



Quebec microbiologist makes his stamp

Dr. Armand Frappier, Canada's champion disease fighter, is 1 of 5 physicians featured on Canada Post's new 68-stamp Millennium Collection. The Quebec-born physician and microbiologist, who was known as a champion disease fighter, helped to demonstrate the use of a vaccine in cases of infant leukemia and created an international laboratory devoted to the study of leprosy.

Loophole closure outrages generic drug companies

Ottawa has closed a legal loophole that it says allowed companies that make generic drugs to bypass Canada's drug-patent policy.

The Canadian Drug Manufacturers Association (CDMA), which represents the manufacturers of generic drugs, describes the retroactive move by Industry Canada as both sneaky and detrimental to consumers. Toronto-based Apotex, which had 6 applications stalled by the fall change, said the move has prompted it to withdraw \$25 million in philanthropic commitments, including \$20 million for the University of Toronto's Cellular and Molecular Biology Research Centre and \$5 million for Mount Sinai Hospital.

The changes to the Patented Medicines (Notice of Compliance) Regulations took effect in December (<http://strategis.ic.gc.ca/SSG/ip00001e.html>). They were introduced after generic manufacturer Nu-Pharm Inc. exploited the loophole to market its own version of Merck Frosst's ACE inhibitor Vasotec (enalapril maleate), even though Merck believed its patents had not expired and the issue was undergoing judicial review. The intent of the original regulations, according to an impact statement accompanying them, was to ensure that the approval process "is not being abused by generic drug applicants seeking to sell their product in Canada during the term of their competitor's patent."

The process used by Nu-Pharm to get a notice of compliance allowing it to market its Nu-Enalapril generic was "perfectly legitimate activity," said CDMA President Jim Keon. He said the company's application was not based on Vasotec but on an approved generic version, Apo-Enalapril.

Last month's amendments, which Keon says change the nature and effect of the regulations, were never debated by Parliament. The government disclosed its intentions in the *Canada Gazette* during an August long weekend, shortening the normal 30-day period for consultation to 15 days. "They did it in the sleepy days of summer when nobody's around," Keon said. The change will result in "continued high monopoly drug prices for longer periods," he added.

However, that statement would surprise US president Bill Clinton, who cited low Canadian drug prices when he announced Oct. 25 that he was launching a "sweeping" study of drug costs in the US. Clinton's proposal to have drug benefits for senior citizens and the disabled included in federal Medicare coverage has been sharply criticized by the US drug industry, which launched a multi-million-dollar advertising campaign.

"I wish they'd spend this ad money explaining why seniors have to get on the bus and go to Canada to buy drugs at less than half the price they can buy them in America," Clinton said. — *David Helwig*, London, Ont.

Yes, but did the operation make a difference?

Vancouver researchers are set to explore the effectiveness of 6 common elective operations from a patient's perspective. The Regional Evaluation of Surgical Indications and Outcomes is the "first attempt at an outcomes-management program for surgical services in Canada," says Dr. Charles Wright, a surgeon who directs the Vancouver Hospital's Centre of Clinical Epidemiology and Evaluation. "We spend a lot of time measuring deaths and survival and intermediate outcomes, but [these studies] don't speak to the final outcome for the patient, to health-related quality of life. We have never done that before."

Wright says that well-known regional variations for procedures such as cataract removal suggest that decision-making is often judgemental. "All of these elective procedures are not designed to prolong survival but to make you feel better," says Wright, who devised the project and obtained Health Canada funding. "So why not measure the quality of life?"

More than 10 000 patients are being recruited from Vancouver-area hospitals, and every surgeon performing cataract removals, total hip replacements, cholecystectomies, prostatectomies, hysterectomies and spinal disc surgery is participating. When patients are booked for surgery they receive a quality-of-life questionnaire, which they also complete at intervals following surgery. Surgeons will provide their indications for recommending surgery prior to performing the operations.

Wright says some surgeons resent being second-guessed, but many recognize that this is an idea whose time has come. "People expect [surgeons] to demonstrate results." — *Heather Kent*, Vancouver