Entrepreneurship in the Medical Academy
Possibilities and Challenges in Commercialization of Research Discoveries

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An entrepreneur in the broadest economic and social sense is a self-employed individual who has autonomy, controls his affairs, and is willing to take risks. Based on this definition, sociologists such as C. Wright Mills have argued that medicine is the apotheosis of an entrepreneurial profession in the United States. Both ideologically and economically, self-sufficiency remains a hallmark of the medical profession, notwithstanding an ever-increasing reliance on technology and the ever-expanding influence of regulation on medical practice. Charismatic authority, according to Weber, is another essential attribute of the professional persona: possession of a complex body of knowledge that can directly affect the health and survival of an individual accounts for the physician’s historically unquestioned leadership, especially under conditions of physical and emotional stress. The legitimacy of the profession grants this charismatic authority; yet this authority can be compromised if it is not frequently validated by physician behavior.

Risk-taking self-interest can present a major challenge for charismatic (as well as traditional legal) authority, and requires careful oversight by every profession, but especially by the medical profession. A unique aspect of medicine is that it optimally balances the dynamic between charisma and entrepreneurship. In contrast to the clergy, who are much more charismatic than entrepreneurial, and attorneys, who, in the extreme, are more entrepreneurial than charismatic, physicians have historically struck a balance between these two important characteristics that has given us a unique position in society: we, in general, achieve financial independence and stability throughout our professional lives, while at the same time we engender the trust of our patients and guard the public health. These are noble sentiments, to be sure, but I believe they are highly relevant to this discussion.

Over the past 20 years, there can be no doubt that entrepreneurship has expanded from a defining characteristic of the individual physician to an influential precept of contemporary academic medical centers. And a right-thinking person can justifiably ask, “Why not?” The openness of the academy has historically offered great opportunities to commercial ventures that have realized significant profits for the pharmaceutical and device industries generally without substantive benefit to faculty or universities. Only in the last 20 years has the academy realized that the source of a commercial idea (ie, the faculty inventor and the sponsoring institution) should share with the developer of that idea (ie, industry) in its human application: it is beneficial to the inventor, the institution, and the entire academic enterprise.

At first blush, the entrepreneurial bond between academic medical centers and industry seems quite reasonable. Academic physicians and the pharmaceutical and biotechnology industries have a shared interest in the advancement of medical knowledge to conquer disease. The raw intellectual talent of academics can quite naturally link to the strong commercial skills of industry to lead to successful product development. There are, of course, numerous examples of success within this paradigm with which we are all quite familiar. Ideally, these entrepreneurial partnerships between academics and industry benefit all parties: the academic inventor and medical center realize financial benefit, and gain broad recognition for the contribution; the industry partner becomes profitable, and meets the expectations of its investors; and the patients treated with the invention have better outcomes than they would were earlier therapies used.

One must, however, exercise caution in forging this bond between academics and industry—not to limit the chance for success, but to deal appropriately with the occasional but inevitable failure. There are clear differences in the ethics and ethos of the medical profession and industry that can become irreconcilable, especially when partnerships between them do not lead to the expected outcomes. The primary ethic of the medical profession is to promote the patient’s best interests, whereas the primary ethic of industry is to promote profitability. Parsons first pointed out that while businessmen are self-oriented, physicians are collectively-oriented, and herein lies a potential conflict of principle. Although in practice this distinction is rarely clear-cut, this difference in principle can lead to tensions between medical and industrial partners that cannot be adequately relieved without the compromise of one or both of them, which renders the physician unable to meet obligations to patients, or which renders the industry partner unable to meet obligations to investors.

The difference in ethos between academics and industry sets the stage for this potential conflict of principle. Physician-scientists espouse the ethos of caution. Ideally, we assume the null hypothesis in each experiment we perform and compare an observed outcome with the expected outcome of no meaningful effect. We are certainly passionate about our ideas and the scientific hypotheses that they generate; however, ideally, we are our own worst critics who

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must be >95% certain of the experimental results before we publically promulgate our findings. Contrast this with the ethos of industry in which the perception of the investor is an important determinant of success and survival. This is especially true in early-phase start-up companies that do not yet have a commercially viable product. Engaging investors at this phase of corporate development is a matter of promoting an idea, and the earlier in the process the investor supports the idea, the greater the potential value that will be added to the investment. Thus, when an academic physician-inventor moves from the academic to the industrial world, he or she must endeavor to maintain the highest level of rigorous scientific scrutiny, and at the same time promote concepts that are often scientifically underdeveloped to ensure that sufficient investment is made in the promise of an idea. Ideally, the academic scientific world is one in which conceptual passions are held in check by rational observation, whereas the industrial scientific world is one in which conceptual passions logically presented are their own currency. This essential difference in ethos can, and very frequently does, lead to conflicts that offer great challenges to the entrepreneurial academic physician who wishes to negotiate successfully in both arenas.

There are many types of conflict that stem from this difference in institutional ethos of which all parties must be aware. The intellectual freedom of the academy dictates that ideas should be openly discussed and disseminated. Publication of scientific results without restraint is critical to the academic process, which includes faculty evaluation for promotion. By contrast, industry rules dictate that intellectual property must be protected, which, by definition, will initially limit the unbridled dissemination of research findings. Although this is not an irreconcilable conflict, it can lead to a less open, more secretive working environment within the academic medical center. In practice, academic medical centers guard the freedom to pursue and disseminate knowledge, as this freedom is a core tenet of the academic mission. Yet, as Streiffer has argued, there may be value in an assessment of the relative benefits of selected restrictions and in the precise definition of the types of activities protected by academic freedom of inquiry and open discussion.

Conflict of commitment is another important challenge that must be addressed directly to ensure that time spent on academic pursuits is distinctly defined as different from time spent on corporate pursuits. Conflict of commitment may also influence the training environment of a research laboratory, especially when trainees are asked to participate in company-related research; doing so must include full disclosure by the academic entrepreneur to ensure that the trainee understands the extent and risk of this conflict and its potential impact on academic productivity and recognition.

The most difficult conflict for the academic entrepreneur is, of course, that of financial conflict of interest. This conflict strikes at the very heart of the physician-patient relationship because it is one that tests, strains, and on occasion breaks the bond of trust between physician and patient. The key challenge is to protect the patient from the physician-investigator’s unproven scientific hypothesis before that hypothesis has been objectively tested. This challenge is magnified by the requirement that the physician-entrepreneur be an advocate for the scientific hypothesis, and promote its acceptance by the practice community to meet shareholders’ expectations and fiduciary responsibilities to them. Failure to manage this challenge carefully and openly can taint the public perception of the academic physician-entrepreneur, and jeopardize the bond of trust between physician and patient.

Financial conflict of interest is generally viewed as the most serious form of conflict of interest with which a physician-entrepreneur (or any academic medical center employee) can be confronted. The reason for the overarching importance of this form of conflict likely lies in the power and independence that financial gain permits, and in the psychological symbolism of money as a means to security and freedom and as a representation of self-esteem. Achievemen- of financial success in a capitalist society is not, of course, suspect per se; rather, in the zero-sum game of constrained economies, the simple view that one’s success necessarily occurs at the expense of others often holds popular sway. This psychosocial backdrop, coupled with the physician’s mandate to protect the patient’s best interests, can set the stage for a serious perceived, if not real, conflict of interest. In the worst case, the dependent patient can no longer trust the physician to protect his or her interests, and the authority of the profession is irrevocably compromised.

Although most physician-entrepreneurs and their academic medical center leaders accept this explanation for the overwhelming importance of financial conflict of interest, it is interesting to note that a recent study showed that patients in cancer research trials were not worried about financial ties between their physicians and the pharmaceutical industry. In fact, many felt that these ties provided access to unique experimental therapies that could benefit them. It is important to point out that these patients had life-threatening illnesses. Thus, the aforementioned study can be conservatively interpreted as an affirmation of the institutionalized charisma of the physician as last hope and healer, rather than as evidence for a uniform lack of concern about financial conflict of interest by experimental subjects treated by physicians with vested interests in the outcome of a trial. Whether patients with chronic or less serious acute illnesses would have the same view of financial conflicts of interest remains an unanswered question.

The academic community has come to recognize the importance of these challenges to academic-commercial partnerships and, in general, takes pains to avoid or manage the conflicts that derive from them. It is important to point out, however, that there are two prevailing and essentially polar views on these relationships that frame an ongoing debate on their value and risk to the academic medical center. One perspective, which is espoused by Angell10 and Kassirer11,12 among others, holds that many conflicts—real or perceived—invariably arise in academic—commercial partnerships, and invariably compromise academic integrity as a result of unethical behavior (eg, overstatement of the value of a marginally useful therapy) or scientific misconduct (eg, failure to report an adverse drug effect in a clinical trial, or falsification of basic research data to enhance the value of a
health.14 The implication of this viewpoint is that ties to entrepreneur-development of a powerful anticommercial advocacy move-
ment that threatens to prevent, or sorely limit, entrepreneur-
ship within the academy and its derivative benefits to human health.14 The implication of this viewpoint is that ties to industry automatically identify a physician as of suspect unethical behavior, if not frank misconduct. The lay press and professional journal editors alike perpetuate this message by inductive insinuation from egregious case example that physician-entrepreneurs simply cannot satisfy their ethical obligations to patients.

The asperity of this perspective and the regulatory atmosphere it has spawned in part reflect a moralistic and somewhat defensive overreaction to highly publicized examples of egregious behavior. It is difficult to know whether these individual events are representative of a far more prevalent group of undisclosed inappropriate behaviors, or are anomalies in an otherwise productive and ethically sound entrepreneurial academic environment. We journal editors have much to learn from these highly publicized individual cases, as Krumholz has pointed out15; however, in my view we must approach them thoughtfully and carefully, limiting our skepticism to a review of the science rather than of the scientist or of the entrepreneurial context within which he or she operates.

Viewed dispassionately, the truth likely lies between the poles of these arguments—physician-entrepreneurs are neither thoroughly altruistic nor thoroughly self-interested: It is naïve to assume the former and defamatory to assume the latter. Recognition that physician-entrepreneurs and their commercial partners are simply human with commensurate strengths and foibles should give us the insight to expect ethical behavior from the majority but provide the necessary guidance and oversight to limit unethical behavior by the minority.

In view of these many challenges, one may justifiably ask whether entrepreneurship should be encouraged at academic medical centers. My personal answer to this question is most definitely yes because I believe the benefits to all parties far outweigh the disadvantages. Academic physician-entrepreneurs can realize firsthand the practical application of their scientific observations and theories, they are given novel opportunities to fund their research efforts, and they often gain access to costly, cutting-edge technologies that they otherwise would not be able to afford in the conventionally funded research program. The disadvantages are, however, real, and must be dealt with openly to optimize the benefits and minimize the risks of entrepreneurship in the academy. Academic medical centers that foster entrepreneurship must guard against the scientific bias of its physician-entrepreneurs, protect human subjects from the scientific passions of physician-inventors, limit if not eliminate terms of partnerships that threaten academic freedom, encourage the transfer of leadership at the appropriate time in a commercial enterprise from the faculty-inventor to the company development team to limit the diversion of creative academic energies, and provide the appropriate education and support for faculty members who wish to embark on an entrepreneurial journey. Ties to industry that entail, or can be perceived to pose, a conflict of interest must be fully and transparently disclosed to all relevant parties, and guidance must be provided to those parties, be they patients, research subjects, trainees, or journal readers, to facilitate their understanding of the implications of these relationships for each of them. Smith and Korn have argued that the American research university is experiencing a “crisis of accountabili-
ty,”16 which will require transparent, consistent, and reliable management of their institutional and individual faculty relationships with industry for resolution; in some cases, these relationships should be prohibited if the potential for personal gain clearly runs the risk of a compromise of patient care. Those charged with the oversight of these relationships must take as guiding principles the protection of the patient and maintenance of essential academic values, but must do so in a way that at the same time encourages rather than proscribes these valuable partnerships. By addressing these challenges successfully, the academic medical center can create an atmosphere that fosters entrepreneurship without compromising its core principles and can offer the promise of successful development of novel therapies that advance knowledge for the good of the public health.

Thomas Sprat, Bishop of Rochester and Dean of Westmin-
ster, wrote in his History of the Royal Society that “invention is a heroic thing and placed above the reach of a low and vulgar genius. It requires an active, a bold, a nimble, a restless mind [that must overcome] a thousand difficulties with which a mean heart would otherwise be broken.”17 The development of the heroic academic physician-entrepreneur must be encouraged, but the physician must also be protected from unbridled passions and conflicts to ensure that the process of medical invention remains a publicly credible and, ideally, laudable element of our time-honored profession.

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References

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