

## In brief

**Drug safety data opened up to patients and researchers:** The UK medicines watchdog, the Medicines and Healthcare Products Regulatory Agency, is to publish anonymous data on suspected adverse drug reactions to patients and researchers on its website. Patients will also be able to report suspected drugs side effects direct to the scheme ([www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)).

**Woman gives birth at age 66:** A 66 year old Romanian woman has given birth to a baby girl weighing just 1.4 kg at the Giulesti Maternity Hospital in Bucharest. The woman reportedly had infertility treatment for nine years before becoming pregnant.

**Global strategy published for development of HIV/AIDS vaccine:** The Global HIV/AIDS Vaccine Enterprise, an international alliance of organisations involved in research on HIV vaccine, has published a strategic plan for overcoming the major obstacles to the development of an effective vaccine. See the Public Library of Science Medicine website ([www.plosmedicine.org](http://www.plosmedicine.org)).

**Pfizer withdraws advertising on COX 2 inhibitors:** Pfizer has withdrawn advertising of its COX 2 (cyclo-oxygenase-2) drugs celecoxib and valdecoxib, the business information company Datamonitor has said ([www.datamonitor.com](http://www.datamonitor.com)). The US Food and Drug Administration said that the advertisements failed to disclose appropriate information about the risks and potential side effects associated with the drugs.

**Alcohol may reduce mortality:** Alcohol may protect against some diseases and death, say the findings of a 23 year prospective study of 12 000 male British doctors who were aged 48-78 years in 1978 and drank an average of two to three units of alcohol a day; 7000 of the doctors died during the study, by Richard Doll, Richard Peto, and colleagues at the Radcliffe Infirmary, Oxford. It is published in the *International Journal of Epidemiology* ("advance access" at <http://ije.oupjournals.org>).

## Royalty payments to staff researchers cause new NIH troubles

Janice Hopkins Tanne *New York*

Patients who took part in clinical trials at the US National Institutes of Health (NIH) had no idea that scientists at the institutes received \$8.9m (£4.8m; €6.8m) in royalty payments and might benefit financially for the use of their discoveries by pharmaceutical companies and device makers, reports from Associated Press allege. This information was not made public until the press agency obtained the information after filing a request under the Freedom of Information Act.

The press agency has reported that 916 present and former NIH researchers received annual royalty payments averaging \$9700 but could receive as much as \$150 000.

At the same time, NIH researchers spent millions of taxpayers' dollars studying the treatments that they had developed that were licensed to drug companies, the agency reported.

A patient advocacy group, the Alliance for Human

Research Protection, says that patients might have thought differently about the risks of trial treatment if they knew of scientists' financial interests.

The NIH has been criticised before for not disclosing conflicts of interest (*BMJ* 2004;329:10). Five years ago, just before leaving office, Donna Shalala, then secretary of the federal Department of Health and Human Services, issued a requirement that scientists disclose their financial interests. But nothing happened until the Associated Press's investigations.

The NIH has received almost \$56m in royalties for its discoveries, the agency says. This money is put back into its research.

The press agency reported that two leading researchers, Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases and his deputy, Clifford Lane, received payments relating to their development of interleukin 2 as a treatment for HIV/AIDS. Dr

Lane told the *BMJ* that the payment was part of his federal compensation. He explained that the government patented the development and shared the payments it received with the inventors. Since 1997 he has received about \$45 000 he says. The institutes awarded \$36m in grants for studies to test the treatment.

Dr Anthony Fauci told the *BMJ* that as a government employee he was required by law to put his name on the patent for the development of interleukin 2 and was also required by law to receive part of the payment the government received for use of the patent. He said that he felt it was inappropriate to receive payment and donated the entire amount to charity.

Both doctors told Associated Press that they had been concerned about an apparent conflict of interest for some time before the agency's story appeared.

The *BMJ* was told by an NIH spokesperson that the NIH had no plans to put information about payments to its researchers on its website and that the *BMJ* would have to make a request via the Freedom of Information Act to find out royalty payments to individual researchers. □

## Pfizer found guilty of breaching code

Tony Sheldon *Utrecht*

Pharmaceutical company Pfizer has been ordered to shut down a Dutch website about erectile dysfunction that it sponsors, after a complaint was upheld that it was guilty of the "unlawful public advertising" of its prescription only drug sildenafil (Viagra).

Dutch MP Agnes Kant brought a complaint after a series of radio commercials from Pfizer last October on erectile dysfunction.

Although Dutch law permits "symptom advertising"—which draws attention to specific medical conditions but does not name pharmaceutical products—listeners were also told that they could visit [www.erectieplein.nl](http://www.erectieplein.nl) [erectio forum] for information.

On the website, references to Viagra were "numerous and

prominent," said the Pharmaceutical Advertising Code Foundation—a self regulatory body of doctors, pharmacists, and industry representatives—which supervises compliance with the code.

The Pfizer sponsored website included an invitation to "click here for the responsible prescription and delivery of erection pills."

The site included information about other products, including Eli Lilly's Cialis (tadalafil) and Bayer's Levitra (vardenafil). But Viagra was placed first with the longest text, saying that comparable medical research had shown no other product to be more effective. The site also linked by email to a doctor and to a pharmacist, who almost exclusively offered Viagra.

Ms Kant argued that the radio commercials in combination with a website recommending Viagra was an unlawful public advertising campaign.

Pfizer argued that the radio commercials gave only information about an illness and did not contain any mention of a

pharmaceutical product. The company maintained that the website was independently run by the Foundation for Medical Information, Literature, and Education. Pfizer claims that it only sponsored the site and had no influence over its content.

The advertising foundation called such claims so "absurd and unbelievable that this defence could scarcely be taken seriously." It accepted the link between the radio commercials and the website. It said the website gave the impression that Viagra was more effective than its competitors and gave an unfair picture of its advantages. This amounted to "unlawful public advertising."

A spokesman for Pfizer in the Netherlands, Dick Vente, said that the company accepted the judgment but hoped to relaunch the website without naming the product and offering only information for patients. The company was disappointed that it no longer had the opportunity to correct misunderstandings about Viagra found on other websites. □