

February 11, 2006

ADHD drugs warning

Clara Pirani, Medical reporter

DRUGS used to treat attention deficit hyperactivity disorder may be required to carry the most serious type of warning on their labels after health regulators found the medications might cause heart attacks and strokes.

A US Food and Drug Administration advisory panel is investigating whether ADHD drugs, including Ritalin, were linked to the deaths of 25 people, including 19 children, between 1999 and 2003.

The drugs were also associated with 54 cases of cardiovascular episodes including heart attacks, strokes and serious heartbeat disturbances.

The warning comes as figures show prescriptions for Ritalin in Australia have jumped since the drug was listed on the Pharmaceutical Benefits Scheme in August last year, reducing the cost of a prescription from \$49 to \$29.50, or \$4.70 for concession card holders.

The number of Ritalin prescriptions processed under the PBS jumped from 523 in August to 3938 in October and 5713 in December.

Joe Tucci, a psychologist and chief executive of children's welfare group the

Australian Childhood Foundation, said doctors were over-prescribing ADHD medication for children "because they are seen as a quick fix for what can sometimes be family dysfunction".

"We need to understand what is causing children's behavioural problems before we just treat the symptoms," Dr Tucci said.

The FDA advisory panel recommended that the drug regulator require manufacturers to put black box warnings -- the strongest warning possible -- on all packaging. The FDA is not required to follow the advisory panel's recommendations but usually does.

"The number of arrhythmia hospitalisations really struck us as surprising," said David Graham, a medical officer in the FDA's office of drug safety.

"Arrhythmia is believed to be the pathway for sudden unexplained death. We wouldn't be going through this exercise if we didn't think there was a real possibility of increased risk."

Steven Nissen, a cardiologist and FDA panel member, said ADHD drugs clearly had the potential to cause more harm than good.

"I have grave concerns about the use of these drugs and grave concerns about the harm they may cause," he said.

A spokeswoman for the Therapeutic Goods Administration, the Australian drugs regulator, said the administration would review the advice of the FDA committee and decide if action was appropriate in Australia.

Dr Tucci urged the administration to introduce stronger warning labels for all ADHD medication. "I think the TGA does need to step up its vigilance of this and any kinds of medication that are

aimed towards children and their behaviour," he said.

A spokeswoman for Novartis, which manufactures Ritalin, said the drug was a safe and effective treatment for ADHD.

"It was approved by the FDA in December 1955 and for more than 50 years it has helped over a million patients lead more productive, healthy lives," the spokeswoman said.