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## Doctors and researchers in Italy protest against dismissal of drug regulator Nello Martini

**Fabio Turone** MILAN

Several Italian researchers and clinicians have sent open letters to the media in recent weeks to protest about the removal of Nello Martini as the head of the Italian drug regulatory agency, Agenzia Italiana del Farmaco.

They say that Dr Martini was doing an exemplary job. He had kept the agency free from drug industry pressure and had managed to contain the Italian drugs bill to 13% of the country's health expenditure. But in doing so he incurred the industry's wrath.

The situation began with an incident earlier this year in which a member of the agency was arrested for alleged falsification of data (*BMJ* 2008;336:1208-9). That investigation is still ongoing.

Dr Martini was himself accused of "causing unintentional disaster" by failing to update the safety warnings on many drugs.

Last month nine experts in clinical pharmacology disseminated a written testimonial to the media, saying that the allegations were groundless because the delay in the updating of the warnings involved only minor rewording.

A report published in June by the director of the Mario Negri Institute for Pharmacological Research in Milan, also came to the same conclusion. And an expert commission, nominated by the minister for work, health and social policies, concluded that there had never been any risk to public health.

Nevertheless, the centre-right government under Prime Minister Silvio Berlusconi, sacked Dr Martini in mid-July. And a few days later it announced that the agency's responsibilities would be curtailed, with several functions, including drug pricing, reassigned in the health and welfare ministry.

Last week an editorial in the journal *Nature* condemned the move. It said, "At a time when all countries are struggling to find a way to pay for hugely expensive new generation drugs within limited budgets, this makes little sense.

"Moreover, the health and welfare ministry's connections with industry are uncomfortably close," it continued (*Nature* 2008;454:667).

Maria Font, president of the International Society of Drug Bulletins, deplored the sacking. "One can already see that the drug industry has a greater influence [than in the past] and that is worrying," she told the *BMJ*.

Many people fear that Dr Martini's important legacy will be lost. Gianni Tognoni, director of the Mario Negri Sud Consortium, and one of the nine authors of the testimonial, said, "The agency's originality was that it not only had the responsibility for controlling drugs but for promoting independent research, especially in response to need, such as in general medicine."

Alessandro Liberati, director of the Italian Cochrane Centre and a member of the



People fear that Dr Martini's legacy will be lost

agency's research and development committee, said that the agency had a vital role in a country where continuing medical education was still relatively new and where investment in drug marketing was high.

The agency offered Italy's 248 000 doctors free access through the internet to unbiased balanced medical information, and its independent research programme funded more than 150 projects and was recognised at international level, he said (*Clinical Pharmacology and Therapeutics* 2008;83:24-5).

Several of these projects have compared different therapeutic strategies and regimens of specific expensive drugs, none of which the drug industry would have directly funded, he told the *BMJ*.

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## Mexico conference considers pre-exposure prophylaxis for AIDS

**Bob Roehr** MEXICO

The possible use of a daily pre-exposure prophylactic pill against AIDS raised interest at last week's 17th international AIDS conference because of the recent failures of trials of vaccines and microbicides.

Several studies of pre-exposure prophylaxis are being launched in different parts of the world.

Most involve a combination of two popular anti-HIV drugs, tenofovir and emtricitabine, in one pill, marketed as Truvada. The combination has amassed millions of people years of use. It seems to be safe, well tolerated, and holds the virus in check.

There are biological reasons to think that pre-exposure prophylaxis

can work, and trials in monkeys are encouraging.

Tom Coates, of the University of California in Los Angeles, said "If it is as effective as we think it is going to be it should revolutionise the way that HIV prevention dollars are spent."

He added, "It is not just giving out the pill, it becomes another

opportunity to have a conversation about sexual behaviour."

Should the trials prove that the drug is useful as a preventive measure there is likely to be pressure on the manufacturer to slash the price to something closer to around the dollar a day that it offers to the world's poorest countries.

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## IN BRIEF

**One in five British childhood cancer survivors are smokers:** One fifth of survivors of adult cancer are current smokers, and a third have smoked regularly at some point, UK research has found. Survivors of Wilms's tumour, Hodgkin's lymphoma, or soft tissue sarcomas were most likely to be current smokers and are at particularly high risk of developing another cancer (*Journal of the National Cancer Institute* 2008;100:1068-91).

**Americans want better healthcare system:** Eighty two per cent of US residents think their healthcare system should be radically overhauled or completely rebuilt, a survey by the Commonwealth Fund has found. Nine out of 10 respondents wanted presidential candidates to propose reforms to improve the quality of health care, provide universal access, and cut the number of people without medical insurance. See [www.commonwealthfund.org](http://www.commonwealthfund.org).

**US drugs regulator tightens conflict of interest rules:** Rules drawn up by the US Food and Drug Administration stipulate that experts with \$50 000 (£26 000; €34 000) or more interest in a company cannot serve on an advisory committee that reviews that company's products or those of its competitors. See [www.fda.gov](http://www.fda.gov).

**Carers live longer:** Men and women who give 50 or more hours of care a week have a lower risk of death than non-carers, research has shown. Their hazard ratios were 0.86 (95% confidence interval 0.81 to 0.93) and 0.75 (0.69 to 0.93). "While this study does not exclude the possibility of significant detrimental health effects of caring..., it does add support to the growing body of literature which suggests that the positive aspects of caring have been underreported," say the researchers (*Social Science and Medicine* 2008 Jul 28, doi: 10.1016/j.socscimed.2008.06.025).

**Diabetes causes more than 10% of deaths in adults in England:** Figures released by the health charity Diabetes UK show that 11.6% of deaths among 20 to 79 year olds in England are caused by diabetes. If current trends continue the disease will kill one in eight people by 2010, the charity warns. See [www.diabetes.org.uk](http://www.diabetes.org.uk).

Cite this as: *BMJ* 2008;337:a1290

# Advisory team for consultation on NHS constitution announced

Lynn Eaton LONDON

Several high profile health service and local government representatives are to be part of the committee that will examine the health minister Ara Darzi's proposed constitution for the NHS. But the BMA says that it is

surprised that it has no representation on the group, and intends to write to the Department of Health about it.

Cyril Chantler, a paediatric nephrologist and chairman of Great Ormond Street Hospital, is among the 22 member commit-



A specially commissioned photograph of Cyril Chantler, who will help advise on public consultation

## Government to offer MMR vaccine to all

Helen Mooney LONDON

The Department of Health has launched a campaign to raise the rate of take-up of the measles, mumps, and rubella (MMR) vaccine in England as concern grows about the outbreak of a measles epidemic.

The government has asked all primary care trusts to offer the vaccination to all children up to the age of 18 who are not yet fully protected.

In a letter to all primary care trusts, the chief medical

officer, Liam Donaldson, asked health service managers to urge parents to have their child immunised.

The measure has been introduced after warnings from the Health Protection Agency that measles has become endemic in Great Britain, 14 years after its spread was halted.

The agency says that the number of unvaccinated children in England is large enough to sustain the "continuous spread" of the

potentially lethal virus.

Figures published by the agency in June show cases of measles in London reached a new peak in May. There were 95 confirmed cases in London and 35 in the rest of England and Wales.

In a statement the agency said that its latest modelling shows that there is "a real risk of a large measles outbreak of between approximately 30 000 to 100 000 cases—the majority in London."

Elizabeth Miller, head of

## Student with spent conviction gains place at medical school

Jessie Colquhoun BMJ

Majid Ahmed, the 19 year old from Bradford with a spent criminal record, has gained a place to study medicine at Manchester University, after his offer was withdrawn by

Imperial College London.

He had been unable to find a place at medical school because of his conviction for a minor offence as a juvenile and was rejected on eight occasions despite having a good academic record and considerable experience (*BMJ* 2008;337:a830, 16 July).

He spent almost two years trying to get a place at medical school. He first applied in 2006, choosing Imperial College, Manchester, Leeds, and Cambridge universities. He

tee, known as the Constitutional Advisory Forum (CAF). It will advise the Department of Health on how best to engage the public in consultation about the constitution.

The team includes representatives from the NHS, local government, the voluntary sector, and other organisations, and is due to report to the government later this year. The Department of Health wants to ensure consultation is as wide as possible, including the NHS and local authorities, patient and public groups, and even schools.

"The NHS constitution is about safeguarding the core principles and values of the NHS for the next generation," said Ivan Lewis, health minister, who jointly chairs the forum with David Nicholson, chief executive of the NHS.

"The draft constitution has been developed based on discussions with thousands of NHS staff and patients across the country," said Mr Lewis. "We've created the CAF to ensure that the final constitution strengthens the foundations of the NHS still further."

But a BMA spokesperson expressed concern that they had not been included in membership: "We were surprised to learn about the launch of the forum without prior

notice, and to discover that the BMA was not to be included," he said.

"Through its paper earlier this year setting out plans for an NHS constitution, the BMA has clearly expressed its interest in this area, and demonstrated its desire to work constructively with the Department of Health. The ideas in our paper were broadly welcomed by doctors, patients, and politicians, including the secretary of state for health.

"It is disappointing, therefore, that the BMA was apparently overlooked when membership of the forum was being considered."

The draft NHS constitution was issued as part of Lord Darzi's review of the NHS (*BMJ* 2008;337:a640). It will give patients a legal right to make choices about their care, including choosing their general practice and expressing a preference for seeing a particular doctor. It also intends to give patients the right to treatment with a drug approved by the National Institute for Health and Clinical Excellence, regardless of where they live. All NHS organisations would be legally obliged to act in accordance with the constitution.

A full list of members is in the 7 August press release at <http://nds.coi.gov.uk>.

Cite this as: *BMJ* 2008;337:a1263

## Watchdog set to reject four kidney cancer drugs for NHS

Adrian O'Dowd MARGATE

The UK clinical watchdog has proposed rejecting four drugs for use on the NHS for advanced renal cancer, saying they are clinically effective but not good value for money.

The National Institute for Health and Clinical Excellence (NICE) issued draft guidance this week that rejects the drugs sunitinib (Sutent), bevacizumab (Avastin), sorafenib (Nexavar), and temsirolimus (Torisel).

The guidance which applies in England, Wales, and Northern Ireland is out for consultation until 29 August, with the final guidance due in early 2009.

The draft guidance says that it does not recommend these drugs for advanced or metastatic renal cell carcinoma but that people who are receiving the treatments should have the option to continue with their treatment until they and their clinicians consider it appropriate to stop.

About 7000 people in the United Kingdom are diagnosed as having renal cancer every year, and about 1700 are diagnosed as having advanced kidney cancer. The four drugs have the potential to extend progression-free survival by five to six months.

A statement from NICE said that the cost of the drugs is about £24 000 (€30 600; \$46 000) a year. But when quality of life was also taken into account the cost was higher. The cost per quality adjusted life year of these treatments varied from the manufacturers' estimate of £28 500 to £90 600 per patient, and the estimate of an independent academic group of £71 500 to £171 300 per patient. That took the cost above the institute's acceptable level, which is £20 000-£30 000.

Peter Littlejohns, NICE's clinical and public health director, said, "If these treatments were provided on the NHS other patients would lose out on treatments that are both clinically and cost effective."

The charity Cancer Research UK said in a statement that it wanted NICE to change the way it reviews drugs for rare diseases, such as this type of renal cancer "where clinical benefit is proved but evidence is limited."

The draft guidance is at [www.nice.org.uk/guidance/index.jsp?action=article&o=41473](http://www.nice.org.uk/guidance/index.jsp?action=article&o=41473).

Cite this as: *BMJ* 2008;337:a1262



## children in England

immunisation at the agency, said, "2007 saw the highest number of measles cases recorded in England and Wales since the current method of monitoring the disease was introduced in 1995. Confirmed cases rose 31% in 2007.

"Measles is a very serious infection as it can lead to pneumonia and encephalitis. It is not possible to tell who will be seriously affected by measles. This is why it's incredibly important to remind parents about the benefits of

having their child vaccinated with two doses of MMR for optimum protection. It is never too late to get vaccinated."

The agency has also reported the year on year increase in cases of measles as a result of outbreaks in areas of the country where uptake of the MMR vaccine has dipped or been low for longer periods of time. In June it reported the second death from measles in the past two years.

Figures for measles cases can be seen at [www.hpa.org.uk/](http://www.hpa.org.uk/)



MMR vaccination rates are too low, warns agency

GREENHILL/MEDISCAN

received an offer from Imperial College, but it was withdrawn when the institution learnt about his previous offence.

He reapplied in 2007, this time to Manchester, Leeds, Cambridge, and Sheffield, having achieved four A grades at A level. He received four more rejections.

He appealed against Manchester's decision on the grounds that he had been rejected on two occasions without an interview despite achieving a high enough score in the UK

clinical aptitude test and having a well rounded CV.

The appeal was successful and this week he had a standard interview followed the next day with a fitness to practise interview. On Thursday Manchester medical school granted him a place to start in September.

Talking to the *BMJ*, he described being "overwhelmed with happiness" and "relieved more than anything else."

Cite this as: *BMJ* 2008;337:a1261



Five communities in Victoria have introduced the Be Active Eat Well strategy after success in Colac

## Australian town slows rise in obesity with community approach

Ray Moynihan MELBOURNE

The small town of Colac in rural Australia is attracting national and international attention for its approach to fighting childhood obesity, and reducing health inequalities.

Two hours west of Melbourne, with 11 000 inhabitants, Colac is the site of a long term community-wide campaign called Be Active Eat Well, funded by the state government of Victoria.

The campaign aims to build the community's capacity to fight childhood obesity, and its action plan was designed and implemented by local organisations, including schools; parents; and local health, housing, and government services.

Key strategies include transforming canteen menus, introducing daily fruit, reducing television watching, and increasing activities after school.

In the first three years of the campaign children in Colac had significantly lower weights (about 1 kg) and smaller waists (about 3 cm) compared with children in a nearby control area (*International Journal of Obesity* 2008;32:1060-7).

"At a population level this is very significant," said Boyd Swinburn, senior author on the evaluation, professor of population health, and founder of the World Health Organization collaborating centre for obesity prevention at Deakin University in Australia. "It wasn't enough to reverse the increase in obesity levels that's occurring with age and time, but it was enough to slow it down."

In what the authors describe as a world first, the community based obesity prevention campaign seemed to reduce health inequalities. In Colac changes in weight and other measures were not related to children's socioeconomic status.

Cite this as: *BMJ* 2008;337:a1238

## US senators propose body similar to NICE to assess treatments

Janice Hopkins Tanne NEW YORK

Two Democratic senators have introduced a bill into the Senate, to establish an institute similar to the National Institute for Health and Clinical Excellence, which decides which drugs can be prescribed in the NHS in England and Wales. It is called the Comparative Effectiveness Research Act of 2008.

Max Baucus, of Montana and chairman of the Senate finance committee, and Kent Conrad of North Dakota, chairman of the Senate budget committee, proposed an institute with participants from government, private industry, and the public to identify the most effective treatments. The Institute of Medicine, the Medicare Payment Advisory Commission, and the Congressional Budget office have all called on Congress to set up such a body, Mr Baucus said.

"In 2006, America spent more than \$2 trillion [£1 trillion; €1.3 trillion] on health care. By any standard, \$2 trillion is an enormous figure," Mr Baucus said. He said that health-care spending amounted to 16% of the US economy and would rise to 20% in 10 years.

However, he said, "In many cases, doctors and patients don't have enough reliable evidence to know what treatments work or don't. Of the \$2 trillion spent on health in 2006, only 0.1% was spent to assess what works and what doesn't."

The proposed institute would set national

priorities for effectiveness research. It would contract federal agencies such as the Agency for Healthcare Research and Quality and the National Institutes of Health or private researchers to conduct research on the effectiveness of drugs, devices, and treatments.

Representatives of the health insurance industry and the drug industry expressed support for the plan.

All the institute's rules, proceedings, and reports would be published on a public internet site, and its meetings would be open to the public. It would also provide public comment periods and open forums to get public input about its activities.

The institute would be a non-profit making private entity called the Health Care Comparative Effectiveness Research Institute. "Keeping it private would remove the potential for political influence on the development of national research priorities," Mr Baucus said.

It would be governed by a board of 21 governors, who would include the secretary of the federal Department of Health and Human Services and the directors of the federal Agency for Healthcare Research and Quality and the National Institutes of Health. The other 18 board members would include representatives from health insurance companies; drug, device, and technology companies; patients; doctors; and agencies that administer public health programmes.

Funding would come from the federal government and by payments from health insurance companies and Medicare, which provides health insurance for the elderly.

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## Doctors call for changes to abortion law

Ganapati Mudur New Delhi

An Indian court has turned down a plea by a Bombay couple to be allowed to abort a 25 week old fetus, stirring a nationwide clamour for changes in India's 37 year old abortion law.

Niketa and Harsh Mehta, had approached the Bombay High Court to seek permission to abort their fetus after diagnostic tests showed a congenital heart block and transposition of the great arteries. India's Medical Termination of Pregnancy Act, passed in 1971, allows abortion up to only 20 weeks' gestation.

The court had asked a panel

of doctors from the Jamsetji Jeejeebhoy Hospital to examine the test results, and rejected the plea last week after the panel predicted little chance that the child would be born too disabled to survive.

The court observed that the existing law allows termination of pregnancy after 20 weeks only if the pregnant woman faces a health risk. It said that it could not make an exception to this case given the medical opinion it had heard and added that it was for the legislature to amend the abortion law.

Sections of India's medical

community have reacted to the court ruling with dismay. "The law needs to keep pace with advances in medical technology," said Jaydeep Tank, chairman of the committee for medical termination of pregnancy at the Federation of Obstetrics and Gynaecological Societies of India.

"We believe that the cut-off date should be extended to 24 weeks," Dr Tank said. "Certain fetal abnormalities are best detected only in the 20 to 24 week window."

In a letter of support for the couple's plea submitted to the

# German court ruling on smoking in public places leads to demands to strengthen federal law

**Ned Stafford** HAMBURG

Germany's tough laws banning most cigarette smoking in restaurants, pubs, nightclubs, and other indoor public areas are at risk of being weakened less than a year after being implemented after a ruling by the nation's highest court.

But advocates of smoke-free areas are hoping that the ruling will prompt the federal government to pass a stronger law that will introduce a complete ban on smoking in enclosed public spaces with no exceptions.

Martina Pötschke-Langer, head of the World Health Organization's collaborating centre for tobacco control in Heidelberg, said, "I think we now have an open situation. It is a very delicate situation. The doors are open on both sides, and this could go either way."

The Constitutional Court of Germany ruled on 30 July that smoking bans in small pubs with one room in the states of Berlin and Baden-Wuerttemberg were discriminatory because current laws allow larger pubs or nightclubs with more than one room to designate a room as a smoking area. Owners of the small bars had filed a lawsuit, arguing that antismoking legislation had put their businesses at risk.

The High Court agreed: "Lawmakers could totally ban smoking in all bars and restaurants. But if they decide to allow exceptions for some barkeepers, then these exceptions



SEAN GALLUP/GETTY IMAGES

**Some German bars have reintroduced smoking after a ruling that the current law is discriminatory**

must also apply to small pubs which are most hit by the ban." The court says laws must be revised by the end of 2009.

Already, small bars and nightclubs in other states have used the High Court's ruling as a reason to reintroduce smoking. Smoke-free advocates worry that the tobacco lobby and supporters will now try to pry open the small crack created by the court rulings to seriously weaken any new laws adopted by the end of next year.

The German Cancer Research Centre ([www.dkfz-heidelberg.de](http://www.dkfz-heidelberg.de)) and the German

Medical Association noted that the High Court in the rulings had declared that passive smoking poses a health risk and that a complete smoking ban in restaurants and bars would be constitutional.

"This is the first time in the history of Germany that the High Court has done this," said Dr Pötschke-Langer.

Both organisations are urging politicians to use the ruling to enact a federal law that completely bans smoking in enclosed public places, with no exceptions.

*Cite this as: BMJ 2008;337:a1258*

## in India to keep pace with advances in medical technology



SACHIN KADVEKAR/FOTOCORP

**Niketa and Harsh Mehta lost their case to have an abortion after 20 weeks, India's current time limit**

court, he said, the federation had cited the law in the United Kingdom, where abortion is permitted up to 24 weeks.

Independent gynaecologists and members of the federation argue that the 1971 law was enacted at a time when prenatal diagnosis was not conducted in India. "There's no strict medical reason for the 20 week cut-off," said Dilip Walke, the chairman of the ethics and medicolegal committee of the federation.

"Abortion procedures have changed significantly since 1971," Dr Walke said. "The risk from abortion to the pregnant

woman at 20 weeks is today the same as the risk at 24 weeks."

"This case highlights the dilemma that doctors in India face," said Nikhil Datar, the couple's doctor who is a consultant obstetrician and gynaecologist at the Nanavati Hospital, Bombay.

Doctors say they are forced to turn away parents who seek abortion after their fetuses are diagnosed with severe anomalies after 20 weeks of gestation.

"An abortion after 20 weeks may appear to some doctors as morally and ethically the

right thing to do, but it is also illegal," Dr Datar told the *BMJ*. Some parents just don't want to see their child suffer, and others seem to have economic reasons for seeking termination of pregnancy, one obstetrician said.

India allows abortion after prenatal diagnosis of genetic disorders or congenital abnormalities as long as pregnancy is terminated by 20 weeks. A few hospitals across India provide prenatal diagnosis of a range of illnesses such as muscular dystrophy.

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