Has the hunt for conflicts of interest gone too far?

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YES Most of us politely ignore street evangelists urging us to repent of our sins. But academic medical administrators base policy on such preaching by anti-business activists. Their sermons, echoed by medical journals, warn that medical practitioners, educators, or researchers accepting gifts from or payments for services to companies producing medical products compromise their objectivity. Strangely, transactions between patients, insurance companies, hospitals, and doctors, encompassing 85% of the medical marketplace, do not count as conflicts of interest.

To be sure, corporations, like everyone else, sometimes behave badly and are punished. The key question, however, is whether detailed disclosure of conflicts of interest and stringent prophylactic management are in the public interest. I believe the answer is a resounding no.

Increasingly, conflict of interest policies exclude conflicted experts, however qualified, from writing reviews or editorials in some journals or from advising regulatory bodies on product approvals.[1] They also limit or prohibit financial rewards from private companies for work done or even ban corporate consulting entirely. Other rules require academics to audit corporate research and eliminate commercial detailing, gifting, and samples.

What the conflict of interest movement does not yet regulate it maligns. It demonises "speakers' bureaus," which organise doctors to provide company sponsored education, and ghostwriters, accusing professional writers hired by companies of routinely creating promotional fiction that is allegedly legitimised by honorary academic authors.

The most extreme rationale for conflict management is that companies distort evidence and flout safety to promote products without substantive benefits and probable harms.[2] A case in point is activists' insistence that the events leading to Merck's withdrawal of rofecoxib resulted from deception driven by profit[3] rather than, as most juries addressing rofecoxib related litigation concluded, from bad luck and inadvertent error.[4]

By juxtaposing examples of overt research misconduct by academics with no corporate ties against far less heinous cases in which researchers failed to honour overblown journal disclosure requirements for corporate support, proponents of conflict of interest insinuate that research sponsored by companies is biased or even fraudulent.[5] The "no free lunch pledge" states: "I am committed to practising medicine in the interests of my patients and on the basis of the best available evidence, rather than on the basis of promotion,"[6] implying that corporate promotional information is not evidence based. Therefore, doctors freely mingling with or listening to corporations may be ill advised, corrupt, or both.[7]

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All of these charges obscure the fact that only private companies bring new products to patients and that medical care has improved steadily and spectacularly because of them.[8] Fraud and pathological bias could never have conferred these monumental achievements.

Lack of evidence

Conflict of interest ideology purports to promote scientific rigour yet is far from rigorous itself. Adverse outcomes objectively ascribable to financial conflicts of interest are almost non-existent, especially in the context of overwhelmingly positive commercially driven medical advances.[9] But purely academic research and education are arguably less reliable than their corporate or corporate sponsored counterparts. They are not, for example, subject to stringent Federal Drug Administration reporting requirements. Misconduct fells a single academic miscreant but can bring down an entire company.

No evidence supports that corporate detailing and gifting adversely affect patient care.[10] Yet anti-business critics misrepresented this fact and have not retracted or corrected the error.[11] Medical journals waste space on meaningless compilations of who receives what payments from companies and dubious "social science research" purporting to prove that most doctors lack the intelligence or character to be wary of promotional claims.[12]

These attitudes and regulations are not only ill founded but also harmful to the public's interest in medical innovation. The management measures exclude the best experts from providing education and advice, cost time and money, and are deeply disrespectful of physicians and researchers. Corporate compliance bureaucracies, fearful of regulators, have refused to renew funding for successful continuing education programmes on the grounds that this success automatically connotes promotion of company interests. Investors have told me that conflict of interest regulations that limit investigator equity inhibit establishment of new companies based on academic technologies. Conflict of interest scolding also promotes distorted and damaging views of science and medicine: it portrays science as devoid of subjectivity and passion and the medicine as irrationally walled off from commercial society.[13 14]

Most doctors realise that asceticism and utopian zeal for behavioural perfection produce nothing and that risk taking entrepreneurs, motivated in part by profit, advance medicine. They do not want pious bureaucrats regulating their rewards or telling them with whom they can associate. Physicians and researchers working in the real world can restore common sense and balance by overcoming their inertia and fear to resist the unproductive and hitherto unopposed conflict of interest alarmists. As a step in the right direction, the University of California System's Academic Senate recently soundly rejected intrusive conflict of interest regulations as vague, overbroad, addressing perceived rather than real concerns, and in violation of academic freedom.[15] Others should follow this enlightened lead.

Competing interests: TPS is on the boards of directors and owns stock options in ZymeQuest and Critical Biologics Corporations, and his employer has licensed intellectual property to these companies, which may result in his receiving milestone payments, royalties and in the stock options having financial value. He receives fees for speaking to corporations and other organisations on the topic of conflict of interest. He has served on scientific advisory boards for Biogen, Dyax, and Merck.

Thomas Stossel argues that restrictions on doctors' and academics' interaction with commercial companies are damaging research, but **Kirby Lee** believes it is a price worth paying to maintain public trust

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NO Conflicts of interest occur in health care when clinicians or researchers have personal, professional, or financial interests that could interfere with, or be perceived to interfere with, their professional obligation to act in the best interests of patients or objectively conduct, present, review, or publish research. Although the existence of a conflict does not necessarily mean wrongdoing or harm, it does require management to prevent potential bias, or the perception of bias, in medical decision making or research.

Recent attention has focused on conflicts of interest between healthcare professionals and the drug industry. Marketing expenditures for drugs in 2004 was estimated at $57.5bn, nearly twice that spent on research and development.[1] Drug and medical device companies have been convicted of criminal violations or have settled civil suits for offering clinicians millions of dollars in kickbacks, bribes, or gifts to get them to use their products. The most notable case illustrating how direct marketing to doctors can lead to serious harm was the rofecoxib scandal. According to internal company documents, Merck developed an aggressive marketing campaign to "neutralise" or win over influential doctors known as key opinion leaders by showering them with gifts, grants, and donations and trained its sales representatives to "dodge" questions about the cardiovascular risks of rofecoxib.[2] Illegal marketing activities that overstate a drug's benefit, downplay its risks, or promote it for off-label use have occurred throughout the industry.

Evidence is growing to demonstrate the negative consequences of certain marketing practices and other interactions with industry on clinician behaviour. For example, clinicians with ties to industry are more likely to prescribe the company's brand name product rather than cheaper generic drugs when there is no therapeutic advantage,[3] more likely to request the company's drug is added to formularies,[4] and more likely to prescribe company drugs for off-label use,[5] all of which could lead to unnecessary healthcare costs and harm. Such influence is a serious concern because nearly all doctors have some type of relationship with industry, whether this is receiving food or drug samples, payments for consulting, enrolling patients in trials, or participation in marketing activities.[6 7]

Most doctors believe that they are immune to influence from industry but that their colleagues are not.[8 9] Yet research in social science shows that gifts of any size from drug companies create feelings of obligation and reciprocity.[10 11]

Gifts of any size from drug companies create feelings of obligation and reciprocity

Similar problems have occurred in the conduct and reporting of research, particularly suppression of negative results or failing to disclose harmful side effects as in the cases of rofecoxib and paroxetine.[12 13] In the United States, the death of 18 year old Jesse Gelsinger in a gene transfer trial at the University of Pennsylvania drew widespread public and federal scrutiny of financial conflicts of interest in research. The researchers and the university owned equity in the company developing the gene therapy technology used in the trial. An FDA investigation found serious deficiencies in the conduct of the trial including failure to immediately report serious side effects in two previous patients and doubts about whether Gelsinger was fit to participate. Failure of the university and individual researchers to manage the conflicts subsequently led to lawsuits, negative publicity, and regulatory action, including suspension of all human gene therapy research at the university, which had one of the largest academic gene therapy programmes in the country.[14] The tragic results of this trial shocked the public, were a major setback to gene therapy research, and show the seriousness of managing financial conflicts of interest in research.

Current policy is failing

Clearly, the drug and medical device industry has made large contributions to improving public health through beneficial relationships with clinicians and researchers on product development. However, it is also clear that there are some individual clinicians, researchers, and industry employees who serve their own interests at the expense of patients as evidenced by the recent law suits, complaints, and tragic events. Such individuals are few and far between, but no price is too high to prevent human suffering or erosion of trust from failing to identify and manage conflicts of interest.

Healthcare professionals and the drug industry have tried to manage conflicts of interest with greater self regulation and reform. Despite guidelines for appropriate relationships and gift giving between industry and healthcare professionals,[15 16] problematic conflicts continue to arise. This may be due to the wide variation in defining what constitutes a conflict and how it should be managed[17] or, perhaps, the lure of profits is too great. For example, disclosure is often voluntary and subject to interpretation, resulting in undisclosed or insufficient explanations of potential conflicts.

The hunt for conflicts of interest must therefore go on. The US has recently enacted a law mandating state disclosure of payments to clinicians by drug companies,[18] and there are proposals to ban all gifts to clinicians and prohibit healthcare professionals who have financial ties with drug companies from making certain decisions (drug formularies, clinical practice guidelines) and publishing articles that have been ghostwritten by industry.[19] Such requirements may frustrate clinicians and researchers but, in doing so, will help to ensure the safety and welfare of the public, uphold scientific integrity, and preserve trust. Trust and credibility, once damaged, are difficult to restore. And when you become the patient, wouldn't you want to be assured that medical decisions are made in your best interest?

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All references are in the version on bmj.com

See last week's feature 'The Invisible Influence' doi:10.1136/bmj.39496.430336.DB