Roche is suspended from ABPI for "actions likely to bring discredit" on the industry

Roger Dobson ABERGAVENNY

Roche has been suspended from membership of the Association of the British Pharmaceutical Industry (ABPI) for a minimum of six months over serious breaches of the association's code of practice.

In particular, the company was held to be in breach of clause 2, which deals with actions likely to bring discredit on, or reduce confidence in, the drug industry.

The action followed a complaint made by a former Roche employee, Ryta Kuzel, who referred to an article in the *Financial Times* (www.ft.com, 12 Feb, "Diet pills case sheds light on Roche practice") that alleged the company had sold large quantities of orlistat (Xenical), a prescription only drug for the treatment of obesity, to the operator of a group of private diet clinics. The article also alleged that Roche had agreed to provide £55 000 (€70 000; $110 000) for the operator to purchase another clinic.

The code of practice panel of the Prescription Medicines Code of Practice Authority (PMCPA)—an arm's length body that administers the association's code of practice—ruled that the supply of orlistat was inappropriate. The panel also ruled that the proposed payment was linked to the use of orlistat and was in breach of the code. "The highest possible ethical standards are required by the pharmaceutical industry in all its activities," said Chris Brinsmead, president of the association.

Two years ago Roche denied to a Bedford employment tribunal that it had sacked Dr Kuzel, its head of UK regulatory affairs, for whistleblowing after she claimed that she had been dismissed for uncovering dealings with a network of private slimming clinics (*BMJ* 2006;332:1175).

She said she had discovered that quantities of orlistat worth between £70 000 and £80 000 a month were being sold to a network of Derbyshire slimming clinics (*BMJ* 2006;332:441), a claim that Roche has always denied (*BMJ* 2006;332:1175).

Dr Kuzel won her case for unfair dismissal, but the tribunal did not uphold her secondary claim of whistleblowing. She is appealing against the tribunal's ruling.

In a statement Roche said that it regretted the breaches of the code: "We are committed to complying with the code of practice, and it is disappointing that we have fallen short. This is why the company has already taken and continues to take steps to try to ensure that breaches do not happen."

A Roche spokesman added, "Regarding the employment tribunal, we accepted the tribunal's ruling that the claimant was unfairly dismissed, as we acknowledged from the outset that the correct process for dismissing her was not followed. However, we are pleased that the tribunal recognised that the claimant was not dismissed because of whistleblowing concerns."

Dr Ryta Kuzel uncovered Roche's sale of its drug orlistat to a network of private slimming clinics

Details of the cases are available at www.pmcpa.org.uk.

Cite this as: *BMJ* 2008;337:a835

Fraud office prosecution over fixing price of generic drugs collapses

Clare Dyer BMJ

Five drug companies and nine directors accused of a multimillion pound conspiracy to swindle the NHS by fixing the prices of generic drugs are poised to escape criminal charges after a judge threw out the case against them, subject to appeal.

The eight year prosecution, which has cost taxpayers around £25m (€31m; $50m), looks set to collapse after the ruling by Mr Justice Pitchford at Southwark Crown Court last week.

Operation Holbein, the largest prosecution ever handled by the Serious Fraud Office (SFO), accused the five companies—Goldshield Group, Kent Pharmaceuticals, Norton Healthcare, Generics UK, and Ranbaxy UK—of fixing the supply and prices of penicillin based antibiotics and the anticoagulant warfarin in the 1990s.

The SFO began investigating the allegations, referred to it by the Department of Health's counter-fraud directorate, in 2000. In 2002 investigators made dawn raids at 30 addresses in England, Wales, and Scotland, and prosecutors alleged that a cartel had cost the NHS £400m.

Price fixing itself became a criminal offence only in 2003, when the Enterprise Act 2002 came into force. So the SFO decided to charge the defendants with the common law offence of conspiracy to defraud.

But the prosecution was derailed by a House of Lords ruling last March that price fixing alone cannot be charged as a conspiracy to defraud unless there are additional aggravating features. That ruling suggested that the indictment in the Holbein case could be amended, but Mr Justice Pitchford refused to allow the amendment and, subject to appeal, said he would quash the indictment.

The SFO immediately said it would seek permission to appeal against the ruling.

Keith Hellawell, chairman of Goldshield, claimed in an interview broadcast on its website that the company had been vindicated.

The five companies have paid sums totalling an estimated £38m in civil settlements with the NHS, without admitting liability.

Cite this as: *BMJ* 2008;337:a814

Amendments to make abortion easier will not be debated

Clare Dyer BMJ

Controversial pro-choice amendments to the law on abortion in England and Wales, which were due to be debated in parliament on 14 July, have been shelved until the autumn in a last minute scheduling change that surprised MPs.

The amendments to the Human Fertilisation and Embryology Bill, put down by a group of cross party pro-choice MPs, are intended to make it easier for women to obtain early terminations. But with just four days to go to the report stage of the bill the government announced on 10 July that the debate would be delayed until the autumn.

The move angered MPs who want the current restrictions maintained or tightened but was welcomed by pro-choice MPs, who had complained that they would have only around three hours for debate on 14 July. The rescheduling means that more time will be available to debate the issue when the bill comes back.

Newspapers speculated that the debate was deferred to avoid airing the fraught issue of abortion before the Glasgow East byelection later this month. The byelection is seen as a crucial test for Gordon Brown's premiership amid record low ratings in opinion polls, and the seat has a high proportion of Roman Catholics.

The pro-choice amendments would allow nurses to perform abortions, would end the "two doctor rule" by allowing an abortion to be carried out with the approval of just one doctor, and would allow women undergoing an early medical abortion to take the second of the necessary two drugs at home.

Feelings ran high in the House of Commons last month when MPs failed in their attempt to cut the 24 week upper time limit.

Group publishes standards for adult sickle cell disease to reduce number of unexplained deaths

Susan Mayor LONDON

Adults with acute crises caused by sickle cell disease should start analgesia within 30 minutes of arrival at hospital, be assessed for potentially life threatening complications, and be seen by specialist staff, recommend new UK standards for best practice published today.

A multidisciplinary working group, including haematologists, specialist nurses, and commissioners, developed the standards in response to research that shows an unexpectedly high number of deaths from unknown causes in people with sickle cell disease and a general lack of awareness among health professionals of how to manage the condition.

A study earlier this year by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) of patients with sickle cell disease showed that the cause of death was unknown for more that 25% of patients who had died in hospital. Expert reviewers found room for improvement in the clinical care provided to just over one third of patients (*BMJ* 2008;336:1152).

A recent survey of 110 healthcare professionals who work in emergency departments found that 65% thought that they did not have enough information to provide the best care for a patient with sickle cell disease.

The new standards provide guidance on the minimum levels of care expected for adults with sickle cell disease in the United Kingdom. Key recommendations detail the care that should be provided for managing acute pain, acute complications, and chronic complications.

Archbishop of York John Sentamu talks to Nancy Segilola Scott, a sickle cell service user

People presenting with acute sickle pain should be rapidly assessed and receive a first dose of analgesia within 30 minutes of arrival at hospital, with the aim that their pain is controlled within two hours, the standards recommend.

Pain and sedation scores should be recorded systematically and treatment adjusted accordingly. The NCEPOD found that many patients died of complications caused by excessive doses of opioids.

The standards recommend that patients who present as emergencies should be assessed and monitored for acute and potentially life threatening complications, including infection, acute chest syndrome, neurological problems, acute renal failure, and priapism. Senior support staff from haematology and other specialties should be available to manage these complications.

Patients should be offered regular outpatient follow-up, which includes systematic screening for complications and treatment to prevent or slow progression.

The standards suggest that services should be commissioned to support highest quality clinical management. They should be based on hospital based sickle cell specialist centres and networks acting as "expert resources" for local hospitals that deliver acute care. Community services for sickle cell and thalassaemia should work with general practices to provide ongoing care in the community.

Ade Olujohungbe, consultant haematologist at University Hospital Aintree NHS Trust, Liverpool, and chairman of the working group that developed the standards, said, "The care provision for sickle cell disease is currently hit and miss, depending on the attitudes and experience of healthcare professionals.

"The aim of the standards is to provide a consistent level of care irrespective of the location to ensure every patient receives appropriate care." He added that every patient should be referred to an expert and then have an ongoing package of care provided close to their home.

Launching the standards at the House of Commons, the archbishop of York, John Sentamu, said, "Although sickle cell disease is the most common genetic disorder in England, there is still a vast difference in care between major cities and other areas of the country. These standards are another step in providing consistent care."

The Standards for the Clinical Care of Adults with Sickle Cell Disease in the UK **is at www.sicklecellsociety.org.**

Cite this as: *BMJ* 2008;337:a771

until the autumn

The delay was announced by the leader of the House of Commons, Harriet Harman, who told MPs: "The bill remains a flagship government bill."

The Liberal Democrat MP Evan Harris, a doctor and leading supporter of the pro-choice amendments, said, "I welcome this because the government will have the opportunity of providing more time for the debate. I think that both sides should be pleased. I don't think anybody benefits from the whole house having to debate huge issues with very little time."

Cite this as: *BMJ* 2008;337:a815

Report calls for better coordination to solve devolution problems

Adrian O'Dowd MARGATE

The four national governments in the United Kingdom need to work far more closely and to coordinate formally over health issues or face growing conflict, a major report from the Nuffield Trust says.

Since 1999, devolution has meant ever widening differences in health policy between the four countries.

The report says that extensive overlaps and complexities have arisen since devolution was agreed, leading to "messy intergovernmental relations." Its findings are drawn from research and extensive interviews carried out over the past seven years.

An area of potential conflict comes from flows of patients across the borders, which cause a "remarkable" amount of administrative and political tension, says the report.

This is mostly a Welsh and English problem, as around 13 000 patients from Wales are treated in hospitals in England each year and 7000 English patients in Welsh ones.

Health and Intergovernmental Relations in the Devolved United Kingdom **is available at www.nuffieldtrust.org.uk.**

Cite this as: *BMJ* 2008;337:a832

Thousands of Welsh patients cross the border to attend the Royal Shrewsbury Hospital, Shropshire

Student rejected because of conviction is granted interview

JAMES GLOSSOP/GUZELIAN

Majid Ahmed has been hampered in his attempt to get into medical school by his "spent" conviction

Jessie Colquhoun BMJ

A student whose offer of a place to study medicine at Imperial College London was withdrawn after the college learned of his criminal conviction has been offered an interview at Manchester University after he appealed against Manchester's previous decision to reject him.

Majid Ahmed has been trying to secure a place to study medicine for almost two years, since he first applied to four university medical schools in September 2006, but he believes that his attempts have been hampered by his conviction for burglary.

He was rejected by Imperial College last summer when the college discovered his conviction; and a second attempt to get into medical school this year, by reapplying to three schools, and adding a fourth to the list, has so far failed. His interview at Manchester will take place before the new academic year.

Mr Ahmed was 16 when he pleaded guilty to "burglary dwelling" in December 2005, having been found trespassing in a deserted house with two older friends, aged 21 and 23. He was ordered to carry out eight hours of community service, which he did cleaning benches and making bird boxes.

In an interview with the *BMJ* Mr Ahmed explained some of the circumstances behind his misconduct. His parents had separated and he had recently moved schools—from one where he was considered exceptionally clever to one where he had no special status and no friends. He started spending more time in older company, in particular with the two youths with whom he was later to be arrested.

At sixth form he decided he wanted to be a doctor and so undertook a great deal of work experience and charity work. In September 2006, aged 17, he applied to medical schools at Cambridge, Imperial, Leeds, and Manchester. He did not declare his conviction on the Universities and Colleges Admissions Service (UCAS) application form, in the belief that it did not need to be declared, because it was "spent."

But when he was called for interview at Leeds and Imperial he decided to inform them of the conviction. He was then rejected by Leeds, on the grounds that he had failed to declare his conviction previously, but not by Imperial.

After the interview at Imperial he was offered entry on achieving two As and one B in the A level examinations. He accepted it as his first choice. But when he declared his conviction in the criminal disclosure form that Imperial sends to all prospective undergraduates he was called for a "fitness to practise interview."

A few weeks later, in July 2007, Imperial rejected him. In August 2007 he received his A level results—four As—but he still did not have a place at a medical school.

He reapplied to Cambridge, Manchester, and Leeds in September 2007 as well as Sheffield for the first time but was rejected by all of them. He appealed to Manchester, having been rejected without interview twice. On Friday the board of directors of the university agreed that this was unfair, so he now awaits the date of his interview.

Cite this as: *BMJ* 2008;337:a830

PETFORSBERG/ALAMY

The rising age of starting a family reflects a fall in younger mothers in Holland, not a rise in older ones

Number of Dutch women having first child before age of 25 falls by a third

Tony Sheldon UTRECHT

The late average age at which Dutch women start families not only poses no medical risk to mothers and children but also offers social benefits, epidemiologists said this week in the *Dutch Journal of Medicine* (*Nederlands Tijdschrift voor Geneeskunde* 2008;152:1507-12).

In choosing to have their first child at about 29, Dutch women are practising "prudent family planning," they argue.

The doctor and epidemiologist Luc Bonneux of the Dutch Interdisciplinary Demographic Institute writes that it is wrong to deduce that the rise in the average age at which women have their first child in the Netherlands results from a substantial increase in pregnancies among older women and therefore leads to more medical problems.

Statistics show that since the introduction of the contraceptive pill in 1970, fertility among women older than 40 has seen a "spectacular" fall. But a strong simultaneous reduction in births among younger women has driven up the mean age for having a first child. As a result an increasing proportion of first children are born to mothers aged 25 to 35.

In 2007 the Netherlands Public Health and Healthcare Council published a report called *Postponement of Parenthood: A Medical or Social Problem?* (www.rvz.net). The report pointed out that the Netherlands was one of the European leaders in "late parenthood" and suggested that it posed a problem.

A quarter of the Dutch women aged 40 or more who gave birth in 2005 had their first child, it said. It went on to highlight research by a group of gynaecologists that emphasised the serious consequences of postponing pregnancy, such as greater risks of infertility, complications in pregnancy, and mental and physical disabilities (*Nederlands Tijdschrift voor Geneeskunde* 2007;151:1593-6).

This week, however, Dr Bonneux writes that although the average age at which Dutch women have their first child has risen by five years since 1970 to 29.4, "averages are treacherous." The main cause is a drop of 33% in the chance of having a first child before the age of 25, yet after 35 the chance increases, but only by 4.7%. The fertility of women older than 40 halved between 1970 and 2004, dropping from 20 to 10 per 1000 women.

The Netherlands, more than many European countries, has seen childbirth concentrated into an increasingly narrow age band (table).

The authors accept that women who are planning a family should take into account the natural decline in fertility after 35. But equally they argue that "it would not be wise to encourage women to have their babies at a young age, certainly not before the age of 23" because of disadvantages, including an interruption in education, lower incomes, and instability of relationships.

Dr Bonneux said, "Women in the Netherlands are optimising their social necessities with their biological ones."

Cite this as: *BMJ* 2008;337:a773

Births to women by age (% of births)

	<25	25-35	>35
Netherlands (1950)	15	61	24
Netherlands (2005)	11	73	15
United Kingdom	25	60	15
European Union	17	67	16

US doctors criticised for recommending statins for children

Janice Hopkins Tanne NEW YORK

A storm of criticism has arisen after the American Academy of Pediatrics and the American Heart Association decided to recommend statins for children as young as 8 years old with high lipid concentrations and for those as young as 2 years old with major cardiovascular risk factors.

The American Academy of Pediatrics issued a new clinical report, replacing one from 1998. It said that doctors should measure cholesterol concentrations in children aged 2 years and over and should treat children with high concentrations with statins, probably for life (*Pediatrics* 2008;122:198-208). The report echoed last year's report by the American Heart Association (*Circulation* 2007;115:1948-67).

Timothy Gardner, president of the American Heart Association, said that atherosclerosis begins in childhood. "The earlier we can identify these abnormalities and begin treating them appropriately, the better chance we have of reducing the risk of heart attacks, strokes, and other blood vessel problems in these individuals as they grow into adulthood."

The report recommends using a fasting lipid profile to screen children at risk after the age of 2 years but before 10. Children and adolescents considered to be at risk include those with a family history of dyslipidaemia or premature cardiovascular disease (before the age of 55 for men and before 65 for women) and those with an unknown

EU to introduce plan

Rory Watson BRUSSELS

The European Commission is introducing a new policy to provide free fruit and vegetables to schoolchildren as part of its wider strategy to tackle obesity and encourage good eating habits in young people.

Mariann Fischer Boel, the agriculture commissioner, said, "This shows we're serious about taking concrete steps to fight obesity. Giving kids good habits at an early age is crucial as they will carry these into later life."

At the same time the European Commission has proposed changes to its 30 year old school milk

family history or who have risk factors such as overweight, obesity, high blood pressure, smoking, or diabetes mellitus.

Weight management through dietary change and exercising more is recommended first.

Drug treatment should be considered for children aged 8 or above who have low density lipoprotein concentrations of >190 mg/dl (>4.9 mmol/l); treatment should be considered for those who have a concentration of >160 mg/dl (>4.1 mmol/l) if they have a family history or two or more additional risk factors and for those whose concentration is >130 mg/dl (3.4 mmol/l) if they also have diabetes, the report says.

The goal is a concentration of low density lipoprotein of <160 mg/dl in children with a strong family history of cardiovascular disease, especially if there are other risk factors.

The report says that short clinical trials in children and adolescents "have shown statins to be safe and effective in lowering cholesterol concentrations." Pravastatin has been approved by the US Food and Drug Administration for use in children aged ≥8 years who have a family history of high cholesterol concentrations.

In last year's report the American Heart Association said, "If needed, a statin, started at the lowest dose, is recommended as the first line of treatment for children who meet criteria for starting lipid-lowering drug therapy, if there are no contraindications."

The *New York Times* said in an editorial that it was "appalled when we first heard that… some children as young as 8 be given drugs to reduce their cholsterol levels." (www.nytimes.com, 10 Jul, "Cholesterol drugs for 8-year-olds").

Cite this as: *BMJ* 2008;337:a813

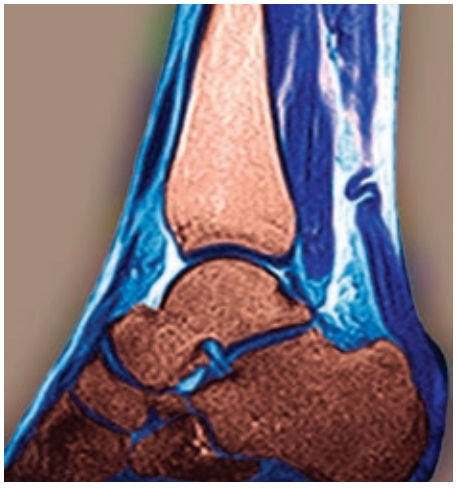
FDA adds "black box" warning to fluoroquinolone antibiotics

Janice Hopkins Tanne NEW YORK

The US Food and Drug Administration has told manufacturers of fluoroquinolones to warn doctors and patients of the raised risk of tendinitis and tendon rupture. The "black box" warning, the most stringent, must be added to drug labels and prescribing information, and manufacturers must also develop a treatment guide for patients.

These measures, the FDA said on 8 July, would strengthen the existing warnings in the prescribing information for fluoroquinolones. The warnings apply to tablets, capsules, and injectable formulations for systemic use but not to ophthalmic or otic formulations.

Public Citizen, a non-profit consumer rights organisation, said that the FDA had accomplished "two of the three steps Public Citizen has urged the agency to do for nearly two years." The third step, which the FDA did not take, was to send a warning letter to doctors "clearly describing possible adverse reactions, such as tendon pain, so that patients can be switched to alternative treatments before tendons rupture."



ZEPHYR/SPL

Fluoroquinolones raise risk of ruptured Achilles tendon

Public Citizen, together with the Illinois attorney general, petitioned the FDA in August 2006 to strongly warn the public about the risk of tendon rupture. When the FDA did not act it sued the agency in January to compel it to act.

Public Citizen says that more than 100 cases of tendon rupture could have been avoided if the FDA had acted more quickly. It said, "From November 1997 through December 2007, there have been 407 reported cases of tendon rupture and 341 cases of tendinitis in patients using fluoroquinolone antibiotics. Because only a small fraction of cases are typically reported to the FDA, the actual number of ruptures and other tendon injuries attributable to the antibiotic is much higher."

The drugs affected by the new warning include ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin, norfloxacin, and ofloxacin.

The FDA said the risk of tendon problems was higher in certain groups, such as transplant patients, people over 60 and those taking steroids.

Cite this as: *BMJ* 2008;337:a816

to provide schoolchildren with free fruit and vegetables

scheme so that a larger range of dairy products may be provided to more children. This scheme will take effect at the start of the next school year (2008-9).

Estimates indicate that some 22 million children in Europe are overweight. Of these, over five million are obese, and their numbers are expected to rise by 400 000 every year. The World Health Organization recommends a daily net intake of 400 g of fruit and vegetables per person. Only 17% of children in Europe meet this standard, as the average rate of consumption of the healthy foods has fallen to 385 g and will decline to 360 g by 2010 if the current downward trend continues.

The European Commission is offering to make €90m (£72m; $143m) a year available for the school fruit and vegetable scheme, which European Union governments are now being asked to approve. Countries will have the choice of whether to participate or not. If they do they will have to provide matching finance.

Several national schemes already exist—the European Commission has identified 21 in 11 EU countries. The most comprehensive is in England, where children are given free fruit and vegetables throughout the school year to eat during breaks.

In Denmark and Germany children receive fruit and vegetables at least once a week over a four to eight week period as part of a comprehensive education programme that includes farm visits.

In Ireland pupils are given free fruit and vegetables for a brief period and are then encouraged to bring their own for lunch.

However, the commission notes that apart from the arrangements in place in England, where all schoolchildren aged 4-6 years are covered, most schemes are small scale, local, and short term and do not have any guaranteed continuity.

Under the EU scheme, which would begin at the start of the 2009-10 school year, governments, in cooperation with public health and education authorities, would have to draw up a national strategy. The EU would finance 50% of the costs of the measures, rising to 75% in Europe's least developed regions.

Cite this as: *BMJ* 2008;337:a829

IN BRIEF

NHS publishes more survival data: The NHS is to publish survival rates for elective and emergency surgery for abdominal aortic aneurysms, hip replacements, and knee replacements for each hospital trust in England, after the successful publication in 2006-7 of survival rates for heart surgery. (See *BMJ* 2008;337:a803.)

New cross border university medical centre is planned: Germany's University Hospital of Aachen and the Dutch University of Maastricht Medical Centre are to co-found Europe's first bi-national university medical centre in the border city of Heerlen. The centre will focus on cardiovascular treatment and research.

Gambling is linked to dopamine agonists: A study has linked problematic and pathological gambling with treatment with dopamine agonists in 140 patients with Parkinson's disease: 9.3% of the patients showed such behaviour, whereas in the general population the figure is 1.6% (*Journal of Gambling Studies* doi: 10.1007/s10899-008-9099-3).

Proton pump inhibitors may be linked to rise in *C difficile* associated diarrhoea: Restricting the use of proton pump inhibitors may be a way to control *Clostridium difficile* associated diarrhoea, say researchers, who note that its prevalence has grown in tandem with an increase in use of the drugs, much of which, they say, is inappropriate (*Journal of Hospital Infection* doi: 10.1016/j.jhin.2008.04.023).

Dutch tourist dies of rare African virus: Dutch doctors have confirmed that a tourist who recently returned from Uganda has died in the Leiden University Medical Centre after being infected with the rare Marburg virus. It is thought that the 40 year old woman was infected after contact with bats while visiting caves in the country. Tourists are advised to avoid caves (www.rivm.nl).

UK collaboration awards £9m for infection research: Two research consortiums have been established this week in London and Oxford to conduct research on healthcare associated infections and antibiotic resistance. The £9m (€11m; $18m) for the centres comes from the UK Clinical Research Collaboration, a partnership of seven funding bodies.

Cite this as: *BMJ* 2008;337:a823

Doctors at BMA's annual meeting call for royal commission on copayments

Zosia Kmietowicz EDINBURGH

Doctors at the BMA's annual representatives' meeting expressed their support for allowing patients to pay for treatments that the NHS does not provide without losing their right to further NHS care.

However, they stopped short of recommending a swift introduction of the system of copayments to run alongside NHS provided care, calling first for a royal commission to review the implications and possible alternatives.

The question of whether to permit copayments produced the most stormy debate and procedurally difficult motion of the meeting.

Those speaking against allowing copayments saw giving permission to fund non-NHS treatments as a "slippery slope" towards privatisation and exploitation of the public by the drug industry. And both sides cited the founding principles of the NHS as a reason to allow and reject payments for extra treatments.

The Department of Health in England has already asked Mike Richards, the cancer tsar, to review the situation, but his remit is restricted to payments for extra drug treatments.

The BMA says that a wider review, in the form of a royal commission, is needed to look independently at what is happening throughout the United Kingdom, how allowing copayments would affect the NHS, what safeguards would need to be put in place, and whether there are any alternatives.

Jacky Davis, a member of the BMA Council, pleaded against the introduction of top-up payments.

"Don't let this genie out of the bottle," she said. "Copayments are an import from the American health industry. They overturn a basic principle of the NHS—that of equitable treatment independent of ability to pay. If you vote to support copayments we will vote for NHS charges because since we have conceded the principle we cannot dictate where it will stop."

Last month the consultants' committee voted to allow copayments. Stephen Austin proposed the motion in Edinburgh to allow copayments and argued that forcing patients to go private for all their care would discriminate against poorer patients, who could somehow find the money to pay for one extra treatment, but not all the tests and other care that they would need.

"This is grossly unfair to these patients at the most vulnerable time of their life. This is not what the NHS stands for, and goes against the founding principles of the NHS," Dr Austin told the meeting. "The patient is hit with the double whammy of not only paying for the additional therapy but also for all of their healthcare costs.

"I believe that the government should admit publicly that health care is rationed and not hide behind public bodies set up to ensure cost effectiveness. I believe that with the reality of healthcare rationing in the real world a form of copayment needs to be allowed in the NHS to assist patients if they do require rationed therapies."

Dr Davis called for alternatives to "deal with this complex and emotional issue."

From the archive: Cancer drug top-ups: can we kill the zombie for good? (*BMJ* 2008;337:a578)

Cite this as: *BMJ* 2008;337:a765

Copayments for anticancer drugs in the US

Fred Charatan FLORIDA

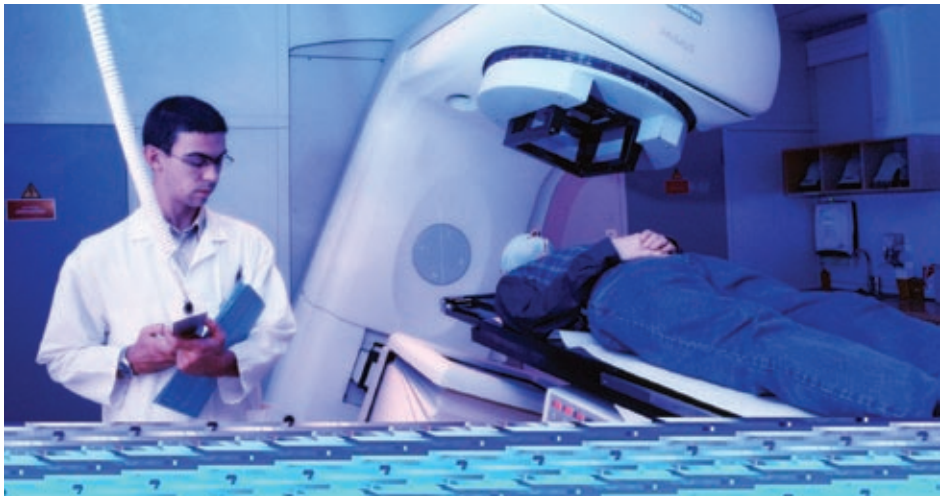
The high cost of anticancer drugs is posing serious problems for patients and doctors in the United States. Even patients who are insured face difficulties because of the expense of copayments.

The American Cancer Society said that the cost of cancer care in the US rose by 25% between 2004 and 2007, from $72bn to $89bn (£45bn; €56bn), partly because of the increased cost of drugs.

The American Society of Clinical Oncology is so concerned about the cost of drugs that it has set up a task force to help doctors discuss costs with patients. It is expected to report this autumn.

Drugs that are causing particular problems include Genentech's trastuzumab (Herceptin) for breast cancer, which costs about $40 000 a year, and bevacizumab (Avastin), which is licensed in the US for metastatic breast cancer as well as colorectal cancer and non-small cell lung cancer, and which costs about $92 000 for a year's treatment. The average wholesale cost for a course of bevacizumab to treat one type of lung cancer is $56 000. If the patient is insured, a 20% copayment comes to $11 200.

Understandably, families of patients want them to receive the best possible palliative treatment. However, doctors and health



GARO/PHANIE/REX

The cost in the US of different treatments for prostate cancer (including radiotherapy) varies by 10-fold

Consensus emerges on need for US agency similar to NICE

Bob Roehr WASHINGTON, DC

Speakers at a conference on integrity in science in the United States have urged the creation of a national agency to provide data on the effectiveness of treatments.

Comparing the effectiveness of various types of therapeutic procedures and not just different drugs was "an elemental building block" and "one of the key ways to learn how to spend smarter and get better clinical outcomes," said Gail Wilensky, an economist and senior fellow at Project Hope, an international charity that aims to achieve sustainable advances in health care around the world.

Such an approach will be an important part of any reform of US health care, she told the fourth US conference on national integrity in science in Washington, DC, on 11 July.

"It is critical that we focus on conditions rather than specific interventions and therapeutics." Although head to head comparisons of drugs are an important part of that, she said, "the serious money is in medical procedures."

The conference was cosponsored by the Center for Science in the Public Interest, which is looking into the possibility of a new body in the United States similar to the UK's National Institute for Health and Clinical Excellence (NICE).

Dr Wilensky called for creation of an agency that was close to government "but not too close," so as to maintain its independence, with an annual budget of $4bn (£2bn; €2.5bn) to $6bn—roughly 0.5% of the total of $2.4 trillion spent on health care in the US.

All stakeholders should play a role in its governance, she said. The agency should focus on generating data, not on deciding what should or should not be covered. Although cost effectiveness was likely to be an element of the data generated, making it the agency's primary focus would be the "surest, quickest death knell" to the idea.

Dr Wilensky said that the agency would initially focus "on high cost medical conditions with a lot of variation in terms of treatment patterns." She said, "That usually is a clue that we don't know enough about what medical procedures should be used."

Ezekiel Emanuel, an oncologist and ethicist at the National Institutes of Health's Clinical Center, agreed that the US held few data on the outcomes of various interventions. "In this country we have tremendously haphazard delivery of quality of care," he said. "Your chance of getting the right care for hypertension or cholesterol is about 50-50 if you are an adult."

Current research on effectiveness is fragmented, repetitive, and wasteful, he said. He and colleagues had previously called for an independent agency to generate data on effectiveness in a paper he and colleagues published last year (*JAMA* 2007;298:1323-5).

Dr Emanuel said that the new agency should be funded through a 0.5% tax or fee on all healthcare payments, which would generate about $5bn a year.

Dr Emanuel said that one disease area where cost effectiveness studies would be useful was prostate cancer. Different treatments for the disease, including surgery, different types of radiotherapy, and watchful waiting, varied at least 10-fold in cost, but few data were available on the best option for patients.

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present problems for doctors and patients

economists say that the costs, equivalent to the deposit on a house or the cost of a college education, must be measured against the life extension derived from these drugs.

Oncologists, who must carry a stock of many anticancer drugs for intravenous office administration, are responsible for their high costs until Medicare, health insurers, or the patient reimburses them. Insurers often instigate delays or denials of final payment. Some patients cannot afford the high copayments or, in cases of denial of insurance, the total amount.

In a statement last year Genentech announced expansion of its Genentech Access to Care Foundation to help tackle the needs of financially eligible Medicare beneficiaries, who are prescribed erlotinib (Tarceva) approved for particular cases of lung and pancreatic cancer. The drug is marketed in the US by Genentech and OSI Pharmaceuticals, and elsewhere by Roche.

Arthur Caplan, bioethics professor at the University of Pennsylvania, said that the cost of drugs was "one of the toughest issues in oncology," especially when the price of one drug can mean emptying out "family assets for the possibility of a few more months of life" (*Wall Street Journal*, 8 Jul, p A18).

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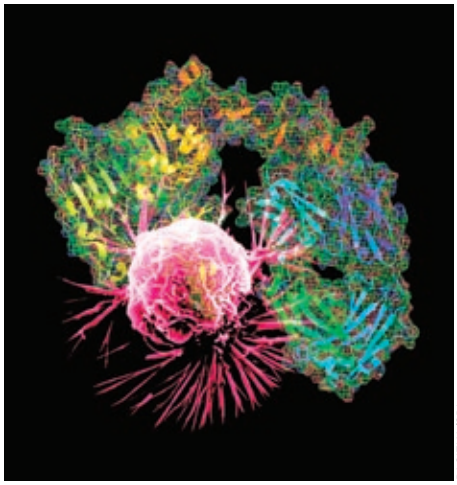

PASIEKA/SPL

Herceptin (green) attacks a breast cancer cell