Stalled US plan for Plan B

Levonorgestrel (Plan B) is available without a prescription in Canada and at least 38 other countries, but not in the US. There, improving access is a highly divisive issue that has led to the resignation of the Food and Drug Administration (FDA) director of women's health and an investigation by the Government Accountability Office (GAO) following allegations of political interference by the Bush Administration.

When Barr Labs first applied for over-the-counter status in April 2003, women's health advocates claimed improved access would reduce the number of unintended pregnancies, while conservative religious groups argued that the drug could lead to an early abortion. Leading Republican members of Congress urged the FDA to reject Plan B for over the counter status.

In the eye of the storm, the FDA focused on scientific evidence recalls Susan Wood, the former director of the agency's Office of Women's Health who resigned over the delays. Studies showed that the pill was extremely safe, and its availability would not lead to an increase in unprotected sex. Two FDA panels of experts voted overwhelmingly in favour of over-the-counter status in December 2003.

But in May 2004 — an election year — the FDA turned Barr down, citing concerns that teenage women would use the pill incorrectly (despite scientific evidence to the contrary).

Members of Congress who suspected political interference asked the federal GAO to investigate. Its Nov. 14, 2005 report stated that the process was "unusual" and that the decision may have been made months before the scientific reviews were completed. It noted that it was "unprecedented" for the FDA to go against the recommendations of its advisory committee.

In addition, 3 high level officials declined to sign the letter that refused approval. The letter was sent anyway. "This action removed decision-making authority from the directors of the reviewing offices who would normally make the decision," stated the GAO.

Barr Labs reapplied in July 2004, this time asking that Plan B be available over the counter only to women over age 16; the FDA failed to issue a decision by its deadline of January 2005. Democrats Hillary Clinton and Patty Murray delivered a 10 000-name petition and pressured the agency to make a decision by Sept. 1, 2005. Instead, the FDA announced in late August that it would solicit "public comment" before settling the issue.

This sparked demonstrations in New York and Washington, DC, and led Wood to resign after nearly 5 years at the agency. The comment period ended Nov. 1. FDA spokesperson Crystal Rice says the agency is reviewing more than 46 000 comments and has no timeline for delivering a decision.

Two members of Congress introduced a bill on Nov. 3 that would force the agency to issue a decision on the drug's over-the-counter status within 30 days. That Bill has gone to committee for review. Its coauthor, Republican Christopher Shays says "The FDA has let ideology and politics get in the way of science.... Our legislation — if passed — will force them to act once and for all, or break the law."

In its Nov. 14 report, the GAO urges Health and Human Services Secretary Mike Leavitt, who oversees the FDA, to intervene to assure that an upcoming decision about the pill's status "is based on the best available science instead of ideology." — Miriam Shuchman, Toronto

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National Organization for Women

The National Organization for Women held a National Day of Action on Aug. 30 to protest the FDA's repeated refusal to approve emergency contraception for over-the-counter use.

Saskatchewan MDs oppose new mandatory testing law

The Saskatchewan Medical Association is opposing a new provincial law that could force non-consensual blood tests for HIV/AIDS and other infectious diseases.

The Mandatory Testing and Exposure (Bodily Substances) Act, which took effect Oct. 17, allows a judge to order a test at the request of a police officer, paramedic, Good Samaritan, victim, or anyone else who believes they've been exposed to body fluids while providing emergency medical care or during a crime. The Act would only cover cases where someone refuses to get tested voluntarily.

The law, modelled on legislation drafted by the Uniform Law Conference of Canada, is the first in Canada to give a judge the authority to order a test, says Justice Minister Frank Quennell.

As part of the legislation, physicians are required to provide the court with an assessment of the level of risk the exposure created.

"This legislation is seriously flawed

in a couple of respects," says Dr. Anne Doig, chair of the SMA's legislative committee. "We're concerned that our names, our reputations and our professional judgment are being used to lend credibility to a process that in itself isn't credible."

It is almost impossible to assess the risk exposure poses without key information about the person who may pose the risk, says Doig.

Firefighters, police officers and paramedics requested the law, says Quennell, who described the Saskatchewan medical community as "split."

"Give the split within the medical community, we prefer to [give the benefit of the] doubt to the victims of crime and emergency service providers that request this protection," Quennell told *CMAJ*.

Dr. Keith Ogle, who teaches medical ethics at the University of Saskatchewan College of Medicine, says he would refuse to complete the assessment form.

"I'm not sure a lot of doctors would want to sign that form recognizing that, as a result of that act, somebody will be tested against their will. It tends to place a physician in a position in which they are almost an accomplice to a coercive act."

Ogle is also concerned the tests will give the applicant a false sense of security, since diseases such as HIV have a period of incubation before showing positive.

Arthur Schafer, a medical ethicist and the director of the University of Manitoba's Centre for Professional and Applied Ethics, says the law invades people's civil liberties.

"Canadian courts have ruled that no one can 'intermeddle' with the body of an adult against their wishes. You need a very good reason to violate that principle," he says.

If a physician refuses to complete the form for the court, an applicant could simply go to another physician, says Quennell.

"I think the circumstances in which a doctor's medical report would result in the court making this order would be relatively rare," the minister says. "I also think the existence of this Act will make voluntary testing more likely." — Amy Jo Ehman, Saskatoon

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News @ a glance

Pandemic plan: US President George Bush unveiled a US$7.1-billion pandemic influenza plan in November that will increase manufacturing capacity for vaccines and commit US$800 million to develop new vaccines, drugs and diagnostic tests, if Congress approves it. Almost $3 billion worth of the funding is intended to accelerate the development of vaccines in cell cultures, instead of the current technology that uses chicken eggs to grow vaccines. The plan also calls for the purchase of US $1.2-billion worth of vaccine against H5N1 bird flu, even though scientists are not sure that strain will eventually mutate into a pandemic strain. The US would vaccinate "essential personnel" against H5N1, in hopes it would give them some immunity. Currently, the US has only one plant manufacturing influenza vaccine.

Art Explosion

Measles in Africa: The number of measles cases and deaths in Africa has dropped 60% since 1999 thanks to improvements in routine and supplementary immunization, says the World Health Organization. African governments and the Measles Initiative partners, including the UN Foundation and American Red Cross, collaborated on the project to vaccinate more than 200 million children. One million lives have been saved since 1999. "This is a major public health achievement," says WHO Director-General, Dr. Lee Jong-Wook. Since 2001, the Measles Initiative has spent $144 million in 40 African countries. The Measles Initiative plans to expand its vaccination campaign into Asia, where 180 000 people die of measles annually. In 2003, 500 000 people — 470 000 of them under age 5 — died from measles. Half of these deaths were in Africa. It costs less than US$1 to vaccinate a child.

Connected youths: Teenagers age 12 to 15 with positive family, school, friend and community ties are healthier and have a higher sense of self-worth, according to report from the Canadian Institute for Health Information's Canadian Population Health Initiative. *Improving the Health of Young Canadians, 2005* explores the association among 5 positive "assets": parental nurturing, parental monitoring, school engagement, volunteering and connection with peers. Teenagers who report having 4 or 5 of these "assets" were more likely (83%) to have good health than those with 2–3 (74%) or less (54%). — Kristen Everson, Ottawa

Tobacco treaty: Over 105 countries have now signed the WHO Framework Convention on Tobacco Control. The global treaty was developed in 2003 to curb current and future tobacco-related deaths. Tobacco kills almost 5 million people a year. Without a change in current smoking trends WHO estimates that by 2030 the tobacco consumption will kill double that number. Signatories to the treaty agree to impose limits on tobacco advertising, sponsorship and promotion, to establish new packaging and labelling of tobacco products and to institute indoor smoking bans. They will also clamp down on tobacco smuggling. — Sally Murray, *CMAJ*

Stock shock: Executives with Guidant Corporation, currently the subject of class-action lawsuits in Canada and the US over its implantable cardiac defibrillators and pacemakers, sold more than US$100 million in company stock recently, the *Indianapolis Business Journal* reports. The executives sold their shares in advance of a deal to sell the company to Johnson & Johnson, an agreement that could unravel given the number of class-action suits pending against Guidant. — Compiled by Barbara Sibbald, *CMAJ*

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