

**National Academy of Medicine Meeting on TMD;  
From Research Discoveries to Clinical Treatment**

Washington D.C., January 29, 2019

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Thank you for the opportunity to address this National Academies Panel on TMD. I've been asked to describe my hopes for the study, and they are:

- 1<sup>st</sup> that you evaluate this problem in a truly objective and unbiased manner; and
- 2<sup>nd</sup> that from your studies you will develop a comprehensive plan, including recommendations for implementation – a plan that will result in a future in which TMD patients could trust they will receive efficacious, rigorously validated, precisely tailored treatments by well-educated and well-trained highly skilled clinical practitioners – in other words, revolutionize the current system.

Over the past 3 decades there have been a number of meetings, conferences, a technology assessment workshop, and a Congressional hearing. Some meetings focused on the science of TMD which revealed a dismal lack of research. Other meetings focused on TMD treatments revealing that there was no consensus on which TMD problems should be treated, when and how. In fact, there was and continues to be controversy on just “*what is TMD?*” Efficacy of treatments is unknown because most are not evaluated in long-term studies and virtually none subjected to randomized controlled clinical trials.

A most drastic treatment is a TM joint implant which is designed to replace one or more parts of the joint. In 1990, the FDA issued a Class 1 recall on a material to replace the joint disc because it worked through the skulls into the brains of patients. I went to Congress on this issue which triggered an oversight committee investigation in 1992 which revealed that no animal, clinical, bioengineering or biocompatibility studies were conducted on this or other TMJ implants. Around 2000, the FDA approved total joint devices, components which were screwed into the skull and mandible. In 2007 we asked the Senate HELP Committee to request a General Accountability study on how these devices got approved. FDA said that they did not hold the small manufacturers to the same standards they hold large ones, that they felt they didn't need *both* clinical and bioengineering data. Since clinical data was non-existent, they chose bioengineering but later state that was inadequate. In 2011, the FDA ordered TMJ device manufactures to conduct a post-market surveillance study after a Med-Watch analysis found 52% of implant devices had to be explanted in the first 3 years because of pain and implant problems.

Over the course of the many meetings, it was up to the patients to describe the harm they had experienced as a result of the paltry science in the field and underlying treatments. The TMD patients viewed each meeting or event with the same desperate hope that the information revealed would be sufficiently compelling that it would trigger the “ah ha moment” when everyone would see TMD for what it was, a major health care problem in urgent need to be addressed – urgent being the operative word here.

So back to HOPE, my charge. We desperately, once again hope that the outcome of this Study will indeed be the real turning point in “*changing the face of TMJ*,” the motto of our Association.

Fortunately, there has been some progress upon which to build. The TMJ Association Scientific meetings and the OPPERA study have established that unlike the simplistic focus on jaws and teeth, TMD is a complex multisystem disorder with many associated medical co-morbidities. Although we cannot over emphasize the importance of these findings, they also revealed the gaps and many opportunities that exist for cross-Institute collaborations to bring the already existing scientific and clinical expertise in other complex conditions to TMD. It is evident that applications of modern of science can indeed guide the future research and treatment of TMD, *just given the will to do so*.

The TMJ Patient-Led Round Table project brought all stake holders in the TMD ecosystem to the table so that everyone’s views, especially the patients could be heard and respected – with all working together to develop solutions to the TMD issues with the HOPE of improving the health care of the patients. The initial intent of the Roundtable was to determine which patients would improve or not with implants. In planning the project, it was clear that it would be necessary to look more broadly at many essential elements. Was the state of scientific knowledge of TMD sufficient to answer such questions? Did the published patient reported outcomes data match outcomes important to the patients? Did professional organizations develop evidence based guidelines and treatment protocols and did members adhere to those, and were they patient centered?

We presented the results of two years of research at our May 11<sup>th</sup> meeting which has been distributed to the panel. We recently developed Next Steps which include several new working groups. One group will focus on the TM joint, the physiology, mechanics and pathology. TMJ devices and outcomes will be compared with other orthopedic devices. We’re excited about moving into unexplored territory with questions related to the effects of surgical procedures and the particulation and migration of implant materials in an area ¼ inch from the brain. And, importantly, we will look at state of regenerative research in this area for future TM joint replacements.

Another group will focus on ethical issues. An example, the ethics of what has evolved to be an informal standard of care from growth of dental groups proclaiming their treatment successes – treatments without scientific evidence and have the potential to cause harm. Other important issues are: revisiting consent for TMD treatments, patient abandonment, and professional codes of ethics.

Another group will examine insurance practices. Questions related to the impact on TMD care based on what is covered by insurance and what is not. If insurance companies pay for treatments lacking scientific evidence, could they be contributing to the cause or exacerbation of TMD in certain patients? Would data from insurance companies provide

information on TMD treatment outcomes, but especially the overall health of the TMJ patient?

Another group will develop a plan for identifying all the medical disciplines necessary to include in building the optimal treatment model for TMD patients. A patient in the Round Table put it this way, *“the current system (for lack of a better word) for treating TMD is broken and patients are falling through the huge gap between dentistry and medicine; abandoned and alone, and it is in this no man’s land that patients find themselves”*.

Now, I have also been asked by the Committee to tell of my experiences with TMD. 33 years ago I started The TMJ Association following my TMJ surgery because my dentist wouldn’t even clean my teeth until my jaw was stabilized. Until that surgery, I had no pain and my jaw functioned just fine. This surgery changed my life and not for the better, The surgery triggered years of relentless overall jaw and body pain, jaw dysfunction, excruciating hyperacusis, and years of recovery from the brain injury during the surgery. It was after the surgery that I learned how little was really known about the jaw joint, the most complex joint in the body, the implant that I received, and the resulting problems. It was then that I began meeting and hearing from other TMJ patients far worse off than I and that compelled me to do something about this.

To my knowledge, we are the only TMD advocacy organization in the world. We are frequently asked to start a branch in other countries of the world, the latest - Mongolia. Our website reach is global having heard from people in more than 135 countries with a monthly visiting rate of 85,000 individuals. We also respond to hundreds of phone calls, emails and social media posts. We have a group of volunteer patients who administrate our social media page “The TMJ Café”. Our Website has the most comprehensive information on TMD and we deliver a monthly electronic Newsletter to over 45,000 people.

My years of TMD blur into several areas but the one that consumes me is patients. They are suffering not only from their condition but the dehumanizing actions and attitudes of dentists, physicians, family members, coworkers, friends who cannot understand what “this TMD thing” is and why they don’t get better. When harmed they feel betrayal from the people they sought help from and trusted to “do no harm.” This distrust permeates many aspects of their lives. I see those endless emails that begin or end with the words, please help! I hear of the financial burdens, the bankruptcies, divorces, about the stresses on their loved ones and the guilt the patients feel. They tell of their daily decision to either eat or talk because they can’t do both; the desperation in their voices when they ask us for help after endless treatments which have only lead to more pain and suffering. And yes, deaths and suicides. Margaret’s sister in Pittsburgh called to tell us that Margaret died after her 62<sup>nd</sup> jaw surgery and 11<sup>th</sup> set of implants. She was 41 years old. And on October 10<sup>th</sup> at the end of the day I thought I’d make one more call to the patient who emailed me the Friday before. A man answered and I asked to talk to Patty. He said, “She’s not here.

Who is this?" I said, "Terrie from TMJ." He said, "She's dead." I said "but she emailed me on Friday, when did she die?" He said, "Saturday." I asked, "How?" He said, "She shot herself." The rest of the conversation was a blur but he ended by saying, "She had over 38 surgeries and couldn't take it anymore. There will be no obituary, no funeral. The past 10 years we haven't had one person in this house. We never went out with another couple. We couldn't because Patty couldn't."

This leads me to my other unending quest. That is, who do I turn to for help to change all of this? Through this journey we have had incredible people who have lent their moral support, encouragement, and strategic guidance that led us to where we are today. And we are eternally grateful to them. There are two people I must thank now, the man sitting behind me, my husband. He has supported me all these years in every way and as a highly respected scientist he organized all of our scientific meetings. Our lives would be so much different if I had not had the surgery and begun The TMJ association. The other person is Deanne Clare who has been my right hand for the past 22 years and is the glue that holds us all together.

Thank you for inviting me to address you.