Relationships Between Academics and Industry

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ABSTRACT
Spine surgery is a technology-driven specialty relying on the innovation of surgeons and researchers to develop new devices, implants, and therapeutics to improve patient care and outcomes. Collaborations with industry have helped fuel this growth with the funding of research, continuing medical education programs, and product development. Recent investigations have scrutinized these relationships, bringing greater attention to issues of conflicts of interest and disclosure. We examine the nature of these relationships and discuss the implications for its future.

KEY WORDS: Academics, Conflict of interest, Disclosure, Industry.

INTRODUCTION

Academia and industry have collaborated for many years, having developed strategies for and implemented the delivery of pharmaceuticals and medical devices to the consumer. This relationship, for the most part, has promoted the advancement of spine surgery, helping innovative surgeons develop and deliver a diverse array of therapies and treatments for patients. Through these relationships, significant contributions to clinical care have been made, though some have resulted in questionable practices that have been criticized by professional, corporate, and governmental organizations. With this growth in innovation, considerable attention has focused on spine surgery and its relationship with device makers, predominantly regarding its financial implications and potential conflicts of interest.

Although these conflicts are not exclusive to academic surgeons, a flurry of media attention has brought scrutiny to academic spine surgeons in recent years. Ethical, legal, and financial concerns have led to growing suspicion regarding such relationships. The primary concern among legislators, politicians and the public is whether these potential conflicts of interest could influence research and its application to clinical practice. With an increasing emphasis on evidence-based medicine, the implications of industry-supported research and potential bias regarding patient care are substantial.

Background of academia and industry

Over the last several decades, academic-industrial collaborations have played an increasingly prominent role in medicine. The rapid growth of medical device and pharmaceutical companies has been accompanied by greater financial influence on physicians and researchers. In the United States, general research support from the biotechnology, pharmaceutical, and medical device companies increased 102%, from $26.8 billion in 1994 to an inflation-adjusted $54.1 billion in 2003.13 It is estimated that approximately 60% of medical research in the U.S. is funded by industry and 28% by the National Institutes of Health, with the rest provided by institutional, government, or private resources(13,16).

In a national survey of U.S. medical school department chairs, Campbell et al.(8). revealed that almost two-thirds had some form of personal relationship with industry, including serving as a consultant (27%), member of a scientific advisory board (27%), paid speaker (14%), officer (7%), founder (9%), or member of the board of directors (11%). Clinical departments were more likely
than nonclinical departments to receive research equipment, unrestricted funds, residency or fellowship training support, and continuing medical education support. More than two-thirds of chairs perceived that having a relationship with industry had no effect on their professional activities or ability to remain objective when performing research.

With more physicians having financial partnerships with industry, the American Medical Association developed voluntary guidelines to address the practice of inappropriate gifts given to physicians by industry(10). To address this issue, similar guidelines have since been adopted by other medical organizations including the Congress of Neurological Surgeons, American Association of Neurological Surgeons, and the North American Spine Society, among others.

Concerned that their financial practices with physicians could be perceived as inappropriate by patients and the government, the pharmaceutical and device companies developed their own ethical guidelines. In 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted a voluntary Code on Interactions with Healthcare Professionals to facilitate transparency in relationships with physicians(15). In 2004, the Advanced Medical Technology Association (AdvaMed), an organization representing the major medical device companies, followed with its own Code of Ethics(3). Both organizations have updated these voluntary guidelines in recent years to reflect the increased demand for transparency from legislators and patients alike.

**Inquiry, Oversight, and Legislation**

Relationships between physicians and industry have been investigated in recent years with considerable scrutiny from federal legislators. Spine surgery has become a focus of inquiry, with accompanying accusations of impropriety related to conflicts of interest between physicians and industry. This has not only caught the attention of legislators but the general print media as well. In December 1990, the Senate Labor and Human Resources Committee held hearings that highlighted questionable practices among orthopedic implant manufacturers and physicians. In 2005, five orthopedic implant companies were subpoenaed by the Department of Justice to investigate the relationship between the companies and the orthopedic surgeons consulting for them. This resulted in even greater scrutiny regarding the nature of such consultation agreements between physicians and companies.

In July of 2006, a whistle-blower suit involving Medtronic resulted in the device company settling lawsuits totaling $40 million(2). It was alleged that the manufacturer influenced surgeons to use their implants through lucrative consulting agreements and kickbacks. Media coverage of lawsuits such as this helped foster an impression that physician-industry relationships could pose risks to patient care, undermining the integrity of the physician-patient relationship.

In September 2007, U.S. Senators Charles Grassley (R-Iowa) and Herb Kohl (D-Wisconsin) introduced the Physician Payments Sunshine Act (S.2029), which sought to require pharmaceutical, medical device, and biotechnology companies to disclose payments made to physicians. This bill would require manufacturers to supply detailed reports which would be publicly available on the internet as well as establish mechanisms of oversight and penalties for noncompliance. The intent of this legislation is to let patients decide whether physician's decisions are influenced by industry perks. Fines of $1,000 to $100,000 would be imposed on companies for each incident of failing to report a gift to a physician as defined by the bill. This bill defined payments as anything of value over $25, and included any compensation, gift, honorarium, speaking fee, consulting fee, travel, discount, cash rebate, or services. This bill was referred to the Senate Committee on Finance and was not voted on during the last session of Congress. The bill was re-introduced in January of 2009 with some modifications, including stipulations allowing individual states to add additional reporting requirements not included in the federal legislation and increasing the defined payment as anything over $100. Several states including Maine, Massachusetts, Minnesota, Vermont, and West Virginia have already enacted laws requiring medical companies to disclose payments to physicians.

As part of his inquiry into the relationship between academics and industry, Senator Grassley requested that Medtronic provide five years of documents and records of physician payments. Senator Grassley and others have accused a number of universities of doing a poor job of policing conflicts of interest among researchers. As a result, the financial details of industry payments of a number of prominent academic spine surgeons were made public by the media.

A spine surgeon at a major academic center was targeted by Senator Grassley for having received $19 million in payments from Medtronic to help develop and promote
spinal implants. As required by the university, the surgeon reported receiving payments of $20,000 or more in each of the five years he received payments from Medtronic. Though the surgeon had followed university policies with regards to disclosure of payments received by industry, Senator Grassley called to question the disclosure requirements of the university. According to the Wall Street Journal, Robert Golden, dean of the university’s medical school, agreed that the disclosure requirements are “insufficient” and “indefensible.” As a result of the scrutiny, the affected university changed its disclosure policy to require specific sums rather than broad dollar ranges.

In another case reported by the Wall Street Journal, an academic spine surgeon at another university was investigated by Senator Grassley for failing to accurately disclose payments from Medtronic, DePuy, and FzioMed Inc. to the university. Other cases involving spine surgeons from additional academic centers have made headlines and emphasize the importance of physician disclosure.

**Implications for bias in research**

Conflicts of interest in physician-industry relationships are not limited to the clinical arena. These may inject bias into research results. Reviews of clinical trials funded by industry in the last decade in various medical fields have demonstrated an increased likelihood of reporting results favorable to industry. With limited governmental, university, and institutional funding sources, researchers have sought industry support for the implementation of clinical trials. According to some authors, approximately one-fourth of biomedical investigators at academic institutions receive funding from industry and up to one-third of lead authors have some financial stake in their research.

A disparity in outcomes has been found between industry sponsored and non-industry sponsored studies. Bhandari et al. examined 332 randomized controlled trials published in 13 leading medical and surgical journals. They found that industry funded trials were more likely to be associated with statistically significant findings favorable to industry. Similarly, Shah et al. reviewed industry support and its effect on outcomes in studies published in the journal Spine. Of 527 articles that met inclusion criteria for study, 84 (15.9%) received industry support. They found that studies with industry funding were 1.6 times more likely to report positive results than studies from other sources.

Industry support was diversified among biomechanics (47%), techniques (31%), randomized clinical trials (23%), basic science (18%), and clinical series (18%).

In a recent review of all abstracts submitted to the 2006 Scoliosis Research Society annual meeting, Roach et al. found that although certain areas of research received more industry funding than others, such did not result in favorable findings toward the funded studies unless the funding was due to a consultant/employee relationship.

**Need for Disclosure**

With increased scrutiny on the relationship between surgeons and industry, many professional organizations as well as universities and hospitals, have initiated mandatory disclosure policies for researchers and physicians. In recent years, there have been legal cases alleging lack of informed consent for participation in research because the principal investigator did not disclose conflicts of interest to the study participants. In January 2008, the New York Times published a report questioning the financial ties between participating surgeons in a clinical trial evaluating a lumbar artificial disc and the potential for bias. Nearly 240 patients undergoing surgery were found to do better with lumbar arthroplasty compared to fusion. It was revealed that about half of the doctors in the study at centers had some degree of conflicting financial interest in the device. Whether this conflict of interest was disclosed to patients prior to obtaining informed consent is currently under investigation by the Food and Drug Administration.

**CONCLUSIONS**

Spine surgery has become a technology-dependent surgical specialty relying on the innovation of surgeons and researchers to develop new devices, implants, and therapeutics to improve patient care and outcomes. Collaborations with industry have helped fuel this growth with the funding of research, continuing medical education programs, and product development. While recent investigations have identified questionable relationships between industry and individual surgeons, this has led to greater scrutiny on the relationship as a whole, calling for greater transparency. As further oversight of this relationship continues, full disclosure of potential conflicts of interest with patients, research subjects, universities, hospitals, and professional organizations will ultimately improve the quality of this collaboration and restore faith in the physician as an objective decision maker.
REFERENCES


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