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NEWS

Trial participants need to represent patients better

Bob Roehr WASHINGTON, DC

A new report is calling for changes in the conduct of clinical trials in the United States to reduce disparities of age, sex, race, and comorbidity. The goal is to give a more representative picture of the benefits and risks of a treatment across the entire population but particularly among those who bear the greatest burden of the morbidity.

The eliminating disparities in clinical trials (EDICT) initiative was conducted over two years by the Baylor College of Medicine in Houston and the Intercultural Cancer Council. It is part of an ongoing four year project to reduce barriers to participation in trials. The report of the initiative was released on 1 April in Washington, DC.

The report describes itself as a "nationwide call to action . . . that removes the barriers to clinical trial participation and advances education and information sharing [as] a critical step to improving the health status of all Americans."

Recommendations include harmonising the Food and Drug Administration's regulations on trial design and conduct with those of the National Institutes of Health requiring diversity; increasing collaboration between government and industry in trials; and fostering community involvement in all phases of trial design and implementation.

It calls on journals to require researchers to include an analysis of how their trial participants match the population that bears the greatest burden of that condition. It also seeks better education of institutional review boards on their ethical responsibilities and of the general public about the trials process.

Calls for better education of review boards and the public are likely to draw little opposition. But other recommendations are likely to require an increase in the size of a trial to provide sufficient numbers for subgroup analysis according to sex, race, age, and comorbidity. This will increase the cost of trials and could delay the introduction of new drugs to the marketplace.

Information on EDICT is available at www.bcm.edu/edict.

IAN HOOTON/SPL

Proposed regular health checks for vascular disease will not be "high tech", said Alan Johnson

Vascular screening of over 40s may save 2000 lives a year

Zosia Kmietowicz LONDON

Everyone in England aged between 40 and 74 is to be offered a health check every five years to screen for the risk of heart disease, diabetes, kidney disease, and stroke, the Department of Health announced this week.

Alan Johnson, the secretary of state for health, said that detailed modelling by the department had shown that universal vascular screening will be clinically and cost effective. Vascular disease affects four million people in England and kills 170 000 people every year.

"The case for a national programme of vascular checks is compelling. We could prevent 9500 heart attacks and strokes every year and save 2000 lives. It would also reduce the health inequalities that blight the lives of the country's most deprived families," said Mr Johnson.

National service frameworks on coronary heart disease, renal services, and diabetes had led to a 40% reduction in the number of deaths from cardiovascular disease in people aged under 75 since 1996, he added. But screening would extend the benefits. It would prevent at least 4000 people a year from developing diabetes and could detect 25 000 cases of diabetes or kidney disease earlier, when they could be better managed.

Bill Kirkup, associate chief medical officer for England, said that vascular disease was the largest single cause of death and premature death in England. At least half the health inequalities between rich and poor people were due to vascular disease, he said.

Although 21% of middle aged people already had the checks that would be offered in the new screening programme, through opportunistic checks offered by GPs, the programme would pick up those people who don't access health services so readily, said Dr Kirkup.

The programme, which will cost £250m (€320m; $500m) a year, will be funded with new money and rolled out from the next financial year (2009-10). Checks will take place in GPs' surgeries, pharmacies, and community settings.

To screen England's middle aged population every five years will mean three million checks a year or seven checks a week for the average general practice, said Dr Kirkup.

Vascular checks were not "high tech," said Mr Johnson. They will involve standard questions and measurements, such as age, sex, weight, height, blood pressure, and postcode (an indication of deprivation), and a blood lipid test.

People would be given lifestyle advice, referrals to weight loss and smoking cessation services and preventative treatment, according to their risk.

Wakefield tells GMC he was motivated by concern for children

Owen Dyer LONDON

The doctor at the centre of a major public health scare over vaccinations gave evidence this week before a General Medical Council panel, where he and two colleagues stand accused of research misconduct.

Andrew Wakefield, whose research paper and comments in 1998 linking the combined measles, mumps, and rubella (MMR) vaccine to autism led to a sharp fall in uptake of the vaccine, told the hearing that he was motivated by concern for autistic children.

He read out a letter that he had sent in 1997 to John Walker-Smith, now also accused of misconduct by the GMC, in which he wrote: "If these diseases are found to be linked to the MMR vaccine, these children are the few unfortunate who have been sacrificed to protect the majority."

In that letter he defended his involvement with solicitors acting on behalf of parents seeking compensation from vaccine manufacturers. Six years after the publication of a study linking measles virus to irritable bowel syndrome and autism (*Lancet* 1998;351:637-41), it emerged that 10 of 12 patients involved in the research had legal aid backing to sue vaccine manufacturers and that the Legal Services Commission had funded his research (*BMJ* 2004;329:1293).

STEVE PARSONS/PA WIRE/PA PHOTOS

Andrew Wakefield received more than £400 000 from the Legal Services Commission

Dr Wakefield also received £435 643 (€550 000; $860 000) from the commission in fees to investigate and write reports on the safety of the MMR vaccine—fees that were not disclosed in the *Lancet* paper. When the payments became known in 2004 the *Lancet* repudiated the paper, and its editor, Richard Horton, said that the journal was compromised by a "fatal conflict of interest."

Dr Wakefield denied that his research was motivated by legal or financial reasons. "The reason these parents were talking to me was nothing to do with the litigation, and litigation was not my primary concern."

He told the hearing that when he was approached by lawyers representing the families of autistic children he had consulted the BMA to ask what the "going rate" was. "They indicated that the fee was £150 to £200 an hour," he said. "I opted for the former of the two figures."

Dr Wakefield also disputed allegations that while at the Royal Free Hospital, London, he conducted invasive tests, including colonoscopies and lumbar punctures, not approved by the hospital's research ethics committee. Those tests were conducted for clinical, not research, purposes, he argued, and were beyond the remit of ethics approval.

Professor Walker-Smith, who is also facing the GMC panel accused of serious professional misconduct, decided which investigations were appropriate on the basis of clinical need, said Dr Wakefield.

A third consultant at Royal Free Hospital, Simon Murch, is also accused of participating in unapproved and unnecessary invasive procedures as part of the research. Professor Murch wrote to the *Lancet* in 2003 repudiating Dr Wakefield's claims about MMR vaccine, calling him "completely wrong."

His testimony continues.

See EDITORIAL p729

Research psychiatrist is struck off for wide ranging dishonesty and lack of insight

Owen Dyer LONDON

A former senior lecturer at the University of London's Institute of Psychiatry has been struck off after a General Medical Council panel found that he repeatedly lied about ethics committee approval for his studies. The GMC also found that he misrepresented his academic qualifications, misused drug companies' proprietary data, recruited mentally ill patients without notifying their GPs, and conducted diagnostic tests without patients' consent or ethics committee approval.

Tonmoy Sharma, 42, described by the GMC panel as a "research psychiatrist of international repute," falsely claimed on five occasions to have obtained ethics committee approval for proposed studies involving antipsychotics and other drugs. He made these claims to local research ethics committees, to the Alzheimer's Society, and to the drug company then called Sanofi Synthélabo.

Dr Sharma misled Sanofi into believing that a study comparing schizophrenia drugs was being conducted under the auspices of the Institute of Psychiatry, when in fact it was conducted by Psychmed, a company in which he had a major financial interest.

A medical adviser to Sanofi became suspicious over payments to Psychmed, and the company hired investigators to look further into Dr Sharma's work. The investigation formed the basis of a complaint to the GMC against Dr Sharma by the Association of the British Pharmaceutical Industry.

Panel chairman Andrew Popat, a barrister and Crown Court senior recorder, told Dr Sharma: "Your persistent and wide ranging dishonesty and untruthfulness, spanning a number of years, together with your lack of insight, are so serious that it is fundamentally incompatible with your continuing to be a registered medical practitioner."

Dr Sharma, who represented himself in the hearing, has 28 days to lodge an appeal.

Guide to diagnosing

Clare Dyer BMJ

A comprehensive, evidence based guide to the physical signs of sexual abuse of children was published this week by the Royal College of Paediatrics and Child Health.

The long awaited publication, which is based on five years' work, will help UK child protection professionals diagnose sexual abuse of suspected victims and gives advice on how they can best present their evidence in criminal and family court cases.

It will also ensure that professionals use an agreed terminology to describe signs, so that everyone involved in a case knows what is meant. Rosalyn Proops, child protection officer for the college, said, "It provides clinicians—paediatricians in particular—with a common language to describe the physical signs, and that is the key to writing better reports and safer practice for children, families, and paediatricians."

The college's project has uncovered a scarcity of high quality research on the subject, and the

NHS chief executive denies BMA took health department "for a ride" over GP contract

Adrian O'Dowd LONDON

Department of Health officials have denied accusations that they were "taken for a ride" by the BMA over the new GP contract.

MPs on the House of Commons Committee of Public Accounts quizzed health department officials last week as part of their inquiry into the National Audit Office's report on pay modernisation for GP services in England, published in February (*BMJ* 2008;336:465, 1 Mar).

Committee chairman Edward Leigh, Conservative MP for Gainsborough, quoted figures from the report when asking questions of witness David Nicholson, NHS chief executive.

"You spent, Mr Nicholson, £1.8bn [€2.3bn; $3.6bn] more than expected, but people still can't see a GP when they need to. Why is that?" asked Mr Leigh.

Mr Nicholson said that "£1.4bn of that wasn't actually extra money paid by the tax payer for the contract; it was based on a miscalculation and an estimate of the amount of money we already paid."

Mr Leigh said the 58% pay increase for many GPs between 2002-3 and 2005-6 came into force in 2004, alongside a productivity decrease of 2.5% per year in 2004 and 2005.

The drop in productivity, said Mr Nicholson, was an estimate by the Office for National Statistics that did not take into account the complexities of delivering primary care or other significant benefits gained from the new GP contract.

MPs on the committee said that the health department had set the bar too low for GPs to meet the targets under the quality and outcomes framework (QOF), the GP contract's performance related scheme.

Mr Leigh said, "You rushed this, didn't you? The primary care trusts didn't have the available resources, and the BMA took you for a ride. That's the honest truth, isn't it?"

Mr Nicholson replied: "I don't think any of those things are true. We set out to completely change the nature and way general practice is remunerated in this country.

"The QOF was a really important part of that. For the first time we could connect a GP's pay to performance and in particular clinical performance."

MARK THOMAS

Wendy Savage of the Keep our NHS Public campaign and others demonstrate outside the Department of Health over the decision to award the contract for three GP practices to UnitedHealth Primary Care

sexual abuse of children is published by royal college

guide highlights the absence of clear evidence that some signs are diagnostic of sexual abuse. An example is reflex anal dilatation, the sign on which two paediatricians in Cleveland, in the north of England, were found to have over-relied in diagnosing sexual abuse in 121 children within five months in 1987.

Elizabeth Butler-Sloss, the judge who chaired the inquiry into the Cleveland case, says of the guide in a preface: "It clearly sets out both the strengths and limitations of the research evidence behind the most important clinical signs in children . . . The book clearly highlights the significant areas where the evidence is either absent, limited, or conflicting. The doctor advising courts will need to be aware of this and offer appropriate assistance."

Despite the limitations of the existing research, the guide says, valuable data are available. "Good quality research has been published which includes study populations with a high security of diagnosis for both CSA [child sexual abuse] and non-abuse." It calls for more such research to be carried out.

Jean Price, a consultant community paediatrician and member of the project board for the exercise, said, "It's the first time—certainly in the UK and, I actually think, in the world—that we've done an evidence based look at the signs and symptoms of sexual abuse."

The guide, produced in collaboration with the Royal College of Physicians of London and that college's faculty of forensic and legal medicine, says that the physical signs are only part of the diagnostic jigsaw. It reminds practitioners of the importance of considering these alongside the case history and the child's behaviour, demeanour, and statements to the doctor.

David Spicer, a local authority lawyer who was consulted on the draft, said, "It's important that [sexual abuse is treated as] a multi-agency issue and that there's a good understanding within social care and the police, so that they can challenge and test the opinions of the local medics and the experts. One of the difficulties in the past is that all the responsibility has been placed on the medics' shoulders."

The Physical Signs of Child Sexual Abuse: An Evidence-Based Review and Guidance for Best Practice **will be distributed for free to designated and named doctors who work in child protection. It will cost £20 to members of the Royal College of Paediatrics and Child Health and the Royal College of Physicians' faculty of forensic and legal medicine and faculty of genitourinary medicine (£25 to non-members).**

REX

Marietta Higgs was found to have over-relied on the sign of reflex anal dilatation in Cleveland in 1987

UN hears demands that 10% of spending on roads should

Emma Wilkinson LONDON

The United Nations has held a debate on road safety, after campaigners warned that numbers of deaths and injuries from road collisions were on a par with the devastation caused by HIV and AIDS, malaria, and tuberculosis. Traffic crashes amounted to a global "epidemic," they said, in which a child dies every three minutes.

The UN General Assembly was told by the Commission for Global Road Safety that more than 1.2 million people are killed every year on the world's roads, a figure that is set to double by 2030.

The debate comes after research from the World Health Organization projected that 20 million lives will be lost through road collisions between 2000 and 2015 and that a further 200 million would be seriously injured.

Young people bear the brunt of the lack of action on road safety, the commission said. Road crashes are now the world's number one killer of people aged 10 to 24 years.

Campaigners, who include the Nobel peace prize winners Jimmy Carter and Desmond Tutu, say that the "appalling toll of death and injury" has been overlooked for too long.

The UN was also presented with a petition of more than a million signatures from the Make Roads Safe campaign, which has set out plans for a 10 year, $300m (£150m; €190m) investment in road safety in middle and low income countries.

The campaigners want UN delegates to agree that 10% of international road infrastructure budgets should be set aside for safety measures.

David Ward, director general of the FIA Foundation, the organisation behind the Make Roads Safe campaign, said, "We desperately need to address a range of key issues, and we need to get all ministers responsible for road safety, from all of the countries of the world, together."

He said that in addition to action on seat belts, helmets, speed, and drink driving, more needs to be done to ensure that roads are built to the safest possible standards, especially in developing countries.

"These are the kind of practical things that a ministerial conference at UN level could agree."

The former UK defence secretary George Robertson, who chairs the commission, said it was crucial that big road infrastructure plans, subsidised by taxpayers worldwide, included a 10% component for road safety.

From the archive: *BMJ* "War on the roads" theme issue www.bmj.com/content/vol324/issue7346/index.dtl

Telemedicine has helped reduce patients' travel at the Royal Cornhill Hospital, Aberdeen (above)

NHS should take steps to cut its carbon footprint, BMA says

Susan Mayor LONDON

The NHS should urgently introduce measures to reduce its energy consumption and emission of greenhouse gases, recommends a report published this week by the BMA. This includes reducing the amount of travel by patients and staff and making greater use of electronic communication, the report says. It warns that the NHS currently produces emissions equivalent to about a million tonnes of carbon dioxide each year and accounts for 5% of all road transport emissions in the United Kingdom.

The report reviews the potential effects on health of climate change and makes a range of recommendations on measures that the NHS and health professionals can take to reduce the contribution of their work to climate change. It notes that the NHS is the largest single organisation in the UK, employing more than one million people. NHS healthcare facilities spend £400m (€500m; $800m) each year on energy.

"As the biggest employer in the UK, and one with a considerable carbon footprint, the NHS needs to take urgent action to reduce its greenhouse gas emissions and the contribution it makes to climate change," recommend the BMA's science and education department and its board of science, whose members developed the report. They say that commitment from the NHS executive and board is crucial to achieving the large scale change required, which should including developing and implementing policies on construction, electricity use, heating, water management, transport, and waste management.

Five per cent of the UK's road transport emissions are attributed to NHS related journeys by staff, patients, and visitors, 83% of which are by car or van, the report says. It recommends that the NHS develop a more environmentally friendly transport policy, including encouraging patients to be treated closer to home; minimising the number of deliveries and pick ups to avoid unnecessary trips; using low carbon vehicles and fuels; and encouraging healthcare professionals to use public transport where possible.

The report cites several examples of good practice. For example, the Royal Cornhill Hospital in Aberdeen uses telemedicine to reduce the amount of travel by patients and staff. The hospital also runs peripheral clinics, whereby one or two specialists travel to run outpatient clinics in general practices in remote and rural areas, rather than several patients travelling to the hospital.

The BMA also encourages health professionals to carry out carbon audits at work.

See EDITORIAL, p 733

***Health Professionals: Taking Action on Climate Change* is available at www.bma.org.uk.**

go on safety measures to save lives

STR/AFP/GETTY IMAGES

Road crashes, like this one in Libreville, Gabon, are the world's biggest killer of people aged 10 to 24 years

New law puts NHS trusts at risk of charges of corporate manslaughter when patients die

Clare Dyer BMJ

NHS trusts will face the risk of prosecutions for corporate manslaughter if patients die as a result of gross negligence, under a new law coming into force this week.

The change could mean fewer prosecutions of individual doctors for manslaughter, as prosecutors turn their attention to systemic failures of organisations instead.

The Corporate Manslaughter and Corporate Homicide Act 2007 covers the whole of the United Kingdom (homicide is the term used in Scotland). For a prosecution to succeed, management failures must amount to a gross breach of the duty of care—in other words, the conduct that breaches the duty of care must fall far below what could reasonably have been expected.

The act comes after years of lobbying for a statutory offence of corporate manslaughter, mainly in the light of rail disasters and injuries and deaths on construction sites. Under the common law, successful prosecutions against large organisations were doomed to fail, as the law requires the identification of a single individual who is the "controlling mind" of the enterprise.

Liability for corporate manslaughter will arise if the way an organisation's activities are managed causes death and amounts to a gross breach of the duty of care to the person who has died. Fines are unlimited and are expected to exceed £100 000 (€125 000; $200 000), and the organisation can also be required to take steps to remedy the breach and to publicise the conviction and the fine levied.

Stephanie Bown of the Medical Protection Society pointed out that the new law will apply to any organisation that is an employer, including general practices and providers of out of hours care, if they have employees.

There is no individual liability for corporate manslaughter, and doctors will still face the risk of individual prosecutions for manslaughter for causing deaths. But systemic problems have been a feature in a number of cases in recent years where junior hospital doctors have been prosecuted for manslaughter, and the police may decide to go down the corporate manslaughter route instead in such cases in future.

Dr Bown forecast more police investigations than at present and warned of conflicts of interest for individual doctors, who will want to throw any blame on to the wider setting in which they work. They should seek separate advice from their defence body early in any investigation, she urged.

"The act will leave police with greater interest in conducting a thorough investigation when there's a death in a medical setting, because they have a new route to go down," she predicted.

Deaths on construction sites contributed to the change

Academic freedom is at risk in dispute over Gardasil, experts say

Melissa Sweet SYDNEY

Senior academics are outraged that the University of Queensland has asked an academic to apologise to a drug company for his public comments on a vaccine against human papillomavirus that was developed jointly by the university and the company.

Academics at the university and elsewhere say that the request is a threat to academic freedom and warn that it raises worrying concerns about universities' independence and ability to negotiate conflicts of interest.

The request came after the company, CSL, wrote to the university's vice chancellor complaining about comments on the radio made by Andrew Gunn, a senior lecturer in general practice.

The programme dealt with the general issue of pharmaceutical marketing and briefly mentioned Gardasil, whose development has reaped millions of dollars for the university as well as public and political kudos.

CSL's director of public affairs, Rachel David, wrote: "I feel Dr Gunn's comments are inappropriate and inconsistent with the long-standing relationship CSL has with the University of Queensland and given the involvement of the university in the development of Gardasil."

On 14 March the university's secretary and registrar, Douglas Porter, wrote to Dr Gunn, asking him to provide a written apology to CSL stating that the "comments were made by you in your personal capacity and were not endorsed or authorised by the university." Mr Porter also asked to be sent a copy of Dr Gunn's letter to CSL.

Dr Gunn said he was disappointed by the university's response and that the company's complaint seemed to be aimed at stopping him from speaking out again. "Even if you're fairly resistant to pressure, it's got to make you think twice about saying potentially critical things about their products," he said.

Wayne Hall, of the university's School of Population Health, described CSL's response as "heavy handed" and said that the university's response was "disrespectful of the rights of academics to speak out."

The University of Queensland's vice chancellor declined to comment and referred the *BMJ* to Mr Porter, who said that Dr Gunn "had no authority to speak on behalf of the university" and should not have mentioned his university position.

IN BRIEF

Majority of *BMJ* readers want to shift responsibility for sick notes: Just over half of respondents to our poll asking whether responsibility for signing people off sick should be transferred from GPs to occupational health teams said it should: 56% (415) said yes and 44% (324) said no (www.bmj.com).

Eli Lilly settles out of court for $15m: The drug maker Eli Lilly has agreed to pay the state of Alaska $15m (£7.6m; €9.5m) in an out of court settlement after the state sued it for failing to warn adequately that its antipsychotic drug olanzapine (Zyprexa) caused serious and sometimes fatal side effects, such as weight gain and diabetes.

GMC offers guidance on disabled medical students: The General Medical Council has issued guidance to medical schools on encouraging disabled people to apply for places. Medical schools now have a legal duty to find out how they can adapt their courses to meet the needs of disabled students. Some have already set up hearing loop systems and provided specially modified stethoscopes for students with impaired hearing. *Advising Medical Schools: Encouraging Disabled Students* is at www.gmc-uk.org.

No link is found between smoking and weight among teenage girls: A new Canadian study in *Annals of Epidemiology* (doi: 10.1016/j.annepidem.2007.12.010) reports that girls aged 12 to 17 years who smoke cigarettes were no more likely to lose weight than girls who do not smoke. But the five year study found that teenage boys who smoke were shorter than other boys and had a lower body mass index.

Israel passes laws to encourage organ donation: Two new laws passed by Israel's parliament aim to encourage organ donation from brain stem dead patients among Orthodox and traditional Jews, Muslims, and others. The laws will also allow compensation for expenses for live donors while formally prohibiting the sale of organs by Israelis in the country or abroad. Doctors who have undertaken a course on medical ethics and brain death will determine the moment of death.

China will invest in cervical cancer screening: China's health ministry has announced that it will invest ¥200m (£14m; €18m; $28m) to set up cervical cancer screening and treatment centres, enabling 200 000 Chinese women to be screened for free in the coming three years.

Australian drug firms give details of sums spent courting doctors

Bob Burton HOBART

Australia's drug industry has said that in the last six months of 2007 alone it organised more than 14 633 "educational events" for the benefit of medical professionals. Detailed monthly reports by 43 companies show that they spent more than $A31m (£14.3m; €18.1m; $28m) and attracted 385 221 people to the events.

Although many meetings were held in hospitals and attracted attendances of only about two dozen, others were more elaborate affairs. Amgen Australia, for example, spent $328 206 on food, alcohol, travel, and accommodation at a Sydney hotel for a two day clinical haematology symposium attended by 142 haematologists and trainees. Amgen sells a range of haematology drugs.

In July 2006 the Australian Competition and Consumer Commission, a government regulatory agency, reauthorised the self regulatory code of conduct developed by Medicines Australia, the major drug industry group.

However, the commission required member companies to submit monthly reports detailing each event for medical professionals, the venue, the purpose of the event, the nature of the hospitality provided, the number attending, and the total cost of the function (bmj.com, 5 Aug 2006, News extra, doi: 10.1136/bmj.333.7562.278-b).

A legal appeal by Medicines Australia against the condition was dismissed by the Australian Competition Tribunal.

Before the release of the reports the industry took out full page advertisements in medical publications seeking to reassure doctors that individuals would not be identified and that attendance at such events "does not imply that the provision of timely information by pharmaceutical companies to your profession is in any way improper."

Ian Chalmers, chief executive of Medicines Australia, said that the industry had "listened to community anxiety about what goes on behind closed doors between doctors and drug companies" and embraced the new reporting requirement. "Transparency is intrinsically valuable," he said.

Rosanna Capolingua, president of the Australian Medical Association, defended drug industry events as keeping doctors informed on new treatments. She said, "Doctors don't get a cut for prescribing one drug over another . . . We have never looked at this through a conflict of interest frame."

Peter Mansfield, a spokesman for the drug industry watchdog group Healthy Skepticism, said that the reports are "useful for telling us the scale of the problem but will have no impact on solving the problem of drug companies influencing doctors' prescribing habits."

Simply by attending such events, he said, "doctors compromise their ability to give patients unbiased advice . . . Drug companies don't sponsor these events to 'educate' doctors . . . but to sell their drugs."

Federal minister for health Nicola Roxon did not respond to a request for comment. But in a response to an earlier article in the *BMJ* about sponsorship of medical education (*BMJ* 2008;336:416-7), she said that prescribing should not be "influenced by any sponsorship arrangements of education" and that "complete transparency" was desirable. But she also made it clear that the federal government would not act to curb the involvement of sponsors in doctors' education.

Peter Mansfield: firms don't sponsor these events to "educate"

The company reports are at www.medicinesaustralia.com.au/pages/page155.asp.

Continuing education should no longer

David Spurgeon QUEBEC

The current system of continuing health education—sponsored largely by an industry with a vested interest in promoting its products—is unacceptable to self regulated health professionals, says the journal of the Canadian Medical Association.

The *CMAJ* editorial says that health professionals should take over medical education and base it on their needs and those of their patients (doi: 10.1503/cmaj.080317).

"It is time to stop the pharma-driven 'free lunch' approach and place our continuing medical education system firmly in the hands of unbiased and qualified people, not corporations whose main concern is the bottom line," says the editorial, written by a team under the byline of the journal's editor in chief, Paul Hébert.

It continues: "To make this vision a real-

Longer, better studies are needed to assess safety of coronary stents, FDA tells industry

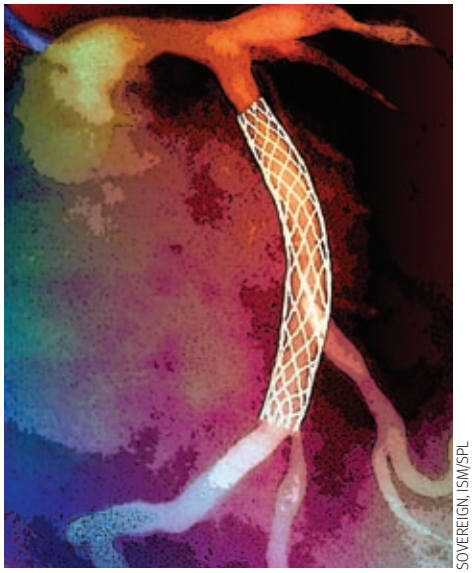
Jeanne Lenzer NEW YORK

After a year of controversy over the relative safety of drug eluting stents and bare metal stents, the US Food and Drug Administration has issued guidance to the industry on the development and testing of stents.

It recommends that all clinical trials should have a follow-up period of 12 months, instead of the current nine months, and that a data monitoring committee should continuously review all studies of drug eluting stents. The agency, which issued the guidance last week, will accept public comments on the recommendations for 120 days before it issues its final guidance.

Daniel Schultz, director of the agency's Center for Devices and Radiological Health, said that the draft guidance "is part of FDA's ongoing effort to provide regulated industry with recommendations on measures that can minimise the risks while preserving for patients the benefits of drug eluting stents."

The guidance comes in response to a fractious debate that erupted at the December 2006 meeting of the FDA's panel on circulatory system devices. Experts were split over the safety of drug eluting stents, citing conflicting research results and conclusions.



SOVEREIGN, ISM/SPL

Experts have argued over the relative merits of drug eluting versus bare metal stents

The panel's chairman, William Maisel, a cardiologist at the Beth Israel Deaconess Medical Center, Boston, said that Johnson & Johnson's Cordis division had failed to report complete registry data for its sirolimus eluting stent, Cypher. The *New England Journal of Medicine* (2007;356:325; http://content.nejm.org/cgi/content/extract/356/4/325) reported Mr Maisel as saying, "This panel required a post-marketing patient registry as a condition of approval [for the Cypher stent]." But, he said at the 2006 meeting, "we now sit here three years later, and you have failed to show us data for more than one year."

The FDA guidance says, "A meta-analysis of all randomized trials comparing drug-eluting stents with bare-metal stents (as well as head-to-head trials comparing sirolimus-eluting stents with paclitaxel-eluting stents) demonstrated similar mortality rates for all groups." However, the guidance acknowledges that studies have been underpowered to assess deaths and heart attacks as end points.

Eric Topol, a noted cardiologist and member of the 2006 advisory panel, told the *BMJ* that the draft guidance was a step forward. But he criticised the fact that the guidance required the reporting of device related outcomes rather than clinical outcomes. "Clinical end points would be preferable," he said.

Pfizer loses bid to force journals to reveal peer review comments

Clare Dyer BMJ

A US federal judge in Illinois has rejected a bid by the drug company Pfizer to force two leading medical journals to hand over confidential documents relating to peer review of studies on its cyclo-oxygenase-2 inhibitors valdecoxib (Bextra) and celecoxib (Celebrex).

The company sought the documents from a number of journals, including the *BMJ*, to help it defend 3000 product liability lawsuits over alleged side effects of the two drugs. But the journals have strongly contested the move as a threat to the process of peer review. In the first case to reach a court ruling so far, a judge has rejected the motion for access to peer review documents held by *JAMA* and the *Archives of Internal Medicine*.

Judge Arlander Keys said that Pfizer seemed to be fishing for documents "that might possibly contain something to counterbalance what was reflected in the medical literature."

But the company had not explained how unpublished information could help defend against claims that were based on what was known in the medical community at the time of the alleged injuries.

be funded by drug industry, says *CMAJ* editorial

ity, we call upon the Canadian Academies of Health Sciences, perhaps involving the US Institute of Medicine, to initiate a dialogue among all stakeholders. Getting thoughtful discussion underway is the first step in fixing a truly broken system maintained by our culture of entitlement.

"Of the US$2.6bn [£1.3bn; €1.6bn] spent in the United States on accredited continuing medical education activities in 2006, US$1.45bn (60%) came from pharmaceutical and medical device manufacturers. Although there are no reliable data in Canada, there is also no evidence that the situation is any different here.

"Worldwide, IMS, a private company specializing in pharmaceutical intelligence, reports that in 2004 the pharmaceutical industry spent US$27.7bn on promotional activities, and US$29.6bn on research and development." Evidence indicates that education sponsored by the drug industry often distorts the selection of topics, embellishes the positive elements of studies, and downplays the adverse effects, says the editorial.

"Free lunches" must end