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NEWS

Pfizer agrees to pay record fine of $2.3 billion for promotion of off-label use of four drugs

Janice Hopkins Tanne
NEW YORK

Pfizer, the world's largest drug company, has agreed to pay $2.3bn (£1.4bn; €1.6bn) to settle charges of fraud and civil and criminal liability over its promotion of off-label use of four drugs.

The US Department of Justice said it was the largest healthcare fraud settlement in the department's history and the largest criminal fine ever.

The *New York Times* noted that $2.3bn amounted to less than three weeks of Pfizer sales (www.nytimes.com, 3 Sep).

Unlike in previous settlements by drug companies, the announcement of the settlement was made at a Washington press conference by Kathleen Sebelius, secretary of the Department of Health and Human Services, the parent body of the Food and Drug Administration. Although the investigation was conducted under the Bush administration, the department's publicity suggests that the Obama administration will be tougher on drug companies that market their products for unapproved indications.

CHIP SOMODEVILLA/GETTY IMAGES

Kathleen Sebelius announces the largest healthcare fund fine ever

In a press release Pfizer said that it had "finalized a previously reported agreement in principle with the US Department of Justice to settle an investigation regarding past off-label promotional activities" related to four drugs. Pfizer said it had previously disclosed financial statements setting aside funds for the settlements.

As part of the settlement with the justice department, Pfizer agreed—for the fourth time—not to do it again. Pfizer agreed to enter a corporate integrity agreement with the Office of the Inspector General of the Department of Health and Human Services to avoid and detect such problems. Pfizer has previously entered into three such agreements.

The many charges related to Pfizer's promotion of the anti-inflammatory drug valdecoxib (marketed in the United States as Bextra) and other drugs for uses not approved by the FDA. US doctors may prescribe any drug approved by the FDA for any indication, but drug companies may not promote off-label use.

The Pfizer subsidiary Pharmacia & Upjohn agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act and to pay fines and forfeitures amounting to $1.3bn. The subsidiary had promoted valdecoxib for off-label uses and at dosages that the FDA had not approved. The drug, a cyclo-oxygenase-2 inhibitor, was withdrawn from the market in 2005.

In addition, Pfizer agreed to pay $1bn to resolve charges that it promoted off-label uses of valdecoxib and also ziprasidone (Geodon), an antipsychotic drug; linezolid (Zyvox), an antibiotic; and pregabalin (Lyrica), an antiepilepsy drug.

Pfizer's promotion of off-label use of these drugs caused doctors to prescribe them and thus to submit false claims to the US government's Medicare insurance programme for elderly people and its Medicaid programme for poor people when these drugs were not approved.

Of the $2.3bn payment, $1bn will go to Medicare, Medicaid, and other government insurance programmes. States that share Medicaid payments with the government will receive part of that $1bn. Six whistleblowers, including a former Pfizer salesman, will share $105m. Also, $635m will go to the Victim Witness Fund, which supports state programmes helping crime victims.

Cite this as: *BMJ* 2009;339:b3657

Key workers lacked experience to deal with killer, inquiry concludes

Clare Dyer BMJ

A "systemic failure" allowed Peter Bryan, a dangerous, mentally ill killer who went on to kill two more people, to be supervised in the community by an inexperienced psychiatrist and social worker, an independent inquiry has concluded.

Mr Bryan, who has schizophrenia and has since been given a diagnosis of a personality disorder, killed an acquaintance, Brian Cherry, in 2004 and then fried and ate part of his brain. Ten days after he had been detained in Broadmoor high security hospital for the killing he attacked a fellow inmate, who later died of his injuries.

The reports of two separate inquiries into the two incidents, carried out for the strategic health authority NHS London, found a catalogue of failings in Mr Bryan's care and supervision. But they point out that he was a highly unusual patient who appeared normal even when he was seriously mentally ill.

The inquiry into the killing of Mr Cherry concluded that no particular failure by any individual professional directly precipitated the outcome. But it found "a systemic failure to ensure that the key professionals allocated to care for him in the community had the necessary experience to deal with someone with his forensic history and complex presentation." The professionals were a general adult psychiatrist who had no experience of supervising a killer and an inexperienced social worker with no training in mental health.

Cite this as: *BMJ* 2009;339:b3648

IN BRIEF

Demand and doctors' uncertainty are behind burgeoning use of radiography: Demand from patients and reassurance for doctors are major factors in the rising use of clinical radiography, finds a poll of 374 radiologists in Norway (*BMC Health Services Research* 2009;9:155). Other factors are availability of services and the expanding medical possibilities of its use. But doctors need more advice to help them decide when radiography is appropriate to reduce unnecessary investigations, the study says.

China brings in new measures to protect patients in trials of devices: China's health ministry has introduced new measures to protect patients who voluntarily participate in clinical trials of medical devices, including a requirement to obtain informed consent, says a report from China's official news agency, Xinhua. Medical devices in clinical trials should be provided free of charge, and clinical test results must be produced by the institutions involved.

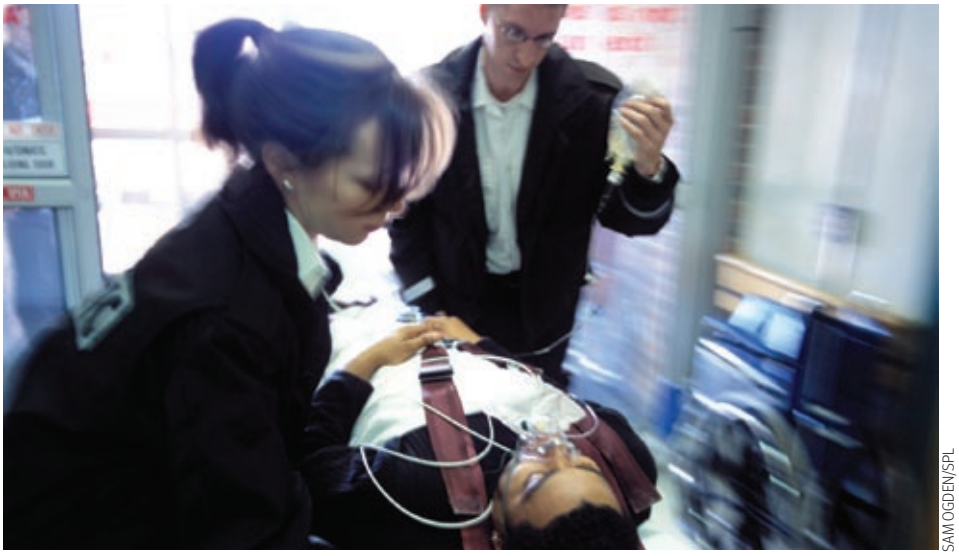
India rejects patents on key antiretrovirals: India has rejected patents on two drugs for HIV and AIDS, tenofovir and darunavir. Tenofovir is recommended by the World Health Organization for improved first line treatment. Darunavir is one of a new class of expensive drugs for patients whose existing treatments are failing. Manufacturers of generic drugs will now be allowed to produce the two drugs and sell them for a fraction of the price.

N95 respirators are better than surgical masks against H1N1 flu: Well fitted N95 respirators offer healthcare workers better protection against inhalation of H1N1 virus particles than surgical masks, the US Institute of Medicine said in a report issued on 3 September (www.nap.edu).

UK agency advises restricting codeine to more severe pain: Preparations containing codeine and dihydrocodeine that are sold over the counter should be reserved for the short term treatment of acute, moderate pain that is not relieved by paracetamol, ibuprofen, or aspirin alone, says the UK Medicines and Healthcare Products Regulatory Agency. Package inserts will warn about the importance of not taking these products for longer than three days.

Cite this as: *BMJ* 2009;339:b3663

Concerns mount over misuse of



SAM OGDEN/SPL

Propofol can help doctors with a tough schedule feel like they've had a full night's sleep, said Dr Earley

Circulation publishes lengthy correction centre of libel action directed against a

Mark Pownall LONDON

The American Heart Association's journal *Circulation* has issued a lengthy correction to a clinical trial at the centre of a libel action directed against a UK cardiologist. It has also replaced the original study with a corrected version on its website.

The correction (*Circulation* 2009;120:e71-2) says that the migraine intervention with STARFlex technology (MIST) trial, originally published in March last year (*Circulation* 2008;117:1397-1404), had "a number of errors and omissions."

The libel suit, against Peter Wilmshurst, a consultant cardiologist at Shrewsbury Hospital, followed comments he was reported to have made to a cardiology website (http://theheart.org) about the trial, of which he was a joint principal investigator.

The MIST trial aimed to see whether closing a patent foramen ovale with the STARFlex implant would reduce or eliminate migraines.

The legal action was brought by the manufacturer of the STARFlex implant, NMT Medical of Boston. A defence fund has been set up by the charity HealthWatch to help pay for Dr Wilmshurst's legal costs (*BMJ* 2008;337:a2822).

The case, and that of the science writer Simon Singh, who is being sued by the British Chiropractic Association (*BMJ* 2009;339:b3166), has started a controversy about how libel law is being brought into scientific debate.

The correction in *Circulation* adds information about how intracardiac shunts were assessed and describes three patients whose implants were described as being in "unsatisfactory" positions. One device embolised to the right atrium and one to the pulmonary artery, but they were not regarded as serious adverse events in the published trial.

The correction also gives more information on patients who were withdrawn from the study and a correction to a histogram that confused headache hours and headache days. It also provides a fuller rationale for the omission of two outliers from a post hoc analysis that found a significant effect of the device (no significant differences were found in the original primary and secondary end points).

In its correction the journal names, for the first time, Dr Wilmshurst and another investigator at Shrewsbury, Simon Nightingale, but only as "investigators," not authors. They were not listed as authors or contributors in the original published paper, nor in the corrected version posted online on 1 September. The correction says that they had not signed the copyright transfer agreement because of an internal disagreement about the conduct of study and therefore had not been listed as authors.

The correction comes after correspondence between Dr Wilmshurst and *Circulation*,

propofol among US healthcare professionals

Fred Charatan FLORIDA

Pressure is mounting in the United States for tighter curbs on access to the anaesthetic propofol, amid fears that a growing number of healthcare professionals are becoming addicted to it.

The drug has been implicated in the death of singer Michael Jackson, who died in June, after the Los Angeles coroner's office said that "lethal levels" had been found in the singer's body. Propofol, which has been licensed for use since 1986, is given intravenously to induce brief anaesthesia and is not generally available outside hospitals and clinics.

In July the American Association of Nurse Anesthetists warned that "abuse of the drug is becoming more common among anesthesia professionals and other health care providers who have easy access to it" (www.aana.com/News). The association recommends that healthcare facilities keep propofol in a secure environment to reduce the risk of its diversion and misuse by providers.

A survey carried out by the University of Colorado in 2007 of 126 academic anaesthesiology programmes in the United States showed that almost one in four (18%) reported one or more incidents of propofol misuse or inappropriate distribution over the past 10 years (*Anesthesia and Analgesia* 2007:105;1066-71). The observed incidence of propofol misuse was 10 per 10 000 anaesthesia providers, a fivefold increase on the findings from previous surveys of propofol misuse.

Seven deaths have also been reported, six of them in residents. Seven in 10 anaesthesiology programmes said they had no established system to control or monitor propofol, as is the case with opioids.

Paul Earley, medical director of Talbott Recovery Campus, a drug misuse treatment facility in Atlanta, Georgia, said, "It is hard to tell the reason for propofol becoming the drug of choice among professionals," but he added that people with a childhood history of violence seemed to be more vulnerable.

He added, "When it is abused it leads to a mild dissociative condition, with euphoria after the abuser wakens to a well rested state—for example, in a resident [anaesthetist] who has had a tough schedule then later feels like they've had a full night's sleep."

Dr Earley said, "Who would have thought that anyone would try and abuse a drug with such a narrow therapeutic window?"

Cite this as: *BMJ* 2009;339:b3673

to clinical trial at UK cardiologist

which he says "amounts to hundreds of pages of documents and a 30 page critique of the published paper."

He considers the correction to be "inadequate." He said, "It's a lengthy correction, of nearly one and a half pages, but it does not adequately address all the points I have made. They have not done what they should to correct the scientific record and have been reluctant to get involved at all. The published paper is not a complete reflection of the trial."

Dr Wilmshurst said that the journal has failed to acknowledge his or Dr Nightingale's involvement in the trial, which included its design. "Many of the key features were my design," he said. Nor, he added, does it acknowledge his role in its implementation. "We were members of the five strong steering committee which effectively ran the trial," he said. "We have been airbrushed out of the paper."

Dr Wilmshurst said that he is not affronted by not being acknowledged as an author of the study but wishes his significant role in the study to be clear so that his criticisms of the published paper are taken seriously.

In response to a number of questions from the *BMJ*, Donna K Arnett, who chairs the scientific publishing committee of the American Heart Association, said, "At this time, we consider this matter closed, and we have no further comment."

Cite this as: *BMJ* 2009;339:b3659

Report recommends banning alcohol advertising and raising prices

Mark Gould LONDON

All alcohol advertising and marketing should be banned, alcohol prices must rise, and the government should sever its links with "counterproductive" healthy drinking campaigns financed by the industry, a scathing report has said.

Under the Influence, written by the BMA board of science, which was chaired by former chief medical officer Kenneth Calman, warns that the true extent of alcohol misuse in the United Kingdom is vastly underestimated.

It says that alcohol sales have increased steadily in the past 20 years whereas data on alcohol consumption show that increase to have slowed in the past 5 to 10 years.

"Survey underestimation of alcohol intake may be as much as 50%. This suggests that levels of alcohol consumption in the UK may be increasingly underestimated and therefore levels of future harm in the population will also be understated," it concludes.

The authors blame policies on alcohol pricing, marketing, availability, and sponsorship, such as the sponsorship of Liverpool Football Club by Carling lager or the Rugby Union's Guinness Premiership, which they argue reinforce social norms that alcohol is acceptable.

Licensing hours must be cut and a direct tax on the drinks industry should be used to fund an independent public health body to oversee alcohol related research, health promotion, and policy advice, the report recommends.

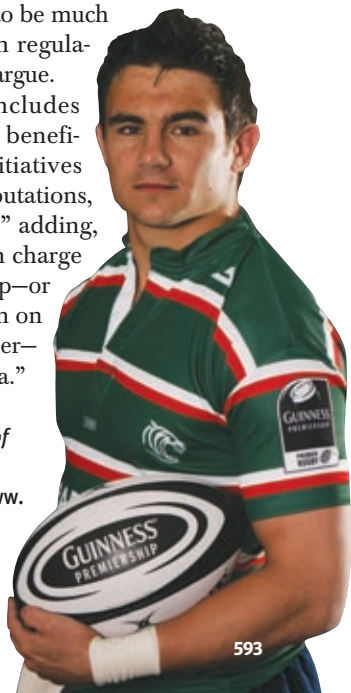
It criticises the government for allowing the Drinkaware Trust, which is funded by the drinks industry, to play a key role in public health education.

"While this form of social responsibility may appear helpful and cost effective, in reality, its impact is likely to be counterproductive. Educational initiatives have been shown by the World Health Organization to be the least effective approach to tackling alcohol related harm and to be much less powerful than regulation," the authors argue.

The report concludes that the principal beneficiaries of such initiatives are "company reputations, not public health," adding, "putting the fox in charge of the chicken coop—or at least putting him on a par with the farmer—is a dangerous idea."

Under the Influence: the Damaging Effect of Alcohol Marketing on Young People is at www.bma.org.uk/.

Cite this as: *BMJ* 2009;339:b3637



DAVE ROGERS/GETTY IMAGES

General practice consultations rose by two thirds in 13 years

Helen Mooney LONDON

General practices in England are conducting 13 000 more consultations a year on average, compared with figures for 1995, show the latest statistics, published last week by the NHS Information Centre.

Surveys based on 108 general practices with 919 000 patients in 1995 and on 503 practices with 4.4 million registered patients in 2008 show that the number of consultations a year for a typical practice in England rose from 21 100 in 1995 to 34 200 in 2008.

The figures show that an average patient had 5.5 consultations in general practice in 2008 compared with 3.9 in 1995.

The figures also show a rise in the proportion of patients seen by nurses in primary care. In 1995, 76% of consultations were undertaken by GPs, 21% by nurses, and 3% by other clinicians. However, in 2008 the number of consultations by GPs had fallen to 62% while consultations with nurses had risen to 34%, with 4% conducted by other clinicians.

The number of telephone consultations also rose, and home visits fell. In 1995, 86% of general practice consultations were conducted in surgery premises, 3% were by telephone, 9% were home visits, and 2% were conducted at other locations. By 2008, 82% of consultations were conducted in surgery premises, 12% were by telephone, 4% were home visits, and 3% were conducted at other locations.

MARK THOMAS/SPL

A third of consultations in general practice in England in 2008 were with nurses

According to the researchers, the decline in home visits is likely to reflect the changes in the delivery of out of hours care in the past 14 years, including the formation of cooperatives for out of hours care and the removal of out of hours care from GPs' contractual responsibilities.

Over the 13 year study period, consultation rates for women were higher than those for men, and the highest overall consultation rates were for elderly people between 85 and 89.

Commenting on the findings, James Kingsland, a GP and president of the National Association of Primary Care, said that increasing consultations in general practice meant that NHS reforms were working. "We should be celebrating these figures to show that NHS reforms are working properly, but this increasing work for general practice needs to be matched by the corresponding resources, and GPs and practice based commissioners have been blighted by a lack of resource," he said.

Trends in Consultation Rates in General Practice—1995-2009 **is at www.ic.nhs.uk/.**

Cite this as: *BMJ* 2009;339:b3604

International trials

Jacqui Wise LONDON

Researchers have found that important information is missing from many trials recorded on the international register of clinical trials ClinicalTrials.gov, a publicly accessible database of clinical trials managed by the US National Library of Medicine.

Joseph Ross, assistant professor of geriatrics at the Mount Sinai School of Medicine, New York, and colleagues sampled a cross section of trials on the registry. After excluding phase I safety trials, they identified 7515 trials that were registered with ClinicalTrials.gov after 31 December 1999 and whose record indicated trial completion by 8 June 2007.

All of the trials reported the essential information required by the registry, but optional data including the primary outcome of the trial

Study suggests smokers are still misled by labelling of cigarette packs

Roger Dobson ABERGAVENNY

New research among UK adults and children shows that the use of words such as "smooth" on cigarette packs and lighter coloured packaging misleads people into thinking that these cigarettes are less harmful than other brands, suggesting that current regulations may be inadequate.

SPENCER PLATT/GETTY IMAGES

Many people still view cigarettes that are branded as "smooth" or "regular" as less harmful

More than half of adults and young people taking part in the study reported that cigarette brands labelled as "smooth" were less harmful to health than "regular" varieties, with, for example, 54% of children considering that the Mayfair Smooth brand of cigarettes was less harmful than Mayfair King Size (*European Journal of Public Health*, doi:10.1093/eurpub/ckp122).

Regulations requiring the use of plain packaging—including removing colours from cigarette packs—and preventing the use of words such as "smooth," "gold," and "silver" would greatly reduce these false beliefs, say the researchers.

"The truth is that all cigarettes are equally hazardous, regardless of what colour the pack is or what words appear on it. These tactics are giving consumers a false sense of reassurance that simply does not exist," warns the lead author, Professor David Hammond, from the University of Waterloo, Ontario, Canada.

The study, described as the first to examine consumers' perceptions of cigarette brands on the UK market, involved 516 adult smokers and 806 children (aged 11-17 years) who completed a survey in which they were asked to compare pairs of cigarette packs on five measures—taste, tar delivery, health risk, attractiveness, and either ease of quitting (adult smokers) or brands they would choose if trying smoking (children).

Results showed that 75% of adult smokers incorrectly believed that a difference in health risk existed for at least one of the eight brand comparisons shown, and more than 80% incorrectly believed there was a difference in tar delivery.

Cite this as: *BMJ* 2009;339:b3623

registry is missing important information, study finds

and start and end dates were less complete. For example, only two thirds of the trials reported their primary outcome (www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000144).

Dr Ross warned, "The potential of ClinicalTrials.gov registry to address selective publication and better inform the public and professionals about the results from completed clinical trials is limited because critical information from trial registration, such as study contact, trial end date, and primary outcome, were not consistently reported."

The researchers also randomly sampled 10% of the trials and carried out a systematic search on the online database Medline to discover what proportion of the trials had been published by two years after completion (regulations require publication within one year for approved drugs and devices and within two years for drugs under review by the FDA). They found that fewer than half of the trials in the sample had been published. Only 40% of industry sponsored trials had been published, compared with 56% of trials that were not funded by the pharmaceutical industry or by government. Of those that had been published, only a third had the citation recorded on ClinicalTrials.gov. The authors state that the small but necessary step of recording the citation should be required so that the public and profession can easily access the trial results.

Dr Ross said, "The scientific community should be prioritising the timely and accurate publication and dissemination of clinical trial results, regardless of the strength and direction of trial results."

One limitation of the study is that many of the trials did not include a trial end date so it was difficult to assess the date corresponding to two years after study completion for publication.

ClinicalTrials.gov was set up in 2000 in response to the US Food and Drug Administration's 1997 Modernization Act, which required preregistration of all trials of new drugs. The mandatory requirements for the register include the trial's title, the condition studied in the trial, the trial design, and the intervention studied.

In December 2007 the FDA Amendments Act expanded the mandatory requirements to include the trial's start date and to report results for the main outcomes at ClinicalTrials.gov within one year of the trial's completion or two years if the drug is unlicensed.

Cite this as: *BMJ* 2009;339:b3627

Safety review shows increased reporting of adverse incidents involving drugs in the NHS

Susan Mayor LONDON

The number of reports of adverse incidents involving drugs has increased considerably, shows a review of drug incidents throughout the NHS in England and Wales published this week, which indicates that the reporting culture has improved.

The National Patient Safety Agency (NPSA) found a large increase in the reporting of drug incidents to the National Reporting and Learning Service (NRLS), a system for collecting reports of health system failures and errors in all NHS organisations, from 64 678 incidents reported in 2006 to 86 085 in 2007.

The report's authors consider that the increase indicates that the NHS has improved its reporting culture and that health professionals are more willing to come forward when drug mistakes have been made.

"It is encouraging to find that there was a significant increase in the reporting of medication incidents to the NRLS," they said. "More reporting enables more learning and opportunities for improving patient safety and should not be interpreted as an increase in the number of medication incidents that are actually occurring in the NHS."

However, they cautioned that there are still very few medication incidents being reported by primary care, mental health, and some acute care organisations.

Analysis of 72 482 medication incidents that occurred (rather than just being reported) during 2007 showed that most (96%) resulted in no harm or low harm to patients.

There were only 100 drug incident reports of death and severe harm to the NRLS. Most of these were caused by errors in drug administration (41%) and prescribing (32%).

Incidents involving injectable drugs accounted for nearly two thirds (62%) of all reported incidents leading to death or severe harm, similar to the number in the year before. The review's authors noted that injectable drugs are often the most complex and potent, requiring complex calculations, methods of preparation and administration, and systems for monitoring.

Overall, incident reports involving unclear or wrong dose, frequency, or rate of administration were the commonest problems and caused the most deaths and severe harm. The review found that miscalculation, failure to titrate the dose to the patient's needs; miscommunication between health professionals; and failure to check the drug dose before dispensing, preparing, or administering a dose were the most common factors that contributed to dosing errors.

The report says that NHS organisations should review the number and quality of drug incident reports received locally and identify whether current arrangements are enabling local learning and action to minimise the risk of harm to patients.

Safety in Doses: Improving the use of Medicines in the NHS **is at www.npsa.nhs.uk/nrls/medication-zone.**

Cite this as: *BMJ* 2009;339:b3613

Nearly two thirds of all drug incidents reported to the National Patient Safety Agency involved injectables

Iran appoints first woman health minister

ATTA KENARE/AFP/GETTY IMAGES

Dr Vahid-Dastjerdi said she would pursue women's needs

Zosia Kmietowicz LONDON

A 50 year old gynaecologist has become Iran's first woman cabinet member since the Islamic revolution in 1979, after being approved as the country's health minister.

Marzieh Vahid-Dastjerdi was one of three women nominated by President Mahmoud Ahmadinejad for cabinet posts but the only one who won approval from Iranian MPs.

Dr Vahid-Dastjerdi studied medicine at Tehran University and held the post of director of the department of nursing and obstetrics there for six years.

She was elected to parliament in 1992, and in 1993 she jointly founded the political party the Islamic Association of Physicians. In 1998 she drafted a proposal to segregate hospitals by sex, but the plan was rejected on grounds of cost and for being impractical because of a shortage of female specialists.

Cite this as: *BMJ* 2009;339:b3665

Researchers call for better trial guidelines

Trish Groves, deputy editor *BMJ*

The over-regulation and bureaucracy stifling the initiation and conduct of clinical trials have been well publicised, said senior clinical triallists attending a meeting in Oxford this week. What's needed now, they said, are workable solutions.

The two codirectors of the University of Oxford's clinical trial service unit summed up the frustration expressed by most speakers and delegates. "We don't just need to simplify the individual rules. How many of them are needed at all?" Richard Peto asked, while Rory Collins added: "How much longer do we have to do things that don't add value?"

An invited international audience of clinical researchers, industry leaders, regulators, funders, ethicists, and patients' representatives debated the many barriers to the efficient running of trials, particularly multicentre international trials run by academics.

Although such trials often pose little clinical risk to patients or legal or insurance risk to institutions and sponsors, they have to go through the same hoops as potentially high risk trials of new drugs and devices. Regulation, monitoring, and inspection of trials could be minimised, speakers said—for instance, by moving towards remote monitoring using statistical analyses instead of numerous site visits—while still ensuring that scientific objectives are met and that participants' safety and privacy are protected. But trial auditors are not currently trained to stratify their assessments by risk.

Many of the speakers confirmed that the problems they had highlighted two years ago at a similar meeting held in Washington, DC, by triallists from McMaster, Duke, and Oxford Universities were still unresolved.

There was, however, some good news. Sally Davies, director general of research and development for the Department of Health and NHS in England, and Janet Darbyshire, head of the Medical Research Council's trials unit, explained that the UK has recently harmonised and streamlined procedures for initiating, registering, governing, and conducting nationally funded trials within the NHS.

Cite this as: *BMJ* 2009;339:b3671

University of Hong Kong's former dean of medicine is jailed

Jane Parry HONG KONG

Lam Shiu-kum, the former dean of the Li Ka Shing Faculty of Medicine at the University of Hong Kong, has been sentenced to 25 months in jail after pleading guilty to misconduct in public office.

The misconduct involved inducing 12 patients who were treated at Queen Mary Hospital, the university's teaching facility, to pay what appeared to be medical bills issued by the university and the hospital but were payable to Gastrointestinal Research, a company wholly owned by Professor Lam.

In addition to these payments—which totalled $HK130 000 (£10 000; €12 000; $17 000)—three patients made total donations of $HK3.8m to the same company. None of the patients were told that it was Professor Lam's company, the court heard. In addition to the charge under which Professor Lam was convicted, the court has kept on file 30 counts of fraud and three of theft.

In his defence Professor Lam said that the money had been used to entertain guests, including potential donors to the medical faculty, and was therefore used for the benefit of the university. However, chief district court judge Li Hon-leung expressed scepticism about Professor Lam's reasons, especially as he had not provided any further explanation of how the money was used.

Starting with a sentence of five years, the judge deducted 20 months because Professor Lam pleaded guilty, nine months in consideration of the defendant's good character, and a further six months because he had made full restitution to the university and the hospital authority, which were entitled to 75% and 25% of the fees, respectively.

Cite this as: *BMJ* 2009;339:b3668

MICHAEL LAURIE/AP/PA

The use of multidose vials would contravene national guidelines

Australia's plan to use multidose vials for

Melissa Sweet SYDNEY

The Australian government's impending programme of vaccination against H1N1 flu has been criticised by some professional groups that have raised concerns about potential risks.

The Australian Infection Control Association this week warned the government against proceeding with the programme, saying that the planned use of multidose vials (used to vaccinate several people) posed a "significant potential risk to patient safety."

The association's president, Claire Boardman, said that use of multidose vials would contravene national infection control guidelines and that numerous adverse events related to their use had been well documented.

Ms Boardman said there was no justification for using multidose vials, as "the occurrence and distribution of H1N1 in 2009 within Australia does not constitute an emergency."

She added, "We advise strongly against the use of multidose vials and do not support this mechanism for dissemination of the vaccine," and warned that the "high risk of failure" of the pandemic vaccination

US doctors and psychologists more complicit in torture than previously thought, says report

BEHROUZ MEHRI/AFP/GETTY IMAGES

Murals in Tehran depict scenes of torture of Iraqi prisoners by US soldiers at Abu Ghraib prison in Baghdad

Peter Moszynski LONDON

The extent to which US doctors and psychologists violated human rights and betrayed the ethical standards of their professions by designing and implementing a worldwide torture programme is greater than previously thought, says a report from Physicians for Human Rights.

The report is based on analysis of a previously classified report from the inspector general of the Central Intelligence Agency (CIA) that was released at the end of August, and which provides more detail on the role of health professionals in the CIA's torture programme, including abuses conducted against 14 detainees between September 2001 and October 2003.

The report says that health professionals played central roles in developing, implementing, and providing justification for torture. Health professionals in the Office of Medical Services and psychologist contractors engaged in designing and monitoring harmful interrogation techniques, it says.

Scott Allen, Physicians for Human Rights' medical adviser and lead author of the report, told the *BMJ*, "From a professional ethics standpoint, the involvement of health professionals in designing, deploying, and monitoring [torture] is deeply troubling.

"Health professionals should have refused to cooperate at every level, and their failure to do so helped the government rationalise the use of torture. Health professional complicity undermined the moral authority and legitimacy of the medical profession."

He added that doctors and psychologists had colluded with the CIA to keep observational records about waterboarding, "which approaches unethical and unlawful human experimentation."

"Interrogators would place a cloth over a detainee's face to block breathing and induce feelings of fear, helplessness, and a loss of control. A doctor would stand by to monitor and calibrate this physically and psychologically harmful act, which amounts to torture."

Another of the report's authors, Steven Reisner, said that the Bush administration's legal justification for torture required health professionals to "monitor" abuse.

"This amounts to health professionals certifying that a detainee is healthy enough for continued torture," he said. "Under the guise of keeping interrogations 'safe' and 'legal,' health professionals provided the cover to permit our interrogators to use tactics usually associated with totalitarian regimes."

Some military and intelligence psychologists had a more insidious role in that they devised the torture protocols, created prisoner profiles, and supervised the process of physical and psychological breakdown, he said. "A few actually applied the torture directly."

"No investigation into our government's torture programme can be complete unless the role of health professionals is fully investigated and until those health professionals who took part are held accountable . . . for violating their time honoured ethical standards," he maintained.

Aiding Torture: Health Professionals' Ethics and Human Rights Violations Demonstrated in the May 2004 Inspector General's Report **is available from http://physiciansforhumanrights.org.**

Cite this as: *BMJ* 2009;339:b3599

its swine flu vaccination programme comes under fire

campaign could compromise future programmes and also risked causing poor uptake of seasonal flu vaccination next year.

The association's comments follow similar concerns raised by the Australasian Society of Infectious Diseases in a letter to the government's chief medical officer, Jim Bishop, widely reported in the media (www.abc.net.au/pm/content/2008/s2662248.htm).

However, some experts involved in trials of an H1N1 vaccine being developed by the vaccine manufacturer CSL Limited believe that any potential risks are minimal and are being blown out of proportion.

Robert Booy, professor of paediatrics and child health at the Children's Hospital, Sydney, and the coauthor of a blog defending the vaccine's safety (www.aussmc.org/ScienceBlog.php), told the *BMJ*: "There is considerable and emerging evidence for safety of multidose vials, especially in the hands of trained nurses. Being stalled by this controversy may make us a laughing stock to the rest of the world."

CSL has repeatedly said that the multidose vials are safe.

But Peter Collignon, an infectious diseases physician and microbiologist at the Australian National University, said it was hard to see why Australia should abandon its usual practice of using mainly single dose, preloaded syringes.

Carol Bennett, head of the Consumers Health Forum, said it was important that the benefits and risks of flu vaccination were openly discussed.

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