

SNIS...A Time to Celebrate!

As Christmas wreaths are hung and Hanukkah candles are lit, SNIS joins in wishing all a very happy holidays. But this season, we are also preparing for another reason to celebrate . . . as we'll soon be adding "Happy Anniversary" to many of our salutations in 2012. A significant milestone for our society, the coming year marks 20 years – yes 20 – since SNIS (under the banner of the American Society of Interventional Neuroradiology or ASITN) became the representative society for the pioneering field of neurointervention.

Since 1992, it would be an understatement to say that our society, and our field for that matter, has made significant strides in the overall goal to advance neurointerventional care for patients worldwide. In the first ten years, we laid the groundwork for success, for what we hoped would be exceptional. We immersed ourselves in all the logistics of starting a society while debuting



several of the technological innovations that were advancing our interventional capabilities and lending credibility to our work. Since then, we have stood on that foundation and dreamed dreams that, once realized, have elevated our stature in the medical profession and, specifically in the neurosciences. We grew our membership from 50 to nearly 600. We started two meetings, the Practicum and the Annual Meeting, the last of

which has become the premier educational opportunity and scientific forum in neurointervention. We forged alliances and found common ground with our sister societies, resulting in groundbreaking standards documents around carotid stenting and stroke. We created the *Journal of NeuroInterventional Surgery* (JNIS), which was indexed within three years, furthering our educational impact and visibility around the world. And most recently, we instituted the SNIS Foundation, an initiative that is making it possible to fulfill our mission of investing in the future of our field by supporting fellowship programs throughout the world.

But despite these wins, perhaps the most noteworthy achievement of the last decade was to refine our identity – as a medical society and as a field. While the origins of our group were mostly

continued on page 9

INSIDE

This Issue

- 2** President's Column
- 3** SNIS Joins the World of Social Media
- 6** JNIS Update
- 7** Brain Attack Coalition Updates
Recommendations for Primary Stroke Centers
- 8** JNIS Editors Head Across the Pond
- 9** FDA Guidances Will Seek to Foster Medical Device Studies
- 10** Photo Highlights from the SNIS 8th Annual Meeting
- 12** SNIS Exhibits at WFITN
- 14** SNIS: Staying Abreast of the Socioeconomic Issues Affecting Healthcare and Neurointervention
- 15** FDA and CMS Begin Parallel Review Pilot Program
- 16** Welcome New Members!
- 17** Proposed Legislation Seeks to Improve FDA Regulatory Process for Medical Devices
- 18** 'Tis the Season to...give to the SNIS Foundation
- 20** Calendar of Events



PRESIDENT'S COLUMN

Joshua Hirsch, MD

Washington Follies



While there are many topics worthy of highlighting in this column, I settled on the latest news out of our nation's capital as the implications are significant – and relevant to our mutual interest in advancing the quality of healthcare in this country. Indeed, the failure of the Joint Select Committee on Deficit, dubbed the “Super Committee,” to move forward in recent days begs many questions. Is this a positive statement for representative democracy or yet another failure to impose the fiscal discipline necessary to secure our nation's future?

I don't know if we can yet answer these questions, but a hard stare at our current state of affairs may provide greater insight. The Budget Control Act of 2011 was enacted by the 112th Congress on August 2, 2011 and subsequently passed into law by President Obama. This brought to an end months of partisan wrangling that jeopardized the full faith and credit of the United States. As many breathed a sigh of relief at the apparent avoidance of a near-term default crisis, the failure of our leaders in

Washington in the last month to reach a consensus on how to get the U.S. on a solid debt-reduced footing looms like a dark cloud over our nation's future.

The goal of the Budget Control Act of 2011 was to identify mechanisms for future deficit reduction in the face of the then recently elevated debt ceiling. The target was to cut at least \$1.5 tril-

...beyond just the frustration of the moment, this latest Washington folly has other more serious implications across many industries – with healthcare being no exception.

lion over the next 10 years. To accomplish such a feat, a “Super Committee” brought into existence by the Budget Control Act, was tasked with producing debt reduction legislation by November 23, 2011. The Committee was comprised of six members from each of the two leading parties, with a key imperative that amendments or filibuster would not encumber the work product.

And so the work began, with the agreement that if bipartisan compromise could not be achieved, \$1.2 trillion in automatic cuts to defense and domestic spending would ensue, a process referred to as Sequestration. To avoid this fate, there is no doubt that the collective minds of our nation rationally believed – and trusted – that these “Super” political leaders would participate in what has become a seemingly lost art – thoughtful compromise.

However, on November 21st, the Committee issued a statement that began as follows: “After months of hard work and intense deliberations, we have come to the conclusion today that it will not be possible to make any bipartisan agreement available to the public before the Committee's deadline.” Thus, gridlock gave way to something just as ominous – Sequestration.

And so here we sit at the end of 2011, bewildered and frustrated at the failure of our leaders to put partisanship aside for what we would all agree is the greater good. But, beyond just the frustration of the moment, this latest Washington folly has other more serious implications across many industries – with healthcare being no exception. In addition to the anticipated 27.4 percent reduction in provider payments set to take effect on January 1, 2013 related to application of the sustainable growth rate (SGR) formula, there may be an additional 2 percent cut in provider fees related to Sequestration.

Quoting from the AMA website, “The deficit committee had a unique

continued on page 5

SNIS Joins the World of Social Media

By all measures, social media is considered one of the most significant communications trends in modern times. Facebook registers millions of users around the world; most individuals and companies now have Twitter accounts in addition to email; and YouTube has transcended its entertainment functionality and become a credible venue for companies to push out their information. The popularity of these new ways of communicating even gave rise to a 2010 blockbuster hit: Social Network.

Keeping pace with the times, SNIS, too, has joined the online world of social media in an effort to broaden its communications with members and the

general public. Specifically, the society has established a presence on Facebook, where we currently have almost 100 members. Designed as a closed page (to block patients, etc.), our Facebook page serves the purpose of facilitating conversations among members related to any variety of topics, allowing each member to not only post thoughts and insights, but pictures and video too. If you are a current Facebook user and would like to join us, just search Society of NeuroInterventional Surgery and put in a request! And while you're at it, let us know how you would like to use this tool. Case discussion? Message board? It's up to all of you!



Additionally, you can find SNIS on Twitter, at @SNISinfo. So far, we have used this venue mainly to push out conference information and highlights in real-time, but we also look forward to leveraging this forum to share SNIS news throughout the year. If you are a "tweeter," please look us up on Twitter and follow us.

We'll keep you attuned to new updates as we have them. Meanwhile, looking forward to joining you online!

Job Advertisement

The University of Utah School of Medicine, Department of Radiology announces an unexpected opening for a Neurointerventional Surgery Fellow beginning July 1, 2012.

As the premier Neurovascular referral center in the Intermountain West, our service provides ample hands-on training for fellows while performing over 100 neurovascular embolizations per year in addition to diagnostic cerebral and spinal angiograms as well as spinal pain management procedures. We utilize a biplane Siemens Neuroangiography suite with DynaCT capabilities. Our clinic Neurosciences center houses clinic spaces for Neurointerventional, Neurology, and Neurosurgery and construction of a new biplane angiography suite integrated with a mobile MRI scanner is scheduled for completion in 2012.

Our Neurointerventional service also performs procedures at the Salt Lake City VA Hospital, the Huntsman Cancer Hospital and Primary Children's Medical Center.

Fellow responsibilities include performing and interpreting neuroangio-

graphic and spinal interventional procedures, image guided biopsies of the head/neck and spinal axis, patient consultations, and preparation of weekly neurovascular conferences for fellows and residents. Approximately one academic day per week is allowed for research activities.

Applications are invited for a one to two year fellowship from US-trained/licensed physicians with board certification in Diagnostic Radiology, Neurology or Neurosurgery. A prior year of fellowship training in Diagnostic Neuroradiology, Stroke Neurology or Vascular Neurosurgery is desirable but not essential.

Neurointerventional Faculty:

- Edwin A. Stevens, MD, Interventional Neuroradiologist, Department Chair
- Perry P. Ng, MD, Interventional Neuroradiology, Fellowship Program Director
- Lubdha M. Shah, Spine Imaging and Intervention

If you wish to apply or have questions or require additional information please contact Janet Holman, Program Coordinator, at (801) 581-4624 or janet.holman@hsc.utah.edu.

Attention Fellowship Directors!

SNIS is updating our website and we are in need of a more complete list of Neurointerventional Fellowship Programs. If you are a Fellowship Director, please send us an e-mail to info@snisonline.org so that we can provide you with the form that will allow us to place your information on the website.

The purpose of this list is to provide potential applicants with an easy reference for contact information and to promote fellowship opportunities.

We trust this promotional venue will be helpful to you in your goal of recruiting fellows to your program.

Mark Your Calendar!

**SNIS 9th Annual Meeting
and 3rd Annual Fellows Course**



July 23-27, 2012

Hilton San Diego

Bayfront Hotel

San Diego, California

opportunity to stabilize the Medicare program for America's seniors now and for generations to come. Once again, Congress failed to stop the annual charade of scheduled Medicare physician payment cuts and short-term patches, which spends more taxpayer money to perpetuate a policy everyone agrees is fatally flawed."

Amongst the many failures of the Congress and its "Super Committee," a real opportunity has been missed to stabilize the Medicare program and permanently repeal the SGR formula. I think it noteworthy that as is so often the case, failure to act has become more costly over time. Continuing from the AMA website, "The cost of repealing the (SGR) formula has grown 525 percent in the past five years and will double again in the next five years."

Perhaps the failure of this Congress is something to be thankful for. Recall that the consistently maligned SGR formula itself was a planned result of the Balanced Budget Act of 1997. The idea was to replace the existing Medicare volume based standard with a sustainable, and, "more reasoned" approach. In retrospect, the many flaws of the SGR, including its linkage to the gross domestic product and failure to account for change in medical practice, seem obvious. As the neurointerventional specialty, at its core, is sustained by technological innovation, providers should be particularly aware of the SGRs flaws.

Cynically, one might note that Sequestration is the law of the land until, as many suggest, Congress changes it through further legislation next year.

While the failure of our nation's leaders leaves our Congress with the unlikely prospect of allowing across the board Sequestration cuts or a modification of the \$1.2 trillion target, the implication for our health care system generally or providers more specifically are, as of now, unclear. What is clear, however, is the ever-increasing need for

**...we now have to hope
that our nation's leaders
will act in a way that
advances our country's
interests...**

our nation's healthcare leaders to keep a finger on the pulse of these congressional and other discussions – and make our voices heard on the issues that we can impact.

Likewise, through the many mechanisms at our disposal, it is the intent of SNIS leadership to communicate regularly the relevant and critical issues of the day. Most recently, we have done our due diligence to outline much of this information in a series of socioeconomic articles in the *Journal of NeuroInterventional Surgery*, *Suite Talk* and the SNIS website.

And, no doubt, the continuing antics in Washington will give way to more news to communicate in the coming election year. Typically, at this time of year, no matter how one celebrates – we all seem to acknowledge this season as one of hope. As we turn the page from 2011 to 2012, it's a bit sobering to realize that amidst all the other challenges that we face in our field, we now have to hope that our nation's leaders will act in a way that advances our country's interests and our citizens' access to a universal need – quality healthcare provided by knowledgeable and practiced experts. Always an aspiring optimist, I do have hope that those we've elected to represent us in Washington will do the right thing. In fact, with our national health at stake, it's not an overstatement to say – we're counting on it.

CMS to Further Review CAS Coverage in January

The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) of the Centers for Medicare & Medicaid Services (CMS) will convene a meeting on January 25, 2012, for the panel to review available evidence on various clinical strategies for the management of carotid atherosclerosis. Treatments and technologies used in the management of carotid atherosclerosis include medical therapy, carotid endarterectomy, and carotid artery stenting (CAS).

The meeting will focus on the impact on patient health outcomes of these strategies for management of carotid atherosclerosis and prevention of stroke in both symptomatic and asymptomatic patients, as well as evaluate generalizability of the available evidence to patients of differing age, sex, and racial/ethnic backgrounds.

Medicare addresses coverage of CAS in section 20.7 of the national coverage determination (NCD) manual (Pub. 100-03) entitled Percutaneous Transluminal Angioplasty. Sections B2, B3, and B4 of the NCD address coverage of CAS. The NCD for percutaneous transluminal angioplasty is available on the CMS website.

SNIS plans to attend the MEDCAC meeting and will provide an update to the members directly following.



JNIS Update

Rob Tarr, MD, Editor-in-Chief

JOURNAL OF NEUROINTERVENTIONAL SURGERY

It is hard to believe that approximately three and a half years ago the *Journal of NeuroInterventional Surgery* (JNIS) was a mere twinkle in the eye of the SNIS executive committee. The future of the journal was an uncertainty. And there were risks – financial and those to the reputation of the society. But in the spirit of innovation, SNIS took the leap and I announced to the membership that the first issue of JNIS would be distributed at the 2009 Annual Meeting.

The plans were comprehensive... the logistics numerous. The first priority was to form a publications committee, which we did under the guidance of Charlie Prestigiacomo. We then hired an expert journal consultant, Morna Conway. And, we solicited requests for proposals from national and international publishing houses.

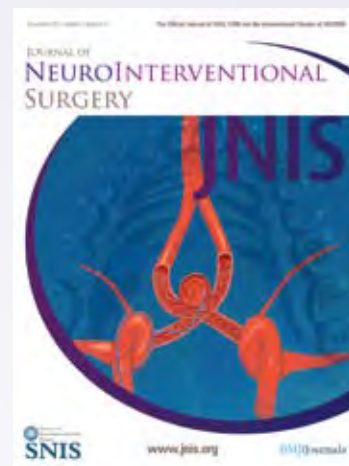
In November of 2008, the SNIS Executive Committee interviewed representatives from the top two publishers. The outcome was the unanimous choice for the British Medical Journal (BMJ) as the publisher for JNIS. The long-standing stability and reputation of BMJ notwithstanding, the decision was further swayed by BMJ's proposal to bundle JNIS with two other neuroscience journals, the *Journal of Neurology, Neurosurgery & Psychiatry* (JNNP) and *Practical Neurology* – an initiative which would ensure immediate international institutional distribution and also provide a measure of financial security. In this win/win scenario, BMJ benefited from the chance to add a United States-based, society-owned journal to its portfolio, as well as the opportunity to better penetrate the U.S. market.

All of these initial steps taken and decisions made, the executive commit-

tee then moved to the business of choosing an editor-in-chief for the journal. I am honored to have been offered the position and remain grateful that I accepted. In the last three years, I am equally honored to have worked alongside an outstanding group of associate editors, including Felipe Albuquerque, Dave Fiorella, Josh Hirsch, Charlie Prestigiacomo, and Sam Zaidat. Their hard work and contributions are evident in every page of every issue of JNIS.

Since our very first issue, which was, as promised, distributed at the July 2009 Annual Meeting, I am proud to say that JNIS has continued to flourish, and indeed, take on a life of its own. The review process remains efficient, and accepted articles are now published online within 22 days of acceptance, thanks in large part to the efficiency of the BMJ production folks, including Aimee Knight. Because of an unanticipated sharp rise in the quality and quantity of submitted manuscripts, we have recently made the decision to increase the print copy distribution frequency from quarterly to six issues per year beginning January 2012. Consequently, in the future, I anticipate that the rejection rate of manuscripts submitted to JNIS will steadily rise, which we can all consider a desired byproduct of the journal's maturation and role in providing the neurointerventional field with the highest quality of scientific literature.

In recent years, JNIS has achieved other milestones that help to establish its scientific credibility and penetration. In the summer of 2010, Thomson-Reuters, the company who issues journal impact factors, offered to index JNIS. The



following summer, JNIS received an initial impact factor of 1.069 – a respectable number, especially given the fact that it was generated based on citation of articles from only the first two issues of JNIS. But, in September 2011, JNIS yielded what I would call a landmark accomplishment. Again, much earlier than anticipated, the journal was accepted by Medline to be included in PubMed indexing. The timing of acceptance for PubMed indexing was critical. If the journal had not been accepted after the initial application, we would have had to wait an additional three to reapply. Acceptance of JNIS for indexing by Medline within three years of the journal's inception guaranteed that articles within the journal would be retrospectively indexed back to the first issue. A major feat.

The journal features many interesting components, but I would like to highlight just a few standouts. We have started a Book Review section which will be spearheaded by Albert Yoo. In the spirit of our conferences, beginning in 2012, each issue will feature a Point/Counterpoint section which will be managed under the stewardship of Kristine Blackham. Additionally, we have initiated an easy-access online podcast for editor's choice articles. This

continued on page 12

Brain Attack Coalition Updates Recommendations for Primary Stroke Centers

The Brain Attack Coalition, of which SNIS is a member, has issued revised and updated recommendations for the establishment of primary stroke centers to reflect the latest data and experience. Mark J. Alberts, MD, et al have published a summary statement of the recommendations in *Stroke* (2011;42:2651-2665). The Brain Attack Coalition noted that its original recommendations were made in 2000; since that time, the formation and certification of primary stroke centers has progressed rapidly.

As detailed in *Stroke*, the Brain Attack Coalition conducted a literature review using MEDLINE and PubMed from March 2000 to January 2011. The review focused on studies that

were relevant for acute stroke diagnosis, treatment, and care. Original references as well as meta-analyses and other care guidelines were also reviewed and included if found to be valid and relevant. Levels of evidence were added to reflect current guideline development practices. The importance of some elements of the recommendations has been further strengthened, and several new areas have been added based on the literature review and experience at primary stroke centers.

Strengthened or additional elements include the importance of acute stroke teams; the importance of stroke units with telemetry monitoring; performance of brain imaging with magnetic reso-

nance imaging and diffusion-weighted sequences; assessment of cerebral vasculature with magnetic resonance imaging angiography; cardiac imaging; early initiation of rehabilitation therapies; and certification by an independent body, including a site visit and disease performance measures. Based on the evidence, several elements of primary stroke centers are particularly important for improving the care of patients with acute stroke. Additional elements focus on imaging of the brain, the cerebral vasculature, and the heart. These new elements may improve the care and outcomes for stroke patients treated at a primary stroke center, concluded the Brain Attack Coalition.

Mark Your Calendars . . .

10th SNIS Practicum

April 27-28, 2012

Sheraton New York Hotel & Towers

New York, New York

Practicum

Society of NeuroInterventional Surgery
SNIS

JNIS Editors Head Across the Pond



In keeping with the extraordinary momentum that is propelling the *Journal of NeuroInterventional Surgery* (JNIS) to new heights, our editors made a special trip to London for a check-in with our publisher, the BMJ Publishing Group. Editor-in-Chief Rob Tarr, along with Associate Editors Felipe Albuquerque, Josh Hirsch and Charlie Prestigiacomo enjoyed a full three days with mostly work, but some play in and around London's most notable sites... including, yes, a few pubs.

Lest you get the impression that the London trip was all fun and games, in between attending charity events with Will and Kate, partaking in tea and crumpets with the Queen Mother, clubbing with Pippa, and brokering compromise between the House of Lords and the House of Commons, we got down to real business. SNIS participated in an exhaustive Editor's Meeting followed by an informative Management Committee Meeting, both designed to determine how best to meet short- and long-term goals for the *Journal of NeuroInterventional Surgery*.



The first order of business in the Editor's Meeting was a review of the Journal metrics which was spiced up brilliantly by BMJ's Claire Jura (Journal Manager, JNIS). The metric data revealed optimistic trends including an increase in manuscript submissions, global participation in the journal and online downloads. Upon reviewing this data, discussion turned to strategies designed to even further increase global awareness for the purpose of continuing to grow the journal's reputation and credibility beyond the U.S. audience. Additionally, the editors, along with BMJ, engaged in a noteworthy conversation around the integration of Case Reports into journal content. While there was consensus that Case Reports are typically not highly cited, all agreed that they can be an important educational vehicle for practitioners in the field of neurointervention. Thus, Peter Ashman, Publishing Director, BMJ Group, proposed a rather Churchillian plan for continued incorporation of Case Reports into JNIS, which the editors will unveil in more detail once particulars are revised to make the plan more operational. Lastly, the Management Committee meeting

revealed that the financial status of JNIS is solid, ahead of budget, and exceeding initial projections.

Beyond the business, the trip across the pond was made all the more beneficial by the opportunity for the associate editors of JNIS to connect a face with the names of our wonderful partners at BMJ, including Peter Ashman, Publishing Director, BMJ Group; Janet O'Flaherty, Publisher, JNIS; Claire Jura, Journal Manager, JNIS; Nick Gray, Ad Sales Manager; and Aimee Knight, Technical Editor. Of course, we anticipate that the meet-and-greet will only strengthen the already excellent relationship between JNIS and BMJ.

As there continues to be a great deal of excitement and momentum around our journal efforts, our trip was all the more exciting when we consider how far we have come in three years. As always, SNIS looks forward to sharing more information as it is available, and there is an open invitation for you to share any and all ideas with the JNIS editors or Executive Committee.



FDA Guidances Will Seek to Foster Medical Device Studies

The US Food and Drug Administration (FDA) issued a draft guidance that is aimed at fostering early-stage development of medical devices within the United States, which the agency says will help to stimulate innovation and contribute to medical research.

According to the FDA, the guidance document contains new approaches to early feasibility studies and provides appropriate protections for human study subjects. The agency noted that such studies are necessary to resolve final design issues before the device is ready for a large clinical trial, as is typically required for product approval.

The draft guidance, "Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, including Certain First-in-Human Studies," applies to medical devices that are in the early stages of development to better inform the final design of the device. It would allow studies to start the device

development process earlier than previously allowed and would permit select device modifications to be made without FDA approval.

The FDA also announced that it is seeking a small number of companies to pilot the new approaches described in the guidance. The results of the pilot program will help to inform the final guidance. Notice of the pilot program was published in the Federal Register.

According to the FDA, participation in the pilot program will be limited to 9 sponsors. To qualify, sponsors should focus on innovative, early-stage development technologies that are most likely to benefit from the efficiencies of the program. Enrollment began on December 12, 2011. Enrollment will continue for 180 days from the November 10 publication of the Federal Register notice of the program or until a final guidance is published, whichever occurs first.

The FDA also issued a draft guid-

ance regarding clinical trials and medical devices. The document describes the agency's process for approving applications from companies that wish to conduct clinical trials involving medical devices. The draft guidance, "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations," clarifies the FDA's process for approving clinical trials of medical devices. The document addresses when the FDA might allow patients to enroll in a study while issues are resolved (ie, approval with conditions). Such issues include data analysis methods that can be resolved before gathering the data or minor divergences from study endpoints or study design assumptions. The draft guidance also discusses when the FDA might allow studies to begin with a smaller group of subjects while companies gather additional data prior to the larger general enrollment (ie, staged approval).

SNIS...A Time to Celebrate!

continued from page 1

rooted in the interventional neuroradiology discipline, we became a growing resource for neurologists and neurosurgeons with expertise in endovascular therapy as well. In a strategic move to coalesce around *functionality* as opposed to *background*, as well as to expand our presence from a United States base to a more global platform, the membership elected to change our name from the American Society of Interventional Neuroradiology (ASITN) to the Society of Neurointerventional Surgery (SNIS). What followed was a complete shift in the characterization of the field . . . now defined under the banner of *neurointervention* as a distinct specialty, and comprised of practitioners from various backgrounds. The implications have been significant, as reflected in tremendous gains in meeting attendance, journal submissions, and representation

in the officer ranks and committee chair appointments. But, all said and done, the most significant impact has been in the defining of a new platform that allows SNIS, along with our counterparts, to speak with one voice on such pressing issues as access to care and training for practitioners.

And so here we are at the end of 2011, on the precipice of a milestone celebration, but also at the beginning of another decade in which we are committed to the continued evolution that will be required of us to stay relevant and visible. But as we look ahead, we'll also look back, and take the time to just be proud of how far we've come. Thanks so much to our members, former and current leaders, colleagues and industry friends, all of whom have contributed to not only our success to date, but also to the belief in our vision. The reality

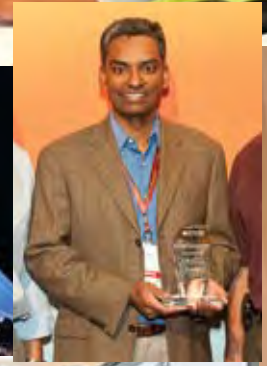
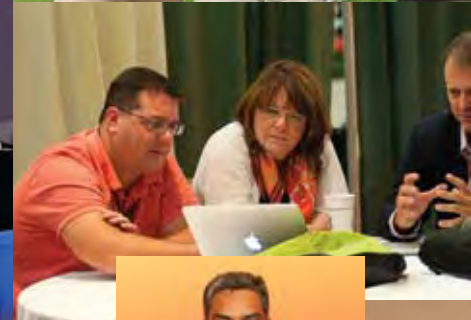
is that as much as we cherish the dreams that have inspired our success these past 20 years, we wouldn't be where we are without the dream-makers who have invested considerable time, resources, energy and ideas to our cause.

In acknowledgement of our 20-year anniversary, we will host various tributes throughout 2012 designed to provide all of us multiple opportunities to celebrate. We hope and trust you will partake in the festivities, recognizing that the success of SNIS is directly tied to our individual and collective success as a field.

Happy Anniversary SNIS! May 2012 be a year that reminds us of the power of great ideas and hard work as reflected in our achievements of the past 20 years, as well as a stepping stone to the next decade and all that will become part of our next chapter . . . our ongoing story.

SNIS 8th Annual Meeting Reaches New Heights in Colorado

July 25-28, 2011
The Broadmoor Hotel
Colorado Springs, Colorado





SNIS Exhibits at WFITN

One of the most valuable opportunities in our international community is the chance to gather together to stay apprised of industry trends and resources, and to continue the ongoing dialogue and exchange of ideas necessary to advancing the field of neurointervention.

In November, SNIS President Josh Hirsch, *Journal of NeuroInterventional Surgery* Editor Rob Tarr, and SNIS Executive Director Marie Williams had the honor of attending such a forum – the World Federation of Interventional & Therapeutic Neuroradiology (WFITN) Annual Meeting in Cape Town, South Africa. Along with the opportunity to attend multiple noteworthy scientific sessions, SNIS representatives participated in the booth exhibition over four days. The time was productive, providing unique opportunities to expose

colleagues from around the globe to the presence and offerings of SNIS and JNIS. Multiple copies of JNIS and *The Embolus* were distributed, invaluable international contacts were made, and relationships with international friends from around the world were cemented, many of whom SNIS hopes to see next summer at our Annual Meeting in San Diego.

Outside of the meeting, there were

grand opportunities to observe some of the splendor of Cape Town and surrounding areas. A more beautiful setting could not have been chosen for this event.

Special thanks to Allan Taylor and David LeFeuvre for their generous hospitality! SNIS looks forward to the 2013 WFITN Annual Meeting and yet another opportunity to forge bonds across all countries and continents.



JNIS Update

continued from page 6

feature provides in-depth discussion by the corresponding authors of their articles. Ray Turner and Marc Lazzaro provided the first podcasts which turned out to be a big hit. In the near future, JNIS will make it possible to display inline videos within articles online. And, finally, another up-and-coming feature

will be CME credits for reviewers.

When I look back over the journey, and, as is my penchant, to capture it in the words of song, I think the Grateful Dead says it best: "What a long strange trip it's been." Strange indeed – who knew we could accomplish so much in so short a time? But a wonderful and exciting journey in that JNIS stands as an emblem of what is possible when

dreams are entertained.

Thanks so much to all of you who have supported JNIS. I anticipate your continued enthusiasm as it undergoes yet more exciting transformation in the months ahead.

To access JNIS, go to the SNIS home page at www.snisonline.org or go to www.jnis.org.

SNIS 9th Annual Meeting

Annual Meeting Abstracts Now Being Accepted

You are invited to submit abstracts for the SNIS 9th Annual Meeting and 3rd Annual Fellows Course, July 23-26, 2012 at the Hilton San Diego Bayfront Hotel, San Diego, California in one of the following presentation categories:

- **Scientific Paper** (*Oral/Oral Poster/ePoster Presentation*)
- **Scientific Poster** (*Oral Poster Presentation Only*)
- **Scientific Poster** (*ePoster Presentation Only*)

Authors are invited to submit abstracts for works not previously published or presented.

SUBMISSION TOPIC AREAS ARE:

- Head & Neck Interventions – Tumors
- Head & Neck Interventions – Vascular Lesions
- Spine Interventions – Vertebroplasty/Kyphoplasty
- Spine Interventions – Spinal Injections
- Interventional Stroke Management – Thrombolytics
- Interventional Stroke Management – Mechanical Revascularization
- Interventional Aneurysm Treatment
- Interventional AVM Treatment
- Other Intracranial Disease Treatment
- Intracranial Angioplasty & Stenting
- Extracranial Angioplasty & Stenting
- Pediatric Interventions

Once again this year, an award will be granted at the SNIS Annual Meeting for the best abstract presented by a fellow. All fellows are encouraged to submit their abstracts to be considered for this award. When submitting your abstract online, please check the appropriate box designating your interest in being considered for an award.

The SNIS Online Abstract Submission site will accept abstracts from October 17, 2011 to 11:59 pm (EST) on Friday, February 17, 2012. Authors are encouraged to submit abstracts early.

Massachusetts General Hospital Neurointerventional Fellow Awarded Prestigious Honor

Ronil V. Chandra, current MGH NeuroInterventional Fellow, has been named the Royal Australian and New Zealand College of Radiologists Thomas Baker Fellow for 2011. Awarded annually since 1949, this honor represents one of the most valuable awards available to an Australian or a New Zealand Radiologist for post-graduate study. It is bestowed as a continuing memorial to both the late Mr. Thomas Baker and Mr. Edgar Rouse, whose photographic firm formed Kodak (Australasia) in 1908, and produced the first X-ray film in Australia in 1924.

The primary purpose of the Fellowship is to allow a qualified Australian or New Zealand Radiologist or Radiation Oncologist to further their knowledge by study abroad. Those awarded the Thomas Baker Fellowship shall also commit to practice in Radiology or Radiation Oncology in Australia, New Zealand or Singapore for at least two years after assuming the Fellowship.

Congratulations Ronil!



SNIS: Staying Abreast of the Socioeconomic Issues Affecting Healthcare and Neurointervention

Today's healthcare environment continues to be impacted by multiple factors, both within our own ranks as well as on the national legislative/regulatory stage. From the infrastructure of stroke neurointerventional practices to the evolving implications of the Patient Protection and Affordable Care Act of 2010, one only has to tune in to any neurointerventional news feed or major newspaper on any given day for yet more information that symbolizes the focused attention of the nation's eye on current socioeconomic issues as well as the complexity that typifies today's healthcare environment.

As neurointervention is a relatively new field steeped in novel technology and innovation, we, to some degree, are still navigating the path to operationalizing our practices and centers in a way that ensures quality of care and patient access to lifesaving services. As such, the small and big decisions being made in the halls of power stand to have significant implications for our practitioners and patients, in the short- and long-term.

So that we can speak with one voice and advocate where appropriate, SNIS is committed to ensuring that our membership stays fully apprised of the myriad socioeconomic issues being debated, decided and implemented in the healthcare and neurosciences arena. Multiple communications channels have been dedicated to this effort, including an ongoing Socioeconomics section in the *Journal of NeuroInterventional Surgery* (JNIS), special editions of *SuiteTalk*, and the *Embolus*.

It is our hope that by ensuring that we remain an informed membership, we can be even better stewards of our practices, and ultimately, our field.

Please see below for a complete listing of articles that have appeared in JNIS over the past three years, organized by informational categories.

- *Detailed review and analysis of critical legislation regarding health care legislation*
 - Patient Protection and Affordable Care Act of 2010: a Primer for Neurointerventionists*
 - The Independent Payment Advisory Board: Impact on Neurointerventionists*
 - The Evolution of the Patient-Centered Outcomes Research Institute*
- *System of delivering neurointerventional care*
 - Benefits of a Multidisciplinary Environment for Neurointerventional Training: Fellows' Perspectives*
 - Development of the Neurological Institute: A Strategic, Improvement, and Systems Approach (JNIS 2011;3:194-201)
 - Evolution of a Multidisciplinary Cerebrovascular Center: Lessons Learned*
- *Crew resource management and its application in neurointerventional practice*
 - Team training: a Safer Future for Neurointerventional Practice (JNIS 2011;3:285-287)
- *Regulatory environment in which neurointervention functions*
 - Letting the sunshine in: Shining a New Light on Physician-Industry Relationships (JNIS 2010;2:80-82)
 - The Neurointerventionist and the AdvaMed Code of Ethics: Examining the Doctor-Device Industry Relationship (JNIS 2011;3:204-206)
 - Coming Soon to a State Near You?*
 - The Red Flags Rule: Controversy Over Application to Physicians (JNIS 2011;3:202-203)
- *Operational issues in running a neurointerventional practice*
 - Applying the Lean Management Philosophy to NeuroInterventional Radiology (JNIS 2010;2:83-86)
 - Review: Establishing Operational Stability—Developing Human Infrastructure (JNIS 2010;2:379-384)
- *Cost data relevant to neurointerventionists*
 - Surgonomics of Unruptured Intracranial Aneurysms (JNIS 2010;2:168-170)
 - Relative Cost Comparison of Embolic Materials Used for Treatment of Wide-Necked Intracranial Aneurysms (JNIS 2010;2:163-167)
 - Safety and Cost Effectiveness of Step-Down Unit Admission Following Elective Neurointerventional Procedures*
- *History/current relevance of an issue*
 - Medicare Physician Payment Rules for 2011: A Primer for the Neurointerventionist (JNIS 2011;3:399-402)
 - Review: Ready or not! Here comes ICD-10*
- *Miscellaneous*
 - The Resistance to Change in Closed Societies: Apropos Our Future (JNIS 2009;1:2-4)
 - Social Responsibility in Medical Reporting (JNIS 2010;2:217-218)

*Indicates an Online First article

Welcome New SNIS Members!

The following new members have been approved for membership from July to December 2011. Please help us extend a warm welcome to them.

Junior Members

Ethan Benardete, MD, PhD

Thomas Jefferson University
Philadelphia, PA

Andrew P. Carlson, MD

University of Illinois at Chicago
Chicago, IL

Richard W. Crowley, MD

Barrow Neurological Institute
Phoenix, AZ

Mark J. Dannenbaum, MD

Emory University
Atlanta, GA

Andrew F. Ducruet, MD

Barrow Neurological Institute
Phoenix, AZ

Samuel Hou, MD, PhD

University of Massachusetts Medical
School
Worcester, MA

Viktor Szeder, MD, PhD, MSc

UCLA
Los Angeles, CA

Ryan B. Viets, MD

Mallinckrodt Institute of Radiology
St. Louis, MO

Medical Students

Philip J. York

University of Oklahoma College of
Medicine
Oklahoma City, OK

Michael Brothers Award Recipient Named at ASNR

SNIS is pleased to announce that the 2011 recipient of the Michael Brothers Memorial Award is Pierre Gobin, MD from Weill Cornell Medical College. His manuscript, *"Intra-arterial Chemotherapy (Chemosurgery) in the Treatment of Retinoblastoma: Four-Year Experience"* was named the Best Paper in Interventional Neuroradiology at the 49th Annual Meeting of the American Society of Neuroradiology, held June 4-9, 2011 in Seattle, Washington.

Congratulations to Dr. Gobin!

FDA and CMS Begin Parallel Review Pilot Program

The US Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) announced that the agencies are soliciting nominations from sponsors of innovative device technologies to participate in a pilot program for concurrent review of certain FDA premarket review submissions and CMS national coverage determinations. The pilot program is voluntary, and it is only available for qualifying new medical device technologies. It will not change the existing separate and distinct review standards for FDA device approval and CMS coverage determination, advised the agencies.

The agencies noted that innovators have generally focused solely on obtaining FDA approval, only to later realize that Medicare payment may not automatically be forthcoming. Parallel review is intended to reduce the time between FDA market-

ing approval and CMS national coverage determinations in order to improve the quality of patient health care by facilitating earlier access to innovative medical products for Medicare beneficiaries.

Complete details of the program can be found in the agencies' notification published in the Federal Register (2011;76:62808-62810).

Device sponsors interested in requesting voluntary parallel review should contact Markham C. Luke at the FDA's CDRH by phone at (301) 796-5550 or by email at markham.luke@fda.hhs.gov.

In the Federal Register, the agencies have outlined guiding principles underlying the pilot program; appropriate candidates for the pilot program; procedures the FDA and CMS intend to follow in conducting parallel product reviews; and general roles and responsibilities of the sponsor/requester, the FDA, and CMS.



Happy Holidays from all of us at SNIS!

*Best wishes for the holidays and happiness
throughout the New Year!*



Proposed Legislation Seeks to Improve FDA Regulatory Process for Medical Devices

United States Senators Amy Klobuchar (D-MN), Richard Burr (R-NC), and Michael Bennet (D-CO) announced the introduction of legislation that they have co-sponsored that seeks to help boost medical innovation by reducing regulatory burdens that unnecessarily delay beneficial new medical products from reaching patients. The senators stated that the Medical Device Regulatory Improvement Act would help to streamline the US Food and Drug Administration's (FDA) regulation of medical devices to continue to encourage innovation and bring new lifesaving products to market more quickly, without compromising consumer safety.

According to the senators, the FDA's regulation has become increasingly longer and more difficult during the past few years, delaying, and in some cases preventing, new and innovative devices from reaching the market. They

cited recent studies showing that the average time to approve a 510(k) application has increased 43 percent from the 2003 to 2007 period to 2010, and the average time to approve a premarket approval application has increased 75 percent. They noted that a recent survey of venture capitalist life sciences investors showed that approximately 40 percent of investors are more likely to shift their operations and investments overseas because of the FDA's regulatory challenges.

The senators stated that the legislation would help to streamline the FDA's regulation of medical devices by clarifying the FDA's current, least burdensome requirements. They believe that these provisions will ensure that when making regulatory decisions on medical devices, the FDA focuses only on the relevant information during the decision-making process; considers appropriate alternatives to reduce the time, effort, and

cost of reaching regulatory decisions; and uses all reasonable mechanisms to reduce review times when making these decisions.

The senators further asserted that current conflicts-of-interest restrictions are overly stringent, resulting in the FDA having difficulty finding qualified experts to serve on advisory committees, which can contribute to unnecessary delays for patients. In response to this problem, the legislation would restore the appropriate balance to conflicts-of-interest requirements by requiring the FDA to be subject to the same conflicts-of-interest requirements as the rest of the federal government. Finally, the legislation would also direct the FDA to contract with an outside entity to conduct a thorough review of the management and regulatory processes at the FDA's Center for Devices and Radiological Health, including the impact on medical device innovation.

Are You Getting the Most Out of Your Membership?

If SNIS does not have your email address, the answer to this question may well be a resounding no! Although we make sure to communicate our news to you through multiple venues – including standard mail, the SNIS web site, and even the occasional phone call – without question, emails rank at the top of the list where it concerns members' preferred communication vehicle.

As we are highly sensitive to the quantity of emails that you receive each day, SNIS carefully aims for no more than 1-2 a month. Why would you want to receive these emails? To get the latest news on items including information on upcoming meetings, breaking news related to society or neurointerventional developments, information on committees or task forces in which you may be interested, valuable membership surveys

that help us gauge your needs and the impact of our work – and much more!

Remember – SNIS prioritizes confidentiality where all of our membership information is concerned; thus, we will never pass on your email address to outside vendors.

Be sure to send us your email address now – so that you won't miss out on valuable news that is pertinent to you! You may provide your email address to us by sending it to info@snisonline.org or calling us at **703-691-2272**.



Tis the Season to...give to the SNIS Foundation

As we approach the end of 2011, we would like to thank all of the SNIS members and friends who have given to the SNIS Foundation. In our inaugural year, we have received a total of \$32,775 in cash contributions, in addition to a very generous educational grant from Codman Neurovascular, Inc. These contributions make it possible for us to fulfill the mission of our Foundation, which is to provide fellowship grants to exceptional programs that are home to the future practitioners and leaders of our field. This year, the SNIS Foundation is pleased to announce that gifts in the amount of \$22,750 will be awarded to ten international programs, including Cleveland Clinic, London Health Sciences Centre, Massachusetts General Hospital, Ochsner Medical Center, Stanford University, University of Medicine & Dentistry of New Jersey, University of Massachusetts, University of Miami, University of Michigan, and

University of Virginia.

Now that we have officially entered the season of giving and are already planning for 2012, the SNIS Foundation Board would like to encourage both members and industry, as companies and as individuals, to consider making a contribution. Our Foundation provides SNIS with a tangible opportunity to lend the resources and support of our society to the programs that provide the training necessary for new practitioners to make their own individual mark on the field of neurointervention. So before the clock strikes 2012, please consider adding a tax-deductible contribution to the SNIS Foundation to your year-end giving list. All contributions will be recognized through a variety of SNIS channels, as we want to publicly thank donors for their generosity and investment in our field. After all, it's the individual and collective commitment of our membership and friends that will

enable us to continue to grow our field with increasing numbers of practitioners dedicated to neurointerventional advancement and patient care.

Throughout 2012, the Foundation will keep its membership apprised of our financial status and further plans to support our field's trainees through research grants and continuing education opportunities. Thank you again for your generous support to date!

Happy Holidays and wishing you a joyful and fulfilling New Year!

Sincerely,

The SNIS Foundation Board

Lee Jensen, MD, Chair
Philip Meyers, MD, Treasurer
Michael Alexander, MD
Italo Linfante, MD
Christopher Moran, MD
Peter Rasmussen, MD

IN MEMORIAM



Former SNIS Member and respected neurointerventional radiologist, Vance Emery Watson, MD, passed away of unknown causes, September 11, 2011 at his home in Arlington, VA. Born in Glasgow, Montana June 1, 1960, he always held a deep fondness for nature and his Montana roots. Vance focused much of his young adulthood earning his many degrees to become a highly skilled and immensely talented neurointerventional radiologist. He did his undergraduate work in biomedical engineering at Tulane University, graduated from University of Maryland Medical School, accomplished his residency in radiology at Duke University, and completed a prestigious fellowship in interventional radiology at UCLA Medical Center. He served as Chief of Neurointerventional Radiology and Assistant Professor at Georgetown University Hospital in Washington, DC for sixteen years. Vance was an avid sailor and scuba diver, and lived on his 45 foot sailboat in Marina del Rey, CA during his time at UCLA. He most enjoyed swimming, beach strolls, mini-golf, dining out and cooking with his two boys. Vance will be deeply missed by his beloved sons, Marsden Vance Watson, age 15 and Barrett Rowe Watson, age 8; and all of his SNIS colleagues and friends.



I would like to make a donation to the SNIS Foundation.

Name
Institution/Company
Address
Address
City State Zip
Country (if not US)

- Friends: Gifts up to \$99
Contributors: Gifts of \$100-\$249
Supporters: Gifts of \$250-\$499
Stewards: Gifts of \$500-\$999
Benefactors: Gifts of \$1000-\$2,499
Sponsors: Gifts of \$2,500-\$4,999
Patrons: Gifts of \$5,000-\$9,999

My donation today is in the amount of \$_____.

PAYMENT INFORMATION:

To pay by check: Make checks payable to SNIS Foundation in US funds drawn on a US bank.

Remit Payment to: SNIS Foundation
3975 Fair Ridge Drive, Suite 200 North
Fairfax, VA, 22033

Please charge the above donation to my:
VISA MasterCard American Express Discover

Fax with credit card information to (703) 537-0650.

If paying by credit card, please list your 3-digit security code (MasterCard/Visa/Discover) or 4-digit security code (American Express) from the signature strip:_____

Credit Card Number Expiration Date
Name of Card Holder
Signature of Card Holder Date

The SNIS Foundation is formed as a charitable organization under section 501(c)(3) of the Internal Revenue Code. Donations are tax deductible as a charitable contribution to the maximum extent allowed by law. Please consult your tax advisor.

SNIS Foundation
Founding Donors
(as of 11/30/11)

Patrons (Gifts of \$5,000-\$9,999)
Joshua A. Hirsch, MD
Mary E. (Lee) Jensen, MD
Philip M. Meyers, MD

Sponsors (Gifts of \$2,500-4,999)
Cameron G. McDougall, MD

Benefactors (Gifts of \$1,000-\$2,499)
Adam Elsesser
Peter Kvamme, MD
Anthony M. Masaryk, MD
James M. Milburn, MD
J. Neal Rutledge, MD
Robert W. Tarr, MD

Stewards (Gifts of \$500-\$999)
Brian Hoh, MD
Ferdinand Hui, MD
P. Kim Nelson, MD
Charles J. Prestigiaco, MD
Peter Rasmussen, MD
S. Kumar Reddy, MD
Leroy Roberts, MD
Jeffrey L. Sunshine, MD, PhD
Marie Williams, CAE

Supporters (Gifts of \$250-\$499)
Michael J. Alexander, MD
Kristine A. Blackham, MD
Andrew J. DeNardo, MD
Andre Fredieu, MD
Steven W. Hetts, MD
Jonathan E. Hodes, MD
Wallace W. Peck, MD
Ansaar Rai, MD

Contributors (Gifts of \$100-\$249)
Robert R. Beskin, MD
Kirk Conrad, MD
Gary R. Duckwiler, MD
B.J. Gralino, Jr., MD
Laszlo Miskolczi, MD
Christopher M. Moran, MD
George Rappard, MD
George P. Teitelbaum, MD
Van R. Wadlington, MD
Wayne F. Yakes, MD

Friends (Gifts up to \$99)
Shaye I. Moskowitz, MD, PhD
Mario J. Polo, MD

CALENDAR OF EVENTS

SNIS Events

Society of NeuroInterventional Surgery 10th SNIS Practicum

April 27-28, 2012
Sheraton New York Hotel & Towers
New York, New York
Contact: SNIS, 703-691-2272

Society of NeuroInterventional Surgery 9th Annual Meeting

July 23-26, 2012
Hilton San Diego Bayfront Hotel
San Diego, California
Contact: SNIS, 703-691-2272

Society of NeuroInterventional Surgery 3rd Annual Fellows Course

July 26-27, 2012
Hilton San Diego Bayfront Hotel
San Diego, California
Contact: SNIS, 703-691-2272

Other Events

International Stroke Conference
February 1-3, 2012
New Orleans, Louisiana
Contact: www.strokeconference.org

The Embolus

Managing Editor: Marie Williams, CAE
Graphic Designer: Barbara Erickson
Contributing Authors: Rebecca Hall
Marie Williams, CAE

The Embolus is published by the
Society of NeuroInterventional Surgery,
3975 Fair Ridge Drive, Suite 200 North,
Fairfax, VA 22033.

Copyright © 2011
Society of NeuroInterventional Surgery

POSTMASTER: Send address changes to
The Embolus, 3975 Fair Ridge Drive,
Suite 200 North, Fairfax, VA 22033.

Send your articles, letters and comments to:
The Embolus, 3975 Fair Ridge Drive,
Suite 200 North, Fairfax, VA 22033;
703-691-2272; FAX 703-537-0650;
www.snisonline.org



3975 Fair Ridge Drive
Suite 200 North
Fairfax, VA 22033