In brief

Death toll from bird flu rises: A Thai girl, aged 9, who contracted H5N1 bird flu from infected chickens that her family raised, has died. It is the 11th death from H5N1 in the country and the 31st in Asia. More than 80 people in Thailand are being tested for the disease after developing flu-like symptoms.

German hospital pays €250 000 in compensation: The University Hospital of Giessen, Germany, will pay compensation of €250 000 (£172 150; $307 225) and a lifelong monthly pension of €800 to a severely disabled girl and her parents. The girl was infected as a premature baby in the hospital's paediatric intensive care unit with *Klebsiella oxytoca* in 1997. The bacterial outbreak was attributed to the use of heavily diluted disinfectant. The parents sued the hospital after doctors published a letter about the outbreak in the *Lancet* (*BMJ* 2000;321:530).

Alder Hey report damaged research: A study by the health think tank, the King's Fund, claims that the report into the retention of children's organs at Alder Hey hospital in Liverpool, published in January 2001, has stifled debate on the issue of organ donation and damaged public interests (*Journal of Medical Ethics* 2004;30:463-9).

Welsh prescription charges cut: From this week, patients in Wales will pay £5 ($8.91; €7.26) for a single prescription instead of £6. This strategy is the Welsh Assembly's first step to providing free prescriptions by 2007. The price of prescriptions remains at £6.40 elsewhere in the United Kingdom.

Working party set up on treatment of newborns: The Nuffield Council on Bioethics has set up a working party to consider the ethical, legal, and economic issues surrounding the prolonging of life in fetuses and newborn babies. Chaired by Margaret Brazier, professor of law at Manchester University, it will review guidance on the treatment for newborns, current practice in neonatal units, scientific advances, and developments in this field.

Merck withdraws arthritis drug worldwide

Debashis Singh *London*

The pharmaceutical company Merck last week initiated a voluntary immediate worldwide withdrawal of its bestselling arthritis drug rofecoxib (Vioxx), because new research shows that it almost doubles the risk of myocardial infarction and stroke if taken for 18 months or more.

Rofecoxib, a cyclo-oxygenase-2 selective inhibitor, has been on the market since 1999 and is used by 2 million people in over 80 countries worldwide with 400 000 taking it in the United Kingdom. It is indicated for osteoarthritis and rheumatoid arthritis, and higher dose strengths are indicated for short term relief of acute pain (VioxxAcute).

The new study, called APPROVe (adenomatous polyp prevention on Vioxx), was a multicentre, randomised placebo controlled double blind trial to determine the effect of three years of treatment with rofecoxib on the recurrence of neoplastic polyps of the large bowel in patients with a history of colorectal adenoma.

The trial, which started in 2000, enrolled 2600 patients and compared rofecoxib 25 mg to placebo. After 18 months, 25 patients taking placebo and 45 patients taking rofecoxib had had a confirmed serious thromboembolic event.

KATHY WILLENS/AP

Raymond Gilmartin: "Withdrawal is the responsible course"

The absolute event rates were about 3 per 400 patient years for placebo and 6 per 400 patient years for rofecoxib—that is, an absolute increase in risk of about 3 thromboembolic events per 400 patient years of treatment. The new data relate specifically to rofecoxib and is not generalised to other cyclo-oxygenase-2 selective inhibitors.

The cardiovascular safety of rofecoxib has been questioned since 2000 when Merck submitted a study called VIGOR (Vioxx gastrointestinal outcomes research) to the US Food and Drug Administration (*New England Journal of Medicine* 2000;343:1520-8). An analysis of the VIGOR study by cardiologist Eric Topol and colleagues at the Cleveland Clinic in Ohio showed that patients taking rofecoxib had a higher relative risk of developing adverse cardiovascular events than patients taking naproxen (*JAMA* 2001;286:954-9). This led to warnings of this risk on the drug's label.

The FDA issued a statement saying it was in the process of carefully reviewing other recent studies showing similar findings when Merck informed them of the new data and the company's decision to withdraw the drug.

The decision to withdraw has already taken its toll on the pharmaceutical giant. In 2003, global sales of rofecoxib amounted to $2.5bn (£1.4bn; €2.0bn). Within a day of announcing the withdrawal, more than £14bn was wiped from the company's stock market value, equivalent to a quarter of its worth and the share price plunged to an eight year low.

Also, a day after the announcement, the first lawsuit against Vioxx and Merck was filed in Oklahoma on behalf of a local resident with the likelihood of more to follow, including class action cases.

Merck's chairman Raymond Gilmartin said, "Although we believe it would have been possible to continue to market Vioxx with labelling that would incorporate these new data, we concluded that a voluntary withdrawal is the responsible course to take." □

FDA to review risks of antidepressants in adults

Jeanne Lenzer *New York*

The US Food and Drug Administration (FDA) announced last week that it will examine whether antidepressants pose a similar risk of increased suicidal thoughts among adults as they do for children, by reanalysing data for adults.

"Our first priority with regard to the adult data is to finish our analysis of the adult completed suicides data, and get this published," said a spokesperson for the FDA's Center for Drug Evaluation and Research. The spokesperson told the *BMJ* that the FDA has also been asked to look at suicidal "ideation and behaviours" contained within the "various antidepressant [new drug applications] submitted in recent years."

"Such data were looked at as part of the [new drug application] submissions and reviews, and no signal [evidence of increased suicidal thoughts] was found," said the spokeswoman. Janet Woodcock, acting director of the FDA, said that the analyses will be a "huge undertaking."

Currently, only about 10% of the FDA's total database of patients taking antidepressants has been reanalysed. A recent set of analyses led to a recommendation by an expert advisory panel that the FDA attach a "black box" warning, cautioning that for every 100 children taking an antidepressant, two or three are likely to become more suicidal (*BMJ* 2004;329: 702, 25 Sep).

Psychiatrist and clinical psychopharmacologist Dr Peter Breggin, who first described the risks of violence and suicide induced by selective serotonin reuptake inhibitors in his book *Talking Back to Prozac*, published in 1994, welcomes the review. "The stimulant effects of antidepressants that cause mania, agitation, insomnia, and akathisia, could be causing deadly reactions," he told the *BMJ*. See p 809. □