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MESSAGE FROM THE MEDICAL EDITOR

Spring Cleaning

“[We want to] make examples of a couple of doctors so that their colleagues see that this isn’t worth it. We want to send the message to the physician community—particularly surgeons—that you can’t [demand lucrative consulting arrangements in exchange for using a company’s products].”

Lewis Morris, JD, chief counsel of the Office of the Inspector General
of the US Department of Health and Human Services

“The recommendations are rigorous and would require many [professional medical associations] to transform their mode of operation and perhaps, to forgo valuable activities. To maintain integrity, sacrifice may be required...”

Rothman DJ, McDonald WJ, Berkowitz CD, et al in *JAMA*, April 1, 2009 (citation below)

“Whoever knows he is deep strives for clarity; whoever would like to appear deep to the crowd, strives for obscurity. For the crowd considers anything deep if only it cannot see to the bottom: the crowd is so timid and afraid of going in to the water.”

Friedrich Nietzsche, German philosopher and “Critic of Culture,” 1844-1900

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Here, in the Spring of 2009, the worldwide economy remains under siege and the government has decided to print more money. Taxpayer fury at bonuses for the failed executives at AIG is but one example of the near universal sense that a spring cleaning is needed across the board.

For spine care providers, spring cleaning means furthering disclosure and transparency efforts. Congress, various federal agencies, and increasingly the American public, are suspicious of the nature and extent of the relationships between physicians and “industry.” The news continues to carry reports of massive royalty payments, rich consulting agreements and a multitude of failures to fully disclose these relationships. In a widely publicized “whistleblower” suit, the plaintiffs alleged that, in 2006, 120 spine surgeons accepted more than \$8 million to promote the off-label use of Infuse, a prod-

uct from which Medtronic reaps blockbuster profits.

The whistle-blower case was dismissed, but shortly thereafter the news carried accounts of another disclosure flap. In this case, the *Journal of the American Medical Association (JAMA)* was accused of failure to diligently pursue unreported disclosures. Reportedly, the authors of a study published May 28, 2008 failed to report conflicts. A reader contacted the journal with evidence of undisclosed conflicts and an investigation ensued. Before that investigation was released, the same reader took the matter public implying that *JAMA* inadequately pursued disclosure issues.

More recently, in a March 3rd *New York Times* report, Lewis Morris, the Office of the Inspector General’s Chief Counsel, reported plans to pursue both civil and criminal charges against a number of surgeons. Allegedly, these surgeons sought quid pro quo deals with implant manufacturers. Profitable consulting

agreements were reportedly demanded to reward use of the company's products.

Clearly, matters of disclosure and ethics are in the public eye. On an organizational level, NASS has been "ahead of the curve" in establishing bold new policies that clearly delimit the extent and value of industry relations. The evolution and practical impact of these efforts are discussed in detail in this issue of *Spine-Line*. First, in his President's Message, Dr. Branch discusses the additional disclosure requirements and their rationale. Then, in her Ethics column, Dr. Eskay-Auerbach amplifies the technical aspects of NASS' new disclosure policy.

At the outset, it should be noted that these policies were hard-fought and long-considered. At the February board meeting, logistical issues surrounding disclosure continued for hours in both full board and small group settings. Critically, NASS's evolving policies seek to do more than simply report. NASS has paired these requirements with additional bodies meant to assist members, volunteers and presenters to manage, minimize or eliminate conflict. When serious misrepresentations or under-disclosure are discovered, sanctions may be imposed.

Both Drs. Branch and Eskay-Auerbach note that the NASS leadership has proposed the strictest level of conflict divestment for itself. Board members, key committee chairs and others will be required to divest themselves of consulting and other industry relationships during their term of office.

Are these steps truly needed? Are these efforts turning into a witch hunt? Sadly, inappropriate relationships and incentives have existed. That does not mean that all or even most physician-industry relationships are camouflaged forms of bribery. Unfortunately, outside intervention from the federal government behemoth is unlikely to understand the subtleties of these relationships.

Regulators and the public do not understand that physician-industry partnerships have produced a number of important advances in spine care. Many of these companies were founded by physi-

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cians to provide useful, but previously unavailable tools. When we have a relationship with industry, the patient needs to understand why. Whether we seek to teach new procedures to less experienced colleagues or to develop better tools or implants, it is the patient who should benefit from these endeavors. Certainly, compensation stimulates effort. Communism does not work because incentives are not commensurate with the time away from family that innovation and education require. Spine care professionals should be compensated for their time and effort. On the other hand, that compensation should be reasonable and should reflect actual work performed. Our patients must never sense that we have been "bought" by the implant industry.

Dr. Branch notes that NASS has responded to, and has increasingly tried to get ahead of, the intense scrutiny placed on our relationships and practices by Congress and federal agencies. These evolving policies attempt to anticipate future rules. By clearly stepping forward and addressing both real and perceived problems, NASS seeks to demonstrate good faith. These good faith efforts, we hope, will afford NASS the opportunity to partner with, rather than get pistol-whipped by, Congressional and federal regulators.

As Dr. Branch states, we do not know where these changes are headed and the NASS leadership cannot pretend to follow a "golden path." Yet, we recognize that improvement is needed. Sound ethics require that we police ourselves, as individuals and as an organization. These policies also make practical sense. Given the powerful forces demanding change, self-regulation is much more likely to preserve the beneficial aspects of industry partnerships while avoiding unhelpful

restrictions.

As we press ahead, we must set the agenda and not simply respond to perceived evils in our ranks. We have to remember why we are seeking to establish transparency and why we seek to address conflicts when they arise. Dr. Branch asks whether these policies represent: bowing to outside pressure, a benefit to our patients and our profession, or an exaggerated response (or too little action). As Dr. Eskay-Auerbach states, the key is to restore our patients' trust in us.

Restoration of trust requires transparent relationships and efforts to decrease bias. All relationships, including those with industry, the hospital, the payor and the patient, introduce bias.

So far, we have seen evolutionary steps in the disclosure process. As of the 2008 NASS annual meeting, a rough dollar value of a presenter's conflict was disclosed. While some participants felt uncomfortable talking about money, it seems clear that \$2,000 for teaching a course and \$400,000 in royalties for the device under discussion represent very different levels of potential conflict. Disclosure to our colleagues is important but, to achieve more complete disclosure, the public must come to understand the purpose of consulting arrangements with industry. The public is most leery of things they don't understand.

For example, few people understand how doctors learn new procedures. Cadaver courses are expensive and time intensive. As providers, we need to explain the time we spend away from our families and practices to teach and to learn.

In his column, Dr. Branch explains the technical aspects of disclosure to NASS. Direct access to disclosure information is available only to key personnel with

signed confidentiality agreements. The information is stored on a secure server and will not be available on the public web site. During NASS activities, dollar values are presented in ranges.

As Dr. Eskay-Auerbach notes in the Ethics column, simple disclosure is not enough. While bias and conflict cannot be completely eliminated, we must devise better methods to address and contain them. As we consider these issues, remember that industry relationships are not the only source of bias facing spine care providers. These relationships are not even the most important form of bias. The literature has repeatedly shown differences in care offered to patients of different races, ages, genders and socioeconomic strata. Some differences reflect legitimate variability in disease presentation. Patients perceived to be litigious may be subjected to invasive tests deferred in others.

Most frequently, practical barriers produce far greater inequities. Privately insured patients have many options not available to uninsured or Medicaid patients. For most doctors, the more service we provide, the better our pay. In some capitated systems, the opposite is true. Those most vehemently opposed to any ties to industry cite studies that suggest even a branded pen will influence physician decision-making. By that logic, the direct economic incentives of unnecessary procedures would represent overwhelmingly conflict. In striving for equitable health care access, it would be futile to focus solely on industry relationships.

Interestingly, Dr. Eskay-Auerbach notes the impact of new disclosure requirements on the Obama administration. The final impact of this intense vetting remains unknown. Certainly, prominent nominees have dropped out of the confirmation process. Others have removed themselves from consideration because of difficulties in eliminating these relationships. Will this result in a “cleaner” government or simply a less experienced government? Will organized medicine see a similar “brain drain”?

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bated on the national stage, an exaggerated focus on internal NASS procedures will not protect our patients or practices. Increasingly, cost containment measures will put access to specialty care at risk. In this issue's Advocacy column, Dr. Raj Rao and Nick Schilligo continue their discussion of the online tools NASS provides to enable the membership to interact with their legislators on both the local and national levels. To ensure a direct line to those most willing and able to help our cause, NASS tools include your representative's contact information and voting records. For those who did not watch “Schoolhouse Rock” as children, this column includes a primer on the legislative process from bill to law.

Over the next years, it will be increasingly important to understand the legislation facing Congress and how it affects spine care, your practice and your patients. With many changes in health care pending, combining forces to maintain access to quality, specialty care is a necessity. As they rightly point out, there is strength in numbers. We must use these tools to engage our partners, our office staff and our patients to contact their representatives.

As most of you know, the Obama administration has proposed a number of economic stimulus plans. These plans seek to fund projects that will not only stimulate economic activity in the short term, but also yield long term benefits. Amidst the bridge building and infrastructure projects are funds for comparative medical outcomes research. In their Research article, Drs. Watters and Mick introduce several of the projects that NASS plans to present as priorities for spine research to the Institutes of Medicine.

In this month's Coding column, David

O'Brien, Chairman of the NASS Medical Coding Committee, discusses codes for facet joint neurotomy procedures. Previously, *SpineLine* has covered the clinical controversies surrounding these procedures. How well do neurotomy procedures work? How long do they last? Will these procedures survive the looming cost/benefit analysis to which most spine care will be subjected?

In recent years, CMS has pursued cost savings by refusing to pay for “never” complications such as urinary tract infections. This issue of *SpineLine* addresses several important complications facing spine surgeons. In his Invited Review, Dr. Jeff Stambough provides an update on postoperative blindness. This complication, while rare, devastates the patient and their family. Postoperative sight loss has dramatic psychological impact on the physician and operating room team as well.

Most forms of postoperative blindness have limited treatment options and nearly a third of affected patients continue to lose vision postoperatively. While this complication cannot be completely eliminated, Dr. Stambough discusses risk factors such as smoking, hypertension and diabetes. Longer operations with higher levels of anticipated blood loss confer additional risk as do certain vasoactive medications.

Dr. Stambough also alludes to the medicolegal aspects of this complication and asks how far the surgeon must go in describing this risk to patients during the preoperative consent process. Do you specifically mention blindness as a potential complication to patients undergoing prone spine procedures? Are we scaring patients out of surgeries that could improve the quality of their lives? How do we discuss catastrophes that

have not affected our own practice lives? I had a mentor who argued vehemently that the statement “this surgery can kill you” should cover most bases. I suspect the plaintiff’s bar does not agree. Those readers with experience in these matters are requested to provide comments.

Certainly the risk of blindness should be discussed with high risk patients. While postoperative sight loss cannot entirely be prevented, care during positioning, avoiding ocular pressure and maintenance of neutral cervical alignment should be routine.

The Literature Review in this issue presents two interesting reports that address perioperative complications. The first addresses the controversy regarding implant retention in patients with subacute spine surgical site infections. As reviewed by Dr. Jeff Stambough, Emans and colleagues described three priorities in patients with difficult SSIs after spinal deformity surgery. The surgeon’s goals, in order, should be to:

1. maintain stability,
2. protect the neural elements, and
3. eradicate the infection.

Emans et al also distinguish acute, postoperative infections from late infections. Acute infections occur when the postoperative hematoma becomes colonized and then infected, often with skin flora or hospital borne organisms. Late infections occur years after the index surgery in the presence of a previously benign wound. In that setting, hematogenous seeding of the surgical site is suspected.

In the current paper, subacute infections included those months out from their index procedure. In this group, aggressive debridement, intravenous antibiotics and utilization of the wound VAC failed to eradicate the infections. Ultimately, implant removal was required. After implant removal, patients were followed closely. In the presence of deformity progression, additional surgeries could be considered after two to three years.

Biswas and Dr. Grauer discuss a randomized, prospective study of the impact of IV corticosteroids on postoperative

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airway patency after anterior cervical corpectomy. Emery and colleagues randomized 66 patients undergoing two- and three-level instrumented corpectomies for spondylotic myelopathy. Eleven patients required delayed extubation. The use of IV steroids did not statistically decrease this risk. Often, common clinical practices rest only on theoretical benefits and other, unrelated risks. Too little level I or II research addresses these practices. The variety of potentially beneficial and deleterious effects of high dose corticosteroid use is well documented. At least in terms of airway compromise prevention, however, it appears that routine use cannot be recommended.

This issue’s Curve/Countercurve patient encapsulates many of the risk issues from the preceding papers. Dr. Jeff Wang presents a 68-year-old myelopathic woman visiting from Japan. She had previously undergone an uninstrumented C5-6 ACDF. Now, she is seen to have increasing myelopathic symptoms including fine motor control problems in her hands and gait irregularities. The MRI demonstrates mild kyphosis with a well healed fusion at C5-6. On the other hand, there is some remaining stenosis at C5-6 along with myelomalacia.

The first discussant, Dr. Hugh Bassewitz, reviews the management options for this patient and ultimately argues for an anterior decompression using either discectomy or corpectomy procedures. Bassewitz presents his thought process and elaborates critical technical points, including the side of approach, decompression levels and reconstruction options.

Drs. Jon Kimball and Langston Holly argue for a posterior approach. The patient’s cervical kyphosis is at issue for all of the discussants. As Holly and Kimball note, many spine surgeons reflexively recommend anterior approaches in patients with neutral and, particularly, kyphotic alignment. The authors then outline their approach arguing that, in the absence of a major anterior compressive lesion, a posterior approach allows for indirect cord decompression even in the kyphotic spine. Bassewitz and Holly & Kimball discuss potential airway problems with revision cervical spine surgery and strategies to avoid this problem.

What would you do? Perhaps your preference in treating this myelopathic patient has arisen from your training or practice experience. Until clear, level I literature guidance evolves, the surgeon will recommend a treatment strategy cobbled together from a complex array of medical data, speculation, personal experience and, yes, bias. Does the surgeon’s relationship with an implant company impact their recommendation? Perhaps. Does the relative reimbursement of laminoplasty versus laminectomy and fusion impact the options offered? What if the surgeon recently cared for a patient with a posterior fascial dehiscence or an anterior recurrent laryngeal nerve injury?

As we think through the issues presented, I refer the reader to *JAMA*’s recent “Special Communication” entitled “Professional Medical Associations and Their Relationships with Industry: A Proposal for Controlling Conflict of Interest” [*JAMA* 2009;301(13):1367-1372]. This

article's lead author, David J. Rothman, now advises the NASS Board on ethical and conflict issues. The article addresses the potential threat to the integrity of professional medical associations conferred by their relationships with pharmaceutical and device companies. The authors argue that current policies are not uniform and "lack stringency." They then outline a series of short and long term goals. Ultimately, the authors recommend a complete ban on industry funding for PMAs (outside of that earned in journal advertising and exhibit hall fees). Shortly after publication, several organizations released statements agreeing with at least some of the recommendations. The American College of Cardiology, for example, had done away with company logos on meeting bags and badge lanyards.

In your own interactions with industry, consider the relationship's impact on your patients. Are you learning in industry sponsored courses? (I have). Is the level of teaching equal to courses offered by NASS, the AAOS, CNS, etc.? (No.) Have you taken home "pearls" that enable better

care? (I have). Have you been tempted to "try" new techniques before solid literature support justifies implementation? (Maybe). Was it simply a glorified golf outing? (I don't golf).

I would add another question: how quickly should we pursue these changes? The leadership must, of course, lead. But, we must not be so far ahead that we alienate the membership. Remember, there is strength in numbers. Will the requirement for complete divestment from consulting activities affect future leadership ranks? Do we risk throwing the baby out with the bath water?

The impact of these policies will, in part, depend on the rate at which companies, hospitals and governments change their own rules. Several states have passed legislation curtailing physician-industry relationships. As we augment our disclosure policies, various spine implant companies have announced plans to begin reporting physician payments online.

It sounds like everyone is doing some spring cleaning.

SpineLine welcomes Letters to the Editor in response to articles published in these pages, as well as on topics of relevance to NASS or its membership. Please address your letters to:

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SpineLine is also interested in stories about members' interests outside of their spine practices. If you or one of your spine colleagues is involved in an interesting activity, hobby, volunteer project or other effort, please let us know by emailing ptowne@spine.org.

Thank you.