

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*

Accutane registry compulsory in US, but not Canada

Published at www.cmaj.ca on May 17, 2006.

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.

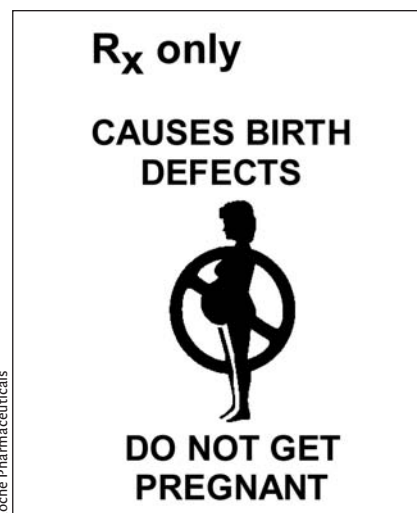
Isotretinoin, used to treat recalcitrant nodular acne, is known to have serious side effects, including birth defects, severe depression and, potentially, vascular incidents.

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.ipleadge-program.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 committees 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



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

(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.”

Health Canada recently stated that although FDA information suggests a “significant 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 Mothenet, 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.

News @ a glance

Rather than an iPLEDGE-type registry, Motherisk suggests a mandatory Web-based training program and certification of physicians as a condition for prescribing isotretinoin. A similar program exists for methadone.

In May 2005, Health Canada's Scientific Advisory Panel on isotretinoin unanimously rejecting the idea of an i-LEDGE type registry for Canada, but otherwise its recommendations were strikingly similar to those measures being taken in the US, including introducing an expanded physicians' checklist, a consent form, a toll-free information number, a Web site, an education program for family doctors and pharmacists, and pregnancy testing.

Dr. Jack Toole, chair of the panel says "There is absolutely no question that pregnancy exposure on isotretinoin must be prevented and that we must do all that we possibly can to do that."

The panel's recommendations have not been acted on. Health Canada spokesperson, Christopher Williams, says the government expects to convene a working group by September to "analyze the best way of putting them into effect. However, it is unlikely that any implementation will take place in 2006."

In April, Health Canada released another advisory about the drug, asking doctors to report any cases of myocardial infarction, cerebrovascular and thromboembolic disorders suspected of being associated with isotretinoin (*CMAJ* 2006;174:1211). Since 1983 there have been 29 reported incidents of vascular disorders. Williams said that "no causal link between this type of side effect and the drug has been established."

The drug ranks in the top 10 of the US FDA's database of drugs associated with reports of depression and suicide attempts. In Canada, 25% of adverse responses reported since isotretinoin was introduced relate to psychiatric events. A warning of the possible link was issued in 2001.

Although it is intended as a drug of last resort for extreme cases of acne, isotretinoin is increasingly being used for milder cases, as well as for psoriasis, rosacea and other conditions. — Margot Andresen, Gatineau, Quebec

US abortion bans: South Dakota banned abortion in February, and 11 other states are poised to consider similar action. "People are afraid here," Dr. Marivin Buehner told the *St. Louis Post-Dispatch*. Buehner's Rapid City office was picketed after he spoke on TV against the ban. "The whole environment of intimidation that is the legacy of the anti-abortion movement has a stronghold here in South Dakota. That's how the ban got through the Legislature without a challenge from the South Dakota Medical Association." The law is slated to come into effect July 1, but Planned Parenthood has vowed to block it through a federal lawsuit. Opponents of the law are also collecting signatures calling for a plebiscite on the ban in November. Similar laws are being considered by governments in Alabama, Georgia, Indiana, Kentucky, Ohio, Mississippi, Missouri, Rhode Island, South Carolina, Tennessee and West Virginia. In related news, the Guttmacher Institute, a not-for-profit corporation for reproductive research, policy analysis and public education, reports that 33 states have made it more difficult or more expensive for poor women and teenagers to obtain contraceptives and related medical services.

Michener finalist: *CMAJ* was short-listed for the Michener Award for Meritorious Public Service in Journalism for its article on barriers to accessing Plan B (*CMAJ* 2005;173:1435-6). The 6 finalists for the award included the *Globe and Mail*, which won for 2 series of articles about breast cancer. The *CMAJ* article, by Laura Eggertson and Barbara Sibbald, informed women about their right to obtain this emergency contraceptive without giving their names and addresses and other personal information to pharmacists, alerted privacy commissioners to this unnecessary practice and, in the end, lowered barriers to access for women in Ontario and, quite likely, in BC and Saskatchewan as well. Ontario Privacy Commissioner Ann Cavoukian said "I applaud you for raising this issue. I can't thank you enough, because it wouldn't have come under anyone's radar screen if you hadn't done this." This is the second year that



Cpl. Issa Paré, Rideau Hall

Governor General Michaëlle Jean (right) presents Barbara Sibbald, *CMAJ* Associate Editor, News, with the journal's Michener Citation of Merit (see news item below).

CMAJ's news department has been short-listed for the award, Canada's highest honour for journalism.

Free Nepali MDs: Physicians for Global Survival (Canada) is urging physicians to sign a petition calling for the freeing of 7 Nepali physicians. The physicians, including Mahesh Masky, the vice president of International Physicians for the Prevention of Nuclear War, were arrested Apr. 8 after peacefully protesting against the Nepali regime and defying the imposed curfew. On Apr. 10, 20 medical students were also arrested; 2 were held at least 48 hours and beaten while in police custody. Health professionals have also been threatened for treating people injured during protests. Article 9 of the Universal Declaration of Human Rights, which Nepal is party to, strictly prohibits the arbitrary arrest and prolonged detention without charge of all persons. Amnesty International, Human Rights Watch and the International Commission of Jurists have called for sanctions against the current regime's violation of human rights. Canadian physician Dr. Neil Arya and Dr. Sonal Singh started the online petition calling for the release of the physicians. — Compiled by Barbara Sibbald, *CMAJ*