



North American Neuromodulation Society

NEWSLETTER

President's Message

Advances in Store for NANS and the Industry



We are living in turbulent times. Big changes have happened since my last message in this newsletter. The collapse of financial institutions in the United States and around the world has

recolored the way many of us think about the immediate future. The first 100 days of the Obama Administration have been eventful and, in some cases, controversial. NANS itself is at a crossroads as a professional society as well. Our rapid growth has led us to reconsider our image, our mission, and our strategic future. This summer, the board of directors will convene to lay out a strategy to guide NANS's direction for years and decades to come. Your input as members of this vital and growing society is more important than ever. Please share your vision of our society's future with me at henderj@stanford.edu.

On April 28, President Obama addressed the National Academy of Sciences in a historic speech (watch the video at www.youtube.com/watch?v=k5-MgZD5IMc or read the transcript at www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-National-Academy-of-Sciences-Annual-Meeting) pledging unprecedented levels of support for research in basic sciences, with the specific inclusion of medical technologies as well as the promise of tax credits for companies that invest heavily in research and development. This is wonderful news for the future of medicine in the United States, and neuro-modulation will be among the fields most directly affected. NANS must take a leading role in helping shape this emerging policy by improving neuromodulation technologies, broadening patient access, and directing funding toward the most promising research. We will be closely following these developments and fully engaged in the ongoing debate.

Through the hard work of the NANS Research and Education Committee, a uniform policy on training requirements for spinal cord stimulation devices

has been prepared, evaluated by the membership of our society, and accepted for publication in *Neuromodulation* this summer. This landmark document sets out minimum requirements for the performance of spinal cord stimulation procedures. We believe this policy will lay the groundwork for improving standards of care throughout the United States, ultimately to the benefit of our patients.

Each of us interacts to varying degrees with industry in our day-to-day work with neuromodulation technologies. Many of you are familiar with the Advanced Medical Technology Association (AdvaMed) and its efforts to define ethical interactions between industry and medical practitioners who use its products. I urge all of you to read the revised code of ethics that is published online at www.advamed.org/MemberPortal/About/code. This recently updated statement lays out firm guidelines for medical device companies to follow when interacting with their customers. Although these guidelines are, for the most part, sound and logical, there are some that may actually impede rather than enhance the efficient and ethical delivery of neuromodulation technology to patients. For example, many of us work closely with manufacturers' representatives when implanting and managing neuromodulatory devices. These representatives, in turn, work with many physicians in the community and are in an excellent position to help facilitate networking between practitioners, which can lead to improved collaboration and, therefore, better patient care. Bringing these practitioners together over a modest meal to discuss areas of expertise and interest is a valuable function once provided by industry with, I believe, a very legitimate goal (improved patient care) and little if any attempt at undue influence. However, such meetings (previously classified as "business meals") will no longer be supported under the new policy. To quote from the AdvaMed Web site, ***"Is a general discussion to build good business relationships a 'business presentation' such that it is appropriate to provide a business meal?"***

No. A business presentation may include "substantial discussions related to medical technology development and improvement of medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes."

Unfortunately, "development of general goodwill and business relationships," as applied to medical practice, is equivalent to the building of referral networks, bringing together practitioners with complementary expertise for the betterment of patient care. In this case, the increased restrictiveness of the new policy will directly affect one of the most helpful roles played by neuromodulation companies: to help serve as the "glue" that connects networks of physicians

continued on page 6

In This Issue

President's Message

Advances in Store for NANS and the Industry 1

Feature

Spinal Cord Neurostimulation: A Review of Reimbursement and Time Spent 2

Article of Interest

Recent Article Discusses Effects of SCS on a Parkinson's Disease Mouse Model 3

NANS 12th Annual Meeting Highlights 4

NTAC Update 5

Members in the News

Michael Oh, MD 6

Meetings of Interest 7



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Feature

Spinal Cord Neurostimulation: A Review of Reimbursement and Time Spent

Alan Miller, MD; Ashwini Sharan, MD

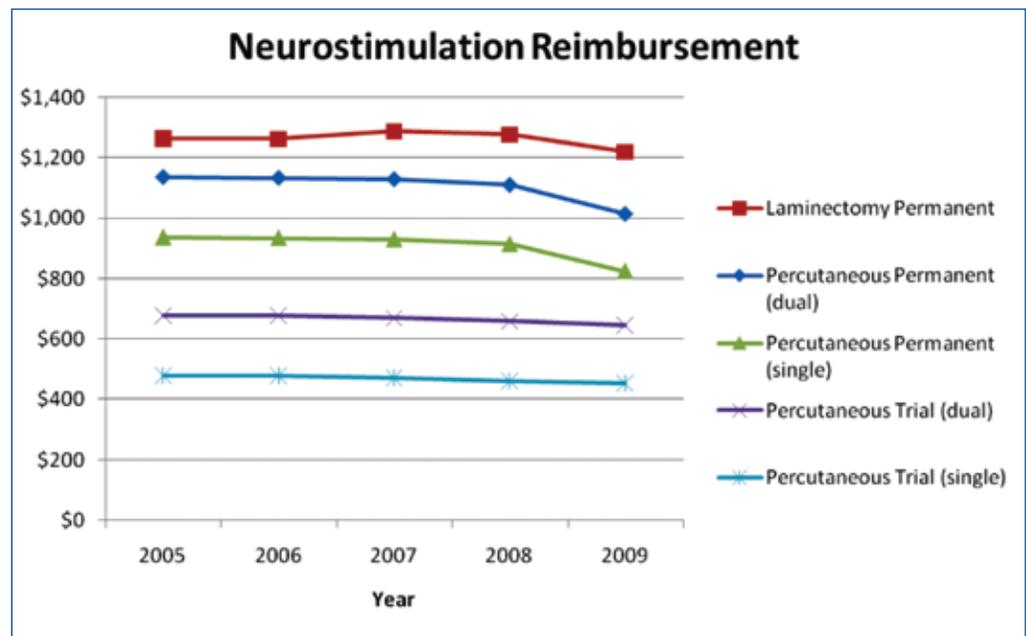
Implantation of percutaneous and laminectomy lead spinal cord stimulators has risen in popularity (see “Advancements in Spinal-Cord Stimulation Technology” in Fall 2008 issue of *NANS Newsletter*). As this technology becomes more widely accepted among practitioners and patient populations, a benefit for physicians is relatively healthy reimbursement for the time spent educating the patient and family, performing the procedure, and in necessary follow-up visits. In this article, we examine the differences in reimbursement for percutaneous and laminectomy spinal cord stimulation (SCS) and how it has changed over the past few years.

a decrease in payment for the implanted pulse generator placement (CPT 63685) from \$452 to \$370.

As of January 1, 2009, CMS announced changes decreasing the global surgery period from 90 days to 10 days for insertion of epidural leads (CPT 63650), insertion or replacement of an IPG (CPT 63685), and revision or removal of an IPG (CPT 63688). CMS will now reimburse for complications, postoperative visits, pain management, and miscellaneous services (dressing changes, etc.) after 10 days instead of 90 days.

Though percutaneous lead placement can be difficult and time consuming on complicated

Figure 1



Data in **Figure 1**, collected from the Centers for Medicare & Medicaid Services (CMS), are a sum of the national carrier billing codes for lead placement (CPT 63650/63655), implanted pulse generator (IPG) placement (CPT 63685), and electronic analysis of IPG (CPT 95972). Dual lead implants are assumed to pay 50% for the second lead. They are assumed to have been done in a hospital (facility) setting.

As is noted, reimbursement has remained fairly stable over the past 5 years, though there has been a slow decline of 7.9% from 2005 to 2009. The largest drop was from 2008 to 2009 for which the majority is related to those who perform permanent implantations with

cases; this still represents an appropriately reimbursed procedure with respect to time when practical factors are taken into account. Depending on the difficulty of the patient, experience of the implanter, and ease of obtaining capture of the patient’s area of pain, typical one- to two-lead percutaneous trials can range from 30 to 90 minutes of physician time. The at-home education by premade informational materials commonly provided by stimulation companies helps reduce patient questions, while the company representative responsible for assisting the physician in programming can often field programming-related phone calls from the patient in the posttrial period.

continued on page 3

Recent Article Discusses Effects of SCS on a Parkinson's Disease Mouse Model

Reviewed by Steven Falowski

Fuentes R, Petersson P, Siesser WB, Caron MG, Nicoletis MAL. Spinal cord stimulation restores locomotion in animal models of Parkinson's disease. *Science*. 2009;323(5921):1578–82.

Deep-brain stimulation (DBS) is an effective modality for the treatment of motor symptoms in Parkinson's disease (PD) and has become a valuable complement to pharmacological treatment allowing a reduction of L-DOPA dosage. However, a disadvantage of DBS is the requirement of a highly invasive surgical procedure, as well as the dependence on accurate targeting. Fuentes et al. set out to identify a less invasive method that could have similar beneficial effects. His hypothesis was based on studies in both animals and epilepsy patients that demonstrate a decrease in aberrant neural activity with peripheral nerve stimulation, which leads to a decrease in seizure frequency and duration.^{1–6}

A series of experiments were designed to create a mouse model of PD. It is well known that the symptoms of PD become clinically apparent after degeneration of 60%–70% of the dopaminergic neurons of the substantia nigra pars compacta, which results in a 30%–50% reduction of striatal dopamine levels.^{7,8} The first set of experiments included mice that had two intraperitoneal injections of a tyrosine hydroxylase inhibitor alpha-methyl-para-tyrosine, which achieved dopamine depletion below the levels observed in PD patients. These mice demonstrated decreased locomotion and signs of bradykinesia.

The effect of dorsal column stimulation (DCS) was next evaluated in the mice before and after acute dopamine depletion. DCS was achieved by chronic implantation of custom-made flat bipolar platinum electrodes positioned epidurally above the

dorsal columns of the spinal cord at the upper thoracic level. High-frequency stimulation (300 Hz) showed the greatest effects on locomotion, with more than 26 times the amount of locomotion in the stimulation period compared to the prestimulation period in the dopamine-depleted group. DCS had a smaller effect using lower stimulation frequencies. In contrast, control experiments were not effective. Alleviation of bradykinesia was also observed in the dopamine-depleted mice with initiation of spinal cord stimulation (SCS).

Another series of experiments were designed to evaluate the effects of SCS in combination with L-DOPA treatment. Locomotion thresholds were tested by gradually increasing dopamine levels through repeated L-DOPA injections. In the group receiving only L-DOPA injections, locomotion typically first occurred after the fifth injection. When L-DOPA treatment was combined with DCS, the same amount of locomotion was displayed after the second injection, demonstrating that one-fifth of the L-DOPA total dose was enough to produce equivalent locomotion to L-DOPA alone.

In summary, it was found that dorsal column SCS restores locomotion, reduces bradykinesia, and alters motor cortex and striatal neuronal activity in a PD mouse model. Although the mechanism of these effects are unknown, they may exert its effects by activating large cortical areas, increasing the cortical and thalamic input to the striatum. This may, in turn, promote the depolarization and, consequently, facilitate the activation of striatal projection neurons. DCS might become an efficient and less in-

vasive alternative for treatment of PD in the future and should be investigated further. **N**

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continued from page 2

Including scheduling for a psychological evaluation, this can usually be accomplished in 2–3 office visits prior to implantation and a single office visit shortly after implantation for removal of the lead(s) and evaluation for permanent placement.

For laminectomy implanters who commonly are referred patients after a successful percutaneous trial, many of the patients' questions have already been answered as they have already experienced stimulation, and

only discussion on procedural techniques, recovery times, and battery placement typically need to be addressed, which usually does not require more than a single office visit. Surgical operating room times are typically 1.5–2.5 hours. Follow-up after the procedure typically involves local wound inspection, care shortly after the procedure, and possibly another visit later in the future for assessment of longer term efficacy.

With CMS's budget neutrality, the pool of money to reimburse physicians is fixed. Increases or decreases to reimbursement for specific CPT codes are made to account for increasing or decreasing use each year to keep the net change in overall reimbursement at zero. Hopefully, in the future, neurostimulation will continue to fairly reimburse physicians for the time and effort spent treating patients. **N**

NANS 12th Annual

December 4–7, 2008
Mandalay Bay Resort and Casino
Las Vegas, NV



Chris Chavez, Neuromodulation Division, St. Jude Medical, receives Diamond-Level Sponsor Award from NANS Past President Joshua Prager, MD.



Senior Vice President and President of Medtronic's Neuromodulation Division Richard Kuntz, MD, receives Diamond-Level Sponsor Award from NANS Past President Joshua Prager, MD.



NANS President-Elect Marshall Bedder, MD, presents President Michael Onuscheck of Boston Scientific's Neuromodulation Division with a Diamond-Level Sponsor Award for their support of the 2008 NANS 12th Annual Meeting.



From left: Senior Vice President and President of Medtronic's Neuromodulation Division Richard Kuntz, MD; NANS President-Elect Marshall Bedder, MD; Medtronic Vice President of Strategy and Portfolio Management Tom Morizio; and NANS Past President Joshua Prager, MD.

Meeting Highlights

The NANS 12th Annual Meeting was held at the Mandalay Bay Resort and Casino in Las Vegas, NV, December 4–7, 2008. Cochaired by NANS President Jaimie Henderson, MD; NANS Immediate Past President Joshua Prager, MD; and NANS Vice President Ali Rezai, MD, the meeting was a resounding success.

The theme of the annual meeting, *Neuromodulation 2008—New Frontiers*, was chosen because of the increasing advances in technology and clinical applications arising out of this rapidly growing field. By focusing on this theme, we were able to assemble an outstanding faculty representing many different backgrounds and specialties. Together, they delivered a program focused on state-of-the-art applications of current and emerging neuromodulation technology. Sessions were grouped around specific themes, including spinal cord and peripheral-nerve stimulation for chronic pain, brain stimulation, clinical trial updates, novel modalities, intrathecal therapies, ethical issues, and reimbursement. Individual sessions were invaluable opportunities for physicians, nurses, physician assistants (PAs), and industry representatives to obtain greater knowledge of and insight into this field.

Highlights of the meeting included keynote lectures “Mechanisms of Neurostimulation: Distributed Effects in Neural Circuits,” by Karl Deisseroth, MD, and “Stem Cells and Neuromodulation,” by Mary Csete, MD. Two open-paper sessions, which included 13 paper presentations, covered the themes of brain stimulation and neurostimulation. Day 2 also included a well-attended breakfast symposium titled “Neuromodulation Therapies: Behavioral Evaluation and Patient Selection for Better Outcomes: Moving from Simple Considerations to Sophisticated Problems.”

Our Diamond-Level industry sponsors provided support for two non-CME-track luncheons during the meeting as well. Boston Scientific sponsored “The Physics Behind Neuromodulation,” presented by Michael Stanton-Hicks, MD, on Day 1, while on Day 2, St. Jude Medical sponsored “Spinal Cord Stimulation: How to Have More Control and Reduce Your Risk,” a panel presentation and discussion with Timothy

Deer, MD; Eugene Mironer, MD; Robert Levy, MD; and Kenneth Alo, MD.

Additional meeting highlights included two faculty-conducted preconference workshops covering spinal cord stimulation (SCS). One workshop provided hands-on practical instruction on SCS implantation for fellows, while the second was billed as a primer for nurse practitioners, PAs, and other medical staff who have contact and involvement with neuromodulation patients. Both were well attended and received excellent reviews.

For the 12th Annual Meeting, NANS also received a record number of abstracts and poster submissions. The best abstracts were selected for presentation, while a dedicated area within the exhibit hall displayed 40 of the best posters submitted. The submissions receiving the highest scores, as judged by the NANS Executive Committee, received awards.

During one of the general sessions on Day 2, NANS members elected four new at-large members to the board of directors. The new board members are David Caraway, MD; Robert Levy, MD; Ashwini Sharan, MD; and Konstantin Slavin, MD.

The meeting’s exhibit hall was supported by 15 exhibitors, including device manufacturers, journals, and publishers. Attendees enjoyed the interactive displays and demonstrations along with an Internet café and coffee bar.

Attendance at the 12th Annual Meeting was the largest, to date, in NANS’s 15-year history. More than 640 attendees were present for the 3-day meeting, along with an additional 202 official exhibitors and sponsor representatives. Of the registered attendees, more than 42% were active NANS members.

It is truly exciting to be involved in this rapidly expanding field, and the future promises to hold even more cutting-edge and fundamental advances. The NANS Board of Directors would like to thank all of our members, sponsors, and supporters who helped make the 2008 meeting such a success. Please don’t forget to save the dates for our 13th Annual Meeting, December 3–6, 2009, at the Encore at Wynn Las Vegas in Las Vegas, NV. **N**

NTAC Update

Joshua P. Prager, MD MS, NTAC chair; David Kloth, MD, NTAC vice chair; Jaimie M. Henderson, MD, NANS representative to NTAC; Eric Hauth, NTAC executive director



As the Neuromodulation Therapy Access Coalition (NTAC) approaches the end of our second full year of operation and the proverbial “end of the beginning,” much has been accomplished, and more exciting and important work lies ahead.

Since its inception, NTAC has grown from its 7 founding organizations to 11 organizations, a significant growth in less than 2 years. Numbers, however, do not tell the full story. More important, membership now includes the two leading national pain advocacy organizations—the American Pain Foundation (APF; www.painfoundation.org) and the National Pain Foundation (NPF; www.nationalpainfoundation.org). Membership by these important organizations speaks loudly to NTAC’s core mission to advocate for appropriate patient access to neuromodulation therapies. In addition to APF and NPF, two additional manufacturers of implantable drug infusion pumps have recently joined NTAC. We are very pleased to welcome both Codman/DePuy (www.codman.com) and InSet (www.insetinc.com) as NTAC’s newest members.

NANS and NTAC share the goal of advancing the field of neuromodulation and patient access to neuromodulation therapies.

As a broad-based national coalition, NTAC is active on several fronts. We continue the fight against the use of flawed low-back and chronic-pain guidelines developed by the American College of Occupational and Environmental Medicine (ACOEM) and their use by state workers’ compensation programs. In particular, we are deeply involved in advocacy in New York, where draft low-back guidelines, issued by the state (but not implemented) and largely based on ACOEM, could significantly erode patient care among the state’s injured workers. Though our work continues and the verdict is far from certain, our coalition and its members have been working extremely hard to ensure that this outcome does not occur.

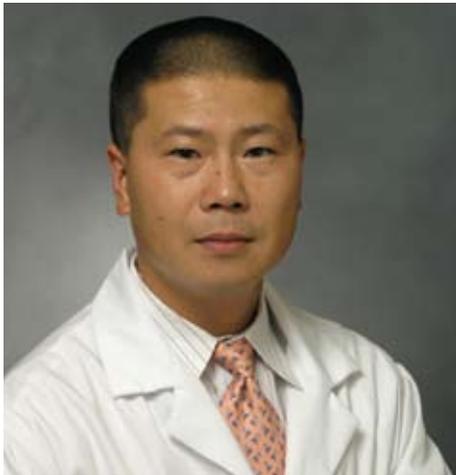
For those NANS members living and practicing in the state of New York, please contact NTAC Executive Director Eric Hauth (eric@neuromodulationaccess) to learn more about this critical effort and what you can do to help.

In Washington State—known for its opposition to neuro-

modulation therapies—we are actively advocating that the

continued on page 7

Michael Oh, MD



In March 2009, Michael Oh, MD, was among the West Virginia University (WVU) neurosurgeons featured by ABC's *Nightline* as a part of its in-depth coverage of WVU's pioneering clinical trial for deep brain stimulation of the lateral hypothalamus for those with severe refractory obesity. The WVU neurosurgery team first performed this procedure in November 2007 and again in February 2009. The *Nightline* feature focused on this most recent surgery, highlighting the patient, her preparations, and postsurgical recovery.

Dr. Oh received his medical degree from the University of Southern California in Los Angeles, CA, and completed his residency training at Allegheny General Hospital in Pittsburgh, PA, where he received the

resident research award in 2001 and 2002. This was followed by a clinical fellowship in Stereotactic and Functional Neurosurgery at the University of Toronto, ON, Canada. Dr. Oh is presently director of the Institute of Computer-Assisted Neurosurgery as well as codirector of both the Center for Movement Disorders and Spasticity and Division of Neuromodulation at Allegheny General Hospital.

Dr. Oh's dedication to the advancement of the field is made evident by his commitment to research and education. He holds several adjunct positions that include residency program assistant director, as well as faculty positions at both the Robotics Institute at Carnegie Mellon University and the Department of Neurosurgery at WVU. His clinical interests include tumors, chronic pain, movement disorders, spinal-cord injury, computer-assisted neurosurgery, robotics, deep brain stimulation, and tic douloureux.

Education remains paramount to Dr. Oh. He has instructed several courses including those on spinal cord stimulation, trigeminal neuralgia, and complex skull-base surgery. He has also served as faculty in the Goodman oral board review courses. His contributions to resident education are made evident by his contributions as chairperson on the Young Neurosurgeons Committee of the American Association of Neurological Surgeons (AANS), where he initiated the AANS Top Gun honor in April 2006. He recently

received a Leadership Scholarship award from the AANS in 2009.

Dr. Oh began making contributions to neurosurgery with his commitment to research, especially in the fields of deep brain stimulation and image-guided/computer-assisted neurosurgery. His early work involved establishing the efficacy, as well as durability, of spinal cord stimulation and deep brain stimulation. Most noteworthy is his work published in *Neurosurgery* on hardware complications related to deep brain stimulation, as well as his technical report in the *Journal of Neuromodulation* on peripheral nerve stimulation for the treatment of occipital neuralgia and transformed migraine. His later work was grounded in his interest in the brain-machine interface. Recently, he published articles on the use of robotic hands in neurosurgical procedures, assessments of the positional accuracy of neurosurgeons, and the viability of surgical skill assessments using a virtual reality simulator.

In addition to his recent appearance on *Nightline*, Dr. Oh has authored several chapters, presented numerous posters, and given many oral presentations pertaining to the various areas of his research. He has authored and delivered presentations on this topic, including a pilot study in 2002.

Dr. Oh has chosen a life of commitment and excellence to advance the field of neurosurgery. Future neurosurgeons will benefit from his contributions. **N**

Call for Member News

If you or a colleague has recently been honored with an award or other recognition in the field of neuromodulation, the *NANS Newsletter* would be happy to feature these distinctions. Please submit a description of approximately 400 words detailing the

recognition received and biographical information on the recipient, including professional and educational background, to Editor in Chief Ashwini Sharan at ashwini.sharan@jefferson.edu. **N**

Advances in Store for NANS and the Industry *continued from page 1*

caring for patients in need of advanced treatment modalities. Life will go on, but I believe this is an example of a policy that may have effects opposite of those intended. As NANS continues to author and comment on various policies, we must be constantly vigilant to avoid similar errors to the best of our ability.

As in any field of medicine, it is incumbent upon practitioners of neuro-modulation to behave ethically—but what does this mean, exactly? There are some obvious examples most of us would recog-

nize as unethical—misleading patients for personal gain, billing for services that were never rendered, performing research without consent—but what about more subtle examples? No policy can cover all situations, and no policy should. We need to always be aware of our own personal ethics and responsibility to our patients and to the larger world of neuromodulation.

Looking to the future, NANS's leadership is excited about the direction our society is taking. The annual meeting being planned for December will once again provide for an

exciting program in a vibrant location. I look forward to updating you on progress in the fall newsletter. **N**



Jaimie M. Henderson, MD
NANS President

Call for Article Submissions

NANS is seeking submissions for upcoming issues. Suggested article topics include

- local and regional challenges
- new technology
- treatments, surgery, and therapy options for various disorders
- clinical trials
- ethical dilemmas and controversy in the field
- members in the news
- tips and strategies
- case studies
- informed consent
- determining risks and benefits
- conflicts of interest
- best practices in neuromodulation
- respecting the rights of patients and families.

Contributions should be 500–1,500 words in length. To submit an article or to suggest topics for upcoming issues, please contact Editor in Chief Ashwini Sharan at ashwini.sharan@jefferson.edu.



Meetings of Interest

NANS members are encouraged to attend these meetings of interest presented by other pain, spine, and neurology associations. Please see the following contacts for more information.

June

1st Annual John C. Oakley Memorial Pain and Neuromodulation Scientific Meeting

National Pain Foundation
June 5
Billings, MT
www.nationalpainfoundation.org

ASIPP 11th Annual Meeting

American Society of Interventional Pain Physicians
June 27–30
Washington, DC
www.asipp.org

July

ISIS 17th Annual Scientific Meeting

International Spine Intervention Society
July 22–25
Toronto, ON, Canada
www.spinalinjection.com

September

9th World Congress of the International Neuromodulation Society

International Neuromodulation Society
September 12–18
Seoul, South Korea
www.neuromodulation.com

October

ISPN 37th Annual Meeting

International Society for Pediatric Neurosurgery
October 11–15
Los Angeles, CA
www.ispneurosurgery.org

2009 ASA Annual Meeting

American Society of Anesthesiologists
October 17–21
New Orleans, LA
www.asahq.org

CNS 2009 Annual Meeting

Congress of Neurological Surgeons
October 24–29
New Orleans, LA
www.neurosurgeon.org

November

NASS 24th Annual Meeting

North American Spine Society
November 10–14
San Francisco, CA
www.spine.org

2009 Annual Pain Medicine Meeting and Workshops

American Society of Regional Anesthesia and Pain Medicine
November 19–22
San Antonio, TX
www.asra.com

NTAC Update *continued from page 5*

state workers' compensation program reverse a long-standing non-coverage policy for spinal cord stimulation (SCS) and adopt a coverage policy for SCS consistent with policies in the other 49 states, Medicare's long-standing national coverage decision, private-payer coverage throughout the country, and the recent positive determination in the United Kingdom.

With our coalition partners, we are also engaged in promoting fundamental changes to the state's Health Technology Assessment program, which has had a questionable track record of stakeholder input, transparency, and evidence reviews. We fully anticipate this program will evaluate SCS in the future, and it is imperative for SCS, and all future therapies evaluated by the state, that this process work as intended by the legislature, not simply as a cost-cutting measure cloaked in evidence-based medicine.

NANS members in the state of Washington are advised to stay tuned for updates on this evolving effort in the weeks and months to come.

Looking ahead, we are focused on an expansive redevelopment of NTAC's Web site, offering physicians, patient advocates, policy makers, and payers a full array of information to inform coverage decisions and empower actions that ensure patient access.

We are extremely grateful to NANS and all our coalition partners for the continued commitment to the work of NTAC, and we look forward to an even greater impact in the months and years ahead. **N**



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Save the Date!

13th NANS Annual Meeting

December 3–6, 2009

*Encore at Wynn Las Vegas
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