

EDITORIALS

The regulation of medical devices

Unsatisfactory, unscientific, and in need of a major overhaul

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Two linked features (doi:10.1136/bmj.d2748 and doi:10.1136/bmj.d2905),^{1 2} an analysis article (doi:10.1136/bmj.d2973),³ several commentaries, and a research study (<http://dx.doi.org/10.1136/bmjopen-2011-000155>) highlight the unsatisfactory and unscientific way that medical devices are approved for use particularly in Europe; the failures in regulatory oversight during clinical use; and the lack of transparency in publishing research findings, device related complications, and competing interests.

Competing interests have an unhealthy influence on drug prescription. Drug companies publish selective data aided by clinical researchers, who accept payment to be gift authors of ghost written articles.⁴ Universities that receive research funding from industry can turn a blind eye to misreporting of research. Publication bias is compounded by medical journals that are seduced by the financial gains from reprint sales if they publish positive outcomes of industry sponsored research.⁵ Opinion leaders are paid to endorse drugs at advertising seminars, disguised as scientific symposiums, and doctors attend because they receive lavish entertainment.⁶ Some doctors even accept bribes from companies to prescribe their drugs.⁷ As a result patients may receive inappropriate drugs. But the competing interests around medical devices are even greater.

In the European Union drugs are approved by a single organisation, the European Medicines Agency, after submission of evidence of safety and efficacy in controlled trials. A medical device, however, may obtain a CE (European conformity) mark for use in the whole EU from one of dozens of notified bodies.^{2 3} Usually there is no need to provide proof of clinical efficacy. For example, there are more than 10 devices with CE marks for closing persistent foramen ovale and tens of thousands of devices have been implanted, but the only two randomised trials of persistent foramen ovale closure reported to date showed no benefit for migraine or stroke recurrence.^{8 9} The sale of devices is not usually evidence based. It is based on recommendation from opinion leaders, many of whom have undeclared competing interests.

Doctors are rarely involved in the initial development of a drug. After a drug is licensed, a doctor needs clinical skills to select those patients who should receive the drug but usually no special skills are required to administer it. Additional technical skills are needed to implant devices, such as intracardiac devices and

prosthetic joints. Those technical skills allow some clinicians to appreciate a gap in the market and conceive a design. They may have built and tested prototypes—for example, the cardiologist Andreas Gruentzig designed coronary angioplasty balloons. They may have done initial in vivo animal or human trials. They or their employing hospital often owns the patent for the device and gets royalties for its sale.¹⁰ They may have founded a company to develop the device or sold or leased the rights to a commercial company. Cohen reports that considerable sums of money are involved.¹

Because, in Europe, a licence may be granted to market a device that has no proved clinical value, the manufacturer will often combine marketing with research to demonstrate utility. At that stage the company needs to disseminate the skills required for implantation. The doctors initially trained to use the device cascade the skills to other doctors. Those doctors are part of the company's marketing arm and are paid accordingly.

Interventional clinicians compete with each other to obtain early experience with new devices. Innovators using the newest and greatest number of devices have most credibility with colleagues and patients. They may be invited to demonstrate procedures at live case meetings, sometimes to audiences of many thousands of potential users. Companies pay for their device to be demonstrated, and they nominate and fund speakers. Those who do the demonstrating gain professional kudos, which brings rewards in the form of consultancies from the device industry and private referrals for expensive procedures. The prominence and income of some opinion leaders is linked to sponsoring companies, and they need to remain in tune with their sponsor's message or risk being dropped and losing income.

The same experienced operators will act as paid investigators in clinical trials to test the efficacy of devices that are already in clinical use. Some clinical investigators receive share options and others buy shares in the company that is marketing the device they are investigating. It is not unusual for the principal investigator in a clinical trial of a device to be its inventor. For example, it is reported that Dr Martin Leon, who invented the Sapien heart valve, received \$6.9m (£4m; €4.6m) from Edwards Lifesciences when it purchased the heart valve company he founded,¹¹ and Dr Leon was a principal investigator in the PARTNERS trial of the Sapien valve sponsored by Edwards.¹²

That does not happen in drug research because the inventor of a drug is unlikely to be a clinician.

Once a device is in general use, we allow much closer links between clinicians and representatives of device companies than we do with drug representatives. Doctors do not allow representatives of a drug company to sit in during patient consultations, but it is routine to have device company representatives in the operating theatre or cardiac catheter laboratory to provide advice about procedures. Such input can be useful, particularly when an unusual device related problem is encountered, but it leads to an even more cosy relationship with the device industry. Good customers, who use large numbers of devices, may receive rewards, such as sponsorship to attend overseas events. Cohen reports that in some cases, bribes have been paid for use of devices.¹ Clinicians can also choose not to report device related complications to regulators such as the MHRA. This may be because of fear that the blame will be shifted to them as the operator, to maintain their relationship with industry and in some cases to avoid the risk of a subsequent legal dispute.

The process of approving medical devices must be entirely overhauled to make it evidence based, particularly in Europe. We still have far to go to minimise competing interests that influence patient care. Where competing interests cannot be prevented, there must be genuine disclosure. Experience has shown that clinicians, journals, and industry cannot be trusted to police themselves. Legal and meaningful sanctions are needed. Token fines for misconduct should be replaced by penalties considerably greater than the amount gained by dishonesty. Regulators such as the General Medical Council should have the power to impose sanctions on doctors who fail to disclose conflicts of interest or who fail to report adverse events related to devices or drugs. Journals should demand that authors publish the actual amount paid to individual investigators involved in trials and should themselves publish annually the amounts they receive from individual companies from reprint sales and advertising.

Competing interests: The author has completed the unified competing interest form at www.icmje.org/coi_disclosure.pdf (available on request from him) and declares no support from any organisation for the submitted work and no financial relationships with any organisation that might have an interest in the submitted work in the previous three years; PW was a principal investigator and principal cardiologist in the MIST trial of transcatheter closure of persistent foramen ovale with the STARFlex device for relief of migraine. The trial was sponsored by NMT Medical. PW is being sued in the High Court in London for libel and slander by NMT for comments he made about the trial when he was invited to lecture at an interventional cardiology conference in the US in October 2007, and some of his comments were reported on a US cardiology website. He is defending the case. He declined an offer to be an author of the paper about the MIST trial to be published in *Circulation* because he believed that the paper was inaccurate and incomplete.

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