BMJ

UK government to put graphic warnings on tobacco products

Amy Davis

BMJ 2007;335;468-469
doi:10.1136/bmj.39325.662222.DB

Pathologist in Sally Clark case wins removal appeal

Clare Dyer BMJ

The pathologist for the prosecution in the Sally Clark murder case, who failed to disclose results of microbiological tests on her second baby, has won an appeal against his removal from the UK Home Office register of forensic pathologists.

An appeal panel of three people, headed by a retired appeal court judge, Sir Paul Kennedy, held that the ruling by a home office disciplinary tribunal in 2005 removing Alan Williams from the register was "unreasonable" (*BMJ* 2005;331:1355).

He was "a competent pathologist who made one serious error which he is unlikely to repeat," said the panel, which substituted an 18 month suspension.

Because the suspension period has now expired, Dr Williams's accreditation is now restored. But he is unlikely to be offered prosecution work because he will always be vulnerable to cross examination by the defence, said the panel.

In June 2005 the General Medical Council also barred him from undertaking Home Office pathology work or coroners' cases for three years, although he was allowed to continue as a consultant histopathologist at Macclesfield General Hospital.

His appeal against the GMC's finding of serious professional misconduct is expected to be heard by the High Court next month.

Mrs Clark was convicted in 1999 of killing her babies, Christopher and Harry, but cleared on a second appeal in 2003 after it emerged that the results of microbiological tests on body samples from Harry had not been disclosed in Dr Williams's postmortem report. The samples showed the presence of *Staphylococcus aureus* in several body sites, including the cerebrospinal fluid.

The appeal panel said that Dr Williams had never sought to hide the results.

Several experts later said that *S aureus* was a postmortem contaminant, although an expert for the defence at the second appeal thought infection was the likely cause of death.

The measles increase is in communities where uptake of the MMR vaccine is low, such as travelling families

Parents warned to curb rise in measles cases by vaccinating their children

Roger Dobson ABERGAVENNY

Parents are being urged to have their children fully immunised with the combined vaccine against measles, mumps, and rubella (MMR) before school starts this month, after warnings that cases of measles are rising.

The latest figures from the Health Protection Agency show 480 confirmed cases of measles in the United Kingdom so far this year, compared with a provisional total of 756 cases for the whole of last

Public support for hybrid embryos rises, poll shows

Zosia Kmietowicz LONDON

The Human Fertilisation and Embryology Authority, the United Kingdom's fertility watchdog, will decide this week whether to approve in principle the use of hybrid animal-human embryos for research.

Results of a public consultation on the matter, which were released before the authority's decisive meeting that was due to be held on Wednesday 5 September, indicate a widespread lack of understanding among the public on the need and worth of creating hybrid embryos. However, support for hybrid research increases as people appreciate its possible applications.

Scientists are keen to develop hybrid embryos and a potential assured source of stem cells for research because the supply of human eggs and embryos is limited.

Results from an opinion poll show that 35% of respondents agreed that scientists should be able to create cytoplasmic embryos—those that use the shell of an animal egg—and implant human genetic material, making them 99.9% human.

But support for the use of cytoplasmic embryos rises to 61% if respondents think that the research may help understand some diseases, such as Parkinson's disease and motor neurone disease.

For full results see www.hfea.gov.uk.

See bmj.com for the outcome of the meeting.

For the full versions of articles in this section see bmj.com

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bmj.com US patients get botox faster than mole checks

year, which was the highest number recorded for at least 20 years.

Most of the cases reported this year have been in England, with 10 in Wales and five in Scotland. No cases have been reported in Northern Ireland.

In England, London had the largest number of cases, with 155; followed by the east of England, with 134; the south east, with 69; and Yorkshire and Humberside, with 49. The east Midlands had 30 cases; and the north west 14. Just one case has been reported in the north east.

The figures also show that the number of cases this year has increased considerably during the summer. At the end of the first week of June, 136 cases had been confirmed—a quarter of the current total.

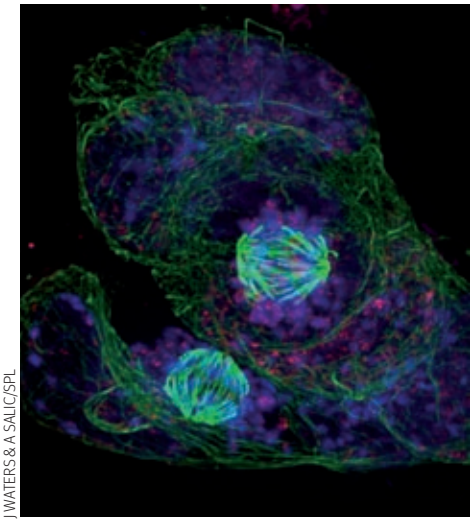
"Over the summer holidays we have seen more cases of measles being reported than we would normally expect," said Mary Ramsay, a consultant epidemiologist with the agency.

"This means it is crucial that children are fully immunised with two doses of MMR before they return to school. Measles is a highly infectious and dangerous illness, and as there is increased close contact in schools, it can spread easily," she said.

"Now is the time parents will be buying their children a new school uniform to prepare for the school year ahead, but being prepared to avoid infection is even more important," she added.

The agency says that the increase has occurred in communities where the uptake of the vaccine is lower—for example, among children living in travellers' sites.

GABRIELE STABILE/GETTY IMAGES



J WATERS & A SALIC/SPL

Embryonic stem cells: hybrid embryos have the potential to provide an assured supply

Agency warns about dosing error for amphotericin

Nigel Hawkes LONDON

Two patients died in an oncology ward at Birmingham Heartlands Hospital in July after being treated with the wrong formulation of injectable amphotericin—a drug to treat fungal infections.

The National Patient Safety Agency (NPSA) has issued a warning over the use of the drug, but without disclosing where the two deaths referred to in its announcement had taken place. When questioned, the NPSA and the hospital confirmed that the deaths had taken place within hours of each other on 20 July (*BMJ* 2007;335:274).

Balgit Singh Sunner, aged 36, and Paul Richards, aged 35, were given the wrong dose of the drug. Amphotericin is available under several names and in different formulations—lipid and non-lipid—which have different recommended doses.

Confusion between the formulations can lead to a dose that is too high or too low, the agency said, leading either to inadequate treatment or a fatal outcome. It said that there had been 53 incidents involving the drug between January 2004 and July this year. Seven resulted in "low harm" to patients, one resulted in moderate harm, and 43 in no harm, it said.

There had been 53 incidents involving the drug between January 2004 and July 2007

Mark Goldman, chief executive of Heartlands Hospital, said, "A detailed investigation into the clinical care given to both patients has now been completed, the findings of which will be presented to the families in the next few weeks.

Two patients with cancer died in July after being given the wrong dose of amphotericin

"However, we can confirm that the drug involved was amphotericin and we have been collaborating with the NPSA on its rapid response alert."

Mr Sunner and Mr Richards died after being prescribed the non-lipid formulation of amphotericin, known as AmBisome, but being treated with Fungizone, the lipid formulation, in error.

Phil Barnes, a solicitor representing the Richards family, said that they were considering legal action against the hospital on grounds of negligence.

Karol Sikora, a leading cancer specialist, was critical of the time it took the agency to issue its warning: "What I find bizarre is how slow this has been to get out," he said. "The NPSA is not behaving in the way it advises—transparency, openness, and immediate transfer of information to the public domain."

See: www.npsa.nhs.org

CORRECTION

GMC clears GP accused of giving court "junk science" on MMR vaccine

In this News article last week by Owen Dyer (*BMJ* 2007;335:416-7, 1 Sep), we wrongly stated that "the GMC panel concluded that all of the substantive charges against Dr [Jayne] Donegan were unproved except for the charge of quoting selectively from research." Dr Donegan was in fact cleared on all six charges, the panel saying that in the reports that she provided she "did not fail to be objective, independent and unbiased." The *BMJ* apologises to Dr Donegan for the error.

IN BRIEF

Alcohol poisoning increasing in the Netherlands: Since 2000 the total number of patients treated for alcohol poisoning in Dutch emergency care departments has more than doubled to about 1800 a year. Cases involving 10 to 14 year olds have also increased, to just fewer than 100. The study, published in the Dutch Medical Association journal, *Medisch Contact*, was based on a representative sample of one in five hospitals (www.medischcontact.nl).

Standards for record keeping produced: The Royal College of Physicians' health informatics unit has produced a national set of standards for record keeping for hospitals in a bid to improve patient care and reduce the risk of litigation. (www.rcplondon.ac.uk).

Care of community mental health patients is improving: Mental health services in the community are improving, but concerns remain over social inclusion and access to counselling, a snapshot survey from the Healthcare Commission shows. The survey, of almost 16 000 service users at 69 trusts, shows that about one in three service users who wanted counselling or help with benefits did not receive it (www.healthcarecommission.org.uk).

NHS likely to end financial year with £1bn surplus

Adrian O'Dowd MARGATE

Clinicians and patients are paying the price for a predicted surplus in the NHS, it has been claimed.

The Department of Health in its latest quarterly report says that the NHS in England will have achieved a surplus of almost £1bn (€1.5bn; $2bn) by the end of this financial year.

The department said that most NHS trusts would be in balance by April of next year, with an overall forecasted surplus of £983m. This compares with an end of year surplus of £510m in 2006-7 and a deficit of £547m in 2005-6.

A small number of trusts will finish the year with a deficit, however. Hinchingbrooke Health Care NHS Trust is expected to have the largest deficit, of £17.5m, 24% of turnover.

There has been a cost to achieving the healthy financial position, however, said Hamish Meldrum, chairman of the BMA, who paid tribute to the staff who had worked hard to reach this point.

"You have to look at what trusts have done to get out of the red," he said. "At the end of last year we saw services to patients being cut, with operations delayed, outpatient clinics cancelled, and referral management schemes—which were really only thinly disguised forms of rationing.

"There are still hospitals that are threatening to lay off hundreds of staff in order to break even. Budgets that used to be set aside for the training of doctors and nurses have been raided."

Dr Meldrum told the BMJ, "There has been an impact on doctors and patients. I wouldn't say doctors have been making sacrifices, but what has been happening has been affecting the way they can deliver best care to patients.

"There was poor financial management that allowed trusts to get into that state in the first place, but the timescale for which they were told they had to get out of it meant the measures they had to take were more extreme than we believed they needed to be, had they been given a longer timescale.

"We now want to work with government to ensure the money that now appears to be available is going back into the right areas."

The quarterly report is available at www.dh.gov.uk.

Government to put graphic warnings on tobacco products

Amy Davis BMJ

The United Kingdom will be the first country in the European Union to use graphic warnings on tobacco products. The announcement coincides with figures released by the Department of Health that show England has 97% compliance with the ban on smoking in enclosed public places, which was introduced on 1 July.

97% of premises complied with banning smoking in enclosed spaces, and 79% displayed the correct signs

More than 88 000 inspections took place in the first two weeks of the smoking ban, including inspections of 1090 hotels, 6783 restaurants, and 9568 licensed premises. The local authority enforcement officers found that 97% of premises complied with banning smoking in enclosed spaces, and 79% displayed the correct signs. These figures are comparable to those for the first month of the smoking bans in Scotland and Ireland.

Dawn Primarolo, minister of state for public health, welcomed the statistics, "We predicted that it would be largely self enforcing based on experience elsewhere and the fact that three quarters of the British public supported the move."

The department says that local authorities are continuing to work with local businesses to ensure that they understand the legal requirement to display "no smoking" signs at the entrance to all public buildings and workplaces.

Meanwhile, the health secretary, Alan Johnson, has said that he believes "picture warnings are the next vital step in reducing the number of people who smoke." From autumn 2008 the packets of tobacco products in the UK will incorporate images that show the devastating effects tobacco can have on health.

"We hope this is a step towards the plain, generic packing of all tobacco products," said Elspeth Lee, senior tobacco control manager at Cancer

One of the images to appear on cigarette packets from 2008

Mixed martial arts and boxing should be banned, says BMA

Caroline White LONDON

The BMA is renewing its calls for an outright ban on boxing, including mixed martial arts, ahead of a combat sport tournament to be held on Saturday 8 September in London's East End.

The BMA's Board of Science, which has issued a new report on the latest evidence of the damaging effects of boxing, says that the relatively new mixed martial arts format is just as dangerous.

Mixed martial arts involves various fighting techniques, in which a combination of wrestling, boxing, and martial arts is used to strike and grapple with opponents.

The sport was forced underground in the United States after sustained political pressure but has re-emerged there and is currently enjoying a surge in popularity, says the report.

London was set to host the Ultimate Fighting Championship, featuring the combat sport this weekend.

For the championship, which first started in 1993, contestants fight inside a metal cage. Each bout lasts three to five rounds of five minutes each until submission, knockout, or disqualification, says the report.

"Because of its no holds barred nature, the [championship] fighters are open to a myriad of injuries, including subdural haematoma, thought to be one of the most common causes of injuries in boxing," the BMA report says.

But contestants also risk fractures, tears, muscle and ligament sprains, as well as electroencephalographic abnormalities as a result of neck holding manoeuvres, it adds.

Supporters claim that this style of fighting is safer than boxing, and so far only one death has been reported.

But the report warns that "[mixed martial arts] tournaments, such as [the Ultimate Fighting Championship] are still in their infancy"; since 1993 there have been only 800 fights in 14 years, "it is still too early to draw any meaningful conclusions," it says.

The BMA has been campaigning for the complete abolition of boxing on medical grounds since 1982.

The report, *Boxing: An Update* is available at www.bma.org.uk.

JOHN PYLE/REX

The Ultimate Fighting Championship in California

Research UK. "International evidence shows that graphic picture warnings lead to a greater awareness of the risks associated with smoking and help encourage people to cut down or quit altogether."

A study published this year in the *American Journal of Preventive Medicine* found that large, comprehensive warnings are more likely to be noticed and rated as effective by smokers (2007;32:202-9).

Lung cancer is the leading cause of cancer deaths in the UK, according to the Office for National Statistics. Robert West, of Cancer Research UK, estimated that between 5000 and 10 000 people would stop smoking as a result of the new adverts. This would save about 2500 lives a year, he added.

Market research and a public vote helped to choose the 15 images that will be used on tobacco products.

The pictures can be seen at www.dh.gov.uk/tobaccopackwarnings.

Cancer expert attacks research paper

Caroline White LONDON

A leading cancer epidemiologist has heavily criticised the funding and science of a report that compares different rates of cancer survival in 25 countries. The report linked cancer survival with access to new and innovative drugs.

The Karolinska 2 report, published earlier this year in the *Annals of Oncology*, concluded that access to cancer drugs affected survival and that the licensing process should be speeded up, with equitable access for all (2007;18(suppl 3):iii2-7).

But the epidemiologist Michel Coleman, who heads the cancer survival group of Cancer Research UK, has in the latest issue of the same journal questioned the credibility of the figures and methods used to arrive at these conclusions (2007;18:1433-5).

He says that estimates rather than actual survival rates were used. And the benefits of access to drugs were calculated using data for about 2003 but for patients who were diagnosed between 1990 and 1994, and the research concentrated on drugs that were not available at that time.

Contrary to what the report implies, he added, "For many adult malignancies, drugs are not the most important element of cancer survival."

And he doubted that Roche Pharmaceuticals, which funded the research through an unrestricted educational grant, would have backed it if the "wrong conclusions" had been reached.

But a spokeswoman for Roche said that the company "has had no involvement in the analysis of data nor did it have any input into the report's findings."

In the same issue of the *Annals of Oncology*, the report's authors, Bengt Jonsson, of the Stockholm School of Economics, Nils Wilking, of the Karolinska Institute, and Franck Lichtenberg, of the University of Columbia, New York, strongly refute any interference by drug companies in their research (pp 1585-7).

Dr Wilking told the *BMJ* that Professor Coleman had focused on "a very minor part" of the report. "We feel there is a political agenda behind this," he said. "We used the data that were available."

Proliferation of firearms is growing global health problem

John Zarocostas GENEVA

The growing number of civilians holding firearms is fuelling gun crime worldwide and is putting healthcare systems, especially in poor countries, under stress, an expert report says. Gun crime kills about 250 000 people a year and injures many more.

"The proliferation of civilian gun arsenals is not likely to slow anytime in the foreseeable future," says the report.

The study was conducted under the auspices of the Graduate Institute of International Studies, Geneva, and was funded by European governments; the United States; Canada; and United Nations agencies, including the World Health Organization.

The researchers estimate that civilians own about 650 million firearms, from handguns to assault rifles, worldwide—about 75% of the world's 875 million known total. US citizens account for 270 million or 90 guns for every 100 citizens.

"There is a correlation between firearm ownership and firearm related injuries and death," David Meddings, medical officer at WHO's department of injuries and violence prevention, told the *BMJ*.

Keith Krause, programme director of the survey, says that a variety of factors are behind the increase in gun ownership among civilians.

"The main one is generally increasing wealth in some parts of the world that make people able to buy weapons, and, frankly, the failure of many states to provide for the security of individuals and their communities . . . leads to raising insecurity in urban zones, especially some parts of Africa and Latin America."

The report says that 36 091 deaths in Brazil in 2004 were related to firearms and adds that men in South America's largest nation are 17 times more likely to be victims of gun violence in urban areas than women.

Dr Meddings said that gun related violence has a considerable effect on healthcare systems and pointed out that research in South Africa has showed that non-fatal shooting, such as serious abdominal gun shot injuries, require care that costs on average 13 times the per capita health expenditure.

Small Arms Survey 2007: Guns and the City **is available at www.smallarmssurvey.org.**

Hold up caught on security camera

Balancing the books

Technically the US Food and Drug Administration goes out of business at the end of September. FDA commissioner **Andrew von Eschenbach** talks to **Bob Roehr**

DAVID AKE/AP/PA

Andrew von Eschenbach, 66, trained as a surgeon. President George Bush chose him to take over at the FDA in 2005.

Bob Roehr WASHINGTON, DC

It's been a tough few years for the US Food and Drug Administration, as it grapples with the problem of partial funding from the drug industry, which may compromise its impartiality; potential conflicts of interest on advisory committees; and the increasing difficulties in assessing risks and benefits of drugs.

Congress is expected to pass a law to cover the FDA soon after it returns from its summer break. Meanwhile the FDA commissioner, Andrew von Eschenbach, a surgeon and friend of the Bush family, says he sees the controversies as part of a more fundamental shift. He thinks medicine is rapidly changing from the observation of symptoms of late stage disease to a molecular understanding of the mechanisms of earlier stages of disease, with interventions becoming increasingly early and pre-emptive.

"The challenge for us is to not be a barrier to that new future but to be a bridge to it," the commissioner told a small group of reporters last month. He acknowledges that the changes the agency must make may not be easy.

The commissioner says that the FDA has to be engaged in the full lifecycle of the drugs, devices, diagnostics, and foods that it regulates: "It has to begin to work much more effectively at the front end of the process and engage more actively in the discovery and development end of the continuum if it is going to succeed in its mission to protect and promote the health of every single American."

The ongoing modernisation effort is known as the critical path initiative (see www.fda.gov/oc/initiatives/criticalpath). "Many of the pieces are intended to help us be able to work before the application, before that product even comes to us, to help build quality in, to help reduce the risk of failure, to be able to change the way that we are discovering, developing, testing, and bringing these products forward."

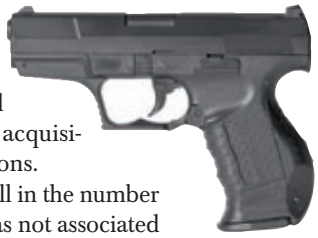
He uses the example of pandemic flu. Under the old model the agency would sit and wait for a vaccine

GLOUCESTERSHIRE POLICE HANDOUT/PA

Gun related suicides fall in Austria, study shows

Jane Burgermeister VIENNA

The number of homicides and suicides involving firearms has fallen dramatically in Austria since gun control laws were tightened in 1997, concludes a study in the *British Journal of Psychiatry* (2007;191:253-7).



In 1997 the Austrian government tightened its legislation on firearms in line with a European Council directive on controlling the acquisition and possession of weapons.

The study found that the fall in the number of firearm related suicides was not associated with an increase in the number of suicides in which other methods were used.

A total of 1392 people, or 17 in 100 000, committed suicide in Austria in 2005, the lowest number since 1986. Before the more restrictive gun legislation the mean number of gun related suicides was 3.96 per 100 000 people, which fell to 2.67 per 100 000 in 2005.

Even after factors that increase the risk of suicide—such as unemployment and alcohol consumption—were taken into account the decrease remained significant.

The study recommends that countries with a high number of gun related suicides should tighten gun legislation as part of their national suicide prevention strategies.

Elizabeth Jandl-Jager, a professor of sociology at Vienna University, said that the study showed the importance of reducing gun ownership in other countries.

"If the weapon isn't there there's no possibility of using it," she said. "There are some traumatic and dramatic events when even quite stable people might lose control, and that is when it is important to make sure there are no firearms about."

She said that the legislation in Austria was effective because it was backed up by effective action. Police, for example, made regular spot checks to ensure that firearms in homes were kept locked away.

application, which might come at about the time of a pandemic itself, and "then start figuring out what was wrong with the application and what they had to go back and redo."

But to truly protect public health "the FDA has to get out in front and start working with vaccine manufacturers [to] facilitate success and not simply try to eliminate failure."

A controversial aspect of this is the programme known as the Prescription Drug User Fee Act, which began in 1992. It allows industry to pay a fee for expedited review of a licensing application. Those fees are used to hire additional FDA staff for that process. The agency has about 10 000 employees and had a $1.5bn (£800m; €1bn) budget in fiscal year 2007. The programme generates about 20% of the overall budget but about 40% of the budget for drug regulation.

Some critics say that the fee and accompanying "fast track" consideration of drug applications compromise the independence of the review—a charge that the agency denies. Congress has been unwilling to directly fund such expanded operations, however, because of financial constraints.

The FDA proposed increases in fees that would raise revenue to a projected $392.8m a year for the next five years. Congress does not want to find $400m a year through cuts to other budgets or raising taxes.

"You can't personalise a therapy until you have a personalised diagnosis; genetics and genomics is becoming an important part of the equation"

Von Eschenbach defends the programme: "It will allow us to be much more engaged in pre-application consultations with developers so that we are helping them get it right from the very beginning. That reduces risk; it makes the process much more effective and streamlined; it aligns things with us in the regulatory process."

At the same time as this uncertainty, the FDA is grappling with scientific advances that affect its work. Tailoring drugs to personal genetic make-up is becoming important , for example, and is creating its own tensions.

"You can't personalise a therapy until you have a personalised diagnosis; genetics and genomics is becoming an important part of the equation," Von Eschenbach says. Increasingly, the FDA does not view products as drugs, biological agents, devices, or diagnostics, "It is beginning to see things as solutions that will almost invariably draw on the integration of those parts and pieces."

The public's perception of the agency is also a challenge. He says that for the FDA transparency means that the public must be able to understand the regulatory process: how the members of its advisory committees are selected and how the agency makes its conclusions. It does not necessarily mean that industry must make more proprietary information public. He argues that the FDA's decisions are being made by dedicated professionals, and he uses the analogy of the doctor-patient relationship, in which "there has got to be a level of trust at some point."

Because the fast track programme and its revenue will expire at the end of September, the FDA must begin the 60 day notification process to terminate employees' positions that are funded through this mechanism. That should have begun on 1 August.

But the commissioner has resisted doing so because of possible effects on employee retention.

"There is nothing more important at the FDA than its people." says von Eschenbach, calling the agency "an information management business that by its very nature is absolutely, critically dependent on intellectual capital." That is reflected in the budget: 84% is spent on staff.

Later this year the FDA will announce a two year fellowship programme to recruit a thousand fellows a year at postdoctoral level.