



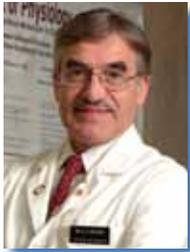
North American Neuromodulation Society

NEWSLETTER

President's Message

Enjoying Growth

Robert D. Foreman, PhD FAHA



As I reflect on the past year and anticipate exciting plans on the horizon for 2011, the word "growth" comes to mind. NANS has experienced growth in many areas during the past year, and I would like to share some of the highlights in this column.

Education

The NANS 2010 Annual Meeting enjoyed generous growth in numbers. A total of 713 people attended the meeting, not including exhibitors and their staff members, resulting in an increase of more than 100 participants from 2009. Because nearly 100 participants were students, the board anticipates future growth as these students complete their studies and join the field.

I want to express my deepest thanks and appreciation to David Caraway, MD PhD, and Joshua Prager, MD MS, who co-chaired the Annual Meeting Committee, and to Ali Rezai, MD, and Ashwini Sharan, MD, who co-chaired the Annual Scientific Committee. Their hours of hard work, imagination, and enthusiasm resulted in a program and venue that were attractive to the attendees and provided an outstanding forum to expand and deepen our scientific, clinical, and ethical knowledge of neuromodulation. I also want to thank Marty Tobin, meeting planner, and Chris Welber, executive director of NANS, for managing the many details of the meeting. The results of the attendee survey showed that most attendees felt the educational content and impact of the meeting was very good to excellent. The Spinal Cord Stimulation Workshop, under the co-directorship of Drs. Prager and Sharan, and the Neuromodulation Review Workshop, codirected by Dr. Rezai and Konstantin Slavin, MD, were both very well attended and received enthusiastic support from attendees. Of course, these improvements were also made possible by the generous

support of our three main diamond-level sponsors: Boston Scientific, Medtronic, and St. Jude Medical.

The Society awarded the NANS Lifetime Achievement Award to Michael Stanton-Hicks, MD, vice chairman of the Anesthesiology Institute at Cleveland Clinic in Cleveland, OH. His outstanding dedication to excellence, not only to NANS but also in treating chronic pain and complex regional pain syndrome, offers members a high standard to strive for in their own practices.

Diversity

Diversity is another priority for NANS. Our vision statement shares our goal to expand the breadth of membership to involve all disciplines that develop and deliver neuromodulation therapies. NANS seeks to represent the varied backgrounds of its membership through a diverse board of directors. Members of NANS helped the board achieve this part of our vision by electing Lawrence Poree, MD PhD, interventional pain management physician, and Jiande Chen, MD PhD, professor of gastroenterology at the University of Texas-Galveston, to the board of directors. In addition, we want to congratulate Drs. Levy, Slavin, and Caraway, who were re-elected to the board. The board encourages NANS members to reach out to colleagues of all disciplines who currently use neuromodulation to join our society.

Visibility

The newly redesigned NANS website and recent interactions with other societies have both provided NANS with heightened visibility. Many thanks go out to Dr. Sharan, Chris Welber, and the redesign team who developed the design and content. We are also reaching more physicians in the field by exhibiting at meetings hosted by the American Association of Neurological Surgeons (AANS), American Academy of Pain Medicine (AAPM), American Society of Interventional Pain Physicians (ASIPP), and the International Neuromodulation Society.

NANS has worked hard to raise its profile. These efforts have included collaborating with ASIPP to cosponsor a legislative session and Capitol Hill visits in Washington, DC, during the 2010 ASIPP Annual Meeting as well as a comprehensive review course and cadaver workshop on spinal cord stimulation in Memphis, TN. NANS also cooperated with AANS, AAPM, ASIPP, and International Spine Intervention Society to provide 20 potential new leaders with intensive political advocacy and public relations training at the 2010 Neuromodulation Leadership Forum, which was co-chaired by Dr. Prager and David Kloth, MD.

Advocacy

Increasing our advocacy efforts remains another priority of NANS. Our society is working hard with other societies, the government, third-party payers, and patients to maintain access to neuromodulation therapies. Drs. Kloth and Prager are working tirelessly to increase our advocacy efforts. For example, NANS is conducting a media campaign in Washington State to strongly counteract the Health Technology Assessment Program, which provided a reason for Washington State to eliminate patients' access to spinal cord stimulation for treating debilitating chronic

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NTAC Update

Spinal Cord Stimulation Guidelines Implemented in New York

David Kloth, MD, NTAC Chair

Since our last report, NTAC has continued its important work to ensure access to neuromodulation therapies through targeted efforts throughout the country.

After nearly 2½ years of advocacy, NTAC and its coalition partners are very pleased to report that state workers' compensation guidelines were implemented in New York to ensure continued access to spinal cord stimulation (SCS). NANS member Nameer Haider, MD, worked closely with NTAC and played a critical role in advocacy efforts to reverse a proposal that would have eliminated SCS as a treatment option for injured workers. Dr. Haider's efforts show that targeted, persistent advocacy can and does make a difference. NTAC continues its involvement in New York to ensure that future chronic pain guidelines fully include the expertise of interventional pain physicians and reflect the needs of injured workers with chronic pain.

As many know, the battles over access to interventional pain care continue in Washington State. Because the state deprived access in publicly funded programs to SCS and intrathecal drug delivery systems (IDDS), NTAC continues to push for needed reforms to their Health Technology Assessment (HTA) program and, eventually, a fair reevaluation of these important options for pain patients.

In late 2010, NTAC also initiated its first lobbying effort in California—a move precipitated by the possibility of workers' compensation fee schedules that would limit access to needed care, including SCS and IDDS. We look forward to reporting our progress on this effort in future issues of the newsletter.

NTAC is extremely proud to have launched the 2010 Neuromodulation Leadership Forum (NLF), which took place in early November 2010. This program was designed to provide physicians with in-depth training in media relations, messaging, and effective policy



advocacy. The 20 physicians who participated in this program represented all four of NTAC's member societies—the American Academy of Pain Medicine, American Society of Interventional Pain Physicians, International Spine Intervention Society, and NANS.

We congratulate each of the following participants for their outstanding commitment to advocacy leadership (NANS members appear in bold): J. Scott Bainbridge, MD; Lora Brown, MD; Hazmer Cassim, MD; **David Columbus, MD**; Ray D'Amours, MD; Michael DePalma, MD; Lewis Frazier, MD; George Girardi, MD; Nameer Haider, MD; David Paul Harries, MD; Leonard Kapural, MD; Michael Osborne, MD; Sanjog Pangarkar, MD; **Jason Pope, MD**; **Lawrence Poree, MD**; **Francis Riegler, MD**; **Konstantin Slavin, MD**; **Alison Stout, MD**; Ajay Wasan, MD; and Mark Steven Wallace, MD.

Finally, NTAC is working closely with our physician society members to enhance collaboration among pain physician societies, which has never been more essential in the increasingly politicized environment of pain medicine. We hope to convene a historic meeting of society leadership in the coming months to assist the core pain physician societies in building a stronger foundation for the field of pain medicine.

Together, these initiatives highlight the hard but necessary work to ensure continued access to needed therapies. We thank NANS for its invaluable leadership role in NTAC. Please do not hesitate to contact NTAC Executive Director Eric Hauth with any questions about the work of the coalition. He can be reached at eric@neuromodulationaccess.org. **N**

News and Views: Humanitarian Device Exemption for DBS in Obsessive-Compulsive Disorder Comes Under Fire

Alexander Taghva, MD

In the February 2011 issue of *Health Affairs*, Fins and colleagues¹ report on the potential for abuse of the humanitarian device exemption (HDE) granted by the US Food and Drug Administration (FDA) for the use of deep brain stimulation (DBS) in severe, treatment-refractory obsessive-compulsive disorder (OCD).¹ Although the authors do not discuss specific transgressions they believe have taken place, they make a compelling argument that the HDE for OCD, as it currently exists, has room for misuse.

The authors discuss the rationale for Congress' original introduction of the HDE pathway in 1990. Namely, it was introduced to encourage research and device development in conditions sufficiently rare that they might otherwise escape the interest of industry. The authors further argue that OCD is not an "orphan condition"—there are 400,000 to 700,000 treatment-refractory patients in the United States alone, from which 50 to 150 patients could be easily recruited for a randomized-controlled trial. Although the numbers argument is convincing, clinical trials in both the United States and Europe have yet to report on such numbers of

patients. In addition, the HDE can provide a loophole for companies with large financial interest in the therapies to piggy-back device-specific safety data onto disease-specific safety data. These data, in many cases, they claim, may not be equivalent.

Despite the above points, a counterargument may be made that the FDA still maintains more stringent standards for device approval than similar agencies in other countries. In September 2010 Medtronic received Conformité Européenne (CE) mark approval for Medtronic DBS therapy in Europe as adjunctive treatment for partial-onset seizures in adults with medically refractory epilepsy.² This therapy, however, was not approved in the United States by the FDA. The FDA requested additional data to support Medtronic's premarket approval (PMA) application, which will require further clinical study. Similarly, Medtronic received European CE mark approval for DBS in severe OCD in 2009, allowing this therapy to be used in Europe. As discussed above, the same therapy remains under HDE status in the United States.

The article by Fins and colleagues regarding misuse of the FDA HDE for OCD

should prompt all practitioners using investigational or newly approved therapies to review their own practices and rigor. Certainly, the moral hazards of any medical therapy are many and are even greater for investigational therapies. Although the FDA approval process is imperfect, it does appear to be more stringent than similar processes overseas, at least with regard to modern neuromodulatory therapies. Clinicians, ethicists, researchers, and others involved in the field of neuromodulation should be at the forefront of trying to achieve a balance between maintaining strict moral standards and offering patients state-of-the-art care. **N**

References

1. Fins JJ, Mayberg HS, Nuttin B, et al. Misuse of the FDA's humanitarian device exemption in deep brain stimulation for obsessive-compulsive disorder. *Health Aff.* 2011;30(2):302-311.
2. Medtronic. Medtronic receives European CE mark approval for deep brain stimulation therapy for refractory epilepsy. Published September 16, 2010. www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1284644553533&lang=en_US. Accessed February 24, 2011.

Letter from the President *continued from page 1*

pain. Further, with the help of Rubenstein Public Relations and in cooperation with ASIPP, press releases are being published to bring attention to the threats to health care posed by the actions of the Washington State Department of Labor and Industry.

NANS will continue to grow strong as we pursue these goals in 2011. The NANS Board of Directors, with the cooperation of members, will make every effort to expand the scope of the society, expand and diversify membership, position NANS as the "go-to society" for all items related to neuromodulation, enhance member education, develop educational guidelines, and promote better access to care and research. The committees established during the

Strategic Planning Committee Meeting in October 2009 are working hard to accomplish these goals.

Again, I want to express my deepest thanks and appreciation to each board member and every NANS member for their enthusiastic support of the society. Your energy, enthusiasm, work efforts, and imagination have tilled the fertile soil of neuromodulation to provide growth for the future and make NANS the premier organization representing neuromodulation.

In closing, I urge you to plan to attend the International Neuromodulation Society's 10th World Congress, May 21-26, at the Hilton Metropole in London. The Congress provides a venue where colleagues from

around the world can share their experiences and knowledge in the exciting field of neuromodulation, drawing attention to the importance of understanding and using this therapy to treat patients in all disciplines of medicine. Finally, please save December 8-11, 2011, to attend the NANS 2011 Annual Meeting in Las Vegas. **N**



Robert Foreman, PhD
President, NANS

NANS 14th Annual Meeting: Overview and Highlights

The NANS 14th Annual Meeting was held at the Encore at Wynn in Las Vegas, December 2-5, 2010, beginning with two preconference courses on December 2. The well-attended Hands-On Cadaver Workshop offered fellows didactic instruction on the principles, techniques, and nuances of spinal cord stimulation (SCS) from experienced faculty members. Surgical aspects of pain management were also explored and instruction was given on techniques in suturing, anchoring leads, implanting paddle leads, and percutaneous cordotomy. Participants in the cadaver course rated it very highly. Favorable impressions were reported by attendees of “A Review of Neuromodulation,” a workshop attended by 92 nurses, physician assistants, and allied healthcare professionals. The multidisciplinary faculty addressed topics such as patient selection, troubleshooting, and complication avoidance for different neuromodulatory procedures such as SCS, intrathecal drug delivery pumps, peripheral nerve stimulation, and deep brain stimulation.

In accordance with the meeting’s theme, Neuromodulation: Vision 2010, emerging applications of neuromodulation and state-of-the-art practices were highlighted. Outstanding speakers from diverse specialties and backgrounds delivered lectures on cutting-edge research in different areas of neuromodulation.

Sessions were designed to highlight specific themes such as SCS, brain stimulation, peripheral nerve stimulation, intrathecal therapies, rehabilitation, and biomedical engineering. The first general scientific session focused on the science of pain neuromodulation; Frank Shellock, PhD, presented an update on magnetic resonance imaging issues for neuromodulation systems. Later that day, concurrent afternoon sessions were held on brain neuromodulation and peripheral nerve stimulation.

Day 2 highlights included general scientific session lectures “Gene therapy for Parkinson’s Disease: Completion of Phase 2 Study,” by Michael Kaplitt, MD PhD; “Brain Machine Interface—Past, Present, and Future” by Peter Konrad, MD PhD; and “Adjusting Brain Circuits with Infusion Therapies in the Brain” by Russ Lonser, MD. During this session, the Presidential Address was delivered by NANS President Robert Foreman, PhD, and the Lifetime Achievement Award was presented to Michael Stanton-Hicks, MD. Simon Thompson, MBBS FRCA, president of the International Neuromodulation Society, then made



Clockwise from top: The NANS 14th Annual Meeting was again held in Las Vegas (top). A speaker presents during Thursday's educational sessions (right). Ashwini Sharan, MD; Ali Rezai, MD; and Joshua Prager, MD, present the Lifetime Achievement Award to Michael Stanton-Hicks, MD (bottom). NANS President Robert Foreman, PhD, addresses attendees during the business meeting (left).

a presentation on “Refractory Angina Management: A Clinical and Cost Effectiveness Study.”

The afternoon sessions on day 2 were on intrathecal therapies and the interface of neuromodulation, rehabilitation, and biomedical engineering. The two newly introduced content-focused concurrent afternoon sessions in this annual meeting (peripheral nerve stimulation and the interface of neuromodulation, rehabilitation, and biomedical engineering) were well received by the participants.

NANS presented diamond-level sponsor awards to the three main industry sponsors: Boston Scientific, St. Jude Medical, and Medtronic. These sponsors provided support for two non-CME-certified luncheons (Boston Scientific and Medtronic) and a well-attended breakfast symposium (St. Jude Medical). During the non-CME-certified luncheon on day 2 of the meeting, David Kloth, MD, made an eloquent presentation on Health Care 2010 and the anticipated health reforms, which elicited a passionate and spirited debate.

The 713 attendees made the 2010 meeting the largest in the 17-year history of NANS. International participants came from Australia, Brazil, Russia, Germany, and China. More than 120 abstracts were submitted and 53 faculty members presented. There were 21 exhibitors at the meeting.

The NANS 14th Annual Meeting was a resounding success. The level of participation points to continuing rapid growth in interest



More than 90 healthcare professionals attended the popular preconference workshop, *A Review of Neuromodulation*.

in neuromodulation. The scientific caliber of cutting-edge research presented demonstrates the potential for the future of basic and clinical research in neuromodulation. The NANS Board of Directors wishes to express its appreciation to our members, sponsors, and participants who helped ensure that the 2010 meeting was such a memorable event. We invite you to join NANS next year for the 15th Annual NANS Meeting, December 8-11, 2011, in Las Vegas, NV. **N**

Redesigned Website Launches at Annual Meeting

Steven Falowski, MD, NANS Webmaster



In addition to an array of high-quality educational sessions, the 2010 Annual Meeting also served as the official launch of the redesigned NANS website. The website was revamped following extensive review by the Website Committee, NANS Board of Directors, and NANS staff team. A major goal of the redesign was to advance the Society’s efforts for education, research, and patient care and to make the website more synchronous with the organization’s goals.

The Website Committee hopes the website will raise patient and physician awareness for neuromodulation and spread awareness of the technology and treatments available. The website offers a searchable member directory for patients and colleagues looking for physicians in a particular area. The new About NANS section spells out a clear mission statement, provides board member contact information, and includes a newsroom section discussing emerging research, new technologies, the latest media coverage, and features of members in the news.

One of the new exciting additions is the About Neuromodulation section, which discusses the different treatment modalities and what they treat and dives into the evolving multidisciplinary approach involved in this field. This will prove useful for patients and physicians alike. The home page will highlight links to the latest information in the news, as well as recent newsletters.

A regularly updated poll located on the home page is a new interactive feature that surveys members about some of the current issues in the field. You can view the results of the survey and then review additional

information on the topic. It’s a great way to stay connected with current topics and gain insight from other physicians.

As in the past, the website will link to the Society’s journal, *Neuromodulation*, as well as list upcoming events and future meetings. In addition, a new educational portal will make talks and didactic recordings from conferences available for viewing and offer uploaded versions of different courses. This is an effort to continue supporting NANS education initiatives. We hope the revitalized website will prove to be an asset to anyone involved or interested in the field. **N**

Meet Steven M. Falowski, MD, NANS Webmaster

Steven M. Falowski, MD, underwent his neurosurgical residency training at Thomas Jefferson University and is finishing a functional fellowship at Rush University in both movement disorder and epilepsy. He has been a member of NANS for the past 7 years, presented at several NANS meetings, and has contributed to several publications, including *Neuromodulation* and the *NANS Newsletter*.

Dr. Falowski’s recent publications have dealt with spinal cord stimulation, epilepsy, and deep brain stimulation. He won the research award at the Pan-Philadelphia Neurosurgical Conference in 2009 for his work dealing with deep brain stimulation in a depression model and its effect on neuroplasticity.

Dr. Falowski welcomes additional feedback regarding the website. Send comments or suggestions to him at sfalowski@gmail.com.

Meet the Newest Members of the NANS Board of Directors

Following elections in November, two new members were elected to 2-year terms on the NANS Board of Directors. Congratulations, Jiande Chen, PhD, and Lawrence R. Poree, MD PhD.



Jiande Chen, MD PhD

Dr. Chen is a professor of medicine in gastroenterology in the department of internal medicine at the University of Texas Medical Branch in Galveston, TX. He is renowned for his expertise in the area of physiology of gastrointestinal motility and the development of electrical neuromodulation therapies for functional gastrointestinal motility disorders.

Dr. Chen completed his graduate education at the Catholic University of Leuven in Belgium. During his graduate research work, he worked in two departments: electrical engineering and gastroenterology. The unique perspectives gained from working in these two areas led him to pursue research interests in electrical neuromodulation for gastrointestinal tract motility disorders.

About 10 years ago, he expanded his research interests to the use of electrical neuromodulation in the gastrointestinal tract to treat obesity. He explains that weight

loss in these models is achieved by decreasing gut motility with resultant easy satiety and reduced food intake as well as reduced absorption from the gut. This research in obesity treatment also has implications for diabetes treatment.

As a member of the board, Dr. Chen hopes to increase the participation of basic scientists involved in neuromodulation research. He is pleased with efforts by NANS in this regard, citing the appointment of basic research scientists to the NANS board. He hopes NANS will continue to encourage basic scientists to address the basic science questions underpinning present clinical neuromodulation applications.



Lawrence R. Poree, MD PhD

Dr. Poree has been involved with pain neuromodulation for more than two decades. As a postdoctoral fellow in biomedical engineering and neuroscience in the

late 1980s (prior to entering medical school), he performed basic research on spinal cord modulation of pain and used spinal cord stimulators and intrathecal drug delivery devices on rat models. It was a logical progression to become involved in clinical pain neuromodulation later in his career.

Dr. Poree earned his master's and doctoral degrees in toxicology and environmental health sciences from the University of California, Berkeley. He went on to earn his medical degree from Stanford University, completing an anesthesia residency at Stanford University Medical Center and a pain fellowship at the University of California, San Francisco.

In his new role as a board member, Dr. Poree hopes to promote training in the area of intrathecal drug delivery device use and management. He coauthored a NANS document on appropriate training in spinal cord stimulation devices and plans to play a role in the development of a document for intrathecal drug delivery devices.

His other passion is the education of the general public and increasing awareness of the new technologies in neuromodulation that can have a significant impact on the patient's quality of life. He has innovative ideas on the use of science museums to increase public awareness of new neuromodulation technologies based on his previous experience of working in science museums.

Dr. Poree believes NANS should continue to take a leadership role in ensuring that all patients have access to available neuromodulatory technology. He also will work to ensure that NANS continues its present efforts to improve clinical standards in neuromodulation. **N**

Members in the News



Joshua Prager, MD MS

Chima Oluigbo, MD FRCSC

Joshua Prager, MD MS, has been actively involved in NANS for the past 17 years. One of the founding members in 1994, he has since served in various capacities throughout his membership—initially on the NANS Board of Directors and later on the Executive Committee, where he served two terms each as secretary, vice president, president-elect, and president. He now serves the society as the senior adviser to the board.

Dr. Prager completed his undergraduate education at Harvard University. After receiving his medical degree from Stanford University, he completed an internal medicine internship and residency at UCLA and later an anesthesiology residency and fellowship at Massachusetts General Hospital at the Harvard Medical School. Dr. Prager became interested in neuromodulation very early in his career when he recognized its ability to improve his patients' quality of life with few side effects. He also enjoyed the technical aspects of neuromodulation.

His practice of neuromodulation for pain management has spanned two decades and has resulted in his involvement in many different emerging technologies. His early practice involved pain pumps, and in 1993 he implanted the first spinal cord stimulator in

his practice. By the late 1990s spinal cord stimulator implantation and management had become a significant part of his practice. He has remained at the forefront of innovative neuromodulation applications and performed the first transverse tripolar stimulation in the 1990s. He also performed the first spinal cord stimulator trial in the People's Republic of China about 10 years ago and was subsequently invited to lecture at the East-West Pain Conference.

Dr. Prager has worked actively to increase the visibility and access of neuromodulation to patients. He is the founder and immediate past-chair of the Neuromodulation Therapy Access Coalition (NTAC). He has also worked to achieve NTAC's objective within NANS and urges NANS to continue its present efforts in advocacy and public relations to ensure neuromodulation remains a well-recognized and easily accessible treatment modality to patients.

The deep sense of public service displayed in Dr. Prager's advocacy efforts for pain neuromodulation on behalf of patients is also seen in his work with the disadvantaged and financially disenfranchised. He has worked to help establish and reorganize inner city healthcare centers, provided internal medicine care as a volunteer at the Haight Ashbury Free Clinic, and provided anesthesia for children in developing countries undergoing corrective surgery for congenital anomalies. His commitment to public service is commendable and truly inspirational. **N**



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.

May

SNS Annual Meeting

Society of Neurological Surgeons

May 21-24

Portland, OR

www.societyns.org/meeting_info.html

INS 10th World Congress

International Neuromodulation Society

May 21-26

London, England

www.neuromodulation.com

June

ISCoS 50th Annual Scientific Meeting

International Spinal Cord Society

June 4-8

Washington, DC

www.iscos.org.uk/page.php?content=56

Pain 2011

Pain Education Society

June 10-12

Huntington Beach, CA

www.paineducationsociety.org/

CNS 5th Annual Conference

Canadian Neuromodulation Society

June 10-12

Vancouver, BC Canada

www.neuromodulation.ca

ASIPP 13th Annual Meeting

American Society of Interventional Pain Physicians

June 25-29

Washington, DC

www.asipp.org

July

SNIS 8th Annual Meeting

Society of Neurointerventional Surgery

Colorado Springs, CO

July 25-28

www.snisonline.org

October

CNS 61st Annual Meeting

Congress of Neurological Surgeons

Washington, DC

October 1-6

www.cns.org/meetings

November

NASS 26th Annual Meeting

North American Spine Society

November 2-5

Chicago, IL

www.nassannualmeeting.org

Views: Reimbursement for Intrathecal Drug Delivery Therapies

P. Rao Lingam, MD

Intraspinal administration of medications to control intractable cancer and non-cancer pain or spasticity has been in use for about three decades. In selected patients, intrathecal administration of medications via an implanted pump has been shown to be more cost effective on a long-term basis than other routes of administration that potentially have fewer side effects. Strict aseptic precautions are mandatory during implantation and refills of these devices' reservoirs. Any break in the asepsis and introduction of pathogens into the cerebrospinal fluid can produce very serious and potentially fatal complications. The dose of medications required via the intrathecal route is much smaller (1:100 to 1:300) compared with other routes of administration. This requires extreme caution, skill, and experience in taking care of patients utilizing this modality.

The above factors are not always taken into account during the reimbursement process for these services. The payments

for implantation, refilling of the pump, and reprogramming are much less than for many procedures that do not have either the high potential for serious complications or require the vigilance at each step in managing this therapy.

For example, consider Ohio, where reimbursement for intrathecal medications has dramatically reduced in the past year or so; sometimes to below what the practitioner has to pay the vendor. Many practices use a compounding pharmacy to get these medications. It could be because (a) they are uncomfortable ordering and storing the high-potency opioids, (b) the concentration used may not be available commercially, or (c) the patient might be receiving a combination of medications. For compounded medications, Medicare demands a copy of the invoice and, at most, pays the invoice price. Ohio Medicaid follows Medicare. Ohio Bureau of Workers' Compensation (BWC) began requesting the invoices

and after much negotiation is proposing a reimbursement of 20%, at most, more than invoice. The BWC is also demanding an itemized list for the overhead costs. These indirect costs (eg, staff time and resources) are significant and difficult to quantify.

The bottom line is that physicians are paying to take care of patients with intrathecal delivery systems. An ethical dilemma presents itself. Do you discharge these patients from your practice because you cannot afford to keep paying to care for them? Do you avoid offering this modality to certain patient populations because you will lose money every time you fill the pump? Neither option is acceptable. We must have the complexity, required time, and vigilance recognized and reimbursed properly, not just as reimbursement of the cost, because the costs are much higher than the "invoice price." **N**



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Save the Date



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