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MULLAWAYS MEDICAL CANNABIS PTY LTD

Submission to the Victorian Law Reform Commission

1 The Victorian Law Reform Commission is asked to review and report on options for changes to the *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations to allow people to be treated with medicinal Cannabis in exceptional circumstances, and to make the recommendations for any consequential amendments which should be made to the:

- ***Therapeutic Goods (Victoria) Act 2010***
- **Any other relevant legislation.**

2 In conducting the review, the Commission is asked to consider:

- **The operation of Victoria's *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations, and how this interacts with Commonwealth law, functions and any relevant international conventions.**
- **Medicinal use of Cannabis in other jurisdictions.**

3 The Commission is asked to appoint expert panels to assist in its review, specifically to examine:

- **Prescribing practices for medicinal Cannabis, including eligibility criteria for access to medicinal Cannabis and the role of Doctors in managing the use of medicinal Cannabis by patients.**
- **The regulation of medicinal Cannabis manufacture and distribution, including which forms of medicinal Cannabis should be permitted for use.**

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Foreword

Mullaways Medical Cannabis Pty Ltd (Mullaways) is pleased to present this Submission to the Victorian Law Reform Commission (VLRC) on options for changes to the Drugs, Poisons and Controlled Substances Act 1981 and associated regulations to allow people to be treated with medicinal Cannabis in exceptional circumstances. We have pin-pointed a number of specific areas for discussion and options for change, which we think should now be considered broadly by the Victorian community. I recognise that progress in this difficult area will come slowly, through incremental steps and careful evaluation of the experience gained along the way. We believe, however, that it is time for Victoria and Australia, with their fine health and welfare systems and their powerful capacity to evaluate the steps we take, to identify our first steps and move to implement them.

Introduction

Mullaways believes it is important that this Committee understands the future of Medical Cannabis does not involve smoking cannabis. Most patients will find relief with other preparations of Cannabis/Cannabinoids and very few if any will end up smoking Cannabis as a medical option. It cannot be outlawed as experience from around the world and by individual Australians has highlighted there are medical benefits from smoking cannabis.

A Grow Your Own Medical Cannabis Scheme is a poor option. This approach was shown to be severely flawed at the NSW Inquiry into the use of cannabis for medical purposes. This approach is fundamentally flawed and is nearly the worst of all options for the patient, for medical practise and from a Policing perspective.

The failed Canadian Model must also be avoided. A scheme where you can only legally smoke Cannabis for medical purposes is fundamentally flawed.

The current Health System in Australia is failing at least 1 in 5 Australians, including children, who live with chronic pain and among people aged over 65 that's, 1 in 3.

Victoria requires a comprehensive scheme regulated through every step of the supply chain which includes cultivation, manufacturing, processing, distribution and use.

Any medicinal cannabis scheme established in Victoria would need to remain effective over time as scientific knowledge; medical practices and technology continue to evolve. In addition, the operation of the scheme should be subject to ongoing monitoring and re-evaluation as it would be likely to generate information that could contribute to the body of knowledge about the efficacy and properties of Cannabis-based medications.

It is encouraging to see a Government responding to the Australian people's desire for a Medical Cannabis Scheme which protects patients/carers from criminal conviction and for the opportunity for these patients to be involved in Clinical Trials, where appropriate, to back up their convictions. 68% of Australians are in favour of a Medical Cannabis Scheme and 75% are in favour of Clinical Trials.

Mullaways presents this submission to the Victorian Law Reform Commission in the belief that Victorians will achieve a scheme which is coherent, humane and which will achieve clear health benefits to Victoria.

It is really important to understand that one of the fundamentals of the preamble, (the second one in fact) of *the Single Convention on Narcotic Drugs 1961*, states: **"...recognising that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that**

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adequate provision must be made to ensure the availability of narcotic drugs for such purposes..."

This was reaffirmed in March 2010 by the United Nations Commission on Narcotic Drugs.

Striking the right balance to achieve the optimal public health outcome.

At the 53rd session of the Commission on Narcotic Drugs (CND) held in March 2010, the Commission adopted Resolution 53/4: **"Promoting adequate availability of internationally controlled illicit drugs for medical and scientific purposes while preventing their diversion and abuse".**

The Commission recalled the recognition of parties to *the Single Convention on Narcotic Drugs 1961* as amended by the 1972 Protocol: **"That the medical use of narcotic drugs continued to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability for such purposes."**

The State and Federal Governments have not made any provisions to ensure the availability of cannabis/cannabinoid products for the relief of pain and suffering. Adequate availability of internationally controlled illicit drugs, like Cannabis, for medical and scientific purposes is not a secondary concern to the policing of recreational use. It is an integral part of the whole approach.

The Victorian Government must be complimented for setting up this Commission not to look at if but how Victoria will setup a Medical Cannabis Scheme and allow the Research and Clinical Trials of Cannabis/Cannabinoid medications.

Central to any issue around medical Cannabis is an individual's right to decide how to protect their own body. Courts here and overseas have consistently rejected claims that the medical profession or the state or international laws have a right to impose, withhold or dictate and individual's medical treatment.

In Rogers and Whitaker the High Court stated that the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to "the paramount consideration that a person is entitled to make his own decisions about his life."

In regards to the application of drug laws against medical users of cannabis, this contention is consistent with the important and well established principle of statutory interpretation, affirmed by Gleeson CJ, Gaudron, Gummow and Hayne JJ in Daniels Corp v ACCC: and referred to with approval by the Queensland Court of Appeal in Meredith v State of Queensland.

For many years now Mullaways has been contacted daily by Australians seeking help for their medical conditions. Currently that's between, 100 to 150 people per day asking for help. Mullaways has a very long list of people waiting to be involved in Clinical Trials of the Mullaways Tinctures and Medical Cannabis in general.

There is a very great need for this Legislation. The National Pain Strategy, developed by more than 150 healthcare professionals and consumers at a 2010 national summit, recommended chronic pain be recognised as a priority health issue and constitute a disease in its own right. Yet it remains one of the most neglected areas of healthcare.

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New-onset epilepsy is more prevalent in the elderly than any other age group and while first-line and second-line antiepileptic drugs are available as potential therapy there is a paucity of rigorous data comparing the efficacy of these drugs. There have been few well controlled trials to examine their use in the elderly population. [1]

In a perfect world the approach to determining the exceptional circumstances in which a person could lawfully use Cannabis for medical purposes would be grounded in an understanding of its therapeutic benefits, efficacy, risks and dangers and this would be a discussion a Doctor has with the person considering medical Cannabis as a treatment option.

But research into Cannabis in Australia, and most of the world, has been restricted to risks and harms of abusive forms of recreational Cannabis use. So there is little clinical proof for or against the medical use of Cannabis as research has not been allowed so far.

This cannot be said for individual Australians who have continually reported their use of Cannabis and Cannabinoid medications to assist with their health issues.

The NDARC (National Drug and Alcohol Research Centre) research paper, *Survey of Australians using Cannabis for medical purposes 2005,* states:
"Results: Data were available for 128 participants. Long term and regular medical cannabis use was frequently reported for multiple medical conditions including chronic pain (57%), depression (56%), arthritis (35%), persistent nausea (27%) and weight loss (26%). Cannabis was perceived to provide "great relief" overall (86%), and substantial relief of specific symptoms such as pain, nausea and insomnia. It was also typically perceived as superior to other medications in terms of undesirable effects, and the extent of relief provided.

However, nearly one half (41%) experienced conditions or symptoms that were not helped by its use. The most prevalent concerns related to its illegality. Participants reported strong support for their use from clinicians and family. There was almost universal interest (89%) in participating in a clinical trial of medical Cannabis, and strong support (79%) for investigating alternative delivery methods." [2]

One of the reasons for the Victorian Government moving to make changes to allow the Medical Use of Cannabis is highlighted by the story of Mullaways Case Study No.1 Tara O'Connell. While Tara uses the Tinctures for treatment of Dravet Syndrome and associated Autism these same Tinctures have been used by Australians to help with a range of illnesses for over 10 years.

One submission to the 2013 NSW Upper House Inquiry into the medical use of cannabis came from Dr Ian Webster AO, Emeritus Professor of Public Health and Community Medicine at the University of NSW. The submission "***Cannabis & Chronic pain: The Poor Man's Analgesic***" is a must read by anyone involved in this committee. Victorians need a Health system that assists them with their health issues and does not criminalise and deny access to a drug they are using therapeutically to achieve a better quality of life.

[1] See - Diagnosis and Treatment Selection in Elderly Patients with Epilepsy. Available at website: http://www.jhasim.com/files/articlefiles/pdf/asm_6_3c_rev1_p195.pdf
[2] See - Survey of Australians using Cannabis for medical purposes 2005. Available at website: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1262744/pdf/1477-7517-2-18.pdf

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The legal system must assist the medical profession to achieve the best outcomes for Victorians Health issues. As the Case Study of Tara O'Connell below highlights documenting the patients' treatment with medical Cannabis and any others drugs allow Doctors to better inform about the treatment. As the Scheme moves forward they would have access to data which shows which medications and dosage are best suited to the patients' medical.

Double-Blind Placebo Clinical Trials are not appropriate for many of these patients with exceptional circumstances. Individuals with late stage Cancer, children with severe uncontrolled epilepsy who have been through the treatment options and many others do not have the time to be subjected to such trials but they all do have time in which their treatments can be documented to help find the best dose and medicines to help with their conditions.

A Medical Cannabis Card would allow not only identification of those on the Scheme but also would record the amount of Cannabis/Cannabinoid medicine prescribed and the outcomes of the treatment. This will allow a big data analysis of the results which medical professionals can use to achieve the best outcome for the patient.

This Legislation must allow companies to be involved in all aspects of the Medical Cannabis Industry via License. Companies must be allowed to make profits which are not considered profits from criminal activity.

Setting up a Medical Cannabis Industry will take a lot of investment to achieve. It requires infrastructure for the security, cultivation, manufacturing, processing, delivery and reporting of regulated cannabis/cannabinoid products. Governments do not develop drugs they implement legislation which allows companies to do so within a regulated framework.

Without proof of impairment a Victorian citizen who is an authorised patient under the Victorian Medical Cannabis Scheme should not be criminalised for driving on the roads or showing up for work without proof of impairment. The current testing on drivers and testing in the workplace does not prove impairment and therefore would breach the rights of an authorised Medical Cannabis patient.

Due to the prohibition of researching Cannabis for medical purposes Australian Medical Expert opinion was used in the drafting of the Commissions Issues Paper and not results from clinical trials. It has to be remembered that not one Medical Expert in Australia studied the Endocannabinoid System or Cannabinoids with regards to medical Cannabis when at University.

The Issues Paper does not mention the Cannabinoid Acids like THC Acid. THC Acid is a major part of the Mullaways Cannabinoid Tinctures used by Tara O'Connell and 150 other children with Severe Uncontrolled Epilepsy to reduce their number of seizures and improve their quality of life. These children's exceptional circumstances are a major reason for this Commission being setup but the Expert opinion employed by the Commission fails to mention, at all, this approach and treatment which has made a difference to their lives.

There was no mention of new approaches like nano technologies delivering a few molecules of Cannabinoids to cancer cells or where needed for the medical treatment.

The Issues Paper mentions CBD in a favourable light a number of times while highlighting THC as the main cannabinoid of concern. **There is no CBD in any Mullaways product.** It is not CBD which has

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kept Tara O'Connell seizure free for two years but an ultra-low dose treatment using THC and THC Acid.

CBD is a political solution to a prohibition problem. As this Commission is not required to prove the validity of the CBD statements made in the Issues Paper Mullaways will not list counter arguments to the Expert opinion expressed therein but will only make a few short comments to highlight the divide in knowledge and experience.

The reason there is no or very low levels of CBD in Australian Cannabis is that Australians don't like to smoke rope. There are good reasons why Australians don't like to smoke cannabis with high CBD levels but none of those were mentioned in the Issues Paper.

CBD creates a much denser vapour or smoke than THC, so much so that it is extremely harsh causing people to cough and choke and spit. Recreational Cannabis users are not seeking a harsh smoking experience and breeds that are harsh to smoke don't make the cut.

Recreational cannabis users are not searching for cannabis with high levels of CBD to attune the THC. How would they know they acquired cannabis with high amounts of CBD? Why would they not just smoke less Cannabis?

CBD is not the answer but it will be part of a Medical Cannabis Scheme. It is extremely important to not limit any legislation to CBD only medications. There are a range of Cannabinoids including their acids which should be allowed under a regulated scheme.

No research on Cannabis mentions or accounts for the quality of prohibition Cannabis and the impact this has on a person's health or the outcome to the research being conducted. Without taking into account this factor much research about Cannabis is of little relevance.

One of the fundamental principles of modern science is that research results must be able to be verified by other parties. Researchers must be able to source the Cannabis or Cannabis medications used in the original research. Currently this is not possible in Victoria or Australia as cannabis required for research must be acquired from Cannabis the Police have seized. It is important that the legislation ensures that raw cannabis and Cannabinoid products are available to researches so that research results are repeatable.

The Issues Paper highlights that in Canada where Medical Cannabis patients can only smoke Cannabis the average amount of Cannabis used is between 0.5 to 1.5 grams per day. This is not a large amount of cannabis per day. Especially when, as was pointed out in the Issues Paper, the amount of pain relief for neuropathic pain was not determined by the amount of THC in the cannabis but by the fact the person had some cannabis with low THC Cannabis being as effective and high THC Cannabis.

Mullaways survey of 150 Australians in 2010 using the Mullaways Tinctures reported pain reduction for a number of illnesses. That is a dose less than that recommended as safe for human consumption by children and adults. [3]

[3] See - Mullaways Medical Cannabis Survey 2010. Available at website: http://www.mullawaysmedicalcannabis.com.au/survey%202010.html

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The legislation must allow for research which was not covered in the Issues Paper. Limiting the Scheme to current Australian knowledge would leave a Victorian Medical Cannabis Scheme stuck in the past based upon outdated research.

What Victoria requires is a Medical Cannabis Scheme which is regulated and encompasses checks and balances. Australians have not just shown their support for Medical Cannabis. They also support Clinical Trials of Cannabis for Medical Purposes.

A Medical Cannabis Card can be used not only to identify the Medical Cannabis patient but to record their use and treatment results. This would constitute an individual Case Study being undertaken with their Doctor(s) supervision. This data can then be turned into Raw Data for data mining. Data mining would allow Doctors to see for example what the current starting dose is for a treatment for Severe Uncontrolled Epilepsy.

It will also highlight areas where it may not work or work so well. The scheme must encompass checks and balances like this to ensure the improvement of the scheme moving forward.

The legislation needs to ensure companies are able to be involved in Clinical Trials of Medical Cannabis medicines to have them approved for therapeutic use. The legal structure must allow companies to be involved in all aspects of the Medical Cannabis Industry via License. Companies must be allowed to make profits which are not considered profits from criminal activity.

Setting up a Medical Cannabis Industry will take a lot of investment to achieve. It requires infrastructure for the security, cultivation, manufacturing, processing, delivery and reporting of regulated Cannabis/Cannabinoid medications and the removal of criminal convictions from those Licensed to be involved in the Victorian Medical Cannabis Industry.

Data mining of patient usage and outcomes during treatment will allow the research community to determine which Cannabis treatments offer the best outcomes and are cost effective. All Cannabis products must meet the equivalent of Therapeutic Goods Standards for cultivation, manufacturing, distribution and reporting of movement and usage of Cannabis/Cannabinoid medications.

Tinctures, oils, patches, pills, creams, edibles, vaporisers and raw Cannabis are just a few of the many Cannabis medications which must be allowed to be researched and produced in a regulated scheme.

Backgrounnd

Many Governments disregard therapeutic Cannabis use for medical purposes such as managing chronic pain, nausea and appetite but there are a few Governments whom are open to the potential Cannabis brings as a medicine, one of great importance is Israel.[4] (THC, was first isolated by Israeli scientists Raphael Mechoulam of the Hebrew University in Jerusalem's Center for Research on Pain and Yechiel Gaoni of the Weizmann Institute in 1964). The claims of Australian medical Cannabis users of moderate to substantial benefits from the use of Cannabis in the management of their medical condition(s) has been confirmed in 2012 by the research coming from Israel.[5]

[4] See Annexure - Israeli medicine goes to pot. By Karin Kloosterman.
[5] See Annexure - Israeli researchers say more Doctors should recommend Marijuana to Cancer patients. By Dan Even.

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Since the early 1990's Israel has permitted medical use of Cannabis, for Cancer patients and those with pain-related illnesses such as Parkinson's, multiple sclerosis, Crohn's Disease, other chronic pain and post-traumatic stress disorders. Patients can smoke the drug, ingest it in liquid form, or apply it to the skin as a balm. The numbers of patients authorized to use Cannabis in Israel in 2015 is about 20,000.

A strong medical research sector under adequate regulated Government supervision makes Israel one of the world's most Cannabis-friendly countries. There are eight Government-sanctioned Cannabis growing operations in Israel, which distribute it for medical purposes to patients who have a prescription from a Doctor, via either a company's store, or a medical centre. The results have been more than positive.[6] [7]

Israel's strong medical research sector with adequate Government supervision has allowed it to become a leader in medical Cannabis research. Israeli research has shown that medical Cannabis is a safe alternative and adjunct to opioid medications for the treatment of chronic pain, nausea and appetite.

Research by Mullaways Medical Cannabis Pty Ltd in Australia is in agreement with the Israeli experience.

The psychoactive effects of Cannabis are comparatively mild compared to Opioids. Opioids pose a much greater risk of dependence and health risks than the use of Cannabis, even when Cannabis is smoked.

Risks associated with Cannabis relate mostly to the smoking of it. These risks are greatly reduced when quality Cannabis is used rather than street bought Cannabis.

There are many solutions to the risks associated with smoking Cannabis. Smoking Cannabis for medical purposes has nothing to do with recreational use and patterns of use. As highlighted in the Issues Paper the average use of cannabis by Medical Cannabis Patients in Canada, where you are only allowed to smoke cannabis, is 0.5 to 1.5 grams per day. This is not a large amount of cannabis and certainly not the dosage implicated, by some research, to be involved with schizophrenia and psychosis.

One area of interest is the use of Vaporisers to ingest the Cannabis (Cannabinoids) as a non-psychotropic or psychotropic vapour so as to achieve the right amount of relief without the potentially harmful effects of combusting the fibre.

The Issues Paper also highlighted the fact that it is not the strength of the cannabis that brings relief for neuropathic pain but having some cannabis, even low dose cannabis.

The Cannabinoid system is a major neurochemical system whose functional significance has only recently been explored. We are witnessing the beginning of a revolution in Cannabinoid research.

The endogenous Opioid system and the Endocannabinoid system are co-localised in pain-processing regions and Opioids and Cannabinoids exert a synergistic antinociceptive effect. The ability of Cannabinoids to induce antinociception in virtually every animal model of acute or persistent pain

[6] See Annexure - Israeli firm's new medical marijuana. By BBC News, Jerusalem.
[7] See Annexure - Some take Cannabis illicitly, Israelis take it seriously. By Pierre Klochendler.

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evaluated has encouraged researchers to try to better understand this important non-Opioid system of analgesia.[8]

A Regulatory System similar to that recommended in the "**Regulator of Medicinal Cannabis Bill 2014"** before Federal Parliament will be required in Victoria.[9] It is not necessary to reinvent the wheel. TGA Manufacturing, Reporting and Labelling standards will be required. Reporting the movement of Cannabis/Cannabinoids and Cultivation is just a Security issue. Specify the level of Security required and Companies will then be able to meet or better them.

Medical Cannabis in Australia - Mullaways Medical Cannabis Pty Ltd

I am Anthony D. Bower an Indigenous Australian of 59 years of age. In 1982 I was in a motorcycle accident and severely injured my lower back and legs, and as a result was given large doses of Morphine for long periods of time. I didn't like the effects the drugs had on my body so I started looking into other medicines and natural forms of pain relief.

Smoking Cannabis helped my pain a lot and was giving me less side effects, so I started researching Cannabis for my own personal medical use. After the NSW Drug Summit in 1999 it was obvious many Australians were self medicating with Cannabis. The recommendations from the NSW Drug Summit concerning therapeutic Cannabis use indicated the direction research needed to take before Cannabis based medicines would be considered a real option. Alternative delivery methods to smoking the Cannabis were necessary.

In 2003 I was shown how to make medical tinctures and since then have made and researched Medical Cannabinoid Tinctures. (Cannabinoid Tinctures not Cannabis oils - Cannabinoid Tincture being an alcohol or Cannabis oil based liquid infused with non-psychotropic THC).

Since then the Cannabinoid Tincture has been found to help people suffering from many conditions and the effects of Cancer treatments and the like. Patients going through Cancer recovery, HIV/AIDS, Hepatitis C, Sleep Apnoea, Phantom Limb Pain, Crohn's Disease, Emphysema, Glaucoma, and many more conditions.

My culture does not allow me to refuse help to people who ask for it and where I know I can help, as it is, and surely should be, in any civilised culture. So as the results continued to be positive and as the demand grew I decided to bring the operation into line with all State and Federal Laws. To this end I setup the company Mullaways Medical Cannabis Pty Ltd.

Mullaways Medical Cannabis Pty Ltd (Mullaways) is a federally registered company under Australian law, and has been since the 21st of October 2008.[10] Mullaways is the first company established and registered in Australia for the purpose of scientific research, Cannabis education and development of medicines derived from Cannabis for the management of chronic pain, nausea and appetite.

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[8] See Annexure - Endocannabinoid Mechanisms of Pain Modulation. Research by Department of Psychology, University of Georgia, Athens.

[9] See - Regulator of Medicinal Cannabis Bill 2014. Available at website: http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbills%2Fs987_first-senate%2F0000%22;rec=0

[10] See Annexure - Copy of Certificate of Registration of a company issued by ASIC dated 21st October, 2008. Note: Mullaways Medical Cannabis Pty Ltd is a registered company pursuant to the Corporations Act 2001 (*Cth*).

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Mullaways first natural Cannabinoid based medicine, Mullaways Cannabinoid Tincture was designed to be an alternative delivery method for Cannabinoids to the traditional method of smoking Cannabis. It was also designed to assist with the regulation of Anandamide[11] in the human body. There is evidence that Anandamide can serve as a neuromodulator or neurotransmitter on its own or in conjunction with inactive precursors in what has been dubbed the "*entourage effect*".[12] Mullaways also proposes to research and develop other Cannabinoid based medicines including patches, creams, oils and edibles[13] that have therapeutic benefits and that may be delivered more safely and effectively than by smoking Cannabis.

The Mullaways Cannabinoid Tincture contains (no CBD "Cannabidiol" and) less THC ($\triangle^9$Tetrahydrocannabinol) than the Standards, 6mg/kg THC per day, recommended by the FOOD STANDARDS Australia/New Zealand for safe consumption of Hemp Foods by children and adults. The Mullaways Cannabinoid Tincture is lower than the safe scientific standards used worldwide for for hemp foods containing THC.

Mullaways Cannabinoid Tinctures have no recreational value and as such it is only the cultivation and manufacturing of these medications which would require high security. Mullaways has endeavoured to undertake all necessary steps to bring its medical Cannabis Company and Cannabinoid Tincture within a legal framework.

An Application for a Drug Manufacturer's license was lodged with the TGA (Therapeutic Goods Administration) on the 26th November, 2008.

On the 19th February 2010, In compliance with TGA Regulations I, Mr. Anthony D. Bower, Director of Mullaways Medical Cannabis Pty Ltd was found to be a fit and Proper Person.[14]

The TGA requires analysis and toxicity tests to be carried out to evaluate Mullaways Cannabinoid Tincture for its quality, safety and efficacy. This scientific data is required to support Mullaways Application for the Cannabinoid Tincture to be registered as a medicine on the ARTG (Australian Register of Therapeutic Goods).

Mullaways proceeded to register its Cannabis breed "*Cleverman*" with IP Australia (Intellectual Property). The registration of the breed cannot be completed until after a license to cultivate, possess and supply Cannabis plants for the purposes of scientific research, analysis and study is acquired.

The registering of the Cannabis Strains with IP Australia would enable researchers for the first time to truly research Cannabis/Cannabinoids in Australia. This has been a problem also highlighted by the INCB (International Narcotics Control Board). All scientific endeavours are based on the principle of being able to repeat the experiment. Using Cannabis seized by Police is not such a basis. Having IP Australia approved Cannabis strains would be such a basis for scientific research.

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[11] See Annexure - Anandamide definition from Wikipedia, the free encyclopedia.
[12] See Annexure - Review: Taming THC: Potential Cannabis synergy and phytocannabinoid-terpenoid entourage effect. Research by Dr. Ethan B. Russo, GW Pharmaceuticals, UK.
[13] See - Hemp Foods and THC Levels: A Scientific Assessment. Available at website: http://www.hempfood.com/thclimits2a.html
[14] See Annexure - Letter to Mr. Anthony Bower from Mr. Michel Lok, TGA dated 19th February, 2010. (Informing him of his approval as a fit and proper person).

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Mullaways has been making application for a license providing it the authorisation to cultivate, supply and possess cannabis plants for the purposes of scientific research, analysis and study, product development and clinical trialling of ultra-low dose THC and THCA based Cannabinoid Tinctures in NSW since 2008. Over the last 2 years Mullaways has made Applications to not only NSW but VIC, QLD, SA and TAS.

Mullaways currently has an Application before Victorian Health for "authorisation to cultivate, supply and possess cannabis plants for the purposes of scientific research, analysis and study, product development and clinical trialling of ultra-low dose THC and THC Acid based cannabinoid Tinctures for the management of severe uncontrolled epilepsy (SCN1-a gene specific and non-SCN1-a gene specific epilepsy) plus associated Autism and Mitochondrial Dysfunction/Disease". [15]

Mullaways have always been very serious in our endeavours. The committee members from the NSW Upper House Inquiry into "The use of cannabis for medical purposes" congratulated Mullaways for their extensive and comprehensive Submission entered.

Inquiry into the Use of cannabis for medical purposes - Submission from Mullaways:
http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/c1116ff3008721e2ca257b1f00075663/$FILE/0010%20Mullaways%20Medical%20Cannabis%20Pty%20Ltd.pdf

Public Hearing 1st Transcript (11th March 2013) - Mullaways on Pages 31 to 39 of Transcript:
http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/1cc51d45541e94d6ca257b330006073a/$FILE/Transcript%20-%2011%20March%202013%20-%20Corrected.pdf

Mullaways has accumulated experience in the tinctures of hundreds of Australians over a number of years. Patients with a letter from their Doctor, stating they are monitoring the patient's treatment and use of Cannabis for medical purposes.

Mullaways does not use any Synthetic nutrients on the growth of their Cannabis plants as part of the Mullaways Batch Process. They are all grown organically in soil.

Mullaways has not taken any money for the Cannabinoid Tincture it has given to people. I have never charged anyone for my medicine.

150 users of the Mullaways cannabinoid Tincture participated in a Survey In 2010 concerned with the outcomes of this use. The results were very positive. Patients with Chronic Pain, Cancer, Multiple Sclerosis and Glaucoma experienced 20-60% reduction of pain and reported less use of other Opioid medicines. Relief of nausea and other symptoms was reported for Chronic Pain, Cancer, Multiple Sclerosis, Glaucoma, HIV and Diabetes.[16] Mullaways will research how much more THCA[17] will be needed to achieve further pain reduction than that achieved with the Mullaways Cannabinoid Tincture alone.

It is of note, that many patients with conditions such as alcohol dependency reported lower alcohol consumption while using the Cannabinoid Tincture.

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[15] See Annexure - Application before Victorian Health for the management of severe uncontrolled epilepsy (SCN1-a gene specific and non-SCN1-a gene specific epilepsy) plus associated Autism and Mitochondrial Dysfunction/Disease

[16] See Annexure - Mullaways Medical Cannabis Pty Ltd, Patient Survey 2010.

[17] See Annexure - Direct NMR analysis of Cannabis water extracts and tinctures and semi-quantitative data on $\triangle^9$-THC and $\triangle^9$-THC-acid. Research by Department of Pharmaceutical and Biological Chemistry, The School of Pharmacy, University of London, UK.

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Mullaways Cannabinoid Tincture may prove to be of immense value to the Australian Health system, providing adequate pain relief to many chronically ill and dying patients without the common side effects experienced through regular use of pain relieving medicines currently on the market and used in many hospitals today, such as Morphine and other common Opioids.[18]

Mullaways has developed a natural low dose Cannabinoid-derived medicine for the treatment of a range of conditions. Mullaways has cross-bred different types of the Cannabis plant to produce new strains that can be used to develop more effective medicines to treat particular medical conditions.[19]

An advantage of this type of low dose approach is that the patient is not impaired by a psychotropic effect which may be the case with very much high strength THC products. As they are not impaired by a psychotropic effect of their medication they can drive without endangering the public and would be able to function in the workplace. These are fundamental rights in Australian Society and should not be taken away without solid scientific proof of impairment and after lengthy discussions with the public to ensure it is their will.

The Mullaway Cannabinoid Tincture should be considered a first line treatment for severe uncontrolled epilepsy, autism and for many of the other illnesses it has been used to treat. It has been used as an Emergency Medication by parents of children with severe uncontrolled epilepsy to stop the onset of seizures or to stop a seizure already in progress. Within an hour or two of administration of the Emergency dose the children are playing and normal again and not in bed for the rested of the day.

It is of note, that Mullaways does not claim its Cannabinoid Tincture to cure any disease. The Tincture is a preventative drug for ongoing health maintenance, and was designed as a natural way (medicine) to help manage/alleviate chronic pain, nausea and appetite.

Mullaways Cannabinoid Tincture - Delta 9 THC content

Analysis of Mullaways Cannabinoid Tincture reveals a rich blend of Cannabinoids but with a low Cannabinoid concentration.

Mullaways Cannabinoid Tincture contains 38ppm (parts per million) of total THC. This is lower in THC content than that of the total daily dose of THC recommended by FOOD STANDARDS Australia/New Zealand as safe for children and adults to consume in hemp foods products. These standards have been used safely throughout the world in hemp foods for a number of years.

Tara O'Connell Case Study – Mia Mia Girl 24 months seizure free, but who cares?

The reason this Commission was formed is because of the growing support in Victoria and Australia for a regulated Medical Cannabis Program. A large majority were already in favour but the much publicised stories of children suffering from Severe Uncontrolled Epilepsy like Tara O'Connell, Mia Mia girl, from Victoria, has captured the attention of a nation, and highlights the need to put into place the proper regulatory system to allow the prescribing of regulated medical Cannabis/Cannabinoid based products.

(Just to recap Tara's case study)...

[18] See Annexure - Two distinctive antinociceptive systems in rats with pathological pain. Research by MGH Pain Center Department of Anaesthesia and Critical Care, Massachusetts General Hospital, Harvard Medical School, Boston USA.
[19] See Annexure - Cannabis Genome Uncloaked: Commentary on the Scientific Implications. Research by Dr. Ethan B. Russo, GW Pharmaceuticals, UK.

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Born in 2005, Tara O'Connell wasn't expected to live to the end of 2013 or to see her 9th birthday...Tara required 24 hour care. She has such a rare disorder that officially it doesn't have a name. The closest known disorder is Dravet's Syndrome. This is similar but Tara was progressing downhill much quicker - Dravet Syndrome is the most catastrophic Epilepsy known with many children dying from it every year. Tara was suffering from 5-10 clonic tonic seizures a day plus 5-6 nocturnal seizures a day and half hourly absence seizures, every day, averaging 65-500 seizures daily (that's over 23,000 seizures a year!) and no treatment had worked to control them. Tara also suffered Autism, Dysphragia, Dyspraxia, Intellectual Disability, Hypotonia, Severe Language Disorder, had a Heart Murmur, and was diagnosed with Drug induced Anorexia, brought on by prolonged use of the Pharmaceutical drug "*Epilim*", Tara was taking 5 different medications, 18 tablets a day of serious medication. She mainly used a walking frame to get around, could not walk more than 200 metres unaided and relied heavily on family members and carers for her everyday needs. She wore a helmet and diapers daily, could barely put a sentence together, and had not slept a single night in her own bed by herself without climbing into her mother's bed during the middle of the night since being a toddler. Doctors/Specialists even informed the family she would never be able to learn to read. She had been resuscitated 8 times (4 times in 5 months). Her Doctors/Specialists informed the O'Connell family the seizures were so severe that without the ability to gain seizure control, to slow or stop the seizures, Tara would continue to suffer massive brain damage and eventually die. The Doctors/Specialists expected Tara at 7 years of age to die within the next 6 months. The family were told her IQ was now too low to score dropping from 82 points four years earlier and her brain had begun to shut down. Most of her waking hours were spent either in her wheelchair or with her walking frame and her oxygen tank could not leave her side. The longest Tara had ever gone seizure free, on any Pharmaceutical medication, was 6 days...

On the first day of taking Mullaways Cannabinoid Tincture, 27th January 2013, she had suffered only 3 minor seizures. 12 days into the treatment and with some adjustment to the dosage she then went seizure free for 55 days, from the 8th February 2013 to the 3rd April 2013. This seizure was a very minor one, about 90secs compared to her average which was around 4-5mins and it was less violent. This would be Tara's last seizure. As of the 4th of April 2015 Tara is 24 months *SEIZURE FREE*.

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That's 26 months suffering 1 minor seizure since starting the Mullaways Cannabinoid Tincture Treatment plan. (That's 730 days seizure free!)

Tara has not had to be resuscitated again. She was weaned off all Pharmaceutical medications, from 18 tablets a day to zero. Her last dose of Pharmaceutical medications was on 30th June 2013. So for the last 22 months Tara has ONLY taken Mullaways Cannabinoid Tincture and since has started to learn again. She can now write her name, spell most three letter words and can memorise a basic text. She is able to pronounce all the 'at,an,ag,ap words such as appropriate which were out of her depths before but now are becoming more common in her speech. She has received her schooling level 10 certificate for reading. Tara can now read books. She no longer uses her walking frame. She has even been able to stop wearing the helmet and diapers and has become toilet trained both day and night. She has learnt to sleep in her own bed and for the first time in over 7 years slept in her own bed all by herself 7 nights in a row, until 7am. Her heart murmur is gone. She no longer suffers Drug induced Anorexia, Tara is now at a normally healthy weight/height range. She is feeding herself and her need for thickened fluids is gone. She has even been able to preform such motor skill tasks on her own as riding a bike, for the first time in her life. She has been rock climbing and has achieved her "Swim & Survive, Active" Royal Life Saving) level D3 certificate for swimming, and has also recently been given a new IQ test, in which she scored a "measurable" IQ once again (59 points. Tara's IQ is no longer "to low to score".

In the words of Cheri O'Connell the child's mother..."Today marks 23 months seizure free for our little darling, Tara...Medical Cannabis has been our miracle drug...She is such a different child and not just in the way of no seizures, but more alert, switched on, better mobility and NEVER shuts up now, I would be happy if even just these things had happened, although we are ever so grateful for the seizure control too...Tara will always be 'special' but her quality of life is fantastic now. I would never go back, I am so glad that 26 months ago we took the plunge and became the first Aussie family to openly use medical cannabis for Epilepsy...Thanks Tony for letting us finally meet the real Tara...Thanks for changing our lives".

A Neuro-Psychologist wrote of this child's case study: ***"There is a convincing clinical history of improvements."***

While A Paediatric Neurologist wrote of this child's case study: ***"As nothing short of miraculous."***

This child's miraculous story was featured on several news stories over the past year and can be viewed at: https://www.youtube.com/watch?v=mKwTy0tIyEw (The Feed, SBS).

Tara's Medical Case Study can be viewed below: (As outlined on the adjacent Pages 16-22).

NOTE: Tara has been able to wean all of her pharmacy drugs (5 medications, 18 tablets a day). It is important to understand that these 5 antiepileptic drugs have never been clinically trialled together via use as combination medications and especially clinically trialled on children. Each of the antiepileptic drugs cause a range of differing side-effects and the combining of these drugs compounds the problems further.

NOTE: Mullaways Cannabinoid Tincture has been used by Australian parents as a emergency rescue medication during active seizure events and has caused children to stop seizing immediately during events and with only oxygen given, has seen children up and playing happily minutes after a seizure.

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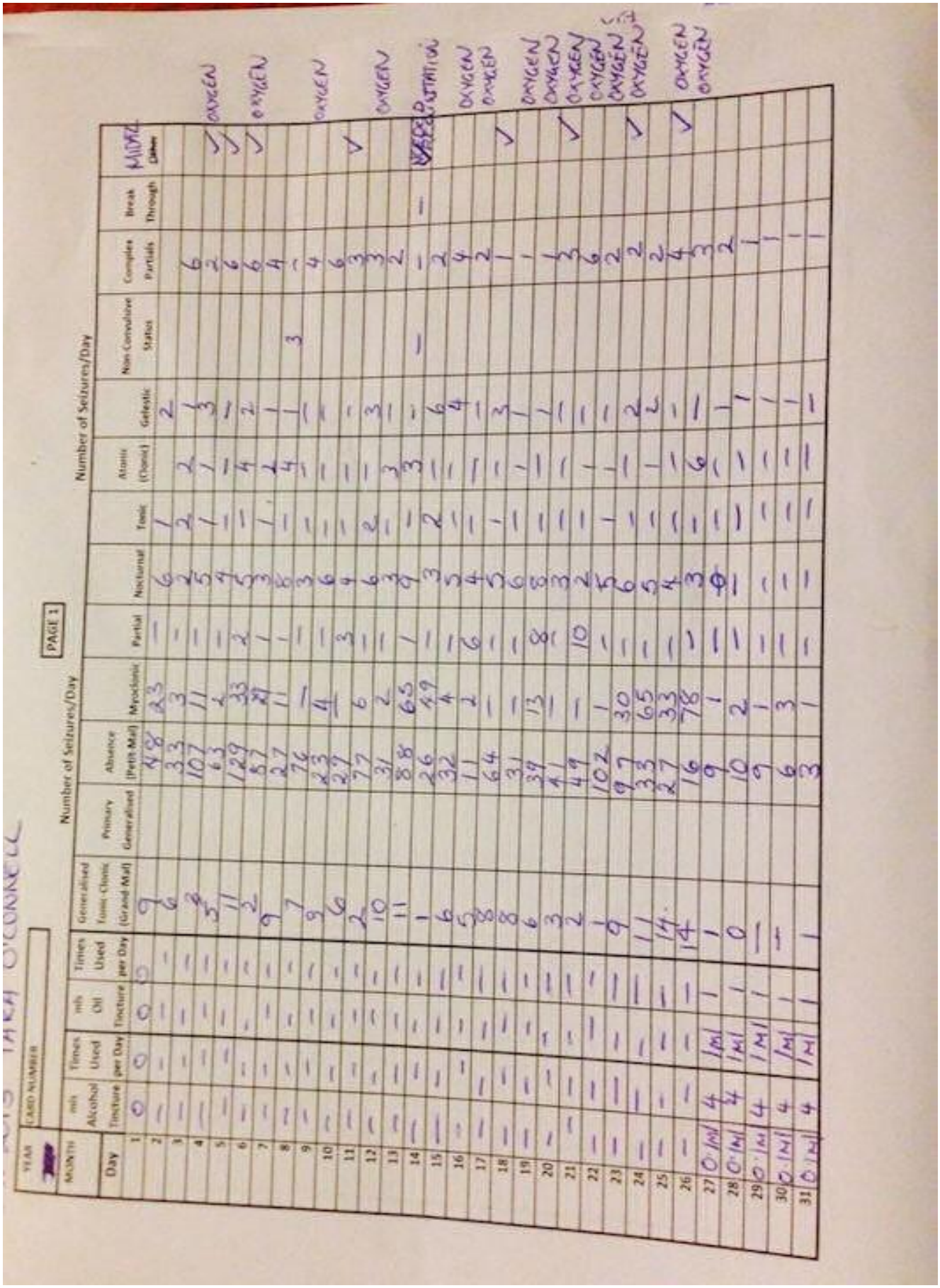

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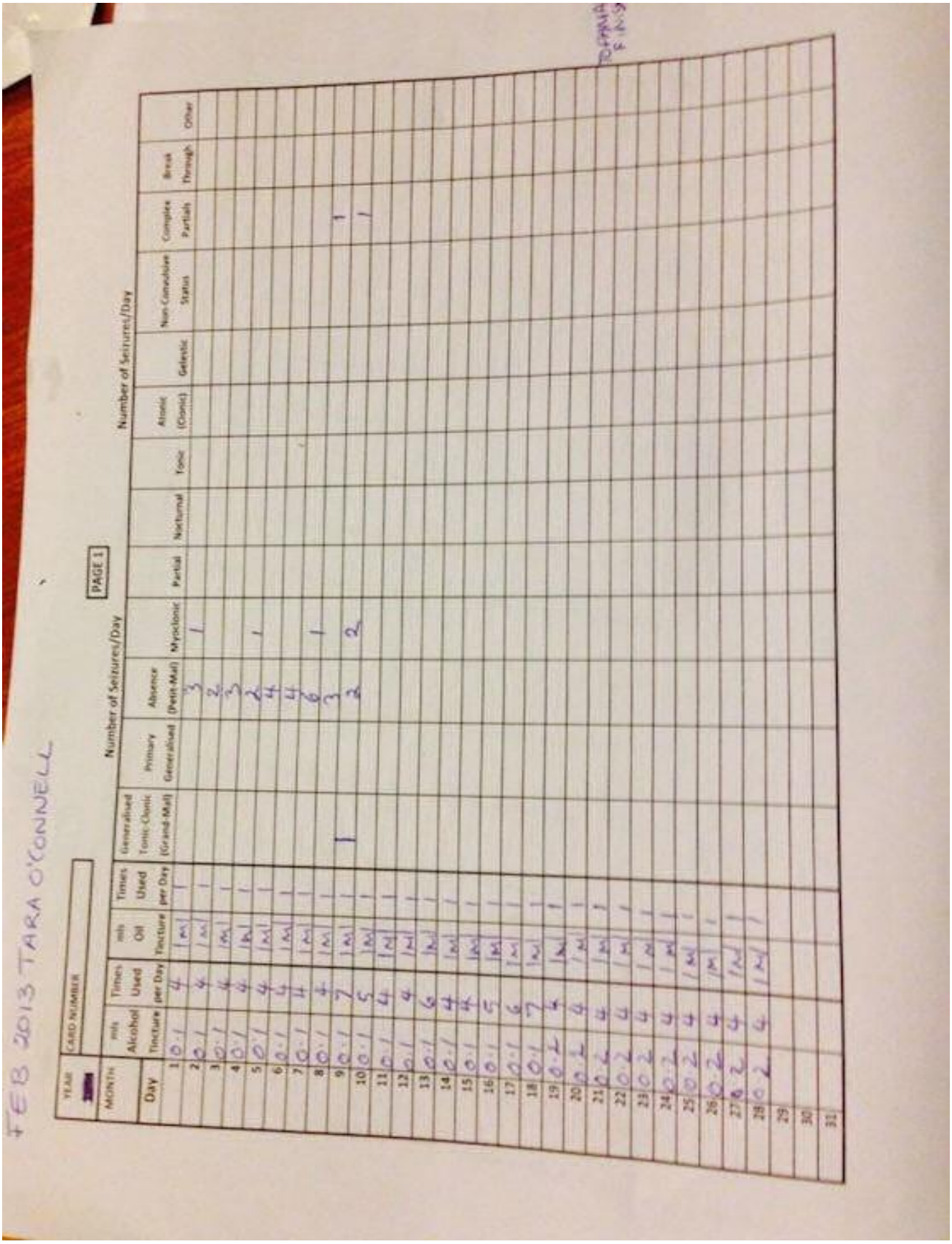

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Dr Lindsay J Smith
FRACP
Melbourne Child Neurology

12/212 Clayton Rd
Clayton Vic., 3168
Phone: 9542 0000
Fax: 9545 5355

04 March 2013

Dr Paul Carter
17 High St
Lancefield VIC 3435
5429 1331

Dear Paul

Re: Tara O'connell
63 Blacksmith Lane, Mia Mia VIC 3444
DOB: 20/06/2005
Diagnosis: 10/09/2005 Generalised convulsive epilep. 10/09/2005 FH: Epilepsy
Medications:

Clonazepam 0.5mg ¼ at night	Stop in 2 weeks
Clobazam 10mg 1 twice day	Stop August
Epilim 200mg 2 morning & night	
Topiramate 25mg 1 twice day,	May night only, stop June.
Ethosuximide 250mg/5mL 5mls twice day	Stop September
Midazolam 5mg/1mL 4mg nasally for sz > 7 minutes	

Tara returned with Cheri Sean and Jasmine.

Findings: Cheri is one of those unstoppable forces of nature. Following a very bad run of seizures with hospitalisation at the Children's Hospital, mother has sourced medical cannabis from New South Wales in a liquid form 0.1 ml four times a day and then a different concentration of one ml at night-time. This has been at this point in time, nothing short of miraculous.

She has not had any seizures for the last three weeks. She looks extremely well the most focused stable in her fine and gross motor control that I have ever seen. The clonazepam which is at 0.125 mg twice a day will drop to 0.125 mg at night for the next two weeks then stop.

A reduction in the rest of the medicine as listed above.

I think it is unlikely she will totally come off medication but if we can just get down to Epilim that would be fabulous

Today the measurements height 129 cm weight 25 kg.

Follow- Up: 09 September 2013 at 11:30:00 AM

Best wishes and kindest regards,

Lindsay J Smith

Copy: Parents
Prof. Ingrid Scheffer Neurosciences, 246 Clayton Rd, Clayton VIC 3168
Med Rec RCH 1149214R

This letter has been directly generated by voice dictation and my digital signature is encoded.

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Dr Lindsay J Smith
FRACP
Melbourne Child Neurology

12/212 Clayton Rd
Clayton Vic., 3168
Phone: 9542 0000
Fax: 9545 5355

09 September 2013

Dr Paul Carter
17 High St
Lancefield VIC 3435
5429 1331

Dear Paul

Re: Tara O'connell
63 Blacksmith Lane, Mia Mia VIC 3444
DOB: 20/06/2005
Diagnosis: 10/09/2005 Generalised convulsive epilep. 10/09/2005 FH: Epilepsy
Medications: medical cannabis Liquid 0.2ml 4 times day
medical cannabis Night Liquid 4mls night

Tara returned with Cheri.

Findings: It is certainly impressive to see her coming in, holding a conversation and playing quietly with good concentration. She is now reading at level 5 at school, she was assessed several years ago as having an IQ **too low to measure.**

She has not had a seizure for five months, the medical cannabis is supplied free of charge from Nimbin and I need to write to both the Victorian Health Authority and the Medical Board to just find out what the status is. I do not "prescribe it as such" I merely confirm that she has intractable epilepsy.

There certainly does not seem to be any side-effects, some people have said that she is moody but I think that is just the emergence of her personality from the fog of medicine and seizures. We worked out roughly that the monthly cost of the five prescription medicines, the non-PBS clobazam and midazolam was in the order of 90/$100 per month.

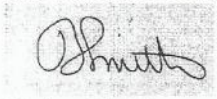
Today the measurements are Height: 130cm Weight: 27.0kg Head Circumference: 53cm.

As John Laws famously said in his radio ads "when you're on a good thing stick to it".

I issued an epilepsy plan for her and her brother stating that midazolam was no longer required.

Follow- Up: 27 March 2014 at 02:30:00 PM

Best wishes and kindest regards,



Lindsay J Smith

Copy: Parents
Prof. Ingrid Scheffer Neurosciences, 246 Clayton Rd, Clayton VIC 3168
status of the chromosome investigations?
Dr Phil Rosengarten 122 David St, Dandenong VIC 3175
Med Rec RCH 1149214R

This letter has been directly generated by voice dictation and my digital signature is encoded.

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Austin Health

U.R. Number 2053810
Surname O'CONNELL
Given Name(s) Tara
Date of Birth 20/06/2005
AFFIX PATIENT LABEL HERE

REFERRED BY: (Print Name) WARD/UNIT/CLINIC: DATE 18 11 13

FAH053000

CONFIDENTIAL
NEUROPSYCHOLOGICAL ASSESSMENT REPORT

This 8-year-old girl with a history of intractable epilepsy and an Autism Spectrum Disorder (PDD NOS) was seen in the Department of Clinical Neuropsychology on the 11th November, 2013 for a review of her neuropsychological functioning. She was accompanied to the session by her mother, Sheri.

Tara is well known to our department, having been seen in January, 2012, and last reviewed in December, 2012 (i.e., 12-months ago). At the time of her last review, there was a pattern of *generalised decline* in cognitive function (between January – December, 2012), in the context of daily absence and myoclonic seizures and tonic clonic events occurring approximately every second day. At that time, Tara was also on multiple anticonvulsant medications. She was exceedingly difficult to engage in formal testing and her cognitive results were modest, at best. The finding of cognitive regression, at that stage, was supported by the reports of functional deterioration noted by her mother and increasing difficulties at school described by her teachers. In view of the findings to emerge on testing, a 12-month neuropsychological review was recommended to monitor her cognitive function over time.

At review on this occasion, Sheri pleasingly described that Tara has remained seizure free for at least 7 months. As I understand, Tara was commenced on medical cannabis at the end of January of this year and her 'conventional' antiepileptic medications were gradually weaned between January – June, 2013. She currently takes 0.2mls of medical cannabis four times per day and 4mls at night. The only side effects related to the medical cannabis have been a heightened appetite and an increased need for sleep.

Sheri described "massive changes" in Tara since her epilepsy has become controlled. Cognitively, she is now reading at a Level 5 level at school. She can count, can recognise most of the alphabet, and has some sight words. She is able to write her first name and most of her surname. Her drawing skills have also improved, as has her language output (she is now speaking in full sentences). I note that she is no longer attending a dual schooling program (i.e., mainstream + specialist school). She now attends Langley Primary School (mainstream) three days per week, and is home-schooled for two days. She is currently in Grade One, and has full-time integration aide assistance at school. She also has fortnightly Speech Pathology intervention, as well as a Visiting Teacher who attends on a weekly – fortnightly basis. Whilst fatigue continues to be an issue, this too has improved, with Tara no longer having to sleep at school (which she was previously doing).

Socially, Tara now has friendships, although she still tends to interact with other children who have special needs. Functionally, she is now completely toilet trained during the day, and although she wears a nappy at night, she is only wet approximately once per week. She is no longer on a thickened diet, and eats a fairly normal diet. She can mostly feed herself. She is reluctant to shower but will shower with her sister's assistance.

Behaviourally, Tara has also improved a great deal. Although she continues to have daily "tantrums", Sheri feels that her outbursts are much shorter and more manageable. Overall, she was described as "much more calm" now, and far more willing to "entertain herself". Tara's interests have also become increasingly more age-appropriate.

I undertook a phone interview with Tara's current classroom teacher, Vicki Nettleton. Vicki similarly described that Tara has shown "huge improvements across the board" since earlier this year. She is far more engaged at school and is happy to participate, including in group situations. She remains on an Individual Learning Plan,

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and has full-time integration aide assistance, which works very well. She is now reading published texts (rather than listening to dictated material only) and her understanding of numbers is also steadily improving. Vicki believes that Tara probably functions academically at a prep-level standard. Vicki has also noticed gains in Tara's gross motor skills, with perhaps less obvious improvement in her fine-motor control. Socially, she is more engaged with other children, will often seek other children out to play, and is far more assertive in the social context. She has developed a particularly close relationship with one other girl, who unfortunately is soon to leave the school.

EXAMINATION FINDINGS

Tara was in much better form when I saw her on this occasion. Qualitatively, she looked much brighter, happier and generally 'more available' than she had been at the time of previous assessments. She was no longer wearing her helmet (which had been a consistent feature), and she volunteered much more in the way of spontaneous speech, at times speaking in full sentences. Although she tended to become 'squirmish' when tasks became difficult for her, she was far more readily engaged in the formal assessment process on this occasion. Sheri remained in the room, which was very helpful as she was also able to encourage Tara to persist with tasks. From a basic attentional point of view, Tara remained somewhat distractible and instructions needed to be repeated and simplified at times. Behaviourally, she impressed as a little immature, but was otherwise appropriate at all times. Her walking style appeared more robust on this occasion, and she was far less tremulous when completing fine-motor activities.

On formal examination, Tara's overall cognitive performances were significantly improved on those documented 12-months ago. This improvement was noted at both a qualitative and quantitative level.

Whilst her overall intellectual score was consistent with a mild intellectual disability (WISC-IV Full Scale IQ = 59, 0.3rd percentile), this overall score masks variability in her intellectual profile. Specifically, Tara's verbal and nonverbal intellectual skills fell broadly within the 'borderline' range of the scale. Against this background, and in keeping with her clinical presentation, her attention/working memory performances were significantly degraded ('extremely low' range), and these served to reduce her overall intellectual quotient.

Tara's processing speed abilities fell within the 'borderline' range, as did her visuo-motor integration skills (which underlie her ability to draw).

On tasks of academic function, Tara's performances were consistent with approximately a *5½-year-old* equivalent level across tasks of both literacy and numeracy. On this occasion, she was able to identify all the letters of the alphabet presented to her (with the exception of 'i'). She was able to work with the beginning and ending sounds of words (albeit somewhat inconsistently) and she showed knowledge of letter-sound relationships. She was also able to read some high frequency words (e.g., *you*, *the*, *up*, *so*). On a task of writing, she was able to confidently write her first name, and needed a little assistance with her surname. She demonstrated knowledge of single consonant letter/sounds relationships (*g* sound in gate), but struggled with consonant letter/cluster sound relationships (e.g., *bl* sound in black). She was able to write the word 'is' but otherwise struggled with all other words presented to her. Mathematically, she could discriminate numbers and write single and double digits numbers. She was also able to count by rote and write numbers to correspond to her rote counting. She was unable to complete any written sums (e.g., *3 + 3*) and seemed reluctant to use her fingers to assist (despite encouragement). Tara was able to apply mathematical concepts to 'real life' examples at an elementary level (e.g., using whole numbers to describe quantities, using geometric and spatial reasoning to solve problems, using grids/graphs to make comparisons, tell the time).

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Austin Health

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OPINION

It is wonderful to see that Tara is no longer having seizures and has been weaned off her 'conventional' anticonvulsant medications. Since commencing medical cannabis (together with the cessation of her seizures), there is a convincing clinical history of improvement in all facets of her presentation as reported by her mother, and this account is thoroughly corroborated by her teacher's report.

On formal neuropsychological review, Tara has shown remarkable improvements in her cognition over the 12-month period of review (i.e., December 2012 – November, 2013). This improvement is obvious at both a qualitative and quantitative point of view, and is quite striking. Qualitatively, she presents as much more 'available' and engaged, and this is reflected in her objective scores. Intellectually, her core skills (i.e., verbal and nonverbal intellectual skills) fall approximately within the 'borderline' range, although her attention/working memory skills remain 'extremely low' (which serve to reduce her overall IQ score). Academically, she currently functions at approximately a *5½-year-old* equivalent level across tasks of both literacy and numeracy.

Despite the encouraging improvements, it must be duly acknowledged that Tara has a fair degree of academic 'catch up' ahead of her. To this end, it is envisaged that she will continue to require the assistance of full-time integration support at school for the foreseeable future. It is hoped that, in the context of no seizures, such additional one-on-one assistance will translate into 'real' gains at an academic level moving forward.

At this stage, I would like to 'touch base' with Sheri and Tara in early 2015 (when I return from maternity leave) to see how she is progressing from a cognitive/academic perspective. A further formal neuropsychological review may or may not be warranted at that time.

DR. SILVANA MICALLEF
Senior Clinical Neuropsychologist
(tel: 9496-2424; silvana.micallef@austin.org.au)

c.c. *Dr. Lindsay Smith, Paediatric Neurologist, 11/212 Clayton Road, Clayton, 3168*
Professor Ingrid Scheffer, Paediatric Neurologist, Melbourne Brain Centre, Austin campus
Mr. and Mrs. O'Connell, 63 Blacksmith Lane, Mia Mia, 3444 (additional copy given for school files)
SMR, Austin Health

Clinical Neuropsychology

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Mullaways uses a high THC strain of cannabis to produce an ultra-low dose THC-THC Acid medicine which ensures a safe low cost medication. The Mullaways Cannabinoid Tinctures are not Cannabis oils. The Cannabinoid Tincture is an alcohol or hemp seed oil based liquid infused THC which is to be administered easily and safely through oromucosal use. The Mullaways Cannabinoid Tinctures have no recreational value and as such it is only the cultivation and manufacturing of these products which will require high security.

The Mullaways Non-Psychotropic Ultra-Low Dose Cannabinoid Tincture makes use of the body's biphasic dose response to an environmental agent typically characterised by a low-dose stimulation and a high dose inhibitory effect. The Biphasic Effects of delta-9-tetrahydrocannabinol (THC) and Anandamide have been reported.

Comprehending the Biphasic Effects of THC and Anandamide is essential in understanding how the on-demand activation of the endocannabinoid system controls neuronal excitability and epileptiform seizures and how this response can be used therapeutically to stop seizure activity.

The low dose stimulation is a measure of biological performance and not toxicity. It determines how much a system can respond. The hermetic low dose response employed by Mullaways ensures the Safety of the Tincture even for long term use.

This Case Study highlights what is required to be regulated to implement a Medical Cannabis Scheme which is coherent, humane and which will achieve clear health benefits to all Victorians citizens.

Question 1)

Which of the following considerations should determine whether there are exceptional circumstances for medicinal Cannabis to be made available to a patient?

a) The circumstances of the patient;

b) The state of clinical knowledge about the efficacy or potential efficacy of using Cannabis in treating the patient's condition;

c) Both of the above;

Answer 1)

In an ideal world both would be the preferable choice, but here in Australia that is not the case right now. Going on the overseas experience, from countries like Israel, patients ranging in age from children through to the elderly are using Cannabis medications under medical supervision to achieve better patient outcomes. A medical Cannabis regime which caters to patients care under regulated Doctors supervision is achievable in Victoria.

Cannabinoid/Cannabis based medications made at such ultra-low doses of Cannabinoids that it falls in the range of hemp foods, such as hemp seed oil, lower in total THC content than that of the total daily dose of THC which FOOD STANDARDS Australia/New Zealand has recommended as safe for children and adults to consume in hemp foods products must be considered as a safe Therapeutic dose.

The concept that drugs exert their beneficial effects by hormetic mechanisms of action can be traced to the 16th century and a Swiss chemist and physician called Paracelsus who wrote "***All things are poison and nothing is without poison, only the dose permits something not to be poisonous***".

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In 1988 after a two-year hearing to reschedule cannabis
U.S. DEA Chief Administrative Law Judge, Francis L. Young, said:

"Nearly all medicines have toxic, potentially lethal effects. But marijuana is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality ... Simply stated, researchers have been unable to give animals enough marijuana to induce death ... In practical terms, marijuana cannot induce a lethal response as a result of drug-related toxicity ... In strict medical terms marijuana is far safer than many foods we commonly consume ... For example, eating 10 raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death ... Marijuana, in its natural form, is one of the safest therapeutically active substances known to man ... By any measure of rational analysis marijuana can be safely used within the supervised routine of medical care ... It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance."

Cannabinoid/Cannabis based medications made at higher level doses than that recommended as safe by the FOOD STANDARDS Australia/New Zealand should be regarded in similar fashion to that of opium medications. Higher dosage level medications should require further Doctor's supervision and medical data retention. Conventional Australian medicine allows patients access to opium products under a regulated medical regime with supervision via Doctors monitoring the patient's condition. Higher dosage level Cannabis based medications have a place in a regulated medical regime with Doctors supervision. Patients such as those suffering high levels of pain may require much higher levels of THC medications to achieve pain relief. It must be remembered a medical patient is not attempting to get high they are attempting to relieve their pain and suffering.

Question 2)

For what conditions is there sufficient knowledge of the therapeutic benefits, dangers, risks and side effects of Cannabis to justify allowing sufferers to use it lawfully in Victoria?

Answer 2)

In 2013 the NSW Upper House Inquiries parliamentary report recommended allowing the medical use of Cannabis under certain circumstances, for a limited range of medical conditions. One Submission to the NSW Inquiry, *Cannabis & Chronic pain: The Poor Mans Analgesic by Dr Ian Webster AO (Emeritus Professor of Public Health and Community Medicine, from the University of NSW)* pointed heavily to the current trend in patients self medicating using Cannabis via the black market. In his submission the well respected Dr Webster states:

> "This submission is based on the clinical management of patients with continuing chronic pain. It is an attempt to portray the predicaments of these patient's and to argue that because of their needs they turn to Cannabis for symptom relief.
>
> I am aware of the public health epidemiological evidence about Cannabis; the prevalence rates, its adverse effects and the evidence of the relationship to mental disorder(s) and physical conditions. This submission accepts that others will submit analyses and views of the wider issues not canvassed here.
>
> However, I want to add to the other evidence before the committee the dimensions of the lived experience of people from disadvantaged communities and backgrounds who struggle to manage their lives in the presence of unremitting pain.
>
> Purpose:
> To highlight for the committee that, in clinical practice, it is common to encounter patients with unremitting pain who use Cannabis to deal with pain, its sequelae and associated health problems.

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To propose that persons, who out of necessity and with some benefit use Cannabis, need to be protected by legislation rather than being criminalised by existing law.

In Control, Not addicted:
Each patient managed their drug use in order to relieve or ameliorate pain and/or the modulation of the distress, anxiety and dysphoria secondary to continuing pain. They were fully aware of the negative aspects of drug use and used Cannabis sparingly.

They were seeking assistance to better manage their lives. In these patients the effects of chronic pain on day-to-day functioning and quality of life had features similar to patients diagnosed as sufferers from the mental condition - depression. The principal difference being that in pain patients the suffering is attributed to a physical condition although not necessarily cause by a physical condition.

Self-Management:
Each patient tailored their personal use to minimise unpleasant symptoms setting this against being able to function in day-to-day living and the harmful effects of chronic pain on interpersonal relationships, mental and physical health.

Effectively the patients were self-managing a chronic relapsing health problem in much the same way as those with other chronic conditions, such as diabetes and asthma, are encouraged to do.

Beneficial effects on symptoms:
In addition to the personal experiences reported by patients using Cannabis there is a large body of literature which indicates that components of Cannabis can have beneficial effects on pain and mental distress. I have referred to some of the evidence above. This is an on-going area of research and development around the world.

Summary:
The problem of unremitting pain is ubiquitous and Cannabis in the form of marijuana is readily available in most of Australian communities. Given that the population problems of chronic pain will increase and, to this point, chronic pain is an intractable problem it is inevitable that a proportion of patients, for their own reasons, will turn to Cannabis use as a way of ameliorating their suffering.

Whatever recommendations the committee might make, the least that should happen is that a person using Cannabis to deal with persistent pain should be protected within the legislation from being dealt with by the criminal justice system."

Dr Ian Webster's submission can be viewed at:
http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/478366553b04b0afca257b2700149981/$FILE/0108_Dr_Ian_Webster_AO%5B1%5D.pdf

With Victoria's population at around 5.8million, that's roughly 1.2million Victorians suffering daily in chronic pain and/or suffering.

It is time to implement a regulated Medical Cannabis Scheme to improve Victorian's health and to protect them from criminalisation while doing so.

Regarding the Single Convention on Narcotic Drugs 1961,
to which Australia is a signatory.

It is really important to understand that one of the fundamentals of the preamble,
(the second one in fact) of *the Single Convention on Narcotic Drugs 1961*, states:

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...recognising that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...

This was reaffirmed in March 2010 by the United Nations Commission on Narcotic Drugs.

Striking the right balance to achieve the optimal public health outcome.

At the 53rd session of the Commission on Narcotic Drugs (CND) held in March 2010, the Commission adopted Resolution 53/4 "Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse."

The Commission recalled the recognition of parties to *the Single Convention on Narcotic Drugs 1961* as amended by the 1972 Protocol:

"That the medical use of narcotic drugs continued to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability for such purposes."

Convention control measures to ensure safety and availability (Page 7)

The objective of the international drug Conventions - balance between ensuring availability and preventing diversion and abuse - is promoted by an international regulatory system that provides the framework for national drug regulation. Pursuant to the international regulatory system, States agree to adopt certain regulatory requirements.

The control provisions of the Conventions are designed to (a) ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and (b) combat illicit manufacture, trade and distribution.

They are designed to serve what the INCB has described as the overall goal of a "well functioning national and international system for managing the availability of narcotic drugs and psychotropic substances" namely" to provide relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, to prevent the diversion of drugs for the purpose of abuse."

This Commission must also take into account **The Common Law and Doctrine of Informed Consent.**

The legal recognition of the principle that "every human being of adult years and sound mind has the right to determine what shall be done with his own body" predates modern constitutional jurisprudence.

1. In 1765 Blackstone described a common law right to bodily integrity as including a right to "the preservation of a man's health from such practices as may prejudice or annoy it."

2. Courts here and overseas have consistently upheld the right of the individual to decide how to protect his or her own body and have rejected claims that the medical profession or the State has a right to impose, withhold or dictate an individual's medical treatment.

In Australia, the same Doctrine has been affirmed by superior courts. In F against R the Supreme Court of South Australia considered a surgeon's duty to inform the patient of the risk that an operation will not succeed in its aim. Chief Justice King stated:

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"The Governing consideration is the right of every human being to make the decisions which affect his life and welfare and to determine the risks which he is willing to undertake."

In Rogers and Whitaker the High Court stated that the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to "the paramount consideration that a person is entitled to make his own decisions about his life"

In regards to the application of drug laws against medical users of Cannabis, this contention is consistent with the important and well established principle of statutory interpretation, affirmed by Gleeson CJ, Guadron, Gummow and Hayne JJ in *Daniels Corp vs ACCC, and referred to with approval by the Queensland Court of Appeal in Meredith vs State of Queensland.*

"It is now well settled that statutory provisions are not to be construed as abrogating important common law rights, privileges and immunities in the absence of clear words or necessary implication to that effect."

In Re Bolton; Ex Parte Beane, it was expressed in this way:

"Unless the Parliament makes unmistakably clear its intention to abrogate or suspend a fundamental freedom, the courts will not construe a statue as having that operation."

In Bropho vs Western Australia, citing Potter vs Minahan, the practical foundation for this principle was explained as lying in the fact that it is:

"In the last degree improbable that the legislature would overthrow fundamental principles, infringe rights, or depart from the general system of law, without expressing its intention with irresistible clearness; and to give any such effect to general words, simply because they have that meaning in their widest, or usual, or natural sense, would be to give them meaning in which they were not really used."

The Single Convention on Narcotic Drugs 1961, the United National Commission on Narcotic Drugs 2010 and the Common Law Doctrine of Informed Consent all hold one common truth, their primary legislation does NOT take away from ones fundamental right of choice over ones body and ones overall care. With these fundamental human rights taken into consideration the following internationally recognised illnesses/conditions, effectively treated by Cannabis should be authorised under the Victorian Medical Cannabis Scheme to allow people to be treated with medicinal Cannabis in exceptional circumstances;

1. *Epilepsy and/or Severe Uncontrolled Seizures (SCN1-a, gene specific and non-SCN1-a gene specific Epilepsy)*[20]
2. *Autism and/or Fragile X Syndrome*
3. *Cancer*
4. *A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes severe and Chronic Pain*

[20] See Annexure - Activation of the Cannabinoid type-1 Receptor mediates the anticonvulsant properties of Cannabinoids in the Hippocampal Neuronal Culture Models of acquired Epilepsy and status Epilepticus. Research by Department of Neurology; and Department of Molecular Biophysics and Biochemistry; and Department of Pharmacology and Toxicology, Virginia Commonwealth University, USA.

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5. *A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes severe Nausea, including but not limited to, Patients undergoing Chemotherapy*
6. *Human Immunodeficiency Virus and/or Acquired Immune Deficiency Syndrome (HIV/AIDS)*
7. *Hepatitis C*
8. *Skin Cancer and/or Tumours*
9. *Glaucoma*
10. *A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes severe or persistent muscle spasms, including those characteristic of Multiple Sclerosis (MS); or Sclerosis*
11. *Phantom Limb Pain (PLP)*
12. *Crohn's Disease*
13. *Amyotrophic Lateral Sclerosis (ALS)*
14. *Post-traumatic Stress Disorder (PTSD)*
15. *Diabetes*
16. *Parkinson's Disease (PD)*
17. *Alzheimer's Disease (AD)*
18. *Attention Deficit Hyperactivity Disorder (ADHD)*
19. *Emphysema*
20. *Any illness which is officially considered a Rare Disease*
21. *A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes severe or persistent inflammation of the joints or muscles, including those characteristic of Arthritis*
22. *A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes seizures, but which are not characterised as that of Epilepsy*
23. *chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes Cachexia or Wasting Syndrome*
24. *A chronic and/or debilitating medical condition or treatment approved by the Health Department*

NOTE: Rare Diseases affects more than 2 million Australians and are defined as a condition, syndrome or disorder that affects 1 in 10,000 people or less and are either life-threatening or chronically debilitating. Many are alone in their plight to tackle and come to terms with an incredibly unique, debilitating and life-threatening illness.

NOTE: 10% of people will suffer a seizure event at some stage in their life. An individual seizure alone is not sufficient for a diagnosis of Epilepsy. Multiple seizures are required to be classified as that of the condition categorised as Epilepsy. Risk of seizures increase dramatically in the elderly and aging population.

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This list will need to be amended in the light of further medical research. It should be specified by regulation rather than by primary legislation.

Any scheme implemented should be as far reaching as possible, while maintaining the expected level of medical standards and regulations.

There is a great interest in the Pharmacological properties of Cannabinoids like compounds that are not linked to the adverse effects of Δ^9Tetrahydrocannabinol (THC), eg/ psychoactive properties, the anti-inflammatory properties of unheated Cannabis sativa extracts and its main non-psychoactive constituent Δ^9Tetrahydrocannabinolic acid (THCA) in vitro and in vivo studies. These results suggest that THCA and unheated extracts have anti-inflammatory properties and are acting via different metabolic pathways than THC and heated Cannabis extracts. The anti-inflammatory effect of THCA and unheated extracts was not only observed in vitro, but also in vivo. In a pilot EAE animal study the effects of THCA, and unheated Cannabis extracts on the clinical and histological signs of EAE collectively suggest that these may have therapeutic potential for Multiple Sclerosis, Arthritis etc.[21]

Question 3)

What special considerations, if any, justify access to medicinal Cannabis for?

a) Patients who are under 18 years of age;

b) Patients who lack capacity by reason of age or another disability (other than youth) to consent to using medicinal Cannabis;

Answer 3)

The Common Law Doctrine of Informed Consent is the fundamental right to choice over one's body and one's overall care. This premise of the right to choose one's own medical care does not start or end with any age barrier. Whether an individual is of a certain age has no bearing in one's fundamental right to this premise. All children have a parent or legal guardian who is responsible for deciding what is right for the child, as they do in all circumstances like this.

What the documentation, (As outlined above in Pages 14-22), from Tara O'Connell's Case Study highlights is the safety and efficacy of a low dose cannabinoid treatment for a patient under the age of 18 years of age and with a severe disability.

Most medical conditions are not generally age related. Cancer and chronic pain, etc. can affect anyone from childhood to adulthood all the way to old age. Childhood Cancer is widely regarded as one of the most painful Cancers.

Again, Cannabinoid/Cannabis based medications made at higher level doses than that recommended as safe for children and adults to consume in hemp foods by the FOOD STANDARDS Australia/New Zealand should be regarded in similar fashion to that of opium medications. Higher dosage level medications should require further Doctor's supervision and medical data retention. Conventional Australian medicine allows patients, children included, access to opium products under a regulated medical regime with supervision via Doctors monitoring the patient's condition. Higher dosage level Cannabis based medications have a place in a regulated medical regime with Doctors supervision. Some patients such as those suffering high levels of pain during late stage Cancer treatment may require much higher levels of THC medications to find the required amount of pain relief.

[21] See Annexure - Unheated Cannabis Sativa extracts and its major compounds THC-acid have potential anti-inflammatory properties not mediated by CB1 and CB2 receptor coupled pathways.

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Children with severe uncontrolled epilepsy often have associated Autism. One of the first things parents mention about their child's behaviour, once they start a cannabinoid treatment, is that for the first time in their lives they are interested in the world. They start tracking their parents with their eyes and start to interact with them. In the stories from parents it will often be stated that they are meeting their child for the first time in their lives.

Research by Mullaways is in agreement with such findings. Case studies of parents using the Mullaways Cannabinoid Tincture further back these claims. Children such as Tara O'Connell initially suffering Epilepsy and Autism suddenly do not display the usual traits of their conditions, but instead "Socialized more quickly, make eye contact more quickly and were easier to engage" these were basic yet important improvements marked by many Australian families.

Medical Cannabis should not be withheld from patients under the age of 18 or due to lack by reason of age or another disability. Autism does not wait until a person is over 18 years of age and therefore treatment for such illnesses should not be withheld especially when there are options which are safer than food standards for children and adults.

Question 4)

On which of the following should the law creating a medicinal Cannabis scheme base a person's eligibility to use medicinal Cannabis?

a) A list of medical conditions;

b) A list of symptoms;

c) A list of symptoms arising from certain medical conditions;

d) Evidence that all reasonable conventional treatments have been tried and failed;

Answer 4)

A combination of a, b and c above will likely be required.

Any legislation must not enshrine that all reasonable conventional treatments must have been tried and have failed before a cannabis treatment can be tried. How many years of failed conventional treatments, with all their side effects and cost, must a person with exceptional circumstances endure before they have a right to a cannabis treatment?

Question 5)

Should there be a way to allow for special cases where a person who is otherwise ineligible may use medicinal Cannabis? If so, what should that be?

Answer 5)

Consideration of the dose would be one of the first options investigated for those ineligible for use of medical cannabis.

Under a Doctor's supervision any Cannabis Medicine which is safer in THC content than 6 micrograms per kilogram per day, produced under the regulations of the Victorian Medical Cannabis Scheme, should be able to be used by those considered a special case.

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A special case could be included in the Victorian Medical Cannabis Scheme by having the person agree to being, a case study under the supervision of their doctor.

Question 6)

If Victoria acted through a State agency, in what circumstances would it be legally entitled to establish a medicinal Cannabis scheme which manufactured Cannabis products without breaching the terms of the Therapeutics Drugs Act 1989 (Cth) or the Narcotic Drugs Act 1967 (Cth)?

Answer 6)

Both of these Acts currently fail at least 1 in 5 Australians, including children, who live with chronic pain and among people aged over 65 its 1 in 3 Australians.

The research paper, *Pain Management: A Fundamental Human Right*, states:
"We conclude that, because pain management is the subject of many initiatives within the disciplines of medicine, ethics and law, we are at an "inflection point" in which unreasonable failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right." [22]

Victoria requires a comprehensive scheme regulated through every step of the supply chain which includes cultivation, manufacturing, processing, distribution and use. It is within the Victorian Government's power to do this.

As the Safe Injecting Room Legislation in NSW has highlighted breaching the terms of the Therapeutics Drug Act 1989 or the Narcotic Drugs Act 1967 does not stop a State government from implementing Health measures which have become considered world's best practise in medicine and policing.

Question 7)

Are the regulatory objectives identified by the Commission appropriate? What changes, if any, would you make to them?

Answer 7)

The regulatory objectives identified by the Commission are appropriate.

Question 8)

Would the creation of a defence to prosecution for authorised patients and careers in possession of small amounts of dried Cannabis or Cannabis products be an adequate way of providing for people to be treated with medicinal Cannabis in exceptional circumstances?

Answer 8)

[22] See - Pain Management: A Fundamental Human Right. Available at website: http://www.anesthesia-analgesia.org/content/105/1/205.full.pdf+html

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We are talking about a medicine not a recreational drug. Whatever amount of cannabis or cannabis medicine a person requires for the treatment of their exceptional illness is not a crime but a part of their medical treatment. As such there should be no criminal offence for the use by a registered medical cannabis patient of any amount of cannabis or cannabis medicine which has been prescribed or the use of which is being overseen by a Doctor for the treatment of their illness.

As *Dr Ian Webster AO* stated "The least that should happen is that a person using Cannabis to deal with persistent pain should be protected within the legislation from being dealt with by the criminal justice system."

Dr Webster's statement is inline with what has been taught in Australia's Addiction Studies Course at Curtin University by Associate Professor Bill Saunders who was hired to set up the Addiction Studies Course at Curtin University. **"The greatest harm which can happen to a person who uses Cannabis, and this harm far outweighs any other harm associated with Cannabis use, is getting a criminal record."**

It is really important to understand that one of the fundamentals of the preamble, the second one in fact, of *the Single Convention on Narcotic Drugs 1961*, states: **"...recognising that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes..."**

Adequate provision would have to include legislation removing criminal convictions for authorised patients and careers in a government regulated Medical Cannabis Scheme.

Any legislation enacted must ensure the protection from criminal conviction of all Victorians participating in the Victorian Medical Cannabis Scheme.

Question 9)

What mechanism should Victoria use to regulate the cultivation of Medicinal Cannabis?

Answer 9)

Cultivation, processing and distribution by licensed operators is the system which offers the best outcomes. Any regulated system must have checks and balances to ensure licensed operators are operating within their license but this is nothing new to Australian Industry. TGA regulations for manufacturing, distribution, supply and reporting are already in place for drugs of all Scheduling.

It is only the level of security around the cultivation and manufacturing facilities which needs to be determined. Industry will meet or better the regulated security measures outlined in the legislation.

A Regulatory System similar to that recommended in the "**Regulator of Medicinal Cannabis Bill 2014"** will be required in Victoria**.** It is not necessary to reinvent the wheel. The Opium Industry is an example of how this can be done but is not a blueprint. TGA Manufacturing, Reporting and Labelling standards will be required. Reporting the movement of Cannabis/Cannabinoids and Cultivation is just a Security issue. Specify the level of Security required and Companies will then be able to meet or better them.

The Parliamentary Bill can be viewed at:
http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbills%2Fs987_first-senate%2F0000%22;rec=0

In light of further legislative guidance around this specific area I would propose.

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Licenses are to be distributed by appropriate Government agencies, and thereafter all license holders must meet the required regulations set forth in Australia, by the appropriate Governing Cannabis regulating body formed in that State, and any other regulations implemented by State or Federal Government law.

Recommendations of licenses to be made available;

1. *Growers/Farmers & Manufacturers License* - A license authorising the cultivation and manufacture of Cannabis for the purpose of producing safe, quality Cannabis based medicines. Under outlined Government regulations;
2. *Dispensers License* - Although it would be preferable to distribute the Cannabis based medicines from hospitals and pharmacists, provisions should be made allowing private business to obtain a license authorising the dispensing of Cannabis based medicines. Under outlined Government regulations.
3. *Researchers License* - A license authorising the cultivation of Cannabis for the purpose of scientific research, analysis and study of Cannabis based medicines. Under outlined Government regulations.

Regulation should allow for high strength THC raw product grown for the extraction into tincture and other medicinal products.

All plants or breeds grown must be registered with IP Australia and comply with all relevant regulations.

Quality control for medical Cannabis Growers/Farmers - All Cannabis grown must be tested for quality analysis. This quality control must be of the highest and most stringent standards to ensure no residue of chemicals or fertilisers remain in the raw product at harvest.

Question 10)

What approach, or approaches, should Victoria take to regulating how medicinal Cannabis is processed and distributed?

Answer 10)

A Regulatory System similar to that recommended in the "**Regulator of Medicinal Cannabis Bill 2014"** will be required in Victoria**.**

The Parliamentary Bill can be viewed at:
http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbills%2Fs987_first-senate%2F0000%22;rec=0

In light of further legislative guidance around this specific area I would propose.

All manufacturing facilities and facilitators must meet TGA approval and licensing. All processes and medicinal products must also comply with TGA standards.

Products must also be regulated to meet the appropriate Government scheduling classification. High THC Cannabinoid medicines must also be available for hospitals.

Dispensaries - The low dosage Cannabinoid medicines can be supplied by Pharmacists. Cannabis Clinics setup within major hospitals could dispense the high dosage Cannabinoid medicines to authorised patients.

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Licensed Dispensaries will only be allowed to dispense medical Cannabis products. Dispensaries do not have authority to grow or manufacture. Dispensaries would be required to keep extensive records of;

- Employees identification and contact with the Cannabis based medicines;
- Quantities of Cannabis based medicines stored at the premises;
- Customer/Patient identification and sales records for the Cannabis based medicines dispensed;
- All Cannabis based medicines declared faulty in some aspect and deemed fit for destruction;

Dispensaries shall be required to ensure that access to the enclosed, locked facility where Cannabis/Cannabis based medicines are stored is limited to principal officers, board members, and designated employees of the dispensary.

Dispensaries shall be required to provide Security equipment to deter and prevent unauthorized entrance into limited access areas, equipment that include;

- Employee identification/authorisation cards;
- Video Cameras (With recording resolution at least 704x480 or the equivalent. Providing coverage of all entrances to and exits from limited access areas and all entrances to and exits from the building, capable of identifying any activity occurring in or adjacent to the building; and providing coverage of each point of sale where the Cannabis based medicines would be purchased);
- Exterior lighting to facilitate surveillance;
- A computer with internet access, capable of identifying and authorising patients information on a nation wide Government registry;

Video recordings from video cameras would be stored for at least 30 calendar days.

Safe destruction/removal of Cannabis based medicines - Hospitals and Pharmacists already have necessary regulations in place for the safe destruction/removal of medicines and other items declared faulty and deemed fit for destruction (Hazardous waste/material) any Cannabis based medicines declared faulty (broken seal of packaging ect) and deemed for destruction in hospitals and Pharmacists would fall under their current guidelines.

However licensed Dispensaries would need to create a system similar to those used in hospitals and Pharmacists for the safe destruction of faulty medicines, or at very least a system to safely store and deliver faulty medicines to a hospital/Pharmacist where destruction would take place.

Tax - All Growers/Farmers, Manufacturers and Dispensaries would need to meet an initial Application fee for license and registration. An annual license renewal fee would also be implemented.

A Yearly Cannabis Tax can be implemented to fund medical Cannabis. It could fund the following;

- The Cannabis Regulator Special Access Scheme Card program;
- Centralised website and access for critical medical data retention programs;
- Cannabis education programs;
- Adequate Cannabis research and development programs

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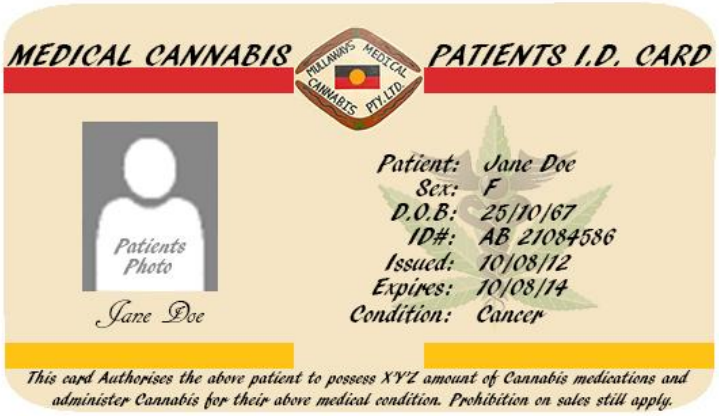
Cannabis Regulator Special Access Scheme Card for patients and carers - It is recommended that the Government introduce a compassionate regime to assist those suffering from a range of illnesses to gain the benefits associated with the use of Cannabis without facing criminal sanctions.

The most important part of this regime must be the issuing of a Cannabis Regulator Special Access Scheme Card(s), for medical Cannabis (CR-SAS Card) to qualifying patients or designated caregivers. The CR-SAS Card would protect a medical Cannabis patient from getting a criminal record and would solve a huge problem for law enforcement.

The CR-SAS Card program will establish a computerised system of data retention which will keep track of who is authorised to use Cannabis for medical purposes, their use and the type of Cannabinoid medicine being used. (The Royal Australian College of General Practitioners have in the past suggested a similar nationwide electronic system that would allow Pharmacists, Doctors and State health authorities to monitor the prescribing and dispensing of addictive drugs).

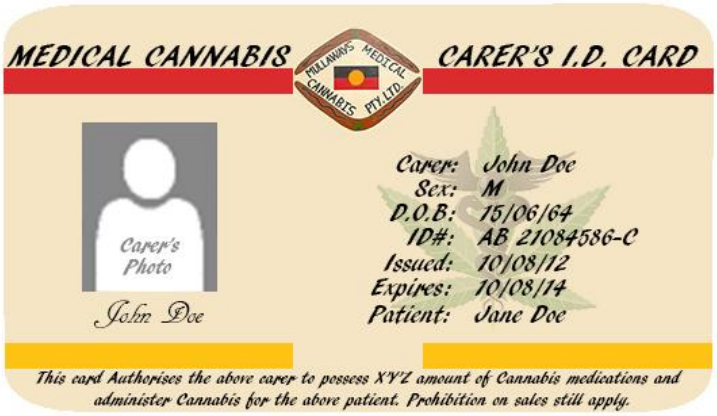
Cannabis Regulator Special Access Scheme Cards (Medical Cannabis)

Patients Card (Front)



Patients Card (Back)

Carers Card (Front)



Carers Card (Back)

The Victorian Health Department is to establish and maintain a program for the registration of qualifying medical Cannabis patients and their primary caregivers through a state wide online identification card system. This system will also need to cover a national network for interstate travellers.

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The CR-SAS (identification) Cards are intended to help law enforcement Officers, Health Professionals and Dispensaries identify and verify that cardholders are medical users of Cannabis.

Identification cards offer the holder protection from arrest; they are issued only after verification of the cardholder's status as a qualified patient or primary caregiver, and are verifiable. The CR-SAS Cards represents one of the best ways to ensure the security and non-diversion of Cannabis for medical use.

Further regulations for any such CR-SAS Cards should apply;

Carer Cards should only be eligible to carers if in-fact their patient applies and is granted a Patient Medical Cannabis Card, ensuring carers who receive a Carers Card do in-fact require the card for their patient's wellbeing. This would restrict carers from applying and receiving a card enabling them to possess Cannabis purely because they are a Carer when their patient does not actually require the medicine.

Both Patient and Carer Cards should have regulations set on the amount of Cannabis medication that can be possessed by any one cardholder at any one time, ensuring patients and carers are able to easily acquire adequate amounts of Cannabis medication yet limiting mass possession of Cannabis medication by individual citizens not licensed as Pharmacists or Dispensaries, or any other licensed medical practitioner performing under the guidelines of their profession. This would restrict potential threats of large scale movement of Cannabis based medicines on the black-market.

Both Patient and Carer Cards should of course still comply with current law on sales, and the prohibition of any and all sales of Cannabis or Cannabis based medicines by anyone except licensed Pharmacists and Dispensaries would remain a criminal offence.

The CR-SAS Cards will allow law enforcement to easily determine who is a registered medical Cannabis user and who is not. This will finally end the criminalisation of medical Cannabis patients and/or their Carers. It will also provide specific guidelines for law enforcement. The online system will allow for back up checks by authorities.

Physicians must comply with acceptable medical standards when recommending cannabis. These accepted standards are the same ones that a reasonable and prudent physician would follow when recommending or approving any medication.

Acceptable Medical Standards include the following:

- Taking a history and conducting a good faith examination of the patient;
- Developing a treatment plan with objectives;
- Providing informed consent, including discussion of side effects;
- Periodically reviewing the treatment's efficacy;
- Consultations, as necessary;
- Keeping proper records supporting the decision to recommend the use of medical Cannabis; and
- Completing 6 monthly Surveys of treatment so that a comprehensive database can be built concerning the best Cannabis medicines for different treatments.

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Standards for obtaining the CR-SAS Cards include:

- Points system personal identification;
- Online registration or a letter from a practicing General Physician

Cannabis should be prescribed by Doctors to patients with one of the following treatable medical conditions; (As outlined above in Pages 27-28).

Doctors can submit an application online for a patient. Once the application is approved a SAS-MC Card will be issued to the patient and they can then have their Cannabis/Cannabinoid prescriptions filled.

Doctors can check the online research to see which Cannabis/Cannabinoid medicines are working best for a patient's particular medical condition. They can then discuss the range of Cannabis/Cannabinoid medicines available for use with the patient and design up a treatment plan.

In a Cannabis Treatment Plan smoking Cannabis would not be the first option recommended. It would be part of an overall treatment plan, which would include medicines; (As outlined on the adjacent Pages 40-41).

As the therapeutic potential has been confirmed, a system is required so that Cannabis and its constituents can be prescribed, dispensed, and regulated in a manner similar to other medications that have psychotropic effects and some abuse potential.

Question 11)

How should the Victorian medicinal Cannabis scheme interact with the National arrangements for the control of therapeutic products under Therapeutic Goods legislation and Narcotic Drugs legislation?

Answer 11)

Any Medical Cannabis Scheme should be operated alongside the national scheme for evaluating and approving the supply of pharmaceutical products. In line with the Scheduling the cannabis material will determine the relevant TGA standards for manufacturing, distribution, supply and reporting of the movement and use of all cannabis material.

The Scheduling of cannabis concerning recreational use should not interfere with the operation of a regulated Medical Cannabis Scheme for patients with exceptional circumstances and those companies or individuals involved via license in the Victorian Medical Cannabis Scheme.

Question 12)

What responsibilities should be given to health practitioners in authorising a patient's use of medicinal Cannabis?

Answer 12)

This Question and the Issues paper seem confused around the issue of authorising. It states;

> *"7.50 to provide a way for people who are eligible to use medicinal cannabis to be authorised to use it. Although a person may meet the eligibility criteria of the scheme as set out in legislation, their access to medicinal cannabis should be determined by their individual health needs. This is a medical decision that requires a professional assessment by a designated medical practitioner.*

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7.51 If the designated practitioner concludes that the person should use medicinal cannabis as part of their treatment, the person could then be authorised to use it. This would be an administrative procedure."

The legislation will determine who is eligible and a medical practitioner is required to determine that the person is eligible due to meeting the criteria outlined in the legislation. The medical practitioner would confirm the person does suffer from severe uncontrolled epilepsy for example. By medical practitioners confirming eligibility requirements a person achieves the right to be authorised to use medical cannabis.

The medical practitioner would then discuss treatment of the person's condition and include medical cannabis medicines as part of that discussion.

If the person is eligible by the fact of having met the legislation requirements to be authorised to use medical cannabis medicines under the Victorian Medical Cannabis Scheme the medical practitioner cannot rule out medical cannabis medicines as part of a treatment.

At this time when there is a lack of clinical evidence for or against medical cannabis it is likely many medical practitioners will not feel informed enough to authorise medical use of cannabis for an eligible person. As the Scheme moves forward more and more case studies will be added to the store of research allowing a big data analysis of the information. In the future medical practitioners will have the knowledge to make the decision to include medical cannabis as a treatment option or not.

Tara O'Connell is 2 years seizure free. Would she even be authorised by medical practitioners to be part of a Medical Cannabis Scheme? More to the point would they recommend her the cannabis medicine which has kept her seizure free for 2 years?

Medical practitioners will confirm a person has an illness or symptom, outlined under the Victorian Medical Cannabis Scheme regulations and it is based upon this confirmation that a person becomes authorised.

Question 13)

Who should have the authority to access whether a patient is an appropriate candidate to be treated with medicinal Cannabis?

a) All registered medical practitioners;

b) Certain designated specialist medical practitioners;

c) Registered health practitioners who have prescribing entitlements;

d) A subset of these;

Answer 13)

Registered health practitioners who have prescribing entitlements would be best placed to handle this issue. A patient's regular doctor is the medical practitioner who knows and spends the most time with the patient. Specialist medical practitioners are often only seen a couple times a year and are no more qualified regarding the use of cannabis as a medicine than the local general practitioner. But as most patients with exceptional circumstances have a team of doctors overseeing their treatment it will likely be a specialist medical practitioner who makes the call or changes the medical cannabis treatment.

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Scheduling classification of Cannabis based medicines in Australia

Cannabis based medicines, such as Mullaways Cannabinoid Tinctures, require classification of Schedule 4 to allow for diagnosis and prescription by General Practitioners and subsequent accessibility to and from licensed dispensaries.

Schedule 4 (plus inclusion in Appendix D to the *Poisons and Therapeutic Goods* Regulations): Drugs in this schedule are usually those subject to abuse. Supply is by Doctors prescription. Health Department approval to prescribe is not required. Other basic controls are the same as for Schedule 4 drugs.

Classification in the Poisons list would allow Cannabis and Cannabinoids to be prescribed by licensed medical Practitioners. As with other prohibited prescription drugs, all the other prohibitions would continue to apply.

Resin based extraction products are recognised to be a more effective treatment for some cases of chronic illness and chronic pain and need to be made available to patients through hospital admission/referral. While smoking is not a recommended form of administration of medical Cannabis, some Doctors may deem necessary to recommend to a patient the use of a vaporiser to more effectively treat some conditions of chronic pain and illness. These medicines also need to be considered for classification to allow for their manufacture to meet demand for use.

Question 14)

What requirements, restrictions, guidance or other assistance should health practitioners be given in monitoring a patient's use of medicinal Cannabis?

Answer 14)

The structure of the regulated Medical Cannabis Scheme would be designed in such a way that the system provides feedback on all recorded medical cannabis medicines and dosage and patient treatment and outcomes so that the best treatment plan can be put together with the patient's involvement based on the current state of recorded Case Studies.

Individual Case Studies add up to a Mass Data Retention Solution:

- Taking a history and conducting a good faith examination of the patient;
- Developing a treatment plan with objectives;
- Providing informed consent, including discussion of side effects;
- Periodically reviewing the treatment's efficacy;
- Completing 6 monthly Surveys of treatment so that a comprehensive database can be built.

Question 15)

What additional restrictions or requirements, if any, should apply to patients who are vulnerable by reasons of age of lack of capacity, so as to provide adequate protection for their welfare?

Answer 15)

Patients who are vulnerable by reasons of age or lack of capacity have a parent or legal guardian who makes these decisions on what is adequate protection for their welfare.

Question 16)

In what form(s) should medicinal Cannabis be permitted to be supplied and used?

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Answer 16)

Tinctures, oils, patches, pills, creams, edibles, vaporisers and raw Cannabis are just a few of the many Cannabis medications which must be allowed to be researched and produced in a regulated scheme.

Cannabis based medicines for research and manufacture such as:

Non-Psychotropic Treatments:

- Cannabinoid Tinctures
- Cannabinoid Tablets/Pills
- Patches
- Creams
- Oils
- Edibles (Not heat treated; Yogurts, Honey, etc)
- Resin
- Vaporisers (for use with Resin, Oil or a medical grade form of Cannabis)
- Hemp Oil
- Essential Oils

Psychotropic Treatments:

- Cannabinoid Tinctures
- Cannabinoid Tablets/Pills
- Patches
- Creams
- Oils
- Edibles (Heat treated; Cookies, Cakes, etc)
- Resin
- Vaporisers (for use with Resin, Oil or a medical grade form of Cannabis)
- Medical grade form of Cannabis (Cannabis Cigarettes)

Notable Information about certain Cannabis based medicines;

Tinctures:

- Sub-Lingual - A patient simply places a few drops of Tincture under the tongue.
- Titration or dose control is easily achieved by the number of drops a patient places under the tongue where the medicine is rapidly absorbed into the arterial system and is quickly transported to the brain and body.
- Since Tinctures average some 75% ethanol there is little worry of bacterial or other biological contamination.
- Tinctures are best stored in dark bottles in the refrigerator.
- Tinctures can be flavoured for better taste. (Flavours such as Orange, ect)
- If desirable a Tincture high in THC can be made to give the necessary Pain Relief instead of using the Vaporiser or Smoking Cannabis or Resin.
- Tincture may also be added to foods and drinks.

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Vaporisers (Vaporisation):
Vaporisation is an effective way to deliver the therapeutic components of Cannabis (Cannabinoids) without the toxic by products of combustion. The vegetable material is placed in the vaporisor and heated to a temperature of 180-200°C (356-392°F), just short of combustion which occurs at 230°C (446°F). This causes the essential oils to volatilize, or evaporate, into a pure vapor, which is then collected and inhaled. The resulting vapors contain no tars, hydrocarbons, benzene, carbon monoxide or other toxic pryolytic gases and by products of combustion. Respiratory risks associated with smoked Cannabis are eliminated.

Edibles:
Cannabis is unique as a food source in providing highly digestible protein. It is balanced for all of the essential amino acids with an ideal ratio of omega 6 to omega 3 essential fatty acids. Cannabis is the only known source with nutritionally significant levels of the essential Cannabinoid acids.

Hemp Seed & Hemp Seed Oil:
The Hemp Seed and the Oil derived from it are nutritional food sources which can also be used in a medical Cannabis Treatment plan as does with the Resin Products. Cannabis with a high percentage of THC can be grown and turned into medicine of any %THC.

Nutritional Analysis of Hemp Seed:

Protein	22.5%
Carbohydrates	35.8%
Fat	30 %
Moisture	5.7 %
Ash	5.9 %
Calories	503 per 100gms
Dietry Fibre	3.51% (3.0% soluble)
Carotene	7.63 iu per gm
Vit E	30 mg per kg
Vit C	14 mg per kg
Vit B1	9 mg per kg
Vit B2	11 mg per kg
Vit B3	25 mg per kg
Vit B6	3 mg per kg

Percent Fatty Acids in 100 varieties of Hemp Seed:
(Average Amounts in 52 foreign and 48 Russian domestic varieties)

Linoleic Acid (Omega-6)	55.6-59.5%
Linoleic Acid (Omega-3)	16-24.3%
Palmitic Acid	5.8-7.4%
Steric Acid	1.6-3.0%
Oleic Acid	10.6-15.3%

As hemp seed is an extremely rich source of linoleic acid, it has long been employed to treat deficiencies. 1-2 tablespoons of hemp seed oil can be taken daily, and for degenerative conditions, or inflammatory intestinal disorders 3-5 tablespoons may be taken daily.

Question 17)

In what ways could Victoria's medicinal Cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of Cannabis and other changes in scientific knowledge, medical practices and technology?

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Answer 17)

Monitoring of a patients use and outcomes allows a big data approach to be taken with the Medical Cannabis Scheme and will assist researches to find and target the best treatments to achieve the best health outcomes for Victorians.

Also important is to put into place regulations which allow companies to go through the whole process of Clinical Trials to have cannabis medicines registered as therapeutic goods.

Other Related Matters

Drug Testing on the Roads and in the Workplace

Under the current systems used via Police enforcement in Australia, there is insufficient scientific evidence for random saliva testing of drivers on the roads and/or workers in the workplace surrounding Cannabis to prove actual impairment at the time of actual testing. The level of impairment is not currently what is being considered when evaluating whether a person (driving or in the workplace) is actually impaired at the time of testing. They are simply acknowledging Cannabis is in a person's systems and by default this equals impairment. This is not by default scientifically the case though.

Legislation and laws must reflect the advances in science, social justice issues and the basic democratic rights of Australian citizens.

Any Legislation must follow Australian practise of a person being innocent until proven guilty. Without proof of impairment a Victorian citizen should not be criminalised for driving on the roads or showing up for work. The current testing on drivers and in the workplace does not prove impairment and therefore breaches an individual's rights. Given the limited scientific evidence for a per se level of THC the drug testing regime in Victoria lacks evidential support.

There was no extensive public debate conducted in Victoria, or the rest of Australia, concerning the civil liberties or deterrent effects preceding the introduction of random saliva testing.

Without proof of impairment a Victorian citizen who is an authorised patient under the Victorian Medical Cannabis Scheme should not be criminalised for driving on the roads or showing up for work without proof of impairment. The current testing on drivers and testing in the workplace does not prove impairment and therefore would breach the rights of an authorised Medical Cannabis patient.

Professor Wayne Hall, School of Population Health, University of QLD, and Ross Homel, Key Centre for Ethics, Law, Justice and Governance, Griffith University of QLD wrote a paper, *Reducing Cannabis-impaired driving: Is there sufficient evidence for drug testing of drivers?,* which states:

"Given the limited scientific evidence for a per se level of THC the drug testing regime in Victoria lacks evidential support.

Proponents of these laws argue that random drug testing will save lives, but so far no scientifically persuasive evidence has been produced that these laws have done so. The success of Australian road side drug testing accordingly needs to be thoroughly evaluated to see if it reduces drug driving at an acceptable social and economic cost. If evidence of an impact on drug driving is forthcoming, citizens should have the right to debate whether these public health benefits offset the threats to democratic freedoms. Public debate is essential if

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random alcohol testing is not to serve as a Trojan horse for the introduction of wider and scientifically questionable laws without adequate public scrutiny." [23]

Expert opinion does not compare to analysis incorporating adjustments for age, gender, ethnicity, and alcohol concentration levels. Expert opinion cannot be relied upon as proof for criminalising a Medical Cannabis patient. Proof of impairment is the judicial requirement here.

The NHTSA (National Highway Traffic Safety Administration) research paper, *The Drug and Alcohol Crash Risk*, states:

"This study of crash risk found a statistically significant increase in unadjusted crash risk for drivers who tested positive for use of illegal drugs (1.21 times), and THC specifically (1.25 times). However, analyses incorporating adjustments for age, gender, ethnicity, and alcohol concentration level did not show a significant increase in levels of crash risk associated with the presence of drugs. This finding indicates that these other variables (age, gender ethnicity and alcohol use) were highly correlated with drug use and account for much of the increased risk associated with the use of illegal drugs and with THC...

...The higher drug prevalence rate at night-time strongly suggests that recreational use is a significant component of overall drug use. Medical drug use would not be expected to differ between day and night, nor weekday or weekend." [24]

The Journal of the Australasian College Road Safety research paper published in February 2009, *The Policy Context of Roadside Drug Testing*, states:

"Roadside testing of oral fluids for a suite of illegal drugs has been taking place in Victoria since late 2004, is now operating in some form in all of Australia's States and the Northern Territory. I suggest that the current roadside drug testing regimes have been introduced with insufficient rigour in the underlying policy analysis. The authorities state that it is a road safety initiative and not about punishing drivers for using illegal drugs, but this assertion can be challenged. The research evidence linking particular levels of drugs in the body and driving impairment is limited, no convincing evidence exists demonstrating that roadside drug testing improves traffic safety at the population level, the initiative fails to target some of the drugs the use of which has been demonstrated to be a traffic safety risk, the opportunity costs seem to have been ignored, and it may well fail the human rights test of proportionality." [25]

The NCPIC (National Cannabis Prevention and Information Centre) research paper, *Driving under the influence of Cannabis: A brief review of the literature*, states:

"The importance of identifying whether or not the driver was intoxicated at the time of the crash has been highlighted in a recent longitudinal study by Puliso, et al., spanning one year.35 In the year of study, 68 of 503 young Cocaine and Cannabis using participants were involved in a motor vehicle crash following the use of cannabis within one to two hours prior to the incident. The risk of crash dropped from a relative risk ratio of 7.0 when cannabis was smoked within one hour, down to 2.2 when smoked within two hours, after controlling for other substance use. As such, the authors concluded that when reviewing epidemiological study identifying

[23] See - Reducing Cannabis-impaired driving: is there sufficient evidence for drug testing of drivers? Available at website: http://www.griffith.edu.au/__data/assets/pdf_file/0008/188756/reducing-cannabis.pdf

[24] See - The Drug and Alcohol Crash Risk. Available at website: http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0CCUQFjAB&url=http%3A%2F%2Fwww.nhtsa.gov%2Fstaticfiles%2Fnti%2Fpdf%2F812117-Drug_and_Alcohol_Crash_Risk.pdf&ei=DcQhVbbNGZHy8QWZ7YLwCA&usg=AFQjCNFZGgFgZg-VIRDgltIopPnjXSgomQ

[25] See - The Policy Context of Roadside Drug Testing. Available at website: http://adlrf.org.au/wp-content/uploads/2012/09/ACRS-Journal-20-1LowRes.pdf

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cannabis use involvement in motor vehicle crashes, it is important to be wary when attributing a causal relationship, particularly without first identifying intoxication at the time of crash." [26]

The issues paper rightly highlights that "Research into the medical effects of Cannabis was significantly inhibited by its criminalisation…" A central view to the Australian way of life is that a person is innocent until proven guilty. But this right has been continually eroded over a long time now by Politicians.

Food Standards Australia/New Zealand recommended that 6 micrograms of THC per Kilogram of Body weight per day as safe for children and adults to consume. They also informed the Government Heads of State that Hemp Seed Oil is a nutritious food product, like many other Hemp Food products consumed in most countries of the world. But currently it is illegal in Australia to consume Hemp Seed Oil because of concerns about the impact this might have on Police drug testing of drivers.

Hemp Seed Oil is currently illegal to consume because Police in Victoria and all States of Australia now are criminalising Australians who have used cannabis without proving they are impaired. These are political decisions which are not based on Science and were never discussed with the public before implementing legislation which criminalise Victorians and other Australians without proof of guilt.

To criminalise a person registered as a medical cannabis patient under the Victorian Medical Cannabis Scheme for driving on Victorian roads without proving impairment would be unjust.

To discriminate against a person registered as a medical cannabis patient under the Victorian Medical Cannabis Scheme in the workplace without proving proof of impairment should be unlawful. It is well established that Cannabis users can test positive for days to weeks after they last consumed Cannabis. While the effect of Cannabis may last for 3 to 4 hours the level of impairment starts to decrease within 20 minutes of last consumption.

A single dose of 5 mg THC can be regarded as a placebo dose. In various clinical studies, psychotropic reactions were also observed following single doses of 5 mg THC. However, these cannot be distinguished from effects that occur after administration of placebos. As the duration of action of THC in therapeutic dosage ranges between 4 and 12 hours, a daily intake of 2 x 5 mg which equals 10 mg THC, administered orally in a lipophilic carrier, will not have any effects that could be distinguished from placebo effects. [27]

Unless a Drug Driving Test includes testing for THC, 11-hydroxy-THC and THC-COOH then time of consumption and levels of impairment cannot be determined. To criminalise a person based on a positive result for THC-COOH without proof of impairment is a poor indictment of the Victorian Justice System, Politicians and Police.

[26] See - Driving under the influence of Cannabis: A brief review of the literature. Available at website: https://ncpic.org.au/media/1911/driving-under-the-influence-of-cannabis-a-brief-review-of-the-literature.pdf

[27] Hemp Foods and THC Levels: A Scientific Assessment - http://www.hempfood.com/thclimits2a.html

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To do that to people suffering under exceptional circumstances shows how out of touch all these groups are with the ethics and responsibilities the community expects and requires.

The Oxford Journal of Analytical Toxicology, Vol. 29, Published July/August 2005, states:
"This commentary has addressed one domain of traffic safety policy. It is not an argument for or against the roadside testing of drivers for the presence of illicit drugs in saliva. If this initiative were found to be a cost-effective instrument for achieving traffic safety objectives I am sure that all readers would support it. My argument, however, is that roadside oral fluid testing for illegal drugs, the initiative known as 'random drug testing', has been developed and implemented without a transparent policy analysis underlying it. ***It is a highly intrusive intervention with significant implications for human rights.*** *It does not have a sound evidence base in research and a program logic analysis raises questions as to the likelihood of achieving its traffic safety goals of reduced crash incidence, injuries and fatalities.*

Proponents of these laws argue that random drug testing will save lives, but so far no scientifically persuasive evidence has been produced that these laws have done so. The success of Australian road side drug testing accordingly needs to be thoroughly evaluated to see if it reduces drug driving at an acceptable social and economic cost. If evidence of an impact on drug driving is forthcoming, citizens should have the right to debate whether these public health benefits offset the threats to democratic freedoms. Public debate is essential if random alcohol testing is not to serve as a Trojan horse for the introduction of wider and scientifically questionable laws without adequate public scrutiny." [28]

A Public Health Issue vs A Policing Issue (Regulation not Discretion)

The current political trend relating to medical Cannabis of furthering Police powers to allow harsher enforcement and punishment of medical users is a failed strategy.

Australia's scheduling of illicit drugs is based on historical precedent rather than any objective measure of harm and evidence shows some illegal drugs are less harmful than alcohol to users in society with most harm a direct result of there illicit status.

Comparative risk assessment of Alcohol, Tobacco, Cannabis and other illicit drugs using the margin of exposure approach. http://www.nature.com/srep/2015/150130/srep08126/full/srep08126.html

This issue surrounding medical Cannabis must be brought out of Police control and into the health spectrum.

Making limited legislation such as, Victorian Police have the power of discretion is a precarious idea for numerous reasons. The first issue being that Police officers are not Doctors and are not trained to understand the full complexities of medical conditions and the second issue being that a Police officer by nature does not have the power of discretion, if an officer knows of a crime they are entitled by duty, ethics and oath to act upon it. Allowing Police to deciding wether or not a crime is a crime is actually somewhat a dangerous road, an officers duty is not to decide what is law there job is to uphold the law hence why they are not allowed discretion, by nature it conflicts with the duty to uphold each and every Australian law, individually and yet as one whole overall process.

The argument and most importantly any *legislation* must be based on good valid science not on hysteria about things such as: any perceived drug high, etc. We already have systems in place in

[28] See - The Oxford Journal of Analytical Toxicology, Vol. 29, Published July/August 2005. Available at website: http://jat.oxfordjournals.org/content/29/5/327.full.pdf

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Australia to manage and control drugs/medications which contain higher values of intoxication and dependence than Cannabis.

Poison and Therapeutic Goods Act

Mullaways would like to point out what it believes to be a massive contradiction of Law, and a failure in said law to provide any real life results.

The Poison and Therapeutic Goods Act 1966 No.31 ... Division 1: Restrictions on possession, manufacture, supply, ect, of drugs of addiction ... Part 23: Possession and supply of drugs of addiction by carers ... "Despite any other provision of or made under this or any other Act, a person who has the care of, or is assisting in the care of, another person (for of to whom the supply of a drug of addiction has been authorised by the prescription of a medical practitioner, nurse practitioner, midwife practitioner or dentist) is not guilty of an offence in relation to the possession or supply of the drug if the person is in possession of the drug for the sole purpose of administering or assisting in the self-administration of, the drug to the other person and does so in accordance with that prescription."

So can the Government please explain how this clause (which is there in the Act for the sole purpose of protecting the carers of chronically ill Australians) is in proper effect? When no medical practitioner can prescribe Cannabis as a therapeutic medicine, because there is no place to legally get the Cannabis from under a Pharmacist or licensed dispensary, therefore putting the clause null and void as all these carers must get their patients required medicine off black-market street dealers. Thus putting the Health of the patient at risk with unregulated Cannabis and quite literally putting the freedom of the carers at risk by fining and locking them up for doing nothing more than possess and administer a drug for a patient who requires it for pain relief and who more often than not has a letter of support from their Doctor just not an official prescription, which as mentioned is impossible to get leaving the clause null and void from the beginning.

As such something must be done to ensure protection against criminal prosecution of patients whom require Cannabis for medical relief, and the carers of said patients. The NSW and Australian Government MUST at minimum set in place a Special Access Scheme Medical Cannabis Card for patients and carers to be protected from criminal prosecution, (As outlined above in Pages 35-36).

Exportation Value and Opportunities

One remaining issue is Exportation properties. Mullaways Cannabinoid Tincture is a medication that would fit into the legal regulations of current Import/Export laws, which brings forth the possibility of exportation overseas to countries such as, China and India, etc. (Which would bring untold potential to and for the Australian economy).

Under the Standards for the Uniform Scheduling of Medicines and Poisons (SUSMP), Hemp Seed Oil must contain less than (or up to) 50mg of THC per kilogram of oil to be excluded from the standard. This equates to a total THC content of 0.005% for hemp seed oil. The Drug Control Section of the Office of Chemical Safety at the Department of Health recognises the same threshold for import control, whereby if Hemp Seed Oil is imported with a THC content of less than 0.005%, then no permit is required for its importation.

As the Mullaways Cannabinoid Tincture contains only 25mg of THC per kilogram of Tincture it does NOT fall under Schedule 9 of SUSMP regulations and is therefore not illegal under these regulations.

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Its potential impact and growth on a struggling Australian economy, particularly in rural areas is unsourced.

Medicines Overall Cost-Value to the Patient Market

One remaining issue is the overall cost value of CBD medications against the cost value of THC medications, and the cost value of whole plant medications against single Cannabinoid compound Pharmaceutical medications.

CBD medications made via companies, such as GW Pharmaceuticals are far too expensive in their initial manufacturing value to justify giving it to suffering Australians on mass.

The UK cost agency rejected the Pharmaceutical medication, "Sativex" as to expensive after a major review by the agency on improving care for multiple sclerosis (MS) patients in a variety of ways concluded that the drug was not worth using.
http://www.dailymail.co.uk/wires/reuters/article-2784340/UK-cost-agency-rejects-British-company-GWs-cannabis-drug.html#ixzz3FXGfpjHu

The cost of "Sativex" in countries where it is approved has already proven to be a barrier. In New Zealand, an average annual prescription of "Sativex" costs about US$16,000 - That's an average of US$285 per week for treatment. Likewise, according to Professor Gavin Giovannoni of The London School of Medicine, "Sativex" has "not been proven to be cost-effective" in the UK, which has led a large number of MS patients to continue using illegal forms of cannabis.

Dr. Alex Wodak from St Vincent's hospital has publicly stated of "Sativex": "At an estimated cost of $800 a month it would be unaffordable for most and especially for people who are elderly, frail, ill and have eroded their life savings."

THC medications, such as the Mullaways Cannabinoid Tincture, do NOT require this high based price frame. Effective THC medications can be produced safely and affordably in Australia, for as little as $1-$2 a day = roughly $30-$60 a month cost value to the patient. This is without being on the Australian PBS (Public Benefits Scheme).

The cost value to the patient, of a high strain THC Cannabis plant grown and produced into an ultra-low dosage THC medication is not in the same category as that of the cost value of a low strain THC Cannabis plant grown used for either the production into a low dosage THC medication or a high CBD medication, the cost value to the patient, most of which are sick and therefore generally have lower financial income is astronomical.

No legislative changes in Australia help sufferers if the end result medication is essentially out of reach to the consumer, once legislative hurdles are solved, we do not require patients to be further burdened by an underlying inability to purchase a medication due to a overall cost value based on the medication. Especially when we can in-fact keep production cost value low to the consumer.

End Product Medication (Medicine based on Science not Hysteria)

One main remaining legal/legislative issue I would like to point out to the commission would be that, there are two base types of Marijuana:

Cannabis: Which is commonly used recreationally and has the potential of producing a euphoric-high (as it contains higher content levels of THC and no CBD, or low levels of CBD)

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Hemp: Which is commonly used as fibre and has the potential of producing clothes, paper, brick, concrete and many other fibres/materials of use (as it contains higher content levels of CBD and lower content THC)

Now while both have different values, they both have potential medical value.

The legislative concern should NOT revolve around (nor should it dictate) which Cannabis plant is cultivated to produce a safe, effective and affordable medication for Australians. The only thing that should be of concern is the end result medication that would be given to patients and public, etc. Whether the medicine comes from the original cultivation of a high or low grade THC Cannabis/Hemp plant is not the concern the issue is the end result medication. (Which we have current systems in place to manage and control the safety and efficiency of in Australia). The cultivation of high grade Opium Poppies are allowed in Tasmania (and Victoria) under regulation, to produce medication of varying dosages, as long as the end product meets the designated medication criteria for safety and effectiveness there is no current concern. And as such any medical cannabis system set in place should follow similar guidelines to that of Opium Poppies in Australia.

Were the cultivation of Cannabis/Hemp plants requires certain restrictions and/or regulations. (As would be set-up and outlined) But that ultimately any medication would continue to fall under the regulation of the current medical system (to prove scientifically its safety and efficacy before being made available to the public for mass social use).

In 1996 California became the first State in the U.S. to legalise medical Cannabis use for chronically ill and dying individuals, over the next 18 years we have seen a dramatic rise in other states following their lead, now 24 States in the U.S. have some form of medical Cannabis legislation, and many States have even decriminalised possession of small quantities of Cannabis.

In recent times though, a new trend has emerged throughout the more conservative states of the U.S. one which is quite alarming, the replacement of medical cannabis bills and legislation with the much more limited, CBD-Only legislation...Why is this alarming? Well...

Dr. Kevin Chapman, a Neurologist at the Children's Hospital Colorado, outside of Denver, and co-author of a study released at an American Epilepsy Society meeting in December 2014, shows us why legislative reforms in Australia must be based heavily on scientific reasoning and flexibility and not overwhelmed by public hysteria.

Dr. Chapman's study, which involved a review of the health records of 75 children who took CBD, found that 33% of them had their seizures drop by more than half. However, 44% of the children experienced adverse effects after taking CBD, including increased seizures. Of the 30 patients whose records included the results of brain-wave tests, a less subjective measure of seizure activity, only three showed improvements in those exams. "It really wasn't the high numbers we were hoping for," Dr. Chapman stated.

In 2005 research from the University of Mississippi, USA showed Cannabis contains 489 identifiable chemical compounds known to exist in the Cannabis plant. At least 200 of these are Cannabinoids, Terpenes and Flavonoids which are found in a wide range of concentrations within the flower, leaf, and stem, and which are the basis for medical and scientific use of cannabis. The Cannabinoids can serve as appetite stimulants, antiemetics, antispasmodics, and have some analgesic effects.

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So with the Cannabis plant producing around 80 known/discovered types of Cannabinoids, and 489 identifiable chemical compounds, for legislators to say CBD (Cannabidiol) is the only compound with any medical benefits when it's simply one of nearly 500 chemical compounds to exist in the Cannabis plant is more than short-sighted.

Once again, whether a Cannabis/Cannabinoid based medicine comes from the original cultivation of a high or low grade THC Cannabis/Hemp plant is not the concern.

The issue is the security surrounding the cultivation and the manufacture of the Cannabis plant into medications, and the safety and efficacy of the end result medication which would be given to medical patients.

Submission Conclusion

A Regulatory System similar to that recommended in the "**Regulator of Medicinal Cannabis Bill 2014"** will be required in Victoria**.**

Let me remind the Commission that it is not the strength of the Cannabis that you need to be concerned with but the poor quality of the Cannabis available on the black-market that these medical Cannabis patients must use.

A medical cannabis scheme designed along the lines outlined in the above Bill could achieve all six regulatory objectives. It would be a comprehensive scheme regulating every step in the Cannabis supply chain from cultivation, manufacture, processing, through to distribution and use. Security of the facilities would be regulated.

A regulated Medical Cannabis Scheme would allow pharmaceutical medications derived from the Cannabis plant or containing synthetically produced cannabinoids or cannabinoid analogues. There are already TGA standards for cultivation, manufacturing and processing operations, producing therapeutic goods which encompass security, operating procedures and reporting standards.

Double-Blind Placebo Clinical Trials are not appropriate for many of these patients with exceptional circumstances. Individuals with late stage Cancer, children with severe uncontrolled epilepsy who have been through the treatment options and many others do not have the time to be subjected to such trials but they all do have time in which their treatments can be documented to help find the best dose and medicines to help with their conditions.

Checks and balances must be at the heart of a regulated medical Cannabis scheme to ensure the best outcomes based upon the latest scientific knowledge, medical practise and technology. Recording the use of Cannabis medicines and the outcomes of the treatment will allow a database of information about all Cannabis medicines and thus would allow data mining of this information to ensure the safety and efficacy of the Cannabis medicines and treatments.

As the experience of Tara O'Connell highlights medical cannabis is all about the right dose of the right Cannabinoids. Finding exactly why Tara O'Connell is 2 years seizure free while using an ultra-low dose Cannabinoid medicine should be a priority for medical researchers and all Victorians. Mullaways have 12 detailed Case Studies recorded surrounding Paediatric Epilepsy, like Tara O'Connell's and many more patient survey results available for analysis. Case Study No. 2, Tara's older brother Sean O'Connell, will be 2 years seizure free on the 28 April 2015. Not one Neurologist, Doctor or researcher in Victoria or Australia understands why. It is time that changed.

All of this requires a regulated scheme through which companies like Mullaways working with the research community are able to cultivate Cannabis, and to develop, manufacture and produce

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Cannabis medicines which are affordable, safe and efficacious. Companies need a pathway to clinical trials of Cannabis/Cannabinoid based medicines which would led to them being registered as a Therapeutic Goods in Australia.

A medical Cannabis scheme is about improving the quality of life of the people with exceptional circumstances for whom Cannabis can provide therapeutic benefit while removing them from the criminal justice system. The design of the scheme can reduce the opportunities for diversion of Cannabis medicines into the recreational market.

Checks and balances must be at the heart of a regulated medical Cannabis scheme to ensure the best outcomes based upon the latest scientific knowledge, medical practise and technology. Recording the use of Cannabis medicines and the outcomes of the treatment will allow a database of information about all Cannabis medicines and thus would allow mass data retention of this information to ensure the safety and efficacy of the Cannabis medicines and treatments. The available knowledge based increasing with time, research and re-evaluation.

I will leave the commission with these final words;

"The legitimate object of Government is to do for a community of people, whatever they need to have done, but cannot do at all, or cannot so well do for themselves, in their separate and individual capacities. - Abraham Lincoln"

Tony Bower
Founder and Director,
Mullaways Medical Cannabis Pty Ltd