

Working with Industry: What Is the Conflict?

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Abstract

Keywords

- ▶ conflict of interest
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- ▶ industry-sponsored trials
- ▶ industrial relationships

The relationship between medicine and industry has always shared conflicts. There are obvious benefits to these relationships and inherent potential risks. The collaboration between academic medicine and industry has allowed for great advances in medicine in terms of drug, technology, and procedural developments. However, for-profit companies' interests may not align with those of academic universities. Companies tend to undertake research when the results of such work leads to company profits or enhances their reputation, and not solely for greater scientific understanding. In this article, the author reviews the types of conflicts of interest, the role of industry-sponsored trials, the adoption of new technologies from industry, and the role of industry with our medical society.

Objectives: Upon completion of this article, the reader should be able to summarize the types of conflict of interest and their management.

The relationship between medicine and industry has always shared conflicts. There are obvious benefits to these relationships and inherent potential risks. In terms of benefits, the collaboration between academic medicine and industry has allowed for great advances in medicine in terms of drug, technology, and procedural developments. Here the key elements are aligned to advance the fields of medicine. Patients require new treatments to cure their disease, academic medicine wishes to convert scientific research to new therapies, and industry needs to develop new products to remain viable. However, for-profit companies' interests may not align with those of academic universities. Companies tend to undertake research when the results of such work leads to company profits or enhances their reputation, and not solely for greater scientific understanding. Here I will review the types of conflicts of interest, the role of industry-sponsored trials, the adoption of new technologies from industry, and the role of industry with our medical society.

Types of Conflicts of Interest

The most obvious conflict between medicine and industry is financial. Physicians receive money and or stock/stock options from industry to consult, serve on advisory boards,

perform speaking engagements, and conduct industry-sponsored research. Industry needs the advice and opinions from physician leaders in their field of specialty to understand the current treatments and future direction of medicine. Physicians who serve on advisory boards or who consult for a company serve a vital role and should receive compensation equitable to their time spent outside of work. For those who receive cash payment for their time and effort, the value of their work is transparent. For those receiving stock or more potentially concerning, stock options, the value of the work provided is not so clear. For start-up companies that are successful and bought out by larger firms, the value of those stock options can be considerable. In this case, the compensation for the work provided by the consultant would be overvalued, netting the consulting physician a potentially handsome reward for their work. Are physicians who hold stock or stock options in a company influenced in their decision making for the use of medical products in caring for their patients? Are physicians who own stock or stock options involved with research with a specific company influenced in their research because of the potential profit from the sale of stock or stock options? This is clearly in the spotlight of industry-sponsored research and has been made public in the media headlines. Most academic medical centers with their institutional review board (IRB) and compliance committee have set limits on the yearly income one can receive from industry. At our own institution, Lahey Clinic,

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we have created a Research Compliance Committee (RCC), of which I am Chairman, which reviews on a regular basis the relationships of Lahey Clinic physicians and the industry with which they perform research. The Lahey Clinic has set a yearly limit of \$5000, which can be earned by a physician consulting with a company and engaged in industry-sponsored research. The federal government in August 2011, through the Department of Health and Human Services (DHHS), has set similar guidelines for physicians involved in research who receive federal grants.¹ These specific guidelines should be reviewed by all physician researchers (<http://grants.nih.gov/grants/policy/coi/>) and should have been reviewed by each investigators' institution by August 24, 2012 to remain in compliance and to continue with National Institute of Health (NIH) sponsored research. The DHHS also requires physicians to disclose any ownership of stock or stock options by the physician and immediate family members. Most institutional compliance committees or RCCs require similar reporting. Again, the issue of the potential value of stock options makes it difficult to manage a physician's conflict of interest. I have personal experience with this very issue, having earned potential stock options more than a decade ago, in a company that is still privately held. In the past, I gave little thought to the value of the stock options and whether they had influenced my personal clinical research. Although I could still legally own these options, the issue is now one of personal ethics and public perception. Though not asked to do so, I have chosen to relinquish these stock options at this time, so there can be no potential conflict of interest. I believe this will soon be the policy of the government and of one's own IRB and RCC. I have chosen to remove any doubt of conflict and allow myself to continue performing research in what I believe to be the most ethical of standards. I believe others will soon have to choose either to retain their stock options and forgo clinical research or to relinquish their stock or stock options and continue to pursue studies of clinical research. Although I do believe one can ethically receive monetary gains for their time spent working with industry in the development of pharmaceuticals and devices, and perform clinical research in an unbiased fashion, the reality is that it will be increasingly difficult to do so within the boundaries of regulations set forth by the government and academic centers, and more critically, while maintaining the trust of the public.

Although the majority of conflicts that are evaluated may be financial, there are other more subtle research conflicts of interest, such as conflicts of conscience and conflict of commitment.² A conflict of conscience occurs when an individual's own personal beliefs interfere with their ability to perform research. Examples of this would be an investigator who is an animal rights activist and is asked to be involved in animal research, or religious beliefs that would preclude an investigator from performing stem cell research. Could an individual's personal or religious belief interfere with the integrity of the research? There are no federal regulations regarding this type of conflict. And though rare, these types of conflicts do occur and need to be brought to the attention of an individual's own IRB or RCC. A conflict of commitment exists when a physician's outside interests or relationships

with industry compete for time and effort with the investigator's work for their institution. A researcher who performs work for industry instead of their institution's research can be difficult to discover and regulate. Again, there are no federal guidelines regarding conflict of commitment; however, many institutions are developing their own regulations for conflicts of commitment. One example is Duke University's Office of Research Support, which states in their policy, "A conflict of commitment can be said to exist when a member of the University community has a relationship that requires a commitment of time or effort to non-University activities, such that an individual, either implicitly or directly, cannot meet the usual obligations to the University."³

Finally, there can be institutional conflicts of interest.⁴ Here academic centers can have a potential conflict if they receive grants for research from companies with a vested interest in the outcomes of research. An example would be a brewery donating money to an institution to study alcohol addiction, or a medical device company donating large sums of money for a new cardiac care unit, while the institution performs clinical research with the company regarding cardiac devices. In these circumstances, it may be difficult for the investigators to remain impartial in their work when the sponsorship comes directly from industry to the academic center. Bernard Lo, Professor of Medicine at the University of California San Francisco, has written extensively about the relationship between medicine and industry, which was highlighted in a recent editorial in the *New England Journal of Medicine*, entitled "Serving Two Masters—Conflicts of Interest in Academic Medicine."⁵ In this he writes, "The mission of Academic Health Centers (ACHs) may diverge from that of for-profit medical companies in important ways (→Table 1). Whereas ACHs are driven largely by goals of deepening understanding of health and providing high-quality care, companies need to develop profitable new products." The academics medical centers' IRB, Compliance Committee, and Research Compliance Committee (if available) must ensure the integrity of the research being performed and ensure adequate measures and sanctions are in place to maintain the welfare of the patients involved in clinical research.

Industry-Sponsored Trials in Colon and Rectal Surgery

Over the past century, colon and rectal surgeons have performed clinical research with governmental, institutional, and industry support and sponsorship. Each has played a vital role in the advancement of treatments for colon and rectal diseases. When research is sponsored by industry, one should question the relationship of sponsor to the research project in question as discussed above. Who designed the research protocol? Was the research performed by physicians independent of the sponsor? Who had acquisition to, ownership of, and analysis of the primary data? Who was responsible for authorship of the manuscript and were industry sponsors allowed access to the manuscript before publication? All of these questions and more need to be carefully

Table 1 Missions of academic health centers and medical companies

Mission of academic health center	Mission of drug, medical device, or biotech company
Conduct basic research to understand the mechanisms of disease and human functioning	Develop new products that will generate profits for the company
Train graduate students and fellows to become independent investigators who can compete effectively for funding from the National Institutes of Health	Encourage graduate students and fellows to carry out research on the company's promising products for development
Promote evidence-based medicine and independent critical judgment by physicians	Develop marketing strategies to improve sales and profits
Provide cost-effective care to patients and achieve a profit margin from clinical care that can be used to subsidize other activities	Increase profits through increased sales of products
Improve public health, global health, and care for orphan diseases for which patients seek care at the hospital	Work on issues of public health and global health and on treatments for orphan diseases if it fits the company's business model or plan for charitable giving or enhances its reputation

Source: From Lo.⁵ Reprinted with permission of the Massachusetts Medical Society.

scrutinized by the researchers, societies involved with their presentation, clinicians interested in the research, and the editorial boards who review these manuscripts. I personally have been involved in several industry-sponsored research projects in a variety of different roles. These roles include that of principal investigator, co-investigator, a member of the American Society of Colon & Rectal Surgeons (ASCRS) Program Committee, ASCRS Program Committee Chairman, and ASCRS Awards Committee, as well as an editorial board reviewer for leading medical journals, and as a member of a sponsor's scientific review committee. In nearly all interactions, I have noted no conflict of interest except as my role as an editorial board reviewer. I have been fortunate to participate in some of the landmark research studies both with and without industry sponsorship. These include the COST trial comparing open and laparoscopic colectomy for curable colon cancer,⁶ an industry-sponsored prospective randomized trial comparing stapled hemorrhoidopexy to conventional hemorrhoidectomy,⁷ and as principal investigator in a trial comparing hand-assisted and laparoscopic colectomy.⁸ Each of these studies was performed with the highest of integrity, and when presented at our ASCRS annual meetings, each was the recipient of an award for clinical excellence by the Award Committee of the ASCRS. As principal investigator in a trial comparing hand-assist colectomy and laparoscopic colectomy, I had first-hand experience working with an industry sponsor. In this study, the investigators had control of study design, data acquisition, data analysis, and manuscript preparation. The sponsor provided funding to each of the investigator's institutions for support of the research, and did not seek to interfere with the conduct of the trial. When the manuscript was published, the journal added an editorial comment, which in part drew into question the relationship of the sponsor to the research. In the authors' reply, I welcomed the opportunity to explain the conduct of the trial and the need to continue industry-sponsored research.⁹ I believe the members of our society have worked well with industry to advance the field of colon

and rectal surgery without significant conflicts of interest. As governmental funding dwindles, collaboration with industry is essential to maintain and continue clinical research in the field of colon and rectal surgery. I believe the research can be maintained without bias or conflict of interest; however, this will mandate continued close scrutiny to ensure its integrity.

Incorporating New Technology

Incorporating new technology into one's practice is a constant challenge. Surgical techniques and technology continually evolve in hopes of benefiting our patients. How does one keep up with this? Where does one receive the training for new techniques and technology? Is it through society-sponsored courses, institutional-sponsored courses, colleague mentorship, or industry-sponsored events? In many circumstances, the answer is "all of the above." Much of this depends on the complexity of the new procedure or device and the potential for patient harm as a consequence of the procedure. In my own clinic practice over the past 15 years, examples of this have included, among others, the performance of laparoscopic colorectal surgery, stapled hemorrhoidopexy, collagen fistula plug insertion, endoscopic submucosal dissection, and most recently, sacral nerve stimulation for fecal incontinence. To incorporate these technologies, I have utilized all the methods of learning described above. Industry has played an important role in each of these new techniques and technologies that I have learned and have since taught to others.

The area of new technology and procedures with which I am most intimately involved would be minimally invasive colorectal surgery. Having been mentored by my colleague, Dr. Jeffrey Milsom while at the Cleveland Clinic, I assisted in my first laparoscopic colorectal workshop in 1997 at the Cleveland Clinic. Since then, I have assisted in more than 120 laparoscopic colorectal workshops at my own institution, and at regional society events, national society events, industry-sponsored events, and international society events.

Industry has played a vital role in supporting these courses. Without their sponsorship, many surgeons would not have had the opportunity to participate in these courses. Industry has collaborated with investigators, the medical societies, and with each other to advance the training and education of surgeons around the world. This has led to the standardization of teaching courses with outlines for these courses published in *Diseases of the Colon and Rectum* and *Surgical Endoscopy* in 2006.¹⁰ Although the adoption of laparoscopic colon and rectal surgery has been slow, it has been performed I believe with success and integrity. In reviewing the experience of surgeons coming to a weekend laparoscopic colon and rectal surgery workshop, roughly 60% of surgeons have incorporated laparoscopic colectomy into their practice with reasonable outcomes.¹¹ Although the overall adoption of laparoscopic colorectal surgery stands at less than 50%, it has not suffered the early deleterious results associated with laparoscopic cholecystectomy or laparoscopic bariatric surgery. This, I believe, is in part a testament to the training and education provided by the industry-sponsored workshops and the physicians who instructed them, whether they were held at society events, regional events, institutional events, or industry-sponsored events. There are many potential ethical dilemmas in teaching new technologies and procedures to surgeons. This was recently highlighted in an article on "Issues in Surgical Ethics" by Wall et al.¹² The article focused on the dilemma of teaching natural orifice surgery techniques to practicing surgeons. The authors concluded "Laparoscopic techniques represent a major paradigm shift in modern surgery, and the lessons learned from training surgeons in these techniques should not be lost as other new technologies are introduced. With every novel surgical approach, patients have the opportunity to benefit from improvements over the standard of care; however, patients are also at risk of harm from surgeons who practice these techniques without adequate training. The surgery community has an obligation to ensure patient safety as well as benefit when new procedures or techniques are introduced. That obligation means that leaders should teach these techniques adequately, credentialing bodies should require specific competencies before allowing surgeons to use these techniques, and surgeons in training should make sure that they are comfortable with these techniques before using them on patients."¹²

Industry and Our Society

Industry has also played an important role within the American Society of Colon & Rectal Surgeons. Industry supports our annual meeting, symposia, workshops, the training and education of our surgical residents, the Research Foundation of the American Society of Colon & Rectal Surgeons, and our journal, *Diseases of the Colon & Rectum*. The ASCRS could not function solely on the income generated by the annual dues without industry sponsorship. The collaboration between industry and our society has been mutually beneficial. The highlight of this relationship I believe is the unrestricted support given to the Research Foundation of the ASCRS. This has allowed for the financial support of research

vital to our profession without conflict of interest. I hope and believe this collaboration will continue. How industry will continue to support our annual meetings and symposia in the future remains unknown. It is my hope that our mutually beneficial collaboration will allow us to continue to support the education and training of physicians and professionals in the field of colon and rectal surgery with the least potential for conflict of interest. Balancing this relationship with the utmost integrity and transparency is essential to our society's future success.

Conclusions

As we move further into the 21st century, it will become increasingly vital to maintain the integrity of clinical research while still fostering the fruitful relationships with industry. This applies to the individual physician, the academic health centers, and our professional societies. We cannot develop new therapies, devices, or procedures without collaboration with our industry partners. I believe the work performed by colon and rectal surgeons has met the standard by which other health professionals can hope to achieve. But I also recognize that this standard will continue to rise, as public, institutional, societal, and governmental scrutiny rises. As Bernard Lo wrote, "The public grants the medical profession considerable discretion in setting its own standards because it trusts that physicians will place patients' interests ahead of their own or those of third parties. To maintain this trust, AHCs should take the lead in addressing conflicts of interest in medicine, rather than merely responding to government requirements and adverse publicity about troubling cases. Taking the initiative will promote a culture of accountability and a commitment to professionalism."⁴ In their roles as clinicians and researchers, physicians tackle difficult, complex problems, clarify countervailing interests and values, make tradeoffs explicit, develop innovative approaches, and rigorously analyze the advantages and disadvantages of various options. Physicians should apply these skills to help improve conflict-of-interest policies for AHCs and professional societies."⁵

References

- 1 Federal Register / Vol. 76, No. 165 / Thursday, August 25, 2011. Rules and Regulations. Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>. Accessed August 31, 2012
- 2 Conflicts of interest. Available at: August 31, 2012 <http://ori.hhs.gov/education/products/RCRintro/c05/2c5.html>. Accessed August 31, 2012
- 3 Duke University Office of Research Support. Conflict of commitment. Available at: <http://ors.duke.edu/orsmanual/conflict-commitment>. Accessed August 31, 2012
- 4 U.S. Institute of Medicine Committee on Conflict of Interest in Medical Research, Education, and Practice. Institutional conflicts of interest. In: Lo B, Field MJ, eds. Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: National Academies Press; 2009:216–229. Available at: <http://www.ncbi.nlm.nih.gov/books/NBK22934>. Accessed August 31, 2012

- 5 Lo B. Serving two masters—conflicts of interest in academic medicine. *N Engl J Med* 2010;362(8):669–671
- 6 Clinical Outcomes of Surgical Therapy Study Group. A comparison of laparoscopically assisted and open colectomy for colon cancer. *N Engl J Med* 2004;350(20):2050–2059
- 7 Senagore AJ, Singer M, Abcarian H, et al; Procedure for Prolapse and Hemorrhoids (PPH) Multicenter Study Group. A prospective, randomized, controlled multicenter trial comparing stapled hemorrhoidopexy and Ferguson hemorrhoidectomy: perioperative and one-year results. *Dis Colon Rectum* 2004;47(11):1824–1836
- 8 Marcello PW, Fleshman JW, Milsom JW, et al. Hand-assisted laparoscopic vs. laparoscopic colorectal surgery: a multicenter, prospective, randomized trial. *Dis Colon Rectum* 2008;51(6):818–826, discussion 826–828
- 9 Marcello PW, Milsom JW, Fleshman J, et al. Response to editorial on hand assisted vs. laparoscopic colorectal surgery. A multicenter randomized trial. *Dis Colon Rectum* 2008;51:818–827. *Dis Colon Rectum* 2008;51:828
- 10 Fleshman J, Marcello P, Stamos MJ, Wexner SD; American Society of Colon and Rectal Surgeons (ASCRS); Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Focus Group on Laparoscopic Colectomy Education as endorsed by The American Society of Colon and Rectal Surgeons (ASCRS) and The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). *Dis Colon Rectum* 2006;49(7):945–949
- 11 Ross HM, Simmang CL, Fleshman JW, Marcello PW. Adoption of laparoscopic colectomy: results and implications of ASCRS hands-on course participation. *Surg Innov* 2008;15(3):179–183
- 12 Wall AE, Puppala VK, Kodner IJ, Angelos P, Keune JD. Issues in surgical ethics: teaching natural-orifice transluminal endoscopic surgery techniques to practicing surgeons. *Surgery* 2012;151:484–487