For the record

Conservatives unveil new product safety regime

Progressive licensing for pharmaceuticals and biologics, as well as mandatory reporting of adverse drug reactions by health care institutions, highlight omnibus consumer protection legislation introduced by the minority federal Conservative government Apr. 7, 2008.

The new drug assessment regime is based on evaluation of pharmaceuticals and biologics over the course of what's called their "full life-cycle," using a more flexible form of risk-benefit analysis, rather than having their safety and efficacy strictly determined during pre-market assessment. It lowers the threshold for initial market authorization licenses in exchange for additional safety and efficacy studies as a condition for continuing to sell a drug. The government argues that such a system is needed to allow breakthrough, small population, early access or compassionate use drugs to more readily enter the market. But skeptics like Dr. Jim Wright, managing director of the University of British Columbia's Therapeutics Initiative, and Dr. Mary Wiktorowicz, chair of York University's School of Health Policy and Management, have said that the safety bar is being lowered (*CMAJ* 2007:176[9]: 1261-2). A recent study indicated that more rapidly approved drugs are more likely to be recalled or to have subsequent safety problems (*NEJM* 2008; 358[13]:1354-61).

Prime Minister Stephen Harper and Health Minister Tony Clement cast the legislation — Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts* — as a warning against corporate greed. Clement said the government is "cracking down on irresponsible corporate behaviour," while Harper said negligent firms "cut corners and play fast and loose with safety. To these outfits I say: Be warned. You will soon face severe punishment if you wilfully expose Canadians to danger."

Fines for manufacturing or distributing unsafe drugs will rise to as much as $5 million, from a current level of $5000 to $250 000, under C-51, which amends 17 existing pieces of federal legislation. Miscreants could also be jailed 6 months to 5 years, depending upon the severity of the crime.

The legislation will also impose mandatory adverse drug reaction reporting by hospitals and other prescribed health care institutions. The government will establish "a public register in which is to be kept the prescribed information about therapeutic products."

Drug manufacturers will also be required to disclose adverse drug reactions to regulatory authorities.

In addition, the government will also extend its authority to recall unsafe products beyond foods to include any therapeutic, cosmetic or consumer product deemed to present "a serious or imminent risk of injury to health." — Wayne Kondro, *CMAJ*

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United Kingdom updates ethics guidance

The United Kingdom General Medical Council has issued supplementary guidelines for doctors on proper behaviour when patient care conflicts with their religious or personal beliefs.

The new "Personal Beliefs and Medical Practice" guidance is predicated on the proposition that "doctors must not allow their personal beliefs to compromise patient care." It warns that persistent failure to follow the guidance will put registration at risk.

Among specifics is recommended behaviour in cases where a doctor is asked to perform a procedure to which he or she has a conscientious objection, such as abortion or the circumcision of male children for religious or cultural reasons.

In such instances, the doctor must inform the patient of their right to see another doctor and if necessary "ensure that arrangements are made, without delay, for another doctor to take over their care. You must not obstruct patients from accessing services or leave them with nowhere to turn."

As well, a doctor has no legal or ethical right whatsoever to refuse to provide a patient care prior to, or after, the surgical procedure.

Among other specifics:

- Doctors who oppose cremation cannot refuse to sign the cremation form.
- A female Muslim doctor must be prepared to remove her face veil if it "presents an obstacle to effective communication and the development of trust."
- Doctors who have a Jehovah's Witness patient who refuses blood products should contact the local hospital liaison committees established by the governing body of the religious group, the Watch Tower Society, for "advice on current Society policy regarding the acceptability or otherwise of particular blood products. They also keep details of hospitals and doctors who are experienced in 'bloodless' medical procedures." — Wayne Kondro, *CMAJ*

News @ a glance

Needle therapy: British Columbia has become the first province to include acupuncture as a supplementary benefit under its health insurance plan. Residents earning less than $28 000 per year will be reimbursed $23 for each visit (maximum 10) to an acupuncturist. Acupuncture is recognized worldwide as "safe and effective," said Health Minister George Abbott.

HIV trends: A government of Manitoba report indicates HIV infection is spreading more rapidly in heterosexual First Nations populations than other groups (www.gov.mb.ca). The update on HIV 1985–2007 indicates 24%, or 20 of 82 newly diagnosed cases of HIV in 2007, self-reported their ethnicity as Aboriginal. Of those, 14 self-reported their risk factor as heterosexual activity. — Wayne Kondro, *CMAJ*

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