When the drug company Cephalon took 13 British doctors to the European pain congress in Lisbon in September 2009, the expenses it provided did not stop with travel, fees, and accommodation—and its presentations were not limited to a balanced scientific explanation of its products at a day time satellite meeting. An internal feedback document circulated to the sales team at the company (now owned by Teva) described one evening’s festivities that it funded for staff and doctors: “Dinner was fantastic . . . we then went to a few bars and to a club till 3am. All the customers were really looked after and spoke positively about Effentora [fentanyl]—let’s make sure they start Rxg [prescribing] now!”

It was a complaint from a former Cephalon sales representative that triggered an inquiry by the Prescription Medicines Code of Practice Authority, the self regulatory arm of the Association of the British Pharmaceutical Industry. That led to a sharp public rebuke for the company, while providing a rare public insight into the tactics and motivations behind corporate links to doctors.

Such incidents—and many far more troubling and extensive ones exposed and penalised through lawsuits in the US in recent years—have led to increasingly tough codes of conduct being introduced by drug companies around the world, and to calls by politicians and regulators for far greater “sunshine” to highlight their activities.

Similar pressures are now building in Europe. Since 2008, Denmark has required companies to disclose to the Medicines Agency any payments they make to doctors, and even details of extensive “unpaid involvement” such as unremunerated work on advisory boards.1 There have been calls for a similar approach in the Netherlands, and politicians in France recently drafted legislation that requires companies to release details of payments to doctors, drafted in response to concerns over the marketing tactics of Servier that were exemplified by the scandal around its drug benfluorex.2

“I think sunshine in Europe is both desirable and inevitable,” says Richard Bergstrom, head of the European Federation of Pharmaceutical Industries and Associations, the Brussels based industry trade body that represents companies across the EU. But he stresses the need to take into account the varied approaches and interactions between doctors and companies in different countries.

US lead
With widespread direct to consumer television advertising of medicines, free product samples, and extensive support of continuing medical education, the US has led the world in the aggressive marketing of pharmaceuticals. Not coincidentally, it is now also leading the way in the provision of information about such activities. Twelve drug companies have recently begun publishing details on their websites of the payments they make to physicians in the US, declaring payments or expenses incurred for meals, travel, consulting, and research to each of thousands of named doctors. While far from complete and difficult to compare, the records are starting to reveal the extent of the links between the two, and shifting practices as a result.

According to an analysis by the Financial Times, conducted with the US based consultancy PharmaShine, in the first quarter of this year alone payments amounted to more than $110m (£71m; €84m).3 Last year, they totalled $4.37m, paid to 262 000 doctors across the country. Some doctors received more than $100 000 each in 2010, and one got $234 000, most of which was speaker fees from Cephalon.

The companies often claim they are championing an ethical stance in releasing the data, and all stress that such links with the medical profession are essential for the development and uptake of innovative drugs to improve patient outcomes. In practice, most have been forced to provide the information because of legal settlements, often “corporate integrity agreements” imposed by the Department of Justice. Some of the large drug companies are yet to provide the data in the US, including Shire, Sanofi, and Bayer. They point to the enormous complexity and cost of compiling all the information from a wide range of internal computer systems and the lack of any legal obligation to do so. Yet companies will soon have no choice. As part of President Barack Obama’s healthcare reforms, putting “sunshine” on physician payments—fuelled by public pressure and exposure of past practices—becomes compulsory in 2013.

The new regulations may provide some much needed consistency. Currently, each company has published different types of data in different ways, making the information hard to access or compare. The differences may reflect particular legal requirements in each case reached in negotiations with prosecutors, but they leave the impression that the companies are doing their best to make the information as inaccessible as possible.

Few allow their data to be easily searched, ranked, or extracted for analysis. Each has different thresholds below which they do not provide information. Some publish only ranges of support rather than providing specific figures. Some companies’ figures are inflates by the sums they provide in research funding to prescribers’ academic institutions, while others are limited to personal payments to doctors.

The result has been periodic and labour intensive efforts by external organisations to make comparisons from the data. ProPublica, a US non-profit journalism organisation, has recently updated its analysis of the figures, “Dollars for Docs,” which allows anyone to search by company, state, or doctor.4

The project, and the sunshine data on which it draws, has met with mixed reviews. “Our once proud profession has been totally corrupted by the insurance cartel and PhARMA [the US industry association],” wrote one retired doctor on the ProPublica site. “No longer is the Hippocratic Oath the ethical basis of medical care . . . by [and] large making money has become the ideal.”

Yet others—both doctors and drug companies—defend the financial connections, stressing that the payments to most physicians are modest; that...
they can legitimately provide information without distorting prescribing practice; and that connections are essential between top disease specialists and companies developing new drugs.

Eli Lilly said in a statement: “Lilly is committed to ensuring that our relationships with healthcare providers are conducted in a manner that complies with applicable legal and ethical standards. Our collaboration with healthcare providers is essential to our ability to provide innovative medicines, improve health education, better understand patients’ needs and improve individual patient outcomes.”

**Behaviour change**

It is difficult to tell what impact sunshine has had on drug industry practices. Though the data remain incomplete and the timescales are still short, some companies seem to be providing less support than in the past. But the entire sector is also under broader financial pressure to save costs by cutting back on marketing expenses, reducing the number of sales staff they employ in the US and cutting support to prescribers.

Following recent legal settlements, drug companies have also introduced tougher ethical codes. Travel and entertainment expenses have been pared back and the maximum value of gifts sharply reduced. GlaxoSmithKline this year removed any direct bonus for its sales staff linked to the volumes of prescriptions by the doctors they target. AstraZeneca has introduced a ban on paying doctors’ travel expenses to international medical conferences.

Allan Coukell, head of the Pew Prescription Project, a US drug safety watchdog, says: “Sunshine has certainly heightened awareness of the concerns. Many individual companies have changed practice. I don’t think we have data yet that lets us say there are measurable trends.”

But there are already some indications of the impact of the public data. With more information on the totals paid by companies to physicians some have since set—or made public—annual caps. Others have ceased payments to doctors whom ProPublica has highlighted were the object of disciplinary action.

George Dunston, founder of PharmaShine, which sells its own constantly updated database derived from the disclosures, says his clients include academic and medical institutions that are keen to see whether the figures provided by industry tally with staff declarations.

For now, the pressures for greater disclosure in the UK and much of the rest of Europe have been more limited. The principles to limit conflict are clear, but the evidence of abuse is limited. In its 2009 report *Innovating for Health*, a working party convened by the Royal College of Physicians concluded that there was mistrust in the relationship between industry and doctors and called for changes, including the elimination of drug company funding of medical education.1

So far, progress has been modest. Article 74 of the General Medical Council’s good medical practice guidelines states: “You must act in your patients’ best interests when making referrals and when providing or arranging treatment or care. You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat or refer patients. You must not offer such inducements to colleagues.” The body says it has no record of any recent action against a doctor for violating this clause.

The UK’s Prescription Medicines Code of Practice Authority, which polices a code of conduct that has been tightened considerably in recent years, does periodically clamp down on abuses, from Cephalon’s conference entertainment to Abbott’s excesses in hiring lap dancers during an evening for prescribers. It relies on tip-offs, which often come from rival drug companies or former employees as well as prescribers. It has limited powers of investigation, largely relying on cooperation and honesty from those it questions.

In Scotland, doctors working for the health service are already required to declare any conflicts of interest with drug companies, although accessing—let alone policing—the information is difficult. A parallel requirement by companies to disclose what they are paying to prescribers would allow government officials, health service administrators, patients, journalists, and prosecutors the chance to compare the two sets of data.

Meanwhile, the external scrutiny of industry support for doctors is stepping up. US investigators are now increasingly looking to pursue cases under the Foreign Corrupt Practices Act that take place beyond its own shores, including a $70m settlement against Johnson & Johnson reached earlier this year. The UK’s Corruption Act also scrutinises bribery within and beyond the UK.

Vivienne Nathanson, head of science and ethics at the British Medical Association, points to her organisation’s endorsement of the industry code and stresses the importance of “making sure there is as much declaration of interest as you can possibly make.” She adds that she would “not object to more statutory declarations, but given there’s already so much bureaucracy, so much already declared, people want to make sure it is useful and does not just cloud the issue.”

Companies seem resigned to greater transparency ahead, while also cautioning about the costs of disclosure. David Brennan, head of AstraZeneca, which has released data for the US (showing payments of $32m last year) but not so far for Europe, says: “We’re not afraid to be transparent. The difficulty is our ability as a company to systematically capture that data across multiple Physicians and markets.”

Up till now, transparency has normally been a result of legal actions rather than voluntarily introduced by companies or doctors. Sunshine alone cannot in any case guarantee honesty. But in the current climate of suspicion, pressure for greater disclosure seems likely to grow.

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**Competing interests:** None declared.

**Provenance and peer review:** Commissioned; not externally peer reviewed.

**References can be found on bmj.com**

Cite this as: BMJ 2011;343:d6459