

**Submission
No 10**

INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

Organisation: Mullaways Medical Cannabis Pty Ltd

Date received: 23/01/2013



Mullaways Medical Cannabis Pty Ltd
Application To NSW Upper House Inquiry Into
The Medical Use Of Marijuana
CONFIDENTIAL - 18th January, 2013

MULLAWAYS Medical Cannabis Pty Ltd
PO BOX 334
KEMPSEY, NSW 2440
Email: mullawayman@skymesh.com.au
www.mullawaysmedicalcannabis.com.au

**MULLAWAYS
MEDICAL CANNABIS
PTY LTD**

**APPLICATION TO
NSW UPPER HOUSE INQUIRY
INTO THE MEDICAL USE OF MARIJUANA**



ZERO TOLERANCE OF PAIN AND SUFFERING

(Mullaways Medical Cannabis Pty Ltd is more than willing to discuss in further detail with the NSW Upper House Inquiry, any of the specific areas or options for change proposed in this Application, and is also willing to present any information at the Inquiries hearing process as may be requested).

1 * MULLAWAY Medical Cannabis Pty Ltd *** This document is confidential.** If you are not the intended recipient, you must not disclose or use the information contained in it. If you have received this document in error, please notify us and return the document immediately. Any personal views or opinions expressed by the writer may not necessarily reflect the views or opinions of MULLAWAY Medical Cannabis Pty Ltd.



TABLE OF CONTENTS

Foreword.....	3
Introduction.....	3
PART 1	4
Research into the efficacy and safety of Cannabis for medical purposes.....	4
Cannabinoids and their medical properties.....	4
Medical Cannabis in Australia - Mullaways Medical Cannabis Pty Ltd.....	11
Mullaways Cannabinoid Tincture - Delta 9 THC content.....	15
PART 2	15
If and how Cannabis should be supplied for medical use	15
Who can Grow Opium Poppies in Australia?.....	15
License/Authorisation.....	16
Quality control for medical Cannabis Growers/Farmers.....	17
Manufacture of medical Cannabis	17
Scheduling classification of Cannabis based medicines in Australia.....	17
Cannabis based medicines for research and manufacture	17
Illnesses/Conditions covered by medical Cannabis regime.....	20
Dispensaries.....	22
Safe destruction/removal of Cannabis based medicines.....	23
Tax.....	23
Special Access Scheme medical Cannabis card for patients and carers.....	24
PART 3	27
Legal implications and issues concerning the use of Cannabis for medical purposes	27
Government investigation into the use of Cannabis for medical purposes.....	29
Difficulties associated with legal Cannabis based medicines in Australia.....	32
PART 4	34
Other related matters.....	34
What a medical Cannabis patient goes through.....	34
Special Access Scheme in Australia.....	35
Poison and Therapeutic Goods Act	37
PART 5	38
Submission Conclusion	38



Foreword

Mullaways Medical Cannabis Pty Ltd is pleased to present this Application to the NSW Upper House inquiry into the medical use of marijuana. 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 NSW community. We 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 NSW 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

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 bring as a medicine, one of great importance is Israel.¹ (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.²

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 safer alternative than 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.

¹ See Annexure - Israeli medicine goes to pot. By Karin Kloosterman.

² See Annexure - Israeli researchers say more Doctors should recommend Marijuana to Cancer patients. By Dan Even.



Of particular interest is the use of Vaporisers to ingest the Cannabis (Cannabinoids) as a non-psychoactive or psychoactive vapour so as to achieve the right amount of relief without any of the harmful effects of combusting the fibre.

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 evaluated has encouraged researchers to try to better understand this important non-Opioid system of analgesia.³

PART 1

Research into the efficacy and safety of Cannabis for medical purposes Cannabinoids and their medical properties

In 1988 the first Cannabinoid receptor was discovered and since then researchers have learned that there are two different types of Cannabinoid receptors⁴ which are distributed throughout our bodies and that we make chemicals within our bodies Endocannabinoids⁵ which are similar to the Cannabinoids⁶ in the Cannabis plant.

³ See Annexure - Endocannabinoid Mechanisms of Pain Modulation. Research by Department of Psychology, University of Georgia, Athens.

⁴ See Annexure - Review: Endocannabinoids and their receptors in the enteric nervous system. Research by M. Duncan, J.S. Davison and K.A. Sharkey, University of Calgary, Canada.

⁴ See - Cannabinoids and Animal Physiology. Available at website:

<http://www.druglibrary.org/schaffer/library/studies/iom/iom2.htm>

⁵ See Annexure - Endogenous Cannabinoids: Structure and Metabolism. Research by Endocannabinoid Research Group, Naples, Italy.

⁵ See Annexure - Endocannabinoids in the central nervous system - an overview. Research by Department of Behavioural Sciences, College of Judea and Samaria, Ariel, Israel.

⁵ See Annexure - The Endocannabinoid system in Adipose Tissue. Research by Department of Internal Medicine and Gastroenterology, S. Orsola-Malpighi Hospital, University of Bologna, Italy.

⁵ See Annexure - GABA deficits disturb Endocannabinoid system.

⁵ See Annexure - The Endocannabinoid system: Physiology and Pharmacology. Research by Departamento de Psicobiología, Universidad Complutense, Spain.

⁵ See - The Endocannabinoid system: An Osteopathic Perspective. Available at website:

<http://www.jaoa.org/content/108/10/586.full>

⁵ See - The Endocannabinoid system: A general view and latest additions. Available at website:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1574255/>

⁶ See Annexure - Chemical constituents of Marijuana: The complex mixture of natural Cannabinoids. Research by National Center for Natural Products Research & Department of Pharmaceutics, School of Pharmacy, University of Mississippi.



Both plant and human Cannabinoids bind to and influence these receptors in order to discourage the rise and progression of numerous disease processes.⁷

Cannabinoid receptor type-1 (CB₁)

CB₁ receptors are found primarily in the brain, to be specific in the basal ganglia and in the limbic system, including the hippocampus. They are also found in the cerebellum and in both male and female reproductive systems. CB₁ receptors are absent in the medulla oblongata, the part of the brain stem responsible for respiratory and cardiovascular functions. Thus, there is not the risk of respiratory or cardiovascular failure that can be produced by some drugs. CB₁ receptors appear to be responsible for the euphoric and anticonvulsive effects of Cannabis.

Cannabinoid receptor type-2 (CB₂)

CB₂ receptors are predominantly found in the immune system, or immune-derived cells with the greatest density in the spleen. While found only in the peripheral nervous system, a report does indicate that CB₂ is expressed by a subpopulation of microglia in the human cerebellum. CB₂ receptors appear to be responsible for the anti-inflammatory and possibly other therapeutic effects of Cannabis.

Cannabis contains 483 compounds. At least 80 of these are Cannabinoids, Terpenoids 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. 10 important Cannabinoids found in the Cannabis plant are;

Δ⁹Tetrahydrocannabinol (Delta 9 THC or D9 THC)

Delta 9 THC the most abundant and widely known Cannabinoid in Cannabis, THC is the Cannabinoid responsible for the main psychoactive effects patients are familiar with. The compound is a mild analgesic and cellular research has shown the compound has antioxidant activity. THC is believed to interact with parts of the brain normally controlled by the endogenous Cannabinoid neurotransmitter Anandamide.

Δ⁸Tetrahydrocannabinol (Delta 8 THC or D8 THC)

Delta 8 THC binds to the Cannabinoid G-protein coupled receptor CB₁, located in the central nervous system; CB₁ receptor activation inhibits adenyl cyclase,

⁷ See Annexure - Review: Clinical studies with Cannabis and Cannabinoids 2005-2009. Research by Institute Biology Leiden, Leiden University, Netherlands.

⁷ See - Survey of Australians using Cannabis for medical purposes 2005. Available at website: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1262744/>

⁷ See - Dr. Ethan B. Russo on Medical Cannabis. Interviewed by Lucy A. Charlesworth. Available at website: <http://www.mullawaysmedicalcannabis.com.au/russo.html>

⁷ See - Medical use of Cannabinoids. Research by Dr. Bob Melamed. Available at website: http://www.uccs.edu/~rmelamed/Evolutionism/medical_uses_of_cannabinoid_2/



increases mitogen-activated protein kinase activities, modulates several potassium channel conductance's and inhibits N- and P/Q-type Ca²⁺ channels. This agent exhibits a lower psychotropic potency than Delta 9 THC, the primary form of THC found in Cannabis.

Δ⁹Tetrahydrocannabinolic acid (THCA)

THCA is the main constituent in raw Cannabis. THCA converts to Delta 9 THC when burned, vaporized, or heated for a period of time at a certain temperature. THCA holds much of the anti-inflammatory properties, as well as anti-proliferative (inhibiting the cell-growth in tumours/Cancer cells) as well as anti-spasmodic (suppresses muscle-spasms).

Δ⁹Tetrahydrocannabivarin (THCV)

THCV is found in largest quantities in Cannabis sativa strains. It is currently being developed as a treatment for metabolic disorders including Diabetes. THCV has been shown to block the psychoactive effects of THC.

Cannabidiol (CBD)

CBD is a non-psychoactive Cannabinoid that is believed to reduce the psychoactive effects of THC. Smokers of Cannabis with a higher CBD/THC ratio are less likely to experience anxiety. CBD may also inhibit Cancer cell growth.

Cannabidiolic acid (CBDA)

CBDA, similar to THCA, is the main constituent in Cannabis that has elevated CBD levels. THCA and CBDA hold most of the anti-inflammatory properties that Cannabis has to offer.

Cannabinol (CBN)

A psychoactive Cannabinoid that comes about from the degradation of THC, there is usually very little CBN in a fresh plant. CBN potentiates the effects of THC. The degradation of THC, into CBN, is often described as creating a "couch lock" effect.

Cannabichromene (CBC)

More common in tropical Cannabis varieties. Effects include anti-inflammatory and analgesic.

Cannabigerol (CBG)

A non-psychoactive Cannabinoid, CBG has antibacterial effects and can alter the overall effects of Cannabis.

Beta-caryophyllene (β-caryophyllene)

β-caryophyllene, is a natural bicyclic sesquiterpene that is a constituent of many essential oils, and the essential oil from the stems and flowers of hemp Cannabis *Sativa*. beta-caryophyllene was shown to selectively bind to the Cannabinoid receptor type-2 (CB₂) and to exert significant Cannabimimetic anti-inflammatory



effects in mice. Whether this compound is able to modulate inflammatory processes in humans via the Endocannabinoid system is yet unknown. Beta-caryophyllene does not bind to the centrally expressed Cannabinoid receptor type-1 (CB₁) and therefore does not exert psycho mimetic effects.

Some other important but less known/researched Cannabinoids are;

Δ^9 Tetrahydrocannabivarin acid (THCVA)

Δ^9 Tetrahydrocannabinol-C4 (THC-C4)

iso-Tetrahydrocannabinol (*iso*-THC)

Cannabigerol acid (CBGA)

Cannabielsoin (CBE)

Cannabicitran (CBT)

Cannabicyclol (CBL)

Cannabivarin (CBV)

Cannabidivarin (CBDV)

Cannabidivarin acid (CBDVA)

Cannabinovarin (CBNV)

Cannabichromevarin (CBCV)

Cannabigerovarin (CBGV)

Cannabigerol Monomethyl Ether (CBGM)

There is a great interest in the Pharmacological properties of Cannabinoids like compounds that are not linked to the adverse effects of Δ^9 Tetrahydrocannabinol (THC), eg/ psychoactive properties, the anti-inflammatory properties of unheated Cannabis sativa extracts and its main non-psychoactive constituent Δ^9 Tetrahydrocannabinolic 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.⁸

Studies of the Endocannabinoid system support its importance for multiple aspects of brain function including modulation of the hypothalamic-pituitary-adrenal (HPA) axis, regulation of mood, anxiety, and reward, and extinction of fear learning. It also

⁸ 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.



participates in the immune, cardiovascular, and gastrointestinal systems. Present medicinal uses of compounds that interact with this system include analgesia, suppression of chemotherapy-induced nausea, appetite stimulant for illness and medication-related weight loss, reducing motor symptoms (eg/ spasticity, ataxia, weakness) in multiple sclerosis, and reduction of intraocular pressure in glaucoma.⁹

Some known types of Endocannabinoid ligands are;

- Arachidonylethanolamine (Anandamide or AEA)
- 2-arachidonoyl glycerol (2-AG)
- 2-arachidonyl glyceryl ether (Noladin Ether)
- N-arachidonoyl-dopamine (NADA)
- Virodhamine (OAE)

The endogenous Cannabinoid system is a ubiquitous lipid signalling system that appeared early in evolution and which has important regulatory functions throughout the body in all vertebrates. The main Endocannabinoids (endogenous Cannabis-like substances) are small molecules derived from arachidonic acid, Anandamide (Arachidonylethanolamide) and 2-arachidonoylglycerol. They bind to a family of G-protein-coupled receptors, of which the Cannabinoid CB1 receptor is densely distributed in areas of the brain related to motor control, cognition, emotional responses, motivated behaviour and homeostasis. Outside the brain, the Endocannabinoid system is one of the crucial modulators of the autonomic nervous system, the immune system and microcirculation. Endocannabinoids are released upon demand from lipid precursors in a receptor-dependent manner and serve as retrograde signalling messengers in GABAergic and glutamatergic synapses, as well as modulators of postsynaptic transmission, interacting with other neurotransmitters, including dopamine. Endocannabinoids are transported into cells by a specific uptake system and degraded by two well-characterized enzymes, the fatty acid amide hydrolase and the monoacylglycerol lipase. Recent pharmacological advances have led to the synthesis of Cannabinoid receptor agonists and antagonists, Anandamide uptake blockers and potent, selective inhibitors of Endocannabinoid degradation. These new tools have enabled the study of the physiological roles played by the Endocannabinoids and have opened up new strategies in the treatment of pain, obesity, neurological diseases including multiple sclerosis, emotional disturbances such as anxiety and other psychiatric disorders including drug addiction. Recent advances have specifically linked the endogenous Cannabinoid system to alcoholism, and Cannabinoid receptor antagonism now emerges as a promising therapeutic alternative for alcohol dependence and relapse.

American and European researchers have found that increasing natural marijuana-like chemicals in the brain may help correct behavioural issues related to Autism. A

⁹ See Annexure - Endocannabinoids: Stress, Anxiety, and Fear. Research by Katherine H. Taber, Ph.D. and Robin A. Hurley, M.D.



study examined 2-AG, and found these Endocannabinoids allow for the efficient transport of electrical signals at synapses, which is severely limited in people with Fragile X Syndrome. Researchers treated mice that exhibited symptoms of Fragile X Syndrome with novel compounds that correct 2-AG protein signalling in the brain. And the results were promising, the mice showed "dramatic behavioural improvements in maze tests measuring anxiety and open-space acceptance".¹⁰

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 2012 is about 10,000.

A strong medical research sector under adequate 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.^{11 12}

The Israeli Government has setup a system similar to that of Articles 23 and 28 of *the Single Convention on Narcotic Drugs 1961*.

The Single Convention establishes a system of controls in respect to the cultivation of Opium poppies and Cannabis. In accordance with Articles 23 and 28, parties are required to establish a centralised Government agency to carry out functions in relation to the cultivation of Opium poppies and Cannabis, and only cultivators licensed by this agency may be authorised to engage in cultivation.

The growing and manufacture of Opium products in Tasmania is also covered by these Articles.

Studies by the Scripps Research Institute in California shows that the active ingredient in Cannabis, THC, prevents the formation of deposits in the brain associated with Alzheimer's disease. THC was found to prevent an enzyme called acetylcholinesterase from accelerating the formation of "Alzheimer plaques" in the brain more effectively than commercially marketed drugs. THC is also more effective at blocking clumps of protein that can inhibit memory and cognition in Alzheimer's patients, as reported in *Molecular Pharmaceutics*.¹³ Cannabinoids can also

¹⁰ See Annexure - Marijuana-like chemical may help Autism and Fragile X Syndrome symptoms. By Kathleen Miles, The Huffington Post.

¹⁰ See Annexure - Marijuana Madness. By Autism Support Network.

¹¹ See Annexure - Israeli firm's new medical marijuana. By BBC News, Jerusalem.

¹² See Annexure - Some take Cannabis illicitly, Israelis take it seriously. By Pierre Klochendler.

¹³ See Annexure - A molecular Link Between the Active Component of Marijuana and Alzheimer's Disease Pathology. Research by Mol Pharm.



potentially prevent or slow the progression of Alzheimer's disease by reducing tau protein phosphorylation, oxidative stress, and Neuro inflammation.

Dr. Melanie Dreher (Dean of Nursing at Rush Medical Center in Chicago) did a study in Jamaica. It was published in the American Journal of Paediatrics in 1994. She studied a group of women who did smoke Cannabis during pregnancy and those who didn't. The study went for the duration of their entire pregnancy, and then studied the babies about a year after birth. She expected to see a difference in the babies as far as birth weight Neuro tests, but there was no difference whatsoever. The differences that the researchers did notice were that the babies of the women who had smoked Cannabis, and were talking about daily use during their pregnancy, Socialized more quickly, made eye contact more quickly and were easier to engage.¹⁴

When examining the medical affects of marijuana use, the National Commission on Marihuana and Drug Abuse concluded, "A careful search of the literature and testimony of the nation's health officials has not revealed a single human fatality in the United States proven to have resulted solely from ingestion of marihuana. Experiments with the drug in monkeys demonstrated that the dose required for overdose death was enormous and for all practical purposes unachievable by humans smoking marihuana. This is in marked contrast to other substances in common use, most notably alcohol and barbiturate sleeping pills." The WHO (World Health Organisation) reached the same conclusion in 1995.

An examination of the literature and testimony of the nation's health officials here in Australia, such as done by NDARC (National Drug and Alcohol Research Centre) supports the conclusion reached in the United States.

Between; 1991-2001 there were 8,431 accidental drug induced deaths in Australia between people aged 15-54 years old. And 6,604 (78.3%) of those deaths were due to Opioids. **(None were due solely from the ingestion of Cannabis).**

Between; 1988-2008 there were 10,216 accidental deaths due to Opioids in Australia between people aged 15-54 years old. (An average of 511 Australian's a year).

In 2008 alone, there were 551 accidental overdoses due to Opioids, of which 70% were thought to be due to pharmaceutical Opioids.

Although these Opioid overdoses are of great concern in each individual case, the increasing number of deaths from prescription Opioids reflects a much bigger issue: the millions of Australians whose lives are severely affected by chronic pain.

¹⁴ See Annexure - Marijuana during pregnancy. Research by Dr. Melanie Dreher.



At least 1 in 5 Australians, including children, lives with chronic pain. Among people aged over 65, it's 1 in 3. 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.¹⁵

Medical Cannabis in Australia - Mullaways Medical Cannabis Pty Ltd

I am Anthony D. Bower an Indigenous Australian of 57 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 homeopathic 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-psychoactive 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.

¹⁵ See Annexure - Rise in prescription drug deaths highlights issue of chronic pain. By Lesley Brydon, CEO of Pain Australia.



Mullaways Medical Cannabis Pty Ltd (Mullaways) is a federally registered company under Australian law, and has been since the 21st of October 2008.¹⁶ 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.

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 Anandamide¹⁷ 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".¹⁸ Mullaways also proposes to research and develop other Cannabinoid based medicines including patches, creams, oils and edibles¹⁹ that have therapeutic benefits and that may be delivered more safely and effectively than by smoking Cannabis.

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.²⁰

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).

¹⁶ 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)*.

¹⁷ See Annexure - Anandamide definition from Wikipedia, the free encyclopedia.

¹⁸ See Annexure - Review: Taming THC: Potential Cannabis synergy and phytocannabinoid-terpenoid entourage effect. Research by Dr. Ethan B. Russo, GW Pharmaceuticals, UK.

¹⁹ See - Hemp Foods and THC Levels: A Scientific Assessment. Available at website:
<http://www.hempfood.com/thclimits2a.html>

²⁰ 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).



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 received from the NSW Government.

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.

Mullaways has applied and payed for a license from the NSW Government to cultivate, possess and supply Cannabis plants for the purpose of scientific research, analysis and study in NSW, under the *Drugs Misuse and Trafficking Act 1985*. (License payed for on the 10th Aug, 2009)

My company has worked for many years towards attaining a license. Since 2008 Mullaways has submitted multiple Applications for a license, the latest on the 18th Dec, 2012. (Mullaways received a response for its latest Application submitted.²¹ The exact same response it has received for years. I have 5 letters with the same response in the same wording. The continual ignorance over multiple reigns of Government whom won't take my license Application seriously is astounding).

Mullaways has sent numerous letters informing NSW Health and numerous Government representatives at both the State and Federal level of their operations.

Mullaways has dispensed the Cannabinoid Tincture to people with a signed letter from their Doctor from outside the Nimbin Hemp Embassy for over 2 years²² and from the main street of Kempsey outside the local member's office, the Deputy Premier of NSW, Mr. Andrew Stoner.

Mullaways has accumulated experience in the treatment 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.

²¹ See Annexure - Letter To Mr. Anthony Bower from (NSW Health) Acting Chief Pharmacist and Associate Director, Bruce Battye dated 31st December, 2012.

²² See Annexure - One-man Cannabis van raises queries of legality. By The Sydney Morning Herald.



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

The Mullaways research indicates that an Endocannabinoid imbalance is involved with a number of pathological conditions. In 2010 Mullaways devised a survey of 150 medical Cannabis users, which I, Anthony D. Bower, Director of Mullaways Medical Cannabis Pty Ltd conducted to gather research concerning the use of Mullaways Cannabinoid Tincture. 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).²³ Mullaways will research how much more THCA²⁴ will be needed to achieve further pain reduction than that achieved with the Mullaways Cannabinoid Tincture alone. Highlights of the survey results and other Mullaways research can be found at; <http://www.mullawaysmedicalcannabis.com.au>

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

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.²⁵

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.²⁶

Mullaways patients have been using the natural low dose Cannabinoid Tincture. The Tincture is Non-Psychotropic with No Detectable Prohibited Substances. Not only does this natural low dose Tincture give pain relief for patients across a number of

²³ See Annexure - Mullaways Medical Cannabis Pty Ltd, Patient Survey 2010.

²⁴ See Annexure - Direct NMR analysis of Cannabis water extracts and tinctures and semi-quantitative data on Δ^9 -THC and Δ^9 -THC-acid. Research by Department of Pharmaceutical and Biological Chemistry, The School of Pharmacy, University of London, UK.

²⁵ 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.

²⁶ See Annexure - Cannabis Genome Uncloaked: Commentary on the Scientific Implications. Research by Dr. Ethan B. Russo, GW Pharmaceuticals, UK.



serious illnesses but it will allow them to benefit from the medication while being able to drive and to function at work.

As many patients reduced their use of other prescription medications and even their use of certain recreational drugs (Alcohol and Tobacco) once they started using the Cannabinoid Tincture it should be used as a first line medication for chronic pain relief. Then additional Cannabinoid medicines (Patches, Oils, Edibles ect) or Opioid medications can be added as appropriate to further relieve any pain.

It is of note, that Mullaways does not claim its Cannabinoid Tincture to outright cure any disease, at least yet only time and research would prove results. 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 0.0082mg of Delta 9 THC and as such is;

- 61x lower than the TGA standard for Delta 9 THC of 0.5mg;
- 610x lower than the scientific standard for safe Delta 9 THC of 5.0mg;
- 330x lower than the GW Pharmaceuticals standard for Delta 9 THC of 2.7mg in its Cannabis based medicine "Sativex" which is currently distributed throughout the UK, has been approved in over 20 countries, and is currently being trialled here in Australia. (Sativex has been exported from the UK to a total of 28 countries to date).

Thus the dosage of THC in the Mullaways Cannabinoid Tincture is so low; Mullaways would propose the tincture is in-fact not illegal and the illegality of this medicine simply falls with the cultivation, possession and supply of Cannabis plants to produce said medicine.

PART 2

If and how Cannabis should be supplied for medical use

Who can Grow Opium Poppies in Australia?

An Opium poppy crop can only be grown in Tasmania by a farmer who has a contract with a manufacturing company and a license from the Tasmanian Government. Contracts and licenses are issued on an annual basis.



There are three manufacturing companies in the State licensed to extract the medicinal products from the poppy straw after harvesting.

There are, on average, 800 growers cultivating about 25,000 hectares of poppies annually in Tasmania.

A medical Cannabis system can be setup in NSW along the same lines as the Tasmanian system for Opioids. This is in-line with *the Single Convention on Narcotic Drugs 1961* which requires that adequate provision is made to ensure the availability of narcotic drugs, such as Cannabis, for medical purposes.

Mullaways believe it's time the NSW Government set in place a system to supply Cannabis/Cannabinoid medicines to people requiring them for the management of their medical condition and to remove these people from the Criminal Justice System.

License/Authorisation

The Single Convention establishes a system of controls in respect to the cultivation of Opium poppies and Cannabis. In accordance with Articles 23 and 28, parties are required to establish a centralised government agency to carry out functions in relation to the cultivation of Opium poppies and Cannabis, and only cultivators licensed by this agency may be authorised to engage in cultivation.

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 TGA, 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.

Manufacture of medical Cannabis

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.

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.

Cannabis based medicines for research and manufacture

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.

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 vaporiser 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 pyrolytic 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.



Illnesses/Conditions covered by medical Cannabis regime

The following internationally recognised conditions, effectively treated by Cannabis should be considered;

1. *Clinical Endocannabinoid Deficiency (CECD)*²⁷
2. *Cancer*²⁸
3. *Human Immunodeficiency Virus and/or Acquired Immune Deficiency Syndrome (HIV/AIDS)*²⁹
4. *Multiple Sclerosis (MS)*³⁰
5. *Hepatitis C*³¹
6. *Amyotrophic Lateral Sclerosis (ALS)*³²
7. *Crohn's Disease*³³
8. *Parkinson's Disease (PD)*³⁴

²⁷ See Annexure - Clinical Endocannabinoid Deficiency (CECD). Research by Dr. Ethan B. Russo, GW Pharmaceuticals, USA.

²⁸ See Annexure - Review: The Endocannabinoid system and Cancer: therapeutic implication. Research by Department of Psychological and Brain Science, Indiana University, USA.

²⁸ See Annexure - Δ^9 -Tetrahydrocannabinol inhibits epithelial growth factor-induced lung cancer cell migration in Vitro as well as its growth and metastasis in Vivo. Research by Department of Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, USA.

²⁸ See Annexure - Anti-tumor activity of plant Cannabinoids with emphasis on the effect of Cannabidiol on Human Breast Carcinoma. Research by Endocannabinoid Research Group, Naples, Italy. And by Dipartimento di Scienze Farmaceutiche, Università di Salerno, Italy.

²⁸ See Annexure - Cannabinoid Receptor as a novel target for the treatment of Prostate Cancer. Research by Department of Dermatology, University of Wisconsin, Medical Science Center, USA.

²⁸ See Annexure - Cannabinoid Receptor ligands mediate growth inhibition and cell death in mantle cell Lymphoma. Research by Department of Laboratory Medicine, Division of Pathology; and Department of Medicine, Karolinska Institutet, Karolinska University Hospital, Stockholm, Sweden.

²⁹ See - The medical use of Marijuana: The history, therapeutic potential and legal landscape in S.A. ACSA. Available at website: http://www.acsa.org.au/linked/resources/medicinal_use_of_marijuana.pdf

³⁰ See Annexure - Multiple Sclerosis and extract of Cannabis: results of the MUSEC trial. Research by the MUSEC Research Group.

³⁰ See Annexure - Cannabis truly helps Multiple Sclerosis sufferers. By Anna Gosline.

³¹ See - Mullaways Medical Cannabis Pty Ltd, Use and self-medication with Cannabis by Hepatitis C positive people. Available at website: <http://www.mullawaysmedicalcannabis.com.au/hcv.html>

³² See Annexure - Increasing Cannabinoid levels by Pharmacological and genetic manipulation delay disease progression in SOD1 mice. Research by Department of Motor Neuroscience & Movement Disorders; and Department of Neuro-inflammation, Institute of Neurology, University College London, Queen Square, London, UK. And by Endocannabinoid Research Group, Naples, Italy.

³³ See Annexure - The Endocannabinoid system in the Physiology and Pathophysiology of the Gastrointestinal tract. Research by Department of Physiological Chemistry, Johannes Gutenberg-University Mainz, Germany. And by Department of Internal Medicine II, Ludwig-Maximilians-University Munich, Germany.

³³ See Annexure - Treatment of Crohn's Disease with Cannabis: An observational study. Research by Institute of Gastroenterology and Hepatology, Meir Medical Center, Tel Aviv University, Israel.

³³ See Annexure - Don't forget illegal drug that can heal. By The Sydney Morning Herald.



9. *Alzheimer's Disease (AD)*³⁵
10. *Phantom Limb Pain (PLP)*
11. *Post-traumatic Stress Disorder (PTSD)*³⁶
12. *Autism and/or Fragile X Syndrome*¹⁰
13. *Attention Deficit Hyperactivity Disorder (ADHD)*³⁷
14. *Emphysema*
15. *Diabetes*³⁸
16. *Glaucoma*³⁹
17. *Skin Cancer*⁴⁰ and/or *Tumours*⁴¹
18. *A 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*
19. *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*⁴²

³⁴ See Annexure - Enhancing activity of Marijuana-like chemicals in the brain helps treat Parkinson's Symptoms in mice, Stanford study finds. Research by Stanford University School of Medicine.

³⁴ See Annexure - Parkinson's Disease and the THCV in Cannabis. By Don Fitch.

³⁵ See Annexure - Prevention of Alzheimer's Disease pathology by Cannabinoids: Neuroprotection Mediated by blockade of microglial activation. Research by The Journal of Neuroscience.

³⁶ See Annexure - The Dreaming: The use of Cannabis Tinctures to treat Post-traumatic Stress Disorder (PTSD). By Smokin' Moose.

³⁷ See Annexure - ADHD and the Endocannabinoid system. Research by Dr. David Bearman.

³⁸ See Annexure - The Synthetic Cannabinoid HU-210 attenuates Neural damage in Diabetic mice and Hyperglycemic Pheochromocytoma PC12 cells. Research by Department of Human Nutrition and Metabolism, Braun School of Public Health; and Department of Medicinal Chemistry and Natural Products, Medical Facility, Hebrew University, Jerusalem, Israel.

³⁹ See Annexure - Cannabinoids and Glaucoma. Research by Department of Ophthalmology, Aberdeen Royal Infirmary; and Department of Biomedical Sciences, Institute of Medical Sciences, University of Aberdeen, UK.

⁴⁰ See Annexure - Identification and Characterization of Cannabinoids that induce Cell Death through Mitochondrial Permeability transition in Cannabis Leaf Cells. Research by the Graduate School of Pharmaceutical Sciences, Kyushu University, Fukuoka, Japan.

⁴⁰ See Annexure - Cannabinoid receptors as novel targets for the treatment of Melanoma. Research by Department of Biochemistry and Molecular Biology, Complutense University, Spain.

⁴¹ See Annexure - Review: Endocannabinoids in endocrine and related tumours. Research by Dipartimento di Scienze Farmaceutiche, Università di Salerno, Italy.

⁴¹ See Annexure - A new strategy to block tumor growth by inhibiting Endocannabinoid inactivation. Research by Endocannabinoid Research Group, Naples, Italy. And by Dipartimento di Scienze Farmaceutiche, Università di Salerno, Italy.

⁴¹ See Annexure - Marijuana cuts Lung Cancer tumor growth in half, study shows. By Science Daily.

⁴² See - Cannabinoids in management of difficult to treat pain. Research by Dr. Ethan B. Russo, GW Pharmaceuticals, USA. Available at website: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2503660/>



20. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes severe Nausea
21. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that causes seizures, including those characteristic of Epilepsy⁴³
22. 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; or Sclerosis
23. 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 muscles⁴⁴, including those characteristic of Arthritis⁴⁵
24. A debilitating medical condition or treatment approved by the Health Department⁴⁶

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

Dispensaries

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

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;

⁴³ 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.

⁴³ See Annexure - Compound in Cannabis may help treat Epilepsy, researchers say. By L.A. Times.

⁴⁴ See Annexure - Endocannabinoid Degradation, Endotoxic Shock and Inflammation. Research by Department of Experimental Medicine and Biochemical Sciences, University of Rome, Italy.

⁴⁵ See Annexure - The antinociceptive effect of Δ^9 -Tetrahydrocannabinol in the arthritic rat involves the CB2 Cannabinoid Receptor. Research by Department of Pharmacology and Toxicology, Virginia Commonwealth University, USA.

⁴⁶ See Annexure - Is there a role for the Endocannabinoid system in the etiology and treatment of melancholic depression. Research by Department of Psychology, University of British Columbia, Vancouver, Canada.

⁴⁶ See - Cannabis Treatments in Obstetrics and Gynaecology: A Historical Review. Research by Dr. Ethan B. Russo, GW Pharmaceuticals, USA. Available at website:
<http://www.cannabis-med.org/data/pdf/2002-03-04-1.pdf>



- 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 wast/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 (S.A.S) Special Access Scheme Medical Cannabis Card program;
- Centralised website and access;
- Cannabis education programs;
- Adequate Cannabis research and development programs

Special Access Scheme - medical Cannabis 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 Special Access Scheme Card(s), for medical Cannabis (SAS-MC Card) to qualifying patients or designated caregivers. A SAS-MC Card would protect a medical Cannabis patient from getting a criminal record and would solve a huge problem for law enforcement.

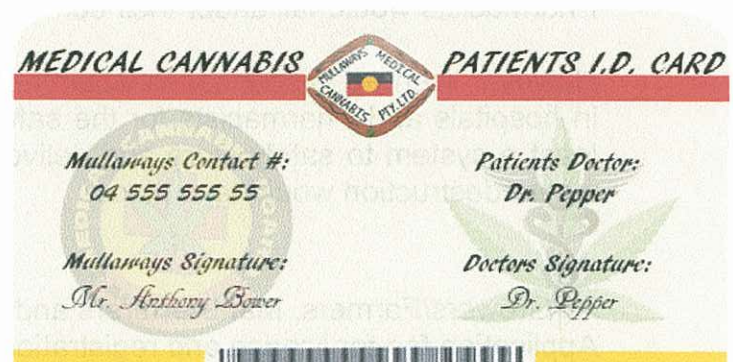
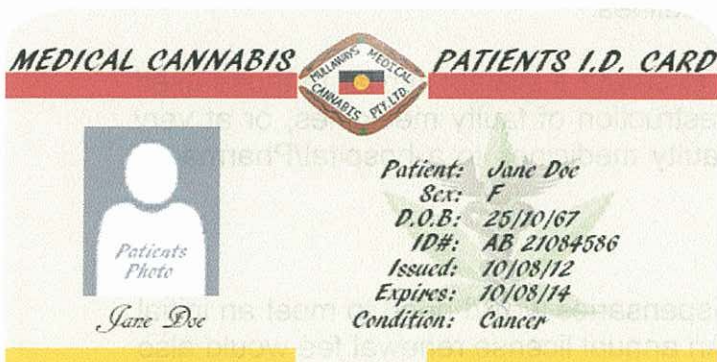
A central part of this regime will be to allow a range of Cannabis medicines to be used in the relief of suffering for a range of illnesses. The range of illnesses for which Cannabis may be used should only be determined by health professionals with knowledge of the medicinal Cannabis field.

The SAS-MC Card program will establish a computerised system 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).

Special Access Scheme Cards (Medical Cannabis)

Patients Card (Front)

Patients Card (Back)



This card Authorises the above patient to possess XYZ amount of Cannabis medications and administer Cannabis for their above medical condition. Prohibition on sales still apply.

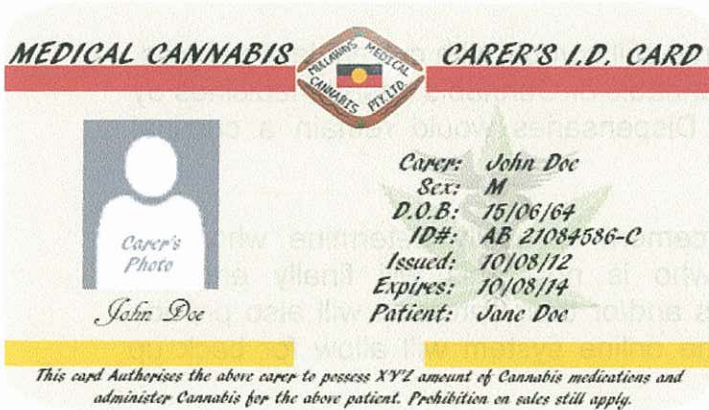
This card has been issued through the Australian Special Access Scheme (S.A.S)



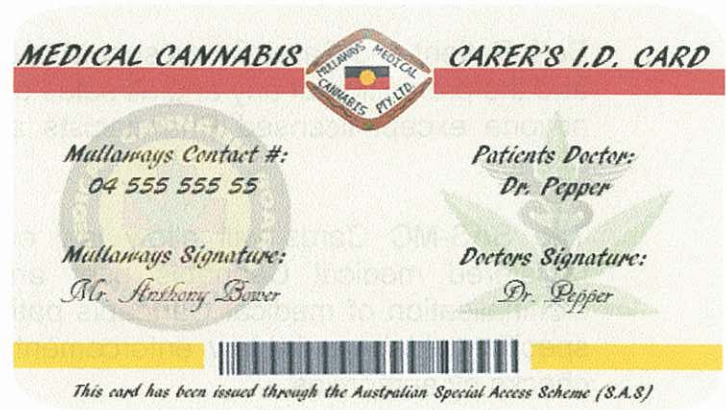
Mullaways Medical Cannabis Pty Ltd
 Application To NSW Upper House Inquiry Into
 The Medical Use Of Marijuana
CONFIDENTIAL - 18th January, 2013

MULLAWAYS Medical Cannabis Pty Ltd
 PO BOX 334
 KEMPSEY, NSW 2440
 Email: mullawayman@skymesh.com.au
 www.mullawaysmedicalcannabis.com.au

Carers Card (Front)



Carers Card (Back)



The NSW 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.

The SAS-MC (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 SAS-MC Cards represents one of the best ways to ensure the security and non-diversion of Cannabis for medical use.

Further regulations for any such SAS-MC 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 SAS-MC 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.

Standards for obtaining the SAS-MC 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 20-22).

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 above in Pages 17-19).

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.

It is time the NSW Government set in place a system to supply Cannabis/Cannabis medicines to people requiring them for the management of their medical condition and to remove these people from the Criminal Justice System.

PART 3

Legal implications and issues concerning the use of Cannabis for medical purposes

Members of this inquiry must you be reminded that medical cannabis is not and never was illegal in Australia under *the Single Convention on Narcotic Drugs 1961*.

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:

...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."

It is also obvious that you are unaware of 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."

So I ask you all, how great is the harm to the sick and/or their carers who find that Cannabis assists with their condition? How much greater is the harm to these people to live under threat of being criminalised for using a drug which works for them?

Now let us be very clear about this. Nobody, that's Doctors, politicians, the legal system, the Police or anyone else you can think of, can tell a person what medicine works best for them.



It would appear you must also be reminded of **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 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."

Now if as has been suggested that Cannabis has no use as a medical product how is it that GW Pharmaceuticals has been allowed to trial its medical product "Sativex" in Australia?

The number of countries around the world that now recognised Cannabis as a medical product grows daily. Is their science somehow different to that in Australia? The EU now funds research projects to develop medicinal Cannabis with low contents of Delta 9 THC but in Australia we are still having an inquiry like this.

Government investigation into the use of Cannabis for medical purposes

A previous Premier of NSW, the Hon Bob Carr MP (now Foreign Affairs Minister), has indicated his support for enabling Cannabis to be legally available to patients suffering from serious illnesses.



After the NSW Drug Summit in 1999 the recommendations concerning therapeutic Cannabis⁴⁷ use indicated the direction research needed to take before it would be considered a real option.⁴⁸ Alternative delivery methods to smoking the Cannabis were necessary if Cannabis based medicines were to be considered an option.

In October 1999, as Premier of NSW, the Hon Bob Carr MP, announced that the Government would investigate the use of Cannabis for medicinal purposes. He referred to the Australian Medical Association's support for prescribing Cannabis to people with Cancer and AIDS, and the finding of a report by the House of Lords Select Committee on Science and Technology that Cannabis could serve a therapeutic function. The Premier explained that a Working Party would first examine the feasibility of making Cannabis available for therapeutic purposes.

The *Report of the Working Party on the Use of Cannabis for Medical Purposes*⁴⁹ was submitted to the Government in August 2000. The Working Party's key findings were that;

- Some Cannabinoid substances may have value in the treatment of a limited range of medical conditions such as HIV-related wasting, nausea caused by chemotherapy for Cancer, muscle spasm in some neurological disorders, and pain that is unrelieved by conventional analgesics;
- Research is required to better assess this therapeutic value;
- Crude Cannabis cannot be, and is unlikely ever to be, prescribed in Australia;
- There are commercial and regulatory obstacles to the medical prescription of synthetic Cannabinoid substances in Australia

The report made 24 recommendations, which followed two themes. Firstly, the report recognised the need for more authoritative scientific evidence on the medical benefits of Cannabis and the development of more effective, safer means of delivering the therapeutic effects of Cannabis than by smoking or consuming parts of the plant directly. Secondly, the recommendations recognised that because research would take time, more immediate action was necessary on compassionate grounds to relieve the suffering of seriously ill people who could be assisted by Cannabis use. Therefore, a two year trial was proposed, whereby approved people with certain medical conditions would be exempted from criminal prosecution for possessing, growing and using Cannabis for personal, medical purposes.

The Inquiry into the Use of Cannabis for Medical Purposes released its *Report on*

⁴⁷ See - Research into the therapeutic role of Marijuana, American College Of Physicians. Available at website: http://www.acponline.org/advocacy/where_we_stand/other_issues/medmarijuana.pdf

⁴⁸ See - NSW Drug Summit recommendations: The use of Cannabis for medical purposes. Available at website: <http://www.mullawaysmedicalcannabis.com.au/recommendations.html>

⁴⁹ See Annexure - Key Findings of the Working Party, Report on the Use of Cannabis for Medical Purposes, Executive Summary (2000 Vol 1) pg 24, 25, 26, 29 and 30.



Consultation on the Findings and Recommendations of the Working Party on the Use of Cannabis for Medical Purposes in July 2001. The report presents the viewpoints of the submissions received, rather than drawing any definite conclusions. Overall, the main areas of concern raised by submissions were over the recommendations dealing with;

- Developing alternative ways of using Cannabis rather than smoking;
- Introducing an interim compassionate regime;
- Illnesses/conditions to be covered by the regime;
- Whether patients should be able to grow Cannabis plants;
- The involvement of Doctors to certify patients for medical Cannabis

In May 2003, as NSW Premier he outlined some key elements of the plan, including the formation of an Office of Medicinal Cannabis, and stated that a draft exposure bill would be introduced at the earliest opportunity to provide for a four year trial of the medical use of Cannabis.

In May 2003, The ACON (AIDS Council of NSW) welcomed the NSW Governments announcement of a four year trial of medical Cannabis and the impact this would have on many people living with HIV/AIDS.

ACON President Adrian Lovney then stated "ACON strongly supports this move to establish a compassionate scheme for medicinal use of Cannabis for people with chronic illnesses such as HIV and Cancer ... It is already well established that Cannabis can assist with pain relief and help alleviate nausea and appetite loss which are common side effects of many HIV treatments ... Anti-retroviral treatments have given many HIV positive people a new lease on life but this often comes with debilitating side effects that have a major impact on their quality of life ... Some people living with HIV/AIDS currently risk criminal prosecution to use Cannabis because this is the only way they can alleviate these side effects ... There are many more HIV positive people who could benefit from access to Cannabis but they don't use it only because it is illegal ... ACON looks forward to working with the NSW Government in the establishment of this trial."

In media interviews, the Premier clarified that the four year 'trial' was not intended to be a clinical trial, as there was already sufficient clinical evidence from overseas: "Its been proven in the other jurisdictions (Canada, the UK and the USA). It would repeat their experience if we were to say timidly this is only going to be a trial conducted by Doctors."⁵⁰

However, in May 2004 the Premier revealed that he had received advice from the Home Office that the Cannabis spray would not be available for "a few years".

⁵⁰ See - Bob Carr: Cannabis trial won't lead to decriminalisation. By ABC News. Available at website: <http://www.abc.net.au/lateline/content/2003/s859641.htm>



Although the Carr Government has continued to affirm its support for the project, no further announcements have been made since May 2004.

So ultimately unless mass changes in laws were to occur there would remain no legal Cannabis based medicines available in Australia until an individual person, company or Government group had gone through all the required avenues of Government law to be granted a license to cultivate, possess and supply Cannabis in Australia under the *Drugs Misuse and Trafficking Act 1985*, or until a safe, quality Cannabis based medicine was made a common medical option overseas enabling importation of the required medicine into Australia.

In 2009 the UK Company GW Pharmaceuticals was allowed to begin trials of its Cannabis based medicine "Sativex" an oromucosal mouth spray here in Australia.

Difficulties associated with legal Cannabis based medicines in Australia

Mullaways has encountered many difficulties along the way in trying to produce Australia's first legal Cannabis based medicine. Many people, inquiries and reports would believe the biggest difficulties associated with the development, research and production of legal Cannabis based medicines in Australia are;

Developing alternative ways of using Cannabis rather than smoking; Introducing an interim compassionate regime; Illnesses/conditions to be covered by the regime; Whether patients should be able to grow Cannabis plants; The involvement of Doctors to certify patients for medical Cannabis; Security regulations to divert medicinal Cannabis from black-market sales and recreational use; Safety and quality of Cannabis based medicines; Cost of medicines, etc.

But Mullaways has not found this to be the case. We have solved many of these issues of concern, by developing a safe, quality non-smoking alternative for medicinal Cannabis, Mullaways Cannabinoid Tincture, which can be produced cheaply and efficiently in Australia; by implementing a compassionate regime for chronically ill and dying patients with the involvement of their Doctors overseeing their treatment; by adhering to TGA standards and regulations required to produce the medicines; and by producing stable Cannabis breeds "strains" that would be registered with IP Australia enabling analysis of a stable traceable breed.

Mullaways has found the biggest road-block in the development, research and eventual production of Cannabis based medicines in NSW and Australia, primarily



the Cannabinoid Tincture to quite literally be the NSW Health Department, and the Pharmaceuticals Services Branch.

Mullaways has worked for many years towards attaining a license to cultivate, possess and supply Cannabis plants for the purposes of scientific research, analysis and study, in NSW. Since 2008 Mullaways has submitted an Application for a license annually, and each year, each Application Mullaways simply gets a response stating; the following requested information has not been provided and as such the Application for a license cannot be assessed until such a time as the information is provided, the questions requested are;

- "The name, position and scientific qualifications of the person from a recognised research institute who is to carry out and take responsibility and supervision of the proposed research, analysis and study";
- "The premises within a recognised research institute where it is proposed that the work is to be undertaken";
- "Detailed information on the nature and purpose of the research, the methods to be employed, the quantities of Cannabis involved, the time-frame involved, and the proposed procedures to be adopted to ensure security of the Cannabis";
- "Whether it is proposed that clinical trials are to be undertaken, and if so, the written approvals of the institution and the relevant Ethics Committee approvals, as will be appropriate under the circumstances"

Now Mullaways is more than willing to admit our first submitted Application for a license (a whole 4 Pages) was probably missing some important information and clarification that the NSW Government required to properly assess said Application, but 5 years is a long time and with time and experience comes wisdom and hindsight, and as such Mullaways would argue that our latest submitted Application in 2012 (27 Pages, with 51 attached Annexures) **did in-fact answer all of the requested questions, and that there is no necessary reason Mullaways should not be issued a license, in NSW.**

This is of course a highly controversial area but I, Anthony D. Bower, Director of Mullaways Medical Cannabis Pty Ltd believe Mullaways has not been taken seriously in our Application and a license has not been issued as many Pharmaceutical company's and representatives do not take Cannabis seriously as many believe it does not fit into their current model for medicine, these are generally the same Pharmaceutical reps and Doctors whom happily recommend evasive surgery and large dose Opioids such as Morphine as common medical options.



PART 4

Other related matters

What a medical Cannabis patient goes through

Mullaways Has encountered thousands of Australians in chronic and debilitating pain asking for help, many asking questions wanting to educate themselves before trying certain methods of receiving Cannabis therapeutically, and many simply asking to receive the Mullaways Cannabinoid Tincture for medical relief, either for themselves or a loved one.

Mullaways has tried to facilitate as many chronically ill and dying Australians with its Cannabinoid Tincture as possible. But simply cannot produce the required amount of medicine to supply these people until a license is received from the NSW Government so that a Cannabinoid Research Centre and Manufacturing Plant can be built (to TGA standards) to do the required scientific research and eventually produce the amounts of safe, quality Cannabis medicines required, and to be made accessible through Pharmacists and licensed Dispensaries.

I have continually been asked by Government, Police, Doctors and medical patients why does Mullaways do what it does.

When you have lived with chronic and debilitating pain day in day out, when you have witnessed the suffering of someone you love living with chronic and debilitating pain day in day out it will change the way you think, and test what you believe to be right.

"You never know how much you really believe anything until its truth or falsehood becomes a matter of life and death to you. - C.S. Lewis"

When you have heard in masses the depths of the pain and suffering of these ill and dying Australians it is hard not to be dedicated to this. Mullaways literally have thousands of cases of ill Australians and their want nay their NEED for a Cannabis based medicine in this country. If this inquiry would really like to know what it is like for the carers and family members of those suffering from chronic pain, serious illness or undergoing Cancer treatment just ask.

If this inquiry would really like to know what it is like to live with the prospect of being criminalised for using Cannabis medically or the carers of these people just ask.



If this inquiry would really like to know what it is like to have to acquire the Cannabis for the ill and dying from black-market drug dealers off the street just ask.

If this inquiry would really like to know the anger and frustration medical Cannabis patients, their carers and family members feel when their health professionals treat them like criminals and junkies because they receive relief from their condition by using Cannabis instead of the heavy drugs pushed on them by these professionals with all the serious side effects of these drugs just ask.

If this inquiry would really like to know the anger and frustration medical Cannabis patients, their carers and family members feel when they know that a non-psychoactive alternative to smoking Cannabis has been available in Australia for over 3 years, Mullaways Cannabinoid Tincture, which has No Detectable Prohibited Substances and is not available to these chronically ill and dying people due the abuse of executive authority just ask.

Let me inform the inquiry 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.

Special Access Scheme in Australia

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

The Special Access Scheme was established in Australia for the purpose of allowing an avenue of access to unapproved therapeutic goods via the TGA, patients requiring access to unapproved drugs such as Cannabis must apply to the Special Access Scheme and if approved must then source the Cannabis medicines through the following avenues;

- Acquire Cannabis based medicines from Pharmacists and/or licensed Dispensaries, based either in Australia or imported from overseas;
- Acquire Cannabis from a licensed medical practitioner who applies to the TGA to grow the medical Cannabis for their patient

Now being realistic, this is highly impractical as very few if any Doctors will take on the responsibilities of growing Cannabis for their patients. As many are unwilling to take on the legal obligations, many are already much too busy, and many simply don't have the required cultivation skill as they are Doctors not horticulturalists.



Leaving the patients to acquire their medicine from Pharmacists and/or licensed Dispensaries;

As there is currently no Cannabis based medicines registered in Australia on the ARTG patients requiring alternative delivery methods to smoking the Cannabis, would need to import Cannabis based medicines such as; Nabiximols sold as "Sativex", Dronabinol sold as "Marinol", and Nabilone sold as "Cesamet". This is a highly impractical alternative as these medicines available through importation are highly expensive⁵¹ and the majority of patients whom require them cannot afford the ongoing costs. The other problem with these imported Cannabis based medicines such as "Sativex" is that they claim not to get patients high, or give the euphoria associated with illegal recreational Cannabis use. Yet many patients have experienced different.⁵¹ ⁵² (The conclusive proof of this actually comes from GW Pharmaceuticals own research documentation, the Sativex Summary of Product Characteristics (SPC), a statutory document, on Page 6, item 4.8 reports that "euphoric mood" is a common side effect).

This generally leaves the patient with one of two options where to source their required medicine. Firstly to grow the Cannabis themselves and secondly to buy the Cannabis off the black-market from a street dealer, for patients who choose;

To grow the Cannabis themselves, this is also a highly impractical alternative as it is of course illegal. But there's the added concern the majority of patients are not horticulturalists, and as such the Cannabis being grown and used is not to the level (medical grade) that these patients should be receiving for medical use. Not to mention that these are patients going through Cancer treatment and the like, HIV/AIDS and other severe diseases and/or treatments. Thus generally are much too physically weak to do the required physical effort in the growth of the Cannabis eg/ lifting a large garden pot filled with soil, lifting buckets full of water, etc.

This generally leaves one remaining option;

To buy the Cannabis off the black-market from a street dealer, for many patients this is the only option available to acquire their required medicine. Some people do not understand that it is in-fact illegal and that you can be arrested for buying Cannabis

⁵¹ See Annexure - The guinea pig's tale of cannabis based medicine. By Graham Irvine, A law lecturer, broadcaster and most importantly first Australian patient with Parkinson's Disease to receive Cannabis based medicines.

⁵² See Annexure - Sativex Scam Part 2.5: Misinformation, Propaganda, Untruths and Lies. By Peter Reynolds.



from a street dealer even if for the sole purpose of relieving the pain of a medical condition. The majority simply are tired of living a life of chronic and debilitating pain. Let me make it clear it is not that these citizens do not respect the law, the majority of them are upstanding members of our community, but when you live in chronic and debilitating pain day in day out or witness a loved one living with this pain day in day out, and think there may be some medicine to relieve said pain and give a higher quality of life then many of these people simply cannot stand idly by and do nothing. This is also a highly impractical alternative as it is of course illegal and comes with the risk of fines and imprisonment but even if the patient gets their required medicine without criminal prosecution, there's the issue that their medicine is an unregulated product from the black-market, thus providing many subsequent underlying health risks.

Until such time as the production of safe, quality therapeutic Cannabis based medicines such as tinctures, patches, creams, oils, edibles and/or a medical grade form of therapeutic Cannabis is available in Australia many chronically ill and dying Australians, their carers and family's will continue to be unfairly punished for simply trying to relieve the severe pain the only way they find possible through Cannabis, and by obtaining the Cannabis the only way they find possible through street dealers.

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 set in place a Special Access Scheme Medical Cannabis Card for patients and carers, (As outlined above in Pages 24-27).

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 set in place a Special Access Scheme Medical Cannabis Card for patients and carers, (As outlined above in Pages 24-27).

PART 5

Submission Conclusion

The production of safe, quality therapeutic Cannabis based medicines such as tinctures, patches, creams, oils, edibles and a medical grade form of therapeutic Cannabis (for patients who would continue to smoke rather than take other Cannabis medications available - as is their base human right) would be of great benefit to Australia and its Health system. As the availability of said medicines would;

- Obviously benefit that of those who are chronically ill and dying in Australia and whom require Cannabis based medicines for the management of severe pain, nausea and appetite, while going through Cancer treatments, HIV/AIDS and other severe diseases and/or treatments in which patients find it helpful in managing their conditions.

But Mullaways believes it would also;

- Have a great impact in the reduction in health problems in Australia related to Cannabis, such as Emphysema, etc. As Cannabis education and a regulated system of growing, manufacturing, producing and supplying Cannabis medicines would greatly reduce patient health problems related to Cannabis, eg/ mould, bad quality seedlings, incorrect growing techniques, etc. Thus reducing the costs in



the Australian Health budget by reducing additional health problems over the country.

- Create a whole new industry, giving Rural Australia the means of production to grow, produce and manufacture Cannabis medicines. Bringing untold jobs to the country, from the initial construction of the Cannabinoid Research Centre and Manufacturing Plant, the workers needed to continually run the plant operations, truck drivers shipping the Cannabis medicines from depot to depot, shop workers in the licensed dispensaries, and many, many more avenues of employment.
- Bring in adequate quantities of taxes through the licensed grower/farmers, manufacturers and dispensaries for Australia to set in place a Special Access Scheme Medical Cannabis Card program, Centralised website and access, Cannabis education programs, and adequate Cannabis research and development programs.
- Reduce Police workload, and stop those chasing chronically ill and dying Australians for minor offence quantities of Cannabis for therapeutic use. Freeing Officers to tackle genuine crimes where higher arrest rates are uneasy to obtain.

At this current time Austria, Belgium, Canada, Chile, Czech Republic, Finland, Germany, Israel, Italy, Mexico, the Netherlands, New Zealand, Portugal, Spain, Switzerland, the UK, and nineteen U.S. States (Alaska, Arizona, California, Colorado, Connecticut, Hawaii, Maine, Maryland, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Washington, and Washington DC) have all started loosening their laws to varying degrees to provide regulated and/or legalized Cannabis based medicines if prescribed for nausea, pain or the alleviation of symptoms surrounding chronic illness.

Mullaways believes its time NSW and Australia joins the majority of the other Developed Nations in the 21st century.

It's obvious certain changes need to occur in order to make therapeutic use of Cannabis a real medical option in Australia.

We are now entering into 2013. The landscape has changed drastically. Mullaways Medical Cannabis Pty Ltd now sits awaiting this opportunity, ready to work with the NSW and Australian Government and Health System. Needing a license/exemption to cultivate, possess and supply Cannabis plants under the *Drugs Misuse and Trafficking Act 1985*, from the Director-General of NSW Health, Dr. Mary Foley, enabling Mullaways to continue to bring its operation further into line with all State and Federal laws. And enabling Mullaways to build the proposed Cannabinoid



Mullaways Medical Cannabis Pty Ltd
Application To NSW Upper House Inquiry Into
The Medical Use Of Marijuana
CONFIDENTIAL - 18th January, 2013

MULLAWAYS Medical Cannabis Pty Ltd
PO BOX 334
KEMPSEY, NSW 2440
Email: mullawayman@skymesh.com.au
www.mullawaysmedicalcannabis.com.au

Research Centre and Manufacturing Plant required too be able to provide Australia's first legal natural Cannabis based medicine, Mullaways Cannabinoid Tincture. A medicine that will be of high safety and quality, won't get patients stoned, and will be produced cheaply and effectively entirely in Australia by Australians.

So I ask. How will the Government treat these important matters at hand? Will Mullaways be given the chance to prove its research and therefore medical value to the Australian Health system or in the end will this all simply be the results of previous inquiries findings into the matter, that something should've and must've been done, but couldn't and wasn't?

I will leave the inquiry 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, Director
Mullaways Medical Cannabis Pty Ltd

