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## Nigerian judge orders arrests of Pfizer officials

Jeanne Lenzer NEW YORK

A Nigerian judge has ordered the arrests of three Pfizer officials for failing to attend court to respond to criminal charges against Pfizer for treating children with an experimental drug during a deadly meningitis outbreak in Kano, Nigeria, in 1996.

Judge Shehu Atiku in Kano ordered arrest warrants for the head of Pfizer in Nigeria, Ngozi Edozien, and the senior officials Lare Baale and Segun Donguro, after they failed to attend court on 6 November.

Government prosecutors in Nigeria say that Pfizer used critically ill children as “guinea pigs” to study Pfizer’s experimental drug trovafloxacin. Four separate legal actions have been filed in Nigeria against Pfizer, including 31 criminal counts against 10 people.

Plaintiffs seek a total of \$9bn (£4.5bn; €6bn) in civil suits. Pfizer says that it will “vigorously defend itself against the ‘untrue allegations’ in the government’s lawsuits,” and it says that the children died from meningitis and not from the drugs. In response to the

judge’s most recent order, the company issued a statement on 26 December saying that the arrest orders are “improper and violate due process” because the summonses were “not properly served on the defendants.”

According to Reuters, Pfizer obtained an injunction in Lagos last month preventing police from serving the summonses. Pfizer argues that the Kano court lacks jurisdiction to hear the case.

The company successfully quashed three previous attempts to sue the company in US courts on the grounds that the US courts lacked jurisdiction.

A committee commissioned by the Nigerian Federal Ministry of Health to investigate the conduct of the study, concluded in a March 2001 report that Pfizer conducted an illegal study of an unregistered drug. The findings were kept secret until May 2006 when the report was leaked by an anonymous source to the *Washington Post* (*BMJ* 2006;332:1233). Pfizer argues that the report is “illegal, inaccurate, and biased.”

Trovafloxacin was not approved for use in the United States when it was tested on the children in Nigeria. Subsequent reports of liver failure caused the drug to be banned in Europe and severely restricted in the US.

The 2001 government report, which is contested by Pfizer, found that “although the protocol mentioned the possibility of elevated liver enzymes . . . it did not consider carrying out any liver function test either before or after the treatment.”

Five of 93 children in the trovafloxacin arm died, and six of 97 in the ceftriaxone arm died, according to Pfizer. Patients’ outcomes are not verifiable, according to the committee, because “no patient record given to the committee by Pfizer was complete with patient names and addresses,” making independent verification impossible.

The study, which was only published as an abstract, shows that 10 of the children enrolled in the study were excluded from the analysis. Pfizer did not respond to queries by the *BMJ* about the outcomes of those 10 children.

## Charity highlights “forgotten crises”

Peter Moszynski LONDON

The plight of people struggling to survive violence, forced displacement, and disease in many parts of the world often goes largely unreported, says the charity Médecins Sans Frontières, which has produced the 2007 version of its annual “top 10” list of the most under-reported humanitarian crises.

The 2007 list highlights the conditions currently faced by people living through “forgotten crises” in eight countries: Zimbabwe, Burma (also known as Myanmar), Somalia, Sri Lanka, the Democratic Republic of Congo, Colombia, Chechnya, and the Central African Republic. It also

focuses on the continuing toll of two “medical catastrophes”: the spread of drug resistant tuberculosis and the failure to overcome malnutrition among children.

Jean-Michel Piedagnel, director of the charity’s UK branch, says that “millions of people trapped in war, forced from their homes, and lacking the most basic medical care do not receive attention commensurate with their plight.”

The agency began producing its top 10 list in 1998, when a devastating famine in southern Sudan drew little attention from the world’s media. Drawing on its wide ranging experience of

emergency medical work, the charity seeks through its list to “generate greater awareness of the magnitude and severity of crises” that are not always reflected in media accounts.

Media attention, it says, is often “critical for generating and improving responses.”

In Zimbabwe inflation is currently running at 12 000%, three million people have fled the country, and 85% of its workforce is unemployed. “Under this extraordinary strain, what had been among the best healthcare systems in Africa has collapsed,” the charity says. Every week 3000 Zimbabweans die from AIDS. For details visit [www.msf.org/unitedkingdom](http://www.msf.org/unitedkingdom).



Street children in Harare

ROBIN HAMMOND/PANOS

## IN BRIEF

### Reactor reopens after isotope

**shortage:** Canada's National Research Universal nuclear research reactor, whose shutdown in November caused a worldwide shortage of nuclear isotopes for medical purposes, was restarted on 16 December and is expected to resume isotope production within days. Parliament hastily pushed through legislation to allow the restart without safety upgrades called for by the national regulatory body.

### BMJ paper tops US medical journal

**chart:** A *BMJ* study by Nancy Cook of Brigham and Women's Hospital, Boston, and colleagues (*BMJ* 2007;334:885) showing that reduced dietary sodium intake can lower the incidence of cardiovascular disease has been cited by the American Heart Association ([www.theheart.org](http://www.theheart.org)) as one of the top 10 advances of 2007.

### Strike has knock-on effect for Israeli

**medical students:** The deans of Israel's four medical schools warn that unless the government swiftly resolves the two month strike by senior lecturers in the country's universities hundreds of medical students will be stuck in their preclinical studies and be unable to proceed to work in hospitals.

### Motor neurone mortality rises:

The death rate in people with motor neurone disease rose steadily from 1975 to 2004 in both sexes in England, Wales, and Scotland. Increases were largely restricted to those aged  $\geq 60$  years, with this group showing rises in the death rate of 70-80% (*Amyotrophic Lateral Sclerosis* 2007;8:337-42). Among those aged  $\geq 60$  the gap in mortality between men and women narrowed, say the authors from Manchester University.

### Department warns on vitamin D

**intake:** England's Department of Health wants pregnant and breastfeeding women to boost their intake of vitamin D in the darker winter months, because more children than ever are presenting with vitamin D deficiency, which can cause seizures and rickets. Incidence of the disease could be as high as one in 100 children in ethnic minority groups, the department says.

### Two more bird flu deaths are reported:

A 25 year old Egyptian woman died on 25 December of avian flu. Of the 39 cases confirmed so far in Egypt 16 have been fatal. Meanwhile a 24 year old woman from Jakarta also died on 25 December.

# US healthcare executive pays back \$600m in stock options

Janice Hopkins Tanne NEW YORK

William McGuire, former chief executive officer and chairman of the board of UnitedHealth Group, has agreed to return \$468m (£235m; €325m) to the healthcare company he ran for about 15 years. With other payments, he is returning some \$600m to the company.

The US Securities and Exchange Commission said that Dr McGuire and other employees had been granted stock options in UnitedHealth Group that were "backdated" to a day when the company's stock was at a low price.

Stock options are usually granted at that day's market price, so backdating them to a day when the company's stock was low means



William McGuire

that anyone exercising the option and selling the stock would be guaranteed a profit. Such transactions could affect a company's reported earnings and its share price and might have tax consequences for the company and any individual exercising the options. The 2002 Sarbanes-Oxley Act made it illegal to backdate stock options and now requires companies to report stock options within two days of their being granted.

The Securities and Exchange Commission (SEC) alleged that, over 12 years, Dr McGuire "repeatedly caused the company to grant undisclosed, in-the-money [profitable] stock options to himself and other UnitedHealth officers and employees without recording in the company's books and disclosing to shareholders material amounts of compensation expenses as required by applicable accounting rules."

"Without admitting or denying the SEC's charges," says the commission's press release, "McGuire agreed to a \$468m settlement that includes a \$7m civil penalty and reimbursement to the Minneapolis based healthcare company for all incentive- and equity-based compensation he received from 2003 through 2006."

The commission's chairman, Christopher Cox, said, "Whenever a corporate officer misleads investors about a company's

performance by secretly backdating stock options, the integrity of our markets is undermined. As demonstrated in this case, the commission is committed to holding corporate officers accountable for illegally backdating stock options and will seek the return of undeserved compensation."

The commission said that Dr McGuire "knew, or was reckless in not knowing," that annual reports filed to the commission contained "materially false and misleading statements concerning the true grant dates and proper exercise prices of stock options."

In March 2007 UnitedHealth restated its financial statements for each year from 1994 to 2005 and disclosed material cumulative pretax errors in stock based compensation accounting that totalled \$1.53bn for that period, the commission says.

"The \$468m settlement in this case, including the largest penalty assessed against an individual in an options backdating case, reflects the magnitude and scope of Dr McGuire's misconduct," said Linda Chatman Thomsen, director of the commission's enforcement division.

The commission said that Dr McGuire consented to various requirements as a result of the ruling, including a bar on his serving as an officer or director of a public company for 10 years.

UnitedHealth Group is the parent company of United Healthcare, the second largest healthcare insurer in the United States, covering about 70 million people.

The commission's investigation came after an article in the *Wall Street Journal* ([www.wsj.com](http://www.wsj.com), 18 Mar 2006, "The perfect payday") questioned whether companies, including UnitedHealth Group, had backdated stock options. The article won a Pulitzer Prize, the highest award in US journalism. The Internal Revenue Service (the US tax collecting agency), the Department of Justice, the Attorney's Office for the Southern District of New York, and the Minnesota Attorney General's office also began investigations as a result.

UnitedHealth Group appointed a law firm, Wilmer Cutler Pickering Hale and Dorr LLP, to conduct an independent review. Its report said that many stock options had been backdated, with adverse accounting consequences.

The report was released in October 2006, and Dr McGuire resigned in November 2006.





A lighthouse converted to a home, close to a nuclear power station near Brokdorf, northern Germany

## Research sparks public concern about risk from nuclear power

Annette Tuffs HEIDELBERG

German research shows that children younger than 5 years old who live near nuclear power stations are more likely to have leukaemia than otherwise (*International Journal of Cancer* 2007;122:721-6; *European Journal of Cancer* 2007 Dec 12 doi: 10.1016/j.ejca.2007.10.024). This has started controversial public discussions about the risks of power stations. Opponents of nuclear power have demanded the closure of all 16 German

nuclear power stations.

However, the research did not show that radiation from nearby power stations was the cause of a higher incidence of cancer, the authors say, because no radiation leaks had occurred, and the level of radiation near the stations was substantially lower than in normal exposure.

The research was carried out by the German Register of Child Cancer in Mainz ([www.kinderkrebsregister.de/english](http://www.kinderkrebsregister.de/english)),

financed by the German Federal Radiation Protection Agency, the government agency that advises on nuclear health.

The case-control study was initiated because previous epidemiological studies had already indicated higher risks among children who live near nuclear plants. The research looked at 1592 cases of leukaemia from the child cancer registry between 1980 and 2003 and compared them with randomly chosen control children in the same area.

Thirty seven cases of leukaemia were diagnosed between 1980 and 2003 among children who lived within 5 km (3.1 miles) of a nuclear power plant. The statistical average for Germany would have predicted just 17 cases in that group.

The authors of the study, Maria Blettner and Peter Kaatsch, were convinced of the epidemiological relevance of their study but had no explanation for the surplus of leukaemia cases: "The current state of knowledge on radiobiology does not explain why more children living near power stations have more cancer." The authors speculate that other unknown causes may have led to the rise in the number of cases.

The government's radiation protection agency said that statistically the 20 extra cases could be associated with living close to the plants, but more research was needed to discover whether the presence of reactors was the cause of the cancers.

## Child in gene therapy programme develops leukaemia

Andrew Cole LONDON

Doctors at Great Ormond Street Hospital for Children in London have admitted that other children may be at risk after leukaemia was diagnosed in a child on its pioneering gene therapy programme.

The unnamed 3 year old was taking part in a clinical trial treating children for X linked severe combined immunodeficiency (X-SCID), also known as "baby in the bubble syndrome," in which boys are born with no immune system. Around six to eight children are affected by the condition each year in the United Kingdom.

The trial, which began at Great Ormond Street in 2001

and ended earlier this year, involved 10 children with X-SCID and five with the related ada-SCID. Until now it seemed that most of the children had recovered successfully. However, four of 11 children involved in a similar trial in Paris were found, by 2002, to have gone on to develop leukaemia, one of whom died.

Bobby Gaspar, consultant immunologist on the London programme, admitted that other children taking part in the UK trial remained at risk. "Although we understand the mechanics of how this leukaemia happened, we can't say at this stage what the frequency will be."

Professor Gaspar insisted

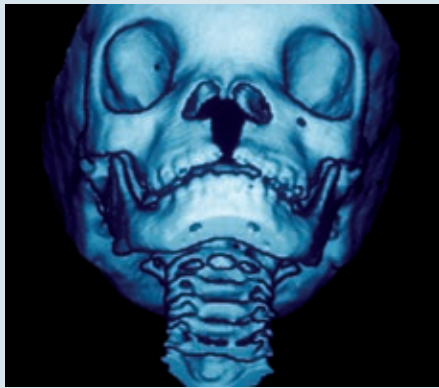


Aaron Nawaz, who lived in a protective bubble at a Newcastle hospital

that all the families involved had been carefully counselled about the risks—including that of leukaemia once it was known—and none chose to pull out.

"You have to realise that these children are faced with

a fatal disease," he said, "and they need to have some form of treatment." The conventional treatment was bone marrow transplantation, but if a full match wasn't possible the success rate was only 80%.



**A computed tomogram scan of a child with a cleft lip. Private whole body scans are not advised by experts**

ZEPHYRUS/SPL

## Committee warns of unnecessary radiation

**Zosia Kmietowicz** LONDON

Private clinics should stop offering whole body computed tomography scans to people who are without symptoms, because of a lack of evidence that the benefits outweigh the risks, the UK's radiation watchdog has said.

In its report the Committee on Medical Aspects of Radiation in the Environment also says that computed tomography should not be used to check for lung

cancer, because there is no evidence of benefit. In addition, anyone who presents with any symptoms that may indicate a serious condition should be referred back to their GP rather than be offered a scan.

The committee is concerned about the increasing amount of radiation that people are being exposed to. It estimates that in the United Kingdom 15% of an individual's exposure comes

from medical sources; and although the average dose of radiation exposure was falling in the 1990s, it is likely to increase in the future as technology becomes more sophisticated.

The report says that although the risk of radiation exposure from computed tomography is low, people need to be aware that it exists. A typical scan is associated with a risk of one in 2000 of getting fatal cancer in

## Royal college tries to improve relations with drug industry

**Annabel Ferriman** LONDON

The Royal College of Physicians has set up a joint working party with the drug industry to try to create a better relationship between doctors and drug companies, so as to improve the care of patients.

The group, chaired by Richard Horton, editor of the *Lancet*, is taking oral evidence from doctors and academics and representatives of the industry, medical journals, and regulators. It has also asked interested parties to submit written evidence by 31 March.

In a letter inviting submissions Dr Horton and Ian Gilmore, the college's president, say: "There are barriers perceived to exist between the industry, the NHS and academic medicine that inhibit a truly dynamic and productive relationship between the key players, working in the best interests of patients."

"The Royal College of Physicians identified a need to look into this relationship and to examine in some detail the political, economic, commercial, organisational, professional and public barriers to creating an ideal relationship. The overwhelming principle is to improve patient care."

People wishing to contribute to the debate are asked to consider certain questions, such as what would be the nature of the ideal relationship between the drug industry, the NHS, and academic medicine, and how can doctors help to advance ethical and productive relations between the industry, the NHS, and academic medicine.

More details are at [www.rcplondon.ac.uk/wp/pharma](http://www.rcplondon.ac.uk/wp/pharma).

## BMA officials reject proposals for longer GP surgery hours

**Lynn Eaton** LONDON

GPs' leaders have found themselves fighting back over plans—stemming from 10 Downing Street—to force general practices to open for longer. The government said just before Christmas that it intended to impose a contract on GPs that could mean that practices that don't comply will lose as much as £36 000 (€49 000; \$72 000) a year.

The BMA leaders argue that the proposals don't reflect what most patients want and that doctors will be too tired to provide a good service.

At a briefing just before Christmas, Laurence Buckman, chairman of the BMA's General Practitioners Committee, told journalists that the government had "effectively put a gun to our head."

He said, "We are being bullied so that the prime minister can tick a box next to a politically driven target without regard for the damage this could do in the long term to patient services in primary care."

Within a matter of hours the government responded by announcing sweeping changes in the funding arrangements for general practices in the quality and outcomes framework (QOF). Many of these would be withdrawn to fund the proposed new opening hours, says the BMA.

The BMA argues that the proposals will undermine care for patients with the most need. "GPs will do their best

to continue to provide good quality care, but Gordon Brown's political objective will inevitably affect the chronically ill," said Dr Buckman.

The government wants doctors to open their surgeries for three more hours a week. Surgeries normally close at 6 30 pm, and merely adding an extra half an hour each evening would not meet the government's desire to make it easier for people at work to get to their doctor. It is understood that the prime minister, Gordon Brown, wants to see surgeries opening until 8 pm one night a week.

Dr Buckman said that a Department of Health survey of patients' experiences conducted last summer (the GP patient survey 2007, available at [www.dh.gov.uk/en/Publicationsandstatistics/PublishedSurvey/GPpatientsurvey2007/DH\\_075127](http://www.dh.gov.uk/en/Publicationsandstatistics/PublishedSurvey/GPpatientsurvey2007/DH_075127)), had shown that 84% of patients were happy with the current opening hours of their practice. "A significant number of GPs do not consider longer opening hours to be an efficient use of resources," he said.

The government has rejected an alternative proposal from the BMA and now intends to consult the profession over the next 13 weeks, before introducing the changes in April.

Dr Buckman was at pains to point out that talks "have most definitely not broken down," and he explained that the 13 week consultation was a legal requirement where a change in the contract was proposed. Consultation would therefore begin immediately.





## risk from private computed tomography

a lifetime, whereas the natural risk of getting cancer is 1 in 4. It says that if 100 000 people had a scan every five years between the ages of 40 and 70, an additional 240 deaths from cancer would result.

Alex Elliott, chairman of the committee, said that it was not known how many people in the UK have had private medical scans. But new data just published in the United States

indicated that between 1% and 2% of cancers there are due to medical exposure to radiation.

“[This is] not an inconsequential problem,” said Professor Elliott.

Besides exposure to radiation, people can become unnecessarily alarmed and anxious if a scan reveals something that turns out to be harmless, says the committee. They may also be subjected to a number of further tests, many

of which themselves carry risks and the cost of which is picked up by the NHS.

However, people at high risk of heart disease may benefit from a scan to assess coronary artery calcification, it says.

*The Impact of Personally Initiated X-ray Computed Tomography Scanning for the Health Assessment of Asymptomatic Individuals* is available at [www.comare.org.uk](http://www.comare.org.uk).



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## Lords urge doctors to train in aviation medicine to assess fitness to fly

Jacqui Wise LONDON

The UK postgraduate curriculum for GPs should include a basic overview of aviation medicine and the effects on health of flying, recommends a report from the House of Lords Science and Technology Committee.

At present training for GPs in aviation medicine is not mandatory. In evidence to the committee Michael Bagshaw, professor of aviation medicine at King's College London, said, “My experience with lecturing to GPs . . . is that there is an amazing ignorance among the medical profession about the health effects of flying.”

The update to the committee's highly influential report *Air Travel and Health*, published in 2000, also calls for various specialties such as cardiology, orthopaedics, and psychiatry to follow the lead of the British Thoracic Society in producing guidelines on fitness to fly.

Committee member Baroness Finlay of Llandaff said, “We are aware that GPs are in a difficult position when deciding on a patient's fitness to fly, as there is not a single place to access all the relevant information.”

The update calls for information that is already available, such as that from the British Thoracic Society, the BMA, and the World Health Organization, to be pooled in a single publication for ease of reference.

It also criticises the inconsistent health advice available from airlines and on the internet, particularly on the use of aspirin to prevent deep vein thrombosis. Committee spokesman Lord Patel said he had been alarmed to discover that 20% of passengers on long haul flights had taken or planned to take aspirin before, during or after their long haul flight. “For most passengers taking aspirin may do more harm than good,” he said.

Although taking aspirin may reduce the risk of arterial thrombosis it has no effect on venous thrombosis, says the committee's report. About 24 000 people have to be treated to prevent one thrombosis, whereas the number needed to treat for harm to result from taking aspirin is in the region of one in 17 000, it says.

*Air Travel and Health: An Update* is available at [www.parliament.uk/hlscience](http://www.parliament.uk/hlscience).

## Plans to meet costs of cross border care are temporarily halted

Rory Watson BRUSSELS

Plans to clarify European Union rules for patients to receive reimbursable health care in countries other than their own have unexpectedly been put on hold after several EU commissioners strongly criticised them. The plans were due to have been presented on 19 December.

At least half a dozen of the 27 commissioners have lodged forceful objections to the proposal, which had been drafted by Markos Kyprianou, the health commissioner, and his advisers.

Some of the objections are openly political, given the sensitivity of healthcare issues and the fact that health care is the responsibility of national, not European, authorities. Margot Wallström, senior vice president of the European Commission, has expressed her “fundamental reservation” over the proposal and questioned its political advisability.

One of her concerns is that the EU should not be seen to be doing anything remotely controversial at a time when governments are ratifying the new Lisbon Treaty, which, after the failed EU constitution, is a final attempt to reform EU institutions so that they can function effectively with 27 or more member states.

Opponents also point to practical problems that they believe are not fully dealt with in the current text. These include the cross border recognition of prescriptions and the question of a doctor's or hospital's liability if treatment goes wrong once a patient has returned home. In addition, the proposal is facing opposition in countries with a national health service, such as the United Kingdom, and those, such as in Scandinavia, that have a high level of public funding.

The decision to remove the proposal at the last minute from the commission's final agenda before Christmas—ostensibly for lack of time—is a severe setback for Mr Kyprianou. EU officials say that the plan might now be examined again at the end of January or early February.

The commission estimates that on average 1% of EU states' public health budgets—roughly €10bn (£7.2bn; \$14.4bn)—is spent on cross border health care each year. The practice is most common in small countries, in border regions, in areas that attract lots of tourists, and when patients have rare diseases.