



North American Neuromodulation Society

NEWSLETTER

President's Message

A New Era for Neuromodulation



It is my great pleasure to greet all of our members in this, my first message as President of NANS. I am humbled by the opportunity to follow in the footsteps of Dr. Joshua P. Prager

and all of our distinguished past presidents, one of whom we sadly lost recently. Dr. Sam Hassenbusch was a true innovator in neuro-modulation, as well as a tireless advocate for fair reimbursement and recognition of the special role neuromodulatory therapies play in the treatment of patients with chronic pain. He had been battling brain cancer for some time, trying many different experimental therapies (leading him to describe himself as the "6-foot lab rat"). He will be dearly missed. Dr. Richard B. North, Dr. Prager, and Dr. Michael Stanton-Hicks, all past presidents of NANS, have teamed up to write a brief obituary for Sam on page 6, which I urge you all to read.

As a field, neuromodulation is simultaneously facing its most exciting period of growth and expansion and its biggest challenges in terms of therapeutic acceptance. We are now entering an era when implantable devices are becoming commonplace, accompanied by the dawning realization of the expenses involved, not only with implantation, but also with ongoing maintenance. Although a growing number of studies are convincingly demonstrating the cost-effectiveness of neuromodulation techniques with comparison to noninterventional or medical management in a number of disorders, insurers are increasingly questioning the up-front expenditures involved. Of course, this is basic human nature. Lenders make their livings on the premise that small monthly payments over a long period, despite overall higher costs, are more palatable than spending that one big chunk at the beginning. And, unfortunately, insurance companies are building up steam to make the situation even worse

for our patients. As detailed in the Update from the Neuromodulation Therapy Access Coalition (NTAC) on page 2, a set of recently published guidelines may be used by insurers to deny patient access to many of the therapies we use on a daily basis.

Luckily, we have a lot of help on our side in the battle to convince payers to do the right thing. NTAC, local advocacy groups, the Neurotechnology Industry Organization (NIO), and our own newly-formed advocacy committee are all joining the fight on local, state, and national levels. But each of us has to do his or her part as well. We need to educate referring physicians and insurance companies about the efficacy of neuromodulation therapies. We need to select patients appropriately, ensuring that payers see satisfied clients and positive outcomes. We need to interact appropriately with industry, informing them about the challenges and benefits of their therapies. Whenever possible we need to seek out legislators and administrators at all levels, engage them in conversation, and present success stories and data to ensure that we will have allies in our continued struggle to maintain patient access to effective treatments. I personally traveled to Washington, DC, in mid-March with the NIO to speak with the Centers for Medicare and Medicaid Service, the Food and Drug Administration, and members of Congress regarding the exciting advances in our field and ways they can help assure that both brand-new and well-established therapies make their way to patients in need.

What will happen as the world of neuromodulation continues to expand? As more and more devices become available, at potentially increasing cost, a point may come when our deteriorating and ever-more-cost-conscious health system will not be able to support the added expenditure. What are the alternatives? Cheaper devices? Narrower indications? Abandonment of continuously delivered therapies, such as neurostimulation and continuous medication delivery, in favor of "delivered-once" therapies, such as stem

cells, gene therapy, or even a return to ablative options? These are vital questions that will play out during the next decade. However, in the near term it behooves us to advocate fiercely for the current state-of-the-art therapies for patients who would clearly benefit. I would appreciate receiving photos of any of our members interacting with legislators, governors, members of Congress, insurance company administrators, or any other advocacy effort you may be involved in. At the 2008 NANS Annual Meeting, I intend to personally recognize our members who have been fighting and lobbying for NANS and neuromodulation.

I am proud to be a part of NANS and its continued growth and proud to work with an outstanding board of directors that is stepping up admirably to the challenges. Led by President Elect Marshall Bedder, Vice President Ali Rezai, Secretary Robert

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Classified and display rates are available. Please contact NANS Senior Manager, Professional Relations Sheila Lee at 847/375-4760, fax 877/594-6704.

Members in the News

Joshua P. Prager Wins Clinical Excellence Award

Last fall at the Reflex Sympathetic Dystrophy Syndrome Association's 9th Annual Bounty of Hope Silent Auction and Fundraising Dinner in New York City, NANS Past President Joshua P. Prager, MD MS, director of the Center for Rehabilitation of Pain Syndromes (CRPS) at UCLA Medical Plaza, was the recipient of the Clinical Excellence Award.

As the keynote speaker, Dr. Prager used a Microsoft PowerPoint® presentation to graphically depict the symptoms of complex regional pain syndrome to the audience. He also described the success of the comprehensive multidisciplinary treatment program he directs at CRPS. Congratulations, Dr. Prager! **N**



Dr. Joshua P. Prager receives the Clinical Excellence Award from the Reflex Sympathetic Dystrophy Syndrome Association Executive Director Jim Broatch.

Update from the Neuromodulation Therapy Access Coalition (NTAC)

In December at the INS-NANS Joint Meeting, the NTAC Board of Directors, chaired by Joshua P. Prager, MD MS, approved a new multistate advocacy campaign to challenge the use of the American College of Occupational and Environmental Medicine's (ACOEM's) recent publications, *Low Back* and *Chronic Pain* guidelines by workers' compensation programs. Thanks to the hard work of the NTAC Policy and Advocacy Committee, this comprehensive and focused plan will help ensure continued patient access to essential interventional pain medicine.

These guidelines are deeply concerning. Specifically, the ACOEM guidelines

- recommend against approximately 50% of all low back and chronic pain tests, treatments, and therapy options despite coverage of many of these interventions by the Centers for Medicare and Medicaid Service, state Medicaid programs, and private payors
- fail to include specialty and subspecialty physicians—and their physician societies—who are experts in many of the therapies evaluated by ACOEM. Although they did provide a limited comment opportunity on the *Low Back* guidelines to American Society of Interventional Pain Physicians (ASIPP) and NANS, the final product ignored their input
- incorporate outdated evidence that distorts the assessment of many therapies; they also

omit certain high-quality, peer-reviewed studies for spinal cord neurostimulators and other interventions

- fail to adhere to ACOEM's own evidence-ranking criteria, illustrated by the large percentage (48%) of "recommended" interventions in the draft *Chronic Pain* chapter based on evidence that ACOEM itself deemed "insufficient."

Further, unlike other medical societies, ACOEM's marketing, sale, and public advocacy efforts to promote its guidelines stand in stark contrast to other established medical societies who typically develop and disseminate clinical guidelines free of charge as a public good intended to advance medical understanding and guide treatment decisions.

What is NTAC's Plan?

The coalition's strategic plans to address the significant threat posed by ACOEM's guidelines includes a multistate lobbying initiative, assessment of possible legal implications (and the possibility of future action based on this assessment), grassroots outreach to physicians throughout the country, and mobilizing both physician and patient advocates. Since the Acapulco meeting, NTAC has already hired professional lobbyists in three critical states (NY, TN, and WA) and is looking to possibly hire a fourth lobbyist where threats to neuromodulation access are greatest. The coalition has also contracted with legal

continued on page 6

Complex Spinal Cord Stimulator Configuration and Placement in a Difficult Patient: A Successful Technique

Ryan Rahhal, MD, Resident for the Department of Neurosurgery, University of Oklahoma, Norman, OK; Eric Sincoff, MD, Department of Neurosurgery, University of Oklahoma, Norman, OK; Randall Henthorn, MD, Anesthesia and Pain Medicine, University of Oklahoma, Norman, OK

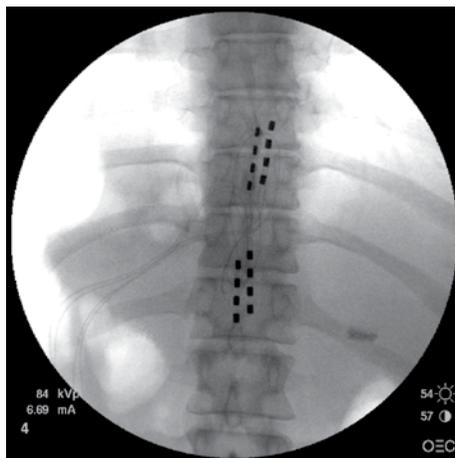


In recent years, our institution has demonstrated variable success with placement of spinal cord stimulation electrodes. Problems that have arisen have stemmed from less-than-ideal initial

laminectomy that has resulted in difficulty placing the electrodes at their planned locations. In some instances, operative time has been longer than desired because of difficulty manipulating the electrodes. We have not had this problem in recent cases, a result which we owe to better preoperative imaging and planning. In one such case with a single level (T11) laminotomy, we were able to place an eight contact lead rostrally and a four contact lead caudally, with ideal postoperative imaging and a successful clinical outcome.

The case is that of a 43-year-old female who developed left foot reflex sympathetic dystrophy (RSD) in 2000 after she had a ganglion cyst removed from the top of her left foot. She had complaints of burning pain and sensitivity to touch. On exam, she was noted to have hyperesthesias to both light touch and pin prick. She had previously been treated with a spinal cord stimulator that had to be removed because of infection. A second device was subsequently placed and then removed due to irritation and patient discomfort. She had also been treated with a morphine pump. The pump was removed after the patient underwent a gastric bypass, resulting in weight loss, and developed rib pain owing to the device rubbing against her rib. Our plan for a cord stimulator was to place a long stimulator lead superiorly and a shorter lead caudally.

Preoperative clinical assessment and planning was undertaken in the outpatient fluoroscopy suite. As is standard in our preoperative assessment, a trial percutaneous electrode placement was attempted. Because of the patient's multiple previous surgeries, the



An example of a multi-lead stimulator configuration.

wire was not able to be threaded cephalad above L2 because of scar tissue. For that reason, we decided to place a long-segment of electrodes to attempt to treat both her RSD as well as her back pain. The patient was placed prone on the table and the leads placed over her skin. The leads were manipulated to achieve a long segment encompassing the low thoracic levels as well as upper lumbar levels. We found it best to use a two-electrode configuration as described previously.

For the operation, the patient was placed prone on the Wilson frame. Her T10 interspace was localized using fluoroscopy. Localization was first undertaken by counting up from the sacrum while using live fluoroscopy with an instrument on the back in the midline. The

C-Arm was then rotated to localize in an A-P plane. Of note, we have found it very beneficial to rotate the C-Arm to about 15–20° caudally for this step. Doing this maneuver aligns the endplates of the lower thoracic and upper lumbar vertebral bodies, such that accurate counting of levels can be better achieved. Next, our leads were placed over the prepped skin in the orientation that they were to be placed in the canal. Again, a modified A-P image was taken. Only after this final planning step was taken, did we mark our incision. The remainder of the procedure entailed removing the inferior portion of the T10 lamina and a smaller superior portion of the T-11 lamina bilaterally. Once the dura was identified, the plastic semi-rigid, curved “hockey stick” was used to further develop the plane between dura and lamina. The longer lead was placed cephalad and the shorter lead caudally. Leads were tunneled and attached to the stimulator over the iliac crest in the usual manner. Fluoroscopy was again used to confirm that the leads were in the planned position. Postoperative films looked like those taken in preoperative planning. The patient's clinical outcome was successful overall. She obtained significant relief of her left foot pain. She got some relief of her back pain as well.

The experience we have gained from this case is important for a few reasons. First, the percutaneous electrode trial placement was not possible in this patient. We therefore proceeded with operative placement in attempts of covering a long segment for stimulation. An octopolar electrode was placed cephalad. In addition, a quadripolar electrode was placed caudally. Both were placed through a small laminectomy encompassing part of T10 and part of T11. Preoperative radiographic analysis allowed us to minimize exposure and operative time. The overall result was successful. **N**

Annual Meeting Highlights

Marshall Bedder, MD FRCP(C), President Elect NANS

The beautiful Acapulco Fairmont Princess Hotel was the venue for a perfect week of weather and the joint meetings of the International Neuromodulation Society (INS) and NANS December 9–12, 2007. The title of this event, *Neuromodulation: Technology at the Neural Interface*, was chosen because it defines this field of medical, bioengineering, and manufacturing endeavor, which is the fastest growing field in medicine today. The combined event focused on all aspects of neuromodulation and provided a learning tool for physicians, nurses, and bioengineers. Cochairs were Elliot S. Krames, INS President, and Joshua P. Prager, NANS President.

One of the absolute highlights of the meeting was the plenary address by Dr. C. Norman Shealy. Dr. Shealy was the pioneer of dorsal column stimulation in 1967 using intradural electrodes fashioned for him by a jeweler. He continues to remain on the cutting edge of experimental electrical stimulation. His lecture focused on his newest protocols the Five Sacred Rings: energetic circuits that specifically optimize DHEA, Neurotensin, Beta-Endorphin, Aldosterone, and markedly reduce free radicals. Perhaps down the road we will embrace these concepts as we do spinal cord stimulation today!

The meeting dedicated individual days to specific topics. Sunday started out as “brain day” with the entire day of scientific sessions devoted to neuromodulation for the brain. Discussions focused on deep brain stimulation for psychiatric disorders, movement disorders, epilepsy, and motor cortex stimulation for pain and rehabilitation. Dr. Ali Rezaei, Chairman of Functional Neurosurgery at the Cleveland Clinic, and professor Bart Nuttin of the University of Leuven, Belgium, chaired these sessions. The following day was dedicated to pain and neuromodulation with Dr. Prager chairing these sessions. Paul Meadows, President of the International Functional Electrical Society, chaired the day on functional electrical, and Dr. Magdy Hassouna from Toronto, Canada, chaired the day on stimulation of the organs (heart, gut, and bladder).

There was a non-CME track sponsored by industry including our platinum sponsors ANS, Boston Scientific, and Medtronic. Boston Scientific opened these sessions with “Advances, Physics, and Outcome Improvements in Spinal Cord Stimulation.” The following day ANS sponsored “What Physicians Need to Know to Keep Interactions with Manufacturers from Turning into Infractions” and followed with a second session on “Innovative Approaches and Provocative Debate.” Medtronic presented “The PROCESS Studies in Spinal Cord and Neuro Stimulation.” There were 45 poster presentations in addition to the oral presentation abstracts.

The following is an important study that was the subject of a press release during the meeting and is worth reviewing in this column.

Press Release: Implant Designed to Deliver Electrical Pulses to Dorsolateral Prefrontal Cortex Shows Promise in Major Depression Disorder

ACAPULCO, MEXICO (December 11, 2007)—A study presented today at the International Neuromodulation Society’s (INS) eighth world congress demonstrated promising results for the use of cortical stimulation to treat major depressive disorder (MDD). These results were presented for the first time during the year’s largest conference on neuromodulation, the alteration (or modulation) of nerve activity by delivering electrical or pharmaceutical agents directly to a target area.

Brian Harris Kopell, MD, with the department of neurosurgery, Medical College of Wisconsin, shared the outcomes from this multi-center feasibility study, which is the first to use an epidural cortical stimulation (CS) system on the dorsolateral prefrontal cortex (DLPFC). Epidural cortical stimulation delivers electrical pulses to the cortex using an electrode implanted over the protective outer layer of the brain.

“Nearly 10 percent of the U.S. population lives with major depression



A lateral skull X ray showing a two contact electrode placed on the brain via a craniotomy.

and it affects people of nearly all age groups and demographic backgrounds,” said Dr. Kopell. “This novel use of a Cortical Stimulation system takes advantage of our growing understanding of the role of brain metabolism in depression. These results are promising for MDD patients whose depression is resistant to other antidepressant treatment options.”

In this multi-center study, 12 patients with treatment-resistant MDD received investigational implantable Cortical Stimulation systems (Renova, Northstar Neuroscience, Seattle, WA) after an initial observation period. For eight weeks, patients were randomly assigned to active or sham stimulation; following this period, all patients received active stimulation. The CS system targets the left DLPFC, an area of the brain that is hypometabolic in patients with MDD, and increases glucose metabolism in this region to antidepressive effects. Using the Hamilton Depression Rating Scale (HDRS) and the Global Assessment of Function (GAF) as assessment tools, Dr. Kopell and colleagues measured the patients’ baseline and post-treatment levels of depression. The data showed that active cortical stimulation lowered patients’ levels of depression and also indicated that CS may have a treatment effect that increases over time. The study was conducted at the Medical College of Wisconsin (Milwaukee, WI), Massachusetts General Hospital (Boston, MA) and the University of Pittsburgh (Pittsburgh, PA).

According to the National Institute of Mental Health (NIMH), major depression is a serious medical illness affecting more than 20 million American adults, or approximately 9.5 percent of the adult population in a given year. Antidepressant medications and psychotherapies are commonly used to treat depressive disorders. While some patients do respond to these traditional therapies, about 10 to 20 percent of all depressed patients do not have satisfactory sustained responses. New therapies, such as cortical stimulation, offer hope for these patients.

For more information, please contact Brian Harris Kopell, MD, Assistant Professor of Neurosurgery and Psychiatry at the Medical College of Wisconsin, at bkopell@mcw.edu.

Both the cutting edge research in neuromodulation and the scientific merit of the research presented makes our annual meeting the must-attend meeting for those involved in this rapidly expanding field.

The NANS Board of Directors wishes to thank all our sponsors for sharing in our success, and we invite all current and future NANS members to join us in Las Vegas for our 12th Annual Meeting December 4–7, 2008, at the Mandalay Bay Hotel and Casino. **N**

Annual Meeting Award Winners



Incoming NANS President Dr. Jaimie M. Henderson presents a NANS Gavel Plaque to Dr. Joshua P. Prager, in recognition of his 2 years of service as NANS President.



Dr. C. Norman Shealy accepts the 2007 Lifetime Achievement Award from Dr. Joshua P. Prager.



Dr. C. Norman Shealy speaks at the 2007 INS-NANS Joint Meeting.



Members of the INS Executive Committee and the NANS Board of Directors with C. Norman Shealy.



Samuel J. Hassenbusch III, MD PhD

1954–2008

NANS President, 2001–2002

On February 25, 2008, Dr. Samuel J. Hassenbusch passed away after a long illness. All of us who have been a part of NANS (of which he was a founding member and past president) remember him fondly with respect and admiration.

Sam was born on February 6, 1954, in St. Joseph, MO. He married his high school sweetheart, Rhonda, in 1972, and together in Baltimore they began to rear three children while Sam pursued his MD and then his neurosurgical training at Johns Hopkins. He developed an interest in medical oncology, and in parallel with his residency, he obtained a PhD in pharmacology, working in chemotherapy for malignant brain tumors.

In 1988 the Hassenbusch family relocated to Cleveland, OH, where Sam became the head of the department of neurosurgery, Section of Neuro-Pharmacologic Oncology and Pain Management at the Cleveland Clinic Foundation. There he did seminal work in implantable drug delivery systems, peripheral nerve stimulation for neuropathic pain, cingulotomy, and treatment of cluster headache.

In 1993 the family moved to Houston, TX, where Sam joined the department of

neurosurgery, Division of Surgery at the University of Texas M.D. Anderson Cancer Center. He advanced quickly to professor in the department of neurosurgery. From 2005 to 2008 he was the medical director of the Physicians Referral Service at M.D. Anderson Cancer Center. In 2006 he received a joint appointment at Baylor College of Medicine.

Sam was the third president of NANS, succeeding John Oakley, MD, whom we also dearly miss. Sam was president during trying times for our nascent organization. His dedication and hard work preserved our society so that it could later flourish. His work on intrathecal therapy, including the creation of consensus panels, helped to position the therapy where it is today.

Taking on the dual challenges of reimbursement and coding, Sam represented neurosurgery and pain medicine on the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel. He was active in the American Academy of Pain Medicine (AAPM) and the American Board of Pain Medicine (ABPM). He made important contributions to the study of healthcare economics. In short, Sam was a modern Renaissance man, and he earned a host of awards, including lifetime achievement awards from AAPM and NANS in recognition of these and other contributions to our field.

In 2002 Sam appeared on a Houston television show that highlighted one of his patients, Marnie Rose, a physician with a malignant brain tumor, and he and his family subsequently became active in supporting a research fund named for her. In 2005 he had

the misfortune to find himself diagnosed with a glioblastoma. Characteristically, he orchestrated his own surgery and adjuvant therapy, referring to himself (with his typical good humor) as a “6-foot lab rat,” with the impressive result that he remained clinically free of disease for 2 years. His remarkable story was widely publicized in national media, as he bore his illness with dignity, setting an example for his peers and his patients.

Sam’s fondness for devices that modulate the nervous system also included his beloved ’68 Charger, which has rumbled from the 70s through the present, and his motorcycles, which he most recently rode in cancer benefits while sporting his post-chemotherapy “biker haircut.” His ubiquitous laptop was always active and always one step ahead of ours. We should all visit www.hassenbusch.com in Sam’s memory.

Sam was an exemplary member not only of our community but of society at large through his devotion to his family and church. All of us were privileged to see Sam and Rhonda together over the years, and many of us enjoyed seeing Jack, Jason, and Amanda grow up. Sam’s buoyant spirits and deep religious convictions have been and remain an inspiration. He succeeded in living a long life in a lamentably short time. We miss you, Sam, and will do our best to carry on in your memory and in your absence. **N**

Richard B. North, MD
Joshua P. Prager, MD MS
Michael Stanton-Hicks, MD MBBS
NANS Past Presidents

Update from the Neuromodulation Therapy Access Coalition (NTAC) *continued from page 2*

counsel and is evaluating potential legal implications from ACOEM’s approach to guidelines.

In addition, NTAC met in March to discuss broader public relations and communication to ensure that all stakeholders understand and are prepared to call for appropriate access to neuromodulation and the full range of interventional pain therapies.

Three Things You Can Do

- Take a few moments to review NTAC’s position statement on the ACOEM guidelines. You can access the position statement at www.neuromodulationaccess.org.
- Forward the position statement to your colleagues in pain medicine, emphasizing the need to understand this threat.
- Encourage your colleagues to contact Eric Hauth, NTAC Executive Director, at eric@neuromodulationaccess.org or

651/278-4238 to learn about what may be happening in their states and join our list of physician advocates. **N**

Questions or Comments?

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Call for Article Submissions

The North American Neuromodulation Society is seeking experts to submit articles for upcoming newsletters.

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.

Suggested length for newsletter articles is 500–1,500 words. To submit an article or 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 neurological associations. Please visit their Web sites for more information.

May

33rd Annual Regional Anesthesia Meeting and Workshops

American Society of Regional Anesthesia and Pain Medicine
May 1–4, Cancun, Mexico
www.asra.com

APS 27th Annual Scientific Meeting

American Pain Society
May 8–10, Tampa, FL
www.ampainsoc.org

SNS Annual Meeting

Society of Neurological Surgeons
May 18–20, Madison, WI
www.societyns.org

June

ASSFN Biennial Meeting

American Society for Stereotactic and Functional Neurosurgery
June 1–4, Vancouver, BC, Canada
www.assfn.org

NSA Annual Meeting

Neurosurgical Society of America
June 1–4, Whistler, BC, Canada
www.neurosurgicalsociety.com

ASIPP 10th Annual Meeting

American Society of Interventional Pain Physicians
June 21–25, Washington, DC
www.asipp.org

July

ISIS 16th Annual Scientific Meeting

International Spine Intervention Society
July 23–25, Las Vegas, NV
www.spinalinjection.com

September

CNS Annual Meeting

Congress of Neurological Surgeons
September 20–25, Orlando, FL
www.neurosurgeon.org

October

ISPN 36th Annual Meeting

International Society for Pediatric Neurosurgery
October 12–16, Cape Town, South Africa
www.ispneurosurgery.org

NASS 23rd Annual Meeting

North American Spine Society
October 14–18, Toronto, Canada
www.spine.org

ASA Annual Meeting

American Society of Anesthesiologists
October 18–22, Orlando, FL
www.asahq.org

November

Annual Pain Medicine Meeting and Workshops

American Society of Regional Anesthesia and Pain Medicine
November 20–23, Huntington Beach, CA
www.asra.com

December

NANS 12th Annual Meeting

North American Neuromodulation Society
December 4–7, Las Vegas, NV
www.neuromodulation.org

A New Era for Neuromodulation *continued from page 1*

Foreman, and Treasurer Dean Willis, we are reinvigorating the committee structure of NANS, and the sense of volunteerism is inspiring. The Annual Meeting Committee and Scientific Program Committee are assembling a spectacular program for the annual meeting at Mandalay Bay Hotel and Casino in Las Vegas. This meeting

promises to be the most exciting ever. Of course, we say this for every meeting, but in neuromodulation it's easy to say it and mean it, given the explosive growth of our field. There are many tasks left to do, and we need your help. Please e-mail me at henderj@stanford.edu, and we'll get you involved! **N**

Sincerely,

Jaimie M. Henderson, MD
NANS President

Next newsletter: Science and progress in neuromodulation.

Save the Date for the 2008
NANS Annual Meeting

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



NANS Newsletter Available Online

Visit www.neuromodulation.org to read current and past issues.



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