

Cisapride fallout? Canada to gain access to largest adverse-event database

Canada will soon have access to 350 000 adverse event reports annually through the world's largest repository of such data.

Health Canada's acting director general, Dr. Chris Turner, says an agreement providing access is slated to be signed with the US Food and Drug Administration this fall. The database, which includes information from Europe, should be accessible by early 2003. Negotiations began 4 years ago.

Canada's small population makes it difficult to assess the risk a new drug may pose (see *CMAJ* 2001;165[10]:1293).



Terrence Young

Vanessa Young: fallout from her death still being felt

The larger database will provide Health Canada with more accurate information so it can issue timely warnings and advisories, or withdraw a drug.

Creation of a database was 1 of 17 recommendations directed at Health Canada after a coroner's inquest into the death of 15-year-old Oakville, Ont., resident Vanessa Young. She died of a cardiac arrhythmia in March 2000 while taking cisapride (Prepulsid) to treat digestive problems. The drug, contraindicated for patients like Young, who had bulimia, was pulled from the Canadian market in August 2000.

Her father, Terrence, says the larger database might help, but complains that Health Canada's 36-page response to the inquest addresses little else. "Health Canada gets an A for rhetoric and an F for substance," says Young. "The real question is, are we any safer? I would say No. There have been a couple of positive steps but not enough and not quickly enough."

Turner says all initiatives outlined in Health Canada's response "were already in development [before the jury issued its recommendations]. If we hadn't been thinking of it already we couldn't have responded so quickly, so comprehensively." He said the department is "seriously considering" the jury's recommendations. "We've been looking at many for a while, but many

also take extensive work to bring about."

One source for delay is the fact that many of the 17 recommendations require cooperation between government agencies and professional bodies. For example, the jury recommended that only standard Health Canada information be given to patients at pharmacies. "We can only act in partnership," says Turner.

Health Canada has also concluded that mandatory reporting of adverse events, which was recommended by the jury, is no solution. It says it has had little impact on reporting rates in countries such as France and Sweden, and in some countries has lowered the quality of reporting. Turner says it is the culture of reporting that must change so that physicians and others feel free to make reports.

Young says his greatest frustration concerns Health Canada's reluctance to take responsibility for producing warnings and other advisories, as the jury recommended. "Health Canada should just issue them, not negotiate with the drug companies over the wording." But Turner says the Dear Healthcare Professional letters that provide these warnings are the manufacturers' responsibility.

Young disagrees, and calls for an independent drug-safety network. "We don't allow the airlines to investigate their own crashes," he says. — *Barbara Sibbald, CMAJ*

Seize this chance or pay the price, McLellan warns

With Roy Romanow set to release his report on the future of medicare, federal Health Minister Anne McLellan has spent her first months in the portfolio trying mightily not to stir up any controversy that might undermine his work.

McLellan promises the usual — to "work collaboratively" with everyone from doctors to fellow health ministers to respond quickly to Romanow's recommendations. However, she also recognizes that the clock is ticking.

"We — federal, provincial, territorial health ministers — have the opportunity and a small window to do something that will be profoundly important to the quality of life of all Canadians," McLellan told *CMAJ*. "We will pay a very

huge price as politicians if we miss this window of opportunity and fail to seize this time to do the right thing."

The "right thing" will be a detailed plan to ensure sustainability. "I don't think there's a politician in this country who doesn't know that now is the time to try and renew the system. I don't think Canadians should think there's a quick fix, but rather a report with short-, medium- and long-term recommendations on sustaining the system."

McLellan has already faced some controversy. In her first days on the job she was painted as favouring privatization after suggesting that private hospitals could operate within the Canadian system. More recently, she expressed

her "discomfort" over the prescribing of marijuana and cited her concerns about the potential liability issues facing physicians who prescribe it.

However, she had her baptism of fire while serving as justice minister, when she had to deal with controversial issues such as gun registration.

She refuses to speculate about what Romanow will recommend. "This is a man who has been on the front lines making very tough decisions around the long-term sustainability of health care. He understands the political risks of doing certain things and, being from Saskatchewan, he certainly understands Canadians' attachment to medicare." — *Steven Wharry, CMAJ*