Forget sponsorship—welcome to Pharmacare

Drug companies are now helping prescribe how healthcare is designed and delivered

Among the most salacious stories in Australia last year were revelations about healthcare officials being flown around the world, business class, courtesy of the global drug giants. Conferences in Paris, Milan, and London were among the destinations for the antipodean decision makers, who were also generously provided with accommodation. The practice was defended by the government but horrified consumer groups. The health economist Gavin Mooney described it as a “culture of bribery that needs to be stopped.”

It seemed bizarre that health department officials were accepting largesse from companies that were simultaneously negotiating sales with the same department. Government acceptance of this corporate influence peddling seemed stranger than fiction. But a recent warming of relations between the drug industry and the NHS in England well and truly eclipses the sponsorship—joint working between the NHS and pharmaceutical industry—is a toolkit produced in 2010 by the Department of Health for England and the Association of the British Pharmaceutical Industry. It says that the NHS and drug companies “share a common agenda to improve patient care outcomes,” using a range of strategies that include “healthy living,” identifying “appropriate patients,” and optimising the numbers of those patients receiving treatment. Potential benefits for patients and the system are claimed to include better care and improved health. Benefits for companies, according to industry documents, are “more and/or better use of medicines, including the company’s medicine(s),” better understanding of customers’ needs, and “improved reputation.”

The notion that public health systems and drug companies share a “common agenda” is a public relations fantasy. Companies aim to maximise profits from drugs sales; the health system aims to maximise population health. To confuse these aims is as dangerous as it is disingenuous.

After many years in denial, clinical medicine is finally facing up to the distorting effects of financial entanglement with pharmaceutical marketing. The evidence is impossible to ignore: sponsored trials favour the sponsor’s drug; and doctors who expose themselves to company promotion tend to prescribe more, with higher costs and lower quality. Yet as doctors move towards greater independence from drug companies, health system managers seem to be jumping into the still warm bed. Food, flattery, friendship, and funding make for a powerful aphrodisiac.

Although the project involving Janssen doesn’t deal with specific drugs, it will touch on how mental illness is understood and treated in the new commissioning environment—subjects in which the company has direct interests. Concerns about over-medicalisation and diagnostic creep in mental healthcare are a direct threat to the size of medication markets, making it more important for drug firms to maximise their influence on those running the system. In fact, better access to key decision makers is an industry benefit highlighted by those pushing the “joint working” model.

Along with improving access, the partnership will certainly offer reputational benefits at a time when Janssen is facing major legal action in the United States. Its parent company, Johnson & Johnson, says that government authorities are “continuing to actively pursue both criminal and civil actions” relating to the marketing of risperidone. Attorneys general in at least 10 states have legal action pending against Janssen, with many more states indicating potential interest in litigation. In the past two years Janssen has been forced to pay penalties and compensation totalling almost $600m (£390m; €460m) in relation to drug promotion in 2003, though it’s confident of ultimately winning those cases on appeal.

It’s clear why companies want to buy improved reputations and access to decision makers. For the health system, however, there’s an obvious danger that these new arrangements will see healthcare become progressively even more like “Pharmacare,” where drug-centric decision making maintains over-medicalisation and continues to divert attention away from finding effective prescriptions to fight the social and environmental determinants of ill health.

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References are in the version on bmj.com

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Previous columns by Ray Moynihan are available on bmj.com
Investigating beneficial drug reactions

It is time to move from serendipity to systematic searching

All clinicians are familiar with drugs that have multiple uses. Codeine, for example, may be given to reduce cough (when it may have the adverse effect of constipation) or to treat diarrhoea (when suppressing the cough reflex becomes the unintended adverse effect). Shaughnessy has recently named these additional uses that are identified and introduced after a drug has been established in its initial role as “repurposing.”

There are many other examples, such as sildenafil (Viagra), which was initially developed to treat ischaemic heart disease. Once its effects on erectile dysfunction were serendipitously noted from pharmacodynamic studies, the entire rationale for its development and prescribing changed. Other examples abound, in the professional and lay literature, such as recent discussion, including on the BBC, concerning clomipramine’s potential to have a beneficial effect on brain tumours.

In general such potential repurposings have been identified serendipitously by alert doctors who have observed an unexpected beneficial effect that might be due to a prescribed drug, in the same way that they might note possible adverse drug reactions. However, adverse reactions are identified in numerous ways that should also be adopted and modified appropriately for beneficial drug reactions. Of course, as with adverse reactions, such possibilities need careful investigation, again using the validated methods already in place.

**How might we identify beneficial drug reactions?**

We suggest three main approaches to generating and testing hypotheses about drugs’ beneficial reactions (figure).

- **Serendipitous data reporting**—A system for reporting beneficial reactions could use the methods established for reporting adverse drug reactions (the yellow card system in the United Kingdom), with similar validation systems. Hypotheses would be generated from data derived from clinicians (of all kinds) and from patients. Such hypotheses could be tested by the green card monitoring system currently used in the UK for post-marketing surveillance (that is, by prescription event monitoring). This system requires doctors to report all events, beneficial or adverse, that occur after the introduction of the particular drug under investigation, as well as any changes in the patient’s medication. Currently there is no major systematic effort to identify beneficial effects from this dataset (personal communication, V Marshall, Drug Safety Research Unit). Hypotheses derived from serendipitous data on beneficial drug reactions could also be tested by systematic interrogation of routine databases.

Involving patients in reporting of beneficial drug reactions has the potential to enhance the doctor-patient relationship, increase involvement of patients in monitoring treatment, and maximise the usefulness of data being reported. Admittedly, increasing patients’ involvement also has the potential to increase the amount of “white noise” in reporting, but again this is no different from reporting of adverse reactions by patients.

- **Routine data mining**—General practice and hospital databases contain large amounts of validated data that could be explored. Such exploration would include drugs that reduce the use of other treatments, making their effects difficult to spot (the “dog that didn’t bark” problem), drugs whose effects are significantly delayed, or cases involving complex interactions between drugs. The recent case of daily aspirin leading to reduced incidence of some cancers is one where a database was investigated for a reduction, rather than an increase, in events.

- **A new monitoring system**

Opportunities to identify beneficial drug reactions are unappreciated and unexploited, but a range of approaches could be used to generate and test appropriate hypotheses. If reporting beneficial reactions became standard practice, we would expect to identify important new uses for current drugs (for which the adverse reaction profile is generally well established) and to reduce the costs of drug development.

Patients may not wish to bother their doctor with possible benefits they have experienced, but for the greater good of all future patients we need to devise a mechanism for patients’ positive experiences to be gathered, monitored, and, when appropriate, reported to the medical community. New agencies would not need to be set up, as the remit of existing agencies could be expanded. This would limit the additional expenditure needed to maximise benefits, making the system even more attractive to governments and healthcare providers.

**References are in the version on bmj.com**

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FROM BMJ.COM Mary Robinson

Protecting all women against cervical cancer

Every two minutes a woman dies from cervical cancer. Not surprisingly, 90% of these deaths occur in the poorest countries, where women often do not have access to screening tests and treatment or they are simply too expensive. Because of the lack of these services, vaccination against the human papillomavirus (HPV) that causes 70% of cervical cancer cases can mean the difference between life and death.

Several times in my life I have witnessed profound suffering in some of the most underprivileged corners of the world. And I am always struck at the strength of the local women I meet. In difficult environments and lacking even the most basic elements to provide a healthy life for their children, they grasp my hands, smile, and tell me their stories. Like majestic acacia trees on the African plain, these women are the deep roots and the strong trunk and branches that support their families. They cannot fall sick. If they die, all is lost for their children.

Cervical cancer exacts a terrible and unjustifiable social and economic toll on women, their families, and communities—a toll that will rise in coming decades if left unchecked. It is estimated that, if current trends continue, as many as 4 300 000 women a year will die by 2030, 85% of them in low and middle income countries.

Like HIV and AIDS, HPV kills women in the prime of their lives, with enormous effects. Children whose mothers die prematurely have a lower chance of getting a good education and of receiving adequate healthcare. It is with these women in my heart, and in memory of those who died from cervical cancer, that I so warmly welcomed the news on 17 November that millions of women in developing countries may soon be protected against HPV. On that date the GAVI Alliance announced that it will support the introduction of HPV vaccination. GAVI’s decision will lead the way for poor women to enjoy the same access to the vaccine as women in richer nations. This is truly justice for underprivileged women.

Mary Robinson, the first woman president of Ireland (1990–7) and the United Nations high commissioner for human rights from 1997 to 2002, is a former chairwoman of the GAVI Alliance board.

LOBBY WATCH Jane Cassidy

The Sugar Bureau

What is it?
The Sugar Bureau was established in the 1960s to provide information on sugar and health. The organisation, which is funded “principally by UK sugar manufacturers,” says that its new look website aims to help improve knowledge and understanding of the contribution that sugar and other carbohydrates make to a healthy balanced diet (www.sugarnutrition.org.uk). The site, titled “The Sugar Nutrition UK site” and subtitled “Researching the science of sugar,” focuses on providing upbeat statements on a range of topics from health to weight control.

A “Facts” section, described as being “based on the latest scientific evidence on sugars and health,” says that sugar is natural, that active people need it, and even that it may help people stick to slimming diets.

What does it say about sugar and health?
Unsurprisingly, it is mostly good news. Expert scientific committees have noted that the balance of available evidence does not implicate sugar in any “lifestyle diseases,” says the bureau. The scientific evidence is that there is no specific link between sugar consumption and obesity or coronary heart disease, it asserts. People with diabetes can include moderate amounts of sugar as part of mixed meals and within the context of a healthy balanced diet.

On the subject of “empty calories” the bureau says, “Sugar improves the taste and increases the range of food that people will eat. For example, without sugar, many breakfast cereals, which provide important vitamins, minerals and fibre, would not be palatable.”

It does concede, however, that frequent intake of food or drinks containing carbohydrates such as sugars can cause tooth decay, especially in people who do not brush their teeth twice a day with fluoride toothpaste.

Where does it seek to spread its messages?
Children, new mothers, teachers, patients, health professionals, academics, and the media are all target groups. Information for schools on the site includes sections on the history, geography, and science of sugar and its production, types, and uses. Health and nutrition professionals can sign up to a section of the site designed for use solely by them.

Also available are downloadable leaflets for patients, such as “Important things to do to protect your baby’s first teeth,” written by the former chief dental officer Brian Mouatt. This and “Food and fitness for school aged children” were funded from education grants from the bureau.

Health professionals will soon have access to regular online bulletins and a publication providing nutrition information called “Nutrition in practice.” A link to a questions and answers page offers the bureau’s position on such questions as, “Aren’t naturally occurring sugars healthier than added sugar?”

The bureau’s answer is: “There is no difference between the sucrose in a banana, the sucrose in a cake or the sucrose added to a cup of tea.”

Who runs it?
The director is Alison Boyd, former senior dietitian at the Royal Hospitals Belfast. Appointed research director to the bureau in 2001, she took up her current post in 2007. A member of the British Dietetic Association, Nutrition Society, European Association for the Study of Diabetes, and Diabetes UK, she also sits on the scientific and communication committee of the World Sugar Research Organisation (www.wsro.org), an international association supported by the world’s sugar industry. It too provides its members with position statements on sugar and health and responds to frequently asked questions on the subject on its website. The Coca-Cola Company is a member, along with more than 20 national sugar associations.

Documents of the organisation’s Scientific and Communications Committee are available only to members, on a password protected area of the website, along with minutes of other committee meetings. The special research section for members includes research summaries and an abstracts database.

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