

# **Pioneering treatment options: How medical cannabis improves patients' lives**

**Though not without its critics, medical cannabis has been used as a therapy of last resort. Despite growing evidence that medical cannabis can offer further medical benefits, accessing this treatment can be a challenging process for patients – and can raise questions regarding dosing and treatment planning for medical professionals. Researchers and companies, including Sandoz Canada, are working to improve access to this medicine and related information.**





In order to ensure the safety of patients, medical cannabis is produced with meticulous care.

**J**ames O'Hara's illness had taken over his life. A life-long migraine sufferer, in his 50s he began experiencing sudden seizures. For about two weeks after each seizure, O'Hara was left in a state of confusion and with poor memory. "I couldn't function properly," he explains from his hometown of Toronto, Canada. His neurologists ran a battery of tests including MRIs and CAT scans. After they diagnosed focal awareness seizures, O'Hara received standard anti-seizure medication. But his seizures continued, no matter which treatment he was given. And the medications brought their own side effects, including exhaustion. "I was completely disconnected from work and my family – and I knew it."

Purely by chance, an acquaintance suggested that medical cannabis might help. O'Hara knew little about it. However, the more he began to research it himself, the more he became convinced it was worth a try. Out of desperation, O'Hara searched for a physician who was willing to support him in attempting this treatment. "It was a challenge, but I was lucky to



## The history of cannabis as medicine

Long before any research-based explanation of its molecules and receptors in the human body, cannabis was held in high regard as a herbal therapy in ancient cultures. The earliest record is from 2737 BC, when Chinese Emperor Shen-Nung recognized its suitability as a treatment for over 100 ailments including gout, rheumatism and malaria. Around the same time, cannabis was also

used medically in what is now Romania. In 2000 BC, cannabis was mentioned in Ayurvedic medicine; by 1550 BC, it was being used as a medicine by Egyptian healers and, by 400 BC, among the Romans. Since then – with the exception of the past century – healers and medical practitioners around the world have treated their patients with medical cannabis.



Out of more than 500 components of the plant *Cannabis sativa*, two are mostly used in medical cannabis.

find the right doctor." The results, says O'Hara, were like night and day. "All of a sudden, I was able to control the seizures while functioning better in daily life. To put it simply, I could work more and contribute to my family more." But, as O'Hara's overall health stabilized, he says he also began wondering: Why were people not more aware of medical cannabis? Why didn't more people have access to it?

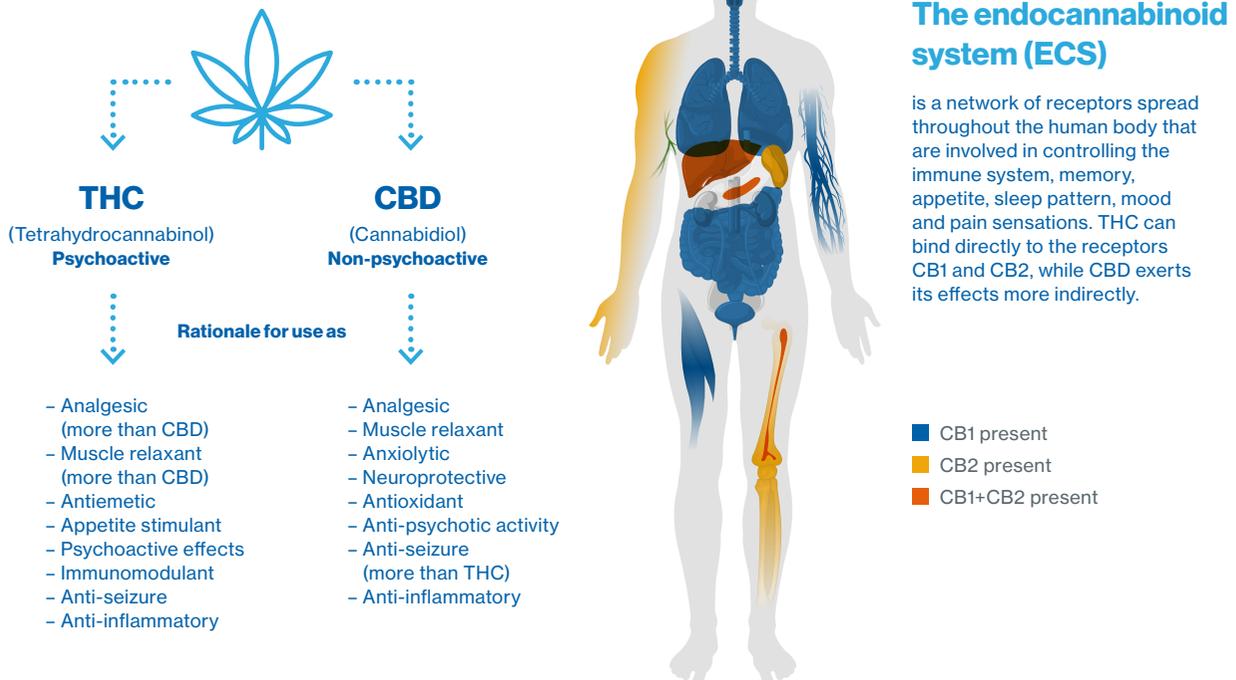
### A complex situation

Now a medical cannabis patient for almost a decade, O'Hara admits that the idea of using cannabis for medical reasons can raise eyebrows. "One issue may be the distinction, legally as well as culturally, between cannabis and medical cannabis," he points out. A central problem is that some believe that medical cannabis produces a 'high' like recreational cannabis. But, in fact, as a patient "you are using medical cannabis as an alternative to traditional medicine."

It's not just the public that has questions or lacks information, resulting in uncertainty towards medical cannabis. In Canada, the national health service (Health Canada) has approved the use of medical cannabis, but the Canadian Medical Association (CMA)



## Medical cannabis – Its effects on the human body



Sources: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741114/>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2241751/>; Tilray

has not. With this lack of official CMA endorsement, not all Canadian doctors may be comfortable or willing to authorize medical cannabis (*see our interview below*). Although Canada has legalized recreational cannabis as of October 2018, this does not affect the current regime for medical cannabis.

Once patients find a doctor who will authorize this treatment, they face another obstacle. Canadian patients must order their prescription online from approved producers. Bricks-and-mortar Canadian pharmacies, with live pharmacy professionals, cannot at this time provide medical cannabis. This also means that Canadian patients cannot currently (as of

October 2018) get any advice about dosing or contraindications from their local pharmacists.

### Looking for answers – filling the gap

This shortage of information about medical cannabis has been a reality around the world for some time. While cannabis has been used as medicine in various cultures for at least 4,000 years, Western civilizations turned their back on this treatment in the 20th century. The precedent was likely set by the US, where cannabis became illegal for any purpose in 1937. Other countries followed the US lead, and cannabis largely disappeared as a recognized means of medical treatment. As



Researchers continue to study the physiological and pharmaceutical effects of medical cannabis to be able to offer patients a safe treatment option.



a consequence, an information gap emerged and developed over the past 80 years.

In order to begin filling this gap, some licensed producers like Tilray are currently conducting clinical and observational studies examining a number of indications, including the use of cannabis extracts in the treatment of pediatric epilepsy, chemotherapy-induced nausea and vomiting, and essential tremors. “The focus of these studies is examining how different doses and ratios of THC (Tetrahydrocannabinol) and CBD (Cannabidiol), both active compounds of cannabis, affect different symptoms and conditions,” explains Philippe Lucas, Vice President of Global Patient Research & Access at Tilray. The cannabinoid THC is psychoactive and may provide analgesia and reduce inflammation in chronic pain, and may combat symptoms such as nausea and vomiting (often a side effect of chemotherapy). However, CBD, a non-psychoactive compound, may be able to lower anxiety, depression and pain.

Strict dosage of medical cannabis may be required to influence various physiological processes of the human body. The central nervous system has a specific ‘network’ of cannabinoid receptors and receptor antagonists, the ‘endocannabinoid system.’ Here, within this system, THC and CBD trigger signals that are involved in immune responses as well as mental and motor actions including appetite, pain-sensation, mood and memory. “Effectively, the human body’s endocannabinoid system has receptors that interact with cannabinoids from the cannabis plant,” explains Lucas. It is this system that mediates the effects on the human body and is, thus, central to the medical use of cannabis. Adds Lucas, “The human body’s endocannabinoid system engages with plant-derived cannabinoids like a lock-and-key.” (See *infographic*, page 19.)

#### **Alternatives for managing pain**

From his office in Nanaimo, British Columbia, Lucas personally investigates a range of applications. As a researcher for the last 15 years, he is interested in “medical cannabis as an alternative to other prescription medications.” He estimates that 80% of

“I think there still is a huge need to educate the general public, policy makers and healthcare providers in order to help people have better access to this treatment.”

**James O’Hara**, patient and CEO of CFAMM (Canadians for Fair Access to Medical Marijuana)

the approximately 270,000 Canadian cannabis patients use it for chronic pain and mental health conditions.

Tilray’s research department has multiple studies underway on the broader effects of medical cannabis use, including one called TOPS (the Tilray Observational Patients Study), says Lucas. The data for the study’s first six months has been extremely insightful. “There was a significant rate of substitution for all classes of prescription drugs that we’re tracking – including muscle relaxants, antidepressants, anti-seizure and pain medications,” Lucas explains. Medical cannabis is also being investigated for its potential role in fighting the ongoing opioid crisis in Canada and the US.

#### **Creating access solutions: Informing and supporting**

While all of this might be good news for patients suffering from a range of chronic conditions, access to this medicine – and access to information about it – is still required to maximize its potential benefits among doctors and patients. Patient advocates like O’Hara and researchers like Lucas agree. “I think there still is a huge need to educate the general public, policy makers and



## Three questions with

# Dr. Blake Pearson

**Advocate of medical cannabis because, from his experience, it works**

### Do you prescribe medical cannabis to your patients, and why?

For some of my patients, traditional pharmaceutical treatments weren't effective, or patients couldn't tolerate the side effects. So that's when I first started to prescribe medical cannabis. I continued to prescribe it because of the positive results, with less risk of serious side effects. I educated myself on the endocannabinoid system. And once I understood the underlying physiology, I had to acknowledge that medical cannabis is a scientifically reasonable option for the treatment of certain conditions.

I also support medical cannabis because it's a multimodal treatment. This means that it can treat more than one symptom with just one medication. For example, in pain management, I am often able to manage someone's pain and at the same time treat related issues like insomnia and anxiety with one cannabis formulation. So it's a medication that can also lead to a reduction in polypharmacy, which is the simultaneous use of multiple medications by a patient.

### What problems do you see with medical cannabis?

Unfortunately, there is a lot of misinformation about cannabis, even in the medical community, and there continues to be an inherent bias against it due to a variety of political and personal ideologies. There is already a significant body of high-quality evidence to indicate that cannabis is effective in treating conditions including chronic pain, chemotherapy-induced nausea and vomiting, MS spasticity and short-term sleep disorders – and the body of evidence is growing around a host of other conditions.



Physician, CEO of Greenly Medical, Toronto, Canada, and medical cannabis researcher

Undoubtedly, we need more controlled trials to investigate the effectiveness of cannabinoids for the multitude of other conditions that it has the potential to benefit. But, apart from that, we need to consider the double standard – and stigma – regarding medical cannabis amongst some in the medical community: We demand much more rigorous evidence for cannabinoid therapy than we do for other treatments. For example, in Canada, one in nine drugs is being used off-label, meaning that it is prescribed for different indications or types of application than originally approved by the authorities. Within pediatrics, this number rises to 75% of medicines being prescribed off-label.

As physicians, we seem to be okay with this. Although, according to the Canadian health department, Health Canada, 79% of off-label prescriptions were not supported by strong scientific evidence – with “strong evidence” being described as having at least one randomized controlled clinical trial. Off-label prescribing is not prohibited in Canada, and most physicians agree it is essential in ensuring health professionals can pursue treatments that are in the best interest of their patients. There are many examples of innovative uses for existing drugs, and I see a parallel here. I see the positive impact of cannabis therapy on my patients every day, and I question this double standard.

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## Based on your experience with your patients, does access to medical cannabis improve lives?

To put it simply, medical cannabis works for certain conditions – and for some patients, it is the only medication that is effective. A number of my elderly patients rated their pain as severe enough to limit themselves from gardening, going for walks and spending time with their grandkids. For many, it was also preventing them from getting a good night's sleep. With medical cannabis treatment, they experience less pain, and they enjoy their lives again. Specifically, I'm thinking of a female patient with chronic pain, who had multiple operations on a tumor on her jaw. For her, this was an access matter: A pain specialist refused to give her medical cannabis, so she was given an opioid that's a hundred times stronger than morphine - but it wasn't providing relief. So, she was referred to me. Within a couple of months, we had her pain better controlled, and she was able to completely come off the opioid, by using a cannabis oil.

“I prescribe medical cannabis because it is a scientifically reasonable option for the treatment of certain conditions.”

From my perspective, medical cannabis is a medication that can be effective for treating certain conditions. And when you consider its low risk for serious side effects and its ability to potentially reduce other medications, medical cannabis needs to be considered as a reasonable option. It's not the only option, but it should be an option. ■

health care providers in order to help people have better access to this treatment,” says O'Hara.

Fortunately, the situation is changing. The body of anecdotal evidence has increasingly encouraged doctors to consider medical cannabis as a treatment option, and scientists worldwide have been giving it a second look – which has led in turn to a stunning amount of new research work. As an example, according to a summer 2018 article published in the “*Deutsche Ärzteblatt*” (German Physicians' Journal, a publication co-owned by the German Medical Association), there are 750 scientific publications on the medical effects of cannabis, and more than 600 cases, open and controlled studies, have been reported since 1970. Just as importantly, 80% of these studies have been carried out in the past 20 years.

Motivated by patient experiences such as O'Hara's, and by the growing amount of scientific evidence and medical efficacy, several pharmaceutical companies are investigating the medical cannabis stream. At the forefront is Sandoz Canada and its partner Tilray, a licensed producer of medical cannabis. Together, they have partnered to provide greater access to medical cannabis products for Canadian patients. With their experience in manufacturing medicines, Sandoz Canada will help to develop new and innovative medical cannabis products, including new product dosage forms and delivery systems suited to specific medical uses. In addition, Sandoz and its partner will invest in research studies to advance the science in a variety of medical conditions.

Vincenzo Ciampi, Executive Director of Innovation and Strategic Projects at Sandoz Canada, and his team believe that making these products more widely available may improve patients' health outcomes. In 2016, the team embarked on a journey to further legitimize medical cannabis as a mainstream medicine and trusted treatment option, and to support patients to confidently access quality treatments. Sandoz Canada has a strong vision to distribute these treatment options via pharmacies to further ensure accurate usage and invite consultation throughout treatment. “What we have begun doing is educating the pharmacists about medical cannabis,” continues Ciampi.

### Facing the questions – understanding the concern

“Sharing medical information and evidence backed by credible research about medical cannabis is crucial for prospective patients, the medical community and the public in general,” he adds.

Along with the perception that it has unwanted narcotic effects, common concerns are that patients could become dependent on medical cannabis or that this medicine is dangerous; neither is correct, according to the World Health Organization. However, others wonder what potential side effects medical cannabis could have. A report by WHO in 2017 states that medical cannabis is generally well-tolerated. “Critics have concerns, and it’s important to provide the facts behind medical cannabis. Further research should clarify the potential benefits of medical cannabis,” says Ciampi. “We trust doctors to make the decisions that they feel best with, whether it’s authorizing medical cannabis or prescribing other treatment methods.”

### No ‘must’ – but a choice

For James O’Hara, medical cannabis was the right treatment, and he would like the public to have the same information and options as he did years ago. While his health condition was improving through medical cannabis, he discovered the non-profit CFAMM (Canadians for Fair Access to Medical Marijuana) and became a volunteer. Today, as a healthy 60-year-old, he is the organization’s CEO.

As he moves confidently through meetings, speaking engagements and office-based managerial decisions, it’s clear that O’Hara believes in this mission: to help more Canadians gain access to medical cannabis and experience the relief that he did. “There was a time, however, when a fully productive professional, and family, life was unimaginable to me,” he says. Today, under an authorized and monitored regime of medical cannabis, O’Hara can look back at his past health issues and say “I’m living again.” Adds O’Hara, “Wouldn’t it be something if even more people knew that such alternative treatment options are already out there that could help them too?”



## Three questions with

# Dr. Claude Cyr

## Critical but open, careful medical cannabis prescriber



Family physician in Montreal, Canada, and Associate Researcher for the Quebec Cannabis Registry

### Do you prescribe medical cannabis to your patients, and why?

I prescribe medical cannabis for a limited number of conditions and mostly for pain relief. But, for me, it still is a last resort medication, for example in cancer and palliative care. Patients sometimes come to my office asking for medical cannabis as a first line treatment for chronic non-cancer pain after having tried one or two other medications. They often haven’t had physiotherapy or steroid injections or any other type of medication. So I send them back to their general practitioner and explain that they need to go through the algorithm that has been set by pain societies before considering cannabis as a treatment option.

Once they have gone through the standard process for pain management, many patients are usually satisfied and don't even need medical cannabis.

### **What problems do you see with medical cannabis?**

One of the major obstacles to using medical cannabis right now is that every physician seems to have his or her own personal opinion. There is no medical regulatory authority in Canada that recognizes medical cannabis right now. So, many doctors who prescribe it are like pioneers and rebels out there, in a manner of speaking. I'm a very conservative medical cannabis prescriber.

One reason for this is the lack of guidelines. Right now, they do not tell us how to properly dose and choose which patients will benefit the most from medical cannabis. Now that Sandoz Canada has teamed up with a cannabis producer, they can provide the background to make these products a lot more accessible for physicians who want precise dosages. And I think this is very good news for pharmacists as well. If Sandoz Canada can make precise formulations, pharmacists will want to work with them and so will physicians.

### **Based on your experience with your patients, does access to medical cannabis improve lives?**

Oh, absolutely. There is no doubt in my mind. But there is a danger here of using personal experiences with your patients as the basis for general recommendations for medical cannabis. We simply need more than just empirical evidence. But I believe it is already extremely helpful for certain people in certain circumstances. I've had patients telling me

– and this is a recurring theme in many patients with chronic conditions – that medical cannabis has had a really positive impact on their quality of life. The one comment I keep hearing is 'I have my life back.'

“I'm a very conservative medical cannabis prescriber because of the lack of guidelines for physicians.”

I think there are probably thousands of people right now in Canada who would benefit from medical cannabis but can't access it because their physicians are either too afraid or skeptical. Also, patients who are really sick, elderly patients or people with difficulty finding someone to advocate for their condition will have access problems. On the other hand, there are probably thousands of people who shouldn't be getting medical cannabis because there are better treatment options available for them. This is a very strange situation we're in. But things may be about to change. ■