have seen positive changes. Congressman Towns has expressed a commitment to continue oversight of the FDA and the NIH in all aspects of the TMJ problem. Senator Harkin has supported TMJ patients by urging the NIH to direct funds toward this disorder. And the NIDR has initiated meaningful responses to your concerns through the international workshop (see story on front page) and ongoing cooperation with The TMJ Association in our endeavors.

   As indicated by these successes, if enough people voice their complaints, things will change. Keep writing and keep calling. Don't give up! We encourage all TMJ patients to express their concerns to the following:

   Congressman Edolphus Towns
   Committee on Government Operations
   Sub-Committee on Human Resources & Intergovernmental Relations
   B-372 Rayburn Building
   U.S. House of Representatives
   Washington, DC 20515

   Senate Appropriations Committee
   Subcommittee on Labor, Health & Human Services, and Education
   Dirksen Bldg., Room 186
   U.S. Senate
   Washington, DC 20510

   Dr. Harold Varmus, Director
   National Institutes of Health
   9000 Rockville Pike
   Bethesda, MD 20892

   Dr. Donna Shalala, Secretary
   Department of Health & Human Services
   200 Independence Ave. SW
   Washington, DC 20201

   Dr. David A. Kessler, Commissioner
   Food & Drug Administration
   5600 Fisher's Lane
   Rockville, MD 20857

   President
   American Dental Association
   211 E. Chicago Ave.
   Chicago, IL 60611-2678

   President
   American Association of Oral & Maxillofacial Surgeons
   9700 W. Bryn Mawr Ave.
   Rosemont, IL 60018-5701

   Begin by thanking the appropriate professional and governmental agencies for their concern and support for the TMJ patients of this country. Emphasize, however, that we still have a long way to go and that you expect their continued support. Tell them how this disorder has affected you and your family. (It is particularly effective if your loved ones also write and let the authorities know what this has done to them.) Include your opinion of how the implant issue has been handled and ideas about what needs to be done. Let them know that you expect action. Specifically, stress the urgent need for research into the damage caused by failed implants and the impact this disorder has had on your financial situation and the health care system of this country. Enclose copies of some of the articles that have appeared in the media during the last year, for example, *Woman's Day*, the *Wall Street Journal*, *American Health*, as well as The TMJ Association's newsletters and brochures.

   Make your letter brief — one or two pages at the most. Send a copy to the representatives (The Honorable Name, U.S. House of Representatives, Washington, DC 20515) and senators (The Honorable Name, U.S. Senate, Washington, DC 20510) from your state. Tell them to contact The TMJ Association. We will be happy to cooperate with them and provide additional information.

Things Are Changing

There is no doubt that, compared to where we were before the congressional hearing of June 1992, we've come a long way. The truth is out, and the direction of TMJ treatment and research has clearly been changed forever.

- There is obviously an increased awareness among patients, professionals, and governmental agencies. TMJ has been recognized as a legitimate disorder, and the scientific community realizes the urgent need for research to develop safe and effective treatments for TMJ disorders. Beginning with the hearing, several positive steps have been taken. One of the most important was the first International Scientific Workshop on TMJ held April 17-20 (see page 1 for story). At last we are witnessing success, as evidenced by NIDR's willingness to work with us.
- The FDA has been forced to re-evaluate all TMJ devices, and they are in the process of drafting a final rule to classify TMJ IPIs and total joint prostheses into class III, which is the highest risk category and requires pre-market approval. They

are also re-proposing classification of the condylar and fossa prostheses into class III. A proposal will be published requiring manufacturers to submit PMAs (Pre-Market Approval Applications) or IDEs (Investigational Device Exemptions).

However significant these measures may appear to be, it is inexcusable that something was not done much sooner. The condylar and fossa prostheses "were inadvertently omitted from the dental devices considered for reclassification" by the FDA in 1987. And, at a Dental Products Panel meeting in April 1989, no recommendation was made regarding classification of these devices. When the first proposal was published in the Federal Register in September 1992, again an FDA advisory panel had not recommended a classification for these implants. In February 1993, six years after it could have been done, the Panel finally recommended the reclassification of the condylar and fossa prostheses into class III. Even now, the manufacturers will have 2 1/2 years to submit pre-market safety and effectiveness data, and will be allowed to continue marketing their devices in the meantime. "It is inconceivable ... that the situation has not begun to be remedied until now" (Public Citizen, Letter to Dockets Management Branch, FDA, 4/15/94).

- Effective August 1993, the **Device Tracking Regulation** program requires manufacturers to establish systems to track jaw implants. The manufacturer must be able to notify the recipient, within 10 working days, of a problem with a device. Tracking must continue for the life of the device or the life of the patient.
- On the congressional front, report language was included in the Senate Appropriations bill for the 1994 NIDR budget urging this agency to increase funding for TMJ research. We feel strongly that the hearing, along with The TMJ Association's testimony presented last April before the committee, was instrumental in this important success.
- Finally, thanks to the media attention given to the implant disaster, many people are now aware of the serious risks associated with implants and are able to obtain some sort of control over their situations.

Conclusion

TMJ implants were claimed to be a "cure" for TMJ sufferers. Yet, for many, the result has been a never-ending nightmare. This "Great American Medical Disaster," as one scientist called it, should motivate all of us to demand accountability and responsible action from our professional providers, governmental agencies, and everyone who contributed to this disaster.

As TMJ implant patients ourselves who have talked with thousands of other implant recipients, we fully understand the dilemma faced by people with TMJ disorders — with or without implants. The TMJ Association is doing everything possible to help implant patients by communicating with medical professionals in various fields and helping to synthesize the information we receive from patients so that experts can begin to assess the extent of the damage caused by TMJ implants. Since what is happening to TMJ implant patients is in the infant stage of scientific research we, the patients, with the help of scientists, are literally the ones who will ultimately put the pieces of the puzzle together to find out what is happening to people with TMJ implants, why it is happening, and what can be done to stop it.

At this point, the most valuable thing we can offer you is the truth. This truth must empower you and your loved ones to become advocates and demand medical care and attention which you rightly deserve. Many people have told us they are more capable of learning to live with their situations once they learned the truth and had their own experiences and problems acknowledged for the first time. This acknowledgement has reinforced a belief in themselves and has given them back their self-respect and self-esteem. They now know they were not wrong, and they are not alone. Many feel as though they are taking control of their lives. These people are getting involved in helping themselves as well as others.

Knowing the truth also gives us the courage to question our professional providers and treatment modalities. You are not just a TMJ patient. You are a human being, and you are entitled to the dignity every human being deserves. You have the right to express your opinion about the way you have been treated, receive answers to questions you have, and expect honesty and respect from your professional providers. We can now make informed decisions for ourselves, which makes us responsible for our own treatment and future. Armed with the truth, professionals cannot keep raising our expectations that, with each surgical procedure, "we'll just go in and you'll be all right." We now know they don't have the answers, and we don't have the answers, but maybe we can now enter into a relationship based on honesty and mutual responsibility and accountability for our health care decisions.

As we hear daily from patients who tell us, "We did not do this to ourselves. It was done to us." It is now up to us to ensure that this is never done to us or anyone else again. And it is our responsibility to support one another in our quest for good health care and research. The TMJ Association is in the process of developing support networks through which you can exchange information about treatment, helpful mechanisms for pain management, and perhaps find a doctor.

We're all in this together — patients, medical/dental professionals, as well as scientists. And we all have a vested interest in working together to achieve the best health care possible and improved quality of life for every TMJ patient in this country.