Should the drug industry use key opinion leaders?

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YES This question is a microcosm of the broader debate about how the drug industry and clinicians should interact. It leads to two tempting but indefensible end points—either that doctors are immune to marketing and should be free to do as they wish with industry or that industry is inherently corrupting, making all contact with it unethical.[1]

Both positions are flawed, and the reality is much more complex: neither medicine nor industry can realise their true value independently of one another.[1] Both have a role in the advancement and delivery of health care. It is not in the interest of the industry to have its products used incorrectly or in the wrong patients, and there are appreciable benefits to healthcare professionals from interactions between industry and opinion leaders.

Current practice

The International Federation of Pharmaceutical Manufacturers and Associations has a clear position on the ethical promotion of prescription medicines. It seeks "to preserve the independence of decisions taken by healthcare professionals in prescribing medicines to patients—nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practice."[2]

Other industry bodies, such as the Pharmaceutical Research and Manufacturers of America and the Association of British Pharmaceutical Industry, have similar codes of practice with specific rules on how the industry should work with healthcare professionals. There is always the question of whether these codes of conduct are meaningful (or enforced), but in my experience companies and individuals are acutely aware of their obligations.

Opinion leaders, who range from experts with educational influence across many countries to local experts on a given topic in an individual hospital or clinic, can act as educators. They provide analysis, critique, and guidance to other doctors regarding the appropriate placement of a drug in clinical practice.

What is wrong with that? In the era of the internet, with the explosion of social networking and open access, expert opinion is increasingly diluted by opinions from any and all who wish to express a view. In this environment it becomes even more important for companies developing new treatments to work with the leading experts in clinical science and clinical practice, so those experts are supported in having the loudest voice possible.

Responsible cooperation

Even some of the strongest critics of industry working with clinical experts understand why doctors engage with industry in joint research or consulting on scientific issues.[3] However, concerns remain that these interactions will bias opinion and compromise patient care. The worry is that invisible influence and subconscious reciprocity have an insidious effect on clinical practice[3] or simply that entitlements and obligations created through these interactions conflict with the primary obligations to patients.[4]

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However, the fact that drug industry interactions can affect doctors' clinical practice is not necessarily a bad thing, since it could be through these interactions that doctors become more aware of the legitimate benefits of some drugs.[5]

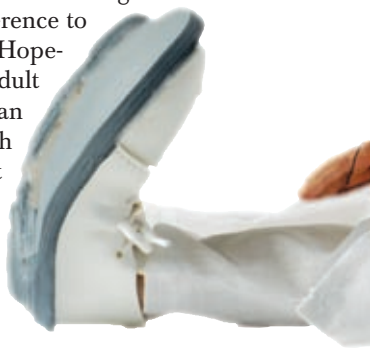
Furthermore, opinion leaders in my experience are extremely capable of expressing their views, focusing on the right decision for patients, and maintaining their independence. This is what makes them opinion leaders. As long as any engagement with industry is transparent, clinicians can make up their own minds about what they believe and test any conclusions with other experts, colleagues, treatment guidelines, or whatever source they wish. The key is for all parties to have the courage to be transparent about these interactions.

Opinion leaders ought to have more guidance on how and when to work with industry, so as to remove as much ambiguity as possible. Interestingly though, while industry has its codes of practice, there has been a gap in guidelines for opinion leaders on how to work with industry. Those provided by the Association of American Medical Colleges contain useful recommendations, even if the supporting arguments for those recommendations are based on perception of industry motives rather than the reality.[6] Similarly, some of the recommendations in a recent *JAMA* article are already well accepted by industry.[7] However, both of these articles contain more extreme recommendations that are impractical. For example, recommendations to actively discourage doctors from participating in speaker programmes[6] or to require a statistician from a not for profit organisation to review all publications[7] are either not helpful or not viable in practice.

The drug industry has an ethical obligation to work with the most influential healthcare professionals to ensure they understand the leading edge thinking of these experts and that the experts have the most up-to-date and accurate perspectives from the companies. There is really no viable option other than to work with opinion leaders. The big question is how this should be done to ensure a fair balance and to reassure all parties that nothing underhand is happening.

If all the stakeholders can operate within rigorous transparency frameworks and be open about what they want to achieve and what they are not willing to do, then there is much benefit to be gained on both sides. However, even with perfect transparency, problems will remain until the industry is widely accepted as a stakeholder in healthcare provision. The solution is not to exclude the industry but to accept that it has a role and to more precisely define that role to minimise suspicion and misunderstanding. Fundamentally, the drug industry is populated with people of high integrity who are passionate about making a positive difference to patient care. Hopefully a more adult relationship can emerge which recognises that fact.

Competing interests: Complete Medical Group provides services to the drug industry.



Industry commonly works with experts to put across its message. **Charlie Buckwell** believes that such interaction is essential for medical advancement, but **Giovanni Fava** argues that it threatens scientific integrity

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NO The proliferating connections between doctors and the drug industry have brought the credibility of clinical medicine to an unprecedented crisis. Corporate actions that have placed profit over public health have become regular news. High profile examples include the misrepresentation of research on rofecoxib and on the use of selective serotonin reuptake inhibitors in children. Recently, two respected scientists who work for a drug company wrote that the problem of conflict of interest "could well erode the credibility of the entire enterprise of academic medicine, if not properly and promptly addressed."[1 2]

Industry objectives

The game is clear: to get as close as possible to universal prescribing of a drug by manipulating evidence and withholding data. A recent paper illustrates how selective publication of trials of antidepressants exaggerated their efficacy.[3] Thirty seven of the 38 studies that had positive outcomes were published in peer reviewed journals compared with only three of the 36 studies with negative results.[3] Industry tactics take the form of commercially strategic clinical trials (which have been defined as "experimercials"[4]), journal publications that are actually "infomercials,"[4] and continuing medical education activities and scientific meetings whose main aim is to sell the participant to the sponsor.[5]

Who are the winners of the game? The drug companies and, apparently, the key opinion leaders who are hired for performing their parts. These experts get not only money and visibility[6] but power, particularly if they become members of special interest groups.[5] Because of the resultant contacts, members of these groups often get leading roles in editing medical journals, advise non-profit research organisations, and act as reviewers and consultants, enabling them to prevent dissemination of data that may be in conflict with their special (corporate driven) interests. The most prominent way they display their power is through meetings and industry sponsored symposiums. By carefully selecting the literature presented, key opinion leaders help the drug industry take control of scientific societies, clinical practice guidelines, and reporting of investigations.[5 7]

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Managing the problem

Patients and society at large are harmed by these practices as a result of irrational prescribing, omission of safety issues (such as with rofecoxib), and increased costs. But doctors are also affected because when trust goes so does the healing power of doctors.[8] And, ultimately, the drug industry risks losing as well.[1 2]

So what can we do? The problem of conflict of interest has been viewed mainly in negative terms: how to limit corporate influence in medical research. Little attention has been given to the fact that the scientific community is draining itself of a reservoir of truly independent experts who can advise government policy makers.[9]

Truly independent investigators are still available[10] but they need support.[5] This could include giving them priority for obtaining grants from public agencies, key positions in scientific societies, editorship of journals, and producing clinical guidelines. Despite journal policies, disclosure of conflict of interest is rare and at times meaningless.[5] Conflict-free investigations and reviews should be emphasised in medical education, have priority in medical journals, and be clearly identified as such.

A crucial problem lies in the lack of a definition of substantial conflict of interest. If we assert that eating a pizza at a drug sponsored lunch and being a regular consultant to a firm carry the same weight, we have the perfect excuse for doing nothing. However, criteria can be agreed for establishing substantial conflict of interest. My suggestions include being an employee of a private firm, being a regular consultant to or on the board of directors of a firm, being a stockholder of a firm related to the field of research, and owning a patent directly related to the published work.[5] These criteria, which are based on the work by Krimsky and colleagues,[9] all imply a long term relationship with a private firm. Occasional consultancies, grants for performing investigations, or receiving honorariums or refunds on specific occasions would not constitute a substantial conflict. Indeed, it is perfectly legitimate for academic physicians to collaborate with the industry on scientific projects. Collaboration should not be extended, however, to business disguised as science (such as signing ghostwritten journal articles or speaking at promotional symposiums) and should be subject to universally agreed rules.[5]

The drug industry may recruit doctors for marketing its products. But we can no longer accept these doctors as key experts. Taxpayers and members of professional societies deserve scientific leaderships by researchers who have no substantial conflict of interest and are defending our intellectual freedom. And to all experts acting as the marketing arm of the drug industry we should convey a clear message: your time is up. We can no longer afford it.

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