AUTHORIZING MEDICAL MARIHUANA in Canada's Regulatory Policy Framework

BY DR. HENRY J. MOLLER, BSC(HONS), MD, MSC, MPP, FRCP(C), DR. RYAN YERMUS, BSC, MD, CCFP, DR. GWYLLYN S. GODDARD, BSC, MD, CCFP

We have followed with some interest recent discussion in the CMAJ regarding the status of marihuana authorizations by physicians within the Canadian healthcare system. [1,2,3,4,5] As Canadian doctors are becoming aware, medical marihuana is currently regulated by Health Canada under the Marihuana for Medical Purposes Regulations (MMPR). This program was created in order to provide patients with reasonable access to medical cannabis while also protecting the public. [6] Being attuned to MMPR-related provincial and federal regulatory changes, we offer a fact-based policy analysis, using Ontario as a case study for practice parameters that physicians involved in this area of practice within any Canadian jurisdiction may wish to take note of.

Whether warranted or not, Health Canada has placed Canadian physicians in the position of gatekeepers for patients' legal access to medicinal cannabis. Medicinal marihuana is not permitted to be sold in pharmacies; it is ordered directly by patients after a doctor authorizes them with a "medical document", which allows the herbal product to be sold and delivered directly to either the patient or to a hospital or patient's physician (to be dispensed to a patient) via secure courier commissioned by the cannabis Licensed Producer of the patient's choice. [7]

Throughout the MMPR, Health Canada refers to the formal written approval of medical marihuana by a physician as "authorization" or as "providing a medical document." Nowhere in the MMPR does Health Canada refer to this action as a "prescription".[7] The reason for this may lie in the fact that Health Canada's policy maintains that "cannabis is not an approved therapeutic product."[8]

The College of Physicians and Surgeons of Ontario (CPSO) has recently released to the public an initial draft of their proposed policy on medical marihuana. In this draft, the college proposes: "the medical document required under the MMPR is equivalent to a prescription." [9] While it may be more convenient to equate the authorization of medical marihuana with a "prescription", this ignores the distinction that has been intentionally made by Health Canada in the MMPR. It also contradicts the CPSO policy on Prescribing Drugs, which states that doctors should only prescribe drugs, which have been approved by Health Canada.[10]

In what may be an effort to fit a square peg into a round hole, some of the provincial colleges essentially suggest reverse-engineering the definition of what a prescription is to allow for the singling out of medical marihuana as the one unapproved product that can be prescribed. For example, the CPSO has proposed that "a minor housekeeping amendment to the Prescribing Drugs policy will be required to ensure it does not conflict with the draft marihuana for Medical Purposes policy. The amendment would involve adding a footnote to the Prescribing Drugs policy content that prohibits prescribing unapproved drugs to clarify that there is an exception for dried marihuana."[11] It is curious that a provincial college would term a change to the actual definition of a prescription as a "minor housekeeping amendment" despite the realities that Health Canada has not approved medical marihuana, that it does not carry a drug identification number (DIN) and that its effectiveness and safety profiles have not been scientifically determined.

In its own policy response to the MMPR, the Ontario Medical Association (OMA), similarly to recent authors in the CMAJ [1,2,3] has expressed concern over physicians being placed in the role of gate-keeping an unauthorized product. In a report earlier this year, concern was raised over the fact that "the physician is being asked to provide the patient with a legal exception to possess an otherwise prohibited, untested drug."[12] An approach more respectful of the federal governance of this program may be the one crafted by the Canadian Medical Protective Association (CMPA), which cautions: "while it is widely stated that physicians issue "prescriptions" for marihuana, the medical document issued by physicians is distinct from a prescription.

Prescriptions are required to access drugs approved for use and regulated by Health Canada. Therefore, the medical document provided by physicians to allow patients to access medical marihuana can only be considered to be analogous to a prescription in limited ways". [13] The CMPA also recommends medicolegal responsibility in the act of authorizing marihuana for medical purposes by physicians. This includes ensuring adequate clinical knowledge in an effort to protect public safety – actions that are not limited to the scope of medical marihuana.

Many physicians remain rightfully concerned about potential adverse outcomes of cannabinoid therapies, as this is a relatively novel area of therapeutics for most, and new subtypes of medical marihuana continue to emerge quite rapidly. Fortunately, Health

Canada does have a nationwide Canada Vigilance Adverse Reaction Monitoring system [14] to allow a shared opportunity among physicians [15], consumers [16] and industry [17] to alert Canadians about potential adverse events to all health products marketed in Canada (including prescription and non-prescription medications, biologics, natural health products and radiopharmaceuticals) , and these are registered in the centrally monitored Health Canada MedEffectsTM database.

In conclusion, medical marihuana finds itself in an interesting and unique legal position in Canada. Rather than reacting with major regulatory changes on a provincial level to supersede federal law, it may be most appropriate to refer to marihuana for medical purposes as exactly what it is: an otherwise illegal plant-based substance that has not been approved as a therapeutic product by Health Canada, but which requires the authorization of a physician in order for a patient to access. Physicians are required to act reasonably within their legal and ethical responsibilities. Those physicians who lack training and knowledge or are uncomfortable with medical marihuana should not be required to provide authorizations, as they would not with any other medicine that fit those criteria.

It is apparent that a variety of opinions are being voiced by agencies responsible for providing guidance to doctors and patients, and that there are ongoing political and economic dimensions to this topic involving complex stakeholder networks. As these regulatory frameworks are intelligently and intelligibly defined for the benefit of public health, as under the mandate of Health Canada, we look forward to learning more about the potential medicinal benefits of this emerging therapeutic agent. For the time being, it would seem inappropriate for provincial regulatory bodies to contradict federally mandated health policy legislation. This abbreviated issue analysis summary is provided to ensure that physicians and policymakers exposed to this issue in their clinical, educational or research mandates have up-to-date facts to back up opinions they may encounter. V

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Medical Marijuana in British Columbia Personal Injury Cases BY DEREK K. MIURA

At the recent TLABC Medical Legal Conference, there was a presentation of a mock trial and focus group on the issue of medical marijuana. It was clear from that presentation that juries will likely have little hesitation in making awards for medical marijuana on reasonable evidence.

What about judges?

The cases so far include:

Joinson v. Heran, 2011 BCSC 727
Datoc v. Raj, 2013 BCSC 308
Glesby v. MacMillan, 2014 BCSC 334
Amini v. Mondragaon, 2014 BCSC 1590
Mandra v. Lu, 2014 BCSC 2199
Torchia v. Siegrist, 2015 BCSC 57

Joinson is a medical malpractice case. The plaintiff claims $822,308 for medical marijuana. The Court goes through a rather detailed analysis of the claims and comes to a sub-total of only $79,167.04, then discounts 50% for personal use, and then further adjusts the remaining amount for assumed recovery from future chronic pain rehabilitation efforts. In the end, the Court awards $30,000 for medical marijuana.

Datoc v. Raj is a motor vehicle collision case. The plaintiff claims $20,000 for medical marijuana. The Court awards nothing. This case turns primarily on the credibility of the plaintiff. The Court also states that the evidence does not support the claim that medical marijuana is reasonably necessary.

Glesby v. MacMillan is another motor vehicle collision case. One of the plaintiff's treating specialists encourages the use of medical marijuana for pain management. The plaintiff does not take the medical marijuana. The Court declines to find that the plaintiff fails to mitigate her losses by not taking medical marijuana.

Amini v. Mondragaon is another motor vehicle collision case. A specialist expert for the plaintiff recommends $9,000 worth of cannabis ointment. The Court awards $6,500 for a medical marijuana program noting that the plaintiff is a nurse and can make her own.

Mandra v. Lu is another motor vehicle case. Dr. H recommends medical marijuana in a topical cream. The Court declines to award anything for cannabis cream as this falls more into the category of novel research and there is little evidence it will provide assistance to the plaintiff.

Torchia v. Siegrist is another motor vehicle case. The Court declines to make an award for medical marijuana as there was no evidence before the Court.

It appear that awards for medical marijuana will be made provided that there is a proper evidentiary basis to find that the medical marijuana is reasonably necessary and medically justifiable. So far, the cases where the Court has declined to make such an award have simply fallen short on the evidentiary burden required of the plaintiff on the issue.

This paper is simply a case survey/summary of the judicial consideration of the issue of medical marihuana limited to the context of personal injury cases in British Columbia. It is not meant to be an exhaustive treatise on the topic in Canada at large. Given the novelty of the subject matter, it remains to be seen how the jurisprudence will continue to evolve in British Columbia and other Canadian provinces.