

## Medical Schools at the Millennium: Do Some Partnerships Cost Too Much?

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**Key words:** ethics, conflict of interest, university-industry partnership

IMAJ 2002;4:742-744

Over the last several years it has become increasingly fashionable to speak of collaboration and partnership in all fields, including medical education, research and practice. I am one of those who favor such movement, believing that as health professionals we are informed by our practice community, their needs, their perceptions and their experience; as educators we are informed by our students; and as researchers we should ethically be informed by our subjects. I also believe that the incursion of the notion of accountability between partners is consistent with the idea of a self-governing profession. However, I am increasingly troubled that some partnerships may and have incurred negative consequences, particularly when they are at the corporate or institutional level.

The historical missions of universities are the discovery and dissemination of knowledge. To that end, universities provide independent safe havens for scholars with systematic merit-based career progression. Historically, there has been the expectation that universities remained apart from the marketplace, applied science was devalued relative to pure science, and the language of patents protection and profit had no place in the university.

Yet the reality is that universities and medical schools face fiscal constraints that interfere with the historical mission, such that administrators are exploring options to make it possible to do more than simply survive. Costs for education (especially salaries for faculty and staff) have increased. Newer approaches, such as Problem-Based Learning, entail intensive faculty time. There are fewer community-based physicians willing to donate time to teach as their practice incomes have decreased, while full-time faculty have to compete for a decreased pool of peer-reviewed research funds. Partnerships become attractive in order to pay the educational, research and administrative bills.

Similarly, the pharmaceutical industry has faced constraints in recent years. Industry requires a pool of clinical trialists in order to move new products through the lengthy licensing process. With increasing numbers of drug benefit plans in place in jurisdictions, industry needs to ensure that products are included in formularies. Market share demands that practitioners prescribe particular products, yet the environment is encouraging decreased prescribing and the use of older less expensive agents, even going so far as providing funds 'saved' by decreased prescribing to physicians

through their professional organizations, as in New Zealand. It is essential that industry has access to respected investigators who will act, overtly or by implication, as spokesmen for products. Clinical Practice Guidelines can become a vehicle for increasing prescribing; compliance research is seen as helpful to industry; and research that encourages lower thresholds for diagnosis of hypertension, diabetes and cholesterol potentially results in increased sales. The potential for conflict of interest when partnerships are formed between faculty members and industry is evident.

In reaction to the potential for perceived if not 'real' conflict of interest, universities are struggling with what safeguards should be introduced to protect institutions and investigators. Marcia Angell, former editor of the *New England Journal of Medicine*, was very outspoken regarding conflict of interest [1]. More recently, we have seen editorials and discussion papers that recommend minimal engagement of scientists in spin-off companies, another source for potential conflict [2-5].

Even the 'good' partners, i.e., the non-profit ones – such as government, community agencies, hospitals, and sister universities and medical schools – may engender conflicts and 'cost too much'. Governments see medical schools as sources of information for policy development, often concerning whether to purchase new technology or to contain drug costs. Foundations may create strategic initiatives to encourage researchers to answer particular questions – a different relationship than traditional investigator-driven research. Communities expect assistance from universities in asking and answering questions of relevance; these may include special interest communities such as aboriginal communities, or breast or prostate cancer patients. In turn, universities need community support as well as government to obtain increased funding or, more recently, to decrease the erosion of funding, and may engage with communities with the unspoken intent of gaining such support.

### So why should we partner?

Out of necessity, the funding from partners provides support for research and infrastructure for both research and education, and for the support of our students and faculty – all consonant with the academic mission. Towards these aims, the best partnerships are

with paying customers – other countries that will pay full costs of education for their students abroad, industrial sponsors, and government contracts. A second reason for partnering is that the current environment demands matching private dollars in order to obtain both federal and provincial grants for research and equipment.

It can be argued that there is an altruistic aspect to such partnerships, in that we contribute knowledge and expertise within our regional, national and international community. Social contribution is also invoked by those who argue for commercialization of research findings, in that investigators have an obligation to make basic research available for application to develop new drugs or new technology that will benefit the general population. The profit motive is translated to a social good, to patent protection and to an industrial partnership, which are seen as morally grounded, for the good of humankind.

### **What are the possible negative consequences of such partnerships?**

The research agenda to some extent has always been driven by the funders and the funding available. But if most young investigators come to depend on industrial funding, will that shape the questions they select for investigation – even if they believe that it will not do so?

Even those investigators who are able to juggle possible conflicts of interest may be seen to have conflict of interest, and thereby lose credibility. The same holds true for institutions: the public may have trouble believing that the drug company-named research facility does not give that company preferred status to the potential disadvantage of ‘the customer’.

Meanwhile, there are true competing aims between partners, whether they are industrial, government, or community partners. For-profit researchers or researchers hired by special interest groups may know the answers that they wish to find and may be tempted to suppress that which does not support the chosen position. At its worst, this can constitute scientific fraud.

The issue of ownership of data and analysis and control of publication has been debated by ethicists and researchers alike. This is a problem not only in corporate relationships but also for those of us who have worked with historically disadvantaged communities and who have attempted to develop participatory research relationships that give voice to participants’ views of the data, while maintaining intellectual autonomy as researchers.

However, these issues are especially apparent when we look at single-source sponsorship from the pharmaceutical industry. Studies have shown that sponsorship is associated with research outcomes favorable to a sponsor’s product, that unfavorable results may tend to be suppressed or under-interpreted, and that prescribing decisions may be influenced, wittingly or unwittingly [2–6]. Others counter that those who are most informed about a drug are able to design better studies. It has been shown that a sense of obligation may be engendered, which is one reason why companies invest in expensive gifts or weekend trips to attractive resorts to discuss research findings. Equally important is that the

public may perceive bias, even where no bias exists, and thus the university and its missions become tainted.

Let me give an industrial partnership example and another example that could be seen as morally above reproach – an attempt to give voice to an aboriginal community that was historically without voice.

The industrial example is that of a hematologist who had been engaged for many years in research on drugs to treat thalassemia, with publications in the *Lancet* [7] and the *New England Medical Journal* [8]. A 1998 paper on the long-term safety and effectiveness of oral iron chelation therapy with deferiprone was the controversial paper [9]. The pharmaceutical company that funded the research disagreed with the researcher’s conclusions and invoked a clause in the research agreement that would prevent publication of the findings for three years. However, the article was published and the researcher was subsequently dismissed from her post as division director by the hospital – in what she deemed to be punishment for her behavior. It was implied publicly by her supporters that pressure was exerted by the company on the hospital to get her in line or else face the consequences of loss of funding. Ultimately, after a bitter dispute, an external review and the payment of damages, the investigator was reinstated at the hospital, though those involved in the matter remain at odds.

It is interesting that the *New England Journal* article is accompanied by an editorial that raised questions regarding the validity of her conclusions [10]. Thus, it can be argued that the usual mechanisms of peer review in the published literature acted as the appropriate vehicle to raise scientific objections. But this is very different to agreements with industrial funding agencies, which could result in loss of trust by the public who may believe that findings that are unfavorable to the product are being suppressed.

The second example is a participatory action research project that involved university researchers from a university department of family practice, community-based family physicians, aboriginal health workers, and the members of an aboriginal community [11,12]. This community had previously been subjects of what has been termed ‘parachute’ or ‘helicopter’ research and, in common with other native communities, felt that they had been exploited. Community members had been angered by the publication of a book by an anthropologist who worked in the community as a teacher, but meanwhile, without consent, wrote a book that identified individuals. This resulted in refusal of research involvement for some years. Concomitantly, other aboriginal communities had been embarrassed by the publication of results demonstrating social pathology, at a time when land claims and control of health and social services were in contest and the credibility of aboriginal communities was very important. This forms the backdrop to the Code of Research that we adopted [13], which included assurance that no results would be published if objected to by the community health workers, acting as community representatives. The only objection raised was to the publication of details regarding native remedies, to which the investigators readily agreed. While no veto was exercised regarding substantive research findings, it could be argued that such an agreement in a partnership ‘costs too much’.

The final costs I want to draw attention to are time and backlash. It takes time to develop partnerships, whether it is with researchers from other disciplines or with communities. As one who has engaged in participatory action research, I estimate that it takes about a year to establish trust with a community to enable true collaboration. This is a substantial time commitment before any data collection can take place. And if the partnership is not sound and trust is broken, further research partnerships may be inhibited, as has occurred in aboriginal and poor communities worldwide. Even community-based physicians are resisting involvement, for example to recruit patients for clinical trials, unless they are involved in developing the research protocol or receiving the results as an educational product.

Do some partnerships cost too much? Potentially yes, though protection is afforded if there is careful attention to a written agreement at the outset that includes mechanisms for resolving conflict and if obvious situations of conflict of interest are avoided. As the lines between business and academe become blurred, it is essential that we ensure clarity in research relationships.

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