

Doctors, patients, and the drug industry:

PARTNERS, FRIENDS, OR FOES?



The relationship between the drug industry, academia, healthcare professionals, and patients is widely held to be at an all time low, and it is in the interests of all parties to improve it. A report issued by the Royal College of Physicians this week gives 42 recommendations aimed at forging a more productive partnership with industry. Here we set out five views on what the ideal relationship between industry and prescribers and patients should be and what steps need to be taken to achieve it

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Which view of the relationship between industry, doctors, and patients do you support? Vote on bmj.com

The academics in public health: We need explicit standards of conduct

The relationship between drug and device companies, the medical profession, and the public is at a critical juncture. Individuals who have placed their interests in profit and influence over patients and public health have overshadowed much of the good work and reputations of those who have engaged in constructive interaction.¹ As a result, public perception of the drug industry, doctors and scientists is at an historic low.^{2,3} The public is well served when industry, clinicians, and academicians work together for the common good, generating new knowledge and ensuring appropriate and rapid dissemination of effective products to save lives and improve quality of life. To restore the public's trust we must set a path forward that encourages ethical collaboration and discourages activities by industry, researchers, or practising doctors that are largely self serving or place financial benefit above patients and the public good. Setting explicit standards of conduct for interactions between industry and both patients and physicians can assist all parties. We propose six.

Standards to restore trust

Firstly, let's dispense with promotional activities such as direct to consumer advertising and distribution of drug samples in settings where prescribing decisions are made. Promotions, samples, and advertisements are intended to

create demand and rarely provide educational value.⁴ They can have the unfortunate consequence of influencing patients to request treatment that is not indicated or for which less expensive, equally effective alternatives exist.

Secondly, we should forgo gifts. Doctors do not need trinkets, meals, or other gifts, and industry can probably do without the expectations of giving them. Small gifts may seem innocuous, but cognitive psychologists have shown that they have outsized influence.⁵ The value of the interaction between industry representatives and physicians should relate to information exchanged, not the gift received.

Thirdly, clinicians, researchers, academic institutions, clinics, and hospitals must disclose all payments and gifts from industry, regardless of size or whether they were paid directly, through a third party, or to a charity or other organisation. Transparency cannot ensure ethical conduct, but disclosure will open up interactions with industry to the public and should inhibit payments that are embarrassing or questionable.

Fourthly, industry sponsorship of continuing medical education must stop because it diminishes credibility regardless of its quality. Physicians should fund their own education, perhaps subsidised by government or private-public partnerships to reflect its value as a public good.

Fifthly, industry sponsored clinical studies should be visible, accountable, and comply with mandatory standards set by institutional review boards, data safety and monitoring boards, and steering committees to protect patient volunteers. In addition, external investigators should receive the study's raw data and rights to publication. Seeding trials and ghostwriting should be prohibited. Trials should be publicly registered and their results should be posted within two years of completion regardless of peer review publication. Registration should include naming members of the data safety and monitoring board and steering committee (which is ideally composed of non-employees), investigators, and pre-specified data analysis plans including primary and secondary outcomes.

Finally, let's accept divergent views, defend free speech, and acknowledge that there is great value in the respectful exchange of ideas. We need to overcome an unfortunate history of intimidation exhibited by some companies against physicians who have expressed opinions that did not favour their product.⁶ We also need to eliminate efforts by opinion leaders at some academic centres to leverage funding from companies in exchange for favouring industry products or neutralising critics.

All six of these actions are practical and can be taken immediately if industry, researchers,

and clinicians commit to a new era of interaction to restore the public's trust. They reflect a widely shared view in industry,⁷ the Association of American Medical Colleges, and the Medicare Payment Advisory Committee. They are also in line with recent legislation and ongoing discussion in the US Congress. Leading companies and physicians have already taken many of these steps to promote the best care for patients—it's time for the rest to follow.

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The industry chief executive: Closer working will improve outcomes for patients

Healthcare professionals and patients need to have the most up to date information on all the treatment options available to them, including medicines. There is therefore a legitimate place for a responsible relationship between the drug industry and the NHS, prescribers, and patients. This relationship should support the promotion of good medical care, improve health outcomes, and reduce health inequalities. It should include the provision of information to guide valid patient choice.

Prescribers

Doctors, nurses, and pharmacists all receive rigorous training, and patients demand a high degree of medical and pharmacological knowledge from them. Despite this, there are those who would deny healthcare professionals access to the drug industry, which researched and undertook the clinical trials to develop the medicines.

It is paradoxical that some do not consider doctors capable of separating good information from bad. Relations with industry have changed in recent years. The appropriately derided medical conference junket culture is over,¹ and interaction between doctors and the drug industry is highly regulated by a code of practice and UK law.²

Both the Department of Health and the Association of the British Pharmaceutical Industry are seeking to re-cast the relationship between the pharmaceutical industry and the NHS and promote joint working to improve outcomes for patients. To this end a ministerial industry strategy group was established in 2001,³ and in 2007 this group published a strategy report recommending ways to strengthen the relationships between government and the drug industry. Guidelines and a toolkit for joint working have been developed.⁴

Joint working has the potential to create breakthroughs in how the UK tackles major health challenges including cardiovascular disease and teenage pregnancies. It draws on complementary skills from the NHS and the drug industry. For example, Ashton Leigh and Wigan Primary Care Trust is tackling low life expectancy and high rates of heart disease and diabetes by working with industry on a "find and treat" strategy for high risk patients. Typically such work involves the promulgation of good medical practice by addressing a local public health priority using nationally agreed guidance such as that provided by the National Institute for Health and Clinical Excellence (NICE) and national service frameworks. Industry may work with the NHS on stratification of patient risk, treatment intervention skills, local clinical leadership, and creating connections between different parts of the NHS.

If these initiatives are to fulfil their promise appropriately trained staff from the NHS and the pharmaceutical industry need to be assigned to joint working projects. Accreditation criteria for such posts are being evaluated.

Educating patients

Lord Darzi's recent review of the NHS called for greater empowerment of patients and a better understanding of the impact of ill health.⁵ It also delineates patients' rights to medicines and treatments approved by NICE. If patients are to make informed choices they need access to information about their disease and treatment options. The European Commission has recently undertaken extensive consultation on the topic.⁶ Although there is a consensus that the ban on direct to patient advertising of prescription drugs in Europe should remain, no one should have

an exclusive right to provide the public with information about medicines. Patients should have unimpeded access to multiple sources of information, none of which can claim to be free of any possible bias. Ultimately there is no option but for each party—prescribers, patients, and the drug industry—to build trust with each other.

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The industry spokesman: Current regulation is robust

The primary role of the research based drug industry is to discover, develop, license, and market innovative medicines to prevent, treat, or cure disease. This role has a prime benefit for patients but also helps prescribers in their role of managing disease. The UK industry is committed to a stable and pragmatic partnership with the government and the NHS on medicines—one that enshrines value for money, reward for innovation, and ensures greater availability of new medicines to patients. This should lead to the industry being seen as a trusted partner in the provision of health care by both prescribers and patients.

Information for prescribers

The industry believes it has a legitimate right to provide information about the benefits of its medicines to prescribers. In the UK, the way in which this is done is regulated by the Medicines Act through the Medicines and Healthcare Products Regulatory Agency (MHRA) and Association of British Pharmaceutical Industry's (ABPI) code of practice.¹ Drug companies provide information in various ways including publishing in peer reviewed journals and the summary of product characteristics, which is readily available online.² Of course advertising and sales representatives have an important role but this is robustly controlled by regulation and self regulation.

Many surveys have shown that the public trust their healthcare professionals as the key providers of information, and so it is important that prescribers understand the role of industry in the provision of health care. Also the industry develops a considerable amount of information about disease and its treatments that healthcare professionals can give to patients.

Meeting patients' needs

Increasingly, patients are seeking more information about health related matters, including medicines. All medicines have to come with a patient information leaflet, which legally has to contain certain information,³ but there is scope for them to be more patient friendly. The MHRA is working with the ABPI to improve the patient information leaflet by including, for example, a summary box giving the main benefits and risks of the medicine, better definition of the risk of side effects, and website addresses for patient organisations.

About 20% of calls to company medical information departments are from the general public inquiring about particular medicines. Currently, the information that can be given is quite limited and industry will be working with the MHRA to broaden this. Another source of information for patients with chronic conditions is patient organisations. Many of these work with rel-

evant companies to develop user friendly information about the disease and possible treatments. All funding for patient organisations from companies has to be publicly declared in order to make the relationship transparent.

Another important source of patient information, the medicine guides available on the NHS Choices website,⁴ provides a good example of the potential of collaboration. The guides are written by medicines information pharmacists based on the summary of product characteristics. Although the guides are funded by industry, they have been developed through the Medicines Information Project Board, which includes representatives from the MHRA, ABPI, patient organisations, Royal Pharmaceutical Society, Royal College of General Practitioners, and Royal College of Nursing.

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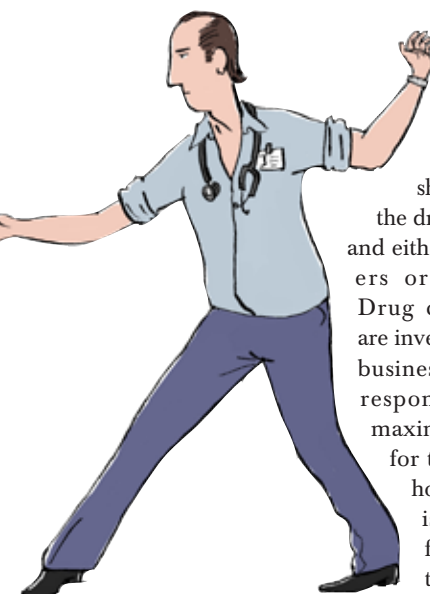
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The former medical editor: There should be no relationship with prescribers or patients



I believe there should be no relationship between the drug industry and either prescribers or patients. Drug companies are investor owned businesses with a responsibility to maximise profits for their shareholders. That is quite different from the mission

of the medical profession, which is to provide the best care possible for patients. I start with this simple fact, because it is so often obscured by the industry's public relations. Drug companies are not confused on this score. Their major output now consists of "me-too" drugs for mild or ill defined conditions in essentially healthy people. This is because that market is big and more easily expanded than the market for innovative drugs for serious diseases.¹

The purpose of drug companies' contact with prescribers is nearly always to increase sales, and it usually involves payments of one form or another. These are often disguised as education—for example, sponsored continuing medical education, professional meetings, and conferences or dinner sessions to hear presentations about drugs. Companies provide meals, gifts, and subsidies of various sorts. But drug

companies are not educational institutions. These activities are funded from their marketing budgets. Drug companies may, of course, provide accurate information to prescribers, but only if it serves their commercial interests. A growing body of evidence shows that they suppress or distort information that does not serve their interests.² Prescribers are faced with the impossible task of sorting out good information from bias or misinformation.

The fact that drug companies pay prescribers to be "educated" underscores the true nature of the transaction. Students generally pay teachers, not the reverse. The real intent is to influence prescribing habits, through selection of the information provided and through the warm feelings induced by bribery. Prescribers join in the pretence that drug companies provide education because it is lucrative to do so. Even free

samples are meant to hook doctors and patients on the newest, most expensive drugs, when older drugs—or no drug at all—might be better for the patient.

Education and information should be provided by health professionals

It is time the medical profession took full responsibility for educating prescribers about prescription drugs, instead of abdicating it to drug companies.³ Doctors should pay for their own continuing education, just as other professions do. Similarly, professional organisations should pay for their own meetings and publications, not go hat in hand to industry. Drug companies are not charities; they expect something for the tens of billions of dollars they invest in marketing. The evidence is that they get it, and that patients

foot the bill in higher drug prices.

As with prescribers, the purpose of contact between drug companies and patients is to sell drugs. In the US, drug companies spend about \$5bn (£4bn; €4bn) yearly on direct to consumer advertising on television. The adverts are mostly for me-too drugs and are designed to convince viewers that one is better than another, despite the fact that these drugs are seldom compared in clinical trials at equivalent doses. Many seek to convince people that they have chronic disorders that require lifelong drug treatment. Thus heartburn is elevated to gastrointestinal reflux disease, with the implication that it needs to be treated to prevent serious complications. If people can be convinced they have a treatable medical condition, then it is an easy step to sell them drugs to treat it. Many

doctors connive in this deception because it is easier to write a prescription than to counsel changes in diet or to offer reassurance. We need to stop accepting the fiction that marketing, whether to prescribers or patients, is good education.

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The free market policy analyst: We need less but better regulation, and closer collaboration

Medical treatments are becoming increasingly more individual, with respect to both disease and patient. They are also becoming more complex, and precise diagnoses and close monitoring are needed to optimise their use. In this environment, consumers and doctors need to work more closely with product developers. Yet increasing regulation of the drug industry is restricting its ability to disseminate the results of its clinical studies. This risks shrinking the opportunities patients have to improve their health. In the face of regulatory steps to restrain their scientific speech, drug makers need to take new steps in their relationship with doctors and patients and establish transparent guidelines for those interactions. They should also focus more squarely on matters of advancing science, monitoring for safety, and improving health education.

Science not marketing

A large part of the industry's current problems stems from the way its relationship with academic physicians and medical institutions has evolved over the past few decades. Formerly, the industry depended on academic doctors to conduct basic and clinical research. Now more of that work is done in house.¹ As a consequence, the relationships forged with the academic medical community are often based on marketing related activities. This feeds the regrettable perception that drug makers ally themselves with medical thought leaders to advance marketing goals, not science, and that information they generate cannot be trusted.

Relationships should be predicated on gen-

uine scientific work. This doesn't mean that drug makers should stop engaging leading physicians to help companies generate and share information about new advances, but that they need to engage with doctors who had a role in discovering those advances rather than those with no or little link to the underlying science. The latter creates the unfortunate appearance that opinions are being rented; the former is unassailable, as a scientist is the most appropriate champion for his work.

Overcoming mistrust

As patients are taking an increasingly active role in treatment decisions drug companies need to take new steps to improve health literacy and patient education while they continue to invest in better ways to monitor the performance and safety of their products. Unfortunately, the existing mistrust means that policy makers continue to create restrictions that impede the ability of drug companies to speak to patients. This creates information asymmetry and denies patients the opportunity to receive truthful, non-misleading information about new products, thus hurting health outcomes.^{2,3} It also leads to a regulatory edifice that makes it harder for drug companies to monitor the performance of their drugs by talking directly with patients and makes it harder for them to provide targeted information to patients on proper use of prescription drugs. The bot-

tom line remains that the drug firms remain one of the few actors in this marketplace with the financing and incentives to share and collect information. Under proper regulation, public health imperatives should compel us to make better use of these resources on behalf of patients.

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See **EDITORIAL**, p 308, **NEWS**, p 313, **PERSONAL VIEW**, p 359

