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Towards a solution to the controversy?

“The insistent questioners of mainstream practice will not go away and will not be silenced. They will trouble majorities. The wise goal is to promote understanding that can at least see to it that the troubling is creative and not merely disruptive.” (Martin E Marty, theologian)

vaccinationists, it is important to understand that they have deeply held beliefs, often of a spiritual or philosophical nature,¹¹ and these beliefs have remained remarkably constant over the better part of two centuries. The movement encompasses a wide range of individuals, from a few who express conspiracy theories, to educated, well informed consumers of health care, who often have a complex rationale for their beliefs, related to a “mixture of world views held about the environment, healing, holism ... and a critical reading of the scientific and alternative literature.”¹²

Vaccination is unique among de facto mandatory requirements in the modern era, requiring individuals to accept the injection of a medicine or medicinal agent into their bodies, and it has provoked a spirited opposition. This opposition began with the first vaccinations, has not ceased, and probably never will. From this realisation arises a difficult issue: how should the mainstream medical authorities approach the anti-

vaccination movement? A passive reaction could be construed as endangering the health of society, whereas a heavy handed approach can threaten the values of individual liberty and freedom of expression that we cherish. This creative tension will not leave us and cannot be cured by force alone.

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Working with the private sector: the need for institutional guidelines

Gill Walt, Ruairi Brugha, Andy Haines

Cooperation between academic institutions and the private sector does not always run smoothly. Gill Walt, Ruairi Brugha, and Andy Haines from the London School of Hygiene and Tropical Medicine point up the need for guidance on entering into partnership with a commercial partner and describe the school’s experience in formulating guidelines for its staff

London School of Hygiene and Tropical Medicine, London WC1E 7HT
Gill Walt
professor of international health policy
Ruairi Brugha
senior lecturer in public health
Andy Haines
dean

Correspondence to:
G Walt
gill.walt@lshtm.ac.uk

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One of the most striking changes in the research environment over the past 10 years has been the marked expansion of links between the private and public sectors. While certain research groups in universities and research institutes have long received some funding from the private sector, such sponsorship is growing and is often now described as “partnership.” The increasing frequency and complexity of interactions between research and industry suggest that institutions require policies, especially when dealing with potential conflicts of interest. A number of academic institutions, mainly in the United States, have developed policies and procedures to guide staff in developing relationships with the private sector (box 4), as have many of the organisations of the United Nations. Research institutions in the United Kingdom are beginning to look at this issue. For example, the Confederation of British Industry has collaborated with a number of bodies to produce general guidelines to better practice for industry and universities — *Partnerships for Research and Innovation*.¹ In this paper we argue that academic institutions, in consultation with their staff, should

Summary points

Links between the private and public sectors have expanded over the past decade

Such links are broadly welcomed, but the potential for conflicts of interest is a matter of concern

Conflict could affect research priorities; the quality, outcome, and dissemination of results; and public trust in science and research institutions

Draft guidelines on public-private collaboration cover prerequisites for considering a collaboration, terms and conditions of contracts, and screening and monitoring procedures

Such guidelines are needed if the academic community is to fulfil its privileges of “self governance and academic freedom”

develop guidance and ground rules for staff contemplating engagement with the private sector in order to make explicit the principles on which such relationships should be based, avoid potential conflicts of interest, protect academic reputation, and maintain the quality and integrity of the scientific outputs.

Why promote research ties between public and private sectors?

Although they are contested, reasons for seeking to strengthen ties between the private and public sectors include a belief that such ties are an inevitable outcome of technological change and an essential feature of the “knowledge” society. The British prime minister has been reported as saying, “In the knowledge economy entrepreneurial universities will be as important as entrepreneurial businesses, the one fostering the other.”² Another reason for closer collaboration between sectors is to harness private resources, reducing public expenditure. In the United States, industry funding of research and development is increasing steadily—up to \$2bn (£1.3bn, €2bn) in 1999.³ In the United Kingdom, according to data received from the Higher Education Statistics Agency, income to universities from industry, commerce, and public corporations rose from 11% to 15% between 1995-6 and 1999-2000. Partnerships are also recommended so that the public sector can learn from what are perceived to be the private sector’s superior management skills.⁴ The private sector has some overlapping interests in working more closely with the public sector—for example, to capitalise on research outputs and expertise, and to promote a socially responsible image.

Although many welcome the expansion of links between the private and public sectors, others are understandably cautious. These are new relationships, even social experiments, the very long term effects of which are difficult to predict. The concerns expressed over the current UK government’s promotion of private financial initiatives in education and health and for the London Underground⁴ are typical of a wider discourse, at both national and international levels. In the United Kingdom there have been major public debates and resignations over Nottingham University’s decision to accept £3.8 million from British American Tobacco to establish an international centre for corporate responsibility.^{5,6} At the international level there are continuing debates about representation, accountability, and transparency in global public-private partnerships.^{7,8}

Concerns range from issues of principle (such as the role of the state in provision of services) to possibly incompatible values and motivations which may affect outcomes. Rutherford, for example, says that corporate culture differs from academic and research culture because of its primary focus on profit rather than on the disinterested production and transmission of knowledge.² Ziman has also drawn attention to the increasingly instrumental nature of much scientific research, saying it may result in universities focusing on partisan, pragmatic research, primarily for commercially exploitable outputs, rather than the self critical pursuit of knowledge for wider public benefit.⁹

Drawing up conflict of interest policies

At the heart of the academic debate, however, is the potential for conflicts of interest in interactions between public and private sectors; these may affect research priorities, and the quality, outcome, and dissemination of results, as well as public trust in science and research institutions.¹⁰ For example, the University of Toronto has for several years been embroiled in two separate cases relating to the analysis and interpretation of drug trials, involving academics, industry, and the administration. The university has been accused of attitudes protecting its corporate sponsorship (by two different pharmaceutical companies) rather than supporting the findings of disinterested researchers.¹¹

Given the increasing challenges to research bodies, with the growth of public-private links, there is surprisingly little guidance on how to anticipate, avoid, and deal with potential conflicts of interest. The US National Institutes for Health issued a research conflict of interest rule some six years ago, but has only recently insisted on enforcement. When individual researchers apply to the US Public Health Service or National Science Foundation for funds, a 1995 federal regulation requires disclosure of financial interests, but only to institutional officials.¹⁰ In a recent survey of 100 leading US biomedical research institutions, 89 provided written policies¹⁰ but most lacked specificity with regard to types of relationships permitted or prohibited and showed wide variation in how conflicts of interest should be managed. For example, 55% of policies required disclosures of interest from all faculty members, while the remainder required them only from principal investigators. Prodded by this study, the National Institutes for Health began gathering conflict of interest policies from all its major grant recipients; by July 2001 it had about

Box 1: Staff experiences of working with the private sector

Positive aspects of collaborations

- New opportunities to tackle research problems relevant to developing countries, utilising private sector infrastructure
- Professional, accommodating, and rapid two way communication
- Opening up of research opportunities in allied companies
- Rapid implementation of interventions perceived to be valuable
- Fast turnaround of decisions and contracts

Negative experiences

- Attempts by a company to dictate the research agenda
- Potential conflicts of interest, leading to delays and withdrawal by companies
- Dishonest dealings over patents
- Unauthorised use of individual staff and the school’s name
- Inaccurate claims made for a diagnostic test
- Attempts to restrict dissemination of work done at the school, but funded by other bodies
- Huge amounts of time in meetings giving help and expertise, all unpaid
- Dispute over intellectual property rights



300 written policies from medical schools, universities, and other research institutions.¹²

United Nations organisations have long had policies regarding potential conflicts of interest in collaborations with the private sector. There are differences between them, particularly over issues of selection of suitable commercial partners and use of

the UN name and logo. Some UN organisations provide their representatives with a checklist of items meant to facilitate the selection of corporate partners. Unicef's guidelines, for example, reflect a concern for the ability of corporations to work within Unicef's "core values."¹³ In 2000 the World Bank established a special office—a business partnership and outreach group—which has produced guidelines for staff considering partnerships with the private sector (box 4). The World Health Organization presented draft guidelines on working with the private sector to achieve health outcomes to its executive board in January 2001. Although conflict of interest is a major point of concern for the United Nations, there has been surprisingly little policy guidance for staff within the organisations¹³; this is beginning to change.¹⁴

Drafting guidelines

In the face of growing public sector collaboration with the private sector, the London School of Hygiene and Tropical Medicine has drafted principles to guide staff, after a process of consultation with staff with experience of such partnerships. Guidelines were developed within the bounds of the school's mission, which is: "To contribute to the improvement of health worldwide through the pursuit of excellence in research, postgraduate teaching, advanced training and consultancy in international public health and tropical medicine." In working towards its mission, the school collaborates with many different organisations and bases its relationships on principles which promote sound and independent science, proper use and stewardship of all funds, and benefits to society that are greater than those to the institution alone. Although many of the experiences of working with the private sector have been positive, staff have provided examples of negative experiences, ranging from time-wasting (unpaid) meetings with a unidirectional flow of expertise to disputes over intellectual property rights and patents (box 1). On several occasions the school sustained a financial loss when small private companies commissioned work but were then unable to meet their financial commitments.

The guidelines drew from a number of different sources (box 4) and cover several areas: prerequisites to considering a collaboration (box 2), and terms and conditions of contracts (box 3). The guidelines are likely to evolve with increasing use; currently their main purpose is to guide staff on the suitability of partners and the protection of academic independence. For example, companies unsuitable for collaborative activities would include those involved in manufacture of tobacco and related products, and in manufacturing or dealing in arms. The guidelines suggest a number of criteria on which to screen companies (such as workers' health and safety standards, and social, ethical, and environmental principles), but do not as yet give minimum standards. Essentially, the school's guidelines suggest that staff must be comfortable with making public the nature of the relationship with the private sector.

There is still some uncertainty in US universities and research bodies about when financial gain should be disclosed: the National Institutes for Health benchmark is "income of more than US\$10 000 per year from a company that might be affected by the research involved, or ownership of equity worth more than

Box 2: Prerequisites to considering a collaboration

Be clear about how the potential collaboration fits within the overall mission and priorities

Be comfortable with the partner's broad mission and public image, and potential public health impact, not just in the area of mutual concern. For controversial issues, multiple collaborators should be sought, to represent a broad spectrum of opinions and interests

Avoid participating in indirect collaboration (for example, as an advisory group for another project) unless a direct relationship with the partners is comfortable

Avoid working directly or indirectly with companies whose activities or interests threaten public health, such as making tobacco and tobacco related products, and arms dealing or manufacturing

Box 3: Terms and conditions of contracts

Independence and objectivity of scientific judgment should be paramount and should be considered in relation to scientific independence and utilisation of outputs (including conferences, publications, and intellectual property rights)

Such issues should be agreed in advance and form part of a signed contract. Once in the public domain, reports and publications will be subject to the normal scientific debate and media scrutiny

Private partners should be informed that the relationship will be made a matter of public record

\$10 000 or representing more than 5% ownership of such a company.¹² The current policy of the London School of Hygiene and Tropical Medicine is that any potential conflict of interest, however small, should be declared at the outset, as well as at the time of publication of the study results.

Of course, drawing up guidelines is only part of the process of working towards transparent public-private interactions and so allaying some of the above concerns. Much will depend on how they are implemented and monitored. In the London School of Hygiene and Tropical Medicine, and other institutions, the value of such guidelines will be demonstrated through their application. Currently the school's guidelines are implemented through ad hoc meetings to discuss new initiatives and the research grant and contractual process. However, we are establishing a peer review process for deciding whether to accept private or charitable funds where the source of funding is closely linked to a company with a product that may be damaging to health or where concerns exist about the potential impacts on health of its labour standards or relationships with the local community. A task force on research governance is currently considering policies which may lead to additions to the guidelines. It would clearly be helpful if private sector bodies interacting with public sector institutions developed their own guidelines and made them available on their websites. This would facilitate investigators' assessments on the potential for collaboration, and allow the public to ascertain their corporate values and principles.

Conclusions

The case for institutional guidelines is now compelling, given the increasing pressure in competing for research funds, if the academic community is to fulfil "the responsibilities that accompany its fiercely defended claim to the privilege of self-governance and academic freedom".¹⁵ Inevitably such guidelines will need regular review and updating in the light of new developments, and mechanisms need to be in place to ensure that they are being implemented. The effectiveness of different approaches, given that public-private interactions can have a number of potential outcomes affecting a range of stakeholders, will need to be assessed. Pending such evaluations, guidelines can still help institutions and staff to think more systematically about risks and benefits in terms of academic credibility, financial returns, influence on policy and practice, and the implications for the institution's capacity to fulfil its primary mission.

The London School of Hygiene and Tropical Medicine guidelines were the result of a series of meetings, in which a number of the school staff (listed, together with sources of information for the guidelines, on bmj.com; also available on the school's intranet or from the authors) participated.

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Box 4: Useful websites

National Institutes of Health/Office of Extramural Research (http://nih.gov/grants/compliance/compendium_2000.htm) NIH's conflict of interest rule

Harvard Medical School (www.hms.harvard.edu/integrity/industry.html) Faculty of Medicine statement on research sponsored by industry

Association of American Medical Colleges (www.aamc.org/research/dbr/coi.htm) Guidelines for dealing with faculty conflicts of commitment and conflicts of interest in research

American Society of Gene Therapy (www.asgt.org/policy) Policy on financial conflicts of interest in clinical research

World Bank's Business and Partnership and Outreach Group (www.worldbank.org/business/03assessment.html)

KLD Research & Analytics (www.kld.com/research/) Socrates social research database

Association for University Research and Industry Links (www.auril.org.uk)

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Corrections and clarifications

Cat scratch disease

An error occurred in this Lesson of the Week by Alexander Williams and colleagues (18 May, pp 1199-200). The third paragraph gives the impression that the histopathological diagnosis was sarcoidosis. This is wrong; this was the diagnosis suggested in the referral letter from the surgeon. In fact, the histopathologist had suggested cat scratch disease in his differential diagnosis. Also, in the same paragraph, the third sentence should read: "Culture of the lymph node was not undertaken [not "Cultures were Gram negative"]."

Hormone replacement therapy

A dosage given in the final paragraph of this editorial by John C Stevenson and Malcolm I Whitehead (20 July, pp 113-4) was wrong. In recommending that the starting dose of oestrogen is kept low in women aged over 60, the authors suggest 1 mg oral (or 25 µg [not 50 µg] transdermal) estradiol 17β.

Limits of teacher delivered sex education: interim behavioural outcomes from randomised trial

We inadvertently failed to amend some numbers in the flow chart of participants, which appeared in the full (web) version of this paper by Daniel Wight and colleagues (<http://bmj.com/cgi/content/full/324/7351/1430>); the chart was not published in the paper version (15 June, pp 1430-3). The chart contains two errors. In the first level, the number of schools should be 25 [not 2], and in the left hand box in the second level, the number of control schools should be 12 [not 2].