



TMJA's Sixth Scientific Meeting: A Paradigm Shift

The TMJA held its 6th international scientific conference June 5-7, at the Federation of Societies for Experimental Biology Conference Center in Bethesda, MD.

The topic: *Comorbid Chronic Pain Conditions—Mechanism, Diagnosis and Treatments*—followed up on the Association’s scientific meeting of 2008, which initially explored the topic of comorbidities (conditions that occur together more often than chance can explain). In the interim, there has been further evidence that TMD patients often experience other chronic pain conditions, including endometriosis, fibromyalgia, chronic fatigue syndrome, migraine and chronic headaches, irritable bowel syndrome, chronic pelvic pain, vulvodynia, and interstitial cystitis.

The meeting was a resounding confirmation that there must be some underlying mechanism that links the conditions in question, and that the answer may lie in the nervous system.

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2011—A Year We’re Proud of and Our Plans for 2012

This issue of the Communiqué recapitulates some of our best stories for the year: new research, new findings and new initiatives that reflect what we have been fighting for all these years—efforts we are beginning to see pay off!

A Paradigm Shift. We’ve argued for some time that Temporomandibular Disorders (TMD) are not just about teeth and jaws, but represent a family of painful disorders that can co-occur and interact with other painful conditions in the body, such as chronic fatigue syndrome, fibromyalgia, chronic headache, endometriosis, irritable bowel syndrome, and vulvodynia, to name a few. These are all complex conditions influenced by genes, sex, age and behavioral and environmental triggers. See the story on TMJA’s sixth scientific meeting.

OPPERA Act One. Biggest research news of the year was the publication of eight papers on TMD as a special supplement to the November issue of the *Journal of Pain* (see **OPPERA: A Game Changer** article). The investigators described these papers as only “Act One,” anticipating even more exciting findings to come as the data mounts and continues to be analyzed.

An Alliance of Friends. TMJA joined forces with the Chronic Fatigue and Immune Dysfunction Syndrome Association of America and the Endometriosis and National Vulvodynia Associations to form The Chronic Pain Research Alliance (CPRA) to advocate for research on these conditions as well as on Chronic Headache, Fibromyalgia, Interstitial Cystitis and Irritable Bowel Syndrome. Not only do these conditions primarily or predominantly affect women, they often occur together. If you have one, you are apt to get another or others. In May 2010, CPRA launched a **Campaign to End Chronic Pain in Women** on Capitol Hill to a standing room only crowd of legislators and staff. We showed a video and distributed a White Paper detailing the physical, psychological and financial impact of these conditions, the lamentable lack of research on them and the consequent cost of ineffective and even harmful treatments in the absence of quality science. You can view the video and read the White Paper on the website: www.EndWomensPain.org. *continued on page 7*

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The TMJ Communiqué

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FDA Orders TMJ Implant Postmarket Surveillance

On February 7th The TMJ Association received a call from Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health, of the Food and Drug Administration (FDA) advising us of the FDA's action on TMJ implant devices. Terrie Cowley, President of The TMJ Association, had met with Dr. Shuren in July 2010 and discussed device issues that TMJ implant patients brought to our attention.

Dr. Shuren sent us the press release announcement ordering three manufacturers of temporomandibular joint implants to conduct postmarket surveillance studies to determine the length of time before the implants are removed or replaced due to pain or other reasons. The TMJA continues to closely monitor this action and we'll keep you updated. ♦

Demanding the Best Science!

For years The TMJ Association has kept the needs of the TMJ patients on the radar screen of Congress. We want the best science this country has to offer for these devastating conditions and we are fortunate to have the support of members of the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee, responsible for funding the National Institutes of Health (NIH). We have garnered their support through personal contacts with staff and elected officials, by reporting regularly to them on the state of research on Temporomandibular Disorders and letting them know what we, the patients, need. In our advocacy efforts we are fortunate to have the volunteered advice and guidance of Peter Reinecke, former Chief-of-Staff to Senator Tom Harkin, Chairman of the Subcommittee.

2012 SENATE REPORT LANGUAGE FOR TMJ DISORDERS:

National Institute of Dental and Craniofacial Research

Temporomandibular Joint (TMJ) Disorders.—The Committee encourages the National Institute of Dental and Craniofacial Research (NIDCR) to collaborate with other Institutes and Centers (ICs) regarding the etiology and pathogenesis of TMJ disorders as well as the co-morbid chronic pain conditions and disorders that solely or predominantly affect women. In particular, NIDCR should work with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to develop research opportunities in the area of joint pain. Examples of topics that need more exploration include: a basic understanding of the kinematics and biomechanics of TMJ Disorders as they relate to normal jaw function and in disease; the development of biomarkers in bone, muscle and cartilage that are predictive of temporomandibular disease progression; the interactions of the TMJ musculoskeletal system with the nervous system; and the development of non-invasive measures of TMJ bone structure, growth, degradation and repair. The recent scientific meeting of The TMJ Association, co-sponsored by NIDCR and other ICs, concluded that there needs to be a shift in research toward a systematic exploration of common underlying root causes. The Committee strongly urges National Institutes of Health (NIH) to heed the recommendations from this meeting, which have the potential to accelerate scientific progress not just in TMJ Disorders but in the other coexisting conditions.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Temporomandibular Joint (TMJ) Disorders.—Many people who have TMJ Disorders suffer from conditions that routinely affect other joints in the body, such as trauma and arthritis.

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Institute of Medicine: Pain Report

The TMJA joined consumers, health professionals, advocates, and media on June 29 in Washington D.C. for the Institute of Medicine (IOM) press conference and the release of the executive summary and full report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. This event attracted considerable media attention to the 116 million Americans who experience chronic painful conditions and its high economic toll, costing the nation up to \$635 billion annually. *AP, CNN, Reuters, Time, US News & World Report* and many others covered this story.

The IOM Report was in response to a provision in the Patient Protection and Affordable Care Act of 2010 (President Obama's Healthcare plan). It called for the IOM, one of the National Academies of Science, to explore the public health significance of pain in the US. The IOM convened a Committee to develop the report and provide recommendations for improving pain care.

Terrie Cowley, President of the TMJA, provided testimony and answered questions from IOM Committee members for 45 minutes at the first of several public meetings held around the country to hear what the public had to say about pain research, treatment and care. Terrie was quoted four times in the IOM report and TMD was included in Chapter 2: *Pain as a Public Health Challenge*.

Following the IOM event, the Chronic Pain Research Alliance (CPRA) held a press conference that included a statement from 32 organizations including the TMJA. CPRA members called upon the IOM to "seize this historic opportunity" to help the millions of afflicted American women suffering from prevalent, and all too often neglected chronic pain disorders. In a letter thanking the IOM Committee for its work, the TMJA along with fellow CPRA members, stated that the recommendations laid out a clear path toward improvements in pain research, care, education and treatment with the potential of relieving the pain of TMJ patients and the millions of other Americans living with chronic pain. The CPRA updated its 2010 white paper for this occasion. We invite you to read it on: www.EndWomensPain.org.

Because the Preface of the IOM report is such an eloquent statement of the issues and experiences of the Committee Chair, Philip A. Pizzo, M.D., Dean of the School of Medicine, Stanford University School of Medicine and Vice-Chair, Noreen M. Clark, Ph.D., Director of the Center for Managing Chronic Disease at the University of Michigan as well as their vision for the future, we quote the following excerpts:

“Protection from and relief of pain and suffering are a fundamental feature of the human contract we make as parents, partners, children, family, friends, and community members, as well as a cardinal underpinning of the art and science of healing. Pain is part of the human condition; at some point, for short or long periods of time, we all experience pain and suffer its consequences. While pain can serve as a warning to protect us from further harm, it also can contribute to severe and even relentless suffering, surpassing its underlying causes to become a disease in its own domains and dimensions. We all may share common accountings of pain, but in reality, our experiences with pain are deeply personal, filtered through the lens of our unique biology, the society and community in which we were born and live, the personalities and styles of coping we have developed, and the manner in which our life journey has been enjoined with health and disease...”

“...While we came to this study with our own expectations, we have recognized as a consequence of our shared efforts that the magnitude of the pain suffered by individuals and the associated costs constitute a crisis for America, both human and economic. We recognize further that approaching pain at both the individual and the broader population levels will require a transformation in how Americans think and act individually and collectively regarding pain and suffering. We believe this transformation represents a moral and national imperative...” ♦

OPPERA: A Game Changer

The Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) study is the long-range comprehensive study of 3,200 volunteers 18 to 44 years old who were free of TMD at the outset but some of whom developed TMD in the course of the years of the study. There is also a subset of patients who had already been diagnosed with TMD who are being followed. Now we are excited to report that the first papers analyzing the wealth of data that has accumulated have just been published as a supplement to the November issue of the *Journal of Pain*.

The papers nail down in no uncertain terms the complexity of TM Disorders and what factors may make some people more susceptible. The key findings are:

1. In women, the risk for chronic TMD increases between the ages of 18 and 44, the range evaluated in the study. In young men (ages 18-44), age was unrelated to TMD incidence.
2. Unlike other chronic pain conditions, chronic TMD incidence does not correlate with low socioeconomic status.
3. Chronic TMD seems to be associated with alterations in some parts of the nervous system that control pain perception.
4. TMD patients frequently experience many more chronic pain conditions, such as lower back pain, headaches, and fibromyalgia. Evidence of abnormal jaw function associated with teeth grinding and clenching was also observed.

The findings will go far to eliminate the stigma patients experience when they seek care from healthcare providers who will become educated about Temporomandibular Disorders as a result of these studies. It will be a wake-up call to the dental community to re-evaluate the ethics and scientific bases for current practices.

Dr. William Maixner, the Director of the Center for Neurosensory Disorders at the University of North Carolina, and a member of TMJ Association's Scientific Advisory Board, is the Principal Investigator of this multimillion dollar study which was funded by the National Institute of Dental and Craniofacial Research (NIDCR). If you have internet access you may listen to the National Institutes of Health radio clip and hear him describe the findings along with NIDCR grant administrator Dr. John Kusiak by visiting: www.nih.gov/news/radio/nov2011/20111110NIDCR-TMJD.htm.

Dr. Samuel Dworkin, Guest Editor of the journal special issue, provided comments and a summary of the eight papers for our e-newsletter, *TMJ News Bites*, and we appreciate his help. You can read this on our website at: www.tmj.org/site/pdf/OPPERA_S_Dworkin.pdf or contact us if you'd like a hard copy mailed to you.

As an organization that has long advocated for scientific research to understand Temporomandibular Disorders in all their complexity and develop treatments that work and don't harm patients, we congratulate Dr. Maixner and his colleagues for conducting this elegant study. We are grateful also to the National Institute of Dental and Craniofacial Research for supporting the study in every way. On behalf of the millions of TMD patients, thank you! ♦

TMJ Implant Patient Communication Center

In light of the recent FDA Postmarket Surveillance announcement concerning TMJ implants (see article on page 2) and the growing number of concerns and questions we are receiving from the implant patient community, the TMJA will be launching a TMJ Implant Patient Communication Center section on our website in January 2012. The Center will provide a place for TMJ implant patients to share experiences and concerns as well as ask questions of fellow TMJ implant patients. This will also be a place where those who are doing well can offer support and coping skills to those in need. We also welcome those considering a TMJ implant device. Stay tuned for more details in the coming weeks. ♦

Botox's Effect on the Jaw Joint

Dr. Susan Herring and her colleagues presented research findings at the 2011 International Association for Dental Research (IADR) meeting and Dr. Herring prepared the following lay summary for our readers. Dr. Herring received her Ph.D. in Anatomy from the University of Chicago, IL. She is a Professor of Othodontics at the University of Washington. Dr. Herring and her colleagues study the biomechanics of normal function to growth processes of the skull and cranial muscles of animals.

Mandibular Loading and Bone Quality Following Injection of Botulinum Neurotoxin Type A in the Masseter Muscle

Rafferty K., Liu Z-J., Ye W., Slamati A., Gross T., Herring S.,

Oral Presentation at the 89th General Session & Exhibition of the IADR, San Diego, CA, March 19, 2011

Botox works by inactivating the nerve endings that cause muscles to contract, thus paralyzing the muscle. The paralysis usually lasts for a few months, although the muscles may remain visibly small for longer times. Some providers feel that treating the jaw muscles of TMD patients with Botox could be helpful even if the muscles are not in spasm. For example, it has been argued that the jaw muscles place loads on the Temporomandibular Joint, and if these loads are temporarily removed, the joint might have a chance to recover.

One possible worry about unloading joints, however, is that bone strength might be lost from the unloaded area, similar to astronauts losing bone strength while in space. Because bone is rebuilt slowly, the jaw joint might actually lose needed structure. To test this idea an animal study was carried out. In 40 adult female rabbits, one masseter muscle was injected with either saline or Botox, with a dose adjusted to be comparable to a human dose. The muscles and mandible were examined 4 weeks later, when the masseter would still have been affected by the Botox, and 12 weeks later, when the muscle was expected to have recovered.

The rabbits did not experience problems in chewing and seemed comfortable. As expected, the Botox-injected masseter muscles were atrophied at 4 weeks. They were larger at 12 weeks but still statistically smaller than the other side. From this and other evidence, the experiment was successful in unloading the jaw. However, this unloading did have adverse effects on bone content, especially for the mandibular condyle (the mandibular part of the TMJ) on the Botox-injected side. On average, 40% of bone area was lost from the head of the mandibular condyle 4 weeks after injection, and after 12 weeks the bone of the condylar head was still depleted by 22%. The bone loss occurred in the porous bone in the internal region of the condyle, which has limited capacity to regenerate once it is lost.

In conclusion, Botox in the masseter caused an osteoporotic condition in the TMJ of rabbits, raising some concern that this treatment might not be healthy for the joint in the long term. ♦

Free TMJA Brochure

We have just updated our brochure, *A Resource Guide for Temporomandibular Disorders*, which is now available as a downloadable PDF on our website. You may also request hard copies by mail. We encourage you to share this brochure with your friends, health care professionals and family as it is a great educational resource for everyone. Our thanks to Drs. Daniel Laskin, Sharon Gordon, and William Maixner and to Joan Wilentz and our volunteers for their contributions to this brochure. Last but not least, we thank Purdue Pharma L.P. for making the production of this publication possible through an education grant of \$5,000 and the National Institute of Dental Craniofacial Research, grant #R13DE019079. ♦

A Gift That Keeps Giving

It is an opportune time to let you know that we greatly appreciate your help in our ongoing efforts to improve the quality of health care and lives of everyone affected by Temporomandibular Disorders. Know that the many ways you contribute to changing the face of TMJ are greatly appreciated! In this season of gift giving we ask you to consider supporting The TMJ Association. We have accomplished much but there is much more to do and we cannot do it without your help.

And remember 100% of your gift is tax deductible! ♦



Can Drugs Help TMD Patients?

No drugs specifically targeted to treat TMD have ever been approved by the Food and Drug Administration. Yet many drugs—analgesics, non-steroidal anti-inflammatories (NSAIDs), opioids, muscle relaxants and others—are commonly prescribed. How effective are they? To answer that, two dentist-Ph.D. researchers, Drs. Sharon Gordon and Raymond Dionne, and a graduate research fellow, Archana Viswanath, combed the medical literature published over five decades to see which drugs showed some measure of effectiveness in reducing pain and/or improving function in TMD patients. In gathering the data, Dr. Gordon, associate professor in the Department of Oral and Maxillofacial Surgery at University of Maryland School of Dentistry, and Dr. Dionne, with a Ph.D. in pharmacology and 25 years of clinical research at the National Institute of Dental and Craniofacial Research, selected only those articles where the level of evidence was relatively strong, such as randomized controlled clinical trials (as opposed to case studies, for example).

They have now provided the TMJA with a summary of their results and a table categorizing the type of drug, the level of evidence and whether or not it demonstrated effectiveness. We have this information posted on our website at: www.tmj.org/site/pdf/TMD_Drug_Treatment_Evidence.pdf. If you do not have internet access and would like to receive a hard copy by mail, please call or write the TMJA.

The good news is that drugs in several categories proved effective. But the investigators conclude that more research is needed, especially in light of the finding that many TMD patients experience comorbid painful conditions, necessitating new drug discoveries. ♦

Major Ideas for Pain Research

A Direct Result of The TMJ Association's 6th Scientific Meeting

The National Institutes of Health (NIH) Common Fund supports exceptionally innovative research programs that are inherently high-risk but have the potential for high payoff. We have just learned that among the Common Fund's list of ideas submitted to the community for comment, are three that focus on pain research. They are:

1. Biomarkers for Chronic Pain Using Functional Brain Connectivity
2. Venture Fund for Research and Development of New Medications to Treat Chronic Pain
3. And one that directly includes research on Temporomandibular Disorders: Transformative Classification for Stimulating Research, Improving Diagnosis, and Personalizing Treatment

This last idea is a direct result of the Sixth Scientific Meeting of The TMJ Association. Twelve percent of the US population suffers from TMD. That amounts to approximately 36 million people suffering from mild TMJ discomfort to severe and unrelenting pain. The majority also suffer from other pain conditions. This project would greatly accelerate scientific progress on TMD but more importantly, bring understanding to the condition and with it, the hope for treatments that work and don't cause harm. ♦

Patient Comments

"I am 28 years old and have been consistently suffering from Temporomandibular Disorders for 4 years with little to no relief. I have been to 3 specialists for treatments, including 2 different mouth appliances, and consistent visits to doctors. I have purchased a TENS machine, special pillows, different suggested vitamins, been on several muscle relaxers, and take NSAIDs on a regular basis. I am super depressed and I spend most of my free time sleeping because I feel exhausted all day long. It even hurts to smile. I have distanced myself from family and friends because no one knows how to deal with someone who hurts all the time. My doctors have given up on me and my family doesn't know what to do anymore. This is not a normal life. Where do I go from here?" Ashley

"I remember when my painful suffering began back in 1988 and all the doctors thought I was stressed or imagining the horrible pain. After all the years of suffering and all that I've been through I feel victimized and distrustful of doctors when it comes to TMD. With expensive medication, I deal with it and focus on the "good" things in my life and try not to dwell on the pain and the hand that fate has dealt my life. I am most grateful for your wonderful, informational and support organization. It's soothing to know I am supported by others who totally understand." Carol ♦

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Institute of Medicine Input. The TMJ Association testified at the first public hearing in Washington DC of the Institute of Medicine Committee which drafted the **Report on Pain in America**. We gave examples of TMD patients' experiences to emphasize the importance of research and the need for safe and effective treatments.

NIH Action. As a result of our 5th and 6th scientific meetings, the **NIH has formed a trans-NIH committee to address TMD and comorbid conditions. A scientific meeting is planned for 2012.**

* * *

You tell us that when you talk about new scientific findings about TMJ to your healthcare provider—your family doctor, internal medicine specialist or other medical professional, he or she pleads ignorance. At the same time, most dentists continue to treat TMJ problems the same way they have been doing for decades. It is as though research scientists live in one world and healthcare providers in another.

It is time for a change. We need to spread the word that TMDs are a complex family of conditions, often occurring in common with other painful conditions. We intend to explore all avenues of communication to make sure that the medical and dental communities are educated about the jaw joint and their role in treating TM Disorders. **Patients deserve to receive the benefits of scientific discoveries in a timely manner.**

You can help. To that end we will develop informational materials you can use to engage more actively with your healthcare professionals as well as enable you to make informed healthcare decisions.

* * *

The first bioengineering conference on the TMJ was held in 2006. The report from that meeting stated: "The Temporomandibular joint is one of the least studied joints in the body, despite the large patient population and the significant morbidity related to a plethora of TMJ disorders."

We aim to change that so that the Temporomandibular joint receives the same quality of scientific research as other joints in the body. We need fundamental knowledge of how the joint is designed to do the work it does so that safe and effective treatments can be developed when things go wrong. We have five strategies for 2012:

1. We will participate in a **TM joint project** under the auspices of the Cornell University Department of Biomedical Engineering. More about that when the project is set to begin.
2. Following FDA approval of clinical protocols to be developed by TMJ device manufacturers, we will convene a **Round Table** consisting of all interested parties: the manufacturers, representatives of FDA, NIH, The TMJ Association, and others. The intent of the Round Table is to provide an open exchange of ideas and build a body of data on implant performance, patient satisfaction, adverse events and complications. This information will empower patients to make better healthcare decisions as well as guide the design of future devices to yield optimal patient outcomes.
3. We will develop a **TMJ Implant Patient Communication Center** within our website for the exchange of information among TMJ implant patients so that they, and we, can be better informed about their needs and experiences.
4. We will convene a **Bioengineering Advisory Council** to obtain the professional expertise necessary as we move forward with TM joint initiatives.
5. We will encourage and facilitate interaction among the pertinent government agencies to **evaluate the state-of-science of the Temporomandibular joint** and recommend directions for future research.

I hope you're as excited as we are about our future plans. We look forward to another productive year with your support and participation.

Terrie Cowley

President & Co-Founder ♦

TMJA Receives Outstanding Public Advocacy Award

The Friends of the National Institute of Dental and Craniofacial Research (FNIDCR), a non-profit organization, is a broad-based coalition of individuals, institutions and corporations who understand the critical importance of dental, oral and craniofacial research to the health and well-being of people in the U.S. and globally.

This year the FNIDCR awarded the 2011 Outstanding Public Advocacy Award to The TMJ Association. Terrie Cowley will accept the award on behalf of the TMJA. Members of the TMJA Board and staff will attend the FNIDCR event on December 6, 2011 at the National Press Club in Washington D.C. ♦

Does Estrogen Diminish TMJ Pain?

The typical profile of patients with TMD is of women in their child-bearing years. This means that they undergo fluctuating levels of estrogen in the bloodstream, depending upon the phase of the menstrual cycle, with estrogen levels highest near ovulation.

Researchers studying an experimental TMJ pain model in rats have noted that pain in these female animals appears to be reduced in the pre-ovulatory phase when estrogen levels are highest.

Now, a team of scientists, headed by Dr. Philip Kramer at Texas A&M Health Science Center, Baylor College of Dentistry, Dallas, TX, have screened animals' nerve tissue that supplies sensation to the TM joint area to see whether there are specific genes which are turned on in response to stimulation by estrogen. (There are estrogen receptors in the nerve tissue of interest.) Their article cites two genes in particular which code for proteins that can reduce pain signals from the joint area and which are more active (gene expression is increased) in response to estrogen. In continuing studies the researchers are manipulating expression of these genes to see how changes in gene activity affect the animals' pain behavior and whether this is, in fact, the mechanism by which estrogen affects responses to pain. ♦

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Instead of looking for clues in the end organ—the jaw, the intestine, the reproductive tissues—the focus should be on how the nervous system has changed because of chronic pain, becoming hypersensitive and dysfunctional. This is a paradigm shift and attendees agreed it should inform how future research should be conducted.

The meeting was attended by scientists with unusually diverse research expertise in chronic pain disorders and other research areas. The significance of the meeting was underscored by the participation of seven National Institutes of Health Institutes, Office, and Center Directors; the leaders of four patient advocacy organizations comprising the Chronic Pain Research Alliance; and numerous NIH Program Staff. Following the formal presentations, attendees developed recommendations that will be disseminated to the research community.

Now that the pain issue has been brought to the forefront, the TMJA will encourage research to explore the interactions between the TM joint and the nervous system that give rise to chronic pain. ♦

Demanding The Best Science!

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Therefore, the Committee calls on NIAMS to collaborate with NIDCR to study the jaw anatomy and physiology and the complex neural, endocrine and immune system interactions that orchestrate jaw function and trigger jaw joint pathology. NIAMS should integrate findings from studies of the structure, mechanical function, metabolism and blood flow of bone, joints and muscles with studies of central and peripheral neural pathways, as well as the endocrine, paracrine and cytokine factors that impact upon craniofacial structures as a means to understanding the underlying causes of pain and dysfunction. The Committee also urges NIAMS to support comparative studies of the TMJ with other joints that could document similarities and differences at the clinical and molecular levels. ♦