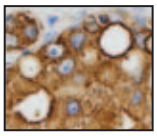

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US drug companies have paid $15bn in fines for fraudulent marketing

Janice Hopkins Tanne NEW YORK

Illegal marketing activities by drug companies have risen over the past five years, leading to major penalties when companies are prosecuted, says a report from Public Citizen, an independent US watchdog organisation. It says that the drug industry is "the biggest defrauder of the federal government."

Industry spokespeople said that the problems were in the past and that the industry had put stricter guidelines in place.

Sidney Wolfe, director of Public Citizen's health research group, told the *BMJ* that in the past five years the drug industry moved ahead of the defence industry and all other industry sectors in the number of civil and criminal settlements of actions against the federal government and state governments.

The report said that of 165 drug company settlements comprising $19.8bn (£12.8bn; €15bn) in penalties over the past 20 years, 73% of settlements and 75% of penalties occurred in the past five years.

Dr Wolfe said that the rise in the number of cases was largely because of drug companies' greater use of illegal marketing practices, such as the promotion of off-label uses of drugs, and increased enforcement by authorities, which were getting more insider information from whistleblowers, who can receive substantial rewards.

He said, "The only way it will stop is . . . if someone goes to jail, because these are criminal violations and they endanger the public health."

In November the US Department of Justice indicted Lauren Stevens, a retired lawyer for GlaxoSmithKline, charging that she obstructed a Food and Drug Administration proceeding relating to the off-label prescribing of bupropion. Her trial is scheduled to begin on 1 February in Boston. If convicted she faces five to 20 years in prison. Her lawyer told the *BMJ* that "she had done absolutely nothing wrong" (*BMJ* 2010;341:c6570).

Rapidly Increasing Criminal and Civil Monetary Penalties against the Pharmaceutical Industry: 1991 to 2010 **is available at www.citizen.org/hrg1924.**

Cite this as: *BMJ* 2010;341:c7360

BEN BURCHALL/PA

Abandoned: guidelines on road safety for children

NICE is told to halt its work on 19 public health topics

EXCLUSIVE

Zosia Kmietowicz LONDON

The UK government has asked the National Institute for Health and Clinical Excellence (NICE) to stop working on guidance on six public health topics and "to put on hold" work on a further 13.

NICE has been told to abandon its guidance on preventing road injuries in children and young people; spatial planning for health (changing the physical environment to improve health); policies for smoke free homes and cars; support for people buying nicotine replacement products; and what commissioners and local authorities can do to combat trade in illicit tobacco products.

Changes to the NICE workload follow the publication of the public health white paper, *Healthy Lives, Healthy People* (*BMJ* 2010;341:c6938), says a statement on the NICE website. Ministers have decided that the "six topics previously referred to NICE are not appropriate for NICE guidance and should therefore be removed from the NICE work programme," the website says.

In the white paper the government outlined the new "responsibility deals" it intends to draw up with business and the voluntary sector, in which voluntary agreements rather than regulation will be used to help people make healthy choices. But the inclusion of representatives from the food and drinks industry on committees that will oversee the deals, including from Kellogg's, McDonald's, and Pepsico, has been widely criticised by public health doctors (*BMJ* 2010;341:c6691).

The announcement of NICE's shrinking public health portfolio comes in the same week that the health secretary for England, Andrew Lansley, launched two public consultations, one on the funding and commissioning routes for public health and one on the public health outcomes framework.

Alan Maryon-Davis, honorary director of public health at King's College London, who chairs the NICE public health topic consideration panel, said he was very disappointed by the changes to the NICE programme.

"It is a shame, because a lot of work has been done on these subjects already. They are important determinants of health—'the causes of the causes,' as Andrew Lansley himself has said," he told the *BMJ*.

Five further pieces of guidance have been "put on hold" until the results of separate government initiatives are known, says the statement on the NICE website. **The full list of topics can be seen at www.nice.org.uk/guidance/phg/indevelopment/.**

Cite this as: *BMJ* 2010;341:c7306

Cancer survival in UK and Denmark lags behind Australia

MARK THOMAS

Mike Richards said a new campaign in England aimed to ensure early diagnosis of cancer

Zosia Kmietowicz LONDON

Late diagnosis means that patients in the United Kingdom and Denmark are less likely to survive bowel, lung, breast, or ovarian cancer than patients in Australia, Canada, and Sweden, a new study concludes.

The study of the records of 2.4 million adults who were given a diagnosis of one of the cancers between 1995 and 2007 found that patients were living longer in 2007 in all the six countries studied than they were in the late 1990s (*Lancet*, doi:10.1016/S0140-6736(10)62231-3). But survival rates were persistently higher in Australia, Canada, and Sweden, intermediate in Norway, and lower in Denmark and the United Kingdom (excluding Scotland), especially in the first year after diagnosis and in people aged over 65.

Many countries have implemented cancer plans since the later 1990s, including England (2000), Northern Ireland (1996), Wales (2004), and Denmark (2005), with the specific aim of improving survival.

The study was carried out by the International Benchmarking Partnership, a collaboration of more than 80 researchers across the six countries involved, to find out whether international differences in survival have changed. The study was funded by the Department of Health of England and Cancer Research UK.

It found that differences between countries in cancer survival have narrowed for

NHS breast screening leaflet glosses over harms, say critics

Susan Mayor LONDON

A new NHS leaflet on breast cancer screening is "a disgrace and should be scrapped," an international screening researcher has said. He is concerned that the information is unbalanced in favour of screening and that the major harms of screening—overdiagnosis and overtreatment—are not clearly explained.

Peter Gøtzsche, director of the Nordic Cochrane Centre, Denmark, said, "The leaflet [published on 13 December] is very unbalanced. It includes figures that overestimate the number of breast cancer deaths saved by screening and fails to give sufficient information on the harms to enable women invited for screening to give fully informed consent."

Michael Baum, professor emeritus of surgery and director of clinical trials at University College London, agreed. "The whole thing is self serving," he said. "It aims to encourage women into screening by manipulating the data," he alleged. "The agents of the state are behaving in an almost Stalinist fashion to coerce women into an activity that has marginal benefit."

In a statement Juliette Patnick, director of NHS Cancer Screening Programmes, said, "The leaflet was produced independently from the NHS by a team led by Joan Austoker, a leading expert on informed choice [who has since died]. Her team used robust research and testing techniques."

Professors Gøtzsche and Baum are concerned that the leaflet claims that the number of deaths saved by breast screening is higher than that seen in randomised trials. It states, "For every 400 women screened regularly for 10 years, one less will die from breast cancer. This means that around 1400 women are prevented from dying from breast cancer each year in England."

Professor Baum said that several studies show that the mortality reduction that can be attributed to breast cancer is around 15%. This would mean that the number of women needing to be screened to avoid one breast cancer death would be around 2000 screened regularly for 10 years.

Valerie Beral, director of the cancer epidemiology unit at the University of Oxford, said that the figures used in the leaflet came from a major review published in 2006.

"Mortality rates [from breast cancer] have fallen by almost 50% in the screened age group over the past two decades. The decline is greater than the estimated 1400 lives saved every year by screening," she said. Although much of this reduction is from improved treatment, she considered that the reduction resulting from screening fits that described in the leaflet.

The leaflet is at www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp.pdf.

Cite this as: *BMJ* 2010;341:c7267

NCI/SPL

Critics said the leaflet was unbalanced

Price war may errupt as trusts win right to compete on price

Jeremy Laurance THE INDEPENDENT

NHS trusts in England are to compete on price for the first time in what could become a supermarket style discount war as they strive to attract business in the new NHS market.

As part of the health secretary Andrew Lansley's drive towards "liberating the NHS"—the subtitle of his white paper published in July (*BMJ* 2010;341:c3796)—the rule requiring NHS trusts to operate with fixed prices, competing only on quality, is to be scrapped.

The change is contained in a single paragraph in the NHS Operating Framework for 2011-12, published on 16 December (*BMJ* 2010;341:c7286). Critics have described it as "politically explosive," with the potential to reduce quality, force hospital closures, and increase death rates.

Paragraph 5.43 on page 54 of the document says: "One new flexibility being introduced in 2011-12 is the opportunity for providers to offer services to commissioners at less than the published mandatory tariff price, where both commissioner and provider agree."

In making the change the government is jettisoning research conducted during the era of GP fundholding in the 1990s and widely quoted in Whitehall. The research, by Carol Propper, professor of health economics at Imperial College London, showed that price competition led to lower quality of care and higher death rates. Professor Propper and her colleagues examined, as an indicator of quality, the death rate among patients with heart attack who were admitted to hospital as emergencies.

some cancers but not others. Survival rates from bowel cancer rose at a similar rate across all six countries, but the UK and Denmark still lagged behind Australia, Canada, and Sweden. For example, in 2005-7 the percentage of patients surviving five years after a diagnosis of bowel cancer was 54% in the UK but 66% in Australia.

Similarly, survival from lung cancer is improving at a slower rate in the UK than in other countries. In 2005-7 30% of UK patients with lung cancer were still alive after one year, whereas the proportions were 35% in Denmark and between 39% and 44% in Australia, Canada, Norway, and Sweden. Five year survival was 9% in the UK and 11% in Denmark but 15% to 20% in the other four countries.

Breast cancer survival rates improved more in the UK and Demark than in the other countries from 1995 to 2007 but were still lower by 2007, because survival in the other countries may have hit a ceiling while the UK and Denmark are still catching up. Five year survival was 86% in the UK and 91% in Australia.

The lower survival rates in Denmark and the UK indicate that late diagnosis remains a problem there, the authors say. They add that the UK had a low NHS staffing level in the 1990s and that elderly people and less affluent people were affected by late diagnosis, treatment delays, and lower survival. And previous studies have shown that UK women with breast cancer were operated on less often, had axillary dissection less often, and had fewer nodes sampled than did women in other countries.

Cite this as: *BMJ* 2010;341:c7372

"Price competition leads to higher death rates," said Zack Cooper of the London School of Economics

They found that the rate rose from 1991, when the internal market began in the NHS, to 1999 (*Economic Journal* 2008;118:138-70; *Journal of Public Economics* 2004;88:1247-72).

Zack Cooper, of the London School of Economics, one of the advocates of increased competition in the NHS whose research has shown that it can increase quality where prices are fixed, also criticised the change. He said, "I was very worried when I saw that paragraph. Research shows that with price competition prices go down but quality tends to fall. In simple terms price competition leads to higher death rates. With fixed prices, quality tends to rise. "

John Appleby, a health economist at the health policy think tank the Kings Fund, said, "There is the potential for a price war. It is clear that some hospitals are well positioned to offer discounts: big hospitals can cross subsidise their services. Price is easily observable, quality is not. They [the Department of Health] are saying commissioners must watch out for any detrimental effect on quality—so they are saying themselves there is potential for that. How can they reassure themselves that patients won't be deleteriously affected?"

Nigel Edwards, acting chief executive of the NHS Confederation, which represents most NHS trusts, said, "We could see people being pressured by commissioners. That would be a worry."

The Operating Framework for the NHS in England 2011/12 is at www.dh.gov.uk/en/Publicationsandstatistics/Publications/.

Cite this as: *BMJ* 2010;341:c7366

Government spells out how value based pricing will work

Nigel Hawkes LONDON

A clearer picture of the UK government's plans for value based pricing of drugs has emerged from a consultation paper published this week.

The new system, to be introduced at the beginning of 2014, aims to price drugs according to the value they deliver to patients. It will apply only to new branded drugs, not to generics or drugs already on the market, and will provide a series of maximum prices that depend on the burden of illness treated, the wider social impacts of a new treatment, and whether the product breaks new ground.

The basic price (confusingly called a "threshold" in the paper) of all new drugs will be calculated on the basis of other services that will be displaced elsewhere in the NHS if the new treatment is to be paid for—but the paper does not specify how costs will be compared.

Drugs to treat illnesses where there is an unmet need or that are particularly severe—the "burden of illness" premium—will attract a higher threshold, as will those that show innovation or that have effects that go wider than the patient treated, for example by easing the burden for carers.

In this way the new system will respond to complaints from carers that their interests are disregarded in the present system and from drug companies that a "one size fits all" pricing regime would penalise genuine innovation. Under the scheme a "me too" drug would be priced at a lower level than an innovative one.

The National Institute for Health and Clinical Excellence (NICE) will determine the value of each new drug, from which its maximum price can be determined. QALYs may be used (as at present) to assess value; or an alternative measure may be considered. But ministers, assisted by advisory panels, and not NICE will determine whether a drug meets the criteria needed to qualify for a higher threshold.

The consultation paper says that the manufacturer will be free to set the opening price for a new drug, which would be accepted as long as it was equal to or less than the basic cost effectiveness threshold. But, if a higher price were sought, "robust evidence demonstrating that the new medicine merited a higher weighting" would be demanded.

The consultation paper and response form are at www.dh.gov.uk/en/Consultations/Liveconsultations/DH_122760.

The consultation closes on 17 March 2011.

Cite this as: *BMJ* 2010;341:c7296

"Andrew Lansley is bright and committed," says new adviser

David Kerr tells **Nigel Hawkes** why he agreed to become adviser to the Conservative health secretary, Andrew Lansley, after campaigning for Tony Blair in 2001

Nigel Hawkes LONDON

Andrew Lansley's new health adviser, the oncologist David Kerr, is a rather unlikely recruit. A Labour supporter who campaigned for Tony Blair in the 2001 election and later wrote a report for the Scottish NHS that stressed the virtues of a collective approach, he doesn't seem the most likely apostate.

David Kerr: "The medical profession has been pushed to the sidelines"

He admits that he "hummed and hawed" for a while after Mr Lansley invited him to serve as an adviser. "The story was always going to be 'top doc defects,'" he acknowledges, "and there was a bit of that. But Andrew Lansley is bright and committed, and David Cameron is right behind him. So far he's delivered on his promises to the NHS."

The promises that attracted Professor Kerr are to return power to clinicians and to create and publish proper outcome measures. "Clinical engagement is absolutely critical—the medical profession has been pushed to the sidelines, into a state of disgruntled passivity," he says. "We now have a chance to come on to the pitch and influence crucial decisions.

"There's been a lot of argument and discussion about structures, GP commissioning, and so on, but the structural stuff is only a tool to deliver better clinical endpoints, not an object in itself."

Disenchantment with Labour policy clearly played a part in his decision. "I think they intellectually ran out of steam," he says of Gordon Brown's government. "Somewhere the narrative was lost. Remarkable progress had been made in reducing waiting times, but then process targets proliferated. All we were doing was inventing more and more targets and getting away from choice and competition. It became a tick box exercise."

Professor Kerr is no dewy eyed neophyte at health policy. Before Labour came to office in 1997 he had carried out the first national audit of cancer services, and later he instigated the Department of Health's networked approach to clinical cancer research. He chaired the national Cancer Services Collaborative and was a founding commissioner of the Commission for Health Improvement, predecessor (but one) of the Care Quality Commission. He aided the sticky passage through the Commons of the bill enabling the creation of foundation trusts by writing to all MPs arguing the case.

But a few questions remain unanswered about his commitment to competition and choice. In 2005 he wrote a blueprint for the future of the NHS in Scotland that emphasised a collectivist approach, calling for "strength through integration" and putting patient choice second to certainty of delivery. "I believe that Scotland is better suited to health improvement through collaboration and internal cohesion," he concluded.

Professionally he is very much a "top doc." A specialist in colorectal cancer, he has been Rhodes professor of clinical pharmacology and cancer therapeutics at Oxford since 2001, moving there from the University of Birmingham. Scottish by birth, he trained at Glasgow and still lists Partick Thistle Supporters' Club (along with the Reform) in his *Who's Who* entry.

"If I'm in big headed mode, I would say I'm in the top 10 in my field," he says. "I lecture round the world, I'm president of the European Society of Medical Oncology.

"But if you came to see me as a patient and peeled all that stuff away and asked what are my results in the clinic, I couldn't tell you. I don't know. I think I'm in the top 5 per cent, but I don't know. I can't benchmark myself.

"Let's agree on an outcome measure that can compare us best, both nationally and internationally, and digest it in a way that patients can understand. Patients say they are satisfied with their care, and all they complain about is car parking, because they assume that care is of universally high quality, and it isn't. As a nation, we're far too trusting.

"Professional pride is the way to turn this round. If I discovered my outcomes were in the lowest 10%, I'd work every moment of the day to make them better, and so would the vast majority of clinicians. But there's no point in collecting crude data that clinicians disregard—they have to own the data and take responsibility for it."

Cite this as: *BMJ* 2010;341:c7093

Six Kosovar doctors face charges of illegal organ trafficking

Paul Lewis LONDON

Six doctors have denied running an illegal organ transplant clinic in Kosovo this week, in a case that has been linked to an international network of organised criminals.

Details of the allegations against doctors involved in the Medicus clinic, in a suburb north of the capital, Pristina, emerged at a confirmation hearing in the city's district court.

The EU prosecutor Jonathan Ratel told the judge that Russians, Moldovans, Kazakhs, and Turks were lured into the capital "with the false promise of payments" for their kidneys after meeting brokers in Turkey.

After blood tests that matched them with suitable recipients, between 20 and 30 "donors" are said then to have been given plane tickets to Pristina airport between 1 January and 4 November 2008.

They were taken to the clinic, just a few

Opposition to NHS changes gathers momentum

Adrian O'Dowd LONDON

Opposition to the government's reforms of the NHS reached a crescendo in the second half of December as doctors, politicians, and health policy analysts all went on the offensive.

The wisdom of the changes—to replace primary care trusts with GP led commissioning consortiums and to have the new bodies operating by April 2013—was questioned by numerous diverse sources. The criticisms came in the same week that the government published its response to the consultation on its white paper *Equity and Excellence: Liberating the NHS* by declaring that the reforms would go ahead with minimal change.

More than 200 clinicians signed a joint letter published in the *Times* on 13 December warning that the government's plans would "destroy" the NHS (*BMJ* 2010;341:c7224).

The letter, signed by 206 medical professionals, said that the desire of England's health secretary, Andrew Lansley, to put patients at the heart of care and involve clinicians in decisions about service provision could be achieved without the "massive structural upheaval" of abolishing primary care trusts and health authorities.

kilometres from the airport, where their kidneys were removed, Mr Ratel said. Recipients, who included patients from Canada, Germany, Poland, and Israel, each paid up to €90 000 (£76 400; $120 000) for the kidneys.

In a separate development, a Council of Europe inquiry into the organ trade in Kosovo linked the Medicus operation to another case, in which the Kosovo Liberation Army (KLA) is accused of killing Serb captives for their organs in the aftermath of the 1998-9 conflict.

The report, which was released to the public on 16 December, said a "handful" of Serb captives were smuggled across the border into Albania where they were killed in a detention facility north of the capital, Tirana.

The doctors indicted in the case of the Medicus clinic—but not named in connection with the KLA's alleged organ harvesting after the Kosovo war—include some of Kosovo's best known physicians.

Lutfi Dervishi, who stands accused of setting up the clinic with his son, Arban, is one of the country's premier urologists. He has maintained his position at Pristina University Hospital despite his arrest. Four local anaesthetists are co-defendants in the case.

VISAR KRYEZIU/AP/PA

Between 20 and 30 "donors" had their kidneys removed at the Medicus clinic in Pristina (above)

Kosovo's former permanent secretary in the ministry of health, Ilir Recaj, is accused of abusing office by giving the Medicus clinic a false licence to conduct organ surgery.

The Medicus victims were made to sign declaration forms saying they were donating their organs "for humanitarian purpose only," according to the indictment read out in court.

However, Mr Ratel said that the clinic was being used "for the purposes of exploitation, namely the removal of organs."

Paul Lewis is special projects editor at the *Guardian*.

Cite this as: *BMJ* 2010;341:c7290

A day after the letter appeared politicians across the spectrum on the parliamentary health select committee published a report from their recent inquiry into public expenditure, highlighting their worries (*BMJ* 2010;341:c7217).

The report said that there wasn't a sufficiently detailed and credible plan for how the NHS would meet the government's expectation of efficiency savings of £20bn (€24bn; $31bn) over the next four years.

Chris Ham: People took time to appreciate the radicalism of the changes

NHS staff will struggle to maintain NHS services at their current levels, given the unprecedented financial challenges they are working to meet, the MPs said in their report.

Evolution rather than revolution was the route suggested in the week's third critical report. The right leaning independent think tank Civitas took many of the government's proposals to pieces in its report *A Risky Business: The White Paper and the NHS*, published on 15 December (www.civitas.org.uk/pdf/Riskybusiness2010.pdf).

James Gubb, director of the Civitas health unit and author of the report, said, "The risks of ripping up the current commissioning structure in its entirety in favour of new, inexperienced organisations at a time when the NHS must focus squarely on driving productivity like never before are unquantified and in all likelihood unacceptably high."

On the same day, the *Guardian* newspaper published a letter predicting that the reforms would turn out to be "this government's poll tax disaster" (www.guardian.co.uk/politics/2010/dec/15/nhs-chaos-reform-cameron-poll-tax).

Commenting on the wave of criticism, Chris Ham, chief executive of the health policy think tank the King's Fund, told the *BMJ* that "a lot of external organisations and stakeholders have been consistent in expressing their concerns about the reforms."

He said, "As people studied in more detail what the white paper and then the consultation documents said, there was an increasing sense of more and more concerns being expressed. People took time to get their minds around how radical the government's reforms were going to be in the context of the funding pressures.

"I think a lot of organisations, such as the BMA and the Royal College of General Practitioners, have been expressing their concerns without coming out and saying the government has got it completely wrong. It's been a reasonably measured response from the medical profession.

"But over time there have been more concerns and criticisms expressed than was the case when the white paper was published."

Professor Ham considers the letter in the *Times* to be significant, saying, "There are some very respected senior figures in the medical world who are now prepared to be more vocal and visible in expressing concerns.

"Now we are getting closer to the health bill being published, and [given] that the government has reaffirmed its continuing commitment to go ahead with the reforms, it's not surprising that more people are willing to put their heads above the parapet.

"The combination of taking forward the white paper and the structural changes, delivering the efficiency objectives, and taking out management costs to the level of 45%, as the government is requiring, is a very powerful cocktail of policies that are being pursued all at the same time when the NHS budget is getting very tight."

Judith Smith, head of policy at the fellow think tank the Nuffield Trust, said, "I think many doctors agree with the spirit of the reforms in terms of greater clinical engagement in shaping services and commissioning and the stronger focus on patients.

"But I also think what they are voicing at the moment is concern about the scale of organisation and management change at the same time as the very significant efficiency challenge. It's an expression of significant concern rather than it being actual resistance.

"As time goes past and people think through the nature of the changes, they see they are radical."

Given the growing scepticism in the medical profession, it seems unlikely that the health bill will have an easy ride when it is published in January.

Cite this as: *BMJ* 2010;341:c7359