embed it in every aspect of professional and organizational activity; indeed it is part of the ethical duty to care."

The report's authors argue that the recently established, $8-million Canadian Patient Safety Institute (CPSI) could be transformed into such an agency by being given total independence and in-house analytic capacity. But CPSI chief executive officer Philip Hassen wants no part of it. "We don't want to be a regulatory agency. That work is better done by the provinces, who have all the authority in health care, except for a few areas, such as drugs, which the federal government has responsibility."

University of Toronto Professor of Health Policy Management and Evaluation Dr. Ross Baker, co-authored the Canadian Adverse Events Study (*CMAJ* 2004;170:1678-86) that estimated 9000 to 24 000 Canadian patients die annually following an adverse event in hospital and that 7.5% of patients admitted to acute care settings experienced adverse events. Baker argues that a national patient safety agency probably isn't feasible given Canada's fractured jurisdiction over health care.

"I don't think it would be workable to have one national agency that's charged with the regulatory responsibilities. We'd fight so long about what that would look like, and who would get to sit on what bodies, that it would takes years to set up and meanwhile, we have this agenda to work on, which is improving patient safety. Let's work on that."

Federal Health Minister Tony Clement was equally lukewarm, saying the new Conservative government has other priorities that'll do more to promote safety. "The best thing we can do is to continue to pursue the Patient Wait Times Guarantee and an Electronic Health Record via Infoway. Both will enhance patient safety."

Sheps says the jurisdictional nightmare and inertia aren't reason to ignore safety concerns, particularly if the end result is erosion of public confidence. "You want to be seen to be proactive and ahead of the game. But I have no illusions it's going to be easy." — Wayne Kondro, *CMAJ*

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Federal budget focused on tax cuts, not health

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There was, to be sure, little in the way of deviation from Conservative script. But then, Prime Minister Stephen Harper made it clear from the time he began campaigning for the nation's highest office that he wanted his government to be known for tax relief, enhanced security and a sort of salt-of-the-earth accountability and predictability in which politicians unleash few surprises on unsuspecting Canadians.

From that perspective, the new minority government's first budget, delivered May 2, was a resounding success in that it ventured nary an inch from oft-repeated Conservative priorities, delivering a projected $26 billion in tax relief over 5 years, while reserving the bulk of its new spending for security measures.

It was, as Canadian Medical Association president Dr. Ruth Collins-Nakai noted, immediately apparent that it wasn't "a health-focused budget, [but rather] a tax cut budget."

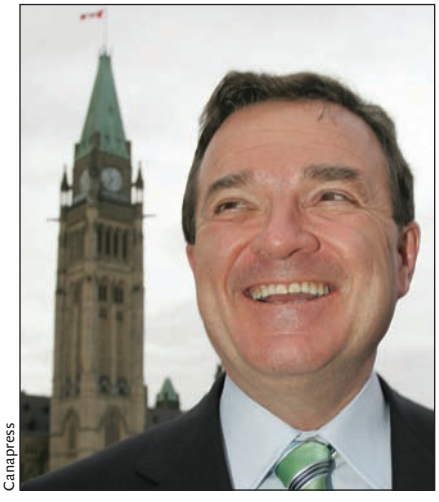
Still, Finance Minister Jim Flaherty's fiscal blueprint for 2006–07 had its health moments: new monies for pandemic preparedness, a national cancer strategy and, potentially, international AIDS and polio initiatives. But it offered nothing to alleviate the chronic shortage of health care professionals, Collins-Nakai said. "We would have liked to have seen some specific targeted money in terms of health human resources. We have a tremendous shortage here and it is patients who are going to continue to wait until we address that."

Flaherty did, however, re-affirm Conservative intentions to honour federal commitments under the September 2004 federal/provincial/territorial 10-year Plan to Strengthen Health Care; to iron out a Patient Wait Times Guarantee with the provinces; and to reopen intergovernmental negotiations to redress the so-called fiscal imbalance to help the provinces fund delivery of health care.

Although the budget offered little insight into how the imbalance will be addressed, it clearly positioned the Conservatives by asserting that health care is a strictly provincial jurisdiction. Canadian Health Care Coalition President Sharon Sholzberg-Grey lamented the stance, inquiring "Where does that leave the federal government as the guardian of comparable services and in charge of the Canada Health Act?"

Among specific health initiatives was a new $1-billion/5-year outlay for pandemic preparedness, including a $400-million contingency fund for quick responses to any potential new strain of the H5N1 influenza virus that mutates into something easily transmissible among humans. The remaining $600 million will be divvied up amongst 4 departments and agencies primarily for the purchase of additional antivirals for the national stockpile or the expansion of ongoing public health programming, like one to develop domestic manufacturing capacity to produce an influenza vaccine (through the Quebec-based firm ID Biomedical).

Flaherty also honoured a Conservative campaign commitment to provide $260 million over 5 years to implement the Canadian Strategy for Cancer Control, a multi-pronged initiative developed over the past 7 years by advocacy groups and governments to oversee a forecast future explosion in the incidence of cancer, across a spectrum of activities rang-



Canapress

The minority government budget, tabled by Finance Minister Jim Flaherty, included 26 tax measures.

ing from prevention to surveillance, screening and palliative care.

"It's a comprehensive approach to managing cancer in Canada," said Canadian Cancer Society Public Issues Manager M. Michelle McLean. "When the first iterations of the plan were developed years ago, several other countries took our plan and implemented it before we were able to and they've seen great success. In the United Kingdom, they've seen a 10% drop in cancer rates since implementing the strategy. We know this plan will have substantial impact in Canada."

McLean and other public health advocates were also effusive about the new government's willingness to revisit so-called "sin taxes" to achieve health objectives, particularly its plan to hike cigarettes levies by $16.41 per carton starting July 1 to help offset revenues lost as a result of the 1% reduction in the federal Goods & Services Tax.

Other health measures included:

- a $500 tax credit to cover registration fees associated with children's participation in sports;
- expanded tax breaks for persons with disabilities, including increasing the maximum of the refundable medical expense supplement to $1000 from $767 and several measures to extend benefits under the Child Disability Benefit;
- an additional $450 million over 3 years for Aboriginal programs, an unspecified portion of which will go to health, including the provision of safe drinking water; and
- as much as $320 million for international health programs, including up to $250 million to the Global Fund to Fight AIDS, Tuberculosis and Malaria; and $45 million to support the Global Polio Eradication Initiative, providing the federal budget surplus tops $2 billion at the end of the current fiscal year.

Among the 26 tax measures were ones that will reduce the tax burden for physicians who are incorporated as small businesses and who earn their income through dividends. Potentially, their tax rates could be reduced as much as 4 percentage points. — Wayne Kondro, *CMAJ*

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Accutane registry compulsory in US, but not Canada

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The United States has ramped up efforts to mitigate the risk of birth defects associated with isotretinoin (Accutane) by requiring physicians and patients to register before they can prescribe or take the drug. The response in Canada has been markedly less stringent, despite recommendations last year from a federal government expert advisory committee.

Isotretinoin, used to treat recalcitrant nodular acne, is known to have serious side effects, including birth defects, severe depression and, potentially, vascular incidents.

On Mar. 1, the US Food and Drug Administration (FDA) made iPLEDGE, its risk management program aimed at preventing use of the drug during pregnancy, compulsory (www.ipledgeprogam.com). To obtain the drug, patients must register with iPLEDGE, complete an informed consent form and obtain counseling about the risks. Women of childbearing age must take 2 pregnancy tests and be on 2 forms of birth control or abstain from sex. Physicians must also register with iPLEDGE prior to prescribing isotretinoin.

The FDA made the changes following recommendations from 2 of its advisory committee in 2000 and again in 2004. "Fetal exposures continued to occur, and the risk [of pregnancy] had not been adequately mitigated," says Dr. Jill Lindstrom, acting deputy director, Division of Dermatologic and Dental Products Centre for Drug Evaluation and Research of the FDA.

Between 1982, when the drug first came on the US market, and 2000, its manufacturer Roche Pharmaceuticals reported 1995 pregnancy exposures and 383 live births. Of those births, 162 infants had birth defects. Between 2001 and 2003, there were 325 known pregnancy exposures. The FDA estimates that 100 000 prescriptions are written for the drug each month in the US.

In Canada, an estimated 224 600 prescriptions for isotretinoin were filled in the past year, according to IMS Health (retail value of $32 million). The manufacturer reports an average of 3.6 pregnancy exposures per year between 1996 and 2003. Between January 1983 and December 2004, Health Canada identified only 3 "fetal disorders" as "possibly due to Accutane exposure."

Roche Pharmaceuticals

This image appears on the Roche Pharmaceuticals patient information for Accutane.

Health Canada recently stated that although FDA information suggests a "signficant rate" of pregnancy exposures "Health Canada's pharmacovigilance program... has shown no evidence of a comparable situation in Canada." (*CMAJ* 2005;172:15).

However, the Motherisk Program at the Toronto Hospital for Sick Children receives an average of 10 to 20 pregnancy exposure reports annually.

Not all cases are reported, says Motherisk Director Dr. Gideon Koren, because Health Canada doesn't have a comprehensive monitoring system. Health Canada discontinued the development of Mothernet, which would have captured such cases, several years ago.

"Unfortunately pregnant women are not a priority for Health Canada," says Koren.

Health Canada requires that women taking isotretinoin give written informed consent, receive education about the teratogenicity of the drug, and agree to use 2 contraceptive methods while on the drug. Similar measures in the US were ruled by the FDA to be insufficient to protect fetuses.