Highly lauded drug assessment program under attack

Published at www.cmaj.ca on May 28, 2008. Print version revised.

International experts are condemning a British Columbia report's recommendation that an independent prescription drug watchdog based at the University of British Columbia be dismantled.

The 14-year-old Therapeutics Initiative "is the only source of critical assessment of new treatments in Canada that is not political or partisan," says Dr. Andrew Herxheimer, a clinical pharmacologist who helped establish the Cochrane Collaboration and spent 30 years as editor of the *Drug and Therapeutics Bulletin* in the United Kingdom.

Dr. Jerome Kassirer, former editor of the *New England Journal of Medicine*, says there "are enormous advantages to having independent people assess therapeutics. I strongly support any [such] organization that has no ties to industry." Kassirer recently publicly praised the objectivity and scientific validity of the Initiative's analysis of the cholesterol guidelines issued by the National Cholesterol Education Program (United States) in 2004.

The Report of the Pharmaceutical Task Force, made public in late May (www.health.gov.bc.ca), was written by a 9-member team, appointed by the provincial government, which included Russell Williams, the president of Rx&D, the trade association for brand name pharmaceuticals in Canada; David Hall, vice president of Angiotech Pharmaceuticals Inc.; and Dr. Mark Schonfeld, chief executive officer of the province's medical association.

The British Columbia watchdog's mandate is to provide evidence-based information about drugs to physicians and pharmacists. It operates at arm's length from the pharmaceutical industry, government and other interest groups, (*CMAJ* 2007;176[4]:429-31).

It is one of a limited number of similar bodies; others include la revue Prescrire in France and the National Prescribing Service in Australia, Herxheimer says.

Photos.com

A British Columbia task force recommended that the province's independent prescription drug evaluator be replaced.

In its report, the task force slammed the Therapeutics Initiative as "narrow, insular and resistant to meaningful stakeholder engagement" and argues that the watchdog does not meet "current and future public interest needs of the province."

However, advice from the Initiative has led to lower rates of prescribing in British Columbia of some drugs that have subsequently been shown to have significant safety concerns or been withdrawn from the market, says Dr. Ken Bassett, professor of medicine and chair of the initiative's drug assessment working group. Examples include the osteoporosis drug alendronate sodium (Fosamax), the diabetes drug rosiglitaone maleate (Avandia), donepezil (Aricept), rofecoxib (Vioxx) and valdecoxib (Bextra), he says.

The work of the Initiative has been deemed useful by 2 provincial Auditor General reports, has undergone numerous external reviews and is currently being reviewed by the University's Faculty of Medicine, said Bassett.

But the report authors state that the Initiative is "widely regarded as being in need of either substantial revitalization or replacement. The Task Force regards replacement as the better option."

Some of the task force's recommendations are "clearly an effort to increase industry influence," says Dr. Sidney Wolfe, director of the Health Research Group of the United States watchdog Public Citizen.

The report, which urges faster approval of patented drugs, says the conflict of interest guidelines which rule the Therapeutics Initiative are "so restrictive" as to exclude the participation of stakeholders and some disease specialists. (The Initiative does not work with anyone who works with industry, Bassett says.) For his part, Wolfe supported recommendations that called for more expert involvement, but only under strict conflict of interest guidelines.

The Therapeutics Initiative, an advisory body, is funded by a $1 million grant from the province. It consists of a

drug assessment working group, which analyzes clinical trial data to assess benefit and harm; a therapeutics letter working group, which writes short articles for physicians and pharmacists; an education working group which disseminates information puts on a course for doctors and pharmacists; and a pharmaco-epidemiology group which assesses drug use data and outcomes.

The task force was clearly struck to give a voice to industry's concerns, says Steve Morgan, a professor of health economics at the University of British Columbia. It represents the advice "of one sector, not of all of British Columbia."

Provincial Health Minister George Abbott, who had said he accepted the recommendations, later indicated the government will likely wait for the report from the Faculty of Medicine before making a decision and told the *Vancouver Sun* that "it's fair to say that what we'll see is a transformation or an evolution of the TI [Therapeutics Initiative] process to make it, first of all, more transparent and timely in its decisions, and more inclusive in terms of the number of qualified professionals who might be part of that process." — Ann Silversides, *CMAJ*

DOI:10.1503/cmaj.080845

Immigrant workers flood training program

Faced with a growing shortage of medical professionals, the Alberta government is spending $1.4 million over 3 years on groundbreaking programs designed to get more foreign-trained workers into the health care system.

The Bredin Centre in Edmonton provides support for foreign-trained doctors, nurses and pharmacists, for example, it brings faculty from the University of Alberta, holds peer-led study groups to prepare for licensing and accreditation exams, and provides referrals to language training programs. There is no cost to the participants.

While there are other centres across Canada that support physicians in the licensing process, "we are the only ones in Canada with specific training programs to address the gaps," says Bredin Centre Executive Director Debbie MacDonald.

The bulk of the new monies will be used to establish a similar program at Bow Valley College in Calgary, Alberta. Calgary project leader Karen Jenkins says 100 health care professionals who need Canadian licences are already registered in the fledgling Calgary program.

Grace Onah, once a physician in Nigeria, says training at the Edmonton centre has been invaluable, particularly in providing exposure to unfamiliar medical technologies.

Janardhana Reddy Bade, a pharmacist from India who recently arrived in Edmonton, says navigating the Canadian system is hard when you don't know what steps to take.

The study groups at the centre help because participants can share common experiences and help each other with difficult questions. "If I was alone it would be hard. It is about clearing doubt about the subject."

MacDonald says her clients often find it challenging.

"To them it can be a huge step back because they may not be that up on diabetes or mental health and they have to go all the way back and study."

After they obtain their licences, physician clients still need residencies and internships. This year, 200 hopefuls applied for 50 international medical residencies; Bredin clients capture 23 spots.

Shannon Haggarty with Alberta Health and Wellness says the province has added over 300 residency spaces since 2001 and hopes to add more. International spots rose from 28 to the current 50 in the same period.

A report commissioned last year suggested the province would be short some 17 000 workers by 2017 if the government doesn't take serious steps.

Haggarty says the province is working hard to avoid that. "We hope that we will be able to address those shortages before it comes to that." — Ryan Tumilty, Edmonton, Alta.

DOI:10.1503/cmaj.080838

Breast cancer rises in India

India faces a potential breast cancer epidemic over the next decade as women adopt Western lifestyles by marrying and bearing children later in life, oncology experts say.

With women nursing fewer children and weaning them earlier, altering hormone flows and putting them at higher risk of contracting breast cancer, oncologist Umberto Veronesi told delegates to an Apr. 11–12, 2008, conference held in Gurgaon (near Delhi) and sponsored by the Indian Breast Cancer Initiative and The Artemis Health Institute.

Veronesi, scientific director of the European Institute of Oncology and a pioneer in breast conservation surgery, urged the Indian government to aggressively adopt early detection strategies, including the purchase of mammography machines for hospitals and health care facilities.

Studies indicate that as India becomes Westernized, the incidence rate for breast cancer increases. A 2005 study conducted by the International Association of Cancer Research, based in Lyon, France, projected that there would be 250 000 cases of breast cancer in India by 2015, a 3% increase per year. Currently, India reports roughly 100 000 new cases annually.

There are also significant regional variations in incidence rates. The overall rate is now estimated at 80 new cases per 100 000 population per year. But in Delhi, that rate is pegged at 146 per 100 000. By contrast, the national rate was 23.5 in 1990 (*Current Science* 2001;81:465-74).

"Breast cancer is increasing in India with such a pace that we may face a serious burden of this disease in coming years," says Diptendra Sarkar, assistant professor of Surgery at the Kolkata-based Institute of Post Graduate Medical Education and Research. "Thanks to the lifestyle changes in common people and lack of a system to properly facilitate mass-awareness and an early diagnosis and treatment facility in various regions, the incidence of breast cancer is getting increased in India." — Sanjit Bagchi, Kolkata, India

DOI:10.1503/cmaj.080763