

# AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS BULLETIN

The Socioeconomic and Professional Quarterly for AANS Members • Volume 13 No. 2 • Summer 2004

## Neurosurgery & Industry: A Delicate Dance



### INSIDE THIS ISSUE

- New Leadership Takes Office, New Strategic Plan, **19**
- NERVES Survey to Cure Information Disability, **21**
- "Neurosurgeon as CEO" Debuts, **29**
- Technology and Creativity Evidenced at 2004 AANS Annual Meeting, **22**



American  
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Neurological  
Surgeons







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# CONTENTS

VOLUME 13 NO. 2

## AANS MISSION

The AANS is dedicated to advancing the specialty of neurological surgery in order to provide the highest quality of neurosurgical care to the public.

## AANS BULLETIN

The official publication of the American Association of Neurological Surgeons, the *Bulletin* features news about AANS and the field of neurosurgery, with a special emphasis on socioeconomic topics.

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## COVER STORY

### Neurosurgery and Industry: A Cautious Interdependence.

H. Louis Harkey III, MD, 6

### Information, Influence, Innovation: Public Discourse Documents Evolving Science-Industry Relationship.

Manda J. Seaver, 10

### AANS Ethical Guidelines: A Compass for AANS/Industry Interactions. 11

### Normal Pressure Hydrocephalus Registry: Industry and Neurosurgery Demonstrate Productive Partnership.

Robert E. Harbaugh, MD, 12

### Regulating Devices: How Device Approval Involves FDA, Neurosurgery. Catherine Jeakle Hill, 13

### In Delicate Dance, Is FDA Out of Step? Long Approval Process Stresses Safety, Costs Access. Alon Y. Mogilner, MD, PhD, and Deborah L. Benzil, MD, 14

### Partnership Can Pave New Product's Way to Market: AdvaMed Expert Sheds Light on Process—Interview.

Patrick W. McCormick, MD, 15



## FEATURES

**Technology and Creativity Exhibited in Orlando.** Manda J. Seaver, 22

## DEPARTMENTS

**Calendar of Neurosurgical Events** Managing Coding and Reimbursement Challenges, 40

**News.org** New, free AANS benefits for residents and fellows, 37

**Newsline** *From the Hill*, *Neuro News*, New EMTALA guidelines issued May 13, 4

## COLUMNS

**AANS Answers** Thomas A. Marshall prescribes cautious optimism for AANS growth and expansion, 44

**Bookshelf** Gary Vander Ark, MD, reviews "The Quantum Mind," 26

**Coding Corner** Gregory J. Przybylski, MD, explains how Medicare makes physicians pay for technology, 32

**CSNS Report** Frederick Boop, MD, recounts action at the spring plenary session, 28

**Education** Manda J. Seaver reports on the newest AANS course, The Neurosurgeon as CEO, 29

**Governance** Fremont P. Wirth, MD, seeks ideas for next AANS Strategic Plan, 19

**NREF** Michele S. Gregory shows how "beautiful friendships" further neuroscience research, 20

**NS Innovations** Paul House, MD, and Joshua Rosenow, MD, review expanding indications for brain stimulation, 30

**Personal Perspective** James R. Bean, MD, tells why neurosurgery and industry must guard ethical limits, 17

**Practice Management** Mark Mason describes the NERVES plan to gather benchmarking data, 21

**President's Message** Robert A. Ratcheson, MD, sets forth his vision for the AANS, 2

**Timeline** Michael Schulder, MD, offers examples of successful neurosurgery-industry partnerships, 18

# The Courage to Act

*Neurosurgery Is Meeting Its Challenges*

I am truly honored to have been selected as the 72nd president of the American Association of Neurological Surgeons (AANS). From my viewpoint, this position offers the opportunity and confers the responsibility for the president to engage the organization in activities and offer policies that can best serve our patients and promote our profession.

## The "First of Qualities"

I have long been an admirer of Winston Churchill, a man whom I consider the ultimate leader. Churchill had many faults and his career had its ups and downs, but he was always courageous, never hesitated to take a stand and utilized his courage to prevail in the most perilous of times. I have always thought that he set standards which, while born of conflict, are of great importance in everyday life. In his own words, "Courage is rightly esteemed the first of human qualities because it is the quality which guarantees all others." This concept signals an appropriate response for neurosurgery during this time of relentless challenge to our profession. It will take some courage to continue to focus upon our core mission while expending the energy and resources necessary to meet the challenges that have been brought upon us by a legal system gone astray and to confront the constant barrage resulting from obscure and intrusive regulatory mismanagement.

The AANS is responsible for providing a foundation and infrastructure that allows neurosurgeons to provide the most modern and best quality care for our patients by serving our educational and practice needs. Despite the highly charged times we live in, we must be sure to keep on track. Many citizens question our country's involvement in a war that daily



Robert A. Ratcheson, MD

confronts us with a loss of American lives. Differing opinions and interpretations of momentous issues such as religious values and tolerance, individual liberties, abortion and gun control have fostered political partisanship with a rancor not seen in our country since Vietnam.

## Primary Threat, Fundamental Focus

Our own profession is earnestly engaged in a campaign to set straight an aberration of societal intent that has led to the medical liability crisis. Neurosurgeons are committed to combating this threat to private and academic practice and career opportunity. For a growing number of us, the crisis is a real threat to our survival as neurosurgeons and our ability to serve our patients. At present, it is not clear that we will be successful, but it is clear that we must have the courage to persist in our efforts to overcome this suffocating, litigious atmosphere and prevail in our campaign for medical liability reform.

Concurrently, we must keep the focus upon our core mission as a professional association, for it is through this mission that we will best serve society and society's expectations. The fact is that the fundamental responsibility of the AANS is to serve as the primary resource for the medical education of practicing neurosurgeons. Neurosurgical education is the core value of the AANS quite simply because it is the cornerstone of our profession and of direct benefit to our patients.

In coordination with the American Board of Neurological Surgery, the AANS will participate in the ABNS Maintenance

of Certification program, not only by tracking continuing medical education requirements for all American neurosurgeons, but also by providing resources that will be utilized specifically to develop educational programs that meet MOC requirements. Many of these programs will utilize Internet technology, and some will capture existing venues, such as *Neurosurgical Focus*; however, it is anticipated that the annual meeting of the AANS will continue as the most effective provider of continuing medical education to neurosurgeons. The 2005 Annual Meeting, scheduled from April 16 to 21 in New Orleans, "Education and Innovation in Neurosurgery," will offer a blend of cutting edge neuroscience and clinical information germane to the practice of contemporary neurosurgery.

Another area in which we will move forward is in defining our relationship with commercial partners. The AANS has enjoyed a long and fruitful relationship with industry and remains grateful for its generous support. However, society has rightly seen it as appropriate that this relationship be further clarified in order to ensure that the material presented by medical associations such as ours is unbiased and accurate. The AANS is currently undertaking a review of its guidelines and interactions with commercial and corporate sponsors in an effort to foster the continuation of appropriate relationships.

For society's benefit we also must act with courage in our efforts to promote the performance of appropriate and ethical scientific research. A case in point is stem cell research, which currently is hampered by governmental restrictions. If we are not courageous in our support for this remarkable technology, which holds promise for the treatment of devastating neurological and neurosurgical diseases, we will find

ourselves involved in the same partisan political stalemate regarding stem cell research as we now find ourselves with medical liability reform. We must do all we can to prevent the politicalization of this issue. While there are thorny questions associated with stem cell research, I do not believe that we can allow even the sincere theological beliefs of a few to prevent the alleviation of suffering for so many.

On a related topic, neurosurgeons have made and will continue to make great advances in basic and clinical research for the benefit of our patients, yet relatively few of us contribute to the Neurosurgical Research and Education Foundation of the AANS. The NREF has been a remarkable success, yet there is still much more that can be done. Every neurosurgeon should consider the support of neurosurgical research through the NREF as an obligation through which all of us, and our patients, will receive appropriate reward.

### **Courage in Conduct**

We have shown courage in our programs to monitor professional conduct. Despite the opposition and legal challenges of well-funded trial lawyers, we will continue to identify and discipline those who give false and inaccurate legal testimony. In addition, we must make sure that our professional conduct activities address other forms of inappropriate and harmful practices. We must develop appropriate methodology to allow neurosurgeons to demonstrate competency, and we must eliminate from practice those who do not meet these standards. A major step in this direction is exemplified by the AANS' interaction with the previously mentioned ABNS Maintenance of Certification program. This program has the

potential to offer great benefits and security to our patients. As such, it is deserving of strong support, not only in terms of compliance, but also through organized neurosurgery's commitment to ensuring that the required educational activities are meaningful to neurosurgical participants. This aim can only be accomplished by keeping educational activities under the direction and control of neurosurgeons.

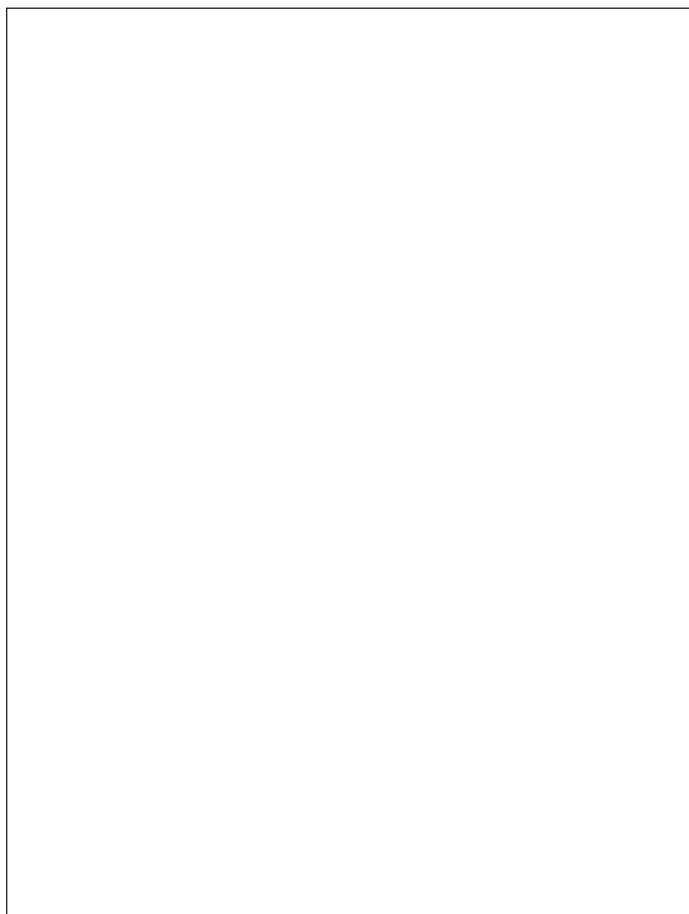
I have briefly touched upon a number of issues in which the AANS has been and will continue to be a bold participant. There are a whole host of other issues upon which we must have the courage to speak out so that

we can ensure that the benefits neurosurgery provides to society are not sidetracked through partisan political concerns.

I feel particularly fortunate to lead the AANS at a time of organizational and financial strength, and I hope that this year you will join the AANS Board of Directors and me in furthering our attempts to discover bold and innovative ways to meet all of neurosurgery's challenges. ■

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**Robert A. Ratcheson, MD**, is the 2004-2005 AANS president. He is the Harvey Huntington Brown Jr. professor and chair of the Department of Neurological Surgery at Case Western University and at University Hospitals of Cleveland.



# NEWSLINE

News Members Trends Legislation

## FROM THE HILL

### HOUSE AGAIN PASSES MEDICAL LIABILITY REFORM LEGISLATION

On May 12, by a margin of 229 to 197 (with 7 not voting), the U.S. House of Representatives passed H.R. 4280, the HEALTH Act of 2004. This bill is identical to H.R. 5, which passed the House last March by a similar margin. The legislation includes, among other things, a \$250,000 cap on noneconomic damages. The focus shifts once again to the Senate, where Bill Frist of Tennessee, the majority leader, has vowed to continue pressing for action on this legislation.

For frequent updates to legislative news, see the Legislative Activities area of [www.AANS.org](http://www.AANS.org).

- **CMS Issues New EMTALA Guidelines** On May 13 the Centers for Medicare and Medicaid Services issued revised Emergency Medical Treatment and Labor Act interpretive guidelines to all CMS regional offices and state survey agencies. The guidelines serve to interpret and clarify the existing statutory and new regulatory requirements set forth by EMTALA and are meant to be used to assist the enforcement agencies in making consistent determinations about a provider's compliance with EMTALA. Neurosurgeons can consult this document, available at [www.cms.hhs.gov/medicaid/survey-cert/sc0434.pdf](http://www.cms.hhs.gov/medicaid/survey-cert/sc0434.pdf), to ensure that they are meeting the on-call requirements of EMTALA.
- **Antitrust Report Raises Questions** The Federal Trade Commission and Department of Justice jointly released a report in July on antitrust violations in healthcare. The report opposes physician collective bargaining and questions the anticompetitive nature of independent practice associations, messenger model physician networks and other types of provider networks. The report did, however, provide greater guidance on the "clinical integration" requirement of such networks. Instead of giving physicians countervailing powers to oppose insurer pricing tactics, the agencies instead favor further monitoring of the insurance industry for signs of anticompetitive behavior. The report stated that low reimbursement levels in themselves are not a sign of antitrust violations, but may be an indication of an insurer's market power. It also denounced as anticompetitive "most favored nation" clauses, which require physicians to give an insurer its best price at all times, and "any willing provider" laws, which require insurers to accept all physicians willing to enroll in its network. The report is available at [www.usdoj.gov/atr/public/health\\_care/204694.htm](http://www.usdoj.gov/atr/public/health_care/204694.htm).
- **CMS Advisory Opinion Says Specialty Hospital Is Not Subject to Moratorium** A physician-owned orthopedic and neurological surgery hospital will be exempt from the 18-month moratorium imposed on specialty hospitals in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, known as the MMA, according to a rare advisory opinion issued June 23 by the Centers for Medicare and Medicaid Services. Physician-owned specialty hospitals have, until now, qualified for the whole-hospital exception in the physician self-referral regulations, meaning doctors with ownership interest in a specialty hospital could refer Medicare patients to the facility. However, some lawmakers and acute care hospitals have criticized the whole-hospital exception as a loophole for physicians to self-refer inappropriately for financial gain. The 18-month moratorium in the MMA was to allow CMS time to study the effect of specialty hospitals on the industry. The opinion, with the hospital's name redacted, is available at [www.cms.hhs.gov/medlearn/ao-sh-2004-06-01.pdf](http://www.cms.hhs.gov/medlearn/ao-sh-2004-06-01.pdf).
- **Doctors for Medical Liability Reform Launches Additional Television Programs** On July 6 Doctors for Medical Liability Reform launched new and updated 30-minute television newsmagazines in Georgia, North Carolina, South Carolina and Washington state. DMLR's Protect Patients Now programs tell the story of the medical liability crisis and feature physicians, patients, public officials and concerned activists who are deeply troubled by ever-decreasing access to healthcare. The programs will be televised in every media market in these four states from now until October. Additional programming and campaign materials are forthcoming. The newsmagazines are fully downloadable from the DMLR Web site at [www.protectpatientsnow.org](http://www.protectpatientsnow.org). The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons are members of DMLR through their advocacy organization, Neurosurgeons to Preserve Health Care Access. Information about the campaign and medical liability reform in general is available from the AANS/CNS Washington Office, (202) 628-2072.



## NEURO NEWS

### AMA APPOINTS AANS PRESIDENT TO RRCNS

Robert A. Ratcheson, MD, the 2004-2005 president of the American Association of Neurological Surgeons (AANS), will serve a two-year term beginning Jan. 1, 2005, as the American Medical Association's appointee to the Residency Review Committee for Neurological Surgery. The committee, which includes representation from the American Board of Neurological Surgery and the American College of Surgeons, is charged with maintaining the quality of graduate medical education in neurosurgery.

Send Neuro News briefs  
to the *Bulletin*,  
bulletin@AANS.org.

- **Online CME Credit Through *NS Focus*** Beginning with the Aug. 18 issue, *Neurosurgical Focus*, the online, rapid-publication journal of the American Association of Neurological Surgeons (AANS), offers AANS members an opportunity to earn continuing medical education credit in category 1. For each issue, the NSF editorial board selects articles and compiles related questions into a 10-question online exam. To take the exam, members can access *Neurosurgical Focus* at [www.AANS.org](http://www.AANS.org). The articles pertinent to the exam are clearly identified, and the link to the exam is located in the issue's right-hand margin. After selecting the exam link, participants will be asked to login or register at [MyAANS.org](http://MyAANS.org) before access to the exam is allowed. Participants have two chances to pass the online exam with a score of 70 percent or better. The online questionnaire reports incorrect answers and directs the exam-taker back to the appropriate article for the answer. Once the exam is passed, one credit is posted automatically to the participant's CME transcript on [MyAANS.org](http://MyAANS.org). AANS members can complete the exam or view their CME transcripts, by subspecialty if preferred, at password-protected [MyAANS.org](http://MyAANS.org); new users will need to register using member number and e-mail address. Assistance is available from AANS Member Services at (888) 566-AANS (2267) or [memberservices@aans.org](mailto:memberservices@aans.org).
- **AANS Announces Officers to Plan WFNS' 2009 International Congress** Roberto C. Heros, MD, leads a team of officers in planning the XIV International Congress of Neurological Surgery, to be held Aug. 23-28, 2009, in Boston, Mass. In addition to Dr. Heros, who serves as president, the officers are: Albert L. Rhoton, MD, honorary vice president; Arthur L. Day, MD, vice president; A. John Popp, MD, secretary; James T. Rutka, MD, assistant secretary; Robert A. Ratcheson, MD, treasurer; Warren R. Selman, MD, assistant treasurer; and Jacques S. Morcos, MD, scientific program chair. The selection of the American Association of Neurological Surgeons (AANS) as the host society took place at the September 2003 meeting of the World Federation of Neurological Societies in Lisbon. Information about the 2009 meeting, including the seven-minute video that demonstrates the capacity of the AANS and Boston to host the meeting, is available at [www.AANS.org/international/aans\\_us.asp](http://www.AANS.org/international/aans_us.asp).
- **Universal Protocol to Prevent Wrong Site Surgery Effective July 1** More than 40 medical and health-care organizations joined the Joint Commission on Accreditation of Healthcare Organizations in December 2003 to endorse a new protocol for prevention of wrong site surgeries. The "Universal Protocol," created to standardize pre-surgery procedures for verifying the correct patient, the correct procedure, and the correct surgical site, focuses attention on marking the surgical site, involving the patient in the marking process, and taking a final "time out" in the operating room to double-check information among all members of the surgical team. Originally approved last summer, the protocol became effective on July 1, 2004, for all JCAHO-accredited hospitals, ambulatory care surgery centers, and office-based surgery sites. Additional information is available at [www.jcaho.org](http://www.jcaho.org).
- **AANS Member Suspended** The Board of Directors of the American Association of Neurological Surgeons (AANS) voted on April 30 to suspend indefinitely the membership of William H. Bloom, MD, of Bay Shore, N.Y., pending his recertification by the American Board of Neurological Surgery. Certification by the ABNS or comparable Canadian or Mexican boards is required for AANS membership in the Active or Lifetime categories, and the ABNS had withdrawn its certification of Dr. Bloom.

# NEUROSURGERY AND A Cautious Interdependence



**OPPORTUNITY ABOUNDS** in the exhibit hall during the 2004 Annual Meeting of the American Association of Neurological Surgeons: opportunity to discover the latest innovations; opportunity to identify potential customers; opportunity to develop relationships that may prove mutually beneficial in the future. How to ensure that patients benefit from medical science–industry interactions is a billion-dollar question that neurosurgery, industry and society are working to address.



# INDUSTRY:

H. Louis Harkey III, MD

**T**he relationship between neurosurgery and industry is both complex and vital. In ecological terms this relationship would best be described as mutualism, two interdependent groups that benefit from one another. And as in any complex ecosystem the relationships are interdependent on many levels.

As neurosurgeons, we utilize the products of the medical device industry to make our jobs easier and improve outcomes for our patients. Innovative neurosurgeons provide many of the ideas that fill the research and development pipeline of medical product manufacturers, while industry funds research that leads to the next break-

through in neurosurgical care. The list of interactions goes on, and in each case both parties benefit from the relationship.

## **The Annual Meeting: A Microcosm of Interdependence**

Perhaps the most visible manifestation of neurosurgery and industry's mutually beneficial relationship is the exhibit hall at any neurosurgical meeting. These primarily educational events additionally provide a showcase for industry's latest products and supply a large audience of "customers" who come to view products and information as well as try out the latest devices.

For example, at the recent annual meeting of the American Association of Neurological Surgeons (AANS) in Orlando, Fla., 220 companies were represented in the exhibit hall. With exhibitors outnumbering medical registrants 3,107 to 2,832, there was ample opportunity either to try new equipment with the benefit of the undivided attention of a knowledgeable company representative, or, depending upon one's viewpoint, to develop a potentially fruitful relationship with a prospective buyer.

In addition, some companies sponsored aspects of the annual meeting, such as special lectures, the opening reception, and the scientific program CD-ROM. Perhaps less visible but of vital importance is corporate sponsorship of the practical clinics

through provision of necessary equipment. Typically the course director will decide which equipment best meets the needs of a course—a certain type of spinal instrumentation for a clinic on cervical spine instability, for instance—and will make the initial contact with the equipment's manufacturer.

Exhibition hall fees and sponsorships underwrite a large portion of the annual meeting, while the remainder is covered by participants through registration fees.

While some may believe that an annual meeting the scope of the AANS' could not be held without the financial support of industry, in fact only about 5 percent of the annual meeting is underwritten by industry, while exhibitor fees account for just over one-third of all revenue. It would be correct to say that the annual meeting could survive without corporate support, but it would be transformed into a bare-bones format accompanied by increased registration fees; further it is unlikely that the hands-on practical clinics, so important for trying out new techniques, could continue at all without corporate support.

With regard to the annual meeting, neurosurgery and its mission of continuing medical education clearly benefit from industry support.

Sponsoring companies benefit in return through direct access to nearly 3,000 neurosurgeons and other healthcare professionals gathered in one location for the duration of the meeting. In the exhibit hall, company representatives have the opportunity to answer surgeons' questions and provide hands-on demonstrations of their products. Throughout the week of the meeting, exhibitors have opportunities to interact with neurosurgeons in the convention center, hotels and local restaurants. This face-to-face contact is perhaps the most valuable marketing opportunity a company can get.

Companies receive educational benefits from organized neurosurgery as well. Industry representatives are allowed to attend some scientific sessions during the meetings where they have the opportunity to learn about the latest advancements in patient care and the challenges that our subspecialty currently is facing.

## **Beyond the Annual Meeting**

Organized neurosurgery benefits from industry's financial contributions beyond the annual meetings. Most fellowships, education-

Continued on page 8

Hands-on experience with new instrumentation and techniques is one of the valuable experiences offered in practical clinics held during annual meetings of the American Association of Neurological Surgeons (AANS). Industry makes these practical clinics possible by donating the instrumentation and other necessary equipment specified by each course director.



Continued from page 7

al grants and achievement awards are funded either directly or indirectly by industry contributions. With few if any strings attached, these grants are largely altruistic but garner good will in return. Companies also contribute directly or indirectly to many neurosurgical residency programs in the form of research grants, fellowship funding and educational programs. Many local continuing education programs offered at private and training institutions are underwritten in part by medical product companies.

All this participation in neurosurgical education gives industry an opportunity to influence physician behavior and product utilization. Many years ago I participated in a hands-on practical course to learn how to use a new high-speed drill. I was afforded the opportunity to drill real bone with multiple bits and attachments, each designed for a specific purpose. The intense training was in a controlled environment that allowed me to develop competency with the tool without undue risk to a living patient. After drilling for a period of time with a single bit, the instructor provided a new bit of the same design saying something like "see how much difference a sharp bit makes." In addition to providing invaluable experience with new technology, the company representatives had the opportunity to encourage the use of multiple drill bits that of course would increase sales revenues. The workshop provided a valuable service to the participants but also provided a forum for promoting the sponsor's product.

Industry and medicine work hand in hand toward the advancement of technology. In the formative stages, industry gets ideas for product development from the physician while medicine relies on research and development expertise to bring new ideas to fruition. Large research and development coffers fund much of

the basic research that precedes the manufacture of a new product. New products must undergo the rigors of approval by the U.S. Food and Drug Administration, which requires the participation of test sites and enrollment of patients into trials. Feedback from doctors and patients leads to refinements in a new product. Without mutual participation in this development process, no new product would ever make it to market.

When a company funds research, it often will request the right to review the results and control public access to any data generated by the research. This affords the company some protection against publication of erroneous results but may also keep from the medical community certain vital information that may reflect negatively on the company's product. Surgeons frequently work with company engineers and product managers to develop new medical devices. Surgeons involved in product development often are awarded by contract a percentage of future sales in compensation for their intellectual contributions as well as endorsement. Commitments of this nature can influence the surgeon's utilization of a new product as well as other products the company may sell. Thus, a potential for abuse and unethical behavior exists on both sides of the product development equation.

Individual neurosurgeons typically enjoy mutually beneficial relationships with local product representatives. In my operating room, some industry representatives are as much a part of the operating team as the scrub technician, circulating nurse or anesthesiologist. These reps are immediately available to deal with technical problems encountered with equipment they have provided to the hospital or to assist the scrub technician in the management of complex instrument sets with which the tech is not completely familiar. The distributors

of products that I use most frequently contact me on a routine basis to ensure that my needs are met. Local representatives answer my questions about specific products, and relay to the home office any concerns that arise. It is on the local level that I have formed the closest and most enduring partnerships with company representatives, and I suspect this type of partnership is commonplace.

Competition between companies is fierce, but the battles are largely fought and won on the surgeon's home court. Rival representatives vie for a customer's time and the opportunity to describe, demonstrate and promote the latest company product. Competition can be good when it leads to more economical and higher quality options for our patients. But when it leads to undue influence or loses sight of the patient's best interests, the line has been crossed. We all become accustomed to perks, some small and some not so small. We think little or nothing of the lunch a company representative has provided and a round of golf may be viewed as usual Saturday sport with friends. But at what point do these perks become bribes or kickbacks? Nobody would dispute that it is illegal to receive remuneration from a company simply for using their product in the treatment of a patient. What if a company foots the bill for a physician and a spouse to spend a long weekend at a high-end resort? Is this illegal, or if not illegal, is it not unethical?

### **Codes Spell Out Industry's Commitment to Ethical Relationships**

Mutualism becomes parasitism when personal gain becomes a prime motivation in the interactions between neurosurgery and industry. In order to limit the potential for abuse, industry has recently made a public commitment to ethical relationships with healthcare professionals. The Pharmaceutical Research and Manufacturers of America, PhRMA, a consortium of pharmaceutical and biotechnology companies, and the Advanced Medical Technology Association, AdvaMed, an association of medical device, diagnostic product and medical information system manufacturers, both have adopted voluntary codes of ethics that facilitate responsible interactions with the medical community. Both organizations have expressed an ultimate commitment to benefit patients and to enhance the practice of medicine through education of healthcare professionals and promotion of medical research. Both ethical codes outline appropriate interactions with healthcare professionals that relate to the marketing of their products. These documents are similar to one another in scope, but the AdvaMed code, which is more applicable to neurosurgery because it focuses on devices, is written from the perspective of companies that promote complex medical technology that requires proper education for the safe and effective use of their products.

The codes specify that product training and education that is independently sponsored by a medical device or pharmaceutical company, such as demonstration of new surgical technology, is not only ethical but necessary. However, any meeting of this type

**“Both ethical codes [PhRMA and AdvaMed] outline interactions with healthcare professionals that relate to the marketing of their products.”**

should be held at an appropriate facility that is conducive to learning. That is, the attractive location should not be the sole reason for sponsoring a training meeting in the Caribbean. The company may cover reasonable expenses of the attendees and provide hospitality such as receptions and meals so long as they are modest in value and provided only to bona fide participants. In other words, it is OK to furnish lunch for the doctor but not for the doctor's spouse. Companies also may provide financial support in the form of educational grants, payment for advertisement opportunities, faculty expenses and hospitality for third party sponsored educational programs, such as an AANS annual meeting, as long as the same general principles regarding location and format are met. In addition, the third party conference sponsor should be responsible for and control the selection of program content, faculty, educational methods, and materials. Furthermore, it is inappropriate for a company to cover the personal expenses of non-faculty healthcare professionals attending the conference.

According to the codes, individual physicians may be paid to serve as consultants for medical product companies if they provide “bona fide consulting services, including research, participation on advisory boards, presentations at company-sponsored training, and product collaboration.” Such arrangements assume a written contract, fair market compensation and appropriate qualifications. Simply being a good customer with high utilization of company products does not warrant a consultant's fee. Gifts are allowable as long as they are worth less than \$100 and have an educational purpose or serve the patient. The AdvaMed code also addresses how a company can appropriately assist a doctor with technical issues, give advice regarding reimbursement and make charitable contributions. The complete documents can be viewed online and downloaded from [www.advamed.org](http://www.advamed.org) and [www.pharma.org](http://www.pharma.org).

These codes may seem too restrictive to some, but they go a long way toward preserving mutualism between neurosurgery and the medical product industry. What we must all keep foremost in our minds is our shared mission of helping patients. The patient's well-being should always be the guiding ethical principle in the interactions between industry and the medical profession. ■

**H. Louis Harkey III, MD**, is professor of neurosurgery at the University of Mississippi Medical Center.



# Information, Influence, Innovation

## Public Discourse Documents Evolving Science-Industry Relationship

MANDA J. SEAVER

“If we don’t [fund it], who will?” said Syngenta spokesperson Sherry Ford in an April 12 U.S. News and World Report article that delves into the complex and often tense relationship between science and industry. “It” refers to “cutting-edge research,” the government support for which “has fallen from a high of 73 percent in 1965 to below 60 percent,” wrote the article’s author, Ulrich Boser.

Boser traced the boom in industry-supported research to the 1980 Bayh-Dole Act, which allowed schools to profit from federally funded discoveries, and reported that 62 percent of all biomedical research is being supported by industry today compared with 32 percent in 1980. Along with increased corporate funding, the article referenced a 1980-2002 literature review published last year in the Journal of the American Medical Association in which Justin Bekelman and colleagues reported a 3.6 to 1 likelihood that research supported by a company will favor that company.

In the current era of uneasy interdependence, science and industry, perhaps differing only in primary motivation, strive to advance medical science and benefit patients. But the process is akin to a game of tug-of-war in which individual players switch sides at any time, and the boundary continually moves. As differing priorities create conflict which simmers and occasionally boils over into the public arena, the media documents progress and pitfalls toward ethical and productive relationships.

### August Report Documents Uneasy Alliance

The amount of influence a funder may have on the line of inquiry researchers undertake is among the questions addressed in Michigan State University’s external review, released Aug. 1, of the intensely scrutinized agreement between biotechnology company Novartis, now Syngenta, and the University of California, Berkeley. The amount of industry money—\$25 million over 5 years—and the fact that nearly an entire department was funded made the 1998 agreement unusual. After a two-year inquiry, external reviewers in general found the deal to be “consistent with the behavior of universities adjusting to the emerging norms of university-based economic development,” although they also characterized the deal as an “icon for larger issues.”

Principal investigator Lawrence Busch, a sociologist at Michigan State University, suggested in an Aug. 9 National Public Radio interview that subtle influences of industry funding are difficult to determine when dealing with the broad applications of basic science that were funded by the Novartis-Berkeley agreement. “Another company might have decided they wanted things that were much closer to product development and in that instance might have put a great deal of pressure on faculty members to pursue certain kinds of research projects that would lead to products rather quickly and to avoid others,” he said.

While direct impact on the university was found to be minimal,

the report’s nine recommendations included a provision for greater transparency of such collaborations and culminated with a call to examine the role of a public university today.

### Toward Greater Transparency

Greater transparency also is the motivation behind a recent call for a clinical studies comprehensive registry as well as reaffirmation of major medical journals’ publication rules.

**Clinical Trials Registry** At its annual meeting in June, the American Medical Association endorsed a policy calling for the Department of Health and Human Services to establish “a comprehensive registry for all clinical trials conducted in the United States” that would “ensure that trials with negative as well as positive results are publicly available, by providing every clinical trial with a unique identification and ensuring publication or placement on an electronic database of all results from registered trials.”

Earlier the same month, on June 2, the state of New York filed suit against GlaxoSmithKline, manufacturer of the antidepressant Paxil, charging that the company committed consumer fraud by withholding information on the effectiveness and harmful side effects of the drug when prescribed “off label” to children and adolescents.

“The general public and the medical community should not have to fear that clinical findings of significance regarding a medication may be suppressed and remain unavailable to their physicians because the findings may be deemed unfavorable to the financial interests of the manufacturer,” said Barry B. Perlman, MD, president of the New York State Psychiatric Association, in a statement that took no position on the merits of the litigation.

The complaint said that the company’s literature focused on one study of the drug’s effect on adolescents and failed to disclose four studies that showed no effect or increased risk of suicidal thoughts and behavior, the Washington Post reported.

The favorable study was published in the Journal of the Academy of Child and Adolescent Psychiatry in 2001. None of the unfavorable studies was published. Psychiatrist Robert Milin of the Royal Ottawa Hospital in Canada, reported the results of one of the unfavorable studies at a 1999 conference, according to The New York Times, which quoted Dr. Milin’s view that “If they had got a positive outcome I would suspect that they would have pushed to get it published.”

**New Editorial Rules** An additional impetus for the registry dates to September 2000, when JAMA published research suggesting that the deleterious effects of arthritis drug Celebrex were less severe than those of similar medications, without the editors’ knowledge that six months of data were withheld from the paper. The discrepancy came to light the following year when complete data were published on the U.S. Food and Drug Administration’s Web site as part of the FDA’s review process, and some FDA advisory committee members realized the discrepancy and expressed their concern.

## **“Greater transparency is the motivation behind a recent call for a clinical studies comprehensive registry as well as reaffirmation of major medical journals’ publication rules.”**

In August 2001 the Washington Post reported the story and quoted Thomas Wolfe, the gastroenterologist who had written an editorial accompanying the JAMA article, as saying he was “flabbergasted” and “furious” that the data hadn’t been made available. The Post also quoted Catherine D. DeAngelis, MD, JAMA’s editor, saying, “I am disheartened to hear that they had those data at the time that they submitted [the manuscript] to us...We are functioning on a level of trust that was, perhaps, broken.”

In September 2001, 12 major medical journals—among them JAMA, The Lancet, and Annals of Internal Medicine—published “Sponsorship, Authorship, and Accountability.” The editorial announced a new policy designed to ensure researchers’ independence from sponsors. Journal editors had agreed to the new rules, which among other things require authors to sign statements fully disclosing their role and that of any sponsors, earlier that year at the annual meeting of the International Committee of Medical Journal Editors.

“It’s an utterly serious matter when any part of the healthcare system withholds information that could be helpful to patients and doctors in deciding what to do,” Annals of Internal Medicine Editor Harold Sox, MD, in a September 2001 American Medical News article explaining the reasons for the new editorial policy.

The AMA reaffirmed its support for the editorial policy this summer at its annual meeting.

### **Ethical Guidelines Define Boundaries**

Industry likewise has struggled with the shifting parameters of its role. As Jeff Trehwitt of the Pharmaceutical Research and Manufacturers Association pointed out in the same American Medical News story, “A company cannot afford to have its reputation damaged with doctors, patients and the Food and Drug Administration.”

**PhRMA Codes** On June 20, 2002, PhRMA adopted a voluntary set of principles that delineate the responsibilities of its member companies when involved in clinical research.

“These principles reaffirm our members’ strong commitment to the safety of research participants to ensure the integrity of research and the timely communication of research results,” said PhRMA President Alan F. Holmer in a statement announcing the guidelines.

Continued on page 16

## **AANS Ethical Guidelines: A Compass for AANS/Industry Interactions**

**F**or the third consecutive year the annual dues for membership in the American Association of Neurological Surgeons (AANS) have been held steady. Yet as in other sectors of society, costs of bringing products and services to members continue to increase.

“Economizing and developing non-dues revenue streams as outlined in the AANS Strategic Plan are principles that continue to guide the AANS’ long-range planning as well as day-to-day activities,” said Thomas A. Marshall, AANS executive director. “Because negotiating the competing interests of such relationships is not always a simple matter, guidelines for interactions with corporate partners are under development with the intent of helping neurosurgeons navigate this new landscape successfully and confidently.”

Early this year AANS President Robert A. Ratcheson, MD, appointed a taskforce, led by Jon Robertson, MD, to draft such guidelines for the Executive Committee’s review this summer. Taskforce members are Steven L. Giannotta, MD; Charles J. Hodge, MD; L.N. Hopkins, MD; Paul C. McCormick, MD; James T. Rutka, MD; Thomas A. Marshall, AANS executive director; and Michele S. Gregory, director of development.

Because the potential pitfalls of every situation cannot be foreseen, the guidelines are intended to act as a compass, with “North” defined as the AANS mission: To advance the specialty and serve as the spokesorganization for all practitioners of the specialty of neurosurgery, in order to provide the highest quality of care to patients.

### **New Guidelines Are in Good Company**

The forthcoming guidelines governing relationships with industry join those already in place in various AANS areas.

The AANS Board of Directors, committee chairs and committee members, all course faculty, and AANS management are required to file signed disclosure statements annually. The disclosure statements are intended to ensure that the decisions and actions of AANS representatives are not unduly influenced by any special interests of individual members or employees.

Those submitting abstracts for AANS meetings or papers for AANS journals have long been asked to disclose financial interests or other relationships that might have bearing on their research. Exhibitors likewise are asked to ensure that the display and demonstration of products and services is for the advancement of the art and science of neurosurgery; they also must abide by a set of rules and regulations set forth in the exhibit prospectus.

# Normal Pressure Hydrocephalus Registry

## Industry and Neurosurgery Demonstrate Productive Partnership

ROBERT E. HARBAUGH, MD

**S**ometimes the aims of industry and medicine mesh in a way that is productive for both, as well for the patients they serve. The new national Normal Pressure Hydrocephalus Registry of surgically treated adult patients with NPH represents such a beneficial collaboration.

The registry came about when the maker of products for the surgical treatment of central nervous system disorders, including cerebrospinal fluid shunt systems, recognized a need for reliable prospective data. The company, Codman & Shurtleff Inc., sought development of a registry of surgically treated adult patients with NPH as a source of data for presentations and publications, and as a source of real-time information that be used to direct clinical, marketing and engineering decisions. In addition to collecting reliable data, Codman wanted the registry to be overseen by a scientific advisory panel whose role would be to guide the scientific direction of the registry and generate regular submissions for abstract presentations and publications.

### Codman Selects Neuro-Knowledge

With these goals in mind and with the understanding that such a registry would have value as a national data repository for scientific inquiry and for clinical information for individual surgeons, Codman turned to Neuro-Knowledge™. Established in 2001, Neuro-Knowledge is a program of the American Association of Neurological Surgeons (AANS), the leading association of neurosurgeons in the United States, and Outcome Sciences Inc., a leading provider of e-health and e-research services for the medical device and pharmaceutical industry. Through Neuro-Knowledge, integrated services between the AANS and OSI are provided to meet the data collection, storage, analysis and feedback needs of a wide variety of clients.

Implicit in the choice of Neuro-Knowledge is Codman's recognition that the program could offer not only the best Web-based information management services available but could also help recruit advisers and registry participants. Central to these services is a Web-based information platform that supports electronic practice and research tools including electronic data capture that is compliant with regulations set forth by the U.S. Food and Drug Administration and the Health Insurance Portability and Accountability Act. OSI, which currently manages programs in more than 30 disease areas, uses this unique platform to cost-effectively manage programs for a variety of healthcare clients including medical device and pharmaceutical companies, national medical associations and other healthcare organizations. Neuro-Knowledge brings together a unique blend of Web-based registry experience, neurosurgical expertise and the prestige and name recognition of the AANS.

### How the NPH Registry Will Work

Neuro-Knowledge services for the Normal Pressure Hydrocephalus Registry were initiated by working collaboratively with Codman on

ways to effectively develop and implement the best Web-based data collection program. In addition to developing appropriate electronic forms, Neuro-Knowledge evaluated workflow issues and user incentive opportunities to improve the value of the application to the user. Data from letters to referring physicians, procedure notes, and decision-support can be entered only once and accessed repeatedly depending on the one's practice needs. Beyond the system itself, Neuro-Knowledge worked with Codman to develop and utilize advisory panels that will analyze data for strategic purposes and generate publishable manuscripts.

The registry will consist of standard case report forms encompassing procedural and hospital information and follow-up data. Individual patients will be followed through multiple admissions, procedures and follow-up visits, establishing reliable data over several years. The case report forms were developed to streamline and limit work while maximizing output for evaluation of clinical outcomes and benefits of treatment. Individual surgeons will be able to access data they have provided and will additionally be able to compare their data to the group's aggregate information. The registry will track information such as patient symptoms, complications and shunt procedure revisions in patients with NPH with programmable valves as compared to other groups.

The Normal Pressure Hydrocephalus Registry is built on an information platform that provides many "value-added" features to the neurosurgeon. Surgeons will be able to access patient information securely through the Internet whenever a registry patient presents. Individual surgeons can customize data forms to include additional data elements of interest to them. The Neuro-Knowledge system can be further customized to allow data submission via personal digital assistants and to generate interactive practice guidelines that are displayed as "pop-ups" on the computer or PDA screen. When requested, the Neuro-Knowledge system can generate automatic notes and send letters based on completion of the case report forms.

The decision to use Neuro-Knowledge will give Codman the ability to cost-effectively perform additional clinical and market research studies among individuals or subgroups of the registry participants. The Normal Pressure Hydrocephalus Registry will be launched in September to a pilot group of up to 50 neurosurgeons with plans to expand to up to 250 neurosurgeons. AANS members who sign up for the registry will be compensated for their participation. ■

**Robert E. Harbaugh, MD**, is chair of the Department of Neurosurgery at The Pennsylvania State University College of Medicine, Hershey, Pa.

### For Further Information

Normal Pressure Hydrocephalus Registry, [www.AANS.org/nph\\_registry.asp](http://www.AANS.org/nph_registry.asp)

About Neuro-Knowledge, [www.AANS.org/research/neuro.asp](http://www.AANS.org/research/neuro.asp)

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# Regulating Devices

## How Device Approval Involves FDA, Neurosurgery

CATHERINE JEAKLE HILL

**T**he process for obtaining U.S. Food and Drug Administration approval for new drugs and devices is highly complex. Over the past several years the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons have established a mechanism by which neurosurgery can be more involved in the approval process as new medical devices and technologies move into the healthcare marketplace. This article briefly outlines the device approval process and neurosurgery's structure for interfacing with the FDA.

The FDA Office of Device Evaluation consists of six centers, two of which relate to neurosurgery. The Center for Devices and Radiological Health is responsible for evaluating neurosurgical devices and the Center for Biologics Evaluation and Research oversees biologics that are used by neurosurgeons.

The Medical Device Amendments of 1976 to the federal Food, Drug and Cosmetic Act established three classes for medical devices based on risk to the patient:

**Class I** General Controls—Devices that present minimal potential for harm.

**Class II** Special Controls—Need special labeling or postmarket surveillance to be considered safe. Most medical devices are in this class.

**Class III** Premarket Approval—These devices sustain or support life, are implanted or present potential risk of injury. Approximately 10 percent of medical devices fall into this category.

There are three paths to approval by FDA:

**Premarket Notification 510(k)**—The manufacturer must demonstrate that the device is substantially equivalent to an existing device. If the device is substantially equivalent, it is placed in the same class as the equivalent device. Upon approval of a device as equivalent, the FDA will issue a letter of substantial equivalence, which authorizes the manufacturer to market the device.

**Premarket Approval (PMA)**—The PMA process is more involved and requires the submission of clinical data to support claims made for the device. Generally, these devices would be in Class III.

**Exceptions**—The FDA may give expedited approval of a device for use only in clinical trials if the device is deemed of humanitarian benefit. Clinical trials using unapproved medical devices on human subjects are performed under an Investigational Device Exemption.

To help manufacturers comply with the FDA requirements, FDA provides a number of documents online. For some devices, experts including those of physician specialty societies have developed guidance documents with their recommendations for product standards.

In addition, during the Premarket Approval process, the FDA uses expert panels to review applications for device approval. The meetings are held in public, announced in the Federal Register, and provide the opportunity for any interested parties to com-

ment in person or in writing. The panel then votes to approve, disapprove, or approve with conditions. That information is merely a recommendation to the FDA, which may accept or reject the panel's recommendation.

Currently three neurosurgeons sit on the Neurological Devices Panel: Fernando Diaz, MD, Christopher Loftus, MD, and Stephen Haines, MD. The panel meets several times each year to advise the FDA on premarket applications that involve neurological devices.

In addition to the Neurological Devices Panel, devices used by neurosurgeons sometimes fall within the purview of other panels. For example, devices used in the spine are considered by the Orthopedic and Rehabilitative Devices Panel. That panel does not include a neurosurgeon but often one of the neurosurgeons from the Neurological Devices panel will be sworn in as a temporary member during the panel's consideration of a device used in the spine.

Once a device is approved and marketed, the FDA requires the manufacturer to comply with FDA Good Manufacturing Practices guidelines and Medical Device Reporting regulations. The former guidelines cover the design, package, labeling, and marketing of a device, while the latter include the requirement to report adverse events involving the device.

### AANS/CNS Neurosurgical Devices Forum

Several years ago the AANS and CNS established a Neurosurgical Devices Forum to improve interaction between neurosurgery, neurosurgical device manufacturers, and the FDA. The neurosurgeons on the forum serve as a resource to AANS/CNS Washington Office staff in responding to requests for information from the FDA. One goal of the forum is to ensure that neurosurgery is appropriately represented when the FDA considers devices used by neurosurgeons, particularly when those devices are referred to review panels other than the neurological devices forum. In addition, the forum has worked with the FDA, industry, and other specialty societies in the development of guidance documents. For example, members of the group are currently working with the American Academy of Orthopaedic Surgeons to develop a guidance document for artificial spinal discs.

The Neurosurgical Devices Forum is chaired by Richard G. Fessler, MD, and co-chaired by Fernando Diaz, MD. The forum also includes representatives from the various AANS/CNS sections: Howard Riina, MD, (Cerebrovascular); Robert Heary, MD, and Joseph Alexander, MD (Disorders of the Spine and Peripheral Nerves); Geoffrey Manley, MD, and William Welch, MD (Neurotrauma and Critical Care); Richard Osenbach, MD (Pain); Mark R. Proctor, MD (Pediatric Neurological Surgery); Jaimie Henderson, MD, and Paul Francel, MD (Stereotactic and Functional Surgery); Jeffrey Weinberg, MD, and Andrew Sloan, MD (Tumors). ■

Catherine Jeakle Hill is senior manager-regulatory affairs in the AANS/CNS Washington Office.

# In Delicate Dance, Is FDA Out of Step?

Long Approval Process Stresses Safety, Costs Access

ALON Y. MOGILNER, MD, AND DEBORAH L. BENZIL, MD

**T**he U.S. healthcare system, believed by many to be the most scientifically advanced in the world, is a system in which patients have access to the latest drugs, medical devices, and state-of-the-art techniques. Recent advances in neurosurgery have been closely tied to industry-driven procedures. Image-guided surgery, endovascular surgery and deep brain stimulation are some examples of the latest technological advances that reduce morbidity and improve clinical outcomes.

The United States routinely lags behind other Western countries, however, in the availability of new medical technology. Innovations are routinely available in Europe, Canada, Australia and Japan years before their availability in the United States. This lag period is due primarily to the lengthy approval process of the U.S. Food and Drug Administration. The Kefauver-Harris drug amendments of 1962 expanded the FDA's role from merely assuring the safety of drugs to assessment of their clinical efficacy. It now takes 15 years for a newly synthesized drug to go from the laboratory to use in U.S. patients. In 1976, this authority was expanded by Congress to include medical devices as well. Furthermore, physicians cannot be informed by equipment manufacturers of new uses for existing, approved medical devices (so-called "off-label" indications).

The process of bringing innovation to patients evolves through a delicate dance between industry, clinicians and federal regulatory authorities. Vocal critics of all parties abounds. Have we found the right balance?

Case in point: spinal cord stimulation for angina pectoris.

Angina pectoris has become the number one indication for epidural spinal cord stimulation, or SCS, in Europe. In the United States, despite routine use of SCS for a variety of chronic somatic pain syndromes, the treatment of angina with SCS remains off-label. Medtronic, a manufacturer of SCS implants, had planned initial trials, but never got past numerous FDA hurdles. A manufacturer-sponsored multicenter trial is currently underway, but patient accrual remains low.

In contrast, over 2,000 patients with angina have received SCS systems throughout the rest of the world since this procedure was first performed in Australia in 1987. Numerous controlled studies have demonstrated that SCS decreases the number of anginal attacks and the number of ischemic episodes, while increasing exercise duration and time to anginal attack. European trials have also demonstrated that these patients have a reduced number of hospital admissions with no increased risk of arrhythmias, while not masking the signs and symptoms of myocardial infarction. Indeed, a Swedish study which randomized refractory angina patients to either SCS or coronary artery bypass graft showed comparable symptom relief with both techniques, with lower mortality and morbidity in the SCS group.

The slow FDA approval process impacts patients and clinicians in several ways. Currently, government insurance and most private

**"The United States routinely lags behind other Western countries in the availability of new medical technology."**

insurers will not reimburse for off-label procedures. For the time being, U.S. patients wishing to undergo this procedure must either pay out-of-pocket for the entire costs or travel outside the United States. For treatment. Similarly, for a period of 10 years, patients with Parkinson's disease had to travel abroad or pay out-of-pocket to obtain bilateral subthalamic nucleus or globus pallidus deep brain stimulation implants until the FDA approved the procedure in January 2003.

In the case of angina treatment, the opportunity for collaboration between neurosurgeons and cardiologists may be lost. Other competing technologies such as enhanced external counterpulsation and transmyocardial revascularization target a similar patient population and can be performed by a cardiologist or cardiac surgeons. Comparing benefits such as cost and efficiency of these other procedures with SCS may never be possible if SCS trials fail to gain sufficient recruitment.

There is no evidence to support the claim that the current, slow process of FDA approval has resulted in "safer" medicine for our population compared with the rest of the world. One may argue that the highly litigious atmosphere in the United States necessitates more rigorous approval standards than those that may be required in other countries. Ultimately, however, withholding the benefits of medical advances from U.S. citizens as a consequence of cumbersome regulatory procedures may prove to be more harmful than beneficial for our society. ■

**Alon Y. Mogilner, MD, PhD**, is assistant professor, and **Deborah L. Benzil, MD**, is associate professor of the Department of Neurosurgery, New York Medical College in Valhalla, N.Y.

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# Partnership Can Pave New Product's Way to Market

AdvaMed Expert Sheds Light on Process—Interview

PATRICK W. MCCORMICK, MD

Neurosurgeons interested in taking a medical device from personal inspiration to market would do well to seek out a partnership with an experienced party or device manufacturer as early in the process as possible, advised Janet E. Trunzo in an interview earlier this year. As the senior vice president for global regulatory affairs for the Advanced Medical Technology Association, known as AdvaMed, she is in a position to know.

The path from inspiration to product introduction is heavily dependent on the nature of the product. The process is rather long, complex and unpredictable for novel product concepts; that is, devices that are dissimilar to an existing product. A typical development pathway at a minimum would include the following phases: *in vitro* testing, an *in vivo* animal model focused on testing biocompatibility, and validation of concept.

Through continuous prototype refinement a dominant design may emerge that qualifies for a feasibility study in a small number of patients to justify proceeding to larger-based clinical trials.

Once a device has matured and gained supportive preclinical testing, it is ready to be considered for large, prospective clinical trials. The clinical trials typically include a safety trial followed by an efficacy trial. During this portion of the development process, the U.S. Food and Drug Administration will need to be engaged in order to ensure that the trials are designed to their specifications and that all relevant questions which they anticipate regarding the device are answered. Once the device has completed clinical trials, a final application process for approval with the FDA is undertaken. This often is an iterative process which may generate additional study and data generation before approval. Instances where a novel device meets a clinical need critical to patient outcome or safety may qualify for a priority review process to expedite final FDA approval.

One characteristic of the process from inspiration to product introduction is that the timeline can vary greatly from very short to very long, according to Trunzo. The timeline for a simple, non-implantable device which is made of materials that are known to be biocompatible could be very short; an example of such a device might be an external temperature sensor or a tongue depressor. On the other hand, a device intended for implantation (defined by the FDA as remaining in the body longer than 30 days) and made from materials which have not been previously established as biocompatible may take substantially longer to complete the process successfully.



It is this variability that often affects the willingness of companies to pursue development and introduction of innovations. The specific estimates regarding the difficulty getting through the regulatory process and achieving a successful product introduction will, of necessity, be weighed against the market opportunity and the potential return that a device manufacturer could reasonably expect.

Despite this reality, products are being introduced at an ever-increasing pace in the medical realm. As Trunzo views it, this makes the medical device industry unique, interesting, and exciting. In fact when a new device is introduced, a new model can be expected to make its market debut within a span of only 18 months. This quick cycling is due in part to the FDA's 510(k) approval process, which allows relatively fast

approval if it can be shown that a device is substantially equivalent to an existing device.

Cost is an issue which seems to draw a lot of critical attention to the process of new product development. Many neurosurgeons realize that the implants they use routinely generate licensing, manufacturing and marketing profit margins which summed are possibly greater than the remuneration they receive for surgical services. While this seems paradoxical, it is at least partially justified by the large upfront capital investment necessary to get a product through the FDA process. However, it is not possible to discern a precise profit margin for any given product with publicly available information.

Surprisingly, device manufacturers do not enjoy the same level of patent protection for their intellectual material and design concepts as pharmaceutical manufacturers, Trunzo said. Such market realities may impact the potential revenue estimates of new products, as there is a likelihood of imitation and "fast-follower" products designed for similar indications which will erode the original innovator's opportunity. This encourages manufacturers to try to reach financial targets over a short time, which further escalates prices.

To prevent an otherwise worthy inspiration from being lost in one of the many pitfalls that accompany such a complex, highly regulated, and cost-laden system, Janet Trunzo's advice to seek partnership early in the process seems quite appropriate. ■

Patrick W. McCormick, MD, is a neurosurgeon with Neurosurgical Network Inc. Toledo, Ohio.



Continued from page 11

Effective for trials begun after Oct. 1, 2002, PhRMA's Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results originally was published in July 2002 and was just updated in June 2004. While originally published information remains intact through page 28, the balance of the 53-page document offers additional guidance for 17 new questions. In addition, a new document, Clinical Trials Questions and Answers, acts as a companion for the principles.

In July 2002, PhRMA additionally published voluntary guidelines governing its member companies' relationships with medical professionals. The PhRMA Code on Interactions With Healthcare Professionals was adopted on April 18, 2002, and became effective the following July. In general, the code says that permitted interactions are those that support scientific information and education and that have a benefit to patients. As summarized in a New York Times article discussing the code, "Anatomical models for examination rooms are OK; World Series tickets for a doctor's family are not."

The AMA in 1992 issued its own guidance for physicians when offered gifts from industry. This summer the AMA rejected a proposal to modify those guidelines, siding with doctors who said they feel pressure from drug companies seeking to influence them, *Modern Physician* reported.

**OIG Compliance Program** The federal government, which through the Office of the Inspector General has stepped up efforts in recent years to combat fraud and abuse, also has addressed matters of appropriate conduct. Published in the Federal Register on May 5, 2003, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers recommended that "pharmaceutical manufacturers at a minimum comply with the standards set by the PhRMA code" and further warned that "arrangements that fail to meet the minimum standards set out in the PhRMA code are likely to receive increased scrutiny from government authorities."

**AdvaMed Code** Most recently, the technology industry has weighed in on the matter of ethical conduct. In September 2003 the Advanced Medical Technology Association, representing more than 1,100 medical technology companies, adopted its Code of Ethics on Interactions With Health Care Professionals, which became effective Jan. 1 of this year. The guidelines, updated from AdvaMed's 1993 Code of Ethics, mirror many provisions of the PhRMA code and, like the PhRMA guidelines, compliance is voluntary.

In a letter to healthcare professionals announcing the new code, AdvaMed President Pamela G. Bailey said it was adopted "in response to...scrutiny and to the rapidly changing healthcare fraud enforcement environment" a situation which "presents risks to the industry itself, and to physicians and other healthcare industry professionals who are so critical to the delivery of life-saving and life-enhancing therapies."

## **"As all players acclimate to evolving rules governing science-industry relationships, some are struggling with the changes."**

### **Over the Line/But the Line Moved**

As all players acclimate to evolving rules governing science-industry relationships, some are struggling with the changes. On June 27 *The New York Times* reported a federal investigation into drug marketing practices. Under investigation are accusations that Schering-Plough paid doctors either directly—up to six figures to prescribe a drug for hepatitis C—or indirectly by sponsoring "pseudo-trials" of the drug. The article said Schering-Plough indicated that it has instituted new marketing practices since 2003, and that the investigation is targeting prior practices.

Peter Barton Hutt, identified as a former FDA general counsel who now advises drug companies, summarized the issue this way: "The industry has...had to reshape entirely what they are doing, but it was too late to redo what they'd been doing for years."

The article also contained a warning: "Once the new Medicare drug benefit takes full effect in 2006, the government will pay for almost half of all medicines sold in the nation. So the marketing programs will cost the government even more money and, if they are uncovered and determined to be illegal, will probably result in even larger fines." ■

Manda J. Seaver is staff editor of the *Bulletin*.

### **For Further Information**

Advanced Medical Technology Association, [www.advamed.org](http://www.advamed.org)

American Medical Association, [www.ama-assn.org](http://www.ama-assn.org)

American Medical News, [www.ama-assn.org/amednews](http://www.ama-assn.org/amednews)

Federal Register, [www.gpoaccess.gov/fr](http://www.gpoaccess.gov/fr)

Journal of the American Medical Association, <http://jama.ama-assn.org>

Modern Physician, [www.modernphysician.com](http://www.modernphysician.com)

National Public Radio ("Morning Edition"), [www.npr.org/programs/morning](http://www.npr.org/programs/morning)

The New York Times, [www.nytimes.com](http://www.nytimes.com)

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Pharmaceutical Research and Manufacturers Association, [www.phrma.org](http://www.phrma.org)

U.S. News and World Report, [www.usnews.com](http://www.usnews.com)

Washington Post, [www.washingtonpost.com](http://www.washingtonpost.com)

# On Motive and Mien

## *Neurosurgery and Industry Must Guard Ethical Limits*

Entering the exhibit hall at an annual meeting of the American Association of Neurological Surgeons (AANS) is like wandering into an industrial jungle. The number of corporate exhibitors exceeds 200, with displays ranging from single product booths to elaborate displays of surgical instruments and implantable devices. Product representatives, who often during the day outnumber neurosurgeon customers, are armed with information and enthusiasm enough to convert even passing interest to potentially voluminous product sales. This is the medical device industry in full dress parade. This is also a microcosm of the sometimes conflicted interdependency of neurosurgeons and the companies whose products are integral to their daily craft.

A stroll down the aisles offers the expert eye a quick review of a dazzling array of the newest tools of the trade. The tour is reminiscent of a childhood walk down the aisles of a toy store; one is overwhelmed by the sheer volume of products and attracted by each new object capturing the wandering eye. In succession pass a host of products, from stereotactic frames to spinal stimulators.

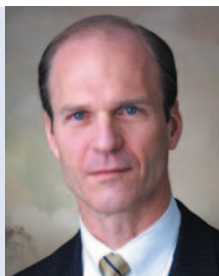
Neurosurgery's dependency on these products is a fact of life. They are the reason lumbar and cervical disc surgeries can be outpatient events, tumors can be volumetrically resected, aneurysms can be occluded with only a groin puncture for access, and basal ganglia stimulation can be translated into control of Parkinsonian tremor. They have expanded the reach and delicacy of neurosurgical techniques, lessened risk, shortened recovery, lengthened survival, and reduced pain. They are the physical extension of the neurosurgeon's knowledge and experience, and the practical application of basic and applied scientific research, converting neurosurgeons' ideas and hopes

to visible and palpable reality.

But these products create a tension, a perpetual conflict between the product vendor and the physician user whose motives and ethical responsibilities differ radically.

The vendor's primary motive is profit, to sell as many products at the best price the product can command and that the market will bear. The product may be of sterling quality and confer outstanding benefit to the recipient, the price may be well within a competitive range, and the service may be flawless, but in the end, the motive of the

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medical product vendor marketplace is profit, acquired through the agency of the user neurosurgeon.

The neurosurgeon's motive, if true to the profession, is patient welfare, not personal gain or vendor profit. A fundamental principle of professionalism, quoting Paul Starr in "The Social Transformation of American Medicine," is "a service rather than profit orientation, enshrined in its code of ethics." Acting as an advocate for a patient's best interest in recommending treatment and conducting surgery, the physician bears a fiduciary relationship to the patient in the interaction, a relationship to which profit is only peripheral and incidental.

These two motives must interact, but must not be confused. To the patient receiving the benefit of the product, the vendor's motive is irrelevant. But the

physician's motive and consequent action is critically important.

Trust is the fundamental quality necessary for a successful relationship between a patient and a physician. In respect to a surgeon, this means not only trusting in the surgeon's knowledge and skills, but also trusting his or her judgment and motives: the judgment to select the most effective treatment and tools to accomplish it; the motives to act with care and compassion only in the interest of the patient, not for personal gain. Trust cannot exist where unethical inducements cloud a physician's judgments or distort a surgeon's motives.

Products do not sell themselves, and good products require expensive and time-consuming research and development, which must be recouped in sales. Product marketing requires education and persuasion. Most of that information dissemination is legitimate: advertising, product brochures, meeting displays, even training courses. But some of it is not, when claims exceed proof, or persuasion crosses into unethical inducement.

In this issue of the AANS *Bulletin*, the relationship between neurosurgery and the medical device industry is explored in some depth. The reciprocal dependency of each on the other to achieve their respective goals is examined, with the public and each patient benefiting when the relationship works well. But an underlying theme also is the need for constant vigilance by individual neurosurgeons in their personal relationships and by the specialty as a whole to guard against the ethical errors that destroy public trust and patient confidence. By guarding our ethical limits, we expand our professional and technical horizons. ■

# TIMELINE: *Neurosurgery Through History*

## Neurosurgery and Industry

When you walked into the exhibit hall at this year's AANS meeting, were you appalled by the profusion of vendors, each hawking its device as the next indispensable tool in neurosurgery? Isn't this just another sign of the ongoing commercialization of our noble profession?

No, it isn't. Neurosurgery and industry have been excellent partners for a long time now. Consider that the neurosurgical operating microscope, first used by Theodore Kurze in 1957, grew out of a century's worth of optical engineering by Carl Zeiss Inc. The collaboration between Zeiss and such neurosurgeons as R.M. Peardon Donaghy, M. Gazi Yasargil, and Leonard I. Malis is well-known.

We all use electrocautery for hemostasis and surgical exposure. The monopolar cautery, known as "the Bovie," is still wide-

ly used. W.T. Bovie, a professor of biophysics at Harvard University in the 1920s, worked with Harvey Cushing to develop a new technique for "electrosurgery," which Cushing reported in 1927. By 1931 Ernest Sachs wrote that "the Bovie...is replacing silver clips to a large extent but it never can entirely supplant the muscle graft." (Never say never.)

Most neurosurgeons today have used a pneumatic or electric power tool to open the skull or drill the spine. These devices were developed first in the late 19th century by a large number of competing manufacturers, most of which began as makers of dental instruments. There were promoters (de Martel, Olivecrona) and detractors (Horsley, Cushing) of power-driven neurosurgery.

We can go further back in time. In 1863 Paul Broca reported on his devel-

opment of the "craniograph," which he used to identify cortical anatomy via surface landmarks. This prototypical stereotactic device was built of wood. Broca sought someone who could construct an iron version of his invention, and noted near the end of his report that "M. Mathieu, maker of surgical instruments in Paris, builds craniographs that are most elegant."

So industry has served the advance of neurosurgery well. Still, you may wish to consider Cushing's words as he began his introduction of the Bovie: "I confess to have been somewhat skeptical about the adaptability of this new procedure to my own purposes." ■

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**Michael Schulder, MD**, is associate professor in the Department of Neurological Surgery and director of Image-Guided Neurosurgery at UMDNJ-New Jersey Medical School.



# Planning for the Future

## *AANS President-Elect Seeks Ideas for Strategic Plan*

**T**he primary charge for the president-elect of the American Association of Neurological Surgeons (AANS) is long-range planning for the organization. This is obviously an ongoing process that includes not only 2005-2006, but also the initial planning for the following years. Many aspects of this planning are already underway.

Any plans that are initiated are dependent on the organization's financial resources to bring them to fruition. We are fortunate that the financial health and stability of the AANS at this time affords us the opportunity to explore the development of new programs. This is to a large extent the result of the truly remarkable progress of the management team in our Executive Office in controlling costs and developing programs that are financially viable.

Much of what we do in the future will be dictated by outside forces that we cannot control. The medical liability crisis is

but one such example, and I am hopeful that everyone reading this issue of the *AANS Bulletin* already will have contributed to neurosurgery's campaign for medical liability reform. Maintenance of Certification is another issue for which mandates from national and state certifying bodies have compelled a response from the neurosurgical community. It is difficult to disagree with the goals of this movement, but designing a mechanism that is both responsible and achievable will require time, resources and effort. The AANS is working closely with the American Board of Neurological Surgery to facilitate implementation of a workable program that will be responsive to the societal needs that compel its development, as well as attainable without disrupting the practice of neurosurgery.

Where do you as a member feel we should focus our efforts? Many of you have the opportunity to express your ideas

and concerns through the 2004 AANS Member Needs Survey. Such a survey is valuable only if enough of the members who receive it take the time to provide the requested data; therefore, I hope you take the time to answer the survey's questions carefully.

Whether or not you are part of the representative sample that receives the survey, I am interested in your thoughts and suggestions about our organization. Is the AANS meeting your needs? Are there areas that need greater emphasis? Are there new services or programs that you would like to see developed? How can we improve our annual meeting? Would you like to get more involved? If you want to work on a committee, what areas interest you? As the planning process for 2005-2006 begins, I invite your comments. Take the time to write to me at 4 Jackson Blvd., Savannah, Ga., 31405, or [fpwirth@bellsouth.net](mailto:fpwirth@bellsouth.net). I look forward to your input. ■

**Fremont P. Wirth, MD**, is 2004-2005 AANS president-elect.

### For Further Information

AANS Strategic Plan, [www.AANS.org](http://www.AANS.org), Article ID 18651

AANS leadership for the 2004-2005 term was elected by unanimous vote on May 3 at the annual Business Meeting, held jointly for the first time by the American Association of Neurological Surgeons, a 501(c)(6) organization, and the American Association of Neurosurgeons, a 501(c)(3) organization.

The new Executive Committee is composed of Robert A. Ratcheson, MD, president; Fremont P. Wirth, MD, president-elect; Charles J. Hodge, MD, vice president; Jon H. Robertson, MD, secretary; James R. Bean, MD, treasurer; and A. John Popp, MD past president. The entire 2004-2005 Board of Directors is listed on the Web site at [www.aans.org/about/membership/executive.asp](http://www.aans.org/about/membership/executive.asp).

Retiring board members were individually recognized for their service. Executive Com-

mittee members were Roberto C. Heros, MD, past president; Randall W. Smith, MD, vice-president; and Arthur L. Day, MD, treasurer. Other board members were Steven L. Giannotta, MD; Regis W. Haid Jr., MD; L.N. Hopkins III, MD; Donald W. Marion, MD; Richard A. Roski, MD; Michael Schulder, MD; and W. Brian Wheelock, MD.

Strong membership numbers and a positive financial outlook were reported. With the AANS expected to finish the fiscal year on June 30 in the black, there was not an increase in membership dues. In new business, the bylaws changes that were proposed to members in March and outlined in the spring issue of the *Bulletin* (article ID 21846) were discussed. A paper ballot via regular mail is underway this summer.



**2003-2004 AANS President A. John Popp, MD**, left, presented Robert A. Ratcheson, MD, with a gavel as a symbol of AANS leadership. Dr. Popp praised Dr. Ratcheson for his "brilliant, incisive mind," and observed that "even when what he says is contrary to what you think, you had better think about what he says because often you will find yourself changing your mind." Dr. Ratcheson officially assumed the AANS presidency at 7:30 a.m. on Thursday, May 6.

# A Beautiful Friendship

## *Industry's Support of Research Advances Neurosurgery*

**L**ouie, I think this is the beginning of a beautiful friendship.” This single sentence, Humphrey Bogart’s famously delivered last line in “Casablanca,” signifies both the culmination of the classic film’s story and the start of a mutually productive partnership between Bogart’s hard-bitten but heroic character, Rick, and the pragmatic police captain, Louie Renault.

In a scenario perhaps less entertaining but more germane to neurosurgery, when I hear the excitement in the voice of a young investigator who is the new recipient of a Neurosurgery Research and Education Foundation research fellowship, I am reminded of Rick’s enduring words. Such a moment does indeed mark the beginning of a beautiful friendship: In such a moment, a productive partnership between NREF and an awardee ignites, propelling forward a meritorious research project, adding to the body of scientific knowledge, and ultimately helping to heal countless people with neurological disorders. Such a moment simultaneously marks the culmination of a complex process that involves numerous individuals and countless hours spent reviewing research proposals to ensure their worthiness for investment, and—crucially—raising the dollars that will fund the research.

### **Who Funds Neurological Research?**

Both public and private entities actively fund scientific research. However, the most prominent public supporter, the National Institutes of Health, does not have a funding category for technical or surgical innovations, which is how most neurosurgical research is classified. Therefore, this type of research is conducted almost wholly in the private sector.

“Most of the research that neurosurgeons conduct is not directly fundable by more traditional, government sources,” acknowledged William T. Couldwell, MD, a past NREF Research Fellowship awardee and current NREF Executive Council member. “Neurosurgeons used to support their research out of clinical income, but over the years that funding source has diminished.”

Even so, in 2003 528 neurosurgeons and other individual donors demonstrated their support of neurological research through gifts totaling nearly \$379,000.

### **Corporate Partnerships Are Essential**

The bulk of support for technical or surgical innovations falls on industry’s shoulders. According to Julian T. “Buz” Hoff, MD, chair of the NREF Executive Council, support of NREF is a worthwhile investment for corporations, “affording them the opportunity to supply research and development funds to their constituents—neurosurgeons in training and in practice—that potentially will lead to both scientific advances and corporate profits.”

For corporations, the return on their investment is having the opportunity to play a key role in the future of neurosurgery while also achieving growth in their neurological areas of interest.

“These companies have a reciprocal obligation to the profession that uses their product,” said Dr. Hoff. “The well-being and corporate success of some corporations is primarily dependent on neurosurgeons.”

For its role in this “beautiful friendship” with the corporate world, the return on investment for NREF is increased funding for important basic science and cutting edge clinical research projects that allows

innovations and new discoveries in neurosurgical medicine to take shape.

In recognition of the value inherent in supporting NREF research projects, companies including DePuy Spine, a Johnson and Johnson Company; Medtronic Neurological; and Kyphon Inc. have made this type of support a company priority in 2004.

### **NREF: As Time Has Gone By**

“Historically, corporations were reluctant to support NREF because the majority of the grants involved basic science research, with little direct benefit to corporate donors,” observed Dr. Hoff.

Despite this fact, many companies supported the foundation from its inception in 1981, regardless of what project their gifts supported. Corporate support of NREF peaked in the late 1990s, and since then funding has steadily declined. The reason for the decline is the same for pharmaceutical, medical device and instrumentation companies as it is for any other corporation: tighter budgets and spending limits imposed in response to declining profits.

NREF has been able to increase the absolute number of grants awarded each year, despite a declining level of corporate support. However, for NREF to continue to increase funding for its research grants, an increase in the amount of corporate support will be needed. To help identify potential revenue sources, James T. Rutka, MD, is leading an NREF subcommittee whose sole mission is to cultivate “beautiful friendships” with corporate supporters.

“We need to continue to educate our corporate representatives as to the importance of their support, and this will mean person-to-person contact between neurosurgeons and industry sponsors,” said Dr. Rutka.

The subcommittee members currently are working to identify, cultivate and solicit much needed grant support. Only time will tell how fruitful their efforts will be. ■

Michele S. Gregory is AANS director of development.

# Inadequate Information

## *NERVES Survey to Cure Neurosurgery's Data Disability*

**A** neurosurgery practice is more than a conduit for delivery of excellent neurosurgical care. It is a business that must remain cost-effective or perish. Quality decision-making, regardless of whether one is a physician, a business administrator, or both, depends upon access to reliable data.

For too long neurosurgery has suffered from a data disability. The sad fact is that entities with which a practice frequently negotiates, such as health insurance plans, frequently come to the table armed with data about neurosurgeons and neurosurgery practices, leaving a practice with little ground to stand on during contract discussions. Perhaps worse, without reliable data a practice is unable to accurately gauge its own performance. For how many businesses would "We don't know" be an acceptable response to the question, "How are we doing?"

Change is underway. In July, NERVES, the Neurosurgery Executive Resource, Values, and Education Society, launched its first socioeconomic survey in what will be an annual effort to arm neurosurgery with the data it so desperately needs.

### **The NERVES Neurosurgery Practice Annual Survey**

The NERVES Neurosurgery Practice Annual Survey was painstakingly developed over the past year to ensure an instrument that will provide the data needed and pass the compliance requirements of the Federal Trade Commission (FTC) and the Department of Justice. Before distribution, the survey's readiness for distribution was reviewed and assured by NERVES legal counsel.

Two principles guided the NERVES Board in development of the survey. First, the information must be gathered in a com-

pletely legal and ethical manner. Second, the instrument must be as simple and easy as possible to complete.

**Legalities and Ethics** This first principle has influenced the nature of the information to be gathered, how the information is gathered, how the information is compiled, and who will have access to the raw data. Only information that is at least three months old and permitted by the FTC will be gathered. A third party—Heaton and Eadie, an Indianapolis consulting and accounting firm—is gathering and interpreting the information. Survey results will be reported in aggregate form, and no individual or practice-specific information will be reported. Finally, only employees of Heaton and Eadie will have access to the raw data, ensuring the privacy and confidentiality of respondents.

**Simplicity and Ease of Use** This second principle is equally important. For years, neurosurgery practices largely have ignored other organizations' surveys, reportedly because of the complexity of those surveys and consequently the time it took to gather and report the information requested. In contrast, the NERVES survey, while comprehensive, has been designed so that whether responses to all or only some of the questions are given, the information still will count. Survey participants will be able to compare survey results to the information they gathered for submission. While it will take time to gather information and complete the NERVES survey, it will be time very well invested.

**What's Covered** The survey gathers data for accounts receivable, provider compensation and production, support staffing, and operating costs, as well as general issues pertaining to practice. Demographics including practice type and size and geographic region will be analyzed. In addition

to neurosurgery, related specialties—neurology, physiatry, radiology, and anesthesia—each are included in separate area of the questionnaire.

### **Taking the Survey**

The survey and instructions for completing it are being sent via e-mail to participants, who will record their answers and send the completed survey by return e-mail to Heaton and Eadie. The e-mail format is expected to save expense, facilitate data collection, and make the survey results available quickly. After the data is compiled, the NERVES Board and legal counsel will conduct a final review. The board's plan is to publish the survey results in September so that by the end of the year, those who participate can put reliable, valid information to use in 2005.

### **Who Will Participate?**

Participation in the survey is open to all NERVES members; information on how to become a NERVES member is available at [www.nervesadmin.com](http://www.nervesadmin.com), or [mmason@neurosurg.com](mailto:mmason@neurosurg.com). Survey participants will enjoy free access to the survey results, which will be available to others for a fee.

The business of neurosurgery will be changed by this effort. My plea to every neurosurgeon is that you will personally become involved and take advantage of this opportunity to make a positive impact on the future of your business. With participation from the greatest number of practices, we can overcome neurosurgery's data disability and acquire the tools necessary to be competitive in today's hostile medical environment. The time to act is now. ■

**Mark Mason**, [mmason@neurosurg.com](mailto:mmason@neurosurg.com), is president of NERVES and practice administrator at Neurological Surgeons PC in Nashville, Tenn.



# Technology and Creativity

*72nd Annual Meeting Mingles Magical Events, Solid Science*

MANDA J. SEAVER

**F**rom the Sunday opening reception at Universal Orlando's Islands of Adventure to the AANS president's closing remarks the following Thursday, the 2004 AANS Annual Meeting demonstrated once again why so many consider the AANS meeting to be the preeminent annual neurosurgical event.

More than 6,000 people, including nearly 3,000 medical professionals, participated May 1-6 in the 72nd annual event, which was chaired by William T. Couldwell, MD, PhD. As a premier educational opportunity, participants could earn up to 21 credits in category 1 toward the American Medical Association's Physician's Recognition Award.



## Superlative Science

As always, the main attraction was the superlative science presented in the scientific program, chaired this year by Richard G. Fessler, MD. Four plenary sessions, six scientific sessions, 80 breakfast seminars, 43 practical clinics and more than 500 posters were featured. In addition, AANS/CNS sections planned nine sessions that focused on neurosurgery's subspecialties.

The cutting-edge medical research featured at this meeting addressed:

- bone marrow-derived stem cells for potential new treatments of glioma;
- a human brain-to-machine interface that potentially will allow a patient to control a neuroprosthetic device such as a wheelchair;
- improved motor functions of patients with Parkinson's disease by stimulation of the injured dopamine system using recombinant-methyl glial cell-line derived neurotrophic factor;
- helmet use to reduce the risk of head injury for riders of all terrain vehicles and motorcycles;
- vaccination using tumor lysate pulsed dendritic cells for patients with malignant and aggressive brain tumors; and
- artificial disc implantation for treatment of degenerative disc disease.

These medical science topics were among those chosen by



The opening reception, for which the islands of Jurassic Park and the Lost Continent at Universal's Islands of Adventure theme park were open exclusively to meeting attendees and their families, was among the thoroughly enjoyable events held during the 2004 AANS Annual Meeting.

peer-review process for release to the media. A socioeconomic paper additionally was selected. The topic, the relative shortage of neurosurgeons in the United States, also was the cover story of the Winter 2003 *Bulletin*. These press releases and other media relations efforts resulted in getting neurosurgery's message to an audi-

# Evidenced in Orlando

ence of nearly 60 million people worldwide to date.

In a related effort, a panel discussion featuring the three winners of the First Annual AANS Media Awards Program debuted at the meeting. The program, which was created to encourage balanced and educational media coverage of neurosurgical topics, featured panelists Laura Biel of the Dallas Morning News, Grendal Jones of Clarian Health, and Judith VandeWater of the St. Louis Post-Dispatch.

A main goal of the panel discussion was to create a productive dialog between reporters and physicians who often view one another as adversaries. Doctors asked the journalists what makes them want to cover a story and why they don't allow the doctor to review

a story before it goes to press. Journalists stressed that no good reporter wants to get a story wrong, and that they value developing trust with doctors because it is an essential ingredient for getting the facts straight and encouraging contacts which in turn will help them develop future stories. Pat Clark, who instructed a two-hour breakfast seminar aimed at helping AANS members learn how to develop and deliver a message via print and broadcast media, also participated on the panel. Seminar participants were invited to practice their delivery via one-minute radio interviews in which 50 AANS members participated; their interviews were carried on 1,847 radio stations nationwide, bringing neurosurgery's message to an audience of more than 40 million listeners.

## AWARDS AND HONORS



### **Cushing Medal— John A. Jane Sr., MD**

Dr. Jane received the Harvey Cushing Medal, the highest honor the AANS can bestow on a member, for his numerous professional accomplishments to the field of neurosurgery.

The editor of the *Journal of Neurosurgery* for the past 12 years, he is also editor for *Neurosurgical Focus*, the *Journal of Neurosurgery: Spine* and the *Journal of Neurosurgery: Pediatrics*. His clinical interests and research have been dedicated to the treatment of head injury, disorders of the spine and pediatrics, and he was one of the originators of modern techniques for the treatment of craniofacial disorders.



### **Distinguished Service Award— John A. Kusske, MD**

Dr. Kusske was honored for his many years of service to the AANS, the neurosurgical community and his patients. His deep interest in the

socioeconomic aspects of neurosurgical practice is evidenced in his extensive writings about the managed care industry and the various regulatory mechanisms that affect neurosurgeons including the EMTALA laws, Stark regulations and various aspects of fraud and abuse and their effects on the practice of neurosurgery.



### **Humanitarian Award— Charles Branch, MD**

Dr. Branch was recognized for his many professional accomplishments and his outstanding service to the development of neurosurgery, particularly as evidenced through

his extensive humanitarian efforts in Haiti, Guyana, and Nigeria. In Aba, Nigeria, Dr. Branch and his wife, Sylvia, raised and donated funds to build the only emergency room within a 50-mile radius and provided the first World Health Organization X-ray machine serving a population of more than 1 million impoverished people.



### **Honorary Member— Jacques Brotchi, MD**

Dr. Brotchi, professor and department chair at the Free University of Brussels, was honored for his outstanding educational, research, or clinical contributions to

the neurological sciences. He has published more than 230 papers in international journals, with special emphasis on meningiomas, intraspinal cord tumors and surgical approaches of pineal lesions. The president-elect of the World Federation of Neurosurgical Societies, Dr. Brotchi has been deeply involved in the WFNS educational program since 1991.



### **Van Wagenen Fellow— Stephen M. Russell, MD**

Dr. Russell of New York University plans to study the molecular pathophysiology of viral infection and reactivation in peripheral and cranial nerve sensory ganglia in

the laboratory of Prof. Michael Strupp at the Ludwig-Maximilians University's Klinikum Grosshadern in Munich, Germany. Applications for the 2005 fellowship are due Oct. 1. In 2005 the 12-month fellowship will carry a \$60,000 stipend of which \$15,000 will be provided to the hosting entity.

## Special Lectures

Special lecturers from neuroscientists to an economist included: Regis W. Haid Jr. (Richard C. Schneider Lecture), Anders Bjorklund, MD, PhD (Van Wagenen Lecture) Pasko Rakic, MD, PhD (Hunt-Wilson Lecture), Robert F. Spetzler, MD (Kurze Lecture); and Uwe Reinhardt, PhD (Rhoton Family Lecture).

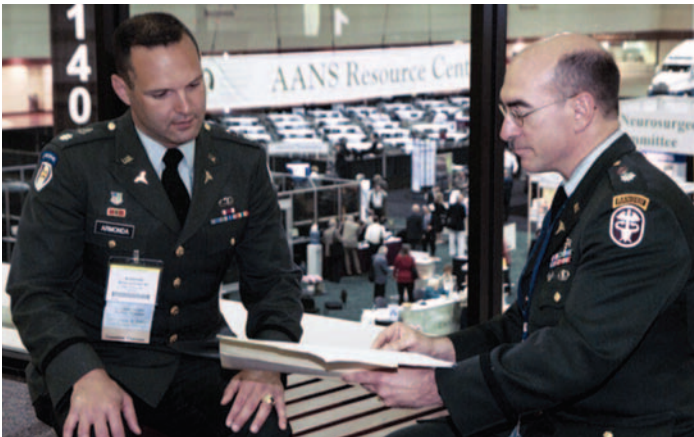
The Thursday plenary session was entirely devoted to socioeconomic topics. Research on resi-

Continued on page 25





Continued from page 23



Rocco Armonda, MD (left), and James Ecklund, MD, pictured here overlooking the exhibit hall, were among the nearly 3,000 medical attendees at the 2004 AANS Annual Meeting. Dr. Armonda and Dr. Ecklund, both Active Military members of the AANS, shared their recent experiences serving in Iraq and Afghanistan, respectively. Dr. Ecklund coauthored "The Neurosurgical Experience at an Echelon 5 Facility During Operation Iraqi Freedom," presented at the meeting. The study concluded that there was a significant decrease in the casualty rate compared with recent conflicts, possibly due to technical and tactical battlefield superiority and advances in antiballistic protective wear.

dent work hour changes, the neurosurgical workforce, and how stressors on the neurosurgical workforce affect patients' access to care were among the papers presented. Dr. Reinhardt, an economist at Princeton University, presented an insightful, entertaining and frequently humorous exploration of why the U.S. healthcare system is so expensive compared with other industrial countries.

"Every other country uses the healthcare system more cheaply [compared with the United States], he said. Dr. Reinhardt also addressed the U.S. medical liability crisis, noting, "We must get over the idea that unless we can prove a doctor is honorable, he isn't."

A. John Popp, MD, who presided over the meeting, hailed Dr. Reinhardt as "one of the most incisive minds in healthcare policy."

In his Presidential Address, entitled "Music, Musicians and the Brain," Dr. Popp contrasted the musical genius with the musically talented individual. His observations and speculations of the specialization of musicians' brain structures evolved into a discussion of neurosurgery as a confluence of technology and creativity, and the consummate neurosurgeon as one who advances patient care through technology and creativity.

"Technology...has made diagnosis and surgery more accurate, safer and faster, resulting in better outcomes," he said. "We are indebted to industry...and to those neurosurgeons and scientists whose creativity has stimulated the development of these technologies."

The 2005 AANS Annual Meeting, "Education and Innovation," is scheduled for April 16-21 in New Orleans, La. Annual meeting information is posted in the Annual Meeting section of [www.AANS.org](http://www.AANS.org) as it becomes available. ■

Manda J. Seaver is staff editor of the *Bulletin*.

### **WINS Hosts Humanitarian and Educator Inspired by Technology and Creativity**

*Contributed by Deborah L. Benzil, MD*

Greg Mortenson used insightful commentary and stunning photography to inspire an enthusiastic crowd during the Ruth Kerr-Jacoby Annual Lecture presented by Women in Neurosurgery during the 2004 AANS Annual Meeting in Orlando, Fla. The lecture is one of a continuing series of programs sponsored by WINS to enhance the scientific program during the annual meetings.

Since a 1993 climb of Pakistan's treacherous K2, the world's second highest mountain, Mortenson has devoted his life to establishing education for girls in remote, often volatile regions of Pakistan and Afghanistan. Through the Central Asia Institute, which he founded, 39 schools supporting over 10,000 children have opened. He often is the only foreigner working in areas where he has established relationships with and the respect of Islamic mullahs, military commanders, tribal chiefs and thousands of villagers.

"It takes three cups of tea to do business here [Pakistan and Afghanistan]: the first cup you are a stranger; the second cup you become a friend, and by the third cup you become family; but the process can take several years," Mortenson explained. "Educating girls reduces infant mortality, slows population growth, and improves the quality of health and life for the entire community, but most important is the intrinsic value of education instilled in her own community when a literate girl becomes a mother."

### **Silent Auction Raises \$28K for NREF**

The Sixth Annual Young Neurosurgeons Committee Silent Auction held May 1-3 during the AANS Annual Meeting raised more than \$28,000 to benefit the Neurosurgery Research and Education Foundation. Through NREF's fellowship grant program, auction proceeds will help support research efforts of early-career residents and faculty members.

A total of 88 items stimulated furious bidding, albeit in an atmosphere of generosity and festivity, down to the last second. Among the items auctioned was a rare copy of "Consecratio Medici" autographed by Harvey Cushing. After 28 bids this priceless book sold for \$800. Another "hot" item was an autographed Mario Lemieux Pittsburgh Penguins jersey, which went for \$260. The victorious bidder planned to frame the jersey as a gift for his son, "a huge hockey fan." Another participant weathered furious bidding to secure a beautiful pair of diamond earrings for his wife at a final bid of \$1,050.

The selection of electronics included four digital cameras, a Sony camcorder, and mini iPods. Also popular were airline tickets, loupes and other assorted items. One pair of binoculars sold for more than \$1,000.

The Seventh Annual Silent Auction is slated for New Orleans. Information for those interested in supporting that event or in reading more about NREF is available at [www.AANS.org/research](http://www.AANS.org/research) or from Terri Bruce, development coordinator, at (888) 566-AANS.

# Outside the Box

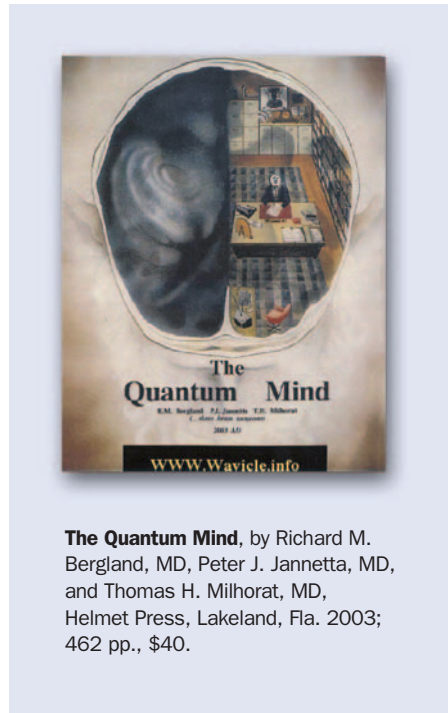
## *Chemistry, Physics Explain Brain Function*

**“T**he Quantum Mind” gives neurosurgical meaning to the catchphrase “thinking outside the box.” The authors, three of neurosurgery’s esteemed senior citizens, present this book as a work in progress; as such it vacillates between memoirs, science, and science fiction, and exhibits a profound need for editing. Yet, with this book the authors make a long-needed and exceedingly admirable attempt to create a bridge between chemistry and physics and bring new understanding to brain function.

### **Hollow Brain Houses Water Pump**

For example, they present a new, heuristic view of why the brain is hollow. On the basis of the fine structure of nerve cells and the heretofore largely unexplained function of billions of Purkinje cells, the authors postulate that the secret to brain water circulation is a cerebellar water pump. Ultra-clean water is sucked into the cerebellum by negative pressure. “Ordered” water within axonal microtubules is pumped up to the cerebrum by Purkinje cell quantum mechanical oscillations. Brain water flows through the brain’s extracellular space like cleansing rain to enter the ventricles. The choroid plexus adds water to the ventricles, and in a process similar to that of the kidneys, the head of the caudate filters out useless molecules to get rid of waste. Debris is swept out of the ventricles, and the circulation process then begins again.

Forty-five bits of evidence are presented to give credence to the new theory of brain water circulation. For example, the authors postulate that there are three brain water pumps energized separately by quantum wavicles, ventricular physics, and choroid chemistry. The cerebellar water pump makes water go up against gravity



by quantum wavicles. The other two pumps make water go down.

Some of the evidence is compelling, but the last six items relate to vascular compression of cranial nerves, which seems far-fetched and unrelated: The authors speculate that patients usually are improved immediately after microvascular decompression because “forceful pulsations against nerve axon microtubules [have] brought disorder to ordered water.”

### **Purkinje Cells Have a Hand in Handedness**

An interesting new theory of handedness is presented. The authors speculate that people are right-handed because the larger right chest bellows sucks more blood than the smaller left chest bellows. As a result a greater tissue pressure decrease in the right cerebellum results in more space for the

right cerebellar Purkinje cells to oscillate and entrain without impedance. The right-sided Purkinje cells provide smoother coordination to the right hand.

Finally, there is a new explanation for consciousness, which also involves the Purkinje cells. Whether we are awake or asleep depends on the synchronicity of the rhythms of the nerve impulse and the nerve anti-impulse.

### **“Heurograms” Convey the Concepts**

Of the 462 pages comprising this book, it is mostly pictures, or cartoons, that have been labeled “heurograms.” Heuristic means providing aid and direction in the solutions of a problem, and true to their etymology, the heurograms are extremely helpful in understanding the authors’ speculations.

I like this book, although I dislike the authors’ heavy-handed and relentless criticism of Walter Dandy and the Johns Hopkins Hunterian Laboratory. However, counterbalancing the anti-Dandy harangue are wonderful speculations by three fertile minds in presentation of a provocative hypothesis.

The book lacks the conventional scientific proof that would make most neurosurgeons comfortable and replaces it with “synthesis by over-analysis.” Nevertheless, I urge you to do what the authors are asking: Read this book and respond via the “Forum” message board at [www.wavicle.info](http://www.wavicle.info). ■

**Gary Vander Ark, MD**, is the director of the Neurosurgery Residency Program at the University of Colorado and president of the Colorado. He is the 2001 recipient of the AANS Humanitarian Award.





# Hot Topics

## *Medical Liability, Medicare Lead List*

**T**he Council of State Neurosurgical Societies (CSNS) semiannual plenary session was held May 1 in conjunction with the annual meeting of the American Association of Neurological Surgeons (AANS) in Orlando. The agenda included discussion and disposition of seven resolutions (see "Final Resolutions"), as well as updates from several committees.

Discussion of resolutions chiefly centered on Resolution I and Resolution VI.

The first resolution proposed a change to CSNS rules and regulations that would allow appointees of the AANS or the Congress of Neurological Surgeons to serve as CSNS officers. The resolution was opposed by some who felt that electing as officers those who already were serving as appointees of the national "parent" organizations would dilute the CSNS' focus on state concerns. An amended resolution was presented, and the motion to pass it carried. Amended language for the rules and regulations is being sent to the membership, as per CSNS bylaws, and it will be voted upon at the fall plenary session.

The sixth resolution asked the CSNS to sanction as ethical individual neurosurgeons' decisions to opt out of Medicare. While the deleterious effect of declining Medicare reimbursement on individual practices was acknowledged, debate centered on whether the resolution should specify Medicare, or if Medicare should be included under the banner of all third party payers. The overriding question was whether organized neurosurgery needed to take a position on what some thought should remain an individual's decision. During discussion, the decision by the AANS to leave the issue in the hands of individuals was cited (see the Winter 2002 issue of the *Bulletin*). An amended resolution narrowly failed and ultimately the resolu-

tion was rejected by voice vote.

It is worthy of note that the third resolution, which proposed that the AANS and CNS undertake a survey demonstrating the effects of the medical liability crisis on neurosurgical practice, failed when it was recognized that NERVES, the Neurosurgery Executive Resource, Values, and Education Society, is distributing the first-ever neurosurgery practice survey this summer (see the Practice Management column in this issue). In addition, the AANS/CNS Washington Committee had recently conducted a medical liability survey; preliminary results were released later in the plenary session.

Of the committee reports, attention focused keenly on the Washington Committee's update of the Protect Patients Now campaign for federal medical liability reform. One of the campaign's 10-minute newsmagazines was screened, and the campaign's strategy and accomplishments to that point were related.

In other news, Lylal Leibrock, MD, was recognized for his many contributions to the CSNS. The addition of the former CSNS chair's name to the Leadership Development Conference was announced. Dr. Leibrock, who was present, invited all to attend the Leibrock Leadership Development Conference, held July 18-20 in Washington, D.C.

The 2004 AANS Annual Meeting closed with a socioeconomic plenary session on Thursday which David Jimenez, MD, and I moderated. Resident work hours, the neurosurgical workforce, EMTALA, and medical liability were among the topics explored. Economist Uwe Reinhardt's stellar analysis of healthcare policy in the U.S. capped the session. ■

**Frederick Boop, MD**, is chair of the Council of State Neurosurgical Societies.

Additional CSNS information is available in the Legislative Activities area of [www.AANS.org](http://www.AANS.org)

## FINAL RESOLUTIONS

### **Resolution I: Proposed Change to CSNS Rules & Regulations: Allowing Appointees to be Officers**

*Adopted Amended Resolution:* Be it resolved, that the current Rules and Regulations be amended to allow CNS and/or AANS appointees who are members in good standing of their state society be elected to officer positions within the CSNS; and

Be it further resolved, that the changes required in the CSNS Rules and Regulations needed for the implementation of those elections be referred to the Executive Committee of the CSNS for development.

### **Resolution II: Hospital Coverage of Medical Professional Liability Insurance in Exchange for Emergency Room Services**

*Referred to Medical Legal Committee:* Be it resolved, that the AANS, CNS, and CSNS present a position statement to hospitals encouraging them to provide medical professional liability insurance coverage in exchange for neurosurgical ER coverage services.

### **Resolution III: Survey to Assess the Effects of the Current Medical Liability Crisis on Providing Neurosurgical Care**

*Not Adopted:* Be it resolved, that a national survey be conducted and facilitated through our parent organizations to gauge the impact that the current malpractice crisis has on providing neurosurgical care.

### **Resolution IV: Supporting Increased Organ Donation**

*Not Adopted:* Be it resolved, that the CSNS endorses the goals and methodology of LifeSharers; and

Be it further resolved, that the CSNS requests that the AANS and CNS include a summary of the LifeSharers in their newsletters in order to facilitate dissemination of this program amongst their memberships.

### **Resolution V: Motorcycle Helmets**

*Adopted Substitute Resolution:* Be it resolved, that the CSNS recommends that the AANS, CNS, and state societies reaffirm the importance of injury prevention programs including the support of mandatory helmet laws for motorcycle riders throughout the United States.

### **Resolution VI: Statement on the Ethics of Non-Participation in Medicare**

*Not adopted:* Be it resolved, that the CSNS issue a statement that it is ethical for individual neurosurgeons to refuse participation in Medicare.

### **Resolution VII: State Society Listings in the E-Bulletin Calendar [AANS E-News]**

*Adopted Amended Resolution:* Be it resolved, that the CSNS recommends that the AANS e-blast shall include a link to the calendar of events on the AANS Web site and that the calendar of events will include submissions by state and regional neurosurgical societies, regardless of whether or not the events are AANS cosponsored.

# The Neurosurgeon as CEO

*New AANS Course Helps Doctors Deal With Business*

A new course from the American Association of Neurological Surgeons (AANS) promises practice management aid for neurosurgeons who, to their consternation, find that for creating a thriving practice in today's complex medical environment, an MBA degree would be a welcome addition to their MD.

Stan Pelofsky, MD, and Samuel J. Hassenbusch, MD, PhD, codirectors of the *Neurosurgeon as CEO: The Business of Neurosurgery* course that debuts Sept. 18, understand the feeling.

"As neurosurgeons we studied and trained from five to seven years after medical school to learn how to perform a variety of delicate and technically skillful procedures directed at saving or improving people's lives, but most of us got precious little beyond friendly advice on how to run a complicated, high stakes business and be successful doing it," said Dr. Pelofsky. "Anyone in our profession today knows that that is not enough. That's why Sam and I decided to put our heads together and come up with a course that would cut to the chase, both from the perspective of someone in private practice as I am and from the viewpoint of someone in academic practice as he is, and show exactly how to run a practice as a successful business."

Dr. Hassenbusch agreed: "Neurosurgeons are used to always being prepared, but few of us can say we were ready for navigating today's labyrinth of governmental regulations or negotiating the coding quagmire in order to get paid for our services," he said. "For Sept. 18 we've planned an innovative program, unlike any other course offered, that will cover creative, 'outside-the-box' concepts and models in a straightforward, no-nonsense

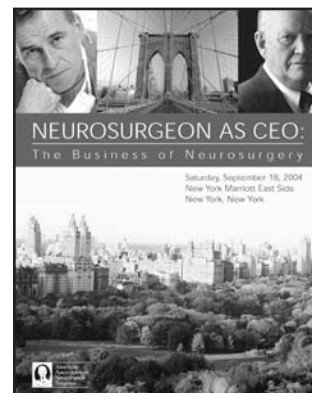
fashion intended to help ensure our colleagues' professional survival and increase their financial success."

Dr. Pelofsky and Dr. Hassenbusch each bring unique experience to the course. Dr. Pelofsky, a past president of the AANS, was a driving force behind the development of a neuroscience specialty hospital in Oklahoma City; he is in private practice with Neuroscience Specialists. Dr. Hassenbusch, of M.D. Anderson Cancer Center in Houston, is co-chair of the AANS/CNS Coding and Reimbursement Committee.

Also lending their expertise to the course are James I. Ausman, MD, editor of *Surgical Neurology*, Rancho Mirage, Calif.; James R. Bean, MD, AANS treasurer, who is in private practice with Neurosurgical Associates, Lexington, Ky.; and Patrick J. Kelly, MD, of New York University Medical Center, New York, N.Y.

In reflection of the faculty's broad experience and each faculty member's particular expertise, the topics addressed include the practice of neurosurgery both at present and in the future, surviving and succeeding in academia, creating a neurosurgical specialty hospital, coding and reimbursement, integrated neurosurgical delivery systems, and the effect of accounting and financials on the bottom line. Ample time for answering attendees' questions is built into the format.

"This interactive course promises to be a fresh and frank review of practice management realities and opportunities today," said Joni L. Shulman, AANS associate executive director-education. "Even though the *Neurosurgeon as CEO* tackles the most sophisticated concepts in the quest for practice management success, the course also is suitable for anyone involved in practice management, from the neurosurgical resident just getting



started to the seasoned neurosurgeon."

Course attendees will learn how to:

- apply "outside the box" thinking that leads to discovery of creative and innovative new revenue streams;
- analyze issues in building a practice, increasing business and adding employees, partners, physician extenders;
- minimize and avoid liability, as well handle skyrocketing overhead costs in patient care;
- enhance practice performance through optimal management and increased productivity while facing current healthcare challenges; and
- improve the bottom line by applying creative business paradigms in patient care.

Attendees can receive up to 7.25 category 1 continuing medical education credits toward the American Medical Association's Physician's Recognition Award.

The *Neurosurgeon as CEO: The Business of Neurosurgery* takes place at the New York Marriott East Side, New York, N.Y., on Saturday, Sept. 18. "The early response to this course has been overwhelmingly positive," said Shulman. "Our tentative plan is to offer the course again next year, if not sooner." ■

Manda J. Seaver is staff editor of the *Bulletin*.

# Indications Expand for Brain Stimulation

*Success of DBS for Parkinson's Sought for Pain, Epilepsy, More*

**E**xtensive expansion in the practice of functional neurosurgery has occurred in the last several years as neuromodulation treatments for movement disorders and pain have flourished. Deep brain stimulation for Parkinson's disease and essential tremor is now performed in most academic centers as well as in a substantial number of community hospitals.

Recently published 5-year results for subthalamic nucleus stimulation for Parkinson's disease demonstrate the durability of the clinical improvement with the technique, even though it did not appear to slow the progression of the disease. Patients achieve approximately 54 percent improvement with stimulation compared to their off-medication state. While some questions still remain, such as the treatment's long-term effect on cognition, the success of DBS for Parkinson's disease has led to the exploration of brain stimulation for several other indications, including psychiatric disease, and medically refractory epilepsy, in addition to neuropathic pain and movement disorders.

## Surgery for Psychiatric Disorders

The earliest forays into brain stimulation in the 1940s and 1950s were for psychiatric disorders. Today, with increased knowledge of the neuroanatomy and neuropharmacology of psychiatric disorders, modes of treatment are cautiously being reexplored. In a recent study 15 patients with medically intractable obsessive-compulsive disorder were treated with bilateral chronic stimulation of the internal capsule. This is the same target area currently and successfully used for lesioning in patients with intractable OCD. Promising early results of the stimulation study have included significant decreases in anxiety and depression, as well as in obsessive-compulsive behavior.

Results from this trial are pending, but it is hoped that the mood improvement of OCD patients treated with stimulation mirrors that noted in the OCD patients treated with lesioning. Similar trials are underway for intractable major depression.

Visser-Vandewalle and colleagues recently reported the successful treatment of three patients with Tourette's syndrome with stimulation of the centromedian nucleus of the thalamus. Cyberonics, the manufacturer of the vagal nerve stimulator, is attempting to gain U.S. Food and Drug Administration approval to add refractory depression as an indication for the device. However, given the checkered history of surgery for psychiatric disease, these studies are proceeding under the most stringent ethical supervision.

## Medically Intractable Epilepsy

Medically intractable epilepsy remains a focus of much interest for cerebral stimulation. Approximately 17,000 Americans are diagnosed with medically intractable epilepsy each year. Several devices are currently in trial for this indication. A corporately funded, long-term trial of chronic stimulation of the anterior thalamic nucleus has recently begun at 10-12 centers in North America. The anterior thalamic nucleus is part of the classic limbic circuit described by Papez. It is theorized that stimulation in this region may block incipient seizures. Human work done by Cooper in the 1970s and 1980s, as well as more recent animal and human studies by Lozano and others, have shown this to be efficacious. Other trials are focusing on stimulation of the centromedian thalamus, subthalamic nucleus, and hippocampus.

A closed-loop neurostimulation system that can sense cerebral activity and adaptively respond, rather than simply consti-

tutively stimulate, is considered a holy grail in functional neurosurgery. Animal studies of a responsive neurostimulator recently have been completed. This device was able to sense stimulation-evoked after-discharges in sheep and stimulate in response, thus eliminating the abnormal activity. An extension of this work has been carried out in patients undergoing invasive seizure monitoring. Once sufficient data for surgical planning had been obtained in the test patients, their monitoring electrodes were attached to an external responsive stimulation unit. This computerized system proved successful at recognizing early epileptiform discharges, delivering responsive stimulation and often aborting clinical seizures. FDA approval has now been granted to a clinical trial, sponsored by Neuropace, which will test a fully implantable version of this system.

## Motor Cortex Stimulation for Neuropathic Pain

Transdural stimulation of the motor cortex has proven to have significant benefits for several types of medically refractory pain. Thalamic pain syndromes and neuropathic facial pain were some of the first syndromes treated. Long-term significant improvement of greater than 50 percent in pain scores has been achieved in the majority of patients reported.

The mechanisms through which stimulation leads to pain diminution are not entirely understood. Imaging by positron emission tomography has shown increased blood flow in the ipsilateral thalamus, cingulate, orbital-frontal cortex and brainstem during motor cortex stimulation. Investigations and clinical studies suggest a functioning corticospinal tract may be necessary to achieve high levels of pain control. In one of the largest series to date,

Katayama noted a 9 percent success rate in patients whose painful limb was paralyzed. This is in contrast to a 73 percent success rate in patients without weakness.

The procedure is still being refined, and a host of issues have yet to be resolved. All series to date have been retrospective in nature, and overall success rates have varied widely. Some of this variability is due to the variety of pain syndromes treated. The optimal site for stimulation is still in debate. Epidural stimulation of the motor cortex likely provides stimulation only to the crown of the precentral gyrus and not to the cortex within the central sulcus. While this is effective for thalamic pain syndromes, recent studies suggest deafferentation pain may be successfully treated using subdural electrodes to stimulate within the central sulcus. Implantation of a subdural lead may also allow better coverage of lower

extremity symptoms by allowing inter-hemispheric electrode placement.

### **Cortical Stimulation for Movement Disorders**

There is an ongoing trial investigating the ability of transdural cortical stimulation to facilitate motor recovery after stroke. It is theorized that stimulation of the motor cortex will encourage the development of new neural networks after the ischemic incident. Similar trials are planned for the treatment of Parkinson's disease and essential tremor.

The practice of functional neurosurgery has changed greatly in the last several years. A substantial amount of research is being directed toward elucidating the therapeutic mechanisms of these procedures. Moreover, a new generation of hardware on the horizon features miniaturized stimulators and rechargeable batteries. Once there is

understanding of how brain stimulation achieves the impressive results seen so far, the number of indications is expected to greatly increase. ■

**Paul House, MD**, is chief resident in the Neurosurgery Department at the University of Utah in Salt Lake City, and **Joshua Rosenow, MD**, is a neurosurgeon at Northwestern University, Chicago, Ill.

The NS Innovations column explores neurosurgical innovations that are changing the way neurosurgeons practice. The column's emphasis is applied science, including topics such as new instrumentation and novel applications of familiar technology, but discoveries in basic science that have the potential to impact neurosurgery and aid our patients will be considered as well. I invite you to send your ideas for this column to me at [william.couldwell@hsc.utah.edu](mailto:william.couldwell@hsc.utah.edu).

*William T. Couldwell, MD, NS Innovations editor*



# Surviving a Zero-Sum Game

## *How Medicare Makes Physicians Pay for Technology*

**T**he rapid growth of the pharmaceutical and device industries has led to exciting technological advances that have improved the quality of life of our patients with safer and more effective treatments. In fact, physicians typically embrace our colleagues in industry and work as partners to advance the availability of these products. Naturally, the tremendous cost associated with new technologies must be recovered. However, most physicians may not realize the direct and indirect effects of this cost upon physician reimbursement; it is precisely these effects that are the focus of this Coding Corner.

### **New CPT Codes Accommodate New Device Use**

The most obvious way that technology is introduced to the physician payment system is through creation of a new Current Procedural Terminology (CPT) code. The Coding Corner in the Spring 2004 *Bulletin* examined the methods by which industry and

physicians for performing new procedures, Congress has set aside \$25 million annually that can be added to the Part B Medicare fund without applying budget neutrality adjustments. In other words, rather than reducing the relative value units (RVUs) of existing procedures in order to constrain growth of the Part B Medicare portion of the federal budget, CMS can add a limited amount of new RVUs to the system to account for technological advances. In short, the Part B Medicare's physician pool of dollars can grow to accommodate new procedures made available by technological advances.

However, growth of Part B Medicare is a double-edged sword. It is important for physicians to understand that the methods by which Congress budgets for physician and hospital payment by CMS are quite different. The budget neutrality adjustment that limits growth of physician payment does not apply to Part A Medicare dollars for hospital reimbursement. As a result, the cost of new technology in the forms of equip-

### **"When Congress allocates more dollars to Part A Medicare, there is less flexibility to increase the budget of Part B Medicare."**

physicians bring CPT codes forward. As that article notes, CPT is the standard method for tracking and billing physician services. Although CPT describes physician work rather than specific devices, new codes are developed to accommodate the use of a particular device during a procedure. For example, carotid stent placement and percutaneous intradiscal electrothermal therapy have procedure codes that describe physician work involving placement of a device or use of a new technology.

The financial impact of new technology on physician procedures is influenced in large part by the Centers for Medicare and Medicaid Services (CMS). To be able to pay physi-

ment and implanted devices purchased by the hospital is often passed through in part or in total to the insurer. For example, the important development of bone morphogenic protein was recognized by CMS, and a new diagnostic-related group (DRG) was created to account for this additional cost. Although on the surface this would not seem to influence the physician dollar pool in Part B Medicare, there is a significant indirect impact that must be recognized.

### **Statutes Force CMS to Constrain Growth of Part B Medicare**

Since the combination of prior limited economic growth coupled with higher-than-

expected cost of physician services resulted in failure of physicians to meet expected "spending targets," statutes force CMS to reduce the conversion factor applied to the RVUs in order to maintain constrained growth of Part B Medicare. In other words, greater than expected payments this year are paid for by reduced payments in subsequent years. Moreover, when Congress allocates more dollars to Part A Medicare, there is less flexibility to increase the budget of Part B Medicare.

Although the cost of new devices does not have a direct impact on the formula used to calculate the available dollars for physician reimbursement, the cost of prescription drugs has a significant influence. When pharmaceutical cost increases, the physician dollar pool in Part B Medicare is reduced despite the limited influence physicians have on the market price of these drugs. This means that prescribing a new brand-name, nonsteroidal anti-inflammatory agent in lieu of a less expensive generic brand will reduce the physician dollar pool in future years.

Finally, performing procedures in the outpatient setting rather than in the inpatient setting has a direct and substantial influence on physician payment. The RVUs allocated to CPT codes include the three components of physician work, professional liability costs, and practice expense. The practice expense component may represent on average 45 percent of the total RVUs used to calculate physician payment for a procedure. While the costs of implanted devices or tools to place these devices are not included in the practice expense of services performed in inpatient setting, they must be included in services performed in the outpatient setting. Although many outpatient procedures are being performed in ambulatory surgical centers, others are being performed in physician offices. Consequently, CMS calculates two different practice expense values, one for facility settings and one for non-facility settings. Therefore, expensive devices used in the office

cause a substantial increase in the practice expense allocation of RVUs.

Although it seems logical for the physician to capture the real cost to the practice of a device or of the tools used to place it, the budget neutrality constraints require a reduction in practice expense RVUs in other areas to maintain budget neutrality. For example, RVUs for performing a lumbar vertebroplasty in the hospital total 13.63, compared with 98.92 when the same procedure is performed in the office. Although the physician work component is the same, the staggering difference in total RVUs is accounted for by the cost of the instruments and devices that are part of the practice expense component. However, to account for this additional practice expense, the budget neutrality statutory limitation requires a

proportional reduction in the dollars available for other practice expenses. Consequently, it is the physician who ultimately bears the cost of these new devices as a result of the reduction in payment for other services provided.

### **For Appropriate Reimbursement, Physicians Must Understand the System**

In conclusion, it is critical that physicians begin to grasp this complicated system of payment that has been developed by Congress. For the last several years, medical advocacy groups have lobbied Congress annually to prevent substantial reductions in physician payment that are mandated to occur by statute. Given that new technology will continue to impact the practice of medicine, we must increase our understanding of the Medicare payment

system, as well as our support of neurosurgery's advocacy efforts, in order to maintain an appropriate level of reimbursement in the future. ■

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**Gregory J. Przybylski, MD**, is professor and director of neurosurgery at JFK Medical Center in Edison, N.J. He is a member of the AANS/CNS Coding and Reimbursement Committee and he is on the faculty for AANS coding and reimbursement courses. He is also council director of socioeconomic affairs for the North American Spine Society and program chair of its coding update courses.

### **Previously in the Coding Corner**

Przybylski, GJ. "CPT Coding Proposals: Difficulties Facing Industry and Physicians." *AANS Bulletin*. Spring 2004;13(1):27. [www.AANS.org](http://www.AANS.org), Article ID 21840

### **Related Article**

Orrico, KO. "Congress Halts Cuts in Medicare Fees." *AANS Bulletin*. Spring 2003;12(1):18. [www.AANS.org](http://www.AANS.org), Article ID 9893

# NEWS.ORG

AANS/CNS Sections Committees Associations Societies

## AANS Humanitarian Awardees

- 1987** Courtland H. Davis Jr., MD  
**1988** Gaston Acosta-Rua, MD  
**1989** Hugo V. Rizzoli, MD  
**1990** A. Roy Tyrer Jr., MD  
**1991** George B. Udvarhelyi, MD  
**1992** William H. Mosberg Jr., MD  
**1993** Manuel Velasco-Suarez, MD  
**1994** E. Fletcher Eyster, MD  
**1995** Melvin L. Cheatham, MD  
**1996** No award  
**1997** Robert J. White, MD  
**1998** Lee Finney, MD  
**1999** Thomas B. Flynn, MD  
**2000** Merwyn Bagan, MD, MPH  
**2001** Gary D. Vander Ark, MD  
**2002** Edgar M. Housepian, MD  
**2003** No award  
**2004** Charles L. Branch Sr., MD

## 2005 Humanitarian Award Nominations Due Oct. 15

Voting members of the AANS are invited to submit nominations for the 2005 Humanitarian Award by Oct. 15. The award will be presented at the 2005 AANS Annual Meeting in New Orleans April 16-21. The Humanitarian Award was established in 1987 to honor an AANS member whose activities outside the art and science of medicine bring great benefit to society. Nominees can be living members from any category of AANS membership who give selflessly of time or talents to a charitable or public activity; who are deserving of recognition by the AANS; and whose actions enhance neurosurgery's image. Nominees may be recognized for activities of international, national, regional or local nature that benefit humanity collectively or individually without providing remuneration to the recipient. Nominations must be submitted using the form available at [www.AANS.org](http://www.AANS.org), or by contacting Deborah Szczesniak at [dms@AANS.org](mailto:dms@AANS.org) or (847) 378-0507.

## AANS Offers New Credit Card to Members

The AANS offers its members the Platinum Plus® MasterCard® with WorldPoints<sup>SM</sup> rewards. Benefits of this credit card include a low introductory annual percentage rate, no annual fee, around-the-clock fraud protection, and 24-hour customer service. Additionally, use of the card for retail purchases accumulates WorldPoints rewards, which can be redeemed for cash, merchandise, gift certificates or travel rewards. This credit card can be requested by calling MBNA America Bank toll-free at (866) 438-6262 and specifying priority code REGR. Further information regarding AANS membership benefits through this and other partnership programs, which are designed to provide members with additional services and discounts, is available at [www.AANS.org/membership/mem\\_services.asp](http://www.AANS.org/membership/mem_services.asp).

**Historian Sought for AANS Board Position** The AANS seeks a member to serve in the position of historian on the AANS Board of Directors. The appointee, who will serve as an ex-officio board member for a five-year renewable term, is charged with reporting to leadership on the status of the

AANS Archives. The historian will maintain the history of the AANS; work with archival information on the field of neurosurgery; conduct archival and historical research about neurosurgery and the AANS; and write scholarly articles about the history of neurosurgery and the AANS. Required travel includes attendance at two annual Board of Directors meetings (one in Chicago and one in conjunction with the AANS Annual Meeting) and up to two trips to the Executive Office annually. Travel expenses are covered in accordance with established volunteer-leader travel policy. Interested individuals are asked to send a letter indicating qualifications and experience, and a CV to Deborah Szczesniak, AANS, 5550 Meadowbrook Drive, Rolling Meadows, IL 60008, or [dms@AANS.org](mailto:dms@AANS.org).

## AANS Treats Residents and Fellows to New Benefits

Beginning in 2005, residents and fellows in North America will be able to attend the AANS Annual Meeting as well as receive the *Journal of Neurosurgery*, *Journal of Neurosurgery: Spine*, and the *Journal of Neurosurgery: Pediatrics* free of charge. These new benefits are in addition to a variety of free benefits that are already in place and reduced rates on courses. Detailed information is available at [www.AANS.org/residents](http://www.AANS.org/residents).

## Tumor Section's Sixth Biennial Satellite Symposium: Oct. 21-22 (Contributed by Jack P. Rock, MD)

The AANS/CNS Section on Tumors presents the sixth biennial satellite symposium Oct. 21-22 at the Palace Hotel San Francisco, immediately following this year's Congress of Neurological Surgeons meeting in San Francisco. An outstanding scientific program has been organized with three special symposia highlighting recent advances in basic and clinical neurosurgical oncology including the role of stem cells in brain tumor biology and therapeutics, molecular imaging, and updates in neurosurgical oncology focusing on spine surgery, skull base surgery, peripheral nerve surgery, and pain management. To complement the general program, more than 100 peer-reviewed oral and poster abstracts will be presented. Additional information is available at [www.neurosurgery.org/sections/section.aspx?Section=TU](http://www.neurosurgery.org/sections/section.aspx?Section=TU).

# EVENTS

## Calendar of Neurosurgical Events

### 32nd Annual Meeting International Society for Pediatric Neurosurgery

Aug. 29–Sept. 2, 2004  
Buenos Aires, Argentina  
[www.ispn.org](http://www.ispn.org)

### European Federation of Neurological Societies Congress 2004

Sept. 4–9, 2004  
Paris, France  
[www.efns.org](http://www.efns.org)

### Western Neurosurgical Society<sup>+</sup>

Sept. 11–14, 2004  
San Diego, Calif.  
(909) 558-4417

### 7th International Neurotrauma Symposium

Sept. 12–16, 2004  
Adelaide, Australia  
[www.plevin.com.au/int2004](http://www.plevin.com.au/int2004)

### North American Conference on Shaken Baby Syndrome

Sept. 12–15, 2004  
Montreal, Quebec, Canada  
(801) 627-3399  
[www.dontshake.com](http://www.dontshake.com)

### UCLA Shaped Stereotactic Surgery Program

Sept. 28–Oct. 2, 2004  
Los Angeles, Calif.  
(310) 267-5217

### The 2nd International Symposium on Microneurosurgical Anatomy

Sept. 30–Oct. 3, 2004  
Antalya, Turkey  
[www.isma2004.org](http://www.isma2004.org)

### ASSFN 2004 Biennial Meeting: Neuromodulation

Oct. 1–3, 2004  
Cleveland, Ohio  
(800) 423-2273 x 53449  
[www.clevelandclinicmeded.com/summit/neuromodulation/index.htm](http://www.clevelandclinicmeded.com/summit/neuromodulation/index.htm)

### American Neurological Association Annual Meeting

Oct. 3–6, 2004  
Toronto, Ontario, Canada  
(952) 545-6284  
[www.aneuroa.org](http://www.aneuroa.org)

### WFNS Tumor Section Meeting

Oct. 11–13, 2004  
Kolkata, India  
(416) 603-5503  
<http://members.rogers.com/wfns>

### 2004 Annual Meeting of the Congress of Neurological Surgeons (CNS)

Oct. 16–21, 2004  
San Francisco, Calif.  
(847) 240-2500  
[www.neurosurgcon.org](http://www.neurosurgcon.org)

### 2004 Annual Meeting of the Society of Neurosurgical Anesthesia and Critical Care

Oct. 22, 2004  
Las Vegas, Nev.  
(804) 673-9037  
[www.snacc.org](http://www.snacc.org)

### 2004 Annual Meeting of the American Society of Anesthesiologists

Oct. 23–27, 2004  
Las Vegas, Nev.  
(847) 825-5586  
[www.asahq.org](http://www.asahq.org)

### Society for Neuroscience

Oct. 23–27, 2004  
San Diego, Calif.  
(202) 462-6688  
[www.sfn.org](http://www.sfn.org)

### 5-Day Gamma Knife Radiosurgery Training Course

Oct. 25–29, 2004  
Cleveland, Ohio  
(800) 223-2273, ext. 47591  
[www.clevelandclinic.org/neuroscience](http://www.clevelandclinic.org/neuroscience)

### Research Updates in Neurobiology for Neurosurgeons

Oct. 30–Nov. 6, 2004  
Woods Hole, Mass.  
[www.societytyns.org](http://www.societytyns.org)

### 4th International 2004 Skull Base Congress

Oct. 31–Nov. 4, 2004  
Darling Harbour, Sydney, Australia  
[www.tourhosts.com.au/skullbase2004](http://www.tourhosts.com.au/skullbase2004)

### American Association of Electrodiagnostic Medicine Annual Meeting

Nov. 3–7, 2004  
Savannah, Ga.  
(507) 288-0100  
[www.aaem.net](http://www.aaem.net)

### American Board of Neurological Surgery Meeting

Nov. 9–16, 2004  
Houston, Texas  
(713) 790-6015  
[www.abns.org](http://www.abns.org)

### Association of Military Surgeons of the U.S. Annual Meeting

Nov. 14–19, 2004  
Denver, Colo.  
[www.amsus.org](http://www.amsus.org)

### Advanced Techniques & Technology in Brain & Spine Surgery: An Intensive Review & Hands-On Practical Course

Dec. 3–5, 2004  
New York, N.Y.  
(212) 241-9638  
[www.mssm.edu/neurosurgery](http://www.mssm.edu/neurosurgery)

### 2004 AANS/CNS Section on Pediatric Neurological Surgery Annual Meeting<sup>+</sup>

Dec. 8–11, 2004  
San Francisco, Calif.  
(888) 566-2267  
[www.neurosurgery.org/sections](http://www.neurosurgery.org/sections)

### Brain 2004: A Multidisciplinary Meeting for Nervous System Diseases in the Asia Pacific Region

Dec. 10–11, 2004  
Shatin, Hong Kong  
[www.acp.cuhk.edu.hk/brain04](http://www.acp.cuhk.edu.hk/brain04)

### CANS 2005 Annual Meeting

Jan. 21–23, 2005  
San Jose, Calif.  
(916) 457-2267  
[www.cans1.org](http://www.cans1.org)

### Neuro-Oncology 2005 Current Concepts

Jan. 28–31, 2005  
Orlando, Fla.  
(800) 223-2273 ext. 53449  
[www.clevelandclinic.org](http://www.clevelandclinic.org)

### Richard Lende Winter Neurosurgery Conference<sup>+</sup>

Jan. 28–Feb. 1, 2005  
Snowbird, Utah  
(801) 581-6554

<sup>+</sup>These meetings are jointly sponsored by the American Association of Neurological Surgeons. A frequently updated Meetings Calendar and continuing medical education information are available at [www.AANS.org/education](http://www.AANS.org/education).

## AANS Courses

For information or to register call (888) 566-AANS or visit [www.AANS.org/education](http://www.AANS.org/education).

### ■ Managing Coding & Reimbursement Challenges in Neurosurgery

Aug. 27–28, 2004 . . . . .Chicago, Ill.  
Sept. 24–25, 2004 . . . . .Philadelphia, Pa.  
Nov. 12–13, 2004 . . . . .San Diego, Calif.

### ■ Neurosurgery Review by Case Management: Oral Board Preparation

Nov. 7–9, 2004 . . . . .Houston, Texas  
May 22–24, 2005 . . . . .St. Louis, Mo.  
Nov. 6–8, 2005 . . . . .Houston, Texas

### ■ Neurosurgical Practice Management: Improving the Financial Health of Your Practice

Aug. 29, 2004 . . . . .Chicago, Ill.

### ■ Neurosurgeon as CEO: The Business of Neurosurgery

Sept. 18, 2004 . . . . .New York, N.Y.

### ■ Innovation in Spiral Fixation: An Advanced Course

Aug. 14–15, 2004 . . . . .Boston, Mass.  
Feb. 26–27, 2005 . . . . .Memphis, Tenn.

### ■ Minimally Invasive Spinal Techniques

Dec. 4–5, 2004 . . . . .Memphis, Tenn.





American  
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Surgeons

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# Cultivating Cautious Optimism

## *Playing Each Moment With the Endgame in Sight*

With the AANS Annual Meeting in Orlando and the AANS fiscal year-end behind us, things are looking extremely positive for the AANS. But as much as members should enjoy the AANS' string of successes, it wouldn't hurt to also keep them all in perspective.

Although the actual Orlando numbers are not final as of this writing, the attendance and exhibits revenue is clearly ahead of projections. The current budget also is ahead of projections; if the investment portfolio holds, the AANS will post the third consecutive profitable year since the 2001 downsizing and retooling of the society.

### **AANS Engages in Phase 2 Restructuring**

The evolution of the AANS from the severe financial and service crises it faced three years ago to the rapid stability achieved since is merely the "end of the beginning" of leadership and management's phase 1 vision for reestablishing the AANS. That phase obviously had one goal: triage. Until we stopped the financial bleeding and created a stable infrastructure, any vision that leadership and management had for AANS beyond the short-term was basically speculative.

Now in phase 2, we're engaging in far more than just rehabilitation. We are very quickly making up for lost organizational development time. We have more than caught up in the evolution to be where most professional membership associations operationally and philosophically exist: that is, significant reliance on multiple non-dues revenue streams, accurate and proactively meaningful fiscal policies, and appropriate levels of infrastructure resource development.

We are past the stage of massive restructuring and wild swings in our year-to-year financials. Now it's about deftly managing our growth: wisely supporting the new programs and services underway, expanding the service mix that we based our rebuilding upon, and aggressively taking on new and innovative programming in a creative, yet fiscally reasonable manner.



Thomas A. Marshall  
is the AANS  
executive director.

### **Forward-Thinking Strategy Is Necessary**

Most importantly, we all need to remember the lessons from our recent past—and in so doing, keep in mind a quote from one of the most fascinating of all the colorful and unique personalities in the history of chess, grand master Savielly Tartakower. (A compelling study in his own right, Tartakower was also a writer, poet, romanticist, gambler, lawyer, and an officer in both World War I and World War II.)

Waving his hand reverentially over a chessboard readied for the first move he remarked, "The blunders are all there, waiting to be made."

For most unstable associations, the wild financial swings from red to black and back result when a cycle of leadership and management decides to live for today, rather than with a perspective that the current year is a part of a continuum of phases. Living for the moment without regard for its strategic direction—or ignoring the boundaries of its current financial position—will quickly devolve an association.

### **Growth and Expansion in AANS' Future**

The new "next phase" for AANS is at hand: AANS' growth and expansion "in the black" must be managed as carefully as was its climb out of the red. It must be expertly analyzed and played—and always should be seen as part of a larger series of moves that, whether played in the opening or middle game, are all intrinsically linked in achieving the success of the endgame. ■