Therapeutics explains, there is little incentive for the pharmaceutical industry to study the naturally occurring cannabinoids found in smoked marijuana, like that produced by the government at an underground mine in Flin Flon, Man. and distributed to patients with physician approval, because they cannot patent it. Instead, the industry seeks cannabinoid-like molecules that can be protected against competition, or, like Cannasat, focuses on new delivery systems — patches or inhalers — for naturally occurring cannabinoids that avoid the hyperpsychoactive effects associated with oral sprays or pills. (Cannasat is at least 4 years away from having such a product.)

Marijuana seeds and plants produced by Prairie Plant Systems (Cannasat is a PPS shareholder) have been distributed since 2003. A week after the MMRP cut, the government allocated $2.2 million to extend PPS's contract for 1 year. Waddell says there are no plans to close the grow-op.

As of September, 1492 people were authorized, with the support of 917 physicians, to possess PPS marijuana for medical purposes. That approvals come with limited peer reviewed data is reinforced by Health Canada's *Information for health care professionals (revised) — marihuana (marijuana, cannabis)*, which states: "While there are many anecdotal reports of the therapeutic value of smoked marihuana, scientific studies supporting the safety and efficacy of marihuana for therapeutic claims are inconclusive."

Despite this, Waddell insists that: "We believe that even with the cut to the medical marijuana research program there is sufficient evidence and support out there to continue the program of distributing medical marijuana."

The Canadian AIDS Society (CAS) disagrees, saying the lack of understanding of risk and benefits, dose requirements or counterindications with prescription drugs leaves physicians and patients in a quandary.

They are calling for the re-establishment of a Stakeholder Advisory Committee on active new substances that was disbanded last year and originally recommended MMRP be established.

While there is no plan to close the grow-op, CAS and others argue that without more data, doctors will remain reluctant to participate. Patients, in turn, won't get legal access, and the grow-op could be indirectly choked.

"We feel it is an important public health issue that needs to be addressed and the government should be involved in facilitating the research so that Canadians can make a more informed decision about their health care," says CAS executive-director Monique Doolittle-Romas.

Waddell said there are no plans to re-establish an advisory committee, but that if doctors feel strongly more research is needed, "then they should speak to Health Canada; we'd certainly listen to what they have to say." — Pauline Comeau, Ottawa

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Supreme Court rules against drug patent "evergreening"

It has become almost axiomatic in the pharmaceutical world that litigation has replaced innovation as the primary mode of operation, says the head of the Canadian Generic Pharmaceutical Association.

The Supreme Court of Canada tossed another salvo into that litiginous world Oct. 3 by ruling that the controversial practice of evergreening — which allowed brand-name pharmaceutical firms to obtain an automatic 2-year extension on the term of patent protection by filing new patents of an altogether marginal nature, such as the shape, dosing range or colour of a pill, and then claiming infringement on its original patent — should not have been allowed under Health Canada's old drug regulatory regime.

This latest decision overturned a lower-court ruling to quash Apotex Inc.'s notice of compliance to market a knock-off of the AstraZeneca proton-pump inhibitor, omeprazole, which was sold in Canada from 1989 to 1996. The drug was removed from the market and its patent expired in 1999 but AstraZeneca used the regulatory system to successfully trigger a series of successive 24-month "stays" to prevent Health Canada approval of a lower-cost generic equivalent.

In his October decision, Mr. Justice Ian Binnie wrote that "Given the evident (and entirely understandable) commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired, the decision of the Federal Court of Appeal would reward evergreening even if the generic manufacturer (and thus the public) does not thereby derive any benefit from the subsequently listed patents."

Digital Stock

Given that the government of Canada moved a month before the ruling with new regulations to limit evergreening to instances in which there is proof of actual infringement of the original patent, the decision was somewhat of a pyrrhic victory for the generic industry.

Nevertheless, Canadian Generic Pharmaceutical Association president Jim Keon was "very pleased. We've felt all along that these evergreening practices were problematic and costly for consumers."

Keon also argued consumers will bear the financial brunt of the Oct. 5 amendments to the Food and Drug Regulations to extend data protection on brand-name drugs from 5 to 8.5 years (including 6 months pediatric exclusivity), as well as eliminate the ability of generic firms to make damage claims for profits made by a brand-name company while it's using evergreening to delay competition.

If a generic product is now held off the market because of a protracted legal dispute, its' maker can now only seek redress for its own lost profits, Keon lamented. "Any disincentive is now gone. If I were the CEO of a brand name

company, I'd be telling my legal people, let's see how many patents we can get, how many various aspects we can patent and then list every one of those and litigate to the maximum. If successful, fantastic. We get the extra profits. If the court later on finds against us, we'll pay a small fine for that because there's no other downside."

Canada's Research-Based Pharmaceutical Companies (Rx&D) spokesman Francois Lessard says they have no comment to make on the decision other than that it "is commercial in nature and applies to a single product. The association doesn't have a commercial mandate." — Wayne Kondro, *CMAJ*

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US relaxes rules for Rx shopping sprees to Canada

Canada can expect even more raids on its national medicine cabinet following 2 significant changes to US prescription drug policy.

US residents are now allowed to return from Canada with a 3-month supply of a prescription medicine and can to receive mail-order drugs from Canada without fear of retribution. The changes, approved shortly before the Nov. 7 Congressional election, were viewed as a means of currying favour with one of the nation's largest voting blocks: senior citizens, who've long appealed for the right to buy Canadian prescription drugs. Prices north of the 49th parallel are typically 40% to 70% cheaper because of Canadian controls on the prices through the Patented Medicine Prices Review Board.

The cost of relaxing US rules may fall heavily on Canadians though, warns the Ontario Pharmacists' Association (OPA), which predicts an American buying spree could spawn shortages and leave Canadians unable to fill their own prescriptions. Retaliatory tactics from the US pharmaceutical industry, such as tightening the overall drug supply to the Canadian market and keeping new expensive drugs in the US, are also feared.

The OPA is calling on federal Health Minister Tony Clement to immediately ban all sales of prescriptions to US patients in order to head-off a "public health and safety threat for Canadians."

"Our job is to provide medications and expertise to Canadian patients, not provide solutions for the shortcomings of the US health care system and its problem with high drug costs," CEO Marc Kealey says

But Clement isn't alarmed. "The changes aren't expected to negatively affect the Canadian drug supply," says Erik Waddell, Clement's press secretary. "The trend has been a decrease in cross-border sales. If something should arise, the Minister of Health is ready and willing to act, but at this point there's no risk to the health and safety of Canadians."

The Canadian Pharmacists' Association Executive Director Jeff Poston says the recent 35%–40% decrease in cross-border prescription drug sales could reverse itself at any time. The drop has been attributed to a stronger Canadian dollar, increased Customs seizures and a revised US government health insurance plan that gave seniors more prescription options.

Parliamentary reaction to the US measures included the tabling of a private member's bill on Oct. 31 by Liberal MP Dr. Carolyn Bennett. She is calling for the Food and Drugs Act to be ammended so that the Minister of Health will have the authority to ban bulk drug exports. "Canada needs to protect itself," says Bennett. "The prospect of the US legalizing large-scale purchases from our domestic supplies is real."

The prescription drug re-importation provision allows Americans to purchase drugs in Canada and personally transport them across the border as long as the prescriptions are FDA-approved and the supply doesn't exceed 90 days. Controlled substances, such as narcotic painkillers and some biological products are excluded. Democrats estimate the move could save seniors $360 million over the next decade.

In a related move, US Customs and Border Protection officials announced that prescription drugs sent by mail to US residents from Canadian pharmacies will no longer be subject to seizure. Custom agents had confiscated over 40 000 packages of mail-order drugs over the past year. More than 2 million American seniors shop at Canadian Internet pharmacies. — Patricia Guthrie, Atlanta, Georgia

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Canapress

Americans can now order less expensive Canadian drugs online without fear of retribution.