## Cut to marijuana research sends strong message

The federal government's decision to cancel the Medical Marijuana Research Program (MMRP) sends a strong message that clinical research into the risks and benefits of herbal cannabis — the kind distributed by Ottawa under Supreme Court order — is not a priority.

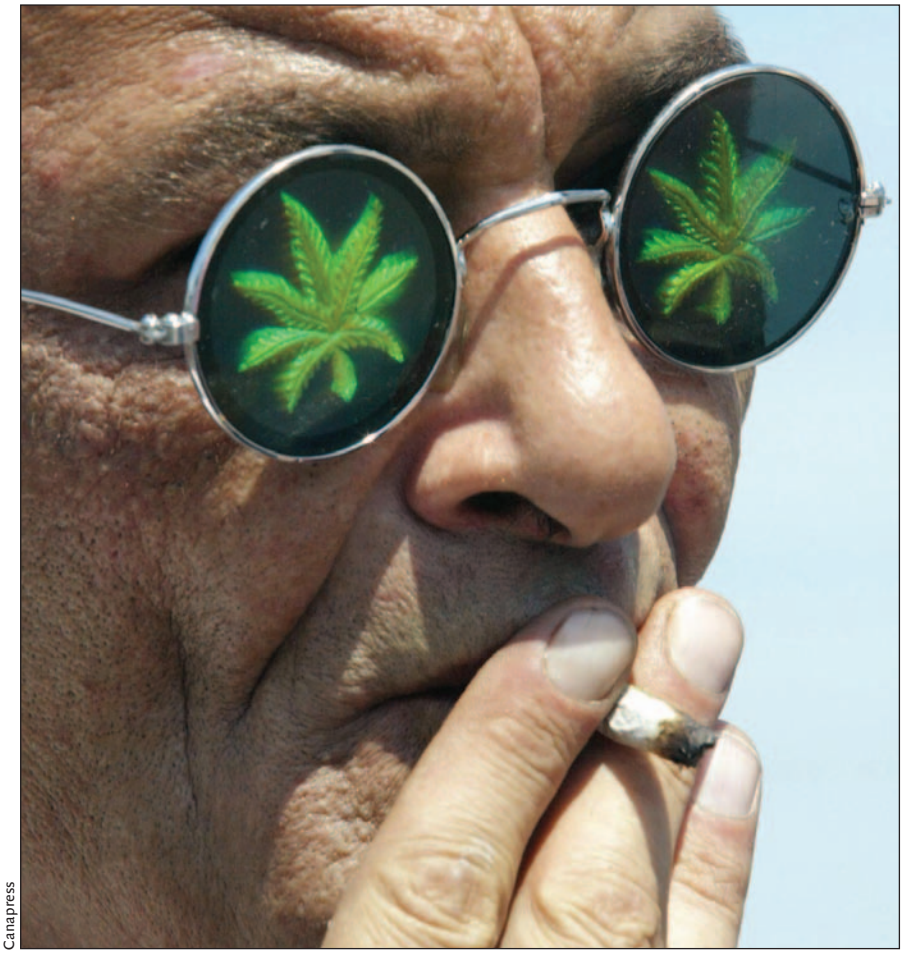
The discontinuation also signals Canada is no longer interested in being a leader in cannabinoid research despite its unique position as the only country with a federally controlled marijuana grow-op to supply registered users.

The federal government has "suddenly taken away the research, or the possibility to do additional research, to inform not only the physicians but patients about safety and efficacy," says Dr. Mark Ware, the sole researcher to receive MMRP funding.

The research cuts also mean policymakers won't have adequate safety and efficacy data, he adds. "They're making laws and regulations around a drug which there is limited data on ... which I think is a very awkward situation to be in," says Ware, from McGill's University Health Centre.

Ware received $262 000 for a 1-year pilot efficacy study launched in 2001 on smoked cannabis for chronic neuropathic pain in 32 subjects. The study didn't begin until 2003, a delay that Ware says was caused largely by licensing requirements and other obstacles related to working with a controlled substance. Results will be published in a few months.

The second grant, worth $1.8 million, was awarded in 2003 for a Cannabis for the Management of Pain: Assessment of Safety Study (COMPASS), which involved comparing 350 medicinal marijuana users to a number of nonusers suffering chronic pain. It began in January 2005 and is ongoing. Physician reluctance to participate without safety data was part of the delay, says Ware.



Canapress

The government offers to sell its medicinal marijuana to the 1492 authorized users in Canada, including Don Appleby (above), but it has stopping funding research into marijuana's efficacy and safety.

The federal government announced in late September that it would not spend the $4 million remaining in the 5-year MMRP, which was launched in 2001 with a $7.5-million budget.

Marijuana researchers can seek funding from the Canadian Institutes for Health Research, but their success rate has historically been low, says Ware.

"The medical research community can decide what its own priorities are," says Erik Waddell, spokesman for Health Minister Tony Clement, repeating the message made by the minister of finance when the cut was announced. And MMRP was eliminated, Waddell says, after an evaluation showed that the monies allocated "weren't producing any results that were beneficial to Canadian taxpayers." Waddell repeatedly noted that only one researcher (Ware) was funded and no results produced.

Waddell also agreed with Health Canada officials who, when asked about the federal government's role in this field, stated: "...clinical research regarding the use of marijuana for therapeutic purposes and the development of marijuana-based products is best undertaken and funded by the pharmaceutical industry."

But, as Umar Syed, vice-president, scientific and strategic affairs for Cannasat

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