Lessons from cisapride

One evening just over a year ago, 15-year-old Vanessa Young sat chatting with her father in his study. She rose to go upstairs, fell to the floor, and died. Her cardiac arrest was undoubtedly caused by the drug cisapride, which she had been taking for stomach complaints associated with an eating disorder. Her pharmacist testified that he was unaware of any particular risk of cisapride; the information sheet he dispensed with the drug made no mention of the ventricular arrhythmias that, since 1990, had resulted in 80 deaths in Canada and the United States.

Health Canada had reported on severe and fatal adverse reactions experienced by patients taking cisapride through the Canadian Adverse Drug Reaction Newsletter in July 1996, January 1998 and January 2000. The US Food and Drug Administration (FDA) started to issue warnings about the drug in June 1998; these culminated in an advisory on Jan. 24, 2000, alerting US physicians to the occurrence of fatal cardiac arrhythmias among patients taking the drug. An equivalent advisory didn’t emerge from Health Canada until May 31.1 Cisapride was off the US market by July 14; Canadians could keep filling their prescriptions until Aug. 7, more than 6 months after the FDA warning.

Warnings to physicians and pharmacists don’t necessarily change prescribing practice. A US study showed that FDA regulatory action in 1998 relating to contraindications to cisapride use had virtually no impact on prescribing.2 Perhaps physicians miss such warnings; perhaps the rarity of catastrophic side effects leaves too much room for complacency. Forty-four cisapride-associated cardiac arrhythmias have been reported in Canada,3 where 7.7 million prescriptions have been dispensed with the drug made no mention of the ventricular arrhythmias that, since 1990, had resulted in 80 deaths in Canada and the United States.

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