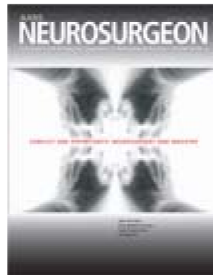


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Feature

Conflict and Opportunity: Neurosurgery and Industry

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The relationship between neurosurgery and industry is multifaceted. Most aspects of this relationship promote the advancement of a highly technical field such as neurosurgery, helping neurosurgeons bring ever more effective therapies to their patients. However, serious ethical and legal concerns also attend this relationship.

In recent months the relationship between surgeons and the medical device industry has been much in the news. Since September 2007:

- The U.S. Department of Justice reached settlements with five medical device makers (Biomet Orthopedics, DePuy Orthopaedics, Smith & Nephew, Stryker Orthopedics, and Zimmer) that subjected the companies to new corporate compliance procedures, federal monitoring, and public disclosure of consulting agreements with physicians, among other things, all following a two-and-a-half year DOJ investigation into violations of the federal antikickback statute.
- The DOJ subpoenaed two more medical device companies (Exactech and Wright Medical Group), requesting 10 years of records documenting consulting and professional service agreements with surgeons.
- Legislation was introduced in the U.S. Senate that would require congressional oversight for and public disclosure of consulting agreements between physicians and device companies that are paid with Medicare, Medicaid or SCHIP funds, as well as the cost of implantable medical devices purchased with such funds.
- Representing the U.S. Senate Finance Committee, ranking member Charles E. Grassley asked Med-tronic Sofamor Danek for five years of documents and records and a "response to allegations that Medtronic's practices of providing inordinately high consulting fees, free travel, and other perks distort decision-making among physicians and obscure the best interest of patients."
- The U.S. Securities and Exchange Commission began looking into whether medical device makers Biomet, Medtronic, Stryker, and Zimmer may have violated the Foreign Corrupt Practices Act, possibly inducing physician consultants outside the United States to use their products.

While these investigations have focused on the orthopedics sector, the relationship between orthopedics and industry is merely a hair's breadth from the relationship between neurosurgery and industry, to which the case of Arkansas neurosurgeon Patrick Chan attests. In January 2008, Dr. Chan pleaded guilty to soliciting and accepting kickbacks for purchasing and using equipment sold by Blackstone Medical, which makes and sells devices used in spinal surgery.

As the federal government, on behalf of the public, delves further into the nature of relationships between physicians and industry, neurosurgery is presented with a prime opportunity to examine its own house and

ensure that it not only is in order, but that it stands for the most stringent legal and ethical standards. To support such an examination, this article offers an overview of the DOJ agreements and some of their possible implications for neurosurgeons. In accompanying articles, several individual neurosurgeons offer their perspectives on the neurosurgery-industry relationship, and related legislation and parameters currently established for AANS interaction with industry are summarized.

The DOJ Agreements

The DOJ has been focusing attention on the sales and promotional practices of the orthopedic implant sector. The sales of hip and knee implants have increased markedly in recent years. There have been accusations that the industry is engaged in aggressive sales practices and certain incentive-based arrangements. The prosecution determined that the industry routinely violated the antikickback statute by paying surgeons for using their products, making "consulting agreements" with individual surgeons thinly veiled mechanisms to induce the use of their product.

The five companies investigated represent 95 percent of all of hip and knee implant sales in the United States. A total of \$311 million in fines was levied on four of the companies, but the amount of fines to be paid by each company varied according to its market share rather than individual liability, with a high of \$169.5 million assessed from Zimmer. Stryker avoided fines, as it was the first company to voluntarily cooperate with the DOJ investigation; the company signed a nonprosecution agreement and promised to adhere to the same reforms imposed on the four other companies, which signed deferred prosecution agreements. Those four companies also reached accord with the DOJ and the Department of Health and Human Services Office of the Inspector General, entering into civil settlements that include both fines and a five-year Corporate Integrity Agreement, which requires additional reforms and monitoring under OIG supervision.

Federally appointed monitors will review compliance activities with all of the companies, and a needs-assessment will be conducted to determine the reasonable educational expenses for each company as well as the amount of revenue to be spent on new consultants. Of particular note to neurosurgeons is that physicians who have consulting agreements are required to disclose them to their patients.

The DOJ recognized several of the companies for their cooperation and willingness to implement reforms. It also noted that many tenets of the agreements were based on the Zimmer Corporate Compliance Program.

Physician consultants and industry payments to them are clearly listed on each company's Web site. A quick scan of the dollar amounts for 2007 indicates that most surgeons received only nominal amounts; some, however, received several million dollars. A criticism from the orthopedic surgical community has been that all monies transferred have been listed, and not categorized. For example, royalty arrangements (such as for intellectual property) that are entirely appropriate are lumped together with questionable payments.

Soon after the details of the DOJ agreements were released, the American Association of Orthopaedic Surgeons issued the following statement:

AAOS supports appropriate financial disclosures to patients regarding relationships between orthopaedic surgeons and implant manufacturers... Financial disclosures that display only the name of the physician and an aggregate dollar amount received without any explanation of the nature of the relationship and without educational context may be confusing and misleading to the public and patients. Specifically, AAOS believes that disclosures of implant manufacturer payments to physicians should be divided into separate categories, such as royalty payments, consulting agreements, funding for the conduct of research, funding for the support of medical education, and that these terms should be defined so that patients and the public can understand them. AAOS supports disclosure that is fair and includes a principled education context that is understandable to patients and the public.

The increased scrutiny evidenced by the DOJ investigation and others will quickly transfer from orthopedics to other device manufacturers that interface closely with surgeons from other disciplines. We should assume that neurosurgeon-industry consulting relationships and the amount of money involved will become public knowledge. These relationships can pose multiple conflicts of interest: to the insurance payers, to the federal funders, to the hospital buying the implants, and to the patient receiving them.

Neurosurgery and Industry: Opportunity

While the recent investigations focus on impropriety in physician-industry relationships, there are many positive aspects of these relationships. Neurosurgery's relationships with industry typically fall into one of the following three categories:

Neurosurgical Education

Industry support for neurosurgery's educational mission is critical and becoming more so over time. The annual meeting of the AANS is heavily supported by industry, especially by the AANS Pinnacle Partners, which now number 12 companies. The educational quality of the annual meeting is not sustainable without industry support. Further, last year five very successful resident education courses, covering various topics such as spine surgery fundamentals and contemporary endovascular techniques, were initiated. This year at least seven courses are planned, adding to the repertoire and covering clinical topics not fulfilled by all training programs. These resident courses, which have received rave reviews from participants and volunteer faculty alike, are fully funded by industry.

Neurosurgical Research

The Neurosurgery Research and Education Foundation, which solicits funding from both neurosurgeons and industry, offers up to 15 major grants annually in support of young investigators in residency or at the junior attending level. In the very competitive NREF grant process, a review board composed of neurosurgeons evaluates applications for funding. Industry sponsors fund or co-fund approximately one-half of the grants. Similar industry support of research is given to the Congress of Neurological Surgeons and to the AANS/CNS sections. Industry also offers major research support of many neurosurgical departments. With the flat budget of the National Institutes of Health and the current extremely competitive nature of NIH funding, industry support likely will comprise an increasing percentage of research budgets in most neurosurgical departments (and medical schools).

Clinical Care

Given the technical nature of neurosurgery, much of the research and development of related instruments and implantable devices is driven by industry support. Surgeon consultants and intellectual property arrangements are fundamental in this process. Payments to consultants and royalties on intellectual property are at the center of the recent orthopedics-related controversy. In neurosurgery, areas of intense industry research and development and correspondingly high profit margins, such as found at present in the subspecialties of spinal and endovascular surgery, are particularly vulnerable for exploitation.

Disclosure Is Key

The vast majority of the money received by organized neurosurgery and neurosurgical departments in the form of educational grants and research monies is entirely legitimate, is used for appropriate purposes, and does further neurosurgery's core missions of patient care, education and research.

While the recent investigations may identify questionable relationships between industry and some practitioners, we must keep our perspective and understand that our core educational and research missions are highly dependent on support from industry.

The relationship between neurosurgery and industry no longer can be characterized as dichotomous; rather than black and white, it is a gray area. To navigate this often uncertain landscape effectively, we must thoroughly discuss and define how we can maintain constructive, mutually beneficial relationships with industry that benefit our patients while holding ourselves and our profession to the highest ethical standard.

Disclosure is the necessary key. The surgeon who is receiving compensation from the maker of an implantable device needs to disclose this information to the patient who is receiving the implant, to the hospital which is buying the implant, and to the partners of the group, whether it is an academic or a private practice.

The AANS is developing guidance for neurosurgeons to assist them in forging ethical and legal relationships with industry. We invite your participation in this important dialogue as we work to ensure compliance with regulations and to develop sustainable, mutually beneficial relationships with industry.

William T. Couldwell, MD, PhD, is editor of *AANS Neurosurgeon*, chair of the AANS Development Committee, and Joseph J. Yager chair of the Department of Neurosurgery at the University of Utah School of Medicine, Salt Lake City, Utah. Dr. Couldwell reported that, while he has previously received research support from industry, he has no current industry relationships to disclose. **Jon H. Robertson, MD**, is 2007-2008 president of the AANS, and chair of the Department of Neurosurgery at the University of Tennessee Health Science Center, Memphis, Tenn. Dr. Robertson reported that he has no industry relationships to disclose.

Your Opinion Counts

Send your letter to aansneurosurgeon@aans.org. Letters should include the author's full name, city and

state, as well as disclosure of any conflicts of interest that might have bearing on the letter's content. Correspondence selected for publication may be edited for length, style and clarity. Authorization to publish the correspondence in *AANS Neurosurgeon* is assumed unless otherwise specified.

For More Information

- *AANS Bulletin*, Neurosurgery and Industry: A Delicate Dance (cover section), www.aans.org/bulletin/Issue.aspx?IssueId=20294
- AAOS Statement on Partnerships Between Physicians and Implant Manufacturers, www5.aaos.org/industryrelationships/pdfs/PressRelease_nov1.pdf
- AAOS Orthopaedist-Industry Conflicts of Interest, www5.aaos.org/industryrelationships/pdfs/standards.pdf
- Department of Justice Press Release: Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring, <http://newark.fbi.gov/dojpressrel/2007/nk092707.htm>
- Letter, Sept. 20, 2007: Charles E. Grassley, ranking member of the U.S. Senate Finance Committee, to Bill Hawkins, president and CEO of Medtronic Inc., <http://finance.senate.gov/press/Gpress/2007/prg092607b.pdf>
- Zimmer Corporate Compliance Program, www.zimmer.com/z/ctl/op/global/action/1/id/9968/template/CP/navid/9549

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