THE ACADEMIC SURGEON AND INDUSTRY

Larry R. Kaiser, MD

Academic surgeons should be aware of the tremendous potential that exists to partner with private companies on projects relating either to basic or clinical research. This is particularly timely now because many of these companies are experiencing unprecedented growth and market valuation. The development of these relationships requires knowing who to deal with as well as how to negotiate. Most academic medical centers have individuals who have expertise in developing sponsored research agreements, and young investigators should take advantage of this expertise. (*J Thorac Cardiovasc Surg* 2000;119:S29-32)

The first question often asked by young surgical investigators is “Why partner with industry at all?” Most young investigators are under the impression that only the “hard money” (ie, National Institutes of Health [NIH]) money, counts when one is seeking academic advancement. In reality this is not the case, but it is the easiest source of funding to track, and the indirect costs that flow to the institution usually are significantly higher when the government is the granting agency. Thus government money (and by this we usually are referring to NIH money) is usually preferred by academic institutions. However, we all must recognize that government support for research is extremely competitive and is likely to become less available in the coming years, especially for “part-time” investigators like surgeons. Despite NIH talk of the desire to fund translational research, money for these types of projects is extremely tight, and the key for successful funding remains hypothesis-driven, mechanistic work. Translational research projects often fall short on mechanistic specific aims, the investigators preferring instead to look at outcomes of various interventions.

In a recent report from the American Medical Association Council of Scientific Affairs,¹ which investigated clinical research, there were several conclusions that must be scrutinized closely by all academic institutions. The Council concluded that future NIH budgets likely will remain constant, at best, and thus additional

dollars to support clinical research cannot be expected. They also noted that traditional financial support of clinical research in academic medical centers through cross-subsidization (ie, the use of clinical revenue) is threatened by competitive pressures from managed care. This, in addition to the loss of patients, denial of reimbursement and competition with managed care organizations, have placed academic medical centers under unprecedented pressure. Despite these pressures, unsponsored clinical research, defined as that not directly grant supported, continues at many academic medical centers. However, the report continues, partnerships between public and private entities serve to maximize productivity.

Weissman and colleagues² recently looked at the role that market forces play on unsponsored research in academic medical centers. He found that approximately 75% of medical school faculty members were involved in some unsponsored research effort. The proportion of direct cost budgets supported by institutional money was smaller in those medical schools in more competitive markets, especially among the most research-intensive institutions. This study also noted, however, that much of the unsponsored research led to publications, grants, and patent applications. They concluded that, as the market becomes more competitive, faculty members may have to work extra hours to do what may be covered by “protected time” in less competitive markets. Because academic output is essential to promotion, these faculty members may have to do “whatever it takes” to achieve their career goals.

With the stock market achieving unprecedented levels of growth and many companies setting records for earnings over the past few years, the corporate world is where the money resides; and there seems to be a renewed emphasis on the part of many of these companies to fund the research of investigators outside of the company. Often these funds are more readily available

From the Department of General Thoracic Surgery, Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine, Philadelphia, Pa.

Address for reprints: Larry R. Kaiser, MD, Department of Surgery, Hospital of the University of Pennsylvania, 3400 Spruce St, 4 Silverstein, Philadelphia, PA 19104 (e-mail: kaiser@mail.med.upenn.edu).

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to fund clinical research questions than are funds from NIH. Most companies are interested in specific targeted research questions and are looking to deal with investigators who possess expertise in the company's area of interest. These monies may be more readily obtainable by junior investigators, especially when there is the backing of a well-established investigator as the sponsor.

Competing interests of academic surgeons and industry

It is safe to say that in the past, and not necessarily the distant past, financial relationships between academic institutions and industry to support research were considered taboo and perhaps even "antiacademic," especially by the more elite institutions. Clearly, there has been a paradigm shift because now these relationships are sought by academicians who are eager to partner with the deep pockets of an industry partner. Both parties in the relationship bring something significant to the table; I will deal with the academic surgeon as the representative of the academic institutions. Most of the relationships between universities and industry are forged by individual investigators who are looking at specific problems that interest a particular company. In beginning a relationship with a for-profit company, the academic surgeon brings a desire to advance knowledge and improve patient care as global objectives and a need to aid in his or her own academic promotion and reputation among colleagues as individual objectives. The company's overall primary objective is to maintain or increase profits, with a secondary objective to improve patient care. The profit motive is always in the background and rightly so, but this does not necessarily have to impede a research effort. The academic investigator must understand that any decisions made by the company (and this includes decisions relating to who and what to fund) have to be made with the bottom line kept in mind. Most companies establish priorities that relate to areas where money is to be spent, recognizing the potential impact of these dollars in the long run.

Where do I find an industry partner?

A common concern expressed by many academic surgeons deals with how one identifies an industry partner and how one develops the relationship. We have found that scientific meetings often serve as an ideal forum at which representatives of industry and academia can come together. Some of these meetings actually may be sponsored by corporations that are interested in the exchange of new ideas. Other meetings that are directed toward specific topics also tend to bring out industry representative who may be involved in similar work.

Whereas in the past, it was distinctly uncommon to see scientists from companies engaged in similar work at meetings such as these, now they almost outnumber those investigators from academic institutions. One such meeting is that dealing with gene therapy of cancer that is held in November of each year in San Diego, California, and is sponsored by the Kimmel Cancer Center at the Scripps Medical Institutions. Young investigators can mingle with representative from various companies at meetings such as this, networking to foster collaborative efforts. One cannot overestimate the importance of this type of networking for a young investigator. It has been the policy of our laboratory to send at least 4 of our people every year and always to have several abstracts on the program for presentation. Other potential sites for meeting corporate representatives include the larger meetings at which multiple exhibitors are present, such as the American College of Surgeons or the American College of Chest Physicians. Younger investigators should be aware of more senior investigators at their home institutions who may have contacts within certain companies.

What you as an academic surgeon bring to the table

There is a symbiotic relationship that exists between industry and academic institutions. Seemingly, they need us as much as we need them. What does the academic surgeon bring to a relationship with a private company? First, and foremost, the academic surgeon offers the company credibility and independent confirmation of research findings that the company may have obtained. Not to be underestimated is the manpower that the academic surgeon brings because many companies, especially smaller ones, do not have the necessary capacity to conduct all necessary preclinical studies or clinical studies. Second, and perhaps as important, the academic surgeon has control over patients who are potentially available for clinical studies and patient material such as tumor tissue. Finally, companies are looking for expertise outside of what they possess, and academic surgeons admirably fill this role. The relationship between the academic surgeon and a company usually is easier to consummate if the investigator already has some expertise in the area of the company's interest. Often someone from a given company will contact an individual investigator either after hearing work presented at a meeting or seeing a published article. This has especially been the case in the field of gene therapy; many start-up companies have benefitted from investigations conducted at an academic institution or when these newer companies have gone looking for additional expertise.

Resources available at academic institutions to foster industry collaborations

Before beginning negotiations with a private company that wishes to support a research effort, it behooves the academic surgeon to seek out available resources within one's own institution. What is available varies from institution to institution, but all institutions have some capability to deal with private industry support for research, so-called sponsored research agreements (SRAs). Many institutions may have an Office of Technology Transfer that is perhaps more involved with the profit potential of new technology developed by faculty members, but this type of work may be the genesis of a relationship with a private company or the beginning of a start-up company (Fig 1). There may exist an administrator who deals specifically with industry relationships, such as the situation we have at the University of Pennsylvania in which we have a Senior Vice-President for Venture and Industry Relationships. The particular individual who holds this position has a Master of Business Administration degree and is a certified public accountant. Likely there are other faculty members at a given institution who have successfully established collaborations with industry, and these individuals should be able to provide support and expertise.

SRAs

Our own experience in initiating and developing an SRA is illustrative and brings up a number of points. It is particularly important to work through the Office of Technology Transfer because that office has the expertise to negotiate these arrangements much more so than any individual investigator. Because as academic surgeons we act as representatives of the university, the university must be a party to any and all agreements, and thus the university assumes some liability. Because of this the university requires certain clauses to be included in any agreement with an outside party. These items vary from university to university, and some universities may even let investigators negotiate on their own, with the university not being included as a party. Mostly the university wants in on these arrangements because of the indirect costs that go to the university as part of any SRA, and most SRAs require the signature of an appropriate university official. Any given SRA may take up to 1 year to successfully complete the agreement between the university and the private company. It goes without saying that the funds from an SRA should be used solely for the purpose intended.

We have certain needs and interests as academic surgeons that need to be protected. As academic researchers, our currency is publication. From the

Fig 1. Organization of a typical Office of Technology Transfer.

standpoint of advancement professionally and promotion academically, timely publication of significant research findings is of paramount importance. This differs significantly from the mission of a private, for-profit company for which profit is always the underlying motive and publication may be a significantly lesser concern, especially if their patent position is weak on a given technology. It is naive to think that any company is engaged in research for any sort of altruistic motive. Helping mankind most certainly is a part of the thinking of most biomedical companies, but they prefer to do this while making money. Academic researchers cannot be in the position of having to agree to a "gag clause" that prevents the unauthorized release of any findings. It is reasonable that a company has the right to review an article before it is published; it is not reasonable for a company to control what a researcher can publish. It is because of these concerns that an Office of Technology Transfer is so important; those individuals engaged in the development of these agreement on a daily basis serve to protect individual investigators and the university. This office also must be involved in agreements between the private company, the university, and the individual investigators with regard to the intellectual property rights to new technology that is developed during the course of an SRA. Finally, institutional overhead often is a sticking point because most companies do not want to pay the same rate negotiated by a given university with the NIH. Most seek to pay significantly less in indirect costs to the university, but many universities take a hard line with these negotiations.

In any SRA, we as academic surgeons must not lose sight of the primary goals of protecting the patient's health, teaching and advancing knowledge despite pressure to seek funds from what were once considered nontraditional sources. Soliciting research funds from

private companies must always be secondary to patient safety and integrity of research. Of course, it remains the responsibility of the investigator to assure the integrity and honesty of the research.

The NIH and industry

The NIH has recognized the role that private industry may play in fostering scientific initiative and advancement and has developed 2 programs of which academic surgeons should be aware. The first, the Small Business Technology Transfer Program is designed to stimulate and foster scientific innovation through cooperative research carried out between small business concerns and research institutions. A second aim of this program is to increase private sector commercialization of innovations derived from federal research and development, which obviously includes research funded by government funds. The second program, the Small Business Innovation Research Program encourages small businesses to explore technologic potential and provides incentive to profit from commercialization. There is a specific percent of federal research and development funds reserved for small business, mainly to support the critical start-up and development stages. Academic surgeons partnered with industry may benefit from both of these programs. More specific information regarding these innovative government programs may be found on the NIH web site (www.nih.gov).

Implications of industry-sponsored research

As academic surgeons, our integrity, character, and intellectual honesty are of paramount importance. Despite the importance of the profit motive to private industry, an academic researcher must not be influenced by a similar profit motive. A surgeon who personally benefits financially while conducting a research study is walking an ethical tightrope, especially if there is not full and complete disclosure. Recently, evidence has emerged that research outcomes can be influenced by those who fund the research.³ This particular study involved calcium-channel blockers. Full disclosure must be made if the investigator has a financial interest in the outcome of a project. This disclosure should be

made both to one's colleagues and peers and to subjects recruited for the study. This disclosure must be a part of any published work and should be made at such time as the work is presented at a research meeting. All conflicts of interest must be fully disclosed. Without such disclosure, our intellectual honesty is subject to questions and all credibility ultimately may be lost. One cannot overestimate the importance of complete disclosure in an era when we are encouraging and seeing more industry-sponsored research. In my opinion, and that of many others, the safest course for the academic investigator is to have no financial interest in the company that is supporting the research.

Conclusions

All academic surgeons engaged in research endeavors should be aware of the potential and desire on the part of private industry to fund either basic (usually translational) or clinical research. Often this type of support leads to the preliminary data necessary to be able to compete for NIH funding, publication, and patent applications. There should be no stigma attached to industry funding as long as there is full and complete disclosure of the relationship between the investigator and the company. Partnerships between academic surgeons and industry can lead to rapid advancement in knowledge and improvements in therapy and thus should be encouraged. It is incumbent on young surgeons to seek out expertise within their own institutions to aid them in developing these relationships.

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