

# THE *TMJ* ASSOCIATION, LTD.

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April 14, 1994

Congressman Edolphus Towns, Chairman  
Committee on Government Operations  
Subcommittee on Human Resources and  
Intergovernmental Relations  
B-372 Rayburn House Office Building  
Washington, DC 20515-6143

The Honorable Congressman Towns:

I am writing as the President of The TMJ Association, an organization representing people suffering from temporomandibular joint disorders. The Congressional hearing held by your committee June 4, 1992, on these disorders and risks of implants brought this tragedy to the attention of the nation and gave legitimacy to our plight. It was clear at the hearing that the patients were in a health care emergency situation; however, the response of the governmental agencies responsible for action in this area did not indicate they understood.

To this day, there has not been one grant funded to investigate the state of health of the implant recipients, or even an attempt been made toward biomechanical or materials research to meet the desperate needs of the implant recipients for total joint prosthetic devices. The FDA is only now considering requesting safety and efficacy data on the two "grandfathered" devices on the market. Clearly, we are not pleased with their responses.

It is apparent that there is only bureaucratic communication between agencies and institutes, not an intense intellectual brainstorming quest or information sharing. This lack of coordinated and collaborative efforts between the various government agencies will only keep this disorder in the dark ages. Patients are desperate for action; unfortunately, government agencies have not appreciated the urgency of this situation nor acted upon it. It is now clear that this disorder must be addressed at the Health and Human Services level. This disorder needs the expertise of scientists at the Agency for Health Care Policy and Research, the Centers for Disease Control, the Food and Drug Administration, and pertinent institutes of the NIH.

The NIH TMD Workshop will no doubt show there is much more unknown and uncertain than known and certain regarding all aspects of TMJ disorders. An RFA and long-term commitment to temporomandibular disorder funding is needed, and this funding should come from the various agencies and institutes.

The following are our Recommendations for Improving the Quality of Health Care of TMJ Patients in the United States. We are also enclosing testimony The TMJ Association presented before the Blue Ribbon Panel on Envisioning the Future of the NIDR Intramural Research Program in January 1993, outlining our recommendations for improving scientific research on TMD.

Sincerely yours,

Terrie Cowley  
President

cc: National Institute of Dental Research  
National Institute for Arthritis and Musculoskeletal Disorders  
Agency for Health Care Policy and Research

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## **Recommendations for Improving the Quality of Health Care of TMJ Patients in the United States**

### **Introduction**

Health care for temporomandibular joint disorders in the United States is literally in a state of emergency. Controversy abounds, from definition to diagnostic and treatment modalities. Several decades of haphazard treatments based on anecdotal information rather than science has finally yielded its tragic product -- millions of broken people whose lives have been destroyed in every way imaginable.

The TMJ Association, since 1986, has been promoting awareness of TMJ disorders among the public and professionals; providing information and support for sufferers and their families; and encouraging the scientific community to research the causes of temporomandibular joint disorders and develop safe and effective treatments for the disorder. From years of listening to TMJ victims and what has happened to them as a result of a lack of science, we have gained insight into ways the current TMJ dilemma can be changed.

Our recommendations to hasten the scientific and governmental processes that will begin to improve the quality of life of the TMJ sufferers of this country are as follows:

### **Center for Disease Control**

We request the CDC to investigate this epidemic. All possible causes and contributing factors of TMJ disorders, in addition to prevalence and distribution, should be investigated. Further, they should investigate the distribution of treatment modalities, including implants, by various factors such as geographic location, and the relationship between insurance coverage and types of TMJ treatments.

### **Agency for Health Care Policy and Research**

We recommend that the Agency for Health Care Policy and Research undertake an investigation of the relative merits of current diagnostic and treatment modalities for TMJ disorders, the incidence and types of side effects, and the costs for clinical treatment modalities. We also ask that they assess the economic impact this disorder has on the health care delivery system, the individual suffering this disorder (including time lost from work), and the family.

## **National Institutes of Health**

We ask that the National Institutes of Health undertake an "urgent care" approach to investigate the basic biomedical factors leading to temporomandibular joint and muscle type problems. We ask that they undertake the development of new technological approaches to TMJ disorders, including new materials/devices for reconstruction and revision procedures of the jaw joint.

## **Food & Drug Administration**

We applaud Commissioner Kessler's singular and courageous leadership on a variety of issues, but we beg him to attend to the needs of the TMJ population of this country.

**PUT TMD ON THE FAST TRACK!** Step up the investigation on the safety and efficacy of all TMJ prosthetic devices, both on and off the market. Thousands of people are in need of revision procedures because of the damage caused by failed devices, and daily people are put into the position of needing a total joint replacement due to trauma, such as an automobile accident.

Establish an 800 number so that people who have suffered from the effects of TMJ implants or who are considering them for implantation can get unbiased information. Establish a linked recording system for TMJ complaints so that every TMJ complaint reported by a patient or professional provider can be cross checked. Establish a standing oversight committee consisting of high-level program managers from the relevant federal agencies as well as members of the patient and provider communities, to evaluate these complaints and recommend an appropriate and timely course of action.

## **Office of Inspector General**

We request that the Inspector General submit a comprehensive report on the impact that TMJ treatments have had on the American public over the last two decades, including surgery and implants. We ask that this office establish the extent of this impact, with or without treatment, the costs involved, and costs of adverse side effects. We also ask that they assess the role professionals have played in policing this activity and ensuring quality of care.

In addition, this report should include recommendations on measures that should be taken to protect the public now and in the future.

## **Office of Assistant Secretary of Health**

We ask the Assistant Secretary for Health to initiate proactive collaboration among the agencies rather than allow the less effective and slower pattern of isolated categorical approaches to continue. This includes a consensus, research, and development agenda. Time is of the essence in arresting the general TMJ disorder, and even more so in addressing the health care needs of the implant victims.

## **Secretary of the Department of Health and Human Services**

We ask that the Secretary of HHS appoint an independent scientific task force to set the agenda for basic and clinical research, consensus, and development agenda, specifically for TMJ disorders. Representatives from the NIH, CDC, AHCPR, and FDA should be included. Within three to six months, this task force will provide guidelines or advisories to the medical and dental professionals stating the optimally known conservative and intermediary measures for treating TMJ disorders. These should be made available to every dental and medical professional. Concurrently, there should be a campaign to broadly inform the public regarding the reality of TMJ diagnosis and treatment. Presently, there are no standards of care. By this time next year, the professional and public sectors should know the basics of TMJ treatment.

HHS should disseminate adequate warnings, by way of a media campaign, to implant patients and those who have had implants removed regarding follow-up.

We request that HHS develop a national database of patients to use for epidemiological and clinical research on the craniofacial and systemic pathology caused by TMJ patients.

We further request that Secretary Shalala use all facilities, authorities, and influence to help establish a fund for medical monitoring and treatment for people injured by TMJ implants. Government authorities have permitted the manufacture and sale of devices that have caused harm and government authorities have permitted practitioners to provide treatments that have caused direct harm to patients: therefore, there is clear governmental responsibility to help make things right.

### **Summary**

We have focused on the areas where government can contribute practically to the improvement of the current dismal state of health care for the millions of people of this country suffering from TMJ disorders.

We will address in more detail the specific responsibilities of the health care professionals in the future. For now, it is sufficient to say that, considering the numerous non-dental aspects of temporomandibular joint disorders, it is imperative that this disorder be a part of medical health care reform. In addition, we ask that the American Dental Association and the many specialty dental associations step forward and take proactive steps to protect TMJ patients from further harm. They have all taken oaths to FIRST, DO NO HARM. Much harm has been done. We ask that they please do no more harm and step forward to do everything in their power to help clean up this mess.