CONFLICTS OF INTEREST
2007 CNS Annual Meeting
Navigating Change
Integrating Discovery and Innovation Into Practice
September 15 - 20, 2007 • San Diego, California

Join us in San Diego, California, as the Congress of Neurological Surgeons advances neurosurgery with our most influential Annual Meeting yet. The scientific program at the 2007 CNS Annual Meeting is designed to help you navigate the dynamic field of neurosurgery and incorporate the latest technological breakthroughs into your practice.

Outstanding Speakers...

L. Dade Lunsford, MD – CNS Honored Guest
Honored Guest Presentations:
- Navigating Change: The Acoustic Neuroma Story: Methods, Outcomes and Myths
- Intraoperative Imaging: Evolution and Options
- Role of Radiosurgery in the Management of AVMs
- Future of Innovation

Douglas Kondziolka, M.D.
CNS President

Salman Rushdie
Second Annual John Thompson History of Medicine Lecturer
Walter Freeman and Lessons from the First Era of Psychosurgery.

Michael Tilson Thomas
CNS Michael L.J. Apuzzo Lecturer on Creativity and Innovation

Robert Sapolsky,
PhD Julian T. Hoff Lectureship
Navigating Change and the Open Mind.

Jack El-Hai
Second Annual John Thompson History of Medicine Lecturer
Walter Freeman and Lessons from the First Era of Psychosurgery.

Robert D. Ballard, PhD
Special Lecturer
Solving the Complex Problems of Discovery.

Paul R. Sanberg, PhD
DSc Special Lecturer
Cellular Repair for the Nervous System.

Steve Squyres, PhD
Special Lecturer
The Mars Rover Mission and Navigating the Universe.

Meeting Highlights
- Introducing Integrated Medical LearningSM (IML) – Sessions during Monday, Tuesday and Wednesday GSS.
- Interactive Neurosurgical Forum and Select Abstracts Session – Monday, September 17.
- 3-D Live Cadaveric Demonstration of Surgical Approaches – Tuesday, September 18.
- NEW! Interactive Case Presentations – Thursday, September 20.

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Dear Colleague,

This issue of the Congress Quarterly (CNSQ) focuses on the conflicts of interest which are increasingly affecting various facets of medicine and neurosurgery.

More than ever before, we are likely to find ourselves in scenarios where our participation in education, research, consulting, industry collaboration, and promotion of ideas or products is being closely examined by our peers, institutions, media, and government. As we evaluate these relationships, we must challenge ourselves to reflect upon what they may mean to us and to our practice. Even the appearance of a conflict of interest can negatively impact our most vital and enduring alliance—the connection we have with our patients. In this climate of increased scrutiny, emphasis should be directed on up-front disclosure, transparency and peer/institutional approved conflict of interest management plans.

Dr. James Harrop of the CNSQ editorial board has compiled a group of experts to discuss various viewpoints pertaining to the subject of conflict of interest. Our contributors discuss a broad range of topics including the necessity for innovation, intellectual property, disclosure, perspectives from the drug and medical device industries, physician ownership, and corporate sponsorships for research, among others. There is also a discussion on how oversight by various governing bodies and statutes helps to further define and clarify our professional parameters.

In this issue, our President, Dr. Douglas Kondziolka, discusses the CNS’s role in unifying the world of neurosurgery. The popular CNS Past-President section features a contribution from Dr. A. Roy Tyrer, Jr., one of the CNS’s founding fathers, who takes us on a journey to the beginning of the CNS, and an article by Dr. Issam A. Awad, who writes an article regarding the history of the CNS and the Archives Committee efforts to preserve it.

Also in this issue, a “How Does it Work?” article describes the planning, preparation and the practical mechanics of our annual meeting scientific program. Two additional articles discuss the crucial topics of guidelines and practice parameters and the evolution of CME. Furthermore, the “Neurosurgery at 30” article discusses the growth of our innovative journal over the past years, with July 2007 marking the 30th anniversary.

We appreciate your feedback on this issue of the CNSQ and other topics of interest to you.

Sincerely,

Ali R. Rezai, MD

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60 Images in Neurosurgery
At the inauguration of the Congress of Neurological Surgeons in 1951, the founders did not name it the “American Congress of Neurological Surgeons” or the “North American Congress of Neurological Surgeons.” Rather it was created as an organization to foster neurosurgical education worldwide. But is the CNS a North American organization with international interests or is it truly an international organization, based in North America? The question may sound semantic, but the difference is important. Approximately 20% of CNS constituents are international members. Early on, the Congress created an International Committee, and it has long supported the work of neurosurgeons on other continents, particularly as it related to the growth of early neurosurgical programs in under-served areas, perhaps with limited financial resources. The Congress created the first World Directory of Neurological Surgeons, initially managed by Dr. George Ablin out of his home in California. When the World Directory went digital about ten years ago, it became more robust and current. Now the World Directory is a joint project between the CNS and the World Federation of Neurosurgical Societies (WFNS), and the current editor is Dr. Charles Liu. The CNS journal, NEUROSURGERY, has a world-wide circulation, yet is published, like most medical journals, only in English. Every CNS meeting since inception has been held in North America, usually in the United States, and once every ten years or so in Canada (the last being in Montreal in 1996). Recently, in order to promote accessibility of the CNS to an even wider array of neurosurgeons in other countries, the International Vista membership category was created, providing internet-based CNS value at a reduced cost. So is the CNS truly international and, if it means to be, how would international members best be served?

One of the privileges of serving as President is the opportunity to choose special ex-officio appointees to the CNS Executive Committee. Such individuals serve in one-year terms that may be renewed to work on special projects. During this year, I asked Dr. Marc Levivier from Brussels, Belgium, to serve on the Executive Committee. He was charged to represent the interests of international neurosurgery in a manner different from every other North American member of the Executive Committee. Dr. Levivier works with the current President of the World Federation, Professor Jacques Brotchi, in Brussels. At an Executive Committee meeting earlier this year, I asked Dr. Levivier to speak to the CNS on the issue of our perception to the international community.

UNIFYING THE WORLD OF NEUROSURGERY
Based on the “Wikipedia” format, we began a project six months ago to create an on-line, living, neurosurgical repository of information for the entire community to access, contribute to, and update.

Marc did an outstanding job with this task. Not only did he provide his own opinions, but he surveyed an array of neurosurgeons from other countries and asked them questions regarding the CNS, AANS, our journals, our meetings, and our international outreach initiatives. Marc told us that for the most part, despite the best interests of the organization, many did perceive us as a North American organization with some international interests. I agree with him. With North American leadership and a majority member base in the United States, with a focus on educational needs particularly as they relate to North America, and with an interest in North American socio-economic issues, it is only natural that the CNS would gravitate to North American interests. This is not to say that a significant amount of time and effort from the CNS leadership and members is not spent on internationalism. During the last decade, the CNS International Committee has been well served through the outstanding efforts of individuals like Dr. Richard Perrin, Dr. Nelson Oyesiku, Dr. Gail Rosseau, and now Dr. Ali Rezai. The CNS has worked to promote education and technology delivery to under-served areas, assisting the World Federation in creating the world directory, creating affordable membership categories to bring education to as many neurosurgeons as possible, creating new web-based initiatives, developing a series of co-sponsored meetings (recently with the Italian Society, the German Society and German Academy, the European Association of Neurological Surgeons, and this year with the Japanese Congress of Neurological Surgeons). In 2007 alone, the CNS assisted the Italian Society with their meeting in Rome and will participate with the EANS meeting in Glasgow this September. In 2008, the CNS is committed to joining the Croatian Society in their annual meeting.

Subscribers to NEUROSURGERY will see that the September issue of our journal, for the first time, includes a dual publication of abstracts in English and Japanese as we work to test the opportunities for publication in additional languages. Although English is the main language of science and medicine, it nevertheless remains a second or third language for many practicing neurosurgeons who, no doubt, may miss content strictly from the perspective of a language barrier. With available technological tools, this does not need to happen.

Similarly, we want to empower neurosurgeons to participate in the global advance of neurosurgical knowledge. To that end, the CNS has begun a novel project in data access entitled, The Congress of Neurological Surgeons NeuroWiki. Based on the “Wikipedia” format, we began a project six months ago to create an on-line, living, neurosurgical repository of information for the entire community to access, contribute to, and update. The project has been spearheaded by Drs. Elad Levy and Ash Sharan. Rather than rely only on journals and textbook publications (often published years after their initial concept was created), our goal was to try to create a real repository of current information. With approximately 25,000 neurosurgeons in the world, countless neuroscientists and medical students interested in our field, there are tremendous opportunities for many great minds to contribute to our knowledge base. Many of these talented people may never have a chance to contribute in the form of an invited textbook chapter. NeuroWiki is an experiment in data acquisition for the medical community, and there are many challenges involved. Nevertheless, we will test its use and vitality beginning in September (wiki.cns.org) and look forward to providing you with information on its utility and value.

So is the Congress of Neurological Surgeons an international organization or a North American organization with international interests? We are in transition, with an organization and staff working on behalf of all members. This transition will evolve as digital technologies continue to make the world a smaller place. It is our distinct hope that with your participation, the practice of neurosurgery in all countries will be advanced, and the careers of neurosurgeons will be enhanced. CNSQ
Announcing a NEW CNS International Membership Opportunity ($135 US) offered online at www.cns.org.

The Congress of Neurological Surgeons proudly announces its International Vista Member category. Because of its commitment to education and innovation, the CNS is investing in the future of every International neurosurgeon worldwide, by offering this new internet membership option.

CNS INTERNATIONAL VISTA MEMBERSHIP BENEFITS

• Internet Access to all CNS Publications via the CNS Personal Assistant (PA) including:
  ◆ Internet subscription to NEUROSURGERY®, the CNS journal,
  ◆ Operative Neurosurgery,
  ◆ Clinical Neurosurgery, journal supplements, and the
  ◆ NEW Congress Quarterly.

• Internet access to the NEW CNS University of Neurosurgery and other selected CNS educational publications and products!

• Reduced CNS Annual Meeting Registration Fees!

• Opportunity to contribute to the CNS through volunteer service on CNS committees (such as the International Committee).

• Low annual fee of $135.00 US.

We Would Love for You to Join Us!

All eligible neurosurgeons must:
• Reside and practice outside North America (United States, Canada, and Mexico).
• Be a member of your local or regional Neurosurgical Society.
• Provide a verification letter from your local or regional society, confirming membership status.

Online applications for the CNS International Vista Membership are available online at the CNS Web site www.cns.org.
The July issue of Neurosurgery marks the 30th Anniversary of the publication. Its birth in 1977 was preceded by the genesis of an idea by Congress President Bernard Patrick in 1972. The notion was subsequently brought to fruition by a number of individuals led by Robert Wilkins, then Professor of Neurosurgery at Duke. Given the reality of individuals' perspectives and camps within our specialty it was not surprising that significant resistance to its founding preceded its coming to practical reality. Principally due to Wilkins's courage, creativity, and intellectual fortitude, the Journal was established. The founding offered authors a fresh venue for their work and carried a unique signature — publication of selected comments of reviewers — a feature rarely evident in the medical literature. Its associated multifactorial publication group has now become a singular and important presence in our specialty as well as a unique and often imitated vehicle in general medical publishing.

During its initial 15 years Neurosurgery was a modest but vital enterprise growing continuously under the direction of Editors Robert Wilkins, Clark Watts, (Missouri), and Ed Laws, (George Washington). Managing editors were, in each case, the spouses of the editors with ancillary support of limited scope and capability.

In 1991, with the impetus of Ed and Peggy Laws, Phil Wirth, Chairman of Congress Publications Committee, negotiated a monumental contract with Williams and
“To chronicle the present, to define the future, to act as a Catalyst within the Field.”
The Journal’s spirit from its onset has been youthful, collegial, supportive, energetic, and open to new ideas. It remains receptive to novel concepts and is a platform for what might be considered the “avant garde.”

Wilkins, (now Wolters Kluwer Health, Lippincott Williams and Wilkins), which allowed the formulation of a professional office for the Journal — a seminal action which set the aperture for the exponential growth and provided impetus for its activities and influences over these past 15 years. Williams and Wilkins’s Timothy Grayson, our original executive publisher for 11 years, was critical as a facilitator and source of support for realization of ideas. This framework allowed a team comprised of the Editor, Managing Editor, office personnel, Publisher, publishing personnel, editorial board, guest reviewers, partners in industry, and contributors to find expression vehicles for their ideas and material efforts.

The Journal’s spirit from its onset has been youthful, collegial, supportive, energetic, and open to new ideas. It remains receptive to novel concepts and is a platform for what might be considered the “avant garde.” In addition, other than presenting only clinical and experimental scientific content and chronicling the evolving times, it is assertive in exploring historical and cultural aspects of neurosurgeons’ life and the “fruits of the mind” in a global sense — the fine arts, music, and literature. It strives to represent not only the scientific but also the humanistic side of the spirit of specialty.

Given this attitude the Journal has been in the forefront of the digital age establishing the field’s first and most expansive website (NEUROSURGERY-ONLINE) and instituting unique features such as the video based OPERATIVE NUANCES, the information magazine SCIENCE TIMES, the unique review composite CONTEMPORARY COLLECTIONS and a robust FEATURES SECTION that explores a multitude of relevant topics pertinent to the informed neurosurgeon. Concepts and Innovations offers the opportunity for “intellectual patenting” of ideas before confirmatory experimentation and lengthy clinical confirmatory studies. Articles of critical importance for clinical or experimental relevance are published immediately upon acceptance at the website.

NEUROSURGERY-ONLINE now has a reach of 13 million viewers through the Ovid database where it is bundled with the New England Journal of Medicine and the Journal of the American Medical Association as part of a select A-list of offerings. The “A-list” is comprised of approximately 100 of the 2,000 journals in the Ovid catalogue. They are considered the elite publications in each field.
Neurosurgery not only heads the citation index listing for major neurosurgical journals but also is in the top tier of all surgical journals to come.

Sensing a need and cognizant that no premier technical journal focused on operative events for the specialty was existent, the applauded Operative Neurosurgery was introduced 3 years ago. This quarterly has earned unique status rapidly.

Multiple supplements addressing clinical needs have been published. These have highlighted important topics of practical importance in the specialty including guidelines for spinal and cerebral trauma management. This year the Journal will publish nearly 5,000 pages in paper print and another 1,000 included in the ever expanding, voluminous website. The website will continue to evolve as the primary global information database. In addition, monthly podcasts have been added as a Web feature with intellectual offerings planned in the near future. These present each issues’ principal papers in depth. Continuing Medical Education (CME) will be offered in conjunction with this feature.

Of singular importance to all is the Journal’s peer-review process which involves hundreds of individuals; in order to exclude bias and provide maximum benefit for the contributors no submission is reviewed independently by fewer than 7 individuals all of whom have relevance to the topic. The Editorial Board is comprised of Principals (primary arbiters and editorial advisors), formal board members, international advisory members (each international submission has a minimum of one reviewer from their country) and guest reviewers. More than 1,200 individuals comprise the reviewer pool. The board proper is composed of individual representative all of age groups and sectors of the specialty assuring ample representation of all viewpoints and biases. Complete disclosure of financial and other benefits related to topics is required on the part of the contributors and reviewer. The journal office processes more than 25,000 individual reviews annually. No scientific material is presented in paper or web content without formal and thorough peer-review.

Having been the first neurosurgery journal to establish internet based submission and review through Pegasus, our average first response date to authors is approximately 30 days — a compliment not only to technology but to busy reviewers and editorial office personnel. Although only 14% of submissions are currently published every effort is made to have the review process be an academically edifying experience for each author.

All of this would not be possible without an extraordinary group of editorial office personnel all of whom work with passion and dedication to produce what has been termed the “miracle” of mailing each month. In a deliberate, intense, deadline laced process, this team interacts with the publishers’ professionals in Baltimore, St. Louis, Boston, Philadelphia, and New York before printing and mailing is completed in Lancaster, Pennsylvania. More than 70 individuals are involved in the formal multi-staged process. James Mulligan now serves capably in the role of Executive Publisher. It is evident that no more detailed or complex publication within the scope of availability exists — neither this content nor the award winning design happens by accident. By plan no two issues are similar or repetitive but are sculpted and polished to create multiple themes and perspectives insuring the energy, vitality, and “freshness” that have come to be the Journal’s principle hallmarks.

As to the future, we all face challenging times and the Journal is not immune to the issue of greater expectations with less resources and fewer elements of support. We have all come to expect innovation, quality, and a certain uniqueness in content and covers. The Journal was born in difficulty 30 years ago and its spirit and vitality will persist. CNSQ.
IML Sessions at the 2007 CNS Annual Meeting were made possible through an educational grant provided by the Integra Foundation. Please be sure to join us for these interactive sessions at the 2007 CNS Annual Meeting:

**Monday, Sept. 17 — Tumor**
Navigating Rational Treatment Strategies for Brain Metastases: Data and Practice.

**Tuesday, Sept. 18 — Spine**
Navigating Rational Treatment Strategies for Spondylolisthesis: Data and Practice.

**Wednesday, Sept 19 — Vascular**
Navigating Rational Treatment Strategies for Cerebral Aneurysms: Data and Practice.
The Annual Meeting of the Congress of Neurological Surgeons supports our mission “to enhance health and improve lives worldwide through the advancement of education and scientific exchange.” The Annual Meeting is also one of our largest and most prominent educational efforts. The CNS Scientific Program Committee is charged each year with the complex task of reviewing membership input and creating innovative, timely and compelling scientific and educational content for the meeting. It is important for every CNS member to understand the process used to create the Annual Meeting scientific program.

Scientific Planning for the CNS Annual Meeting: How Does it Work?

Recent changes in the regulatory environment for medical care in the United States have posed new challenges to organizations (like the CNS) that create and certify continuing medical education (CME). New requirements for CME-granting organizations are increasingly focused on needs assessment, educational outcomes, and seamless lifelong learning. The CNS is intensively involved in efforts to translate these priorities into the most compelling and effective educational experiences available to neurosurgeons. Our additional goal is to push forward the educational science of continuing education and to serve as a leader in innovative surgical education.

As part of this effort, we are significantly changing the definition, and boundaries, of the Annual Meeting. Integrated Medical Learning® (IML), described at length by Drs. Douglas Kondziolka and Anthony Asher in a previous issue of CNSQ, is a new approach to advanced education that breaks down the temporal and spatial boundaries of the traditional lecture hall. The IML process begins up to a year before the Annual Meeting as neurosurgeons from various subspecialties identify knowledge and information gaps in their areas of practice. Topic experts are then invited to identify existing clinical and scientific evidence and to formulate key questions. Evidence and questions are distributed electronically to all learners in order to assess prevailing knowledge, attitudes and practice. This information helps shape the actual content of expert presentations and interactive case-based sessions at the Annual Meeting. Finally, post-meeting electronic feedback assesses not only what was learned, but also which components of the educational process were the most effective.

The CNS is also poised to transform our Annual Meeting into a practical workshop. In the past, some of the information created and shared during six days of intensive activity at each Annual Meeting was preserved only in the published format of Clinical Neurosurgery. In recent years, the CNS has archived selected lectures in a database accessible through the CNS website (www.neurosurgeon.org). In the future, the CNS University of Neurosurgery will capture and house increasingly larger portions of key meeting content in an online archive. The information derived from IML sessions will be analyzed and presented in the peer-reviewed literature. At the 2007 Annual Meeting in San Diego, we will have formal workshops and networking sessions for both basic science and clinical trial design and participation. Finally, at the 2008 Annual Meeting in Orlando, we will have interactive consensus workshops in which participants consider the most pressing medical and socioeconomic issues facing
In each case, the goal of these efforts is to improve the effectiveness of lifelong learning for residents and practicing neurosurgeons, to advance the science of surgical education, and to improve the care of our patients.

neurosurgery today and design concrete scientific, regulatory or administrative interventions to address them. In each case, the goal is to harness the intellectual power of approximately two thousand North American and international neurosurgeons at the Annual Meeting each year to improve the quality of patient care and to enhance the health of our profession. These are ambitious goals that the energy and purpose of the CNS membership and leadership can realize.

Scientific Program
The Scientific Program Committee is composed of nearly one hundred dedicated neurosurgical volunteers. The Program itself consists of five traditional areas of content: general scientific sessions, practical courses, luncheon seminars, special courses, and afternoon symposia focused on content from each of the specialty Joint Sections. New content areas include the Neu- rosurgical Forum (for original scientific abstracts), the Basic and Clinical Trials Forum, and interactive consensus sessions. Each content area is designed by a subcommittee of up to 10 neurosurgeons, and supervised by the Scientific Program Chair and Vice-Chair with overall direction from the Congress President and Annual Meeting Chair.

In addition, various parts of the meeting utilize common tools (including educational processes such as IML) and more advanced interactive technology (such as web-enabled hand-held devices). Because of their complexity, these tools and technology require input from additional expert groups within the Scientific Program Committee.

Years ago, the entire Annual Meeting scientific program was conceived and constructed in detail during one exhausting, day-long session at the preceding Annual Meeting. Remarkably, the entire Scientific Program Committee now meets face to face only once, toward the end of the preceding Annual Meeting. Here, themes and goals for the next meeting are presented by the Congress leadership and strategies for reaching these goals are outlined by the Scientific Program Chair and subcommittee Chairs. The generation of specific meeting content by the subcommittees takes place during the autumn and early winter, based in part on written feedback from previous meetings, identification of knowledge gaps as part of the IML process, and periodic member needs assessment surveys. Most subcommittee meetings happen in smaller groups, both face to face and by conference call. The leadership of the Scientific Program Committee also conducts frequent conference calls during this time and also meets quarterly in conjunction with each Congress Executive Committee meeting.

Original Science
Over the past two years, the CNS has made an unprecedented effort to emphasize the importance of original science in our Annual Meeting programs and to promote the very best basic and clinical science in modern neurosurgery. The most visible part of this effort has been the creation of the Neurosurgical Forum. The Forum concentrates the presentation of all original science (i.e., submitted) abstracts into one afternoon session. The most compelling science is presented as interactive platform presentations during the Open Papers sessions. Each specialty section presents material simultaneously in closely adjacent rooms, allowing participants to shuttle from room to room and choose interesting presentations from various specialties.

Approximately two hundred additional abstracts are presented by their authors during the Select Abstracts session. This session takes place in a large hall adjacent to the Open Papers lecture rooms and begins immediately as the Open Papers sessions let out. Participants interact with the authors of these high quality papers in small, dynamic groups throughout the hall. Authors use laptop computers and posters to support their personalized presentations. The design of the Select Abstracts session is ideal for sharing ideas, networking and developing collaborations.

Abstract Selection
The Congress has also made efforts to ensure that the highest quality abstracts are presented in the Forum Open Papers and Select Abstracts sessions. In the past, a single group of neurosurgeons from mixed areas of expertise reviewed all submitted abstracts. The Congress has changed the abstract review process to better emphasize specialty-specific expert review. Currently, panels of neurosurgeons with relevant expertise grade all abstracts according to their Joint Section subspecialty topic. This allows graders to more carefully apply specific knowledge of the field in grading each abstract. To support this effort, all specialty areas have increased their cohort of volunteer abstract graders. Abstracts are also graded for scientific merit only, irrespective of the presentation format desired by the author. Presentation format is considered only after the abstracts are ranked, in order to properly deploy abstracts into the Neurosurgical Forum (Open Papers and Select Abstracts) or Digital Poster formats. In addition, the Congress Abstract Center software now provides statistical validation of score distribution and of the quality of grading by individual abstract reviewers, to reduce the chance of an unfair result for any given abstract.

The distribution of presentations awarded to each subspecialty content area has also been adjusted to promote evenhandedness.
Open Paper presentations are still evenly distributed between Sections (with Pain and the Council of State Neurosurgical Societies Socioeconomic Abstracts sharing one session). Select Abstract presentations, however, are awarded in proportion to the number and quality of abstracts submitted to the overall pool by each Section. This makes it less likely that a high quality abstract from a large section such as Spine, Tumor or Vascular will fail to earn a place in the Neurosurgical Forum.

Finally, the presentation of posters in digital format allows the Congress to determine the absolute number of posters accepted for presentation based purely on quality, rather than on a limitation imposed by availability of physical poster space. Plus the abstracts from all Forum and Digital Poster presentations are maintained in a searchable electronic database that serves as a resource for future meeting participants and researchers.

Mission
The Annual Meeting has undergone a myriad of changes over the last two years. Some are highly visible, such as the creation of the Neurosurgical Forum and initiation of IML educational methodology. Others, like improvements in meeting design and abstract selection, are more transparent, but should be evident in the quality of the Scientific Program they produce. All of these changes have required the dedication of new technology, resources and countless hours of time from dedicated neurosurgeon volunteers. In each case, the goal of these efforts is to improve the effectiveness of lifelong learning for residents and practicing neurosurgeons, to advance the science of surgical education, and to improve the care of our patients.

The Congress is a volunteer driven organization. The leadership of the Scientific Program Committee welcomes your input, suggestions and guidance. We hope the Annual Meeting will continue to evolve as an educational tool directly shaped and defined by your participation. CNSQ

Dr. Selden serves as Scientific Program Chair, Dr. Rodts as Annual Meeting Chair and Dr. Asher as President for the Congress of Neurological Surgeons 2008 Annual Meeting in Orlando, Florida. They are Vice-Scientific Program Chair, Scientific Program Chair and Annual Meeting Chair, respectively, for the 2007 Annual Meeting in San Diego.
Clinical Practice Parameter Guidelines and Neurosurgery

Clinical practice guidelines are statements that are systematically developed to assist with practitioner and patient decisions about appropriate health care for specific individual circumstances. Using guidelines in clinical decision-making, instead of relying solely on randomized clinical trial (RCT) results, means that professional experience is taken into account in an aggregate and more systematic manner rather than on an individual, or ad hoc, basis. More “experts,” (in the form of the guidelines) are involved in the consensus process, and opinions are based on collected evidence in the literature, rather than on personal opinions or experiences.

Organized neurosurgery and individual neurosurgeons should be interested in and support our own evidence-based medicine (EBM) clinical practice parameter guidelines initiatives, for three main reasons. The first, and most compelling, is that evidence-based guidelines do lead to improved care for our patients as well as reduced costs for our health care system. For example, the first neurosurgical evidence-based practice parameter guidelines, the Traumatic Brain Injury Guidelines, have now been shown to decrease mortality, improve functional outcomes, and decrease costs of care, both short- and long-term (J Trauma 56: 492-499, 2004; J Trauma 51: 369-375, 2001).

Second, a high quality EBM approach holds the greatest chance of preserving individual neurosurgical practitioner autonomy regarding treatment choice in areas where clinical evidence is either absent or of too low a quality to allow for any recommendations higher than level III (Options). A consensus-based model, on the other hand, often leads to ranking one or more treatment choices as superior to others despite the fact that there is inadequate evidence to support such a distinction. And the third reason is the inevitability of regulatory and
Strength of recommendations is a complex topic that implies value judgments on top of methodological assessments.

third party “quality” and “efficiency” measures for healthcare quality improvement efforts linked to physician reimbursement. In the many areas of neurosurgical practice where guidelines are lacking, the void might be filled by guidelines from sources of questionable validity (often produced with limited, or no, neurosurgeon input). Construction of these guidelines involves finding a systematic means of identifying evidence and ranking the relative quality of each study as evidence, and then achieving panel agreement on strength of recommendations linked to the analysis of the strength of evidence for each intervention. Both steps are critically important and have their own drawbacks and limitations. The ultimate validity of any guideline is critically related to three key factors: the composition of the guideline panel and its process, the identification and synthesis of the evidence, and the method of guideline construction applied.

Panel composition is crucial, both for ultimate acceptance of the guidelines by practicing physicians and for its critical influence on the “recommendation” step of guideline construction. Panelists’ recommendations can differ even when they are analyzing the same data. In general, studies have observed that U.S. experts tend to be more action-oriented than those from the UK, surgeons tend to be more certain about surgery than non-surgeons, and generalists tend to be more conservative than specialists. Guidelines produced by advocacy groups and subspecialty societies tend to be more problematic and suspect, due to unbalanced panel representation and methodological concerns. There is a natural tendency for advocacy groups to use evidence selectively to promote their causes. In panels that over-represent certain disciplines or exclude others, dissenting voices may be seen as less credible. Recommendations made by specialists are sometimes more influenced by the specialty to which they belong than by scientific evidence.

Ultimately, the quality and effectiveness of guidelines depends as much on the consensus development involved in determining the strength of recommendations (the second step of guidelines construction), as on the quality of the evidence base. Strength of recommendations is a complex topic that implies value judgments on top of methodological assessments. It should incorporate subjective considerations such as patient- or setting-specific applicability, trade-offs among risks, benefits, costs, etc. Strong evidence for an intervention should not always translate into equally strong recommendations for use.

Not all guidelines are equivalent in quality. There are three main methods of guideline development: informal consensus, formal consensus, and evidence-linked development. From the standpoint of EBM, only the latter have evidentiary status for decision-making. Indeed, the U.S. Institute of Medicine has stated that it hopes to eventually restrict the use of the term “guideline” to systematically developed advisory statements created according to validated methodology. Unfortunately that hope has yet to be realized.

Currently reams of “guidelines” are being collected nationally through the National Guideline Clearinghouse (NGC) supported by the federal government (www.guideline.gov). Unfortunately, unlike the National Health Service in Great Britain that requires strict procedural criteria for including guidelines in their listings, the NGC has no such criteria. The NGC contains consensus as well as EBM structured guidelines. It contains guidelines produced by patient advocacy groups (often corporate funded and influenced), private corporations and non-profit groups, and many professional societies (e.g., neurology, orthopedics, vascular surgery, plastic surgery, cardiology, ENT, etc.) that are promulgating guidelines of questionable quality that include neurosurgical procedures and pathologies. If we do not establish our own high-quality, defensible, EBM-based practice parameter guidelines that we can promote as superior and preferred to CMS and other agencies, we will likely be held to standards foisted upon us by external agencies, groups, and societies.

Donabedian (Explorations in Quality Assessment and Monitoring. Volume I: The Definition of Quality and Approaches to Its Assessment, 1980; Am J Public Health 71: 409-412, 1981; Inquiry 25: 173-192, 1988) is credited with formulating the quality paradigm for healthcare delivery where measures are divided into three categories: Structure, Process, and Outcome. Surgeons have traditionally emphasized and focused on the desirability of outcomes measures for
improving patient care quality. Outcomes measures, although expensive and individual procedure-specific, are superior to structural and process measures for actually improving the quality of a procedure delivered. Unfortunately, outcome measures can only tell you how well you did a procedure and not whether or not you should have done it to start with. We must recognize that unexplainable variation in healthcare delivery was centrally and specifically recognized by the IOM in their seminal 2001 report: “Crossing the Quality Chasm: A New Health System for the 21st Century” as a major symptom of the poor quality of U.S. healthcare, and reducing this variation was listed as a major priority in beginning to improve healthcare quality nationally (Crossing the Quality Chasm: A New Health System for the 21st Century, 2001). Indeed stabilizing processes through reduction in variation is a central tenet, and initial starting point of most quality and quality improvement movements and philosophies (Quality & Cost in Neurological Surgery, 2001). In their 2005 quality improvement roadmap (http://www.medicaldevices.org/public/issues/documents/CMSMedicareRoadmap.pdf) which was heavily influenced by the IOM (Crossing the Quality Chasm), CMS has specifically targeted addressing overuse, underuse, and misuse of medical treatments for measurement. EBM clinical practice parameter guidelines are the most valid source for designing process and efficiency measures to address this practice variation. The good news is that the IOM specifically recommended that CMS and Congress look to professional societies to make the relevant scientific evidence available to regulators and the public (recommendation 8, Crossing the Quality Chasm: A New Health System for the 21st Century, 2001). The bad news is that our progress to date in neurosurgery has been very limited.

Becoming serious about developing neurosurgical guidelines on a national level means becoming professional. Becoming professional means either establishing our own infrastructure of epidemiology, literature research and EBM professionals, or outsourcing these tasks through professional partnerships. Regardless of the avenue chosen, neurosurgeons need to remain in control of topic choice, representative physician panel selection, evidence table judgment calls, and judgments regarding strength of recommendation based on levels of evidence available. This oversight is essential for the good of our patients, as well as for our specialty. CNSQ
Join us in San Diego, California, as the Congress of Neurological Surgeons advances neurosurgery with our most influential Annual Meeting yet. The scientific program at the 2007 CNS Annual Meeting is designed to help you navigate the dynamic field of neurosurgery and incorporate the latest technological breakthroughs into your practice.

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Navigating Change
Integrating Discovery and Innovation Into Practice
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2:00-5:45 PM

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Announcing the Joint Meeting with the Japanese Congress of Neurological Surgeons!
Medicine is a constantly changing and dynamic field. As such, physicians have a great responsibility in acquiring up-to-date knowledge in the diagnosis and treatment of diseases. In 1968, the American Medical Association (AMA) developed and established physician recognition awards for continuing medical education (CME) such that physicians continued efforts could be monitored and documented. The AMA defined a continuing medical education credit as:

Educational activities that serve to maintain, develop, or increase the knowledge, skills, professional performance and relationships a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public (https://ssl3.ama-assn.org/pra/praform.html).

This system has grown into the accepted measure of physician continuing education and is widely utilized by credential bodies such as hospitals, medical societies, state medical licensure boards and medical specialty certifying boards.

CME: Categories Type 1 and 2
These continuing medical education (CME) credits are further categorized as either type 1 or type 2 credits. These AMA category credits are typically based on the amount of time the physician spends on each activity where one hour equals one credit. The CME type 1 activities designated by accredited CME providers can include the following (http://www.ama-assn.org/ama/pub/category/16340.html):

1. **Live activities** – physicians must attend (in person or virtually) activities such as national conferences, live Internet teleconferences, local workshops, seminars, grand rounds or departmental scientific meetings.
2. **Enduring materials** – printed, recorded, audio, video and/or online/electronic activities planned as educational activities.
3. **Journal-based CME** – a peer-reviewed, professional journal designated for credit.
4. **New procedures** – request new or expanded clinical privileges.
5. **Test item writing** – researching, drafting and defending potential questions for examinations given by the National Board of Medical Examiners (NBME) or a member board of the American Board of Medical Specialties (ABMS), or for peer reviewed, published self-assessment educational activities from a national medical specialty society.
6. **Manuscript review** – journal manuscripts are critically reviewed under the direction of an editor.
7. **Performance improvement** – structured, long-term processes by which a physician or group of physicians can learn about specific performance measures, retrospectively assess their practice, apply these measures prospectively over a useful interval, and re-evaluate their performance.
8. **Internet point of care** – self-directed, online learning by physicians on topics relevant to their clinical practice.
9. **Other activities** – other structured activities may be designated for credit, i.e. committee learning, learning plans/contracts.
10. **Direct Credit Application** – activities a physician may engage in and apply for CME credits by completing a Direct Credit Application.

CNS/AANS endorsed or sponsored category or type 1 CME credits are tracked and stored by the American Association of Neurologic Surgeons (AANS) for its members. The AANS requires that active
members maintain 60 neurosurgery specific credits within the CME three year cycle, presently designated as 1/1/05-12/31/07. The Congress of Neurosurgery (CNS) does not require continued certification with CME requirements.

Type 2 CME credits are designated for educational activities that do not meet the criteria for type 1 credits, but do meet the AMA definition of CME, and are determined by the physician to be worthwhile educational endeavors. These activities typically include teaching residents, medical students or other health professionals, in addition to attending grandrounds, or patient centered group or clinical discussions. These activities are performed at a local level and are typically recorded by the individual physician to supplement type 1 credits for state licensures, medical associations, and maintenance of certification requirements.

The American Board of Medical Specialists (ABMS), of which the American Board of Neurological Surgery (ABNS) is a member, has adopted and supports the concept of life long learning through the maintenance of certification (MOC) process. This requirement of MOC holds for an individual board certified in Neurologic Surgery after 1999. Although there are numerous requirements, one that pertains to the CME process requires that at least 150 CME hours must be accumulated every 3 years, and that there must be a minimum of 60 Category I neurosurgery specific hours. The remaining 90 credit hours may be either Category I or Category II, but at least 80% of the 150 hours must be specific to neurosurgery.

**ACCME**

In 1977, due to the rapid expansion of the CME program, the AMA invited other organizations to form a national accrediting body. This eventually evolved into the Accreditation Council for Continuing Medical Education (ACCME) in 1981. The ACCME therefore was devised in order to help physicians meet these dynamic and changing processes so as to improve and maximize patient care. The ACCME is a voluntary organization composed of seven members and governed by a board of directors. It defines its mission as the:

“identification, development, and promotion of standards for quality continuing medical education (CME) utilized by physicians in their maintenance of competence and incorporation of new knowledge to improve quality medical care for patients and their communities.”

In 1998, the ACCME created a model for physician education which has influenced the implementation of structured educational processes for years. This model was designed as a linear thought process; as such, the educational programs that emerged were often construed as rigid.

Although this system was widely utilized, the limitations in providing future modification and alteration in the education process caused the ACCME to create a task force to analyze and redefine the physician education process. As part of this review the concept of closing the “quality gap” was sought after — the difference between present treatment success rates and those thought to be achievable using best practice guidelines. The present focus of ACCME providers is to define an educational concept or mission, implement this educational process, and then further refine that process such that it becomes a more efficient and useful educational experience.

This has changed the provider’s strategy from a linear to a cyclic process such that there is a continual identification, update, and modification of programs in order to maximize physician education. The ACCME has ambitiously implemented this process, and the CNS is anxious to proceed with these guidelines in order to continue its educational goals. CNSQ
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Visit the RUNN website at http://www.societyns.org
N early three score years ago, young neurosurgeons, fully trained, who I will refer to as the Third Generation, were “champing at the bit” for a neurosurgical professional collegiality that wasn’t forthcoming. Like the traditional firehouse horse racing to the fire as smoke wafted in its nostrils, they were ready for action.

The existing neurosurgical organizations, the Society of Neurological Surgeons and the American Association of Neurological
Surgeons, whose members I consider the First Generation of neurosurgeons, each had their own objectives and membership criteria. Membership in both of these organizations was primarily by invitation. The Academy of Neurological Surgeons and the Neurosurgical Society of American, the Second Generation, had recently been established. These organizations purposely limited their membership to promote frank, open discussion at their meetings and so that the meeting site could be planned at a recreational location.

At a meeting in New Orleans in September 1950, a few of the excluded Third Generation informally discussed organizing another society to fill the gap for themselves and others in the field who were eager for affiliation. A few months later at the Chicago Inter-urban Neurosurgical Society meeting, the concept was pursued at another informal meeting. The interest in establishing a new organization
was gaining momentum.

Following this, a letter was drafted and directed to the Third Generation of neurological surgeons who were without a professional "home," inquiring about their interest in establishing a new Society oriented to their age group.

The letter read, in part:

Dear Dr. __________,

For some time a group of neurosurgeons has given considerable thought and intermittently discussed the idea of forming a neurosurgical society. For the most part these individuals form a portion of the younger group of practicing neurosurgeons who will be contemporaries during their professional life. Such an organization would be intended as a medium for the exchange of technical information and experience and for providing annual fellowship. This group has no intention of competing with the other fine neurological societies which have been established. However, the membership restrictions of some of these groups have encouraged us to consider forming a group of our own.

Please respond within the next week with special attention to the following questions: 1) Are you interested in forming a neurological society? 2) What are your ideas regarding the name, purpose, and details of the organization? 3) What are your suggestions in reference to membership (names, location)? 4) Could you meet with us May 9* in Chicago to undertake organizing the society?

Very sincerely yours.

The letter was signed by Bland Cannon, Memphis, TN, Jim Gay, Columbus, OH, Nat Hollister, Dayton, OH, E.C. "Dutch" Schultz, Memphis, TN and Hank Svien, Rochester, MN and was mailed to 40 or 50 neurological surgeons who were known to be interested or were personal neurological acquaintances. The senders were delighted with the prompt and overwhelmingly positive response, and the organizational meeting eventually took place in the Jefferson Hotel in St. Louis on May 10,* 1951. This date and occasion is now recognized as the Founders Meeting of the Congress of Neurological Surgeons. I was privileged to be one of the twenty-two neurosurgeons in attendance.

At this meeting, it was decided there would be no age restriction to membership, but the control of the organization was to be kept in the hands of the younger neurosurgeons. Qualification for membership included Certification by the American Board of Neurological Surgery (or neurosurgical training equivalent) and a provision was made for neurosurgeons actively engaged in practice. International membership was to be fostered and encouraged. It was also decided that a Distinguished Senior Neurosurgeon would be selected to be the Honored Guest at each of the Annual meetings and that he or she would be invited to speak.

Interim officers were selected to serve until the First Annual Meeting to be held in Memphis, Tennessee later in the fall of 1951. The interim officers selected were E.C. "Dutch" Schultz, President pro tem, Bland Cannon, Secretary pro tem, and executive committee members James Gay, Nathaniel Hollister and Hendrick Svien.

The first CNS meeting took place in Memphis, Tennessee on November 15-17, 1951. I was privileged to participate in the local arrangements and the scientific program for this meeting. The initial order of business was discussing the principles of the organization, determining its Constitution and Bylaws, and the election of officers. The first officers were Hendrick Svien, President, Nathaniel Hollister, Vice President and Bland Cannon, Secretary. The Scientific portion of the program included two Neuroradiology presentations, two Neuroophthalmology presentations, and an EEG presentation, among others, covering topics such as diagnosis and localization of brain tumors, cerebral angiography, and the motor system.

There was also time for social activity, including a welcoming dinner held at the Memphis University Club with entertainment provided by Dixieland’s Beale Street Jug Band. The enthusiasm and youthful spirit of the group was evident; members requested the band to play for an extra hour, then individual neurosurgeons entertained the group until the University Club security guard advised it was time to latch the doors. A formal banquet was held the next night in the Continental Ballroom of the Peabody Hotel that included a remarkable African Safari photographic presentation by Memphian Berry Brooks, a highly recognized international sportsman, conservationist and lecturer.

The registration fee for the meeting was $25.00 and 78 neurosurgeons attended from 27 states including the District of Columbia and Canada. CNS Membership at the time of the meeting was 121 neurosurgeons from 36 states and the District of Columbia, and nine international members from five countries.**

Thus was “stoked the fire” of our organization, creating embers and flames leading to the Congress of Neurological Surgeons we fondly recognize and enjoy today. CNSQ

<table>
<thead>
<tr>
<th>Participants in the Founders Meeting who were the following neurosurgeons, each of whom were recognized by a Founders certificate presented at the 25th Annual Meeting of the CNS in Atlanta in 1975.</th>
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<tbody>
<tr>
<td>F.S. Barringer</td>
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<td>Leon M. Becker</td>
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<td>Carroll A. Brown</td>
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<td>Bland W. Cannon</td>
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<td>Richard L. DeSaussure</td>
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<td>John W. Devanney</td>
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<td>Frank Earnest III</td>
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<td>Edward M. Gates</td>
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<td>Frederick C. Rehfeldt</td>
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<td>H.J. Svien</td>
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<tr>
<td>A. Roy Tyrer, Jr.</td>
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*Past references to the Founding date being May 11, 1951 is in error.

** CNS 2007 membership includes neurosurgeons from 50 states and the District of Columbia, including international members.
Without John Morgan Thompson, the first and only historian for the Congress of Neurological Surgeons for half a century, the traces of our kingdom may have been lost to oblivion long ago. John preserved shreds of documents and memorabilia; he told tales and shared stories of the hundreds of champions of our field; of their contributions to the guild of brain surgery; of their efforts that defined our field as a Science, an Art, and a Calling to volunteerism and tireless innovation. These heroes, our predecessors, took pride in raising higher the flag of their achievements with each passing year. We are their children, raised on the epics saved by John Morgan Thompson, and our heritage is built upon their soul and their heart, as well as their skill and their knowledge.

The mission of the CNS History and Archives Committee is to continue the mission that John Morgan Thompson performed so proudly and for so long: to preserve the CNS legacy and showcase its lore. I am humbled to have been invited to chair this important committee, and I will approach this awesome task with a balance of pride and humility. We have set three cardinal goals for organizing the paper archives and numerous memorabilia collected by Dr. Thompson from 1951 to 2005: preservation, retrieval, and consistency. By caring for these precious artifacts, we will maximize their impact and usefulness for future generations of neurosurgeons and leaders.

The tasks at hand include cataloguing current archives for access and retrieval. We have already started to organize the material in durable folders, per year, for lasting storage. We plan to select consistent content for future archive maintenance, preserving the highlights in science, education, and professional service for each CNS year, with input from the current CNS President and Officers. We also plan to digitize and cast select archive materials from each year, past and present, on the CNS website, starting with recent and upcoming meetings. We anticipate this historical and archival webpage becoming a living museum, accessible to our members for research, reference or just good old reminiscing. We shall continue to present a History Exhibit at each Annual CNS meeting to highlight previous meetings in the same venue and other themes. We also seek to enrich our historical heritage with on-going liaisons and contributions by our past Presidents.

Like the CNS itself, our committee is a powerhouse of talent and volunteerism. It includes a CNS Past President, the CNS Secretary, as well as Chairs of Information & Technology and Publications Committees, and has the current Historian and Archivist as its chair. The CNS Executive Director and the Webmaster are ex-officio members.

In recent correspondence, Mrs. Dorothy G. Thompson, widow of our first Historian and Archivist, reflected on her husband’s legacy with this quote: “Man builds better than he knows, Man builds where he knows not, Man departs, but the bridge remains.”

It is truly an honor and a privilege to help lead this effort. Please send me information and documents that you would like to immortalize in our archives. I can’t wait.

“Even when kingdoms were built, only vague information is left... The historian searches everywhere; quite happy when he can follow the traces so as to pull them from the oblivion where they were abandoned.”

AL-MUKADDIMA. Ibn Khaldun, (1332-1406)
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Johannes Schramm, MD
Infections and Infestations
Walter A. Hall, MD, MBA
Endoscopy
Paolo Cappabianca, MD
Pediatric Hydrocephalus
James M. Drake, MD
Adult Hydrocephalus
Marvin Bergsneider, MD
Movement Disorders
Ali R. Rezaei, MD
Psychoaffective Disorders and Pain
Giovanni Broggi, MD
Stereotactic Radiosurgery
Doug Kondziolka, MD

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May 2008
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When exploring the evolving concept of conflict of interest in neurosurgery, we as health care providers must understand how our interactions, discussions, or decisions can be biased because of competing influences. Previous experiences, industry relationships, economic incentives, and patient responsibilities are all factors that may potentially alter our decision-making processes.

The literature defines conflict as “A state of open, often prolonged fighting; a battle or war (http://dictionary.reference.com/browse/conflict).” However, this definition does not truly reflect surgeon/industry relations as both parties share the common goal of enhancing patient care. A more appropriate alternative might be a “situation where a person has a private or personal interest sufficient to appear to influence the...exercise of his/her official duties as...a professional (Journal of Business Ethics 391-392, 67-74, 2002).”

Issues involving conflict of interest are presently being evaluated by numerous national organizations. At the North American Spine Society (NASS) annual meeting 83% of the presenting surgeons self-reported a conflict of interest, defined as a greater than $10,000 monetary influence. Similarly, the 2001-2002 meeting of the American Academy of Orthopedic Surgeons (AAOS) had 519 abstracts in which 40.8% authors reported a conflict of interest (J Bone Joint Surg Am 89:608-613, 2007). Prior studies have shown a positive correlation between the presence of outside funding and positive outcomes (J Bone Joint Surg Am 89:608-613, 2007). Shaw et al. also reported that industry-funded studies have a 3.3 times higher rate of positive findings than studies without industry funding (Spine 30:099-1104, 2005).

The collaboration of surgeons, industry and patients has provided rapid advancements in neurosurgery technology and patient care. Examples of such advancements include Gamma Knife stereotactic radiation, spinal instrumentation and specialty care hospitals.

As neurosurgeons, we must understand our primary responsibility while also being aware of biases or potential conflicts. These conflicts cannot be eliminated, but need to be neutralized so as not to influence patient outcomes.

We have compiled this issue of CNSQ to provide a balanced discussion on the subject of various conflicts, and have included contributions and insights from physicians employed by industry, the government, AdvaMed, and physician inventors and ethicists. From evaluating their viewpoints, and yours, we anticipate much future discussion that further highlights these important issues.
Disclose and Justify: Intellectual Property, Conflicts of Interest, and Neurosurgery

William Manchester, the famed biographer of Winston Churchill and chronicler of American history, was referring to a fallen politician in the quote above. But the idea can also be applied to the topic of this issue of CNSQ — intellectual property and conflicts of interest.

I. We are in a time when neurosurgery’s best and brightest, those with much in the attic, often have intellectual property rights or corporate relationships which grew out of a clinical innovation, novel technology or bright idea. Unmanaged, possible conflicts arising from these interests can disturb the integrity of the clinical enterprise. They can also compromise the public’s trust in scientific studies reported by investigators perceived to be in the pocket of those paying for the research.

Much of this issue of CNSQ is dedicated to the management of conflicts of interest through disclosure, transparency and role sequestration. These considerations should be the focus of procedural ethics when we deal with the complex relationships that have evolved between corporation and clinic.

But it would be a mistake to limit our analysis of conflicts of interest without first properly understanding their etiology and why they are increasing. Taking such a diagnostic stance will allow us to better prevent conflicts and be more accepting of them when they are unavoidable in promoting the greater good (Accountability in Research 8:219-233, 2001).

II. To understand the modern era of conflicts of interest, we need to go back to the early 1980s. At that time there was concern that the pace of clinical innovation was lagging in transforming bright ideas into therapies that would be of use clinically. Moving ideas quickly from “bench to bedside” became the objective.

One important barrier was the problem of intellectual property (IP) rights stemming from discoveries developed with federal funding. Before that time, the federal government owned the IP from research it sponsored and technology transfer was difficult between the federal government and the private sector. Because neither investigators nor the federal government were in the business of drug or product development, good ideas often floundered in the translational phase of development.
Neurosurgeons who engage in corporate relationships need to ask themselves whether they or their patients will profit by their actions.

need for collaboration with industry. The reporter wryly observed “someone needed to develop Benabid’s bright idea into a product (US News and World Reports, March 1, 1999, pp. 52-53).”

Most observers would agree. Device development cannot occur in the isolation of the laboratory or the cool chill of the neurosurgical suite. Neurosurgeons need to go outside the clinic to bring their ideas to the clinic, by way of the marketplace. And therein lies the rub.

We have an aversion to medicine and commerce co-mingling. I have recently written about this and must admit to a degree of ambivalence (Cambridge Quarterly of Healthcare Ethics, In Press).

To many of us there is something unseemly about achieving personal profit from the pursuit of scientific discovery, often paid for with tax dollars, and undertaken for the betterment of humankind. The AMA Code of Medical Ethics speaks to this antipathy between patents and profit:

Physicians have an obligation to share their knowledge and skills and report the results of clinical and laboratory research…The intentional withholding of new medical knowledge, skills, and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and society and is to be condemned (Opinion on New Medical Procedures, 1994, Code of Medical Ethics, Current Opinions of the American Medical Association Council on Ethical and Judicial Affairs).

Having noted this aversion, ethical analysis should be more than a visceral reaction to reality. And the reality is that without intellectual property, technology transfer and conflicts of interest, much of the most promising work in neurology, and neuromodulation specifically, would be impossible. (Replacing private support for innovative research would require a massive increase in NIH funding, something which is unlikely to occur with current budget constraints.)

Our collective ethical obligation is to promote progress. To fail to develop devices and bring relief and succor to patients suffering from Parkinson’s Disease, depression or OCD, or perhaps traumatic brain injury, seems to be the more salient ethical breach. While conflicts of interest can be managed, a failure to promote scientific progress cannot be remediated.

Indeed the prevailing ethical principle should not be a procedural one about dual agency engendered by conflicts of interest, but rather one of distributive justice and access to care. This is the implicit message of the AMA Code of Medical Ethics just cited. Why do physicians have an obligation to share their knowledge and skills? Simply put, it is to provide new knowledge to a wider circle of practitioners so more patients can have access to better and improved therapies.

Patent rights, contrary to uninformed sentiment, are wholly consistent with the dissemination and sharing of new knowledge. Indeed, the granting of a patent imposes upon the inventor an obligation to disclose his invention precisely so others can learn and advance technological progress (Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974); see also 35 U.S.C. 112). This is explicitly noted in the US Constitution and the 1790 Patent Act, which grants inventors a period of marketplace exclusivity in exchange for expert instruction about their discovery, guaranteeing wider dissemination and access to a new product or device (U.S. Const., art. I 8, cl. 8; see also at art. I, 8, cl. 18; Patent Act of 1790, ch. 7, 1 Stat. 109-11, 1790).
III. When dealing with potential conflicts between medicine and intellectual property rights, I believe neurosurgeons, and indeed all physicians, should be motivated by this question of access. In all decisions, their standing as professionals should direct them to ask whether their actions increase access to care or hinder it. If the only way a new device can be developed is through a partnership with industry, then it seems ethically acceptable. Investigators who make this choice should not be viewed in a prejudicial light by their colleagues, journal editors, regulators or society at large.

If personal profit is the byproduct of an effort to improve patient care and not one’s primary motivation, then it is a necessary evil at worst and an aligned incentive at best. But if profit and personal gain is the neurosurgeon’s primary goal, then he or she is deviating from acceptable professional norms.

Distinguishing properly motivated behaviors from ones that are not, however, cannot be done through regulation. Two identical consulting arrangements with industry can have differing ethical valences. Were corporate ties instrumental in getting the work done, or did they merely generate additional income? Ultimately, this becomes a question of personal honesty and self-regulation. One’s intent cannot be discerned by institutional lawyers, but by professional behavior and personal oversight. Neurosurgeons who engage in corporate relationships need to ask themselves whether they or their patients will profit by their actions.

Once this question is answered, neurosurgeons are very well positioned to utilize their expertise on the patient’s behalf when working with corporate sponsors. They can help ensure that patient access to care is governed by a principled commitment to enhancing patient access to care.

Along these lines, neurosurgeons should seek to use their influence with industry to advocate for the underserved. They should work with corporate sponsors to ensure that the exclusivity granted by patents do not make products so prohibitively expensive that access is compromised. One way to do this might be to direct a percentage of proceeds to a not-for-profit use supporting translational research or underwriting surgeries on patients who would otherwise be unable to be treated.

Finally, neurosurgeons whose work is underwritten by corporate sponsorship should voluntarily justify their support in research and clinical papers. Neurosurgeons should move beyond mere disclosure and seek to explain why corporate support is necessary for the conduct of their work. With an eye towards an exposition of an ethical value, and trying not to engage in a post hoc rationalization, they should seek to explain how their collaboration with industrial sponsors furthers the ethical principle of access to care. An inability, or hesitancy, to make such assertions may signal an ethically problematic stance with respect to sources of support.

“Disclose and Justify” might become the expectation for neurosurgeons and neurology as a field. Indeed, it could become a norm for other physicians who collaborate with them or who themselves receive corporate support. And to practice what I have just preached, let me disclose that I collaborate with neurosurgical colleagues who do have corporate relationships sponsoring their translational work, though I do not receive financial support or have a stake in IP. The rationale for their collaboration with such sponsors was, and is, motivated by the forces I have sought to explicate and justify in this paper. I collaborate with them because I believe that their work promotes access to care for patients with neuropsychiatric disorders who have been historically marginalized (Nature Reviews Neuroscience 4: 323-327, 2003; Neurosurgery 59: 713-716, 2006). I voluntarily disclose these relationships in the hope that others might similarly follow with this degree of disclosure and ethical justification.

While expecting this degree of disclosure and justification may seem excessive to some, it does temper avarice and maintain the investigator’s reputation, which is his or her most precious asset and especially difficult to maintain given the complexity of today’s medical economy.

Investigators who explicitly acknowledge these challenges and seek to mitigate them proactively through their altruism and restraint help maintain public trust and our standing as professionals. A neurosurgeon’s ethical propriety should never be sacrificed in pursuit of profits. CNSQ

Acknowledgements: I am grateful to Madeleine Schachter, Esq. for our earlier collaboration on this topic, and also for the helpful comments of Dr. William Andereck.
The Need for Innovation

“Chance favors the prepared mind”
— Louis Pasteur

It may seem intuitive to some that innovation should be avoided or, at the least, cautiously approached by physicians. This is particularly so in the current conflict of interest (COI), paranoia laden environment. Conversely, physician generated or guided innovation is the heart of the medical device innovation arena. This is so because physicians arguably have the greatest knowledge and expertise needed to develop products for physician use and for the betterment of mankind. Physicians are, therefore, in a unique and optimal position to innovate.

Without innovation, idea generation would be stifled. Without ideas, there would be few, if any, scientific advances. New strategies for clinical care would be non-existent. We would not be able to reap the benefits of stereotactic radiosurgery, modern chemotherapeutic agents for brain tumors, and, for that matter, the management of infections with antibiotics would not exist.

Regarding the latter, Alexander Fleming made an astute observation while performing experiments on Staphylococcus infections in 1928. He was culturing bacteria on a culture plate. After returning from a two week vacation, he observed a clear halo surrounding a yellow-green growth that subsequently was shown to be a contaminating mold. This, he hypothesized, was the manifestation of an inhibition of bacterial growth. The mold had interfered with his experiments on bacterial growth. He could have discarded the experiment in disgust and started over. However, his prepared mind asked “Why is this so? What is inhibiting bacterial growth?” Little did he know at that moment, but he had just discovered penicillin — by chance. His “prepared mind” and his observation could have transformed him from scientist (more specifically, bacteriologist) to scientist/innovator.

This, however, did not happen. He did not take the requisite steps that may have included the injection of penicillin into infected animals. He studied. He made observations. He made discoveries. He, however, did not innovate. Without innovation, our world would be one of missed opportunities. As an aside, the observations of Fleming laid dormant for over a decade. It was not until later that others capitalized on his observation — just in time for use in World War II and D-Day, thus saving thousands of lives. Of further note, Fleming, along with the two prime movers of the pre-war “commercialization” of penicillin, Howard Florey and Ernst Boris Chain, were awarded the Nobel Prize for Medicine in 1945.

Innovation essentially consists of three components — idea development, entrepreneurship and commercialization. Idea development involves the flowing and harnessing of creative juices. Entrepreneurship should be thought of as the component of the process that is associated with the assumption of the risks associated with a business or enterprise. Commercialization is the delivery of a product to the consumer. Fleming failed to pursue all three components of the innovation process. Although he had an idea, the notion that penicillin killed bacteria, he did not develop it. Also, he did not take a business or equivalent risk, nor did he take a product from idea to clinical use — the equivalent of taking to market. Florey and Chain accomplished all three. Hence, they are the innovators, while Fleming simply, but very importantly, made an observation.

Research, analysis, creative thinking, collaboration, etc. are all involved with idea development. The idea must be matured and nurtured by developing a strategy for implementation. This process is a precursor to commercialization, which in the vast majority of cases, is associated with the need for profit or the potential for profit in order to fund product development. The assumption of both the risk and the reward of commercialization is entrepreneurship. Thus, innovation is born.

The innovator/vested physician may also be involved with the commercialization of the product as well. This may involve promotion, teaching and involvement with clinical trials and academic publications. At each step of the way, disclosure and other components of a premeditated comprehensive conflict management plan must be exercised — and exercised aggressively.

The innovative physician is, in fact, vested because he/she benefits from the conversion of an idea into a product. This obligatory aspect of new product development is an integral part of our capitalistic culture. It is, in fact, a necessary part of our culture. The motivation to achieve in sports, business, medicine, innovation and in life itself is the driving force for success. Innovation, particularly physician innovation, is not only a good thing, it is essential for the betterment of mankind. CNSQ
Medical Devices: Industry’s Proactive Response to Conflicts of Interest

Medical Devices Present Unique Conflict of Interest Considerations

In contrast to other life sciences sectors, the medical device industry presents special conflict of interest considerations based on product complexity, constant product evolution and the collaborative relationships that fuel ongoing innovation. For example, consider the following common industry ties to healthcare professionals using advanced medical technology:

- Medical devices often require hands-on training and practice to assure safe and effective use. The technique-specific nature of many devices makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are often best suited to provide this training to their fellow physicians (Cleve Clin J Med 74 [Suppl 2]: S26-S28, 2007). Moreover, advanced medical technologies undergo continuous development and repeated changes, and technologies having such short product life cycles (6-9 months in some device segments) may require retrainings with each advance.

- The dynamic process of medical device innovation entails a bidirectional transfer of knowledge. More often than other sectors, clinicians are the inventors, co-innovators and collaborators. Physicians bring practical field and other experience vital to the continued development and improvement of medical technology. Working together, industry and physicians have developed and refined key technologies benefiting patients worldwide.

- Physicians also optimize and standardize the operator techniques, which can lead to improvements in outcome as reductions in operative mortality and driveline infections with left ventricular assist devices illustrate (JAMA 287: 72-77, 2002). This standardization is often reinforced by modifications that render devices more teachable, learnable, usable and sometimes more cost efficient (JAMA 287: 72-77, 2002). It can also lead to a critical mass of clinician operators that promotes further device innovation to improve patient care and quality of life.

Unfortunately, these important ties are often overlooked — or worse, potentially precluded — in some of the academic discussions concerning conflicts of interest.

Perception is Paramount, But Should Not Drive Policy

An undeniably close and ongoing collaborative relationship among healthcare professionals and medical device companies is necessary for patient safety (technique refinement/standardization, education, testing/clinical trials, product support) and medical innovation. This unique relationship can lead to either the perception of or potential conflicts of interest for physicians, in part because the competing pressures from the multiple, overlapping roles as clinician/caregiver/investigator/innovator/customer are significant.

The structure and execution of various industry-physician interactions — such as consulting arrangements, CME funding, clinical trials, gifts, grants, and other arrangements — possess the potential to alter prescription or device usage patterns. Brennan et al. noted that...
social science research demonstrates that individuals receiving gifts are often unable to remain objective, reweighing information and choices in light of the gift (JAMA 295: 429-433, 2006). Currently, with the notoriety of prosecutors’ activity and media scrutiny, the mere suggestion that a conflict of interest may exist is deeply alarming to the public, which expects doctor-patient relationships based on objectivity and transparency. Arguably, interactions or arrangements that could result in the perception of impropriety may be just as damaging to the public’s trust as a conscious breach of the clinician’s obligation to the patient.

However, given the wide range of permissible arrangements and the beneficial nature of industry-physician collaboration, we must resist any one size fits all conflict of interest solution, and acknowledge that it is a difficult area that requires fact-specific analysis.

Bringing Guidance to Industry-Physician Interactions
The Advanced Medical Technology Association, AdvaMed, has developed a Code of Ethics on Interactions with Health Care Professionals to distinguish interactions that result in bona fide contributions to the advancement of medical technology (Code) from interactions that influence medical decision-making inappropriately. The voluntary Code was developed around seven common arrangements in the Med-Tech industry: member-sponsored product training and education; supporting third party educational conferences; sales and promotional meetings; arrangements with consultants; gifts; provision of reimbursement and other economic information; and grants and other charitable donations. AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions and compliance. Independent survey data suggests that most medical device companies have adopted the Code (PWC Compliance Survey, released at the medical Device Regulatory Compliance Congress; March 30, 2006).

To increase sensitivity to these issues and to further encourage ethical interactions, AdvaMed initiated a unique program where medical technology companies can license a unique symbol if a device maker’s CEO signs an agreement attesting to defined compliance standards, and internal structures and procedures to advance ethical interactions (http://www.advamed.org/MemberPortal/About/code/coe_logoquestions.htm; http://www.advamed.org/NR/rdonlyres/F5F11B55-0755-4977-8588-10332F9980C7/0/coe_licenseagreement.pdf). These measures provide some meaningful guidance in an area of increasing scrutiny.

Moving Ahead
Conflict of interest issues can be complex and highly fact-specific. While AdvaMed seeks to expand its leadership in this area, it is able to address only part of the equation: guiding the device industry’s actions. Importantly, many physician specialty societies have active ethics committees of their own and have taken significant steps to provide meaningful and specialized guidance to their members (http://www.aaos.org/about/papers/ethics/1204eth.asp; http://www.aaos.org/about/papers/position/1171.asp). Many of these steps are largely consistent with the Code, and industry welcomes the opportunity to collaborate with specialty societies to advance and develop approaches to conflict questions that promote ethical industry-healthcare professional interactions while maintaining the necessary and beneficial relationships that further patient safety and medical innovation. The continued vitality of the medical technology industry and many promising new technologies yet to fully emerge depends on a reasoned and tailored approach to conflict issues. CNSQ

An undeniably close and ongoing collaborative relationship among healthcare professionals and medical device companies is necessary for patient safety (technique refinement/standardization, education, testing/clinical trials, product support) and medical innovation.
AdvaMed and Endovascular Neurosurgery: The Evolving Relationship Between Physicians and Industry

Endovascular Neurosurgery is a technology-driven field. As such, professional interactions between practitioners and industry are critically important for the development and assessment of novel endovascular products and techniques. Because these interactions have been associated with fraudulent practices on the part of both industry and physicians, they are now rigorously evaluated by the federal government. Anti-kickback legislation has empowered the Office of the Inspector General and the Department of Justice to investigate whether physicians are personally benefiting from a particular relationship with a medical device company.

Such personal benefits include, but are not limited to: financial remuneration for the use of a particular product, reimbursement for travel-related expenses, honoraria, consulting agreements, and monetary research grants. In an effort to protect themselves from this growing federal scrutiny, many device manufacturers have joined the Advanced Medical Technology Association (AdvaMed), a lobbying group that not only canvasses Capitol Hill on behalf of industry, but has also established a “Code of Ethics on Interactions with Health Care Professionals.” This code of ethics details the many potential areas of interaction between practitioners and device manufacturers, including: advancement of medical technology, in vitro device training, and research and education. The overriding premise of the code is to “encourage ethical business practices and socially responsible industry conduct related to industry’s interactions with health care professionals.”

By voluntarily adopting the code of ethics, device manufacturers are theoretically reducing the likelihood that they will be investigated for fraudulent physician relationships. Currently there are more than 100 active investigations by the Office of the Inspector General and Department of Justice involving alleged improprieties on the part of device manufacturers and physicians. Such investigations have resulted in fines and collections of more than $6 billion since 2001. These investigations are often conducted through wiretaps on physicians and members of industry, and scrutiny of e-mails.

John Kilcoyne, chief executive officer for Micrus Endovascular, which produces aneurysm coils and microcatheter technologies, estimates that his company spends more than half-a-million dollars per year addressing compliance-related issues. Micrus’s compliance committee is composed of Kilcoyne, Ted Ruppel, vice president of technical operations and the company’s corporate compliance officer, as well as the company’s in-house counsel. This committee specifically evaluates every compliance-related issue through a multi-step process. Compliance-related issues include physician requests for research funding, consulting agreements between physician and manufacturer, grants and charitable donations, company-sponsored product training and education, as well as gift giving on the part of the company. The latter, according to Ruppel, includes anything having to do “with balls.” Specifically, companies are no longer able to pay for physicians to attend professional sporting events or to go on sports junkets, such as golf outings.

Where once larger companies were able to woo customer physicians through lavish offerings of honoraria, meals, and travel, such practices are no longer acceptable and certainly attract the scrutiny of the Department of Justice. According to Kilcoyne, the AdvaMed code “levels the playing field” by forcing large and small companies to interact with physicians by the same standards. Nonetheless, not all device manufacturers choose to join AdvaMed, a practice that Kilcoyne says “certainly increases their exposure” to federal scrutiny.

While companies may choose to join AdvaMed, the companies themselves police their own compliance with the code of ethics. Given that compliance with the code is voluntary, the fact that the code is not law means that companies are still vulnerable to investigation. Federal statutes, moreover, are often difficult to interpret and broad-ranging. All of these factors have certainly raised the paranoia levels of CEOs and physicians alike.

One particular focus of frequent investigation is the allocation of educational grants from manufacturers to physicians. In June of 2005, the Senate Finance Committee requested that 23 pharmaceutical companies explain their justification for providing educational grants. The overwhelming concern on the part of the Senate was that these companies were using grants as a “backdoor” means of funneling money to doctors in a tacit exchange for the promotion or use of their products. The AdvaMed Code addresses these concerns explicitly, delineating guidelines for the allotment of grants for the purposes of “advancement of medical education, support of research with scientific merit, and public education.”

While physician and corporate adherence to the AdvaMed Code of Ethics will certainly reduce the likelihood of fraudulent behavior, there remains a distinct financial incentive on the part of the federal government to continue to pursue industry-wide investigations. This as well as the fact that not all companies are part of AdvaMed and that federal statutes are significantly broad in scope creates an atmosphere of suspicion that looms over the physician-industry relationship. This vital relationship will continue to be tested in the years to come. CNSQ
Conflicts of interest invariably exist in all aspects of life. In order for them to have a minimal untoward impact on outcomes, one must identify and manage them appropriately. The need for such COI identification and management, and the process by which these are accomplished, whether pertaining to medicine or to the routine activities of daily living, is fundamentally the same. Ethics and ethical issues should be managed by employing good judgment with physician transparency regarding both physician role and physician activities.
Physician consultancy with, or ownership of, a drug or device company is potentially precarious for the physician, the company and society. Many ethical dilemmas may arise as a direct result of such endeavors. Some, if not managed properly, could result in embarrassment and even legal harm to the physician and physical harm to patients.

The management of the drug or medical device development process from a conflict of interest (COI) perspective must be patient-centric. The patient, and humankind in general, is the focus of all clinically oriented research and ultimately the recipient of the benefits derived. It is in this vein that consultancy or company ownership inevitably results in conflicts. These conflicts, if not managed properly, are usually managed in a manner that is not patient-centric, but physician- or company-centric instead. Rarely, is mismanagement of the COI process related to, or attributed to, a patient-centric approach.

In the current environment of cutting-edge medical advances, where technologies are constantly and rapidly evolving, and are used early on research volunteers, concerns regarding conflicts of interest, kickbacks, and “bad press” prevail. It is in this environment that physician consultancy with, or ownership of, a medical device company could and should come under close scrutiny. Although the precarious nature of such endeavors is ever-present, the barriers to successful entrepreneurial interactions are not insurmountable.

The physician owner or company consultant has vested interests. Therefore, he/she is a vested physician. Many of the dilemmas that a vested physician faces are primarily associated with the utilization of new technology in clinical settings where COI policies and procedures have not kept pace with the recent technological advancement “boom.” And, like it or not, society seemingly expects more from physicians than from other professionals from a COI perspective.

It is emphasized that the extent to which physician involvement in a medical device company (including consultancy and ownership) is scrutinized, depends on many variables. The vested physician must deal with the ethical conflicts that arise from the clinical arena, as well as the potential influence, that as a thoughtful leader, he/she could exert on the public and other physicians and health care professionals via publications and other communication forums.

In order for the vested physician to navigate safely and effectively through the COI abyss, while serving mankind via innovation, a fine line must be walked. Rules of the game must be carefully crafted and closely heeded. They differ for each environment and for each physician.

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“policemen” of the human clinical research process and of public safety as it pertains to clinical research. While their level of sophistication and the depth of experience may vary, IRBs can and do put the patient first and provide a safeguard regarding scientific conduct by the physician owner.

The COI Committee. COI committees function as “gatekeepers” or “watchdogs” over the conflict of interest process, and operate in this capacity for both the physicians and other scientists/inventors, as well as the institutions in which they work. In their role, COI committees create and manage processes, procedures and policies to identify and resolve conflicts of interest at potentially all levels of an organization, specifically defining disclosure and managing conflicts of interest for both the individual and the institution itself. Because of the sensitivity related to their activities, COI committees typically report to a standing special committee of the Board of Directors, Governors, Trustees of the hospital, or equivalent with active involvement from the institution’s legal counsel; this gives them an extra measure of organizational authority. Perhaps the most important function of a COI committee and its accompanying institutional legal counsel is to guide and assist in the preparation of a conflict management plan. Such a plan is unique to the specific situation and environment at hand and typically requires very detailed documentation and time for preparation. Although such requirements may seem onerous, the resulting plan and the process of developing its content can provide a mechanism for actively managing a conflict with transparency and sensitivity.

The Ethics Committee. The Ethics committee can provide unique input into the medical decision-making process, not so much by telling a physician what to do in a particular situation, but rather how to think about what he or she is doing. This can be useful when discussing very high risk trials or procedures, in particular where new medical technologies present life or end of life decision-making dilemmas. For this reason, the Ethics Committee can and should be
used as a strategic advisor to a physician owner or IRB when appropriate. Notwithstanding, because the field of modern bioethics is relatively new and there are few trained bioethicists, well staffed ethics committees are in short supply. They usually only become involved at the request of a physician or other institution employees.

The IACUC. IACUCs essentially function like an IRB for animal research, and are devoted to carrying out meaningful scientific research through the use of laboratory animals in accordance with humane standards. To this end, all research and testing involving the use of live animals must be reviewed and approved by the IACUC prior to initiation. However, as with IRBs, it is the investigator, along with other personnel involved in the care and use of animals, that “own” the principle responsibility for the research. They are also responsible for assuring that the institution’s commitment to its stated research values is maintained.

Institutional Legal Counsel. Many institutions, particularly academic institutions, provide legal counsel specifically for the types of business endeavors portrayed herein. They generally function as advisors regarding the development of, the interpretation of, and the enactment of, conflict management plans. When confronted with the absence of certain committees, for example, a COI committee, an institutional legal counsel can, in some respects, serve as a substitute.

The Conflict Management Plan
Although conflict management plans are not federally or regionally mandated, the formal documentation of the COI management strategies employed by the vested physician and affiliated company seems prudent. Such plans may be most appropriate in the non-academic medical center arena for situations in which there is no COI committee or in which the COI committee is marginally active. The conflict management plan describes each of the potential conflicts that may be encountered by all parties involved. Contributors to this document include the COI committee, legal counsel and all board members, CEOs, inventors, etc. Furthermore, and more importantly, all of the aforementioned “interested parties” should have agreed to the content and accuracy of the document. This document thus becomes a very powerful and protective tool in the complex milieu of conflict management.

Ethical Issues
COIs may arise from the use of a company product (e.g., medical device) by a vested physician or his/her surrogates. The vested physician or his/her surrogates, in addition, may potentially exert influence upon others to use the company’s product. Such utilization by the vested physician and by those with whom he/she has direct influence must be disclosed to the patient, as well as the hospital. These factors, in addition, raise concerns regarding kickbacks and self referrals. The potential for anti-kickback and Stark law violations should be very seriously considered under these circumstances. Buyer beware!

In medicine, the physician is ever-present. Such is not so in business. The COI risk increases precipitously as the practicing vested physician enters the business world. Therefore, the fewer business decisions made by a vested physician, the less the chance of experiencing unmanageable COI.

All meaningful actions related to a business venture taken by a vested physician should be undertaken pursuant to written agreements with the parent governing institution — usually the participating academic medical center. These include sponsored research agreements and conflict management plans. These documents clarify the rights and obligations of both parties and maintain physician transparency. It is implied that each “player” in the innovations process should have a clearly defined role. The aforementioned agreements help define and clarify these roles.

The performance of product related research should be performed by the vested physician only as defined by the conflict management plan. The limits of research involvement will vary from environment to environment and from case to case. A fundamental component of any arrangement regarding research involvement by a vested physician is disclosure. When in doubt: disclose.

Finally, checks and balances between the major players of a company should always exist. A vested physician should not be in a position to exert undue influence over others. Conversely others, such as the CEO of a company, should not be in a position to exert influence over the vested physician.

Conclusions
The aforementioned provides food for thought regarding the variety of components of the COI milieu. It is clear that ethical vested physician innovation can be accomplished. The rules of the game must be carefully crafted and closely heeded. They differ for each environment and for each physician. The vested physician has an immense obligation to explicitly disclose his/her involvement whenever research or the product itself is presented in a written format or discussed in the spoken form. Such dual disclosure involves both the disclosure of the vested physician’s involvement with a company and/or product and the nature of his/her involvement with the process of innovation (e.g., research, commercialization, etc.). CNSQ
Industry Conflicts — A Perspective from Inside the Medical Device Industry

Conflicts of interest have enduring consequences and global reach

This issue of CNSQ addresses conflicts of interest similar to those that occur within the health care system in general, during the government contracting process, and in the securities and financial services industries. In all of those domains, the quid pro quo delivery of something of value to an official in exchange for favorable policy decisions or actions represents an outrageous betrayal of public trust or fiduciary duty. Actions arising out of these conflicts, especially in the health care arena, are not narrowly circumscribed deals among corrupt individuals. On the contrary, conflicts of interest have enduring consequences with global reach. One example is the decades-long epidemic of fatal poisonings of people and animals attributed to endemic conflicts of interest within China’s regulatory system for chemical, agricultural, and pharmaceutical products. As will become clear later in this article, conflicts of interest based upon intangible personal or cognitive biases, rather than the exchange of money or other valuables, also have far-reaching consequences. The recent interference of political appointees in regulatory decisions pertaining to women's reproductive health in the U.S. and to the delivery of women’s health-related U.S. foreign aid is one illustration.

Industry has adopted a preventive approach to curtail material conflicts of interest

Here I share observations formed after more than a decade of academic neurosurgical practice, followed by as many years working in the medical device industry. As a former clinical investigator, a current employee of a medical device company, and the medical device industry’s current (non-voting) representative on the U.S. Food and Drug Administration, Center for Devices and Radiological Health (FDA-CDRH), Neurological Devices Advisory Panel, I have a broad experience base regarding conflicts of interest issues. Readers should bear in mind that the statements in this article are mine alone, and do not necessarily represent the views of other individuals at Medtronic, Inc., my employer, or of the industry trade association, AdvaMed (Advanced Medical Technology Association).

The AdvaMed perspective appears in a separate article in this issue; however, broad features of the AdvaMed Code of Ethics merit further discussion. Although the AdvaMed Code does not explicitly define or even contain the words “conflict of interest,” it establishes the ethically acceptable boundaries of relationships between industry employees and physicians. The explicit message is that any transgression of those boundaries creates a material conflict of interest. I encourage readers, especially physicians involved in clinical research, consulting, or other activities with industry, to read the Code on AdvaMed’s website (http://www.advamed.org/MemberPortal/About/code/). Industry and physician compliance with the Code sets a minimum standard that proscribes the exchange of benefits, goods, and/or services (e.g., money, lavish gifts, spousal travel, extravagant meals, etc.) for physician participation in industry-sponsored activities, educational seminars, or promotional/marketing events. Medtronic and many other device and drug companies maintain more comprehensive and strict internal business conduct standards than those promulgated by trade associations. In this sense, industry has adopted a preventative approach to curtail conflicts of interest.

FDA and NIH issue waivers and disclose material conflicts of interest

In the context of medical expert participation in U.S. Food and Drug Administration (FDA) advisory committees, or for reviewers of National Institutes of Health (NIH) grant proposals and other
activities, the respective agencies have codified how they deal with potential conflicts. The following is an excerpt from an FDA Draft Guidance on the subject (http://www.fda.gov/ohrms/dockets/). Note that a special government employee (SGE) is any external (non-governmental) individual appointed to serve for a defined term, usually 3-4 years, during periodic meetings of an FDA advisory panel or committee. “... before participating on a drug or biologic product approval or exemption advisory committee, SGEs must disclose “all conflicts of interest that the [SGE] may have with the work to be undertaken by the [advisory committee].” 21 U.S.C. § 355(n)(4). The Office of Legal Counsel, United States Department of Justice (OLC) has concluded that in order to satisfy this disclosure requirement, SGEs are required to disclose information sufficient to adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the SGE will make.” The guidance also states, “FDA may grant a waiver of any conflict of interest providing certain criteria are met. In addition, both sections (“sections” refers to the Code of Federal Regulations) provide for public disclosure of financial interest information when a waiver has been granted.” Two conditions absolutely exclude potential panelists from participation in a specific meeting: if patent or trademark royalties are payable to the panelist, and/or if the panelist has testified as an expert witness on the matter under consideration. Other material interests, even substantial financial holdings, do not absolutely exclude participation. Rather, the FDA commonly grants waivers, and discloses the nature and value of a panelist’s financial (or other) interests. The FDA has adopted the waiver and disclosure approach in order to maintain a sufficient pool of experts to serve on its numerous committees and panels.

The NIH describes conflicts of interest more broadly, (http://grants.nih.gov/grants/policy/coi/index.htm) “There are several bases for a conflict of interest: employment, financial benefit, personal relationships, professional relationships or other interests. If applicable, any one condition may serve to disqualify a reviewer from participating in the review of an application or proposal. A conflict of interest may be real or apparent.” Although FDA and NIH programs differ substantially, the NIH also has a waiver and disclosure process to ensure the availability of an adequate pool of medical and scientific experts.

One notable difference is that the NIH recognizes intangible personal and professional relationships, and excludes personally conflicted panelists from activities where those conflicts could come into play.

In medical research and ordinary clinical practice, material conflicts can adversely influence an investigator or clinician’s duties to protect human subjects and patients under the Declaration of Helsinki and the Hippocratic oath, respectively (J Hist Med Allied Sci 51:406-408, 1996; http://www.wma.net/e/policy/b3.htm). Undisclosed material conflicts on the part of investigators also compromises the integrity of data acquired in formal multi-center trials or in single-institution case series. In either case, discoveries or allegations of suspect data jeopardizes the validity of the data set, effectively wasting the participation of the investigators and trial subjects. If material conflicts remain undiscovered, biased data, analyses, and conclusions could lead to the erroneous approval or rejection of a particular therapy. Thus, conflicts of interest can adversely affect public health as well as the care of individual patients or research subjects.

Fortunately, most material conflicts of interest are apparent prospectively, or traceable in retrospect. Monetary payments, stock ownership, and the transfer of things of value inevitably leave a paper or electronic trail. Consequently, interested parties have put straightforward processes in place to detect, prevent, or minimize the occurrence and impact of material conflicts. Interested parties include regulatory bodies (the FDA, state and local health departments), institutional review boards and ethics committees, industry trade associations (AdvaMed for devices, PhRMA for drugs) (http://www.phrma.org/principles_and_guidelines/), the auditing and enforcement organs of government health insurance and taxation authorities, and public watchdog groups.

NIH recognizes and excludes intangible personal or professional conflicts

Perceptively, the NIH addresses conflicts that arise from “Longstanding Disagreements: A conflict of interest may exist where a potential reviewer has had longstanding scientific or personal differences with an applicant (http://grants.nih.gov/grants/policy/coi/index.htm).” Longstanding disagreements and their corollary, longstanding advocacy, create sociological and cognitive biases that are as damaging as financial ones to the public trust and to rational scientific inquiry.
Such conflicts certainly are not limited to the NIH grant review process, yet they remain largely invisible when definitions are drawn narrowly. Because paper or electronic trails rarely exist to document personal, social, or cognitive biases and their attendant conflicts, detection depends upon involvement by knowledgeable individuals (for example, medical or industry insiders) in the investigator vetting process for clinical trials or during the peer review processes for grant applications or publications.

One obvious example is the unfavorable review of a manuscript or grant proposal that challenges a reviewer's beliefs or biases. Another situation, where material and intangible conflicts operate in concert, is the development of marginal or ineffective devices, drugs, or therapies in which the innovator has both intellectual property and financial interests. Conflicted investigators and their industry sponsors sometimes achieve regulatory approval for such marginal therapies. The consequences are that patients are poorly served or even harmed, insurers squander financial resources, and physicians eventually become cynical about the regulatory approval process.

Intangible conflicts also have public health consequences
Abandonment of the optimal clinical trial mindset (lack of so-called equipoise) on the part of investigators or sponsors lies at the heart of intangible, or combined material-intangible conflicts. One core manifestation of intangible conflicts is to design, conduct, or participate as an investigator, sponsor or consultant in a clinical trial in order to prove, rather than to investigate, the efficacy of the product under study. That mindset is anathema to the principle that one is seeking to answer important questions by engaging the participation of human subjects in a potentially risky, yet worthwhile project.

However, the personal investment of investigators or sponsors in the outcome of a particular project should not necessarily connect their conflicts to venal motives. Physicians have a natural, and laudable, tendency to treat patients with certainty and confidence, especially when surgery is involved, and not to dwell on the ambiguities implicit in the investigator-subject relationship. The downside of carrying the ordinary attitude of medical or surgical certainty into a clinical investigation is that it can influence the processes of subject recruitment, consent, blinded treatment, if applicable, and data collection, assessment, and integrity, even in the absence of material incentives. Intangible conflicts further operate to enhance an investigator’s susceptibility to expectation and confirmation biases, and influences investigators to undercount or undercode adverse events. In the absence of material conflicts of interest, intangible conflicts and parochial biases may explain the refusal of so many investigators to accept the negative results of their own clinical trials and to abandon ineffective therapies (J Neurosurg 105:175-189, 2006).

Conflicts of interest are on the rise
Recent attention to conflicts of interest between and among clinical investigators and the drug and medical device industries may be due in part to the emergence of a 24/7 news cycle. However, an actual increase in instances of material conflicts is likely to have occurred over the past several years. Remember, Hippocrates lived during the fifth century B.C., and the Declaration of Helsinki dates to 1964; however, the PhRMA and AdvaMed codes of ethics date to 2002 and 2003, respectively. The enactment of those codes was the proper thing to do, but was partly a reaction to adverse public perceptions and regulatory scrutiny. Within neurosurgery, the CNS, AANS, and other professional societies traditionally have nurtured an idealized model of the academic neurosurgeon-investigator. More recently, social and economic mega-trends have fostered a competing model, that of the physician-entrepreneur, often in partnership with her university, and industry or venture capital firms. In contrast to professional societies and philanthropic agencies, for which the intellectual fruits of scientific inquiry are their own reward, investors expect to be paid back in real currency, and with interest. Although benefits definitely accrue to society from the innovations and advances generated within an entrepreneurial system, physicians, citizens, and regulators should remain vigilant of the intangible and material conflicts that influence medical decisions and public health.

Investment/Financial Disclosure: Dr. Coffey is an employee of Medtronic, Inc., Minneapolis, MN. Statements contained in this article are the author’s alone, and do not represent the policies or the views of other individuals at Medtronic, Inc.
As new physicians formally enter the practice of medicine, they take an oath based upon the Hippocratic Oath. It says, in part, “I will practice my profession with conscience and dignity; the health of my patient will be my first consideration.” The Congress of Neurological Surgeons reiterates and amplifies this concept in the Code of Ethics which states in part, “No activity should be undertaken that does not serve the best interests of the patient.” Maintaining this standard has grown complex as the practice environment and models of ownership have evolved. Increasingly, physicians are, consciously or unconsciously, placed in situations with imbedded conflicts of interest that can compromise their professional integrity and much more. The heightened public attention to this issue is resulting in greater scrutiny of physician decisions about treatment options, use of pharmaceuticals, and selection of other “physician preference items” such as implants. The ethical considerations are further clouded when a physician has a financial stake in decisions that impact patient care. This concern was covered on the front page of The Wall Street Journal last fall in a story about the U.S. Department of Health and Human Services’ Centers for Medicare & Medicaid Services (CMS) proposed new regulations on self-referral. The increased scrutiny and proposed new rules were the result of concerns that unnecessary diagnostic imaging tests were driving up costs in the Medicare program.

Regulators, legislators, journalists and patient advocates are raising serious questions about financial conflicts of interest related to the practice of medicine. The growth of physician ownership in treatment modalities, such as Ambulatory Surgery Centers, Diagnostic Imaging Centers, Limited Service Hospitals, is also generating concerns about increased use of services and added costs to the community.

Professional journals and major media outlets have given significant attention to issues of conflict of interest and the financial arrangements available to physicians. The Wall Street Journal recently covered the changes hospitals and health systems have made to protect institutional investment decisions from potential financial conflicts of interest by placing safeguards to remove employees, physicians, or trustees with a personal financial stake from the decision making process. The Washington Post recently chronicled the growing influence and role of pharmaceutical manufacturers in continuing medical education. National media outlets have also taken on the National Institutes of Health over links between the expert panelists who evaluate and draft government treatment guidelines and manufacturers producing pharmaceuticals or other related products. Finally, members of Congress are speaking out publicly about the need to keep closer tabs on the relationship between medical professionals and industry.

The critical issue here is public trust. Patients are increasingly exposed to an avalanche of health information, from websites for top medical centers to significant levels of direct-to-consumer pharmaceutical advertising. Patients rely on their physician to act as a trusted guide as they navigate through this information. That trust can be quickly breached if the patient later learns of a physician’s financial interest in a recommended course of action.

Academic medicine, long trusted by the public and patients to advance the field through research and discovery and to deliver cutting-edge care, has faced this issue of public trust in recent years amid increasing questions about whether scientific integrity or patient safety could be compromised by financial conflicts of interest. The Association of American Medi-
Physicians practicing in our hospital are required to abide by these policies and are governed by additional policies which require disclosure and address potential conflicts. Additionally, all staff members are required to adhere to strict policies related to gifts. Staff members sign a related attestation to underscore the importance of creating a healthcare environment free of question about conflicts of interest. Physicians practicing in our hospital are required to abide by these policies and are governed by additional policies which require disclosure of any potential conflicts of interest related to patient care.

Our own concerns about conflicts of interest prompted the adoption of stricter disclosure requirements and policies along with signed statements disclosing interests from all members of our leadership team. These disclosures are part of a proactive effort to identify and address potential conflicts. Additionally, all staff members are required to adhere to strict policies related to gifts. Staff members sign a related attestation to underscore the importance of creating a healthcare environment free of question about conflicts of interest. Physicians practicing in our hospital are required to abide by these policies and are governed by additional policies which require disclosure of any potential conflicts of interest related to patient care.

Neurosurgeons, as high-profile specialists offering complex and high-risk procedures, must take this issue seriously because they face great public scrutiny for their actions. This is especially true because a variety of opportunities for outside financial relationships for neurosurgeons exist. These relationships, ranging from agreements with implant makers to relationships with pharmaceutical manufacturers to ownership stakes in imaging centers or even limited-service hospitals have the potential to influence, or perhaps simply appear to influence decisions about patient care. The American Association of Neurological Surgeons addresses this issue in its adaptation of the AMA Code of Ethics which states that physicians have “an affirmative ethical obligation to disclose to the patient or referring colleagues his or her ownership interest in the facility or therapy prior to utilization.”

We need to realize this issue will simply not go away. Medicine has entered an era of transparency. Patients and policy makers are increasingly interested in the growing quantity of data available from government sources including CMS and private sources such as The LeapFrog Group. Amid this transparency and public reporting, the best test of a potential conflict might be to consider how it would look on the front page of the newspaper.

Patient concerns and the possibility that the government will take regulatory action if we don’t effectively police ourselves provide both a compelling reason and a strong push to act. The Stark Law and other similar federal regulatory efforts demonstrate the complicated environments, unintended consequences, and organizational demands that can result. We have a limited window to clearly define conflict of interest and to act decisively to address patient and policy maker concerns. As a field, we need to do the following:

• Accept responsibility for defining, identifying, and disclosing interests and addressing conflicts of interest. A proactive response reduces the likelihood of a government “solution” being adopted without our involvement.
• Implement, monitor and enforce conflict of interest policies. The policies must be taken seriously and enforced uniformly to have impact.
• Respond to the changing environment. As healthcare evolves, the conflict of interest policies must also evolve to cover new situations and applications.
• Proactively communicate with policymakers and regulators about the steps we are taking.

I applaud the Congress of Neurosurgeons for its interest in this important issue and encourage you to continue with a proactive response to concerns about conflict of interest. CNSQ
ACCME and Corporate Relations

A few years ago I coordinated a national practical course reviewing cervical spinal instrumentation, recruiting a number of surgeons with expertise in the field to serve as faculty and help develop curriculum. As part of the course, participants could try out various instrumentation systems with some guidance from the faculty. We invited six or seven companies to participate with sawbones models and systems, and I provided a copy of the lecture schedule, topics, and speakers to representatives from the companies.

After seeing the materials, one representative asked if I would consider including other surgeons on the faculty, as none of those listed were familiar with the specific instrumentation his company provided. He informed me that he had provided lists of prospective faculty to organizers of other meetings. He further implied that the company’s enthusiasm for participating was somewhat dependent upon the perception that it was getting valuable exposure at these practical courses.

This request put me in a difficult situation. I wanted to promote the meeting and encourage participation of the vendor, but I felt uncomfortable about the intrusion of this corporate representative into the course planning process. I sought advice from a senior colleague who referred me to the Accreditation Council for Continuing Medical Education (ACCME) regulations regarding corporate relationships with continuing medical education (CME) programs. The ACCME web page provided me with clear guidance as to how to proceed, and I declined the representative’s request.

Since that time, I have become more familiar with the regulations and workings of the ACCME, and the ACCME has also updated their regulations. The “ACCME Standards for Corporate Support” can be downloaded directly from the organization’s website (www.accme.org). It is a must read for any course director, scientific program committee leader, or officer of any organization that is accredited to provide CMEs or receives corporate support (or whose faculty receive corporate support). The following paragraphs provide a few highlights of the ACCME policies and how the Congress of Neurological Surgeons (CNS) has adopted these policies.

The CME provider must ensure that the development of the educational program is free from corporate bias. This organization must determine the educational needs of its membership, identify educational objectives, select topics and select faculty without any input or direction from corporate sponsors.

All educational offerings from the CNS are vetted through its Education Committee. The chairman of the Education Committee as well as four other members and at least one senior member of the Scientific Program Committee have participated in the ACCME workshop in order to maintain familiarity with ACCME processes and learn about future educational initiatives (see Dr. Harrop’s article on page 23 – The Evolution of Continuing Education). The largest CNS educational offering, the annual meeting, is designed by the Scientific Program Committee and then presented to the Education Committee for approval. The CNS Scientific Program Committee is made up of dozens of members, this year totaling over 100, who have demonstrated both an interest in education and an expertise in a subfield of neurosurgery. These members provide opinions on relevant topics and venues for CME activities, but are also required to review survey data from past meetings, focus groups, and member needs assessments performed throughout the year. Based upon these sources of information, a program is designed to meet the educational needs of our members and is approved by the education committee without outside corporate input.

Once the program is designed, faculty members are asked to disclose any financial interest with corporate sponsors. Failure of a faculty member to submit disclosure information eliminates them from the scientific program. This same standard is applied to authors of original research papers. Furthermore, anyone who participates in the planning process, as a member of a committee, a course director, or faculty member, must disclose similar relationships.

These disclosures are kept on file and are published in the program book provided to every medical attendee. Furthermore, it is required that every presentation include a restatement of this disclosure information. The CNS encourages all speakers to list disclosure information on the second slide of their presentation (although a verbal disclosure is acceptable, particularly for the shorter “point” presentations where slide number is significantly limited). Moderators remind the speakers to provide such information at the beginning of each educational session.

Independence from corporate influence and disclosure of corporate relationships are just two of the regulations governing the relationship between CME providers and corporate interests. Other requirements relate to the management of conflicts when they are recognized to exist, the requirement for minimization of bias, and the appropriate use of corporate sponsorship dollars for support of educational activities. Strict adherence to the ACCME regulations, at least in my opinion, serves to greatly improve the quality of our educational offerings and offers our members assurance that they are not attending an “infomercial” when participating in any CNS sponsored event. We take pride in providing educational products that focus on fundamental truths and optimal patient care and outcomes, not marketing strategies.
As the practice of modern medicine has become more complex, so has the relationship between physician and patient. With so many players — including providers, payers, suppliers and researchers — involved in patient care, potential conflicts of interest may seem unavoidable. Such conflicts can exist even if no unethical or improper acts occur. As a result, our professional interactions with patients are being increasingly scrutinized, and in this environment many situations can create the appearance of impropriety.

How do our patients view potential conflicts of interest? From their perspective, receiving the best care and treatment for themselves and their loved ones is the most vital consideration and trumps all other interests. Therefore, we must ensure that possible financial conflicts do not unnecessarily increase costs to patients (or payers) or prevent appropriate treatment. There are also non-financial conflicts, which might include a researcher choosing a treatment option to further the goals of an experimental design. We must be vigilant in monitoring these conflicts as well.

The AMA Code of Medical Ethics provides concrete guidelines regarding conflict of interest as it relates to our patients, stating “Under no circumstance may physicians place their own financial interests above the welfare of their patients.” Similarly, the AMA guideline on biomedical research says that: “Avoidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity.” Although adhering to these guidelines would seem to answer all the questions that might arise, the reality of modern medicine demands a more nuanced interpretation. Since conflicts of interest cannot be avoided, our attention must turn towards mitigation of their effect on our patients.

One of the most common patient-related conflicts involves physician ownership of imaging and treatment facilities, including specialty care hospitals. Physician-owned facilities can
A combination of self-reflection and oversight will ensure that we are aware of and effectively manage potential conflicts.

provide important benefits to the patient, including convenience, improved communication of results, superior quality, increased efficiency, as well as services that would otherwise be unavailable in that community. Yet physician ownership inherently gives the appearance of a conflict of interest, and at least one study has in fact suggested that physicians may be more likely to order tests in a self-referral setting. Ways to mitigate this potential conflict include adhering to appropriate statutes, disclosure of the physician’s interest in the facility to the patient, offering the patient a choice of alternative facilities, and following established guidelines from national organizations for appropriate testing and treatment.

Another conflict that has received considerable attention involves physicians and the pharmaceutical and technology industries. In these cases, a physician may be offered some sort of gift or inducement to prescribe a particular medication, utilize a device, or purchase equipment which increase the cost to the patient, even though other equally effective and less costly alternatives exist. Here our patients’ interest in low cost has to be balanced with their receiving the latest and best care for their condition. The development and application of new drugs, treatments and devices is complex and costly, and requires the involvement of physicians with industry partners. This area is also addressed by laws such as the Anti-Kickback Statute, and detailed codes of ethics have been adopted by the pharmaceutical industry (PhRMA) and technology providers (AdvaMed). These codes allow physician-industry relationships for legitimate training, research, collaboration and consultation agreements. Adherence to these guidelines generally mitigates this conflict, as the relationships between industry and physicians are aboveboard and appropriate.

In the early days of managed care, considerable attention was devoted to denying patients care and limiting testing or treatment in return for incentives from the insurer. These problems continue, although now the denial often comes directly from the insuring entity based on their internal review, rather than the treating physician. Newer developments such as Pay-for-Performance and other proposed “quality improvement” initiatives may have unforeseen implications for our interactions with our patients. Once again, mitigation of this conflict requires that physicians make objective decisions about appropriate medical care for their patients, and utilize practice guidelines from professional organizations to support their choices.

Non-financial patient-related conflicts of interest, such as those involving biomedical research, are less common. Legitimate research is currently conducted under the auspices of an Institutional Review Board specifically designed to protect the potential research subject. These boards mitigate this conflict by providing independent assessment of the researchers’ activities. A more subtle conflict could arise if a physician was utilizing an off-label treatment in what could amount to an unauthorized trial, especially if the physician intended to ultimately publish the results of that impromptu investigation. Analysis of our motives in utilizing off-label treatments and open disclosure and conduct of potential research activities is the solution.

A combination of self-reflection and oversight will ensure that we are aware of and effectively manage potential conflicts. These practices not only benefit our patients, but also result in relationships that allow us to provide the most appropriate and best quality care. CNSQ
Join us in San Diego, California, as the Congress of Neurological Surgeons advances neurosurgery with our most influential Annual Meeting yet. The scientific program at the 2007 CNS Annual Meeting is designed to help you navigate the dynamic field of neurosurgery and incorporate the latest technological breakthroughs into your practice.

3-D Live Cadaveric Demonstrations at the 2007 CNS Annual Meeting!

Operative Techniques with the Masters.
Tuesday, September 18
2:00-5:30 PM
Faculty: Jacques Brotchi, Arthur L. Day, Evandro de Oliveira, Ossama Al-Mefty, Albert L. Rhoton, Jr., Robert F. Spetzler

Don’t miss this opportunity to watch neurosurgical masters demonstrate six microsurgical principals live from our GSS stage! This innovative session features cadaveric demonstrations using state-of-the-art, 3-dimensional imaging technology, followed by cutting-edge videos. Open to all registered medical attendees.

Meeting Highlights
• Interactive Neurosurgical Forum and Select Abstracts Session.
• Enhanced Digital Poster Format.
• New Interactive Case Presentations Session.

NEW! Integrated Medical Learning™ (IML) – New learning process, with opportunities for pre-and post-meeting feedback on the scientific content.
Sponsored fellowship awards represent a strategic investment by the Congress of Neurological Surgeons on behalf of the field of Neurosurgery. The CNS offers several fellowship awards for residents, neurosurgeons who have recently completed training, and established neurosurgeons alike. The awards are meant to defer some of the costs fellows incur during their research and studies and to enhance the education of neurological surgeons at all stages of their careers. For the 2007 grants cycle, we received a total of 68 completed applications for the CNS fellowship awards, which is a larger number than ever before!

In order to provide earlier notification to award recipients, we have moved the new deadline for the CNS fellowship applications to November 1, 2007. The CNS Fellowships Committee will review these applications in December, and announcements of award recipients for the 2008-09 academic year will be made in early January 2008. Applicants must complete the on-line standardized CNS Fellowship Application, which can be found at: http://www.neurosurgeon.org/education/fellowship.asp.

Congratulations to CNS Fellowship Award Recipients!

Twelve young neurosurgeons will share in the nearly quarter of a million dollars of fellowship award monies disbursed this coming year by the CNS.

The CNS Penfield Fellowship provides $40,000 in financial assistance to residents and trained neurosurgeons to help pursue training in clinical or translational research. This year’s
awardee is Rahul Jandial, M.D. Dr. Jandial is in the Division of Neurological Surgery at the University of California, San Diego (UCSD). He received his B.A. in Molecular Cell Biology from UC Berkeley and his M.D. from the University of Southern California (USC). For the CNS Penfield Fellowship, he will be working with Dr. Evan Snyder at the Burnham Institute on a project investigating the stem cell lineage of central nervous system neoplasia.

The CNS Cushing Clinical Fellowship provides up to $25,000 to residents and recent graduates to help facilitate the acquisition of clinical skills and knowledge. This year’s CNS Cushing Fellow is Vaninder Chhabra, M.D., a PGY-5 resident at Emory University Hospital. He received his B.S. in Neuroscience from UCLA and his M.D. from the University of California, San Diego. He will be working with Dr. Nelson Oyesiku at Emory University on a translational research project investigating the natural history and molecular profiles for clinically aggressive pituitary adenomas.

The CNS Dandy Clinical Fellowship provides $25,000 to residents and recent graduates to help facilitate the acquisition of formal training in clinical or translational research. This year’s CNS Dandy Fellow is Isaac Yang, M.D., who is a resident in the UCSF Department of Neurological Surgery. He received his undergraduate degree at UC Berkeley, where he majored in Molecular and Cell Neurobiology, and earned his M.D. from UCLA. Currently, as a neurosurgery resident in the lab of Andrew Parsa M.D., Ph.D., he plans to test the hypothesis that immune status can predict clinical behavior in high-grade gliomas.

The CNS Basic/Translational Research Fellowships are a new set of awards that are meant to assist neurosurgery residents and young faculty in obtaining formal training and laboratory experience in basic science or translational neurosurgical research. This year, three awards, providing up to $10,000 each, were awarded. The recipients are: Dr. James B. Elder, Dr. Daniel Orringer, and Dr. Ben Waldau. James B. Elder, M.D. attended the Massachusetts Institute of Technology (MIT), where he majored in Chemical Engineering. He pursued his medical education at Columbia University and his neurosurgery residency at the University of Southern California (USC). During the fellowship year, he will perform research in the Department of Chemical Engineering at California Institute of Technology under the direction of Charles Y. Liu, M.D., Ph.D., and David A. Tirrel, Ph.D. Daniel Orringer, M.D. graduated from Cornell University and from Ohio State University College of Medicine. He is currently a PGY-4 resident in neurosurgery at the University of Michigan. For the CNS Basic/Translational Research fellowship period, he plans to apply nanotechnology to enhance the precision of brain tumor surgery. He has created collaborations between experts in nanotechnology and neurosurgery at the University of Michigan with the ultimate goal of developing nanodevices designed to delineate tumor margins in the operating room. Ben Waldau, M.D. graduated from medical school in Heidelberg, Germany, receiving a magna cum laude for his medical dissertation on molecular genome analysis at the German Cancer Research Institute. Dr. Waldau is currently a fourth-year resident in neurosurgery at Duke University and has a strong interest in neural regeneration/enhancement. He will use the CNS Basic Science/Translational Research award to study brain-machine interfaces in monkeys and humans.

The new CNS/MGI Pharma Tumor Fellowship, provided through...
Congratulations!

the generosity of MGI Pharma, provides $10,000 for research on the topic of brain tumors. This year’s awardee is Sunit Das, M.D. Dr. Das has a B.A. in English Literature from the University of Michigan and a M.A. in Philosophy from Harvard University. He then completed his medical school degree at Northwestern University, followed by a doctoral program in Neurobiology at the NIH. Currently a resident at Northwestern University, Dr. Das will use the CNS/MGI Pharma Tumor Fellowship to study the molecular processes involved in the transformation of neural stem cells into glial tumors in the lab of Dr. John Kessler.

Two CNS/American Syringomyelia Alliance Project (ASAP) Fellowships, provided through the generosity of ASAP, were awarded this year. Each of these awards provide up to $10,000 for clinical or basic science research on the topic of syringomyelia and Chiari malformedations. This year’s awardee of the CNS/ASAP Monkton Institute Fellowship is Matthew McGirt, M.D. Dr. McGirt obtained his B.S. and his M.D. degrees from Duke University. He is currently a fifth year resident in neurosurgery with the Department of Neurological Surgery at Johns Hopkins Hospital. Under the mentorship of Dr. Benjamin Carson and Dr. George Jallo, his fellowship project proposes to determine the pattern or degree of CSF flow abnormality at the hindbrain or cervical spinal cord via cMR imaging. The CNS/ASAP Mikula Fellowship was awarded to Sandi Lam, M.D. Dr. Lam is currently a Neurosurgery resident at University of California Los Angeles (UCLA). She graduated from Northwestern University Medical School and joined the Orthopedic Surgery residency program prior to pursuing training in Neurosurgery. Under the mentorship of Dr. Ulrich Batzdorf and Dr. Marvin Bergsneider, she will investigate the relationship between intracranial vasomotor instability and MRI CSF flow dynamics with continued symptomatology.

The CNS/Elekta Fellowship in Radiosurgery, provided through the generosity of Elekta, funds a fellowship to help neurosurgery residents or recent graduates acquire additional clinical/research training in stereotactic radiosurgery. This year’s recipient is John Shin, M.D. from the University of Illinois at Chicago. Dr. Shin is a graduate of Brown University with a B.A. in Biology. He received his M.D. from Chicago Medical School. During his CNS fellowship, with the guidance of Dr. G. Michael Lemole, Jr. and Dr. Konstantin Slavin, Dr. Shin plans to study the hemodynamic changes within AVMs following stereotactic radiosurgery using a quantitative MRA model.

The CNS/DePuy Spine Fellowship in Spinal Neurosurgery is provided through the generosity of DePuy Spine, and funds a one-year $50,000 fellowship. This award is meant to assist neurosurgeons in the acquisition of new clinical skills in the field of spinal neurosurgery. This year’s CNS/DePuy Spine Fellow is Patrick Hsieh, M.D. Dr. Hsieh received both his B.S. and M.S. in Biochemistry from UCLA. He then completed his medical education at the University of Southern California (USC), followed by neurosurgery residency at Northwestern University. Dr. Hsieh plans to continue his education in spinal oncology and complex spinal reconstruction with Dr. Ziya Gokaslan with the assistance of the CNS/DePuy Fellowship. He will train with Dr. Ziya Gokaslan at Johns Hopkins University.

The CNS/Synthes Spine Fellowship in Spinal Neurosurgery is provided through a generous grant from Synthes Spine, and funds a one-year $50,000 fellowship in clinical research related to the field of spinal neurosurgery. This year’s CNS/Synthes Spine Fellow is Ilya Laufer, M.D. Dr. Laufer completed undergraduate studies in Neuroscience at Columbia. After graduating from SUNY School of Medicine, he started his neurosurgical training at the New York-Presbyterian Hospital/Weill-Cornell Medical College, where he is currently beginning his fourth year of residency. During the upcoming year, Dr. Laufer plans to complete a Master’s Program in Clinical Research Methods at the Columbia University School of Public Health. He will use the skills acquired in the classroom to conduct clinical research projects on the role of bone metabolism in spinal surgery. CNSQ

Congratulations!
The 4th Annual Neurosurgery Charity Softball Tournament (www.KidsBrainResearch.org) was played on June 9th at the Great Lawn of Central Park in New York City. The event was hosted by Columbia University and sponsored by George Steinbrenner and The New York Yankees, with all proceeds benefiting pediatric brain tumor research. This year’s competing teams included the Departments of Neurosurgery from twelve of the nation’s top medical centers — Columbia, Emory, Harvard, Duke, Yale, Thomas Jefferson, Johns Hopkins, Cornell, NYU, University of Pennsylvania, Albert Einstein, and Mt. Sinai. The University of Pennsylvania came from behind to repeat as champions by scoring 4 runs in the bottom of the last inning to defeat Columbia 9-8 in the Finals. Mt. Sinai once again put on a strong showing to finish in third place. The championship trophy, named “The J. Lawrence Pool Memorial Trophy” in honor of the former Columbia chairman, will be housed at The University of Pennsylvania for another year.

The Annual Neurosurgery Charity Softball Tournament has become a tradition among eastern neurosurgery programs and is rapidly evolving into a national competition. Supported by Mayor Michael Bloomberg, this date has been declared “Neurosurgery Charity Softball Tournament Day” in the city of New York. The first two championships were claimed by Columbia University in 2004 and 2005, while The University of Pennsylvania repeated their title runs in 2006 and 2007. These programs have met in the finals each of the past two years, sparking an intense rivalry.

This charity event has already raised well over $100,000 for Pediatric Brain Tumor Research. The goal of this fund is to eventually support a competitive postdoctoral research fellowship in pediatric neuro-oncology, with applications open to all neurosurgery programs. The planning has already begun for the games to continue next year on June 7, 2008 at the 5th Annual Neurosurgery Charity Softball Tournament, with an expanded field to include 16 teams from across the country. CNSQ
This 23-year-old male was taken to the Emergency Department after being thrown from his motorcycle at a high rate of speed. He had weakness in his legs and decreased sensation in his left leg. A reformatted CT scan of the lumbar spine (shown above) illustrates a complete fracture of the spinal column at L1-2.

Axial CT scan of L1 and L2 vertebra, note the fractured posterior elements of L2 providing expansion of the canal (Images courtesy of James Harrop; Philadelphia, PA).

We would like to invite you to submit interesting images for consideration for the back page of CNSQ. Please contact Editor Ali R. Rezai, MD at info@1cns.org with all submissions.
Introducing Your Newest Way to Experience Neurosurgery

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- Alfredo Quiñones-Hinojosa, M.D.