Senate Legal and Constitutional Affairs Committee

Attention: Committee Secretary

Dear Secretary,

Re: Submissions – Regulator of Medical Cannabis Bill 2014

I am writing in response to the proposed bill to establish a regulator of medical cannabis. I agree that this legislation change is critical to cater for medical patients suffering chronic and terminal medical conditions that can be alleviated by medical cannabis. Most importantly a framework that can include botanical cannabis products is necessary.

Background:

I am the mother and carer of a 16 year old patient with a Brain Tumor (Glioma) who also has intractable epilepsy. I have spent most of last year in the USA with my son for medical treatment. After a period of not responding to other initial treatment in Texas, my son was referred to a clinic in Washington. In Washington he was then recommended to start on a protocol of medical cannabis. This medical cannabis treatment has been effective in controlling seizures, managing debilitating pain and nausea and also has achieved shrinkage and stability of the brain tumor (Glioma) when he is on treatment consistently. The treatment of his Glioma is based broadly on research conducted by the California Pacific Medical Centre Institute Research as well as other Glioma studies with cannabinoids over the years.

My son has been treated overseas by physicians that have significant experience with cannabinoid medicine including significant experience working with brain tumor patients and many cancer patients.

When my son returns to Australia for an extended time without the treatment of the medical cannabis oil which he has been recommended, his brain tumour has grown and he suffers with epilepsy, nausea, and chronic pain.

My sons chronic pain is not sufficiently controlled by painkillers recommended in Australia for him. Pain control options in Australia for him are limited due to the impact to his liver of the pharmaceutical anti-seizure drugs in such high doses (2500mg per day which still did not control his seizures) this pain pharmaceutical drug is completely ineffective for his chronic pain caused by a brain tumour. However in the USA he is able to achieve fast and effective pain management by vaporization of the Cannabis as well as ingested cannabis concentrates and medical edible products.

My son has also experienced significant side effects from anti-seizure pharmaceutical medication in Australia, these side effects have included pain, nausea, fatigue, elevated liver enzymes, hand tremors and even Bradycardia(Bradycardia can be potentially life threatening).

In Australia and globally there exists a critical demand for patients requiring cannabinoid medicine for serious medical conditions which otherwise may remain unresolved or intractable even under treatment with other significant pharmaceutical protocols. Many countries internationally have produced effective clinical trials and research proving its safety and efficacy in successfully treating many of these conditions over many decades.

Important considerations for regulative change

Whole Plant - Full Spectrum Plant Extracts

Most importantly based on our experience in working with doctors who are highly experienced in treating patients with medical cannabis, we want to stress the importance of the option to treat using full spectrum plant extracts inclusive of all Cannabinoids and terpenes.

In reference to Brain tumours for example:

The glioma tumor cell lines (glioblastoma) evaluated in-vitro by McAllister, et al, [Mol Cancer Ther; 9(1) January 2010], exhibit much reduced cell growth proliferation when cannabinoid molecules are mixed as in whole plant extracts, as compared to Glioma response to the single isolated molecules. Synergy of complete cannabis molecules provides much more potent anti-tumor properties than compared to the single molecule pharmaceutical cannabinoid preparations currently available.

Over many years there has been significant research conducted to prove the value of individual cannabinoids. Overseas also right now in many countries medical practitioners that specialize in working with patients with cannabinoid medicine recognise that every patient responds to different strains, which have different terpenes and cannabinoid profiles. Every patient is unique and the treatment and dosing is tailored to the individual's needs.

If the Australian government fails to recognise that it is also all of the cannabinoids and terpenes in the cannabis plant that are medically beneficial and can help a patient with their illness, then they are actually failing to utilise the plant for its full medical benefits.

The Australian government should heavily rely on professionals such as pharmacognosists and scientists within Australia. They should also consider consulting with doctors that have significant experience in working with cannabinoid medicines overseas as well as local doctors that have a specialised knowledge in this field. These measures will assist the government when establishing any legislation surrounding this treatment and help them to get a true and unbiased perspective of the existing medical benefits of the plant and its full properties.

Interim measures for patients and caregivers

It is critical that interim measures are set in place for patients with chronic conditions to have the ability to access tested commercial grade medical cannabis via import through special access scheme or similar until supply and regulation is fully established in their state/territory/federally.

AND/OR

Patients/caregivers be granted the ability to grow sufficient plants for the patients' medical needs.

This will help address any affordability issues and will address interim supply issues. Patients should not have to be in a position of relying on any illicit market.
There are countries now that have successfully adopted this option for patients and its far easier for patients to be sure of quality and supply when they are also able to grow their own plants and have access to testing facilities.
This type of programme works well in many counties within legal states in the USA. I do not believe it's a good idea to have county by county (Council) limits like in the USA in some states. This becomes very cumbersome and is an inconsistent approach. There

should be a consistent federal allowance for medical patients to be able to be authorized to grow a limited number of plants to address both supply and affordability issues immediately. This type of model can easily co – exist with fully regulated medical cannabis commercial grow solutions on both small or large scale to address supply for those not wanting to grow their own plants for medical use.
An amnesty needs to be made available to provide both patients and their caregiver protection from prosecution for genuine medical need as authorized by doctors or specialists.

Laboratory testing should be made available for all patients and caregivers to be able to test plant extracts in a cost effective manner.

No age restrictions

There should not be age limitations in place with medical cannabis legislation. Medical necessity should be assessed on an individual patient basis in conjunction with medical practitioners or specialists.

Age is not a discriminator of patients being afflicted by chronic disease and illness and therefore age should not impact who has the human right to receive this treatment for their chronic health condition or symptoms especially if supervised fully by medical professionals and specialists.

Medical Professional Education

Introduction of education programs for medical professionals including specialists, doctors to be able to understand the Cannabinoid treatment more fully and to be able to recommend and effectively manage and supervise patients using this as a medical treatment. There should also be training available for nurses and allied health professionals who may be also working with these patients.
Caregivers and patients should be able to speak openly to medical professionals and receive medical supervision and recommendations in regards to cannabinoid treatment options especially when faced with such critical and debilitating conditions. It's important that they are able to speak to professionals that are adequately trained in cannabinoid medicine as a therapeutic option.
Quantity limits set by government

Unrealistic limits such as that set for the terminal illness scheme in NSW for example do not cater for the average cancer patient's needs for example.
Overseas the dosages would often be worked out based on body weight or condition and how chronic the condition may be, some patients may even be recommended to juice the plant as part of their treatment regime.
Many doctors overseas work on a basis of paced titration to reach optimal dosing for the patient. These quantities should be determined by a supervising doctor or specialist.
Dosing would also based on tolerance levels which can vary over time. The treatment may include combinations of activated and unactivated oil products (Decarboxylated and non decarboxylated) every day as well as any dried flower for vaporizing for example or any other medical cannabis products.
Based on recommendations of oil dosages for many cancer patients overseas, under the current terminal illness scheme for NSW a patient or caregiver may have to source Cannabis oil products every 1 -2 days to stay within limits. This is simply not practical for any patient or caregiver.
CBD VS THC

Full spectrum of plant profiles should be available for medical treatment due to the diversity of chronic and terminal conditions that may benefit from medical cannabis.

In the USA states that have introduced CBD only legislation have discriminated against other chronic health conditions such as cancer, nausea and chronic pain and many other conditions. This has meant that many patients have been left without suitable medical cannabis treatment for their conditions and in some cases lives have been lost due to options being limited.

Historically in the USA they have learned through trial and error that CBD alone is insufficient in controlling some seizure conditions. 30 – 50% of all intractable epilepsy patients respond to CBD but the remaining 50 - 70% either do not respond to cannabinoid medicine at all OR only respond when THCA/THC or other cannabinoids are introduced.

There has been evidence in cases in the USA that some patients who may also initially respond to CBD may also require other cannabinoids to be included or increased to obtain seizure control over time as tolerance levels adapt.

There are also other cannabinoids which are not so predominant in the plant which have effective anti - seizure properties and a realm of other medical benefits. The value of the terpenes of the plant is also of heightened scientific interest. It is true that all of these components of the plant and how they work synergistically are critical for effective therapeutic benefit.
It is critical that Australian regulation values the full broad spectrum of cannabinoids to alleviate a variety of medical conditions rather than being reliant on the limitations of CBD only and repeating costly and potentially life threatening historical mistakes for patients.
Pharmaceutical VS Botanical Cannabis

I personally believe that there is a critical need for patients to have choice when it comes to how they take cannabinoid medicine.
In my sons case his doctors in the USA did recognize that the whole plant botanical extracts were more effective than pharmaceutically produced isolated cannabinoid medicines at this point in time for treating his conditions. The whole plant and entourage effects have been critical in the success of his treatment.
The research which our sons treatment was based on showed a specific increase in effectiveness when both THC and CBD cannabinoids were used synergistically in treatment rather than these cannabinoids being used in an isolated manner. Also the dosing and methods of treatment can vary from patient to patient and condition, so I believe that it's critical for this to be very personalized medical treatment and tailored to the individual patient and their condition.
There is enormous scope for Australia to benefit from this industry on a commercial scale with the introduction of regulated botanical cannabis treatment options. Of course it is likely that in time there may be more pharmaceutical cannabinoid medical options becoming available but this should never be a compulsory method of treatment over the full spectrum botanical plant and extracts. The ability to choose should be the patients right for their own health and wellbeing.
With the botanical plant extract there is the advantage of using different strains to treat an individual condition. When you consider variables in a patients genetic makeup, condition and symptoms and also their responsiveness to different treatments it makes sense to treat the patient independently with a choice of cannabinoid options. There is no "one size fits all approach" some patients may respond to different plant genetics/strains, different cannabinoids and turpenes to the next patient and that is why the model that is being used overseas in other countries such as US and Israel is extremely effective because it

recognizes and accepts that the patient is as individual as the plant, some may respond better to some strains or extracts than others.

Inhalation for specific medical conditions

In relation to efficiency in chronic pain relief it has been well established that inhaled forms of cannabis are effective within a couple of minutes of inhalation as compared to the ingested forms of cannabis that require approximately one hour before their effects are realized. So, for pain, nausea, vomiting, and in some cases epilepsy it is extremely important to get a very rapid onset of action which can be achieved with the inhaled method(s).

For conditions that may benefit from inhalation it is important that any regulatory change includes access to medical cannabis suitable for inhalation and devices such as vaporisers for example that may be required for inhalation. Cancer wards in some hospitals in Canada and Israel for example allow inhalation for medical patients.

Inclusion of rare and debilitating/chronic medical conditions

It is important that any regulative change will allow inclusion for doctor or specialist discretion to authorise patients with a rare or debilitating medical condition when they deem that the patient may benefit from the prescription of medical cannabis. An example may be a brain tumor that due to potential risks of biopsy may not be able to receive a conclusive diagnosis of tumor type or life expectancy but nevertheless suffers chronic and debilitating pain, wasting, nausea, epilepsy. Or a rare condition that does not respond to pharmaceutical medication and where there may be debilitating symptoms that are not able to be managed effectively or safely with prescribed medications.

Medical Professional Education

As legislation is introduced it is important for the government to recognize that there needs to be specialised education programs available for medical professionals to be able to understand and be able to effectively be trained so that they can confidently supervise or treat patients with cannabinoid medicine. Medical professionals also need to be educated on the endocannabinoid system and be able to have access to ongoing training in this area. Cannabinoid medicine also needs to be included in university medical training.

Trials and research

Trials should also run side by side with observational research studies on patients that are currently using medical cannabis for various conditions. Patients cannot afford to wait years for trials or the outcomes of trials. Australia needs an interim measure now to allow patients to have access to this treatment if they require it for their medical condition. There has been sufficient evidence globally over many decades to prove safety of this treatment. Thank you for your consideration of these important issues and I hope that you can resolve these issues in a timely manner for the sake of many patients.

Thankyou

Lanai Carter