

The 2013 International Endovascular Stroke Conference: A New Partnership, A Milestone Meeting

In recent years, stroke has been a dominant focus in neurointerventional dialogue and news. In 2012 alone, we saw the DMSB recommend IMS III be placed on hold, the debut of new treatment devices and more discussion and debate than in recent history around the state of training, particularly where it concerns stroke. Now, as we prepare to begin a new year, SNIS continues to shine the spotlight on stroke with the upcoming 3rd SNIS International Endovascular Stroke Conference (IESC) and Joint Cerebrovascular Section Annual Meeting, scheduled for February 4-5, 2013 at the Sheraton Waikiki Hotel in Honolulu, Hawaii. Replacing the 2013 SNIS Practicum, the IESC, in a first-time initiative, will be co-hosted in partnership with the Joint Cerebrovascular Section Annual Meeting immediately prior to the International Stroke Conference.

More than a meeting, this alliance is a reflection of the collective understanding that our success in addressing the numerous issues associated with advancing neurointerventional stroke treatment is dependent on more than one group, one approach or one idea...but rather a commitment to the community of neurointerventional thought that can inform our direction and expand our vision.

To provide our membership with more information on this inaugural two-day meeting and what potential attendees can expect, SNIS Program Chair Don Heck, MD has participated in the following Q&A.

Q. What was the impetus for the IESC to join forces with the Joint Cerebrovascular Section to co-host this meeting in advance of the International Stroke Conference?



DH: As we look to the future of neurointerventional medicine, it is important that we forge the kind of partnerships that will allow us to work more efficiently and effectively to achieve our mutual goals. Given that endovascular stroke treatment continues to pose many challenges, in the clinical, research and financial arenas, this meeting represents an opportunity to come together to address those issues in what promises to be the most comprehensive forum

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PRESIDENT'S COLUMN

Michael Alexander, MD

Helping Patients in a Time of Uncertainty

Last week, I was sitting in the neurointerventional suite control room at midnight, getting ready to start an intervention on an 80-year-old patient with acute ischemic stroke (AIS). According to his family, he had still been active working in the family business and was full of life—good reasons to consider aggressive treatment in an elderly patient. Clinically speaking, I could check the boxes that would justify endovascular intervention. His NIH stroke scale score was 24, he received intravenous tPA at four hours from onset of aphasia and hemiplegia with no improvement, and his CT angiogram showed a left carotid terminus occlusion with a small core infarct by CT perfusion, but a large, hemispheric mismatch between cerebral blood volume and cerebral blood flow. He was now six hours into his stroke and here we were in the neurointerventional suite to see if we could help him out.

Yet, as I pondered all the forces against performing interventional treatment in AIS today, it made me wonder what, in fact, I was even doing there at midnight. If I were to base my decision to treat on the still-to-be-released NIH-funded, randomized-controlled trial IMSIII (which was stopped for futility, apparently showing no benefit of thrombectomy over intravenous tPA), then I guess I would have been at home rather than the hospital. Or if I were to base my decision solely on the financial benefit, which is minimal given that this entire procedure is not likely to be reimbursed, I theoretically would not be there. If I were to base my decision on the opinions of some my nation-

ally esteemed neurology colleagues who recently at a NINDS/NIH workgroup meeting expressed that “intra-arterial therapy for stroke doesn’t work,” it is likely I would not be there.

So why *was* I there in the neurointerventional suite at midnight?

Clinical judgment is complex and at times not easily explainable. It is not practice based solely on trial results, nor practice based entirely on personal experience or a well-educated whim. It is an amalgam of the two. In our field, so little of what we do is based on research and studies—I suppose this is good and bad. While randomized-controlled trial data is thought to be the holy grail of clinical practice, it actually is only as reliable and valuable as its trial design. And while we may have only the best intentions when laying the groundwork for a new trial, history tells us that it can be fraught with unperceived design bias, enrollment bias, and other factors not anticipated to impact the ultimate outcome. In those cases where the trial design is significantly flawed, then, even the most esteemed trials can be like the old computer processing acronym: GIGO—garbage in, garbage out. In reality, most of the neurovascular diseases that we address are multifactorial complex pathologies that deserve thoughtful and studied approaches; yet, our most recent trials have fostered a very binary type of thinking: intervention bad, medicine good.

Given these challenges and others, we seem to be navigating uncertain waters in neurointervention. Especially when one considers that recent trials show no clear benefit for neurointerventional

therapy in multiple areas including acute ischemic stroke, intracranial atherosclerotic disease, vertebral augmentation, and perhaps, down the road, arteriovenous malformation (AVM) treatment. From my perspective, these are not therapy failures, but rather failures to correctly select the patient group who would best benefit from endovascular therapy, to exercise technical proficiency in performing these procedures, and to define the appropriate medical management in the peri-procedural period. Considering all of these shortcomings, my prolegomena to any future endovascular randomized-controlled trial would be:

1) Take the lead. Neurointerventionists have to be the Principal Investigator (PI) on neurointerventional trials. We have to be the champions, the torch bearers. While having neurologists as the primary PI on neurointerventional trials may be perceived as less biased, it is true that even well-meaning neurologists may have internal biases against non-medical therapies. It is not clear to me how a PI can design and conduct interventional trials for intracranial atherosclerotic disease (ICAD), AVMs, etc., when they have never personally performed an intervention in a single one of these patients. Their lack of practical and applicable experience, I believe, prohibits them from being able to lend a well-rounded and comprehensive perspective to all aspects of trial development and implementation.

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SNIS Foundation is On the Move

The inaugural year for the SNIS Foundation has proven most successful, with total fundraising efforts exceeding \$480,000. Moreover, funds have been received from individuals and companies across the neurointerventional community to include practitioners, our industry friends and friends/loved ones of patients, a true testament to the collective commitment to improve patient care by supporting the research and educational goals of our society.

But 2012 is not over yet!

In recognition of those donors who are helping to lay the groundwork for the Foundation, SNIS has created a special category, known as "Founding Donor", for any individual or company who contributes by December 31, 2012. To show the Society's appreciation for your investment in our future, Founding Donors will be recognized

by name on an engraved plaque in the SNIS office as well as through various other SNIS channels. If you would like to seize this opportunity to support the SNIS Foundation, please choose any of the following options to make your contribution.

1. Simply go to our website: www.snisonline.org/donate to enter your credit card information.
2. Call the office at 703-691-2272 to request a donation form.
3. The SNIS Foundation now has the ability to accept gifts of stock. Instructions for donating stock are:

All securities held in book-entry form may be sent to:

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To confirm receipt of deliveries and provide donor information, please contact Marlivia Minter at (240) 200-3314 or via e-mail at mminter@brownadvisory.com.

Thank you in advance for your support of our educational and research goals. With your help, we can continue to commit resources and support to valuable research projects that ultimately advance the science of neurointervention and bring innovations in technology and endovascular treatments to life.



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IMMEDIATE PAST PRESIDENT'S COLUMN

Joshua Hirsch, MD

In thinking through the focus of the Past President's column for this edition of *The Embolus*, I am challenged to decide which topic to explore. It's certainly been a year of consequence.

Within our own neurointerventional community, the past year has played witness to many achievements that have served to advance both society and neuroscience goals. On the home front, we've recently completed our 9th Annual Meeting, a forum that has become the must-attend neurointerventional event of the academic calendar. In addition to a strong slate of scientific sessions, discussion opportunities and abstract presentations, all designed to promote dialogue on the most pressing practice and clinical issues of the day, the meeting also featured a few new highlights. Speakers outside of our neurointerventional core, including old friend to SNIS, Walter Koroshetz, Deputy Director of the National Institute of Neurological Disorders and Stroke, and new friends, Craig Mullaney, author of the New York Times best-seller *The Unforgiving Minute*, and Peter Carmel, Immediate Past President of the American Medical Association, gave inspiring addresses that lent new perspective to the roles we serve in the advancement of our field as well as caretakers of quality patient care.

This year, we also celebrated a significant milestone...our 20th Anniversary. Our Annual Meeting Past President's dinner hosted more leaders than ever before, and reminded us of our long legacy of commitment to excellence. But, certainly, no greater testament to SNIS's past exists than our robust organization of the present. In this volume, you'll find updates on the *Journal*

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of *NeuroInterventional Surgery* (JNIS), the newly initiated SNIS Foundation and our highly successful IESC program, which is now entering its third year with an exciting new partnership with the Joint Cerebrovascular Section. Additionally, SNIS was a highly effective (I note with pride) voice in the CAS coverage expansion at MedCAC, Wingspan at FDA and in multiple other specific instances too numerous to mention in this column.

On the national stage, there have been notable developments as well as we have been witnesses to legislative developments that may well impact our field in the short- and long-term. On May 23, 2010, President Obama signed the Affordable Care Act (ACA) into law. While there is discussion about repealing this law, no serious political observer believes this to be realistic even if there is a change in party occupying the White House. Thus, while indi-

vidual components may be challenged, modified and changed the law will likely stand. For purposes of this article I want to focus on the two independent boards developed as part of the ACA and the impact on the future of neurointerventional surgery.

First, the Independent Payment Advisory Board (IPAB) was established to recommend policies to Congress designed to help Medicare provide better care at a lower cost, including ideas on coordinating care, getting rid of waste in the system, offering incentives for best practices and prioritizing primary care. Congress then has the power to accept or reject these recommendations. If they reject or fail to act – perhaps more worrisome for a Congress that has failed to structurally address the SGR conundrum over many years and faces a fiscal cliff at the end of 2012 – the Secretary of Health and Human Services (HHS) is then positioned to follow the IPAB's recommendations. Medical groups have criticized the IPAB for moving away from the careful constructs of the RBRVS (RVU based) system in which SNIS, through several of its members, participates.

Secondly, Comparative Effectiveness Research (CER) is perhaps the most celebrated research initiative in the United States. The Patient Centered Outcomes Research Institute (PCORI) evaluates and compares health outcomes and their clinical effectiveness, as well as the risks/benefits of treatments, services and procedures. Many medical organizations have expressed support for the PCORI. The Washington State Health Care Authority (WS HCA) is relying on CER and as such might be thought

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SPOTRIAS Consortium Experience Supports Intra-Arterial Acute Stroke Therapy for Octogenarians

Investigators conducted a study from the Specialized Program of Translational Research in Acute Stroke (SPOTRIAS) consortium experience on the impact of acute ischemic stroke treatment in patients older than 80 years. Joshua Z. Willey, MD, et al published the SPOTRIAS findings online ahead of print in *Stroke*.

As summarized in *Stroke*, the background of the investigation is that few studies have addressed outcomes among patients older than 80 years who are treated with acute stroke therapy. In their findings, the investigators outlined in-hospital outcomes in (1) patients 80 years or older compared with their younger counterparts and (2) those older than 80 years receiving intra-arterial therapy (IAT) compared with those treated with intravenous recombinant tissue plasminogen activator (IV rtPA).

The investigators concluded that IAT does not appear to increase the risk of in-hospital mortality among patients older than 80 years compared with IV thrombolysis alone.

In the study, stroke centers within the SPOTRIAS network prospectively collected data on all patients who were treated with IV rtPA or IAT from January 1, 2005 to December 31, 2010. The IAT group was defined as those patients receiving any endovascular therapy and was further divided into bridging therapy when the patients received both IAT and IV rtPA or endovascular therapy alone. In-hospital mortality was compared in all patients 80 years or older versus their younger counterparts, as well as IAT, bridging therapy, and endovascular therapy alone versus IV rtPA only among those 80 years and older, using multivariable logistic regres-

sion. An age-stratified analysis was also performed.

A total of 3,768 patients were included in the study: 3,378 were treated with IV rtPA alone and 808 with IAT (383 with endovascular therapy alone and 425 with bridging therapy). Patients 80 years or older (n=1,182) had a higher risk of in-hospital mortality compared with their younger counterparts regardless of treatment modality (odds ratio [OR], 2.13; 95% confidence interval [CI], 1.6-2.84).

When limited to those patients 80 years or older, IAT (OR, 0.95; 95% CI, 0.6-1.49), bridging therapy (OR, 0.82; 95% CI, 0.47-1.45) or endovascular therapy alone (OR, 1.15; 95% CI, 0.64-2.08) versus IV rtPA were not associated with increased in-hospital mortality, reported the investigators in *Stroke*.

Draft Guidance Document Addresses Acceptability of 510(k) Submissions

The US Food & Drug Administration (FDA) has issued a draft guidance document entitled the “Refuse to Accept Policy for 510(k)s”, which explains the procedures and criteria the FDA intends to use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for substantive review. The guidance is applicable to 510(k) submissions reviewed in the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research. This draft guidance is not final nor is it in effect at this time.

Once finalized, the guidance document will replace two existing “Refuse to Accept” documents that were issued in 1993 and 1994. The current draft document states that the FDA has modified its 510(k) “Refuse to Accept” policy to include an early review against specific acceptance criteria and to inform the submitter within the first 15 calendar

days after receipt of the submission as to whether the submission is administratively complete or, if not, to identify the missing element(s). In order to enhance the consistency of the FDA’s acceptance decisions and to help submitters better understand the types of information the FDA needs in order to conduct a substantive review, the guidance, which includes a set of checklists in the appendices, clarifies the necessary elements and contents of a complete 510(k) submission.

The process that the document outlines will be applicable to all devices reviewed through the 510(k) notification process and has been compiled into these checklists for use by the FDA review staff.

The agency stated that it is critical to distinguish the completeness of the regulatory submission, the quality of the data provided, and any studies conducted in support of the submission.

The assessment of the completeness of the 510(k) submission occurs during the acceptance review, while the assessment of the quality of the submitted information occurs during the substantive review. Acceptance will be based on the objective criteria outlined in the associated Acceptance Checklist and not on the quality of the data.

The FDA advised that it is focusing the agency’s review resources on complete submissions, which will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible. Also, with the medical device user-fee legislations of 2002, 2007, and 2012, the agency agreed to performance goals based on the timeliness of reviews. Acceptance review is important for both encouraging quality submissions from sponsors of 510(k) notifications and allowing the FDA to appropriately concentrate resources on complete submissions.



JNIS Update

Rob Tarr, MD, Editor-in-Chief

JOURNAL OF NEUROINTERVENTIONAL SURGERY

*The road is long
With many a winding curve
That leads us to who knows where
Who knows where*

—The Hollies, 1969

Having been on this journey as the editor-in-chief of the *Journal of NeuroInterventional Surgery* (JNIS) for little over three years now, I still consider myself a rookie. I am continuously learning nuances regarding the editorial, production, and publishing process. Fortunately I have had the benefit of an excellent group of associate editors, a wonderful Editor Assistant, a resourceful Production Editor, an insightful Journal Manager, and invaluable guidance from senior management at BMJ. The long and winding road has been all the more illuminated by their expertise and efforts.

From my perspective, JNIS is doing quite well. Because submissions to the journal have continued to steadily increase, we have transitioned from a quarterly print journal to a bimonthly print journal. Even with the increase in submissions, we have been able to maintain efficiency in process. Average time to first decision on manuscripts is approximately 20 days and average time from acceptance to online publication is approximately two weeks.

We continue to publish case reports as these are vital learning tools for our specialty; however, to optimize print publication workflow we have made the

decision to publish them in BMJ Case Reports as well as republishing them online in an assigned issue of JNIS. Thus, case reports are indexed under both JNIS and BMJ Case Reports in all major search engines.

We have added several new initiatives over the past year. One, which I am certain you are thankful for, is that the lead author of the editor column is now alternated amongst the Associate Editors and me. Therefore, you are only subjected to my esoteric thoughts but once per year. More importantly, you now can enjoy the opportunity to digest the erudite thoughts of the Associate Editors. In the past year, they have informed you on such timely topics as the HDE process, the effects of randomized trials on our subspecialty, the impact of the IMS III trial, manpower issues in neurointervention, and journal impact factor.

Also new to JNIS this year are Point-Counterpoint and Book Review sections which are managed by Assistant Editors Kristine Blackham and Albert Yoo respectively. The Point Counterpoint section, presented in debate format, aims to inform you about controversial topics from the perspective of established leaders. The Book Review section summarizes the qualities of recently published text books related to the field of neurointervention.

A special new feature is also making its debut as the corresponding author for the editor's choice article(s) in each issue is invited to participate in a podcast discussing his or her work. The podcasts are accessible online on the journal



website (www.jnis.org) and I would encourage you to peruse them at your leisure. This new addition allows the authors to expand upon aspects of their work which space restrictions may not allow for in the printed article.

In conclusion, JNIS continues to serve as the central home for neurointerventional literature. I thank all of you for your outstanding support and I continue to encourage you to submit your scientific work, review articles, or commentaries to JNIS. Instructions for authors can be found at www.jnis.org. Further, please forward any comments or suggestions to me at editor@jnis.org, as I endeavor to do everything I can to ensure that JNIS meets the various needs of our practitioners and collective field.

As with any new initiative, the size of the vision is often matched by the uncertainty of the outcome. Whereas JNIS is still in the growth phase, I can happily say that our forward direction is leading not to “who knows where,” but to a place of influence in the neurointerventional community.

FDA and Industry Reach Agreement on Medical Device User Fees

The US Food & Drug Administration (FDA) announced that the agency and representatives from the medical device industry have reached an agreement on recommendations for the third reauthorization of a medical device user fee program. The industry associations that have reached the agreement with the FDA include the Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturers Association, and the Medical Imaging and Technology Alliance.

The recommendations, which took effect on October 1, would authorize the FDA to collect \$595 million in user fees over five years plus adjustments for inflation. With this additional funding, the FDA will be able to hire more than 200 full-time-equivalent workers over the five years.

According to the FDA, under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's device review activities while the FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame.

AdvaMed noted that in addition to reducing the total review time on a premarket approval (PMA) application or 510(k) submission, the performance goals in the agreement would:

- Achieve significant performance improvements for PMA and 510(k) applications relative to current performance;
- Leave “no submission behind” by requiring the FDA to meet with companies if a performance goal on

a PMA or 510(k) is missed and work out a plan for completing work on the submission;

- Provide a substantive interaction with applicants halfway through the targeting time for completion of review, thus ensuring that a company can have time to properly respond to appropriate questions; and
- Implement an analysis of the FDA's management of the review process by an independent consulting organization, coupled with an FDA corrective action plan to address opportunities for improvement.

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. Perhaps most telling is that companies, big and small, are dedicating increasing marketing dollars to digital and social media initiatives.

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 an SNIS fan page which we encourage you to “like.” By including us in your friend list, SNIS will exponentially increase its visibility among all your contacts, who, in turn, may choose to “like” our page as well. As we expand



our base of Facebook friends, we also expand opportunities for thousands to learn about who we are and the work to which we are committed.

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!

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.

2) **Design trials for success.** The purpose of an expensive prospective trial is not to simply see what happens with a certain intervention, but to verify existing data that the intervention will be successful. So what would such a trial *not* look like? No five-year trials to examine natural history of a life-long disease, such as AVMs versus surgical or endovascular intervention. No enrolling patients in an AIS thrombectomy trial regardless of their clot burden or perfusion status. Not designing an ICAD stenting trial in which greater than 90 percent of the patients enrolled would not have met the inclusion criteria for the FDA safety trial for that device. And not enrolling patients in an unruptured cerebral aneurysm trial, after you have already determined by your clinical judgment that they are at low risk of rupture.

3) **Incentivize study enrollment.** It is difficult to enroll patients in randomized controlled trials, especially if endovascular devices already **have FDA clearance or approval** and are being marketed. There is no incentive for the patient, and no incentive for the physician to participate in such a trial. In one way, this is a positive because incentives create further potential for bias. On the other hand, if there is no incentive, studies show

poor enrollment, which as discussed above, can introduce its own form of bias.

4) **Ensure comprehensive care.** The patient's outcome is not solely dependent on their intervention. If we are placing stents in a patient's cerebrovascular circulation, we had better be fully knowledgeable about anti-platelet medications, anti-platelet therapy resistance, post-procedural blood pressure management, etc. These factors, in some cases, may affect outcomes more than the differences in technique and other aspects of the actual interventional procedure. Not to account for these factors in the clinical trial may severely skew the results.

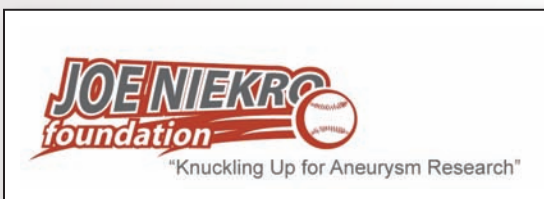
5) **Design trials for the real world situation.** If your trial does not reflect what is achievable at comprehensive neurovascular centers, then it may lack impact. The aggressive medical management system that was used in SAMMPRIS was effective, but not practical. Likewise, the oxygen extraction PET scan imaging in COSS might, in some circles, be considered a gold standard, but again, not achievable in the majority of centers. So a reality check should be the final step before proceeding: Can this be done?

Our late night intervention back in the angio suite ended up proceed-

ing very quickly. Using a mechanical thrombectomy device, we were able to open the carotid terminus and middle cerebral artery occlusion in about 20 minutes, with a TICI score of 3, and high fives all around. The patient had a completed basal ganglia stroke on delayed CT, but regained his speech and anti-gravity strength in his arm and leg. The family was immensely happy and grateful, and was anticipating him going back to work in the family business. I have no doubt, without our intervention, he would have been dead or in a nursing home, dependent for the rest of his life.

So I am glad we didn't allow the results of that well-designed, prospective randomized controlled trial to guide our decisions. I am glad we didn't listen to those nationally esteemed neurologists who literally scoffed at intra-arterial therapy. And finally, I am glad we did not subscribe to the endovascular nihilism that is beginning to infiltrate our specialty. We saved that patient's life with endovascular intervention, based on our team's clinical judgment and technical expertise. So along with all my many colleagues who experience the same kind of victories day in and day out with patients whose lives would otherwise be cut short or never the same, I felt a certain amount of vindication when I walked out of the hospital that night. After all, why else would any of us be here?

SNIS Foundation Partners with National Aneurysm Foundation



The SNIS Foundation is pleased to announce an affiliation with the Joe Neikro Foundation for Aneurysm Research. The Joe Neikro Foundation was established in 2007 by Natalie Neikro in honor of her father, baseball great Joe Neikro, who lost his life from a sudden cerebral brain aneurysm on October 27, 2006.

The Joe Neikro Foundation is committed to aiding in the research and treatment of aneurysm patients and families. Their goal is to raise awareness about aneurysm factors, causes, treatments and research.

We look forward to bringing you more information about this exciting new partnership as it develops.

Legislation Would Require Postmarket Studies After 510(k) Clearance of Devices

US Senators Chuck Grassley (R-Iowa), Richard Blumenthal (D-Connecticut), and Herb Kohl (D-Wisconsin) announced the introduction of legislation that seeks to protect patients from unsafe medical devices and improve the management of recalls.

The Medical Device Patient Safety Act would give the US Food & Drug Administration (FDA) important tools to discover problems with faulty medical devices sooner and to better manage recalls when problems do occur, without slowing down the approval process for new devices.

The legislation would allow the FDA to require post-market clinical studies for medical devices that pose potential safety risks, if they were approved through the expedited 510(k) review process. The bill would also implement Government Accountability Office

(GAO) recommendations for improving recalls and give the FDA new authority to require conditional clearance pending safety studies for devices reviewed under the fast-track 510(k) approval process. The GAO report was issued in June 2011 and can be downloaded at the GAO website.

“This reform legislation should be part of the reauthorization of the medical device user fee law,” Senator Grassley said. “The reforms incorporate well-founded recommendations from the Government Accountability Office and reflect the value of having a robust postmarket surveillance operation in the FDA. Important information can be learned about product safety after a device is on the market, and when there are problems, the sooner the response, the better.”

FDA Issues Draft Guidance on HUD Designations

The US Food & Drug Administration (FDA) announced a draft guidance for industry and FDA staff titled “Humanitarian Use Device (HUD) Designations.” The document is available on the FDA’s website.

The FDA advised that this guidance document is intended to assist applicants in the preparation and submission of HUD designation requests and FDA reviewers in evaluating such requests.

According to the FDA, devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive a HUD designation may be eligible for marketing approval under the Humanitarian Device Exemption marketing pathway.

Topics addressed in this guidance include demonstration in HUD requests that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year; how this demonstration varies, depending on whether the device is intended for therapeutic or diagnostic purposes; how properties of the device may affect this demonstration; and delineating a medically plausible subset of persons with a given disease or condition, stated the FDA.

The comment period regarding this draft document has closed and the FDA is currently reviewing the comments received.

SNIS Charts Bold New Future

In February, the Executive Committee of SNIS met for two intense days of strategic planning. During a facilitated planning session, the Society’s leaders created a dynamic plan that will guide the organization’s future direction, highlight its goals, and ensure its continued growth.

The Executive Committee (now referred to as the Board of Directors) approved the following:

Vision

Be the leading multidisciplinary society for all neurointerventional physicians.

Mission

The Society of NeuroInterventional Surgery is dedicated to excellence in comprehensive, minimally-invasive care of patients with stroke, brain aneurysms, and other diseases in the head, neck and spine.



Goal 1: Foster the growth of the Society

Goal 2: Advance excellence in clinical practice of neurointerventional surgery through education and research

Goal 3: Protect patients with professional standards of practice, training and ethics

Goal 4: Provide services to members that support excellence in clinical practice

Goal 5: Advocate for appropriate health care policy and public awareness

Each of these goals is accompanied by several strategies. The full strategic plan may be found on the SNIS website in the Members Only Section.

to enjoy neurointerventional support in a manner similar to motherhood and apple pie. Indeed, the language used by the WS HCA is that they will endorse “paying for tools and procedures that are proven to work.” In specific relatable terms, the WS HCA no longer supports vertebroplasty for its covered patients. Separately, the Anthem insurance company has labeled mechanical embolectomy for stroke investigational and not medically necessary on the basis of their own Health Technology Assessment. Wellpoint, which is parent company to Anthem, and describes itself as “one of the largest health benefits companies in the United States,” is planning to expand this policy to more covered lives. SNIS, in conjunction with other neuroscience organizations, has been and continues to actively work with Wellpoint to initiate dialogue that may lead to a change of view.

Complicating matters, on April 18, 2012 the IMS III Data and Safety Monitoring Board recommended that the trial be placed on hold, due to pre-specified planned interim analysis that showed the very low likelihood of finding significant outcome differences between the two treatment arms. Many of us believe that these results are mitigated by several factors that doomed the endovascular arm from the start, preventing a demonstrated benefit that we practitioners believe accompanies neurointerventional treatment approaches. Indeed, it is reminiscent of discussions in which SNIS participated following the August 6, 2009 publication of vertebroplasty randomized controlled trial data regarding patient selection. Note carefully that despite the opinions of SNIS members and many other organizations, WS HCA no longer covers vertebroplasty as it does not believe that this treatment has been proven to work. Indeed, in this new healthcare climate, expressed challenges to a trial do not constitute proof with respect to coverage in that CER-based environment.

There are clear lessons for SNIS and its members as we move forward.

So what does the future hold?

We would do well to remember that in this era of PCORI, where stakeholders will certainly include people that have a broad array of opinions regarding intra-arterial stroke therapy, that many stroke neurologists do not agree that mechanical thrombolysis should be offered in an open label fashion. Case in point: Joe Broderick noted after publication of SAMMPRIS that “endovascular devices for the treatment of acute stroke have been cleared by the FDA through the 510(k) pathway and reimbursed by CMS without demonstration of clinical benefit.”

**We need to continue
to advocate where
we can.**

What can we do?

We need to continue to advocate where we can. In the past decade, SNIS as well as others successfully lobbied for the creation of a meaningful DRG for mechanical embolectomy for stroke. We did this on the basis of the MERCI device and perception that this innovation ushered in a new era in the treatment of stroke. In the SWIFT trial, MERCI (as the control) recanalized vessels approximately 30 percent of the time. This DRG is critical for maintaining hospital support for performing invasive stroke therapy, yet in this author's opinion should not be viewed as etched in stone.

Secondly, our collective community must continue to prioritize innovation and advancement. This past year ushered in a new class of intra-arterial stroke treatment options, many of which

are convincingly better with respect to MERCI in randomized controlled trials. Like most SNIS members, I continue to believe that with advanced imaging and improved devices, neurointerventional treatment can make a significant impact on large vessel strokes. As testament to this belief are the many patients whose stories vividly demonstrate the benefit of endovascular therapies. Those that disagree will state that my confidence and belief in the value of intra-arterial therapy does not constitute proof over a placebo control or IV-rtPA. Perhaps not. So we just roll up our sleeves and start over on this front...and give our time and attention to trials that are not flawed from the beginning.

In light of the emergence of the Affordable Care Act with increasing emphasis on Comparative Effectiveness Research through PCORI, neurointerventionists must recognize that arguments of the past might not resonate as clearly in the future. Alongside our profession's commitment to clinical study and excellence, there is much we can do together to maximize the potential of our individual practices and collective field. But it will take all of us. I invite all SNIS members to consider the numerous ways that you can invest in the future of neurointervention. Whether it is contributing to JNIS, donating to the foundation, serving on an SNIS committee or helping with program planning for one or two of our meetings, an engaged membership is the key to a successful future.

Thank you for the many contributions in time and resources that you make already. In a field as young as ours, every gain, every win, every achievement is foundational to the success of the years ahead. With your continued commitment, enthusiasm and help, we'll seize the moments and realize the victories that will distinguish our work, advance our field and, most important, elevate quality of care for our patients.

for practitioners of neurointerventional stroke treatment today.

Q. What are the key benefits of co-hosting this meeting with the Joint Cerebrovascular Section?

DH: There are many benefits to this meeting but a few of the main ones are that, by working together, we can do a better job of reaching stroke neurologists and open surgeons. Also, by hosting the meeting in Hawaii, we can reach an international audience, which builds a greater sense of community.

Q. Given that the Joint Cerebrovascular Section and IESC both have their own meeting traditions, what will be the format of this meeting?

DH: This two-day meeting will offer both co-hosted and concurrent sessions, providing all attendees with numerous choices as to what program elements would be of most interest and benefit to them.

Q. What are some of the stroke highlights on the meeting agenda?

DH: Stroke will command strong attention on both days of the conference. February 4 kicks off with session blocks on iatrogenic and ischemic stroke, the latter addressing such topics as spinal cord strokes, the future of ICAD intervention and predictors of bad intra-arterial outcomes. The following day opens with “stroke debates,” including some lively presentations on controversial topics such as IMS III as well as a rationale for supporting endovascular stroke treatment and reimbursement outside of randomized trials. Following concurrent session blocks dedicated to stroke research updates and microsurgical revascularization and post-stroke care, the day will conclude with a focus on practical stroke intervention to include talks on treatment devices and imaging. To ensure that attendees get the 360-degree clinical perspective of stroke, the program will also include abstract

presentations on both hemorrhagic and ischemic stroke as well as a panel discussion on stand-out cases.

Q. What other meeting highlights can attendees anticipate?

DH: Attendees can look forward to presentations on other neurointerventional conditions and treatments outside of stroke. I also expect that a meeting favorite will be one of the final session blocks of the program entitled “Lessons Learned,” which will include presentations from leaders of the field who will review what they learned from some of their most memorable cases. Of particular note is the annual Luessenhop Lecture introduced by CV Section Chair Sepideh Amin-Hanjani, MD. And then there will be plenty of opportunities for meeting attendees to interact with industry through several sponsored symposia, as well as in the Exhibit Hall.

Q. How can interested parties get more information and register?

DH: The registration brochure for the 3rd SNIS International Endovascular

Stroke Conference (IESC) and Joint Cerebrovascular Section Annual Meeting is available online at www.snisonline.org and has also been mailed to all members. The deadline for registration is January 18, and the deadline to reserve your accommodations at the Sheraton Waikiki Hotel is January 1. Please call Marie Williams at 703-691-2272 if you need any additional information.

As we look forward to this inaugural initiative, we invite you to be part of the action! Join colleagues, friends and industry as we gather in Hawaii for this milestone meeting...both to celebrate our clinical and practice successes as well as consider our future direction. As we stand at the doorway of a unique moment in time where we have the opportunity and responsibility to ensure that the specialty of neurointervention grows its capacity to offer patients life-saving treatments with maximum benefit and value, we are reliant upon you for your insights, contributions and forward-thinking ideas. Bring them all to Hawaii in February!

See you on Oahu.



THE SNIS 9TH ANNUAL MEETING:

The SNIS 9th Annual Meeting was a rousing success by any measure with record attendance, strong science, engaging lectures, diverse industry representation...and no shortage of fun! Please enjoy this Annual Meeting snapshot as a tribute to a week in which we came together to learn, explore, discuss and challenge. It was a milestone celebration...of the past 20 years that have brought us to where we are, and the future that will take us to where we want to go.

Enjoy the memories!

First Neurointerventional Quiz Bowl:

Definitely a Meeting Highlight

In honor of SNIS's 20th Anniversary, Past President and Current JNIS Editor-in-Chief, Rob Tarr, created the First Neurointerventional Quiz Bowl which was presented at the Annual Meeting. Conference attendees were divided into 3 groups led by Quill Turk, J Mocco and Shazam Hussain who engaged in a Jeopardy-style game of trivia and fun. Aside from the serious questions related to the history of SNIS and the neurointerventional field, participants walked away with some less-known tidbits, like Buddy Connors' disco dance-instructor era, Italo Linfante's secret rock star past, Gary Duckwiler's musical prowess with the accordion and Alex Berenstein's alternate career as a tennis racquet magnate. We can all also say that we know ever so much about Rob's favorite neurointerventional pioneer, Egas Moniz. Congratulations to the team led by J Mocco who reigned supreme in the matchup.

Due to the success of the Quiz Bowl this year, it will be included in the program in Miami. Start sending your trivia questions to Marie at williams@snisonline.org now!



Alex Berenstein



Buddy Connors



Gary Duckwiler



Italo Linfante

One Stop Along the Journey

Eighth Annual Golf Tournament a *Swinging Success!*

The Eighth Annual SNIS Golf Tournament was held at the spectacular Del Mar Country Club in Rancho Santa Fe, California. The team of Michael Alexander, Mark Chimenti, Greg Finch & Jay Hallinan won the tournament with a score of 63 (9 under par). Closest to the pin (hole #3) was Mario Polo, closest to the pin (hole #12) was Ray Turner and longest drive was Bob Vaughn.

Anticipation is already building for the Ninth Annual SNIS Golf Tournament, to benefit the SNIS Foundation, to be held on Tuesday, July 30 in conjunction with the SNIS 10th Annual Meeting in Miami, Florida. Start practicing now...you could be our next winner!



SNIS Golf Tournament winners Michael Alexander, Jay Hallinan, Greg Finch & Mark Chimenti



Mario Polo, closest to the pin hole #3



Ray Turner, closest to the pin hole #12



Bob Vaughn, longest drive

And the Winner Is . . .

With the addition of the Fellows Course, which occurs at the end of our Annual Meeting, SNIS continues to dedicate efforts to providing opportunities for the newest members of our field to accent their training as well as make their own contributions to the field of neurointervention. In 2011, for the first time, SNIS created an award category for “best fellow’s abstract” to recognize the individual fellow who submitted the best scientific paper on an area of neurointerventional research. Congratulations to Geoffrey Colby, MD from Johns Hopkins University for taking the honors this year in this category with his paper entitled “Cost



Comparison of Endovascular Treatment of Anterior Circulation Aneurysms with the Pipeline Embolization Device Versus Stent-Assisted Coiling.”

Pictured above, participants of the 2012 Fellows Course

SNIS Would Like to Thank the Generous Supporters of its 9th Annual Meeting

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The Media Spotlight

The Annual Meeting is always home to the most significant media promotion of the year for SNIS, and this year was no exception. In fact, this year's meeting registered the most media activity of any meeting since 2004. Specifically, SNIS promoted five press releases:

- **The Penumbra START Trial Points to Imaging Technique That Could Predict Good Outcome for Acute Ischemic Stroke Patients** which detailed results from one of the first prospective, core-lab adjudicated, multicenter studies to show a correlation between an image of the patient's brain before treatment and their recovery after clot aspiration; abstract submitted by Don Frei, MD, Director of Neurointerventional Surgery, Radiology Imaging Associates/Swedish Medical Center
- **Study May Transform Approach to Patient Selection for Minimally Invasive Stroke Treatment** which addressed CT perfusion imaging as a means of determining those patients likely to have a good outcome from endovascular treatment; abstract submitted by Quill Turk, DO, Professor of Radiology and Neurosurgery, Director of Neurointerventional Surgery, Medical University of South Carolina
- **Endovascular Therapy May Result in Significantly Better Outcomes than Current Standard Treatment for Deadliest Strokes** which offered first-time, single-center retrospective study results designed to provide meaningful comparative data on endovascular treatment vs. IV tPA therapy; abstract submitted by Ansaar Rai, MD, Associate Professor, West Virginia University Medical Center
- **Study Results Show Strong Correlation Between Cerebral Aneurysms and Early Onset Menopause** which

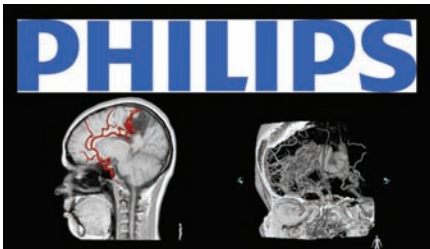
provided proof that the premature loss of estrogen could be a risk factor for aneurysm formation and development; abstract submitted by Michael Chen, MD, Assistant Professor of Neurology, Neurosurgery and Radiology at Rush University Medical Center

- **First-of-its-Kind Technology Enables Physicians to Consult on Stroke Cases Anytime, from Anywhere** which unveiled the Japanese-based-iStroke System™, allowing physicians in any remote location to consult on diagnosis and treatment via a Twitter direct messaging system; abstract submitted by Yuichi Murayama, MD, Director for the Center of Endovascular Surgery at Jikei University School of Medicine (JUSC) in Tokyo, Japan

In total, all five releases were picked up by over 1,200 outlets; received over 5,000 views by journalists and on PR Newswire alone; and registered literally millions of impressions (number of times an individual is exposed to the story). A few of the top outlets that picked up the releases included Reuters, Yahoo News, news stations from Savannah, Georgia to Phoenix, Arizona, the *Boston Globe*, the *San Francisco Chronicle* and the *Dallas Morning News*. Trade outlets that covered SNIS news included *Healthcare Industry Today*, *Clinical Neurology News*, *Interventional News*, *Med Tech Insight*, *Medindia Health Network*, and *HealthSquare*.

Industry News

Many long-time and newer industry friends were on hand to support the SNIS 9th Annual Meeting and celebrate our 20th Anniversary in San Diego, CA. Through sponsored booths in our Exhibit Hall, as well as morning, lunch and afternoon symposia throughout the week, these exceptional partners made invaluable contributions to our time together. Please see below some reflections from just a few of our industry colleagues as to what the week meant to them.



Philips Healthcare has been a proud participant in SNIS since its inception. We find SNIS to be the best forum in North America to meet with clinical leaders, share ideas, and gather valuable insights into neuro challenges. This year we were particularly interested in discussions surrounding trends in stroke care and the challenges/opportunities involved with new neuro devices. At our booth, we had many informative discussions with SNIS members – with topics ranging from the latest in 2D and 3D imaging technologies, to room layout, to future trends and even sunburn care.

Add to this great keynote speakers like Craig Mullaney, along with the inimitable SNIS Golf Tournament, and we are sure to be back in 2013!

Thanks from the Philips Neuro Team



Codman Neurovascular thanks the SNIS for a great experience at the 9th Annual Meeting, a unique opportunity to bring together leaders in neurointervention to discuss advancements in patient care. Codman Neurovascular is proud to have launched three exciting new technologies at the meeting: the **DELTAMAXX™ Microcoil system**, the **ORBIT GALAXY® G2 Microcoils**, and the **ENVOY® DA Guiding Catheter**, a new distal access guide.

The **DELTAMAXX Microcoil System** features Codman's DELTA-WIND® Technology, a unique triangular wind shape with natural deflection points that enable the coil to change direction more easily than traditional circular wind coils. This is the longest microcoil we have ever introduced, with lengths of up to 60cm. The coil is compatible with microcatheters with inner lumen diameters ranging from 0.0165" to 0.019", such as our PROWLER® Catheters, which can also accommodate smaller finishing coils.

We also introduced **ORBIT GALAXY G2 Microcoils**, a system of complex shaped, soft and highly conformable coils with random break points that has been shown to deliver high packing densities and result in low retreatment rates¹. These new coils

are deployed with the ENPOWER® Detachment System, a push-button thermo-mechanical detachment that streamlines the coiling procedure.

Finally, we introduced the new **ENVOY DA Guiding Catheter**, which features a braid design, soft distal tip, and hydrophilic coating and larger inner lumen. These features facilitate navigation through tortuous portions of the carotid siphon and provide the stability required for complex neurointerventional procedures.

¹Bendok, BR, Rahme, RJ. Complex shaped detachable platinum coil system for the treatment of cerebral aneurysms: The Codman TRUFILL DCS ORBIT Detachable Coil System COMPLEX Registry final results. *J NeuroIntervent Surg* 2011; DOI: 10.1136/neurintsurg-2011-010118.

Codman Neurovascular is a business unit of Codman & Shurtleff, Inc.



THE SNIS 9TH ANNUAL MEETING: *Photo Highlights*





2012-2013 Board of Directors Takes Office in San Diego

The 2012-2013 Board of Directors took office at the Annual Business Meeting in San Diego, California. Listed below are your new Board Members. Feel free to contact any of them with questions or suggestions for SNIS.



MEMBER-AT-LARGE: NEURORADIOLOGY

Aquilla S. Turk, DO
Medical University of South Carolina
Charleston, SC

MEMBER-AT-LARGE: NEUROSURGERY

Michael E. Kelly, MD, PhD
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Saskatoon, SK, Canada

MEMBER-AT-LARGE: NEUROLOGY

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RULES COMMITTEE CHAIR

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University of Medicine & Dentistry
of New Jersey
Newark, NJ

Michael Brothers Award Recipient Named at ASNR

SNIS is pleased to announce that the 2012 recipient of the Michael Brothers Memorial Award is Andrew Molyneux, MD from Oxford University. His manuscript, "Cerecyte Coil Trial: Angiographic & Clinical Outcomes of Endovascular Coiling in Patients with Ruptured and Unruptured Intracranial Aneurysms Treated with Cerecyte Coils Compared with Bare Platinum Coils – Final Results of a Prospective Randomized Trial" was named the Best Paper in Interventional Neuroradiology at the 50th Annual Meeting of the American Society of Neuroradiology, held April 21-26, 2012 in New York, New York.

Congratulations to Dr. Molyneux!



Annual Meeting Abstracts Now Being Accepted

You are invited to submit abstracts for the SNIS 10th Annual Meeting and Fellows Course, July 29–August 2, 2013 at the Loews Miami Beach Hotel, Miami, Florida 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 November 5, 2012 to 11:59 pm (EST) on Monday, March 4, 2013. Authors are encouraged to submit abstracts early.



SNIS and the Joint Cerebrovascular Section Proudly Present

The 3rd SNIS International Endovascular Stroke Conference (IESC)/ Joint Cerebrovascular Section Annual Meeting

*February 4-5, 2013 ~ Sheraton Waikiki Hotel ~ Honolulu, Hawaii
Pre-conference Workshop ~ February 3, 2013*



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**.



CALENDAR OF EVENTS

SNIS Events

Society of NeuroInterventional Surgery/ Joint Cerebrovascular Section Fellows Course

February 2-3, 2013
Sheraton Waikiki Hotel
Honolulu, Hawaii
Contact: SNIS, 703-691-2272

3rd SNIS International Endovascular Stroke Conference (IESC)/ Joint Cerebrovascular Section Annual Meeting

February 4-5, 2013
Sheraton Waikiki Hotel
Honolulu, Hawaii
Contact: SNIS, 703-691-2272
*Pre-conference Workshop on February 3

Society of NeuroInterventional Surgery 10th Annual Meeting

July 29-August 1, 2013
Loews Miami Beach Hotel
Miami, Florida
Contact: SNIS, 703-691-2272

Society of NeuroInterventional Surgery/ Joint Cerebrovascular Section Fellows Course

August 1-2, 2013
Loews Miami Beach Hotel
Miami, Florida
Contact: SNIS, 703-691-2272

Other Events

International Stroke Conference
February 6-8, 2013
Honolulu, Hawaii
Contact: www.strokeconference.org

The Embolus

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