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## FROM THE DESK OF THE PRESIDENT

# Changing Tide in Health Care Leads to Guidelines on Medical Ethics

### INTRODUCING JEAN-JACQUES ABITBOL, MD

As First Vice President, this year it will be my duty to introduce you to the NASS President prior to his presidential address at the 20<sup>th</sup> Annual Meeting next September in Philadelphia. It always struck me as odd that we introduce him to you on the last day of his term. So, now that his term is just beginning, please allow me to introduce to you Dr. Jean-Jacques Abitbol as the 20<sup>th</sup> President of NASS.

JJ has been involved with NASS activities for many years. He was on the NASS Board as Education Council Director for three years prior to becoming Second Vice President. In 1998 he was program chair for the 13<sup>th</sup> Annual Meeting of NASS held in San Francisco. Steven Garfin, MD, was President that year. Before that, JJ served in various capacities at NASS particularly in the CME area. He authored the Program Committee Guidelines that govern how we create the world's best spine meeting each year. He is of Canadian descent and became a Fellow of the Royal College of Surgeons in 1988. He was board certified in Orthopedic Surgery in 1990. He did his Internship and Residency at McGill University in Montreal and did a Spine Fellowship under John Kostuik, MD, in 1987-88. He is the author of numerous published articles and book chapters. He currently practices in San Diego, California where he lives with his wife Sara and children, Michael., Stephen and Miriam.

JJ has been one of the most creative Board Members we have had. One of his principle themes for his presidential year will be physician ethics relative to industry relationships. I know that he will challenge us all to examine our critical thinking skills relating to everything from journal articles to presentations at meetings. It should be an interesting year and I look forward, as we all do, to learning from Dr. Abitbol.

**Joel M. Press, MD**  
First Vice President

*No physician, insofar as he is a physician, considers his own good in what he prescribes, but the good of his patient; for the true physician is also a ruler; having the human body as his subject, and not a mere moneymaker.*

Plato

**A**s we approach our 20<sup>th</sup> anniversary as a society, I am reminded of one of our main purposes – “to improve the quality of scientific knowledge and pursuit of high standards of excellence in patient care, clinical practice and related sciences among profes-

sionals in the field of spinal disorders.”<sup>1</sup> In the next decade, we will witness a new generation and continued evolution of spinal devices. Increasingly, the advancement of these technologies is a responsibility and collaborative effort shared by physicians and industry to improve patient care. In our combined efforts with industry, we must all earnestly strive, above all, to promote the best interests of the patient. Maintaining profitability will continue to drive these efforts but it should never occur at the cost of the patient.

In itself, an arrangement between a doctor and industry appears innocent. However, there

are those who believe that any collaboration is suspect and should be viewed with a jaundiced eye. The medical profession has struggled for years with the ethical question of whether it is appropriate for a physician to accept gifts and other financial benefits from a company that wants the physician to prescribe, order or recommend their products for his patients. In a post-Enron, -Arthur Anderson and -Tyco environment, there is nothing the news media seems to like more than a good story of alleged corruption and kickbacks. In fact, the Department of Justice also feeds in the frenzy. In view of this increasing scrutiny under which the medical profession is being placed, a review of existing (and evolving) guidelines outlining ethical relationships between doctors and industry is in order.

#### MEDICAL SOCIETIES AND ORGANIZATIONS PROVIDE GUIDELINES

Several medical societies and organizations recognize the changes affecting health care and the ethical dilemmas physicians face. Organizations such as the American Medical Association (AMA) and its Council of Ethical and Judicial Affairs (CEJA), the North American Spine Society (NASS), the American Academy of Orthopaedic Surgeons (AAOS), the Pharmaceutical Research and Manufacturers Association (PhRMA), Advanced Medical Technology Association (AdvaMed) and the US Department of Health and Human Services Office of the Inspector General (HHS-OIG) continue to address these concerns. They have provided guidelines to help physicians, residents, medical students and pharmaceutical and medical devices sales personnel navigate difficult waters to safe harbor.

#### GUIDELINES HELP REMEDY ETHICAL CONFUSION

**AMA Guidelines.** More than 10 years ago, the AMA developed ethical guidelines for physicians to guide relationships between doctors and industry. Its Council of Ethical and Judicial Affairs, in Opinion 8.061,<sup>2</sup> "Gifts to Physicians from Indus-

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try," presents four conditions a physician can use to test the acceptableness of a gift. The conditions are: (1) the gift benefits patients; (2) the gift is valued at less than \$100; (3) the educational opportunities associated with the gift must be free of bias and (4) no strings or conditions are attached to the gift.

Until fairly recently, many drug, device and biologic companies did not seem to be terribly concerned by the AMA's ethical limitations. They thought that it was up to the individual physician to decide what to do. Many of the types of gifts and incentives prohibited under the recently formulated codes and guidelines, however, have long been considered to be unethical by the AMA. In fact, gifts that physicians may receive from industry are specifically outlined in the AMA Code of Ethics.<sup>2,3</sup>

**NASS Guidelines.** The NASS *Code of Ethics* states "a member shall not participate in any activity which is not in the best interest in the patient" ([www.spine.org/forms/NASS\\_code\\_of\\_ethics.pdf](http://www.spine.org/forms/NASS_code_of_ethics.pdf)).

**AAOS Guidelines.** In its March 10<sup>th</sup> edition of *Today's News*, AAOS reinforced its ethical statement regarding the relationship between the physician and industry and further supported the views of many organizations. In part, AAOS states "...All dealings between orthopaedic surgeons and industry should benefit the patient and be able to withstand public scrutiny."

**PhRMA and AdvaMed.** Two trade associations, PhRMA and AdvaMed, have adopted voluntary guidelines to guide relationships between companies and

physicians. PhRMA, in its *Code on Interactions with Healthcare Professionals*,<sup>4</sup> recognizes the critical nature of helping patients by developing and marketing new medications. In PhRMA's code, detailed guidelines are presented related to informational presentations, financial support for meals and receptions, third-party educational and professional meetings (example continuing medical education), consultants, scholarships and educational funds, and practice-related items. Their code, which went into effect on July 1, 2002, makes it clear that interaction between health care professionals is strictly to benefit patients and the practice of medicine.

Having recognized the scrutiny the pharmaceutical industry has received for abuse in interacting with physicians, AdvaMed, which represents 1100 medical technology companies, developed guidelines to avoid unethical behavior. Effective January 1, 2004, the guidelines recognize the collaborative efforts between industry and health care professionals and the importance of medical technology, device safety issues, research and education. Specifically, AdvaMed's *Code of Ethics*, "On Interactions with Healthcare Professionals,"<sup>5</sup> provides guidelines for member-sponsored product training and education, third-party educational conferences, sales and promotional meetings, consultants, gifts, reimbursement provisions, grants and other charitable donations. Furthermore, these guidelines are applicable to a broad range of health care professionals, including those working in medical, legal, sales, marketing, finance and administration.

The stated purpose of the new code was to promote "ethical interactions" between

the medical device industry and physicians, primarily in the areas of gifts, incentives and subsidies at professional group meetings. As a result of the adoption of this code, some benefits and “perks” historically provided by industry to physicians have been discontinued by some companies.

#### LEGAL ISSUES AND FEDERAL LAWS

Inappropriate economic relationships between physicians and drug and device companies have long been prohibited by state and federal statutes. These laws include the anti-kickback statute, Stark laws, civil and criminal statutes, False Claims Acts and others. Some, like Stark, apply directly to physicians. Others, like the Anti-Kickback Statute, apply more broadly to both industry and physicians. NASS members need to be aware of the laws and ethical guidelines to avoid any detrimental consequences of accepting gifts. The HHS-OIG and the US Food & Drug Administration willingly provide interpretive guidance to both physicians and companies. These regulatory arms of the US government also monitor interactions between physicians and companies and enforce the laws. Both the PhRMA Code and the AdvaMed Code have been lauded by HHS-OIG.

Over the past decade, the government has stepped up its enforcement of these laws dramatically. Drug and device companies have paid millions of dollars in fines. Executives, salespeople and physicians have been fined, excluded from Medicare participation and have even gone to jail. Furthermore, the Justice Department recovers three to four times the cost of an investigator with settlements and fines. As you may imagine, extensive resources are made available to the Justice Department in its recovery efforts. As Washington is struggling to pay for health care, this is also a politically powerful way to mitigate some costs.

The past few years have also seen an explosion of whistle blower suits brought by private individuals on behalf of the government. If a physician or hospital is

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shown to have accepted an illegal kickback from a manufacturer, then every claim submitted to Medicare or Medicaid by that provider that possibly can be related to the kickback is a false claim in the eyes of the government. Private *qui tam* lawsuits seek recovery of the amount of “falsely” paid by the government and may provide a return to the plaintiff of up to 35% of the amount recovered. This provides an almost irresistible incentive for disgruntled individuals to bring up these claims. The combination of increased enforcement, a watchdog media and private *qui tam* actions has left the business and legal environment for device manufacturers turbulent and murky. Significant differences of opinion still exist among government regulators, industry and physician’s groups about the appropriateness of a wide range of practices and economic relationships.

#### ULTIMATELY, WHO DECIDES?

The decision concerning the appropriateness of a gift is ultimately in the physician’s hands. A doctor’s core values include a high level of professionalism that should motivate him or her to uphold what best serves patients and advances medical science and technology without any conflict of interest. To this end, although voluntary, I urge all members to at least acquaint themselves with the ethical guidelines that govern the relationships with medical industry.

I believe that NASS and other medical societies, in conjunction and cooperation with industry, have an obligation to provide leadership for physicians and the companies as a whole to navigate through these uncertain waters. Flagrant abuses must be avoided. These include expensive

dinners, resort trips and all-expenses-paid attendance at meetings and events. Any royalty and consulting agreement must be backed up by extensive documentation of the physician’s integral involvement in the development of a product or services rendered. Reimbursement for these acts must reflect “fair market value” for the time spent directly related to the latter.

The introduction of these guidelines by medical societies and industry, in combination with the physician’s code of ethics and behavior, should serve as voluntary rules for engaging in any financial relationship. Above all, it is a physician’s duty to place the patient’s well-being and benefits ahead of any monetary gain.

#### REFERENCES

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