

## Highly-lauded drug assessment program under attack

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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 international 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. Minister of Health George Abbott has said he has accepted the recommendations.

The British Columbia watchdog's mandate is to provide unbiased, evidence-based information about drugs to physicians and pharmacists. It operates at arm's length from the pharmaceutical industry, government and other vested 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.

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in British Columbia of some drugs that have subsequently been shown to have significant safety concerns or been withdrawn from the market, says Dr.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 drugs rosiglitazone maleate (Avandia), donepezil (Aricept) and 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 U.S. watchdog Public Citizen.

The report, which urges faster ap-

proval 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 analyses 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."

The Health Minister, in a press release, said that implementation of the report will be guided by 6 principles, which include the best interests of the patient, a transparent process and an evidence-based review process. The minister could not be reached for further comment.

The task force had a 5-part mandate, one of which concerned the role of the Therapeutics Initiative. The other 4 were to make recommendations on how to optimize the decision making process around listing of drugs; how to optimize procurement and delivery options for drugs and medical devices; how to build positive relations between government and industry; and how to improve the effectiveness of the Common Drug Review. — Ann Silversides, *CMAJ*

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