Commenter: Cowley, Michael J., MD, FSCAI, FACC, Jaff, Michael R., DO, FACC Wolk, Michael J., MD, FACC
Organization: The American College of Cardiology Date: September 9, 2004 Comment:

The American College of Cardiology (ACC) is a 31,000 member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The Society for Cardiovascular Angiography and Interventions (SCAI) is the primary professional association representing 3,200 invasive and interventional cardiologists nationwide. SCAI promotes excellence in cardiac catheterization and angiography through physician education and representation, clinical guidelines and quality assurance to enhance patient care.

The Society for Vascular Medicine and Biology (SVMB), established in 1989, is a professional medical society dedicated to advancements in research, education, and public awareness regarding vascular diseases. Members are specialists in vascular medicine, surgery, cardiology, and radiology.

The ACC, SCAI and SVMB appreciate the opportunity to provide comments on the Draft Decision Memo for Carotid Artery Stenting in Post-Approval Studies (CAG-00259N).

CMS has announced its draft decision that the evidence is adequate to conclude that percutaneous transluminal angioplasty (PTA) with carotid stent placement is reasonable and necessary when performed consistent with Food and Drug Administration (FDA) approval of the carotid stent device and in a FDA required post-approval study.

Our organizations support CMS' intent to extend coverage beyond Category B IDE clinical trials to include coverage of carotid artery stenting performed under the auspices of an FDA designated post approval study.

Extension of this coverage after the clinical trials have ended is extremely important while the request to provide coverage of carotid stenting for patients at high risk for carotid endarterectomy is under consideration. This will allow beneficiaries an alternative to carotid endarterectomy and will enable physicians to enhance their performance and training of this procedure.

We appreciate the ability to comment on this important decision. As we have indicated in our prior letters on this coverage consideration, the ACC, SCAI and SVMB strongly support the reversal of the national noncoverage policy. We believe the SAPPHIRE and ARCHER trials have demonstrated that carotid stenting can provide safe efficacious revascularization, resulting in meaningful clinical benefit to patients at high risk for carotid endarterectomy.

Commenter: Keus, Peggy Turner, Kristen
Organization: St. Luke's Episcopal Hospital Date:
September 30, 2004 Comment:

Over 350 IRB approved high-risk carotid stent procedures have been performed at St. Luke's Episcopal Hospital in Houston, Texas. We are pleased CMS recognizes the importance of providing new FDA approved technologies to Medicare beneficiaries. Furthermore, we support the decision to provide coverage of percutanueous transluminal angioplasty with carotid stent placement in a FDA-required post approval study.

We request that CMS consider assigning all carotid stent patients to DRG 533 (Extracranial Vascular Procedures with CC) on an interim basis. All patients undergoing carotid stent placement are high-risk patients. In addition, we request CMS review all available data so that future reimbursement determinations will provide for adequate coverage.

We appreciate the opportunity to provide a comment on this decision.

Commenter: Sicard,Gregorio, M.D., Zwolak, Robert, M.D.
Organization: Society for Vascular Surgery Date:
September 24, 2004 Comment:

The Society for Vascular Surgery (SVS) represents 2,300 vascular specialists in the United States. Our society has 40-years experience in the evaluation and treatment of extracranial cerebrovascular disease. SVS members have participated in all major carotid endarterectomy and carotid stent trials performed in the U.S. and Canada. Importantly, SVS represents the only specialty society with a substantial proportion of members who are *expert's at all three treatment options,* open carotid endarterectomy, carotid stenting, and medical therapy. This provides SVS a uniquely objective perspective to address the coverage issue. SVS offers the following comments regarding the Draft Decision Memo for Carotid Artery Stenting in Post-Approval Studies (CAG-00259N), dated September 1, 2004).

SVS supports the CMS decision that carotid stent placement is reasonable and necessary for patients at high-risk for carotid endarterectomy, restricted at the present time to cover 1) patients enrolled in FDA mandated post-approval studies that match the entry criteria for approved PMA patients, 2) FDA approved IDE trials addressing relevant scientific issues related to this technology and 3) other FDA approved commercial studies that address the normal risk patient population. We feel that until much more data are collected the coverage should be very narrow and specific for audited studies. Coverage of patient groups that we feel are not supported by data are listed in our letter of July 18, 2004 (copy enclosed). We have great concerns that without strict controls, the release will be extensive and the devices will be widely used without reporting of data to provide the foundation for evidence-based determination of further indications. We feel that the only recourse to provide appropriate patient protection is limited coverage by CMS with enforcement of appropriate utilization by all available means.

Specifically, SVS supports mandatory outcomes reporting for all carotid stents placed during the next several years in order to allow objective and accurate outcomes data analysis.

SVS agrees that post-approval studies are crucial for the ongoing assessment of this promising new technology to determine which subsets of patients with extracranial cerebrovascular disease will benefit from carotid stenting vs. carotid endarterectomy vs. medical therapy. Indeed, our greatest worry is that without appropriate continued focus on patient selection and provider training, the rollout of carotid stenting may result in excessive morbidity and mortality. We have a brand new treatment option at our fingertips that will help reduce the 700,000 new and recurrent strokes in the U.S. each year if employed correctly and thanks to recent evolution of the evaluative sciences we have the means to measure risk-adjusted outcomes. We strongly urge CMS to maintain an active role in mandating data generation and analysis in order to help determine which beneficiaries should be considered candidates for carotid stenting.

SVS supports the concept that post-approval studies should be performed in the practices of physicians at both academic and private hospitals and we agree with performing these in centers where there will be high, medium and low annual carotid stent implant volumes. Results will help address the "high-volume" question that pervades the medical and surgical literature today.

SVS sees a huge gap in the post-approval studies as currently described in that they exclude further comparison with carotid endarterectomy (CEA). CEA is the gold standard, yet to date we have few randomized controlled trials in high-risk patients (e.g. SAPPHIRE) to help distinguish best therapy. The SAPPHIRE patient cohort represents a blend of symptomatic and asymptomatic patients and it is therefore impossible to interpret the CEA results in light of other published CEA literature. ARCHER was performed using historical CEA results and therefore is subject to the attendant criticism. Many questions persist that deserve concurrent evaluation with CEA. For instance, the CREST lead-in data demonstrate a high peri-procedural stroke risk for octogenarians undergoing carotid stenting. Age over 80 is now an exclusion criterion for CREST, yet age over 80 constitutes an *inclusion* criterion for high-risk patients based on studies underlying the FDA-approved device. Medicate beneficiaries deserve the benefit of further comparisons of stenting to CEA in order to resolve this type of dilemma. We strongly urge CMS and FDA to pursue this issue to the fullest possible extent.

SVS agrees with CMS regarding the importance of post approval data sharing. The upcoming study results should be disseminated to providers and practitioners to allow evolution of best practices. We understand that CMS cannot set forth precise standards for data sharing during the post-approval studies, but we encourage FDA-CMS-Specialty Society collaboration in ensuring that all possible results reach practitioners. For outcomes data generated *after* the FDA-mandated initial groups, we see no reason why HIPAA-compliant full data analysis cannot be published.

SVS emphasizes that one-year follow-up is insufficient to determine the true long-term results of carotid stenting in comparison to carotid endarterectomy. CEA is known to be an extremely durable procedure over time periods extending to a decade. We support the CMS comments in CAG-00259N regarding the need for long-term safety and efficacy data and we strongly urge CMS to pursue all opportunities to help provide this information. Again, comparison to historical controls is inadequate. Best practices will only be determined by concurrent procedures and prospective data collection.

SVS also needs to reiterate that the post-approval trials should include only "high-risk" patients consistent with the patients treated during the PMA studies and that payment should be audited to assure conformity with the approved indications. It is our opinion that the bar for some of the "high-risk" criteria in pre-approval studies was set quite low. We would hate to see "normal-risk" patients misrepresented as "high risk" by carotid stenting enthusiasts. Despite current enthusiasum for carotid stenting, we need results of CREST and other normal-risk patient studies before determining appropriateness of expanded indications.

SVS strongly recommends a widely based, mandatory CMS carotid stenting registry over the next several years, after the FDA-mandated studies, to determine the real-world results of stenting vs. CEA. We recommend the same automated HIPAA-compliant system used by SVS/Lifeline that has worked extremely well for longterm follow-up of endovascular abdominal aortic aneurysm repairs over the past five years. This proven system already has data forms constructed for carotid stenting and is up and ready for implementation. Finally, SVS encourages CMS to mandate thorough and rigorous training for potential carotid stent practitioners. We stated our position at the August 17, 2004 Town Hall meeting, but to reiterate, we believe individuals must be fully trained in peripheral intervention, undergo a thorough didactic educational program, observe a substantial number of stent placements and be proctored for their initial cases. We believe performing 100 diagnostic cerebral angiographies is an inappropriate requirement in an age when cerebral angiography performed purely as a diagnostic test, has fewer and fewer indications. Nevertheless, we recommend a physician have performed at least 25 proctored carotid stents, half as primary operator, before being credentialed for this technology.

Carotid stenting is an exciting new treatment modality that will reduce the incidence of stroke. We urge careful and conservative reconsideration of the current non-coverage policy and we remain entirely

willing to meet with members of the Agency at any time should you believe our expertise in cerebrovascular disease may be helpful. We appreciate the opportunity to submit comments.

Commenter: Bicha, Anne Marie
Organization: American College of Cardiology Date: February 3, 2004 Comment:

The undersigned medical, surgical and radiologic specialty societies, representing over 50,000 physicians in the United States, offer the following comments regarding reconsideration of the Medicare National Coverage Policy for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting (CAG-00085A, dated March 19, 2001). We acknowledge that the 2001 policy contains a thorough timeline of medical scientific and regulatory events plus an in-depth analysis of the data available at that time, and we agree with the appropriateness of subsequent coverage limited to devices placed in clinical trials receiving Category B IDE designation from the FDA.

At this time, however, our societies believe that data collected over the last three years under auspices of the SAPPHIRE and CREST trials provide sufficiently convincing safety and efficacy information on carotid angioplasty and stenting to allow expansion of coverage to the Medicare beneficiaries considered to be at high-risk for carotid endarterectomy.

We know that CMS will undertake a major review of all available scientific data prior to any decision that would expand the current coverage policy, so only a brief summary of the information that was most convincing to us will be provided herein.

The SAPPHIRE trial recently presented one-year follow-up data on 310 "per protocol" high-risk patients randomized to carotid endarterectomy (CEA) or carotid stenting with cerebral protection (Stent). In SAPPHIRE, the definition of "high-risk" was based on anatomic factors that increase risk due to surgical considerations, and physiologic factors that increase the likelihood of postoperative cardiopulmonary complications. Examples of the former include radiation therapy to the neck or previous CEA with recurrent stenosis, while examples of the latter include advanced congestive heart failure or a recent myocardial infarction. At one-year follow-up, there were no major ipsilateral strokes in the Stent group and 5 major ipsilateral strokes in the CEA group (3.3%, P=0.03). At one-year, a total of 9 strokes (major plus minor, ipsilateral and contralateral) had occurred in the Stent group (5.7%), while 11 strokes (7.3%) occurred in the CEA group (P=0.65). There were 4 MIs (2.5%) in the Stent group and 12 (7.9%) in the CEA group (P=0.04). Finally, at one year there were 11 deaths (6.9%) in the Stent group, and 19 (12.6%) in the CEA group, a statistically similar incidence (P=0.12). Many of these deaths at one-year, however, were unrelated to the carotid treatment, such that the cumulative major adverse event rate excluding non-neurological deaths occurring after 30-days was 5.7% in the Stent group and 12.6% in the CEA group (P<0.05). Although many questions regarding carotid stenting remain to be answered, we believe these data support the SAPPHIRE investigators hypothesis of "non-inferiority" of stenting compared to CEA in this high-risk cohort.

The CREST Lead-In data has also been presented recently. This multicenter NINDS, NIH sponsored trial is designed to compare efficacy of CEA to carotid stenting in all symptomatic patients. The lead-in data for interventionalists was obtained from symptomatic patients with >50% stenosis and asymptomatic patients with >70% stenosis. Stroke, MI, death and other adverse events within 30 days of stenting were ascertained by an independent clinical events committee. As of April 30, 2003, 57 interventionalists from 41 sites had implanted stents in 465 patients. Combined 30-day stroke/death rate for all patients was 3.4% (95% CI: 1.7, 5.0). MIs occurred in only 4 patients (<1%). For symptomatic patients, the 30-day stroke/death rate was 5.6% while the analogous incidence in asymptomatic patients was 2.4%. Although no prospective randomized comparison of Stent to CEA is available yet from CREST, these 30-day stroke/death rates for carotid stenting are remarkably similar to published values from the large prospective NASCET and ACAS CEA trials.

Based on this evidence, our societies now believe it is appropriate to expand coverage for carotid artery stenting to certain "high-risk" patients. As data continue to accrue, and while the technology of carotid

stenting and cerebral protection devices, as well as the skill of those performing this therapy, continues to evolve, we believe that a most challenging task will be defining "high-risk". This decision is crucial since withholding stent treatment from those who would benefit is as undesirable as allowing it for subsets in whom equivalence to CEA has not yet been shown. We also acknowledge that this is a moving playing-field, a decision that will need reconsideration several more times in future years.

Our societies have examined the available SAPPHIRE data and suggest that the inclusion criteria from that study may be parsed into two groups. The first of those includes anatomic criteria that have been established in large studies to increase surgical risk. For these we suggest immediate expansion of Medicare coverage to include carotid artery angioplasty with stenting. The indications include symptomatic carotid stenosis >50% in patients with: " contralateral carotid occlusion " contralateral laryngeal nerve palsy " radiation therapy to neck " previous CEA with recurrent stenosis

For the remaining inclusion criteria in SAPPHIRE, we believe that another layer of consideration should be added to the decision-making process to reflect local surgical expertise. In the following patient subsets we believe the degree of risk from CEA faced by the patient is significantly influenced by the outcomes of the surgery / anesthesiology team performing the operation, and that will impact which patients should be offered carotid stenting. We believe it will be important for the interventionalists to collaborate with surgeons who perform carotid endarterectomy at their center to reach agreement on high-risk. If there is concurrence that a particular patient, or patient subset, would be considered "high-risk" for CEA in the hands of the team providing that service, then carotid stenting should be offered as an alternative. As local carotid stenting outcomes data accrue at individual centers we recommend objective review by local peer review processes as a means of certifying the clinical benefit derived from these procedures.

Taken from the SAPPHIRE inclusion criteria set, we suggest the following patients would require a collaborative decision making process including multiple physicians and a surgeon who performs carotid endarterectomy to establish risk level for CEA prior to offering carotid stenting. These would include symptomatic patients with carotid stenosis >50% plus: " severe pulmonary disease (FEV1 <30%) " high cervical ICA lesions or CCA lesions below the clavicle " severe tandem lesions " age greater than 80 years " congestive heart failure (class III/IV) and/or known severe LVEF<30% " open heart surgery needed within six weeks " recent MI (>24 hours and <4 weeks) " unstable angina (CCS class III/IV)

Since potential carotid stent patients will be undergoing arteriography, for purposes of inclusion under this coverage policy, we recommend that the final determination of 50% or greater stenosis must be calculated from the angiographic images using the methodology defined in NASCET.

We do not believe that coverage of "high risk" patients will adversely impact completion of the CREST trial, which will provide invaluable data about treatment of "normal risk" patients with stenting vs. carotid endarterectomy.

The undersigned societies realize the magnitude of the decision facing CMS regarding expansion of the carotid angioplasty and stenting coverage policy, and we offer our services in whatever means possible. We hope the coverage algorithm offered above will be found acceptable because we believe it offers each patient the optimal choice of treatments, based on a combination of national prospective study data, and the experience and outcomes of interventionalists and surgeons at the patient's chosen medical center. Our societies represent physicians with the greatest surgical and interventional skills available in the United States, and our foremost goal is to provide the best coverage policy for Medicare beneficiaries. We emphasize that this decision will require reconsideration as more scientific data becomes available, and finally, we thank you for the opportunity to comment.

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October 1, 2004

Joseph Chin, MD, MS,
Medical Officer, Division of Medical and Surgical Services
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Draft Decision Memo for Carotid Artery Stenting in Post-Approval Studies (CAG-00259N)

Dear Dr. Chin,

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing organized neurosurgery in the United States, appreciate the opportunity to comment on the above referenced draft coverage decision memo.

While we are pleased to see that the Centers for Medicare and Medicaid Services (CMS) has recognized "the importance of carotid artery stenosis as a risk factor for stroke and the importance of making available new FDA approved technologies to Medicare beneficiaries," we are nevertheless concerned with the scope of the proposed coverage decision and urge you to revise your coverage memorandum per our recommendations below. The AANS and CNS, along with seven other national medical specialty societies, previously outlined these proposed criteria in a letter to Sean Tunis, MD, on February 3, 2004 (see attached letter), and we believe that notwithstanding the recent FDA decision, nothing has changed to merit expanding the scope of Medicare coverage for carotid stenting to asymptomatic patients, as your proposal would do.

Food and Drug Administration Action

As the draft CMS memo states, the Food and Drug Administration has approved the premarket application (PMA) for one company's carotid stent system with a requirement that it conduct a post-approval study. The approval is limited for the treatment of patients at high-risk of adverse events from carotid endarterectomy and is subject to two additional criteria:

- Patients with neurological symptoms and ≥50% stenosis of the common or internal carotid artery ***by ultrasound*** or angiogram ***OR patients without neurological symptoms and ≥80% stenosis of the common or internal carotid artery by ultrasound or angiogram*** (emphasis added), AND

- Patients must have a reference vessel diameter within the range of 3.6 mm and 9.1 mm at the target lesion.

The FDA has agreed with the sponsor's proposal to conduct a multicenter post-approval study in the practices of physicians at both academic and private hospitals, who will have a mixture of high, medium and low annual carotid stent implant volumes. The post-approval study will gather data on patient outcomes including stroke and rare adverse events.

CMS Proposed Coverage Criteria

CMS coverage regulations make a distinction between the criteria necessary for FDA approval of a device versus Medicare's criteria for coverage. The FDA determines if a product is safe and effective, while CMS must determine if the product is reasonable and necessary for the diagnosis and treatment of illness or injury. These determinations involve two different sets of standards, and FDA approval and/or clearance alone does not automatically entitle a device to coverage.

CMS has determined that percutaneous transluminal angioplasty (PTA) with carotid stent placement is reasonable and necessary when performed consistent with FDA approval of the carotid stent device and in a FDA required post-approval study. In reaching this conclusion, CMS acknowledges that this is a promising new treatment for carotid artery stenosis, but that it also has considerable patient risks. Furthermore, CMS notes that additional data needs to be collected to ascertain which patients are most appropriate for carotid artery stenting.

Ischemic stroke is a major cause of death and disability to Medicare beneficiaries. Carotid endarterectomy has been conclusively demonstrated to be a safe and effective treatment for the prevention of stroke in both symptomatic and asymptomatic patients suffering from carotid stenosis. Any proposed new treatment for stroke prevention in this patient population should be measured against this well proven treatment. However, as with any medical treatment, carotid endarterectomy is not without risk. Certain anatomic considerations or medical comorbidities may place some patients at a higher risk from endarterectomy lessening the overall benefit form this procedure. The FDA in its approval of a PMA for a carotid stent device, considered evidence that showed the *noninferiority* of carotid stenting compared to endarterectomy in patients that were considered high risk for surgical intervention.

Clearly, if Medicare reimburses hospitals and physicians for this procedure, it will enhance our ability to provide a new and valuable medical treatment for our Nation's elderly patients who are not candidates for carotid endarterectomy, but are at considerable risk of suffering a stroke. It will also expand our ability to collect patient outcomes data to better determine which patients will best benefit from this procedure. At present, however, there are insufficient data to support Medicare coverage for those patients who are asymptomatic. In fact, the available data would suggest that carotid angioplasty and stenting may be inferior to medical treatment for the prevention of stroke in asymptomatic patients.

The AANS and CNS therefore believe that CMS should not completely adopt the FDA's criteria as the basis of the proposed coverage decision, as we believe:

1. **That carotid stenting for asymptomatic patients is not yet proven to be "reasonable and necessary" and coverage should be limited to symptomatic "high-risk" patients (as defined below).**
2. **That ultrasound alone is not acceptable for defining the degree of stenosis necessary to consider treatment of symptomatic "high risk" patients (as defined below).**

AANS and CNS Recommended Coverage Criteria

As noted above, nine national medical specialty societies, representing all physicians who treat carotid artery disease, previously proposed detailed criteria for Medicare coverage of carotid stenting. Based on the evidence gathered through the SAPPHIRE and CREST trials (comparing the efficacy of carotid endarterectomy – CEA – to carotid stenting), the medical societies informed CMS that "it is appropriate to expand coverage for carotid artery stenting to certain "high-risk" patients." In our letter, we noted that:

> As data continue to accrue, and while the technology of carotid stenting and cerebral protection devices, as well as the skill of those performing this therapy, continues to evolve, we believe that a most challenging task will be defining "high-risk". This decision is crucial since withholding stent treatment from those who would benefit is as undesirable as allowing it for subsets in whom equivalence to CEA has not yet been shown.

We went on to recommend that Medicare coverage policy should be based on the inclusion criteria from the SAPPHIRE trial, to wit:

> Our societies have examined the available SAPPHIRE data and suggest that the inclusion criteria from that study may be parsed into two groups. The first of those includes anatomic criteria that have been established in large studies to increase surgical risk. For these we suggest immediate expansion of Medicare coverage to include carotid artery angioplasty with stenting. The indications include symptomatic carotid stenosis >50% in patients with:
>
> " contralateral carotid occlusion
> " contralateral laryngeal nerve palsy
> " radiation therapy to neck
> " previous CEA with recurrent stenosis
>
> For the remaining inclusion criteria in SAPPHIRE, we believe that another layer of consideration should be added to the decision-making process to reflect local surgical expertise. In the following patient subsets we believe the degree of risk from CEA faced by the patient is significantly influenced by the outcomes of the surgery/anesthesiology team performing the operation, and that will impact which patients should be offered carotid stenting. We believe it will be important for the interventionalists to collaborate with surgeons who perform carotid endarterectomy at their center to reach agreement on high-risk. If there is concurrence that a particular patient, or patient subset, would be considered "high-risk" for CEA in the hands of the team providing that service, then carotid stenting should be offered as an alternative. As local carotid stenting outcomes data accrue at individual centers we recommend objective review by local peer review processes as a means of certifying the clinical benefit derived from these procedures.
>
> Taken from the SAPPHIRE inclusion criteria set, we suggest the following patients would require a collaborative decision making process including multiple physicians and a surgeon who performs carotid endarterectomy to establish risk level for CEA prior to offering carotid stenting. These would include symptomatic patients with carotid stenosis >50% plus:

- severe pulmonary disease (FEV1 <30%)
- high cervical ICA lesions or CCA lesions below the clavicle
- severe tandem lesions
- age greater than 80 years
- congestive heart failure (class III/IV) and/or known severe LVEF<30%
- open heart surgery needed within six weeks
- recent MI (>24 hours and <4 weeks)
- unstable angina (CCS class III/IV)

Since potential carotid stent patients will be undergoing arteriography, for purposes of inclusion under this coverage policy, we recommend that the final determination of 50% or greater stenosis must be calculated from the angiographic images using the methodology defined in NASCET.

The SAPPHIRE inclusion criteria did include asymptomatic patients with greater than 80% stenosis of the internal carotid artery. The SAPPHIRE data would suggest that carotid angioplasty and stenting is *not inferior to* endarterectomy in this subset of patients at high risk for a surgical procedure. However, the SAPPHIRE trial did not have a medical treatment arm and could not evaluate the safety or efficacy compared to medical treatment. In fact, if the major adverse event rates from the SAPPHIRE trial are extrapolated and compared to data from the major asymptomatic carotid surgery trials (Asymptomatic Carotid Atherosclerosis Study [ACAS]; Asymptomatic Carotid Surgery Trial [ACST]), no benefit can be demonstrated for carotid angioplasty and stenting beyond medical treatment in these patients.

The AANS and CNS believe that the above outlined criteria provide a more reasonable basis for Medicare's coverage policy for carotid stenting, and we urge you to adopt these limitations as opposed to the more expansive FDA guidelines.

Thank you for considering our recommendations. Please contact us if you have any questions or need additional information.

Sincerely,

Robert A. Ratcheson, MD, President
American Association of Neurological Surgeons

Vincent C. Traynelis, MD, President
Congress of Neurological Surgeons

Attachments:
February 3, 2004 Letter to Sean Tunis, MD

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