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BMJ 2004;329;702
doi:10.1136/bmj.329.7468.702

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FDA panel urges “black box” warning for antidepressants

All antidepressants should come with a “black box” label warning that adolescents treated with the drugs are more likely to become suicidal, according to an advisory panel to the US Food and Drug Administration.

The surprise vote, in favour of imposing such a label, came after the presentation of new analyses by the FDA during two days of hearings on 13 and 14 September showing that children taking the drugs were almost twice as likely to have suicidal thoughts or to attempt suicide as children receiving placebo.

The effects of a black box warning are variable. With some drugs, it has led to abrupt reductions in prescribing, but with others the warning seems to have had little effect. According to Joyce Generali, director of drug information at the Kansas University Medical Center, 192 drugs carried black box warnings by 14 July.

Some panellists expressed concern that a black box warning could reduce the number of doctors willing to prescribe antidepressants in children. But Dr Thomas Newman, professor of epidemiology and paediatrics at the University of California, San Francisco, and a panellist, said: “It wouldn’t be a bad thing if less well defined (New England Journal of Medicine 2004;351: 1285-91).

In the current study, researchers from the valsartan in acute myocardial infarction trial (VALIANT) led by Dr Nagesh Anavekar of the cardiovascular division at Brigham and Women’s Hospital, Boston, Massachusetts, identified 14 927 patients who had had acute myocardial infarction complicated by clinical or radiological signs of heart failure or left ventricular dysfunction, or both. Patients in the study had been randomly assigned to receive captopril or valsartan, or both. Each reduction of 10 units in the estimated GFR was associated with a hazard ratio for death and non-fatal cardiovascular outcomes of 1.10 (95% confidence interval 1.08 to 1.12), which was independent of the treatment assignment.

Scott Gottlieb New York

Patients informed of increased risk of vCJD contact

Up to 4000 patients in the United Kingdom are being sent a letter this week explaining they may be at increased risk of carrying variant Creutzfeldt-Jakob disease (vCJD) because they have received blood products donated by people who have gone on to develop the disease.

The step is a highly precautionary one to try to limit the spread of the agent to other people, says the Department of Health. It follows the identification of two cases of vCJD that may have been transmitted through a blood transfusion, one last December and the other in July this year (BMJ 2004;329:251).

The patients who have been sent a letter, most of whom have haemophilia, will be invited to find out more about their individual risk from their local treatment centre. All of them are also being advised to tell their doctors and dentists about their potential increased risk so that steps can be taken to reduce the risk of further potential contamination.

Zosia Kmiotowicz London

Continental doctors take up top posts in UK heart medicine and surgery

Leading jobs in cardiovascular medicine and cardiac surgery in the United Kingdom are increasingly being filled by doctors from Italy, France, and Germany, says an editorial in the European Heart Journal by leading members of the two specialties.

British doctors are being put off academic jobs by lack of flexibility in training and the rewards of private practice, says the article (European Heart Journal 2004;25:1568-9).

“The pursuit of private practice, which generates enormous incomes among NHS physicians and surgeons, produces role models for junior doctors who aspire to material wealth as opposed to intellectual advance,” says the authors.

The authors—Professor John Martin, director of the Centre for Cardiovascular Biology and Medicine at University College London, Dr Philipp Bonhoeffer, chief of cardiology at Great Ormond Street Hospital for Children, and Professor Gianni Angelini, professor of cardiac surgery at the Bristol Heart Institute—say that continental doctors are attracted to the United Kingdom partly by the belief that merit is rewarded.

Roger Dobson Abergavenny

Study quantifies dangers of renal disease after heart attack

Even mild renal disease, as measured by the glomerular filtration rate (GFR), is a major risk factor for cardiovascular complications after myocardial infarction.

Although renal failure has been associated with one of the highest risks in determining outcome after a heart attack, until now the influence of milder degrees of renal impairment was less well defined (New England Journal of Medicine 2004;351: 1285-91).

The patients who have been informed of increased risk of vCJD contact were among 36 000 patients who were randomly assigned to receive captopril or valsartan, or both. Each reduction of 10 units in the estimated GFR was associated with a hazard ratio for death and non-fatal cardiovascular outcomes of 1.10 (95% confidence interval 1.08 to 1.12), which was independent of the treatment assignment.

Scott Gottlieb New York

Dutch commemorate doctor shot by Nazis for helping injured soldiers

Elderly residents of Arnhem gathered this week to honour the memory of a local doctor who, 60 years ago, was shot by the Nazis for helping injured British soldiers as fierce fighting raged in the Dutch city.

The handful of remaining witnesses met at a small plaque in Bakker Straat that reads: “In remembrance of J Zwolle, doctor, shot 19 September 1944.”

They met as part of the larger and last official commemoration of the Battle of Arnhem. Testimony to the doctor’s courage is shown in a diary of a teacher of English, Wilhelmina Schouten, that remains in a local archive. Miss Schouten recalls how two severely wounded soldiers were carried into the school where she was based as a volunteer with the air protection service. Staff decided to summon a respected local GP, Jan Zwolle, aged 30, who operated on both patients, one of whom died but one of whom is thought to have survived.

When the Germans arrived the next day, Dr Zwolle and four other men were shot in a nearby building, allegedly for “terrorism” and “cooperating with the British.”

Tony Sheldon Utrecht