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Message from the Medical Editor

Broader than the Flood

"It is time for medical schools to end a number of long-accepted relationships and practices that create conflicts of interest, threaten the integrity of their missions and their reputations, and put public trust in jeopardy."

Institute of Medicine Report on Physician-Industry Interactions, May 2009

"It is outrageous that doctors who are testing, and in many cases, recommending the use of certain high-risk medical devices are being compensated with stock in the very companies that make these devices."

New Jersey Attorney General, Anne Milgram, May 2009

"It's true that we don't know what we've got until we lose it, but it's also true that we don't know what we've been missing until it arrives."

Anonymous

"More than ever before, Americans are suffering from back problems: back taxes, back rent, back auto payments."

Robert Orben, American Humorist and Magician, born 1927

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Have you been reading the newspapers? In the past couple of years, I have read more about spine surgery and individual doctors than in the previous two decades. Sadly, almost none of this coverage was positive. This press could not have come at a more sensitive time.

While political or economic factors could still derail health care reform, the likelihood of at least some change is high. Critically, the process has momentum and investment from the president and both houses of Congress. Another motivating factor: Medicare's inevitable insolvency is now projected for 2017. Medicare alone consumes 2.3% of the gross domestic product.

A bipartisan policy paper by US Senate Finance Committee Chairman Max Baucus (D) and Sen Chuck Grassley (R) proposes:

- decreasing aged-based Medicare eligibility to those 55 to 64 without other insurance.
- extending Medicaid eligibility to households with incomes up to 150% of the federal poverty level.
- elimination of insurer's pre-existing conditions restrictions.
- tax credits to help individuals within 400% of the poverty level pay for insurance.

As our political leaders sketch plans for expanded access to health care, reformers are redrawing the relationships between physicians, hospitals and the drug and device industries. In part, these changes stem from a perception that we are incapable of policing ourselves.

Many physicians are conservative by nature. In that group, impending change attracts more worry and derision than excitement and hope. In these difficult economic times, many of us are concerned that these changes may arrive too quickly. As far back as March 2008, Catherine Arnst was warning us in *Business Week* that medicine (and elective procedures in particular) is not recession proof. Against this backdrop, we are being asked to modify business relationships. We worry that our patients and practices may suffer.

These worries are simmering and oc-

casionally boil over. All too often, we blame changes on our representatives in organized medicine, rather than the larger societal forces at play. All too often, organized medicine has been derailed through a divide-and-conquer approach. We must learn from the lessons of the past. Our minor differences have to be tabled in order to adapt the inevitable changes into a form most acceptable to our patients and our practices.

While I have never seen the US Congress as the paragon of ethics itself, it is increasingly clear that, in order to save those aspects of physician and industry relationships that most benefit our patients, we need to "get ahead" of this issue.

Dr. Branch's President's Message amplifies our need for cohesion within the spine care community. The focus of Branch's presidential year has been bridge building. These bridges connect NASS and the other spine-focused societies to which NASS members belong. Particularly in regions oversupplied with spine specialists, times of scarcity amplify historic tensions between groups. Older tensions between academic and private practices heighten as do newer divisions: those accepting and those refusing industry consulting relationships. Do we need another bridge here? To offer high quality care, we have to maintain our patients' trust. In the face of abuses or perceived abuses, clear policies describing our responsibilities to our patients and society are needed. From the outside, this process can seem like a purification ritual or a witch hunt and it can seem unnecessarily harsh. Some remark that NASS has swung from "pro-industry" to "anti-industry." These are matters of perception. The key is that society thinks of us as "pro-patient."

This is not the impression one gets reading the newspaper. Sadly, none of those "exposés" about individual doctors bothered to document their years of service. To improve outcomes for patients with spinal diseases, many of those discussed have participated generously in volunteer and educational endeavors.

The impact of these individual stories is dwarfed by those impugning spine care and research. In the May 6, 2009 *New York Times,* Anne Milgram, New Jersey's attorney general, announced a settlement with Synthes. The company, which did not admit to wrongdoing, agreed to pay $236,000 to reimburse New Jersey for the cost of the investigation, which was pursued as a matter of consumer fraud.

In half of the 17 hospitals participating in the ProDisc IDE trial, doctors were awarded stock options. Thus, the involved doctors stood to profit if the device was successful.[1] These conflicts, it was alleged, were not adequately disclosed to patients or the FDA. Elements of the investigation are apparently ongoing, and may involve other manufacturers. In criticizing the FDA for not pursuing these conflicts aggressively itself, the attorney general's statements leave the reader with the impression that the greedy spine community refuses to police itself. In related news, the government has requested that the Institutes of Medicine investigate complaints from nine dissident FDA scientists that some devices were inappropriately cleared for use. A Congressional investigation is underway through the Government Accountability Office.

So, who will police us? In their Ethics Column, NASS senior staffers Eric Muehlbauer and Nick Schilligo review the disclosure and transparency rules introduced in Congress. Further, some states are more restrictive than the federal government. Pending federal legislation may preempt state efforts, or simply set a minimum level for reporting. For example, the Vermont legislature recently passed a bill prohibiting drug makers, medical device manufacturers and biotech companies from giving free food or other items to medical providers.

Muehlbauer and Schilligo examine the confluence of legal and ethical issues involved. In their view, the law provides a bare minimum of acceptable physician behavior. Ethical behavior, on the other hand, seeks optimal behavior. As an organization, which should NASS espouse? While I have never seen the US Congress as the paragon of ethics, it is increasingly clear that, in order to save those aspects of physician and industry relationships that most benefit our patients, we need to "get ahead" of this issue. Several implant companies appear to have reached the same conclusion and have announced plans to publish physician payments. It is not enough to merely list conflicts; we must try to minimize their impact.

As reported by Mike Theiler from Reuters, the Institute of Medicine (IOM), a part of the National Academy of Sciences, has declared that doctors should stop taking money, gifts and free drug samples from drug and device companies. The IOM report states that, while these relationships have been long-accepted, they create conflicts of interest, threaten the mission integrity and the reputations of doctors and hospitals, and jeopardize the public trust. Reuters quoted Dr. David Rothman, president of the Institute on Medicine as a Profession at Columbia University, and for a time, ex-officio NASS board member: "With the IOM's endorsement, issues that were once controversial now are indisputable…Conflicts of interest in medicine are no longer acceptable."

The drug and device industry spends more money on doctors than on research. This money is spent on free drug samples, food, medical refresher courses and payments for marketing lectures. The IOM recommends an end to nearly all of these interactions. What impact will these changes have? Can we really eliminate *all* conflicts of interest?

For many of us, the disappearance of industry sponsorship will disrupt resident and continuing medical education. Cadaver courses are a reasonable case in point. How many of these courses are required to reach marginal competence in a new procedure? Even those courses sponsored by NASS or one of the academies are subsidized by industry. The real cost of attendance may rise to $15,000-$20,000. If so, physicians will attend far fewer and patient care may suffer.

Muehlbauer and Schilligo report that pending, comprehensive health care reform legislation will most likely contain additional physician-industry rules. In their Advocacy column, Charles Mick, Raj Rao and Allison Wexler dissect the regulatory aspects of health care reform and present an overview of NASS's efforts. First, they describe the typical pathways through which coding and regulatory changes are made. Last year, NASS changed its leadership structure to more closely parallel national decision-making bodies. For example, the Professional, Economic and Regulatory Committee (PERC) was formed and charged with monitoring and responding to private insurance coverage policies.

NASS advocacy efforts exist on several levels:

- lobbying Congress
- working with federal regulatory agencies, including HHS and its components such as CMS
- interaction with the FDA
- communication of changes to NASS members

At the national level, NASS also works closely with the Alliance for Specialty Medicine. This Alliance seeks to ensure, among other things, patient access to specialty care.

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As Dr. Branch states, bridges between various parts of the spine care community are critical. The current stresses on professional medical organizations in general, and NASS in particular, leads to a real risk of fragmentation.

What can you do? The Advocacy column authors urge members to get involved. At least participate in RUC surveys so that our work is fairly valued. Beyond that, participate in a NASS committee. CPT bundling, discussed in Drs. Cheng and Sheehan's Coding column, serves as an excellent case in point. I have heard members complain that NASS "let" cervical arthroplasty RVUs value at 60% of a typical anterior cervical discectomy with fusion and instrumentation. Where did these numbers come from?

Cheng and Sheehan describe the inconsistent code interpretations between CMS and the AMA. AMA CPT instructions allow separate coding in a number of circumstances in which CMS rejects one or several of these "stand-alone" codes. For example, AMA guidelines allow the billing of an exploration of a fusion with a redo fusion. CMS, on the other hand, rejects the exploration under the theory that a surgeon typically surveys the surgical site before further surgery.

Cheng and Sheehan provide an excellent overview of the various forms of code rejection. To address these issues, and to reduce reimbursements, CMS increasingly bundles surgical procedures when the constituent codes are frequently reported together. They then value the combined code at a significantly lower level. NASS continues to monitor coding issues to ensure that the work spine physicians provide is adequately represented.

Aside from bundling our codes, what else is the government up to? In February, President Obama released an outline of the proposed 2010 fiscal year budget. This outline summarizes the Administration's priorities in health care reform. On the upside, the budget calls for $452 and $290 billion increases in Medicare and Medicaid spending, respectively (these are 6% and 10% increases from 2009).

Central to the plan is a $630 billion lay-aside, over the next 10 years, to "finance fundamental reform of our health care system." Other projects supported included health information technology (HIT), Medicare demonstration projects to align provider payments with costs and comparative effectiveness research. NASS has been preparing its membership for these concepts over the last several years. Most critically, we must prove we add value to the system.

First, we must validate common treatment strategies. Dr. Chris Bono discusses how his Guidelines Committee develops this material for NASS members. In the first of a series, Dr. Bono presents the inner workings of his committee. He discusses the processes through which guidelines are selected and how questions are generated. Critically, the method must be repeatable and systematic. He notes that a transparent evaluation process avoids the selection bias often found in book chapters and review articles.

Will these clinical guidelines lead to more uniform care? Across the country, care patterns can vary markedly for even common diagnoses such as cervical radicu-

lopathy. In her Curve/Countercurve case, Dr. Heidi Prather from Washington University in St. Louis provides an illustration. Here, a 55-year-old woman presents with left upper extremity pain. Drs. Beckworth and Dreyer from the Emory Spine Center serve as case discussants to address the role of injections in this patient. Recognizing that particulates or their aggregates may exceed vascular lumen size and lead to devastating embolic phenomena, the authors are asked to consider particulate versus nonparticulate epidural steroids. Both note that serious complications can occur with particulates, but they may be more effective than non-particulates.

As a surgeon, I saw a patient with a broad-based osteophytic ridge and central canal stenosis on her axial MRI image. For many surgeons, a patient that has failed 12 weeks of nonoperative management is offered surgical decompression. After 12 weeks, can cervical epidurals change the natural history of cervical radiculopathy? Perhaps the upcoming cervical SPORT study will offer additional guidance.

If health care reform leads to universal coverage, what will happen to health care costs? Around the world, universal coverage has very different meanings in different countries. I have worked directly in Mediterranean and West African countries with national health plans. Unfortunately, although those plans cover basic office visits, MRIs and surgery require cash. Even in wealthy Western European countries like Ireland, access to specialty spine care is extremely limited and waits are long. Often, health care costs are contained by rationing.

This Curve topic was introduced based on reader interest, controversy and legal questions. The big question: are particulates ever acceptable? In a post–health care reform world, we may view this case very differently. We may not see people until that have had six or more months of symptoms. At that point, how many will be offered injections? Will payers require clear evidence that ESIs change the natural history of this disease state? Will medicolegal risk from particulate steroid vascular embolization continue to haunt us?

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Most of us recognize that our system is inefficient and breeds reduplication of efforts. We can all cite examples of unnecessary MRIs, expensive but unproven technologies, excessive surgeries and repetitive injections. Even definitely indicated tests and procedures cost too much to provide.

In his Invited Review, Dr. Michael Frey discusses one such expensive technology, spinal cord stimulators (SCS). Cord stimulators remain controversial and arouse a wide spectrum of reaction even among this article's peer reviewers. The impact of SCS has been difficult to study because of the heterogeneity of the populations involved. As Frey notes, the term failed back surgery syndrome (FBSS) is not very specific. This group could include those with postoperative instability, inadequate decompression, adjacent segment degeneration, each of which may have reasonable relief with re-operation. Nerve damage, iatrogenic or not, is not likely to improve with additional surgery. Also, repeat surgery after SCS placement tends toward poor outcomes.

As with any spine procedure, a variety of other clinical variables, such as psychological distress and socioeconomic factors, may have profound impact on the results of any intervention. Frey points out that SCS are recommended for leg pain, not back pain. Subjective markers, like self-reported pain, seem to change more than objective markers such as return to work and cessation of narcotics. If we cannot demonstrate improved return to work rates or otherwise decreased health care costs, will a postreform health care payer cover SCS?

The Literature Review also presents emerging spine technologies. First, Dr. Scot Miller reviews Lonner's study of video-assisted thoracoscopic spinal fusion. This *Journal of Bone and Joint Surgery* paper used a matched pair analysis in which 34 consecutive idiopathic scoliosis patients underwent either thoracoscopic surgery or posterior spinal fusion with pedicle screws. The thoracoscopic approach was associated with significantly increased operative times, reduced blood loss and fewer fusion levels. The posterior thoracic approach yielded better correction of the primary curve. Hospital stay and other outcomes were similar. While this is an excellent study, thoracoscopic approaches seem to be on the wane across the country.

In the second paper, Miller and Grauer review Campbell et al's study of collar utilization after one–level plated anterior cervical discectomy and fusion. In that study, the data set of an FDA cervical disc replacement trial was utilized. In the ACDF control arm, 149 were braced and 108 were not. The brace did not improve the fusion rate or clinical outcomes. With increasing evidence that cervical collars add little benefit after surgery for degenerative indications, will future payers cover their cost?

Another source of increased cost arises from the many private and public plans providers accept and their labyrinthine bureaucratic processes. Two recent studies, reported on the online journal *Healthcare Affairs,* examined the costs of the current, multipayer system on physician practices. Lawrence P. Casalino and coworkers reported that physician practices spend $31 billion annually in interacting with insurance plans. Of all US expenditures for

physician and clinical services, 6.9% went to office overhead directed at the insurance bureaucracy. While the average physician spent three hours a week on these activities, their nursing and clerical staff spent more than 67 weeks per physician per year interacting with health plans.

A separate study, led by Julie Sakowski, studied a large multisite, multispecialty California group practice in depth. In that study, clinicians spent more than 35 minutes per day performing billing and insurance-related tasks. These tasks also necessitated 0.67 nonclinical full-time staff per full-time physician. In this California group, the additional personnel cost $85,276 per physician annually (or 10% of their operating revenue). The authors concluded: "We believe that while minimizing billing and insurance-related administration activities is not the only goal of the health care system reform, standardizing health plan features and processing requirements presents a tremendous opportunity for improving efficiency in a multipayer health care system."

Now, what happens if, after reform, we end up with a multi-payor system, just lower reimbursements? As they frequently do with Medicaid, and occasionally with Medicare, the cost of providing care exceeds the revenue. Will this lead to increased insurance nonparticipation? In an April 2009 op-ed in the *Wall Street Journal,* Dr. Marc Siegel, an internist at NYU wrote "Health insurance doesn't automatically lead to health care." He reports that "more and more doctors [are] dropping out of one insurance plan or another, especially government plans." In 2008, more than 28% of Medicare beneficiaries looking for a primary care physician had trouble finding one, up from 24% the year before. Increasingly, doctors are turning away Medicare patients because of the diminished reimbursements and the growing delay in payments. Only 50% of physicians accept Medicaid. Those who continue to participate complain that care is compromised through limited access to specialists and other services, such as physical therapy.

Clearly, improving our health system will require improved care coordination and elimination of waste. One massive source of unnecessary and costly medical interventions: the malpractice system. Meaningful health care reform cannot occur without concomitant tort reform. In a recent editorial in the *Philadelphia Enquirer,* Newt Gingrich, quoted the *American Journal of Public Health*. States could save 3%–4% of their total health spending by imposing reasonable limits on noneconomic damages. In Pennsylvania alone, limits would save $2 billion per year.

For the 25,000 doctors in Pennsylvania, these are not dry and abstract statistics. Since 2002, more than half of them have been sued. The state's Medical Board found that only a fraction of the cases merited action, signaling rampant lawsuit abuse.

Philip Howard, chairman of Common Good, argues in a *New York Times* op-ed for the creation of specialty health courts. A fair and straightforward medical liability system could eliminate $1 trillion in wasteful health care spending each year. States without meaningful tort reform lose physicians. In Maryland, for example, there are only 178 MDs per 100,000 people, as compared to the nationwide average of 212 per 100,000. These shifts affect neurosurgeons and other surgical subspecialists to a greater degree than primary caregivers. In the last decade, almost 40 hospitals, maternity units and other major Pennsylvania medical facilities were closed.

At *SpineLine,* we seek critical assessments of new technologies and up-to-the-minute assessments of clinical, legal and practical spine issues. Many of these topics are necessarily controversial. To avoid the excessive hedging and fawning diplomacy often seen in medical discourse, we have asked our authors to emphasize their viewpoint. Shying away from controversy does little to illuminate these issues. *SpineLine* itself, on the other hand, wants "both sides of the story." We invite our readers to e-mail, write, or call in with questions and comments. When timing allows, the comments will be forwarded to the authors in question and combined responses will be included in the next issue.

This month, we are fortunate to have received some insightful comments which further illuminate the original topics. Some have been published as Letters to the Editor, others are waiting authors response and will be seen in future issues. Work continues on the *SpineLine* Web site 2.0. That community site will allow more timely responses with the ready inclusion, where appropriate, of additional images and video. In the meanwhile, please call, write or e-mail us with your reactions, corrections and interesting cases and images.

Footnote

1. In the interest of full disclosure, my institution participated in the ProDisc trial. Aside from research support, I have not received consulting or other fees related to that product.