Submission No. 069
Received 1 August 2016

Medical Cannabis Advisory Group
Queensland

Queensland Parliamentary Inquiry:
Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

Submission: Public Health (Medicinal Cannabis) Bill 2016

A Bill to replace identical medical cannabis provisions currently in the *Health (Drugs and Poisons) Regulation 1996*

July 2016

Submission No. 069
Received 1 August 2016

Medical Cannabis Advisory Group Queensland

[redacted]

"Patients should not have to choose between breaking an unjust law, and suffering and dying needlessly."

Submission: Public Health (Medicinal Cannabis) Bill 2016

TABLE OF CONTENTS

Parliamentary Inquiry: Public Health (Medicinal Cannabis) Bill 2016

There are two Queensland health Bills that will impact on patients who use cannabis for medical purposes, and the emerging cannabis industry.

- Public Health (Medicinal Cannabis) Bill 2016
- Medicines, Poisons and Therapeutic Goods Bill (QLD) 2015

Public Health (Medicinal Cannabis) Bill 2016

On 10 May 2016 the Public Health (Medicinal Cannabis) Bill 2016 was introduced into the Queensland Parliament,[1] and proposes to put in place a regulatory framework that is almost identical to the medical cannabis provisions that are currently contained as regulations in the *Health (Drugs and Poisons) Regulation 1996,* and also only applies to cannabis that has been cultivated, manufactured and supplied by Commonwealth registered corporations in accordance with the Commonwealth *Narcotics Drug Act* and the *Therapeutic Goods Act,* or imported from overseas and manufactured in accordance with the *Therapeutic Goods Act and Custom Regulations.*

Despite the known risks, the Bill includes provision for FAAH inhibitors, synthetic chemicals that imitate the effects of cannabis. The only cannabis that can be prescribed and supplied under this Bill is cannabis that has come through the federal government's TGA pathways. Therefore, TGA as well as State approval will still be required even when locally made cannabis becomes available under the changes that were made to the *Narcotic Drugs Act* earlier this year to establish a federal cultivation licensing scheme.

The Bill proposes to put in place at a state level a process for doctors to obtain State approval when the doctor has already been approved by the TGA under the Special Access Scheme which is a duplication of the TGA process, and approvals for doctors who have been approved by the TGA as authorised prescribers, another duplication of the TGA process, as well as a State approval only for TGA approved research trials.

- Suitability of patient to undergo treatment heading
- Criminal history checks of the patient at the expense of the patient
- The chief executive can consider the personal circumstances of the patient
- 90 days for the chief executive to provide a response
- The chief executive can refer applications to an expert specialist panel
- The chief executive can request further information
- There are no limits to the number of requests for further information
- No review or appeal rights for patients or carers affected by an adverse decision
- Disclosure of patient information in breach of privacy provisions

The Bill does not provide for approvals for cannabis to be grown by patients or carers or nominated carers, or for the patients who are forced to obtain it from the illicit market, and there are no provisions for cannabis to be cultivated and supplied by the State, Queensland registered not for profits, sole traders, and small business only operating within Queensland.

Medicines, Poisons and Therapeutic Goods Bill 2015

The Medicines, Poisons and Therapeutic Goods Bill proposes to adopt the *Therapeutic Goods Act 1989* as a law of Queensland. This Bill will replace the *Health Act 1937, the Health (Drugs and Poisons)* 1996 and the *Health Regulation 1996.* These instruments include the current regulating powers and regulations that govern the manufacture, cultivation, supply, possession, prescribing, dispensing, storage, transport and use of all medicines and poisons in Queensland today, and also include the new medical cannabis provisions that came into effect on 1 June 2016.

The Bill will benefit corporations holding TGA drug manufacturing licenses, as they will no longer have to apply to the Health Department for a State drug manufacture licence, and will only need to notify Queensland Health

[1] See Ministers Speech introducing the Bill into the Queensland Parliament. Queensland Parliament website at https://www.parliament.qld.gov.au/work-of-committees/committees/HCDSDFVPC/inquiries/current-inquiries/PH-MedicinalCann bas**(sic)-**

that they are manufacturing drugs in Queensland. It will impact on not for profits, sole traders and small business operating and trading only in Queensland as they will need a licence from the TGA and will need to comply with Commonwealth law rather than the less expensive license under State law.

The Department of Health finalised the public consultations on this Bill in 2014 and state it is ready for the introduction of the Bill into the Legislative Assembly.

Inquiry Documents

The Queensland Government has made the following documents and related publications available to the public on the Queensland Parliamentary website:

- Minister's speech introducing the Bill into the Queensland Parliament[2]
- Public Health (Medicinal Cannabis) Bill 2016
- Explanatory notes to the Public Health (Medicinal Cannabis) Bill 2016
    - Policy objectives
    - Rationale for policy objectives
    - Change in government policy
    - Achievement of policy objectives
    - Alternative ways of achieving policy objectives
    - Estimated costs for government implementation
    - Consistency with fundamental legislative principles (FLP)
    - Consultation
    - Consistency with other jurisdictions
    - Notes on provisions
- Guide to making a submission to a committee of the Queensland Parliament
- 9 June 2016: Written brief from Dr Mike Walsh, Director General, Health to the Committee on the Bill (includes amended marked up copy of the Bill).
- 15 June 2016: Transcript of Evidence, Public briefing, Witness - Dr Young, Chief Health Officer, Queensland Health to the Committee on the Bill

Brief Overview: Government's Policy Objectives

The Queensland Government states that its policy objectives are to "create a regulatory framework under which *"medicinal cannabis"* products may be prescribed and dispensed in Queensland while also *preventing their unauthorized use,"* and that it will achieve its policy objectives by creating the proposed regulatory framework to facilitate treatment with *"medicinal cannabis,"* by providing two pathways for patients to be prescribed unapproved cannabis treatment." Our response to the Government's policy objectives is set out below.

The Government also states" "there is a growing body of evidence about the therapeutic potential of medicinal cannabis, in particular that cannabinoids (being the substances contained within cannabis that produce pharmacological effects) may be effective for the treatment of neuropathic pain, muscle spasticity for patients with multiple sclerosis, reducing seizures in children with treatment resistant epilepsy, wasting due to HIV/AIDS and in controlling nausea for cancer patients. Treatment with medicinal cannabis for these conditions and symptoms may have a positive impact on a patient's quality of life, particularly where traditional treatments have failed and the potential benefits outweigh the risks of any unwanted side effects."

The Government then goes on to state: "In Queensland, the controls in the *Drugs Misuse Act 1986 operate to* ***prevent harm to the community from the use of illicit drugs,*** and make it an offence to produce, possess and supply cannabis *without authorisation, justification or lawful excuse*,[3] and its policy position is to allow ***greater use*** of ***medicinal cannabis*** *products* under ***certain circumstances*** and ***for specific patients***."
The Government state to facilitate this, "the Government amended the *Health (Drugs and Poisons) Regulation 1996,*[4] to allow the chief executive of Queensland Health to approve the use of ***certain medicinal cannabis***

[2] See the Ministers Speech introducing the Bill into the Queensland Parliament. Queensland Parliament website at https://www.parliament.qld.gov.au/work-of-committees/committees/HCDSDFVPC/inquiries/current-inquiries/PH-MedicinalCann bas-Bill2016
[3] Explanatory Notes to the Public Health (Medicinal Cannabis) Bill 2016, p 1.
[4] Cannabis Law Reform Proposal for Queensland, Medical Cannabis Advisory Group, May 2015

products for a clinical trial or where the Commonwealth Therapeutic Goods Administration (TGA) has approved an individual accessing those products via the Special Access Scheme (SAS). The Government in creating the illusion of reform, states to facilitate its policy objectives: ***"a more comprehensive regularity framework is needed to effectively regulate the use of medicinal cannabis products."***

The issues we have with these objectives are discussed further below.

The explanatory notes to the Bill state there are "***no alternative ways of achieving the policy objectives*** as the use of cannabis needs to be strictly controlled and monitored through legislation in conjunction with the Commonwealth legislation,." The Office of Queensland Parliamentary Counsel (OQPC) whose function it is to advise on the application of fundamental legislative principles to proposed legislation.

The explanatory notes also state that the Bill "does not raise any Fundamental Legislatives Principles (FLP) issues likely to be of any real concern to a parliamentary committee, and most FLP issues raised at the Authority to Prepare stage have been addressed during drafting."

We disagree with these statements and have outlined several alternatives ways the use of cannabis can be strictly controlled in Queensland. We have also raised a number of issues concerning breach of fundamental legal principles, and lack of public consultation. These issues are also discussed in more detail below and our responses and key recommendations for the committee to consider are set below.

Purpose of Submission

The purpose of this submission from the perspective of patients and carers is to highlight how the State Government has failed patients and carers, and how this Bill is unnecessary, and a waste of tax payers monies as it will only replace almost identical medical cannabis provisions that are already in the *Health (Drugs and Poisons) Regulations,* and in doing so breaches fundamental legal rights.

We also aim to show how the process to access cannabis in Queensland is an abuse of process, and in breach of fundamental legal rights and liberties, as this Bill proposes to give the chief executive and his delegates in the Health Department discriminatory and excessive powers that are not in law now in respect to cannabis, or any other medicine or drug under the *Therapeutic Goods Act,* Health *Act* and the *Health (Drugs and Poisons) Regulation,* and how the Bill puts in place even more restrictions and conditions that will only serve to obstruct and delay the supply of cannabis to patients.

We have also included alternative options for the supply of cannabis using the State *Health Act* and the *Health (Drugs and Poisons) Regulation* rather than only providing supply via the very restrictive Commonwealth TGA schemes, and have included a number of other key recommendations that we hope the committee will consider.

We also aim to show how the Bill breaches privacy rights and lacks review or appeal rights for patients and carers whose interests are adversely affected from decisions made by chief executive.

Outline of Main Issues

We have identified a number of issues of concern with the Bill, and have also referred to issues that patients are experiencing with the current medical cannabis regulations in the *Health (Drugs and Poisons) Regulations,* as these are identical to provisions in the Bill, and are adversely impacting on the fundamental rights and liberties of patients now. This Bill proposes to do the same but also contains far greater discriminatory and excessive powers that come between the patient and doctor relationship, and proposes to put in place a number of other barriers that will make access to unapproved cannabis via the TGA pathways almost impossible for patients to achieve, and will also exclude most patients leaves them at risk of criminal charges under the *Drugs Misuse Act.*

Some of the issues with the Bill are as follows:

- In breach of fundamental legislative principles, undermines and eliminates fundamental rights and liberties of patients and carers.

- The Bill has 143 pages of provisions under an Act, in contrast to 8 pages of almost identical medical cannabis provisions in the *Health (Drugs and Poisons) Regulations* currently in use.

- Restricts access to cannabis only from the TGA schemes, and puts in place an unnecessary and convoluted State approval process that duplicates the TGA assessment process, after the doctor, patient and product/s have already has been assessed and approved by the TGA.

- The Bill also proposes to give to the chief executive far more discriminatory and excessive powers that are not contained in the *Health (Drugs and Poisons) Regulations* for access to cannabis or any other drug for that matter.

- Unnecessary and wastes tax payers monies, as the Premier and Cabinet can make urgent regulations now or amend the *Health Drugs and Poisons Regulations,* and already has, whereas this Bill seeks to give the chief executive powers in the Act itself, and if new provisions or changes need to be made, an amending Bill will need to go to Parliament which is a very lengthy and costly process.

- Discriminates against patients who use cannabis, and the use of cannabis which is a safe non toxic medicine by putting in place barriers and conditions that do not apply to drugs of addiction such as opiates, methadone and benzodiazepines.

- Fails to provide for an amnesty, and a medical cannabis program with approvals for patients and carers to exempt them from criminal charges under the *Drugs Misuse Act,* if they are growing their own cannabis or obtaining it from illicit sources “out of necessity.”

- Does not foster or support the emerging cannabis industry in Queensland, as there are no approvals for Queensland registered not for profit-incorporated associations, and small business to cultivate, manufacture and supply cannabis in Queensland.

- No regard for the requests of over 25,000 Queensland residents who have signed petitions that were tabled in the Queensland Parliament throughout 2015, and no regard for over 4,000 people who signed the change.org online petitions that were sent by email to the Premier, Health Minister, Director General and Chief Health Officer.

- Against the will and demand of patients and carers, includes provisions for synthetic cannabis products, which have already proven to be dangerous and ineffective, and puts patients lives at risk.

- Deprives terminally ill patients and patients with life threatening conditions of their legal right under Commonwealth law as it fails to include a patient prescriber pathway in accordance with the SAS Category A notification scheme.

- The criteria and assessment for an approval under the single patient prescriber pathway in the Bill unnecessarily duplicates at a State level the SAS Category B pathway assessment process.

- In line with the Government’s current policy under the *Health (Drugs and Poisons) Regulations,* can continue to restrict patient class prescribers to oncology, pediatric neurology, and palliative care specialists which is inconsistent with the TGA authorised prescriber scheme which is available to all doctors and has no restrictions on the conditions that can be treated.

- Gives the chief executive excessive and discriminatory powers that come between the doctor patient relationship, and duplicates the TGA approval process when a doctor has already determined that there is clinical justification for their patient to be treated with medical cannabis, and the patient or carer has already given the doctor their informed consent to assume all responsibility for any adverse outcomes, and after the doctor has already been assessed by the TGA, and been granted a Category B treatment approval.

- The chief executive can request criminal history checks of the patient, and information about the patients personal circumstances as part of the assessment process to determine the suitability of the patient to undergo treatment, and at the expense of the patient which is discriminatory and an abuse of process, as these types of provisions do not exist in the TGAct for access to registered or unapproved medicines, or in the *Health (Drugs and Poisons) Regulations* that currently provides for patient access to cannabis and Schedule 8 medicines.

- The chief executive can take up to 90 days to provide a response, and can make requests for further information including updated specialists reports, and there are no limits to the number of requests that can be made for further information, and the chief executive can also refer cases to an expert panel, even though the doctor already has TGA approval.

- The chief executive has the power to impose unreasonable conditions on patient approvals such as using an approved or specific type of vaporiser that is not even available for supply in Australia, and requirements that the patient undergo extensive monitoring and testing, at added costs for the patient.

- Disclosure of certain patient information is in breach of the TGA and privacy laws.

- No review or appeal rights for patients or carers whose interests are adversely affected by a decision of the chief executive.

- No provisions for patient advocates on the expert panel or working party, and exclusion of patients and carers from the decision making process., and no funding to train doctors or support patient groups and Queensland industry.

- The Bill is unnecessarily complex, lengthy, unambiguous and not written in a precise or clear way.

- Other breaches of fundamental right and liberties, discrimination and excess of powers is discussed below.

NOTE: As mentioned there are also still a number of outstanding issues that we are trying to resolve with Queensland Health in respect to vaporizers, ongoing testing and monitoring, and the use and supply of cannabis in hospitals. In addition, as [redacted] medicines have not arrived from Canada, and have not been dispensed or used, no doubt other issues will arise in the future. Therefore it is not possible, and within the time frames set down by the inquiry to cover every aspect about how this will Bill will impact on the health and welfare of patients and carers.

Medical Cannabis Advisory Group

The Medical Cannabis Advisory Group is a Queensland not for profit-incorporated association. We are Queensland patients and carers advocating for botanical cannabis for medical purposes law reform in Queensland. We want an end to the harm and injustice that is being caused by the State to patients and carers who use cannabis for medical purposes, who have been forced to chose between breaking an unjust law and needless pain and suffering. We are all volunteers, and have a no patient left behind policy. We are not aligned with any political, commercial or religious organisation, and have self funded all of our campaigns to date.

Whilst we commend the Queensland Government for amending Health Regulation 270A in December 2015 and removing the long-standing prohibition on the use of cannabis in Queensland, the provisions to only allow for access via TGA pathways do not go far enough, as access via the TGA was something that patients were legally entitled to in the first place, and State funded research trials for a minority, will primarily benefit researchers and overseas companies.

We want the State Government to put the health and legal rights of patients at the centre of any decision making before profits, and to ensure that any reform measures that are put in place are for botanical cannabis and have due regard for the legal rights and liberties of all patients.

We believe that the patient, in consultation with his or her doctor is best placed to determine the individual needs of the patient - not the State or Commonwealth, and ultimately it is the patient's right to make the final decision about using cannabis including the right to decide the form and type of cannabis, how it is used, the duration of treatment, and where it is obtained from, and if necessary to have the right to grow their own as long as they are registered and are not selling their cannabis.

Medical cannabis law reform proposal for Queensland 2015

In May 2015 we submitted a medical cannabis law reform proposal to the Queensland Government highlighting how the Premier and Cabinet could remove the longstanding prohibition on the use of Schedule 9 botanical cannabis in Queensland by making a simple amendment to Regulation 270A of the *Health (Drugs and Poisons) Regulation 1996*[5] using Cabinet's regulating powers[6] in the *Health Act 1937*, rather than needing a new Bill to go before Parliament.

Central to our proposal was highlighting how Queensland has more than adequate regulating powers and health and safety standards in the *Health Act* to be able to provide for a comprehensive regulatory framework in the *Health (Drugs and Poisons) Regulation 1996* for a State medical cannabis program, as unlike most of the other states and territories, Queensland did not adopt the Commonwealth's complex *Therapeutic Goods Act* into State law.

We have been advocating for Cabinet to make regulations in the *Health (Drugs and Poisons) Regulation* for a state wide patient register, and for approvals to be granted to patients and carers, who are "out of necessity" growing their own cannabis or obtaining it from the illicit market. Instead of leaving them at risk of being charged with unlawfully cultivating, possessing, and/or supplying cannabis, an approval from health can provide patients and carers with an exemption from being charged under the *Drugs Misuse Act 1986.* If a person acts outside the scope of their health approval, for example if they sell their cannabis, they can be charged under the *Drugs Misuse Act.*

The Premier and Cabinet can also use a number of the other regulating powers[7] to make regulations for health and safety standards, and for authorisation to be granted to Queensland registered not for profit incorporated associations and small businesses to be approved to cultivate and manufacture cannabis for supply to patients only within Queensland. There are also adequate provisions in Queensland law now to make regulations to cover security, monitoring and enforcement to prevent diversion of cannabis to the illicit market. This is discussed in more detail below. We have also been advocating for an immediate amnesty and funding for patients on low incomes to be able to access imports in the interim via the Special Access Scheme (SAS).

Petitions and protests 2015-16

During 2015 we collected 9,314 signatures from Queensland residents over 4 petitions requesting the Premier and Cabinet to amend Regulation 270A of the *Health (Drugs and Poisons)* to allow for the use of botanical cannabis, and to adopt our amnesty program, and provisions for the establishment of a patient focused state medical cannabis program with a register for patients and carers who grow their own cannabis, as well as provisions for Queensland registered not for profit incorporated associations and industry to cover the cultivation and manufacture of cannabis for supply within Queensland, and funding for the SAS and authorised prescribers in the interim.

It should be noted that 6,665 of the signatures were paper petitions that were collected by spending a significant amount of time out in the community in shopping malls, markets, and at public meetings. All petitions were sponsored and tabled in the Queensland Parliament on behalf of the people by Mr Laurie, the Clerk of Queensland Parliament. In addition to our petition, Steve Dickson MP has also tabled 2 petitions in the Queensland Parliament on behalf of Queensland patients and carers calling for an amnesty and for whole plant cannabis for medicine, and for hemp to be made available for food purposes.

In April 2016 we also collected another 4,305 signatures through a change.org online petition calling on the Premier, and the Minister for Health, and the Director General, and the Chief Health Officer of Queensland Health to stop duplicating the Federal TGA approval process at a state level; and to approve [redacted] doctor's and pharmacist's state applications; and to introduce a state program; and to stop criminalising patients and carers under the *Drugs Misuse Act*. We have also held protests outside the Queensland Health building and Parliament House over the state approval process, and for the government to stop using the *Drugs Misuse Act* to criminalise patients and carers. The MCUA, a national advocacy group also held a protest at Parliament House.

[5] Prior to December 2015 Regulation 270A of the *Health (Drugs and Poisons) Regulation* 1996 read "the Chief Executive Officer must not grant an approval to a person to manufacture, obtain, possess or use a S9 poison for human therapeutic use."
[6] See section 180 of the *Health Act 1937.*
[7] See Part 4 and Part 4A of the *Health Act 1937 (QLD)*

Australia and Queensland first approval Special Access Scheme (SAS) for botanical cannabis

Alongside our advocacy for a state program, we also assisted with the preparation and legal advocacy for [redacted] Special Access Scheme (SAS) application, and a separate application to the Health Minister and Attorney General of Queensland requesting an exemption under the States *Drugs Misuse Act.* Importing via the SAS was to be an interim measure as [redacted] and thousands of other patients with terminal and serious life threatening conditions who need urgent access, are not eligible for research trials, or the products that are being used are inadequate or not suitable to treat their medical conditions, and thousands of patients cannot wait for the Commonwealth to roll out its commercial cultivation scheme.

The TGA and State applications for [redacted] cannabis medicines were both submitted in March 2015, however the TGA made 5 requests to the doctor for further information. When there was still no decision by October, a legal Notice was issued to the Federal Health Minister requesting a review of the matter under the *Therapeutic Goods Act,* and the *Administrative Appeal Tribunal Act.*[8] Within days the TGA advised that [redacted] SAS application could be approved.

A Notice was also issued to the Attorney General of Queensland requesting a Statement of Reasons under the *Judicial Review Act,*[9] which is a preliminary step to file for a Statutory Order of Review in the Supreme Court, as the Queensland Health Minister had already confirmed that he could not grant an approval to any person to use cannabis, even to conduct the research trials because of the prohibition in Regulation 270A.

Although the Attorney General's office went over the 28 day Supreme Court limit they advised that Regulation 270 would be amended to allow access to all patients rather than providing a single exemption as it would not be fair to give one patient an exemption, and not others.

As the US supplier was unable to provide a compassionate supply at that time as Washington State was amending its state laws, a Canadian supplier, Tilray offered to provide a compassionate supply however it took some months to work through the product formula for the oil before the TGA granted final approval in early 2016 for the whole plant cannabis oil and dried bud for vaporising.

It took Queensland Health 4 months from when the amendment was made to provide a form for the doctor and pharmacist as State approval is needed for the TGA to finalise the import licence and permit. These forms were both submitted on 18 March 2016, however several weeks later the Director General went against his word, by requesting information that had already been provided to the TGA and Queensland Health, and also referred the matter to the expert panel under provisions in the Bill that were not law, and at that stage the Bill had not even been presented to Parliament.

The cannabis oil to treat [redacted] brain tumour and epilepsy was not approved until 29 April, and the dried bud to also treat his epilepsy, as well as nausea and pain not until 17 May, with a condition that a vaporizer approved by the TGA or one approved in a similar jurisdiction be used. The TGA did not impose a condition that an approved vaporizer had to be used. We have had to put in a submission explaining how this requirement cannot be met but [redacted] is able to use a similar vaporizer made by the same company, however after 2 months of emailing the Health Department the issue is still not resolved.

After the doctor was approved, Queensland Health then set about requesting the pharmacist to complete an entirely different form, and started the process of investigating the pharmacist, rather than undertaking this process at the same time they were assessing the doctors application. The pharmacist was not granted approval until 6 June 2016. The import section of the TGA approved the pharmacist's import licence and permits within hours of receiving notice of State approval, however the import process was held up as the licence and permits were sent back to the pharmacist by post, as an original copy needs to be sent to the supplier in Canada also by post.

The TGA advised at the start of this process that SAS applications normally take 1-5 days to approve for other medicines imported from overseas or supplied from within Australia, however it is almost 16 months from when the doctor's and pharmacist's applications were first submitted to the TGA and the State in March last year, and [redacted] cannabis is yet to arrive in Australia from Canada as we are now waiting on Health Canada to grant Tilray an export permit.

[8] Section 60 of the *Therapeutic Goods Act 1989* (Cth) - Review of Decisions
[9] Section 20 of the *Judicial Review Act 1991* (QLD - Application for Statutory Order of Review

Unbeknown to us, and straight after the doctor and pharmacist had sent in their applications to Queensland Health, with over 100 pages of supporting documents from TGA process, Queensland Health placed an FOI request to the TGA seeking disclosure of ***all*** of [redacted] documents that were used in the TGA process.

No patient or carer should have to go through this process to be able to access medicine. It is inhuman and an abuse of process, and it is entirely unacceptable and unconscionable how Queensland Health has dealt with [redacted] matter. [redacted] had a right to be able to access his cannabis medicines within 1-5 days, to treat his life threatening brain tumour, and to control the life threatening seizures, and to be able to live with dignity, and have some quality of life.

[redacted] needs his medicine for relief of pain and suffering, and to able to eat, sleep and to have some quality of life and to try to get to school and spend some time with his mates. and to also give his mum and dad some peace of mind, and so that the family can stay in Australia instead of all the costs of relocating [redacted] also doesn't need the added stress of worrying about being wrongly arrested, and the police taking away [redacted] medicine when she has been forced into a position because of unjust laws, and "out of necessity" is carrying out her duties under law to provide for the necessaries of life for her child, as the State has failed to provide access for patients and carers. The State should not stand in the way of the doctor patient relationship if the patient needs access to cannabis for medical purposes to relieve their pain and suffering.

The special access scheme is discussed in more detail below, and [redacted] has also provided a submission, which gives a personal account of what [redacted] and his family have endured throughout this long and difficult process.

Commonwealth and State Amendments Prior to Bill

It first needs to be noted that TGA approvals for doctors to prescribe and supply cannabis, cannabis resin and cannabinoids, as "unapproved" medicines are not new, and have always been available under the *Therapeutic Goods Act* using the TGA's exemption and special use pathways.[10] Similarly provisions for approvals for licenses and permits to import cannabis, cannabis resin and cannabinoids into Australia have always been available under the *Customs (Prohibited Substances) Regulations.*

In direct conflict with Commonwealth law, the states and territories have instead had in place, in health and criminal drug laws, prohibitions and/or restrictions on the cultivation manufacture, supply, and use, of cannabis, making it impossible or almost impossible for even terminally ill patients, and patients with serious life threatening conditions to be able to access cannabis via these TGA schemes. Instead of only targeting drug traffickers under the *Drugs Misuse Act*, the States have targeted the actual users including patients who use cannabis for medical purposes, and charged them with criminal offences.

Commonwealth amendments

On 24 February this year, Commonwealth Health Minister Sussan Ley said that the Department of Health and the Therapeutic Goods Administration were "well-advanced" in considering downgrading cannabis to a "controlled substance" class, putting it in the same category as morphine, and *"This will in turn reduce any barriers to access, no matter what state a patient lives in."*[11] Last year Sussan Ley also said in the Commonwealth Parliament of Australia that she would make the Special Access Scheme work for the patients.

However, the Commonwealth Government has also let patients down, by adopting a very complex and expensive TGA cultivation, manufacturing, and supply model that no other country or US state has used, and that is akin to giving the full control of commercial cannabis to the FDA. Only TGA approved research trials can proceed as the regulations for commercial licenses are still being made and won't be ready to go to Parliament for approval until later this year.

The Office of Drug Control (ODC) also recently admitted that only a small number of cultivation licenses are expected to be issued, and any cannabis that is cultivated will need to come from a legal source which means importing seeds or clones from overseas rather than allowing local strains to be used. The ODC have only recently granted the New South Wales Government a State licence to cultivate for supply within New South Wales as this was provided for in the changes to the *Narcotic Drugs Act* in February.

[10] See section 19 of the *Therapeutic Goods Act 1989*
[11] Jane Lee, Sydney Morning Herald, http://www.smh.com.au/federal-politics/political-news/senate-passes-medicinal-cannabis-legislation-20160224-gn2gjk.html, 24 February 2016.

Victoria has also implemented its own laws earlier this year for the State to cultivate, manufacture and supply cannabis within that state but do not anticipate supply until 2017 to children with epilepsy.

The ODC also only anticipate allowing enough cannabis to be cultivated to supply up to 20,000 patients Australia wide over the next five years. All products will need to be manufactured in accordance with the TGA, and patient access will only be via TGA approved research trials, Special Access Scheme (SAS) and authorised prescribers. It is also likely to take 5 -10 years for companies to develop their patented products for registration on the Australian Register of Therapeutic Goods (ARTG) which means unapproved cannabis will be used in any case which is available overseas upon a doctors recommendation that acts as a prescription, and supplied through dispensaries or online.

Cannabis under this model will not be affordable for most patients. If a company obtains registration on the ARTG for a product, it will be up to them whether or not they make an application for the product to be subsidised on the PBS, a process that can also take years. Unless subsidised by the State, patients will need to pay commercial prices for cannabis under this model. However a small number of patients who are accepted into research trials, may at the discretion of the company, continue to have their cannabis provided to them free of charge for participating in the companies trials.

Ironically patient access under this Orwellian and purely commercial model, means that cannabis will need to be imported from overseas via the existing TGA pathways for some time to come, and will come from overseas medical cannabis programs that rejected the FDA/TGA prescription model adopted by Australia. The cannabis from overseas that will be used in research trials, and for patient access via the SAS and authorised prescriber, as well as seed stock for cultivation also originated from home growers, compassionate suppliers, and the illicit market which makes it a very backward and hypocritical approach by the Australian Government for not allowing the use of cannabis from locally grown cannabis in the first place.

Locally made cannabis will initially only be supplied to a small number of patients, and not until some time in 2017, also via the TGA pathways which require TGA as well as State approval. Only a very small number of patients will be eligible for research trials. Only the rich will be able to afford to pay for expensive imports and all the associated costs involved with specialist's reports and tests, as well as being able to find and afford a private doctor, and a pharmacist that are willing to navigate the complex TGA and State bureaucratic process.

Queensland industry has been put at disadvantage and will more than likely miss out on playing a major part in this industry as the New South Wales Government have not only obtained a licence from the TGA, but have always had provisions in their health law for commercial research and development cultivation licenses for many decades. New South Wales Health have already issued a number of medical cannabis licenses before the federal changes were made. This gives these entities in New South Wales a very clear advantage over Queensland industry. New South Wales have also had provisions for hemp to be manufactured into food products for export for many years, whereas the Queensland *Drugs Misuse Act* still prohibits industrial cannabis to be made into products for human use.

Patients, carers and industry were expecting a lot more from the Commonwealth including provisions for patients to cultivate their own cannabis. However there was a complete lack of regard for the fundamental rights and liberties of patients and the institution of parliament during this process. The Commonwealth Government's Bill to amend the *Narcotic Drugs Act,* had only been made available to the other members of Parliament, and the public for a short period of time, before being rushed through both the lower house and the Senate in less than 24 hours. There was no public consultation, and no debate or scrutiny in the lower house or in the Senate to ensure that there were no unintended consequences for the patients and carers, or industry.

Queensland amendments to State Regulations and the Bill

The changes to the Health Regulation 270A in December 2015 paved the way for significant reform in Queensland, but instead of leading the nation and making changes that actually work in the interests of all patients, the Government has taken a backwards approach, and only made provisions for access via the Commonwealth TGA exemption and special use schemes, which is almost impossible, as the State has put in place an overly bureaucratic administrative process, and as there is still no local supply, patients can only access expensive imports for several years to come.

Instead of conducting ground-breaking research, the tax payer funded research trial that the State proposes to conduct on behalf of an overseas company promised over 12 months ago has not even commenced. Only a few will be eligible for access under trials, and only the rich and the well off will be able to afford to import cannabis

via the SAS, or travel overseas and bring back their own cannabis into Australia via the TGA's personal importation scheme.

Queensland Health took 4 months to provide a form for the doctor and pharmacist, only for 2 months later to provide an entirely different form for pharmacists. It has taken over six months to include regulations in the *Health Drugs and Poisons Regulations* to facilitate patient access to unapproved cannabis via the TGA pathways, and these are identical to what's proposed in this Bill that came out months before these provisions were eventually included.

The Queensland Government failed to put in place provisions for an amnesty, and for the implementation of a state program, with approvals that will exempt patients and carers from criminal charges under the State's drug laws. No provisions were made for Queensland not for profits and small business to start cultivating and supplying cannabis to patients. Industry is also now at an even greater disadvantage to the entities in New South Wales that have been granted licenses to cultivate and manufacture high THC cannabis under New South Wales health laws and commercial cultivation, manufacture and supply licenses under the hemp laws.

Most concerning is that after all the media hype and money spent - Queensland Health have only processed 1 Special Access Scheme application since the Health *Regulation 270A* was changed in December and took almost 4 months and there are still unresolved issues!

There has been no transparency, and everything that has been done, has been done behind closed doors without input from the patients and carers. Patients who actually use cannabis for medical purposes, and their carers have been excluded from the decision-making process altogether.

The only ones to benefit under the changes to Queensland law are drug traffickers who prey off patients and carers, people working in the Health Department and criminal justice system, and the researchers conducting trials for overseas companies using taxpayers monies.

Patient and Community Mandate

The Queensland Government and Parliament have ignored a mandate from the patients and the community to do more and to look after all patients and not just a minority, as almost 30,000 people have signed petitions calling for an amnesty, calling for local supply of botanical whole plant cannabis under a State medical cannabis program with approvals for patients to cultivate their own cannabis, and provisions for cultivation and manufacturing approvals for the not for profit sector and small Queensland business.

There was no mandate for this Bill, or for the State to keep criminalising patients and carers under the *Drugs Misuse Act*, or to only allow access via the TGA pathways through overly bureaucratic administrative processes, or for patients to have to rely on expensive imports from overseas for years to come. There was no mandate to use synthetics, or to use taxpayers monies to conduct unnecessary research trials for overseas companies on conditions where there is already sufficient evidence to prove cannabis is a safe and effective medicine to treat those conditions. There was definitely no mandate to give the chief executive discriminatory and excessive powers to use against patients and carers, or that come between the doctor and patient relationship.

We anticipate taking this matter to the Supreme Court unless the Government rectifies this unacceptable and unjust situation, and puts in place provisions that are in the interests of all Queensland patients, and Queensland not for profits and small business, and the Queensland community as a whole.

Brief Overview Use of Cannabis for Medical Purposes

Cannabis is not new, it has been used to treat a number of ailments since ancient and medieval times. Arabic physicians used it extensively as medication from the 8th to 18th centuries to treat a wide range of conditions, as a diuretic, antiemetic, antiepileptic, anti inflammatory, analgesic and antipyretic.

Between 1840 and 1900, European and American medical journals published more than 100 articles on the therapeutic applications of cannabis, known then as cannabis indica or Indian hemp. Common indications for its use in the nineteenth century included "muscle spasms, menstrual cramps, rheumatism, and the convulsions of tetanus, rabies and epilepsy. It was also used to promote uterine contractions in childbirth, and as a sedative to induce sleep.

Modern day research trials conducted in Israel, Spain, Germany, the Netherlands, Canada and the United States going back a half a century have also proved cannabis to be a safe and effective medicine to treat a wide range of conditions and symptoms with no serious side effects compared to the well documented toxic, debilitating, life threatening and addictive side effects of some of the pharmaceutical drugs that are registered on the ARTG and in use in clinical practice today.

1868 first early reports of cannabis used to treat epilepsy

In the late nineteenth century prominent English neurologists Reynolds and Gower reported using cannabis as a treatment for epilepsy. In 1868 Dr Gower described seizures ceasing at once after the start of treatment with cannabis on a patient: "John K., aged 40, came under treatment in 1868, having suffered from fits for 25 years. They occurred during both sleeping and waking, at intervals of a fortnight. There was a brief warning, vertigo, then loss of consciousness, and tonic and clonic spasm followed by some automatism; acts strangely and cannot dress himself. The attacks ceased for a time on bromide, but recurred when he discontinued attendance. He came again in October, 1870; scruple doses of bromide of potassium three times a day had now no effect, and the fits, at the end of 4 months' treatment, were as frequent as ever. Ext. cannabis indicae gr. (~9.8 g), three times a day, was then ordered; the fits ceased at once, “a wonderful change” the patient declared. He had no fit for 6 months, and then, having discontinued attendance, the fits recurred, but were at once arrested by the same dose of Indian hemp. He continued free from fits for some months, until, during my absence, bromide was substituted for the Indian hemp; the fits immediately recurred, and he left off treatment. He returned to the hospital in 6 months' time, and on Indian hemp passed 2 months without an attack. In the third month another fit occurred, and the patient again ceased to attend, and did not return.”[12]

Medical use and safety profile of botanical cannabis

THC and CBD both have an excellent safety profile with minimal side effects reported. Cannabis has been used since ancient times as a medicine, and despite the widespread use of cannabis today, there are very few if any instances of people dying from an overdose.

Laboratory studies testing enormous doses of cannabis in animals (rats, mice, dogs and monkeys) found that animals can tolerate doses of up to 1000mg/kg. This would be the equivalent to a 70-kg person swallowing 70g of cannabis, which is about 5,000 times more than is required to produce an effect in humans or a high.

The Drug Awareness Warning Network Annual Report, published by the United States Substance Abuse and Mental Health Services Administration (SAMHSA), contains a statistical compilation of all drug deaths, which occur in the United States, and according to this report, there has never been a death recorded from the use of cannabis.

As mentioned above, in 1976 in the first medical necessity case in *US v Randall,* the Court found that "Reports from the President's Commission and the Department of Health, Education and Welfare concluded that there was no conclusive scientific evidence of any harm attendant upon the use of marijuana, and the most recent HEW study had “failed to establish any substantial physical or mental impairment caused by marijuana. Reports of chromosome damage, reduced immunity to disease, and psychosis were unconfirmed. Actual evidence is to the contrary, and unlike the so-called hard drugs, marijuana does not appear to be physically addictive or to cause the user to develop a tolerance requiring more and more of the drug for the same effects. The current HEW report also notes the possibility of valid medical uses for this drug...”

In 1988, United States, Drug Enforcement Agency (DEA) Chief Administrative Law Judge, Francis Young, in response to a petition to reschedule cannabis under federal law concluded that: “In strict medical terms marijuana is far safer than many foods we commonly consume.... 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.”

[12] Gowers W. *“Epilepsy and other chronic convulsive disorders.”* London: Churchill; 1881:223. House of Lords (1988). Op Cit.122

Oral v inhalation

Research has shown that there are some pretty significant differences, and medical reasons between both of these methods, and it's not about getting high. Understanding the differences allows patients to be able to openly discuss the different treatment options, and why inhalation may be a far better treatment option to treat some of the patient's symptoms.

There are two main differences

The first difference has to do with the way the body processes THC. The difference between inhaling and eating: the effect a patient gets from smoking or vaping cannabis tends to be almost immediate and dissipates quicker, while the effect a patient gets from eating takes longer to set in depending on how much is consumed, and the effects from ingesting are usually more intense and last longer.

When a patient inhales cannabis, the THC is absorbed into the body rapidly, with as much as 50 to 60 per cent of the chemicals going straight into the blood plasma. Ultimately, the THC in the bloodstream goes straight to the brain to produce an almost instant effect. This entire process happens quickly, but it also wears off pretty quickly. In contrast, when cannabis is ingested, the THC is sent on an entirely different metabolic route, which creates a significantly different experience.

Mitch Earleywine, professor of psychology, State University of New York, and the author of Understanding Marijuana describes the process of metabolising cannabis when it's taken orally as:

"In a nutshell, eaten cannabis gets metabolized by the liver, so delta-9 THC becomes 11-hydroxy-THC, which passes the blood-brain barrier more rapidly and has more of a psychedelic effect than standard THC. Smoked or vaporized cannabis bypasses the liver and doesn't create the same 11-hydroxy-THC."

To put it in simpler terms, when you eat cannabis, the THC passes through your liver before entering your bloodstream. In effect this gives a "double effect," as the THC affects your body when it hits the liver and again when it gets into the bloodstream. This process takes a bit longer, which is why it takes longer to get an affect from taking cannabis orally, but once it happens, the "double affect" it produces tends to last longer and can often be more intense than the affect produced by smoking or vaporising.

The second reason there are differences between inhaling and ingesting cannabis has to do with what's often called "set and setting." This has more to do with the environmental factors and why people might perceive the effects of ingesting cannabis to be more intense, and also has to do with set and setting."

As the effects of smoked cannabis can be felt within seconds, even mildly experienced users can generally pick the point where they've had enough, a process called 'titration. In contrast, those who ingest cannabis need to estimate what the dose they've taken will do, and the length of the affect means that any unpleasant side effects take longer to go away.

The justification for inhalation is that the rapid effect from smoking or vaping makes it easier for a patient to know when they've had enough, while the slower-working and longer acting effect of ingesting cannabis can make dosages harder to figure out, and the patient ends up ingesting more than they need or would have inhaled because they're unsure of what effect they'll obtain when the cannabis has fully metabolised. By the time the cannabis takes effect, the patient may find that they've ingested more than they need.

Donald Abrams, M.D. Chief of Haematology-Oncology, San Francisco General Hospital; Professor of Clinical Medicine, University of California, San Francisco explains why smoked plant matter has properties that help the body heal, as does vaporized (non-combusted plant matter).

"The operative word is plant, not the pill (form of THC). After we demonstrated that cannabis had a medicinal use. We knew people were against smoking a medicine. My colleagues say Donald, nobody smokes foxglove we have digitalis you know, using a whole plant as medicine is sort of archaic. Well actually my interest in cannabis, that also got me interested in integrated medicine, particularly in traditional Chinese medicine where many treatments that are used are herbal concoctions or decoctions where the whole plant is used. In Chinese medicine extracting the active component and using that as a drug would be sort of unheard of because it removes it from the yin and the yang, the balance, provided by nature when the medicine was given as a plant.

So we knew that we could demonstrate smoking cannabis was effective till we were blue in the face and nobody was going say that it should be approved because of the delivery system. So the institute of medicine report in 1999 suggested that people seek other rapid onset delivery system for delivering cannabis as a medicine. So we did a clinical trial looking at a vaporizer and comparing the levels of cannabinoids that developed in the blood stream after smoking a cannabis cigarette verses vaporizing the same cigarette.

We did this in healthy marijuana smoking volunteers aged 25 40. It was the fastest clinical trial I had ever done because we had people lined up, very easy to enrol. What we proved was that the levels of cannabinoids in the blood stream were equivalent whether it was smoked or vaporized. That there was much less exposure to noxious gasses, when it was vaporized as measured by expired carbon monoxide. That the high was graded as equal and the patients actually had a preference for vaporization."

Side effects, adverse reactions and drug interactions

Most side effects are usually mild and dissipate shortly after the patient becomes accustomed to its use. Cannabis may cause two categories of side effects. Physiological effects: may include dizziness, weakness, tiredness, irregular heartbeat (faster or slower), lower blood pressure and blood sugar levels, increased appetite, red eyes, dryness in the mucous membranes such as the mouth and eyes and lack of coordination and balance.

Cognitive side effects may include impairment to short-term memory and train of thought and an impaired perception of time and space. Regular use of large amounts (more than 5 grams per day) can lead to cognitive impairment but this effect dissipates when use is decreased or ceased. In youth cognitive impairment could be lasting.

Side effects that may occur from overdose and that require special attention: fainting, significant changes in blood pressure, pulse and blood sugar levels or in respiration rates. A high dose of cannabis can in some cases cause a temporary psychotic attack, anxiety, delusions or hallucinations for people that are pre-disposed.

Although cannabis has been used for thousands of years, it is recommended that patents new cannabis seek professional advice before commencing use. There are some patients who may need to be closely monitored ie: first time users. Warnings are to patients where there is a known sensitivity to any of the ingredients, and patients with heart and stroke conditions, or conditions such as epilepsy are advised to take caution when using with or weaning off pharmaceutical medicines, and in pregnancy or when nursing or breast feeding. However most patients in these categories have no issues with its use and find the use of cannabis far better to tolerate than a lot of the medications on the market today and that have known and intolerable side effects.

The use of cannabis with patients new to its use or with alcohol may impair alertness and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and any other activity, which requires alertness. As mentioned above cannabis is a relatively safe herbal substance.

Whole plant cannabis: synergy and the entourage effect

A central principal underlying the use of whole plant botanical medicines is that herbs contain many active ingredients, and the primary active ingredients may be enhanced by secondary compounds, and act in synergy, producing beneficial effects that are not obtained from single molecule or synthetic drugs, including mitigating the side effects of dominant active ingredients. Unlike modern day pharmaceuticals that generally only have one single active chemical ingredient, whole plant cannabis, and cannabis extractions typically include THC and CBD, and the other cannabinoids, and more than 400 other trace compounds including terpenes, flavonoids, ketones, esters, lactones, alcohols, fatty acids, and steroids. The effects of all these chemicals working together and regulating each other has been discovered to be much different and effective than the effects of any one chemical compound working alone.

This theory serves as the foundation for what is a relatively controversial idea within the Australian research and “pharmacology community,” that in certain cases whole plant extractions serve as more effective therapeutic agents in comparison to isolated single compounds or synthetic cannabis.

However the concept is not new. The term the "entourage effect" was first coined in 1998 by Israeli scientists S. Ben-Shabat, and Raphael Mechoulam, [13] when they were working on a novel endogenous cannabinoid molecular regulation route. The “entourage effect,” has been found to magnify or enhance the therapeutic benefits of the plant’s individual components so that the medicinal impact of the whole plant is far greater than individual compounds or isolated cannabinoids on their own.

While THC has received most of the attention since being discovered in 1964 by Raphael Mechoulam, recent studies have demonstrated that many of the secondary cannabinoids and non-cannabinoid compounds found in the cannabis plant or its extracts interact synergistically to produce the “entourage effect,” and may enhance the beneficial effects of THC, and reduce THC-induced anxiety, cholinergic deficits, and immunosuppression. Dr John McPartland[14] notes: “Cannabis is inherently polypharmaceutical, and synergy arises from interactions between its multiple components.”

The basic idea is that the "entourage effect" of cannabinoids within the cannabis plant work together, or possess synergy, and affect the body in a mechanism similar to the body’s own endocannabinoid system. Wagner and Ulrich-Merzenich, [15] define the four basic mechanisms of whole plant extract synergy as follows:

- Ability to minimise adverse side effects.
- Ability to affect multiple targets within the body
- Ability to improve the absorption of active ingredients
- Ability to overcome bacterial defence mechanism

Minimising adverse side effects

Some patients especially those new to cannabis, experience increased anxiety and paranoia that is sometimes associated with the use of cannabis. The "entourage effect" allows certain cannabinoids and non-cannabinoid compounds to modulate these negative side effects of cannabis. CBD has a proven ability to modulate negative effects of THC, an in minimising the anxiety associated with THC, lowering feelings of paranoia.

Wagner and Ulrich-Merzenich also reported that the secondary compounds found in cannabis enhance the beneficial effects of THC, while the other cannabinoid and non-cannabinoid compounds found in herbal cannabis can reduce THC-induced anxiety, cholinergic deficits, and immunosuppression. Studies also show that cannabis terpenoids and flavonoids may also increase cerebral blood flow, enhance cortical activity, kill respiratory pathogens, and provide anti-inflammatory benefits. [16]

Contrary to some of the uneducated opinions and views, reported in the media, this means that there is no such thing as a bad and good cannabinoid, as the THC and CBD and the other cannabinoids don’t compete with one another, but can work in tandem alongside the other compounds found in cannabis to provide effective therapeutic relief for a wide variety of ailments with minimal side effects.

Affecting multiple targets

Terpenoids and cannabinoids have been found to increase blood flow, enhance cortical activity, and kill respiratory pathogens, including MRSA, the antibiotic-resistant bacteria. Many studies have demonstrated the effectiveness of whole plant cannabis as a therapeutic agent to treat a number of symptoms for example muscle spasms tremors, incontinence, and pain associated with multiple sclerosis, and have determined that whole-plant extracts were more effective than THC alone. Researchers compared 1mg THC against a 5mg/kg cannabis extract with the equivalent amount of single compound THC, and found the whole plant extract to have significantly more antispasmodic effect, and attributed this result to the presence of *cannabidiol* (CBD), which helps to facilitate the activity of the body’s endocannbinoid system.[17]

---

[13] Ben-Shabat, Shimon, *"An entourage effect: inactive endogenous fatty acid glycerol esters enhance 2 arachidonoyl glycerol cannabinoid activity,"* 17 July 1998, Jrnl of Pharmacology 353 (1): 23–31. doi:10.1016/S0014-2999(98)00392-6.

[14] John M. McPartland Ethan B. Russo, *"Cannabis and Cannabis Extracts: Greater Than the Sum of Their Parts?"* Co published simultaneously in Journal of Cannabis Therapeutics, Vol. 1, No. 3/4, 2001, pp. 103 130, and: *"Cannabis Therapeutics in HIV/AIDS"* (ed: Ethan Russo) 2001, pp. 103-132.

[15] Wagner H1, Ulrich Merzenich G "Synergy research: approaching a new generation of phytopharmaceuticals" Phytomemedicine, 2009 Mar; 16(2-3):97-110. doi: 10.1016/j.phymed.2008.12.018, US National L brary of Medicine, National Institute of Health.

[16] Wagner H1, Ulrich Merzenich G "Synergy research: approaching a new generation of phytopharmaceuticals" Phytomemedicine, 2009 Mar; 16(2-3):97-110. doi: 10.1016/j.phymed.2008.12.018, US National L brary of Medicine, National Institute of Health.

[17] G. Ulrich-Merzenich, *"Combination screening of synthetic drugs and plant derived natural products, Potential and challenges for drug development"* University Clinic Centre, Medical Clinic III Rheinische Friedrich-Wilhelms-University Bonn, J Nat Prod. 2008 Aug; 71(8):1427-30.10.1021/np8002673. Epub 6 August 2008.

Improving absorption of active ingredients

The skin is made up of two layers, known as a bi-layer, which makes it difficult for very polar molecules like water and cannabioids to pass through, which can also make them difficult for the body to absorb in isolation. With the assistance of terpenoids like caryophyllene, absorption of cannabinoids can be increased, and therapeutic benefits achieved. The "entourage effect" can work to improve the absorption of cannabis and cannabis extracts. The terpene myrcene for example possesses sedating, muscle-relaxing, anti-depressant, anti-inflammatory, and analgesic effects amongst other therapeutic benefits, and also has an effect on the permeability of cell membranes, which allows for the absorption of more cannabinoids by brain cells.

Overcoming bacterial defense mechanisms

The "entourage effect" also accounts for cannabis extracts and non-cannabinoid constituents to be effective in treating various bacterial infections. Cannabis has long been known to contain antibacterial cannabinoids. All of the five major cannabinoids, cannabidiol, cannabichromene, cannabigerol, Delta (9)-tetrahydrocannabinol, and cannabinol have showed potent activity against a number of methicillin-resistant Staphylococcus aureus (MRSA) strains of clinical relevance.

Over time bacteria can develop defence mechanisms, resulting in the effects of antibiotics ultimately becoming resistant to therapies which were previously effective, whereas whole-plant cannabis extracts with non-cannabinoid constituents that also have antibacterial properties, have been found to attack bacteria through different pathways to the cannabinoid pathways, limiting the development of bacterial resistance.[18]

Terpenes

Terpene enriched cannabis medicines are widely available in the United States. Terpenes are the main class of aromatic compounds found in cannabis that are responsible for cannabis's smell, and are believed to affect many aspects of how the brain takes in THC or CBD, while offering various therapeutic benefits of their own. Studies have found that terpenes have also been proven to interact synergistically with cannabinoids to block some cannabinoid receptor sites in the brain while promoting cannabinoid binding in others. Williamson reports that: "Cannabis terpenoids and flavonoids may also increase cerebral blood flow, enhance cortical activity, kill respiratory pathogens, and provide anti-inflammatory activity."[19]

In his review of cannabis terpenoids Dr Ethan Russo [20] reported: "Terpenoids share a precursor with phytocannabinoids. Terpenes are all flavour and fragrance components common to human diets that have been designated generally recognized as safe by the US Food and Drug Administration, and other regulatory agencies. They display unique therapeutic effects that may contribute meaningfully to the entourage effects of whole plant cannabis-based medicinal extracts, and produce synergy with respect to the treatment of "pain, inflammation, depression, anxiety, addiction, epilepsy, cancer, fungal, and bacterial infections (including methicillin-resistant Staphylococcus aureus)."

Low THC hemp for food v CBD whole plant medicine

Hemp was one of the first cultivated crops, and was once a part of worldwide dietary intake. Hemp is a traditional food in Asia, with large-scale production in China, and in other countries such as Chile and the European Union. Hemp production is also expanding in Canada, with the country's annual crop reaching a record high of 66,700 acres in 2013. While it is legal to import hemp products into the United States, and according to the Hemp Industry Association, about $500 million worth of hemp products are imported every year, CBD-infused "nutraceuticals" have not been approved by the FDA as food supplements, however interstate CBD commerce is tolerated by federal authorities. Australia is now the only country that prohibits hemp to be sold for human use, however hemp seed products are available from most health food shops and online, and despite a warning label "not for human use" people use It for food purposes anyway.

---

[18] *"Antibacterial cannabinoids from Cannabis sativa: a structure activity study" G1*, G bbons S, Giana A, Pagani A, Grassi G, Stavri M, Smith E, Rahman MM.

[19] Williamson EM, *"Synergy and other interactions in phytomedicines," Journal of* Phytomedicine, 2001 Sep; 8(5):401 9. This study considered, the body of information that supports the concept that selective breeding of cannabis chemotypes rich in phytocannabinoid and terpenoid content offer complementary pharmacological activities that may strengthen and broaden clinical applications and improve the therapeutic index of cannabis extracts containing THC, or other base phytocannabinoids.

[20] Ethan B Russo,*"Taming THC: potential cannabis synergy and phytocannabinoid terpenoid entourage effects,"* Br J Pharmacol, 2011 Aug; 163(7): 1344–1364. doi: 10.1111/j.1476-5381.2011.01238.

Despite its widespread use and availability overseas, and online[21] as a food supplement, the Australian Commonwealth Food Regulation Australia and New Zealand Food Regulation Ministerial Council rejected a proposal for hemp seed in 2002, and the Australia and New Zealand Ministerial Forum on Food Regulation rejected another one in 2015. Following on from a request from the Australia and New Zealand Ministerial Forum on Food Regulation, FSANZ has recently assessed a third proposal to develop food regulatory measures[22] to permit the sale of food derived from the seeds of low THC hemp, and has called for submissions to assist consideration of the draft food regulatory measure.

Although the focus of this inquiry is about the Bill, and the use of cannabis for medical purposes, there is no reason for the current provisions in the *Drugs Misuse Act*[23] to continue to prohibit hemp farmers from cultivating low THC hemp to be made into products for food consumption for supply to Queensland residents as the Commonwealth continues to stall on this issue as well. It is ludicrous to continue with this prohibition, or require that commercial CBD hemp products go through the TGA process for medicine, or for Queensland residents to wait on a long drawn out FSANZ process rather than moving ahead now under state food standards.

Hemp is natures most balanced oil for human nutrition with a 3:1 LA to LNA ratio, and is easily digestible; and could provide all of our Essential Fatty Acid (EFA) requirements for life, due to the balanced 80% EFA content of the oil. It is also a good source of Vitamin E antioxidants. And packed with minerals such as potassium, magnesium, iron, zinc, calcium, and phosphorus. In 1955 the Czechoslovakian Tubercular Nutrition Study concluded that hemp seed was the *"Only food that can successfully treat the consumptive disease tuberculosis, in which the nutritive processes are impaired and the body wastes away."* [24] However a lot of the information about hemp was systematically removed from written texts from the 1930's, and it has only been in the past decade that it has become available again as a food supplement.

The symptoms of LNA deficiency include growth retardation, weakness, and impairment of vision and learning ability, motor incoordination, tingling in arms and legs, behavioral changes. Other symptoms that can result from LNA (or w3) deficiency include high triglycerides, high blood pressure, sticky platelets, tissue inflammation, edema, dry skin, mental deterioration, low metabolic rate, and some kinds of immune dysfunction.[25]

The symptoms of LA deficiency include eczema-like skin eruptions, loss of hair, liver degeneration, behavioral disturbances, kidney degeneration, excessive water loss through the skin accompanied by thirst, drying up of glands, susceptibility to infections, failure of wound healing, sterility in males, miscarriage in females, arthritis-like conditions, heart and circulatory problems, growth retardation. Prolonged absence of LA from the diet is fatal.

Shelled hempseed is also more easily digested than ground flax seed, as whole flax seed passes through your body undigested. As mentioned above hemp seed and hemp oil also contain higher-potency omega derivatives, GLA and SDA, which flax seed lacks.

The hemp issue has also clouded the medical debate, as many people have been led to believe that low THC hemp should be cultivated to make medicine, as opposed to whole plant CBD enriched varieties from the medical plant, however research has shown that while hemp is not suitable for medicine, it is essential as a food source.

The main reason hemp oil is not suitable for medicine, is that compared to whole plant CBD-rich cannabis, hemp oil from the industrial plant is typically low in cannabinoid content, and a huge amount of hemp is required to extract a small amount of CBD, thereby raising the risk of contaminants because hemp is a bio accumulator, and draws toxins from the soil. While that's great for restoring a poisoned ecosystem, it's not recommended for extracting medicinal oil. Therefore heavily refined CBD paste or terpene-free CBD powder is a poor starting material for formulating CBD-rich oil products for medical use however as mentioned above hemp is essential as a food supplement.

[21] Ebay at http://www.ebay.com.au/sch/i.html?_nkw=raw+hemp+seed+oil&_fromfsb=0&_trksid=m270.l1313&ul_noapp=true
[22] Pursuant to the *Food Standards Australia New Zealand Act* 1991 (Cth)
[23] Part 5B Drugs Misuse Act 1986
[24] Kenneth Jones *"Nutritional and Medical guide to Hemp Seed"* ISBN-0-962563897
[25] Kenneth Jones *"Nutritional and Medical guide to Hemp Seed"* ISBN-0-962563897

Synthetic cannabis trials v whole plant

FAAH inhibitors, are a poorly understood class of synthetic chemical drugs can imitate the effects of cannabis by producing a cannabis-like response in the body by interacting with the body's own natural endocannabinoids preventing it from degrading anandamide, a neurotransmitter generated in the body to activate the cannabinoid receptors but without any of the psychoactive effects.

Despite the known risks, and mounting evidence that FAAH inhibitors are unsafe, expensive and unnecessary, researchers continued to obtain approval to create drugs with funding from drug companies, not only on healthy people, but also on patients with life threatening and serious medical conditions.

Overseas trials using synthetic cannabis funded by pharmaceutical companies

In January this year six study participants in France taking an FAAH inhibitor were hospitalised due to severe neurological injuries, which were fatal in one patient. Phase 2 clinical of the trial involved the testing the FAAH inhibitor on a small group of healthy participants to evaluate the safety and tolerability of the drug. Reports indicated that all of the volunteers were administered the drug orally for less than a week. Paris prosecutors reportedly launched a full-blown investigation into the incident, while Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, immediately suspended their phase 2 clinical trial out of fear it could harm patients.[26]

The New York Times has also recently reported that the University of New York (NYU) shut down eight clinical trials and dismissed the leading research of a study also involving the experimental use of a FAAH inhibitor on very vulnerable patients who had been diagnosed with post-traumatic stress (PTSD) caused by childhood abuse. After showing that people suffering from PTSD have an imbalance in their endocannabinoid system, Alexander Neumeister, the former director of the molecular imaging program in the Departments of Psychiatry and Radiology at NYU School of Medicine, received the go-ahead from NYU to run the clinical trials using FAAH inhibitors with funding from pharmaceutical giant Pfizer.[27] Pfizer has previously tested another FAAH inhibitor as a possible painkiller for patients with osteoarthritis of the knee, but reported in 2012 that it didn't work in a phase II study. However this trial didn't reveal any serious side effects from that drug.[28]

A subsequent federal investigation by the Food and Drug Administration (FDA) found lax oversight of study participants, most of whom had serious mental conditions. The FDA investigators found that records had been falsified and researchers had also failed to keep accurate case histories of the patients." Letters obtained by the New York Times from the FDA to Dr. Alexander Neumeister, the lead investigator state, "The violations jeopardize subject safety and welfare, and raise concerns about the validity and integrity of the data collected at your site." [29]

Whole plant cannabis v *dronabinol* (synthetic THC)

Dronabinol (marketed as Marinol) contains pure synthetic THC, and was approved by the FDA in 1985 for treating the side effects of chemotherapy. *Dronabinol* has been registered on the ARTG in Australia for decades as a Schedule 8 prescription drug, however many doctors and patients have found Marinol to be a very poor substitute for whole plant cannabis and cannabis extracts. As CNN's Dr. Sanjay Gupta explains: "When the drug became available in the mid 1980s, scientists thought it would have the same effect as the whole cannabis plant. But it soon became very clear that most patients preferred using the whole plant to taking Marinol. Researchers have also began to realize that other components, such as CBD and the terpenes might have a larger role than previously realised."[30]

---

[26] Mike Adams, *"French Health Minister: Botch Drug Trial Causing "Brain Death" had Nothing to do with Cannabis,"* High Times, 15 January 2015 at http://hightimes.com/news/french-health-minister-botched-drug-trial-causing-brain-death-had-nothing-to-do-with-cannabis/

[27] Benedict Carey, "*An N.Y.U. Study Gone Wrong, and a Top Researcher Dismissed,"* New York Times, 27 June 2016 at http://www.nytimes.com/2016/06/28/health/nyu-cannabis-ptsd-psychiatry.html?_r=0.

[28] Martin Enserink, *"More details emerge on fateful French drug trial,"* Sciencemag, 16 January 2016 at http://www.sciencemag.org/news/2016/01/more-details-emerge-fateful-french-drug-trial.

[29] Benedict Carey, "*An N.Y.U. Study Gone Wrong, and a Top Researcher Dismissed,"* New York Times, 27 June 2016 at http://www.nytimes.com/2016/06/28/health/nyu-cannabis-ptsd-psychiatry.html?_r=0.

[30] CNN's chief medical correspondence Sanjay Gupta MD is an American neurosurgeon and an assistant professor of neurosurgery at Emory University School of Medicine and associate chief of the neurosurgery service at Grady Memorial Hospital in Atlanta, Georgia. Sandray at http://youtu.be/bDL3_yFx-Ss

Whole plant cannabis v synthetic purified CBD

Groundbreaking research in Israel has also added weight to the use of whole plant medicines over synthetics. In a study titled "Overcoming the Bell-Shaped Dose-Response of Cannabidiol by Using Cannabis Extract Enriched in Cannabidiol," the scientists have documented the superior therapeutic properties of whole plant CBD rich cannabis extract compared to synthetic, single-molecule cannabidiol (CBD). Published in the journal Pharmacology & Pharmacy (Feb. 2015), the study directly challenges the pro Big Pharma notion that "crude" botanical preparations are inherently low grade and less effective than pure, single-molecule compounds.

The pure CBD tests confirmed the findings of earlier research, that singe-molecule CBD administration generated a bell-shaped dose-response curve with a narrow therapeutic window. In stark contrast when whole plant CBD extract was administered, rather than showing a bell-shaped curve, where a therapeutic effect could only be achieved at a certain concentration of pure CBD, the whole plant CBD rich extract "provided a clear correlation between the anti-inflammatory and anti-nociceptive responses and the dose, with increasing responses upon increasing doses, which makes whole plant medicine ideal for clinical uses."

The Israeli researchers also found that a small amount of CBD in the whole plant extract was all that was needed for significant pain relief compared to a much larger amount of the pure CBD that was required to achieve the same analgesic effect. Whereas the pure, single-molecule CBD precipitated a dramatic drop in efficacy if more than a specific dosage was administered, an "overdose" of whole plant CBD extract did not undermine its therapeutic potency. When a greater than optimal dose of the CBD extract was administered, its effectiveness leveled off, suggesting that a therapeutic plateau had been reached.

The Israeli team concluded: "A lot of research has been made to isolate and characterize isolated single constituents of traditional herbal medicine to find their rationale for therapeutic uses. However, our data together with those of others provide legitimation to introduce a new generation of phytopharmaceuticals to treat diseases that have hitherto been treated using synthetic drugs alone. The therapeutic synergy observed with plant extracts results in the requirement for a lower amount of active components, with consequent reduced adverse effects."[31]

Queensland, Australia: 50 years behind the rest of the world on law reform

Due to time constraints with the inquiry, this submission only touches on a few of the issues around overseas law reform measures and the use of cannabis for medical purposes.

Overseas "unapproved" cannabis upon doctors recommendation v prescription

For decades, Israel has had in place a medical cannabis program for doctors to recommend cannabis dispensed through hospitals, and more recently through pharmacies. After a ruling in 1996 in *R v Parker,* Canada implemented a medical cannabis program with provisions for patients to grow their own upon a doctor's recommendation that acts like a prescription, and also issued a licence to a contractor to cultivate cannabis in mine shaft, for supply from the national health department, however the quality was not very good.

After ongoing complaints, and further court challenges, Canada now has one of the leading commercial cannabis programs in the world with some companies providing up to 50 strains for patients to chose from, however oils are relatively new and were only included after a court ruling in 2015. Following the ruling in *US v Randall* the United States federal government made medical cannabis available from the mid 1970's as discussed further below. Now over 30 states have access to cannabis that is regulated under state laws, administered by state health departments and other departments, using food and agriculture standards.

[31] Ruth Gallily, Zhannah Yekhtin, Lumír Ondřej Hanuš, *"Overcoming the Bell-Shaped Dose-Response of Cannabidiol by Using Cannabis Extract Enriched in Cannabidiol"* The Lautenberg Center for General and Tumor Immunology, The Hadassah Medical School, The Hebrew University of Jerusalem, Jerusalem, Israel, Department of Medicinal and Natural Products, Institute for Drug Research, The Hadassah Medical School, The Hebrew University of Jerusalem, Jerusalem, Israel.

In all overseas medical cannabis programs, raw botanical cannabis and more recently oils are available as "unapproved" medicines upon the recommendation of a doctor, and not as a registered prescription medicine. None of these programs relied on imports or made patients wait years while the Government has only funded research trials for the benefit of researchers and corporations to be able to register single molecule cannabis products.

Overseas medical cannabis programs also give patients and designated carers approvals for home growing, and use state food and health standards to regulate cultivation and supply of cannabis from not for profit associations and small businesses. Canada allows patients to grow their own cannabis and in the US the Obama Government has given directives that the DEA and other agencies are not to use federal law enforcement measures against patients, carers, and suppliers in the States that have implemented medical programs as long as they have in place adequate health and safety standards administered by State Health and other departments.

Patients need access to whole plant cannabis and whole plant cannabis extracts, and not single molecule patented products that have been proven to be far less effective and can cause far more side effects. An abundance of research studies from overseas already exists and supports the use of whole plant cannabis therapies for a wide range of conditions and symptoms.

1976 US first medical necessity case - glaucoma

All of the state laws in the United States list glaucoma as an approved condition, which points to cannabis's long established reputation as a viable alternative treatment for glaucoma. *US v Randall, was* the first legal case in the Untied States to extend the necessity defence to the crimes of possession or cultivation of cannabis, and brought about change to cannabis policy In 1972, at 24 years of age, an ophthalmologist told Randall he had glaucoma and would be blind in 5 years, and advised to go on disability and start learning Braill. He tried every treatment option available to ease his symptoms and stop the deterioration of his sight. Several methods temporarily stabilised his elevated intraocular pressure (IOP), which is the primary cause of vision impairment and eye loss in patients with glaucoma but as his tolerance to each treatment increased, so did his IOP, and the drops prescribed by his ophthalmologist came with a side effect of blurred vision. Surgery was ruled out, as it could have resulted in immediate blindness.

One night after smoking some cannabis Randall realised that the halos around the streetlights were gone, and as time progressed recognised cannabis was the only treatment that helped his glaucoma. In 1975, he began cultivating cannabis but was later charged with cultivation and possession. Wanting to prove in court the validity of his claim that cannabis was a medical necessity to treat his glaucoma, he sought counsel from leading researchers. The key witness was Robert Hepler, MD, a UCLA ophthalmologist. In 1971, Hepler and his colleague, Ira R. Frank, MD, were the first doctors to report that cannabis lowered IOP by 25% to 30% in a small number of patients for a short period of 3 to 4 hours. Their findings were published in the Journal of the American Medical Association, and are still mentioned today in reports of clinical trials on cannabis and glaucoma.

Dr Hepler monitored Randall's use of all the pharmaceutical drugs available to treat glaucoma, including an oral form of delta-9-tetrahydrocannabinol, *dronabinol* (Synthetic THC) approved by the FDA, and which is the primary active ingredient in cannabis, before adding inhaled cannabis to the experiment. The results confirmed conventional treatments failed to keep Randall's IOP in check, whereas smoking 8 to 10 cannabis cigarettes reduced it by approximately 35%, and could stop the progression to blindness.[32] In court Randall submitted that cannabis was a medical necessity for him to treat his glaucoma.

Judge Washington in his decision, "This is a case of first impression in this jurisdiction, and one which raises significant issues. Consequently, the Court recognizes its responsibility to set forth clearly and in some depth its understanding of the applicable law."

[32] R.S. Hepler MD, Ira M. Frank, M.D. , J. Thomas Ungerleider, *"Pupil constriction after marijuana smoking,"* M.D. Department of Ophthalmology, Jules Stein Eye Institute, and the Department of Psychiatry, UCLA School of Medicine, Los Angeles, California, American Journal of Ophthalmology, December 1972, Volume 74, Issue 6, Pages 1185–1190. In 1971, Hepler and his colleague, Ira R. Frank, MD, were the first doctors to report that cannabis lowered IOP by 25% to 30% in a small number of patients for a short period of 3 to 4 hours. Their findings were published in the Journal of the American Medical Association, and are still mentioned today in reports of clinical trials on cannabis and glaucoma.

Citing case law, Washington concluded, "the common law recognizes the defense of necessity in criminal cases… where the actor is compelled by external circumstances to perform the illegal act." He listed three exceptions. The necessity defense cannot be used when "1) The duress or circumstance has been brought about by the actor himself; 2) The same objective could have been accomplished by a less offensive alternative which was available to the actor; or 3) The evil sought to be averted was less heinous than that performed to avoid it."

Judge Washington found the first two exceptions clearly don't apply in *US v. Randall*:

"While the exact cause of defendant's glaucoma is unknown, neither the government nor any of the expert witnesses has suggested that the defendant is in any way responsible for his condition. Similarly, no alternative course of action would have secured the desired result through a less illegal channel. Because of defendant's tolerance, treatment with other drugs has become ineffective, and surgery offers only a slim possibility of favorable results coupled with a significant risk of immediate blindness. Neither the origin of the compelling circumstances nor the existence of a more acceptable alternative prevents the successful assertion of the necessity defense.

Judge Washington concluded: "The question of whether the evil avoided by defendant's action is less than the evil inherent in his act is more difficult. It requires a balancing of the interests of this defendant against those of the government. While defendant's wish to preserve his sight is too obvious to necessitate further comment, the government interests require a more detailed examination.

"One of the oldest recognized drugs, marijuana was not regulated in the United States until the Pure Food and Drug Act of 1906, which required that the presence of marijuana be indicated on the labels of products of which it was a component. The modern prohibition began in 1937, in response to primarily economic pressures without significant inquiry into its effects on users. "Liquor manufacturers and distributors, still recovering from the effects of Prohibition, were interested in eradicating the potential competition from a drug often used for recreational purposes. In addition, criminalizing marijuana simplified the task of eliminating the competition for jobs during the Depression posed by the principal users of the drug, Mexican migrant laborers."

"The 1970 *Controlled Substances Act* continued the prohibition of the use of marijuana, but a Presidential Commission was appointed to study its effects. Pending receipt of this report, marijuana was classified as a non-narcotic and although its use was still prohibited, the penalties were considerable reduced, with first offenders being discharged conditionally. The District of Columbia law, however, was not changed, and retains the narcotic classification based on the 1937 *Uniform Narcotics Act*.

Washington continued: "Reports from the President's Commission and the Department of Health, Education and Welfare have concluded that there is no conclusive scientific evidence of any harm attendant upon the use of marijuana. According to the most recent HEW study, research has failed to establish any substantial physical or mental impairment caused by marijuana. Reports of chromosome damage, reduced immunity to disease, and psychosis are unconfirmed; actual evidence is to the contrary."

"Furthermore, unlike the so-called hard drugs, marijuana does not appear to be physically addictive or to cause the user to develop a tolerance requiring more and more of the drug for the same effects. The current HEW report also notes the possibility of valid medical uses for this drug…

"The Court finds that this defendant does not fall within the third limitation to the necessity defense. The evil he sought to avert, blindness, is greater than that he performed to accomplish it, growing marijuana in his residence in violation of the District of Columbia Code. While blindness was shown by competent medical testimony to be the otherwise inevitable result of defendant's disease, no adverse effects from the smoking of marijuana have been demonstrated…

Judge Washington could have ended his decision at this point, but he went on to assert its applicability to other necessity-defense cases. He projected and refuted an argument that would deny the necessity defense based on the literal wording of the DC Code section, which makes no reference to extenuating circumstances. He also discussed whether a defendant should have to prove necessity "beyond a reasonable doubt" and concluded that "by a preponderance of the evidence" was sufficient.

Before Randall 'necessity' had been argued in criminal cases, but never in connection with cannabis. Judge Washington decision for Randall was far ahead of its time, as he was willing to make a decision that might be unpopular or might be on the leading edge of the law. Some 35 years after Randall, the U.S. Supreme Court in *Gonzales v. Raich* 2005 ruled that state medical cannabis laws, do not provide protection for patients or their providers from prosecution under federal law,[33] However the Attorney had framed a "medical necessity" argument on behalf of the Oakland Cannabis Buyers Club, and was unaware of Judge Washington's decision in Randall.

1976 FDA's compassionate IND program

Robert Randall's medical necessity defence case helped establish the legal concept of medical necessity for the possession of cannabis. Not only was Randall acquitted, the United States federal government provided him with a consistent, legal supply of cannabis. After the case, a new ophthalmologist was appointed by the National Eye Institute (NEI) and the National Institute on Drug Abuse to continue researching Randall's case.

Federal agencies, agitated by Randall's outspoken opposition to the medical prohibition of cannabis, sought to silence him by disrupting his legal access to his supply of cannabis. In response, Randall brought suit against the FDA, DEA, NIDA, the Department of Justice and the Department of Health, Education & Welfare. Twenty-four hours later federal agencies requested an out-of-court settlement, which resulted in the provision to Randall with prescription access to cannabis that was grown in Mississippi and processed and packaged in North Carolina, where all the cigarettes are processed and packaged making him the first legal medical cannabis patient in the United States since 1937. Robert collected his cannabis weekly through a federal pharmacy, Morton's Drug Store, 3 blocks from the Capitol of the United States, with a band around it saying 'Property of the United States of America.

At the time of Randall's death in 2001, 8 states in the US had established some form of legislation that allowed for the use of medical cannabis rather than patients needing to rely on the defence of necessity in Court. Since Randall's death, over 30 states have implemented "compassionate use" laws for cannabis.

The settlement in Randall's case also became the legal basis for the FDA's Compassionate IND program. Initially, this program was limited to patients afflicted by cannabis-responsive disorders and some orphan drugs. In the 1980's the concept was expanded to include HIV-positive people seeking legal access to drugs, which had not yet received final FDA marketing approval. The Compassionate IND program was closed in 1992 to any future patients. At that time there were 15 patients receiving cannabis from the NIDA-sponsored cannabis farm at the University of Mississippi. By 1995 seven of those patients had died leaving only 8 federal medical cannabis patients.[34]

1996 FDA prescription v State doctors recommendation

In all overseas medical cannabis programs, cannabis is available as an "unapproved" medicine upon the recommendation of a doctor, and not as a registered prescription medicine. No country has delayed and restricted access or supply to fund and conduct research trials for the benefit of researchers and corporations seeking to make large profits and make patients wait years for access. In the interests of the patients, the State could include provisions for doctors to recommend cannabis instead of prescription via the TGA pathways.

Since 1996, medical professionals in the United States have been recommending cannabis for medical purposes, and have a legal right to recommend cannabis as a treatment in any state as the First Amendment protects them. Cannabis cannot be prescribed under US federal law, but its medicinal use can be recommended under State law, without the doctor facing any legal consequences.

This was established in 2004 by a United States Supreme Court decision in *Conant v Walter.*[35] In this case, the Supreme Court uphold earlier federal court rulings, that doctors and their patients have a fundamental Constitutional right to freely discuss treatment options, including the use of cannabis for medicinal purposes.

---

[33] *Gonzales v. Raich,* 545 U.S. 1 (2005) 352 F.3d 1222

[34] Ethan Russo, Mary Lynn Mathre, Al Byrne, Robert Velin, Paul J. Bach Juan, Sanchez-Ramos, Kristin A. Kirlin, *"Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis,"* Journal of Cannabis Therapeutics, Vol. 2(1) 2002

[35] *Conant v. McCaffrey,* 172 F.R.D. 681 (N.D. Cal. 1997)

Although medical professions in the United States can recommended the use of cannabis as a treatment option, the laws and regulations vary from state to state on qualifying an individual patient for legal protection, and also differ as to who may make the recommendation, and for what conditions, as well as how that recommendation is communicated to the appropriate state authorities, and the supplier or dispensary.

A court ruling in 2005 in *Conant v. Walters*, finally determined what medical medical professionals in the US, were protected from under the Fifth Amendment. This case stems from the earlier lawsuits brought by a group of doctors and patients led by AIDS specialist Dr. Marcus Conant. Dr Conant's first lawsuit was filed in response to federal officials who, had within weeks of Californian voters legalising medical cannabis in 1996, threatened to revoke the prescribing privileges of any physician who recommended cannabis to their patients for medical use.[36] Dr. Conant contended that such a policy would violate the First Amendment.[37] The Ninth Circuit Court of Appeals agreed and held that the federal government, could neither punish nor threaten a doctor merely for recommending the use of cannabis to a patient.[38] In this case the Court set out what doctors may and may not do:

- Physicians and other medical professionals may discuss the benefits and risks of medical cannabis with any patient, and
- may recommend its use whenever appropriate; and
- may put that in writing or otherwise participate in state medical cannabis programs without fear of legal reprisal, and
- may not provide cannabis directly to a patient.[39]
- and
- it remains illegal for a doctor to "aid and abet" a patient in obtaining cannabis. [40]

However, today in the United States, over 30 states provide legal protection for qualifying patients participating in their state medical cannabis program, under the recommendation of their physician. Under the Obama Administration, the Department of Justice has issued three memos providing guidance to federal prosecutors. Each memo indicates that individual patients and caregivers should not be priorities for federal law enforcement agencies, with the latest memo in 2015, indicating that enforcement should be left to the states, so long as they have effective regulations in place for the safe use and distribution of cannabis.

1997 Canada's first Constitutional case – epilepsy

In 1997 a Canadian Judge ruled that certain sections of the Controlled Drug and Substances Act were unconstitutional in cases where cannabis is used for medically-approved purposes. The Court stayed charges of cultivation and possession of cannabis against 42.year-old Terry Parker, an epileptic. The judge ordered police to return 71 pot plants seized from Parker, who argued he needed cannabis to control epileptic seizures.
The Court ruled Terrence Parker's illness is "best controlled with a combination of prescribed medication and smoking marijuana." Depriving Parker of cannabis is "unconstitutional, and extensions should be made to the law for people who use cannabis for medically approved purposes."

> ``It is accepted that in large measure both the Narcotics Control Act and Controlled Drugs and Substances Act are statutes designed to protect the health and well-being of Canadians. However, the effect as it relates to (Parker) is to do, if not the exact opposite, certainly significantly less by leaving him vulnerable to arrest and imprisonment, to the loss of the therapeutic assistance of marijuana, and to greater risk of physical injury in the community by more frequent seizures. Thus, a balance between the state's interest to protect the health of Canadians and the effect it has on this individual is not met. Therefore, the court concludes that deprivation to (Parker) arising from a blanket prohibition denying him possession of marijuana, in the circumstances of this case, does little or nothing to enhance the state's interest in better health for this individual member of the community.

The Ontario Court of Appeal upheld the acquittal a year later. The Canadian Government implemented cannabis approvals for patients, and nominated growers following the *Parker* case.[41]

[36] See "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200" (Dec.30, 1996) at https://www.ncjrs.gov/txtfiles/215rel.txt.
[37] id.; *Conant v. McCaffrey*, 2000 WL 1281174 (N.D. Cal. 2000); *Conant v. Walters,* 309 F.3d 629 (9th Cir. 2002).
[38] id 309 F.3d 629 (9th Cir. 2002) at 634-36
[39] *Conant v. McCaffrey,* 2000 WL 1281174, at *16 (N.D. Cal. 2000).309 F.3d at 634.
[40] id. at 700-01.7. 309 F.3d at 634 & 636
[41] Canadian Foundation for Drug Policy at http://www.cfdp.ca/dec1097.htm

2016 Australia, Queensland first – brain tumour, epilepsy, nausea, appetite stimulant, chronic pain

Cannabis has been available for importation through the SAS for decades. The State health laws have been in conflict and prohibited its use under Regulation 270A of the *Health (Drugs and Poisons) Regulation 1996* discussed elsewhere in this submission. In March 2015 [redacted] doctor's and pharmacist's SAS application was submitted, and a separate application was submitted to the Queensland Health Minister and Attorney General of Queensland requesting an exemption under the States *Drugs Misuse Act.*

The TGA made 5 requests to the doctor for further information. By October there was still no decision. A legal Notice was issued to the Federal Health Minister requesting a review of the matter under the *Therapeutic Goods Act.*[42] Within days the TGA advised that [redacted] SAS application could be approved. A Notice was also issued to the Attorney General of Queensland requesting a Statement of Reasons under the *Judicial Review Act,*[43] *which* is a preliminary step to file for a Statutory Order of Review in the Supreme Court.

The cannabis oil to treat[redacted] brain tumour and epilepsy was approved on 29 April, however the dried bud to also treat his epilepsy, as well as nausea and pain was not approved until 17 May, with a condition that a vaporizer approved by the TGA or one approved in a similar jurisdiction be used. The pharmacist was not granted approval until 6 June 2016. The import section of the TGA approved the pharmacist's import licence and permits within hours of receiving notice of State approval.

It is almost 16 months from when the doctor's and pharmacist's applications were first submitted to the TGA and the State in March last year, and [redacted] cannabis is yet to arrive in Australia from Canada, and at the time of writing this submission[redacted] is now waiting on Health Canada to grant Tilray an export permit.

The SAS and State processes are discussed in more detail below. As mentioned above [redacted] has also provided a submission, which provides a personal account of what [redacted] and his family has endured throughout this long and difficult process.

Queensland, Australia: lags behind the rest of the world on research

Due to time constraints with the inquiry, this submission only touches on overseas research and some of the issues around the Australian research trials, and potential conflicts of interests.

Ground-breaking new research from overseas

As outlined above overseas research has not stood in the way of patient access, and there has already been an extensive amount of research done overseas on the use of cannabis for the conditions that are being researched in Australia. Overseas researchers are now conducting ground-breaking research using whole plant botanical cannabis into important areas such as treating cancer, leukaemia, brain tumours, diabetes, Alzheimer's, and Parkinson's disease, and into the other compounds found in cannabis such as the terpenes.

In contrast Australian researchers are only reinventing the wheel by doing research that has already been done overseas, and is primarily for the benefit of researchers themselves using products from overseas companies to benefit them by collecting data for possible future patents but with no guarantee that any of the products will be registered on the ARTG or PBS or supplied to the Australian public.

Australian synthetic cannabis trials funded by pharmaceutical companies and the State

The Victorian State Government has dedicated $150,000 to a trial at Melbourne's Austin Health Hospital using a synthetic CBD drug developed by US pharmaceutical company Insys Therapeutics Inc as part of an international clinical trial into the effects of synthetic cannabis on severe epilepsy in children. The trial will begin with 10 children whose condition has not improved despite trying three different anti-epilepsy drugs, and will expand to include 60 children by the end of the year.

[42] Section 60 of the *Therapeutic Goods Act 1989* (Cth) - Review of Decisions
[43] Section 20 of the *Judicial Review Act 1991* (QLD - Application for Statutory Order of Review

Lead investigator, Ingrid Scheffer said trialling synthetic cannabidiol (CBD) was a safe option despite recent reports saying synthetic cannabis was more dangerous than plant-based cannabis. “Cannabis has cannabidiol and THC, which is the psychoactive component, and that’s the part that is used at parties and to get high,” she said. “We’re not giving THC, and that’s another reason the synthetic compound is exciting, because they won’t get any THC.” Results from the first phase of the trial may be made available by the end of this year, and there will be three phases. [44]

Research funding and conflicts of interest

While ground breaking research continues to gather momentum overseas, Australia continues to take a backwards approach by allowing researchers to continue to hold up patient access for unnecessary research that has nothing to do with the rights or health and safety of patients, but more to with pursuing long term research funding, and using tax payers monies to fund research for the benefit of overseas companies to collect data when there is no guarantee that the company will register its product on the ARTG or supply to Australian patients.

For example a recent report in the Medical Journal of Australia published in a Sydney newspaper,[45] raised the concerns of Newcastle academic about Australia going too fast. Clinical pharmacologist Professor Jennifer Martin who is one of the researchers involved with the New South Wales trials that will be using overseas cannabis products was quoted as stating: "..the government alluded to this legislation being the missing link for people to access it and what we're saying is there is still a very long way to go.” Professor Martin also said. "There are multiple missing links. We need to be realistic, this is not going to happen quickly if we want to do it safely and effectively.

> "We certainly don't want to stop what's going on at the moment, it's a great investment,” Professor Martin said, referring to the state government funded research. "It's worth waiting to get this right, ***because once it's out there in the community it will be harder to get access to research funding."*** Martin warned “more rigorous research is needed into medical marijuana before it is rolled out as a therapeutic good.”

Professor Martin also went on to state: "despite cannabis being legal in many American states and dispensed from pharmacies in the Netherlands, there had not been any reliable data collected on what form of administration and dosages had been most effective for each condition. In relation to the Pharmaceutical Benefits Scheme, we can't fund a drug for which there is no evidence."

Conflict of Interest: Professor Martin is contributing to pharmacology modules about cannabis for the University of Newcastle's Doctor of Medicine. University of Newcastle is conducting a trial of 30 cancer patients using different dosages of vaporised botanical leaf cannabis. Results are not expected until the end of this year, and will be used in another New South Wales state funded study of palliative care patients comparing this form of cannabis against a placebo.

Australian research for overseas companies obstructs patient access

After any State funded research using overseas products is completed, the TGA cannot guarantee access to any cannabis product, or at an affordable price, because the TGA cannot compel any Australian or overseas company to register their product on the ARTG or the PBS, and cannot compel any company supply its product to the Australian public, and cannot make an overseas company ensure that there is sufficient stock ready and available in Australia at all times for patient access without the need to import.

[44] “*Medical marijuana to undergo clinical trials in Victoria,”* the Guardian, 3 February 2016 at https://www.theguardian.com/society/2016/feb/03/synthetic-cannabis-trial-to-treat-victorian-children-with-epilepsy

[45] Helen Gregory, *“University of Newcastle academic flags concerns over medical marijuana,”* Newcastle Herald, 3 May 2016*, at* http://www.theherald.com.au/story/3936904/concerns-flagged-over-cannabis-use/

Overview of Legislation

There is a number of International, Commonwealth, and State legislation that is relevant to the use of cannabis for medical purposes in Australia and specific to Queensland. Due to time constraints this submission does not cover every aspect of the law but gives an overview of some of the relevant provisions.

- Single Convention on Narcotic Drugs 1961
- *Narcotic Drugs Act 1967 (Cth)*
- *Therapeutic Goods Act 1989 (Cth)*
- Poisons Standard 2016 (Cth) (SUSMP)
- *Constitution of Queensland 2010*
- *Health Act 1937 (QLD)*
- *Health (Drugs and Poisons) Regulation 1996 (QLD)*
- *Health Regulation 1996 (QLD)*
- *Criminal Code 1899 (QLD)*
- *Drugs Misuse Act 1986 (QLD)*
- *Criminal Law (Rehabilitation of Offenders) Act 1986*
- *Legislative Standards Act 1992*

Commonwealth Legislation

In most states the Commonwealth has primary control of the regulatory system with a division of responsibility between the Commonwealth and the States and Territories broadly broken down as:

- Commonwealth regulates the importation and exportation and supply of cannabis for commercial purposes in Australia under the *Therapeutic Goods Act 1989.*
- Queensland and Western Australia have not adopted the TGA into state law.[46]
- The States and territories regulate and control the production, cultivation, sale, supply, possession, handling and use of drugs and poisons within their jurisdictions under state health and criminal legislation.
- In Queensland the production, cultivation, manufacture, sale, supply, prescription, dispensing and possession of therapeutic substances including cannabis comes under the *Health Act 1937* and the *Health (Drugs and Poisons) Regulations 1996.*
- The objectives of the *Drugs Misuse Act 1986* were to "combat" illegal trafficking in drugs, and were not intended to target the actual users of cannabis or other drugs. The *Drugs Misuse Act* also contains provisions for the industrial use of cannabis/hemp, however hemp cultivated under licence in the *Drugs Misuse Act* cannot be manufactured into products that can be consumed for human use.

International Single Convention on Narcotic Drugs 1961

For decades consecutive Commonwealth and State and Territory governments have used Australia's obligations as a signatory to the Single Convention on Narcotic Drugs 1961 (Single Convention 1961), as an excuse to continue with prohibitive and restrictive health and law enforcement policies on the use of cannabis for medical, scientific, industrial and food purposes, and that to do otherwise would put in jeopardy the Tasmanian poppy industry.

The *Preamble* to the Single Convention 1961 provides that signatories to the Single Convention 1961 concerned with the health and welfare of mankind, recognize that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering, and ***must*** (emphasis added) ensure that adequate provisions are made available for medical and scientific use.

[46] See Regulation 3 of the *Therapeutic Goods Regulations 1990* (Cth) for corresponding state and territory legislation.

The Single Convention 1961 clearly sets out that signatories to the Single Convention 1961 are to use law enforcement measures to combat the illegal trafficking in narcotic cannabis and other narcotics, and at the same time **must** provide for it to be available for medical and scientific use, as well as provide treatment for drug dependent people. The Single Convention 1961 also clearly sets out that the seeds and leaves of the cannabis plant when not accompanied by the flowering tops are not drugs, and that the industrial use of cannabis, and cannabis cultivated for food are exempt from the Single Convention 1961. The Single Convention 1961 suggests the parties establish a special administration for the purpose of applying the provisions of the Single Convention 1961,[47] and as far as constitutional limitations allows it to apply throughout the states and territories.

Narcotic Drugs Act 1967 Amendments 2016

In Australia, the Single Convention 1961 is attached as Schedule 1 to the Commonwealth *Narcotic Drugs Act 1967.* The Commonwealth *Narcotic Drugs Act* was amended in February 2016 to include provisions for:

- A licensing and permit scheme to regulate the commercial cultivation of cannabis plants and the production of cannabis and cannabis resin for medicinal purposes and research relating to medicinal cannabis.

- A separate licensing and permit scheme to regulate the manufacture of drugs covered by the Single Convention.

- Cannabis cultivated and manufactured in Australia is to be used to conduct clinical trials and develop therapeutic products in accordance with the *Therapeutic Goods Act.*

The Commonwealth has submitted that it is not expecting a large industry in the short to medium term and that by adopting this model it will not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term, but will facilitate clinical trials that may support such a registration in the future. Applicants for licences must have an identified and described line-of-sight to prescribers and patient groups, in accordance with the *Therapeutic Goods Act,* as well as significant security requirements.

The Drug Control Section (DCS) of the TGA will be responsible for granting licences and permits that authorise the import, export and manufacture of cannabis and cannabis products under the *Customs (Prohibited Imports) Regulations 1956*, *Customs (Prohibited Exports) Regulations 1958* and *Narcotic Drugs Act 1967,* and *also* administer a legislatively-based control regime for licit drugs covering border controls, manufacture and domestic transactions. The Commonwealth has not made any provisions to date to cover the export of locally made cannabis or cannabis products.

Customs Act 1901

Cannabis, cannabis resin and cannabinoids can be imported into Australia, as they are listed in Schedule 4 to the *Customs (Prohibited Imports) Regulations,*[48] as narcotics, that can only be imported into Australia if a licence, permission, consent or approval to import the goods under the regulations,[49] or provisions of the *Therapeutic Goods Act 1989*. Australian Customs Service will only allow these substances to be imported if the Therapeutic Goods Administration has given written approval for importation. The Therapeutic Goods Administration considers that the use of these substances should be supervised by a medical practitioner and will not issue import permits to individuals. Instead, the Therapeutic Goods Administration requires applications to be made in writing by the individual's medical practitioner under the Special Access Scheme. A licenced pharmacist may also apply for an import licence or permit to import the products for supply to the patient.[50]

[47] See Article 17 - The Parties shall maintain a special administration for the purpose of applying the provisions of this Convention.
[48] *Customs (Prohibited Imports) Regulations* 1956 (Cth) at http://www.comlaw.gov.au/Details/F2014C01354
[49] Regulation 50(3)(b)(i)(ii) *of the Therapeutic Goods Regulations 1990 (Cth)*
[50] Therapeutic Goods Administration, *'Application for a licence to import/export narcotic, psychotropic and precursor substances,'* at https://www.tga.gov.au/application-licence-importexport-narcotic-psychotropic-and-precursorsubstances#lists.

Therapeutic Goods Act

The Therapeutic Goods Administration (TGA) administers the *Therapeutic Goods Act (TGAct).* The objects of the *TGAct* are to do the following, so far as the Constitution permits:

- provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere; or exported from Australia; and
- to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and safe handling of medicines and poisons in Australia.

The TGAct is not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.[51] Relevant to cannabis and this submission, the *Therapeutic Goods Act* provides for the following:

- Registration of cannabis products on the ARTG
- Poisons Standard (SUSMP)
- Access to "unapproved" medicines ie: access to products not registered on the ARTG

Australian Register of Therapeutic Goods (ARTG)

Most therapeutic goods for human use that are imported, manufactured in Australia, supplied by a corporation, supplied interstate or to the Commonwealth, are required to undergo an evaluation for safety and efficacy to be included on the Australian Register of Therapeutic Goods (ARTG) for marketing and supply in Australia. Currently the only registered cannabis product on the ARTG Sativex (Schedule 8 *nabiximols)* manufactured by GW Pharmaceutical's.

Poisons Standard (SUSMP)

The Poisons Standard (commonly referred to as the Standard for the Uniform Scheduling of Medicines and Poisons or the SUSMP) contains decisions made by the delegate to the Health Minister, and provides the basis for a uniform system in Australia of access controls for goods containing scheduled substances, and are recommendations only to the states and territories and not law. For the legal definition of substances it is necessary to check with each relevant State or Territory legislation as each State and Territory has very different health and criminal legislation, and can either adopt the decisions, amend the decisions or reject the decisions. Therefore there is nothing uniform about the supply or availability of medicines to patients in Australia.

The matters considered relevant by the delegate include:

a) the risks and benefits of the use of the substance;
b) the purposes for which a substance is to be used and the extent of use of a substance;
c) the toxicity of the substance;
d) the dosage, formulation, labelling, packaging and presentation of a substance;
e) the potential for abuse of a substance; and
f) any other matters that the Secretary considers necessary to protect public health.[52]

According to the TGA the scheduling of substances allows restrictions to be placed on the supply of the substances to the public, in the interests of public health and safety, and is aimed at minimising the risks of poisoning from, and the misuse and abuse of, scheduled substances.[53]

[51] See section 4 of the *Therapeutic Goods Act 1989*
[52] See 52E (1) of the *Therapeutic Goods Act 1989*
[53] Section 52 AA of the *Therapeutic Goods Act 1989*

Scheduling history of cannabis - SUSMP

Cannabis: is currently a Schedule 9 substance: "Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law ***except when required for medical or scientific research, or for analytical, teaching or training purposes*** with approval of Commonwealth and/or State or Territory Health Authorities."

Dronabinol: (delta-9-tetrahydrocanabinol (synthetic THC)) -1994 included in Schedule 8 of the SUSDP, for use in patients with advanced HIV disease with irreversible weight loss.

Nabilone: July 1994 included in Schedule 8 for use as an anti-emetic in the treatment of nausea and vomiting caused by chemotherapy, primarily for patients who are not responsive to conventional anti-emetic treatments.

Sativex®: 2009 the NDPSC considered scheduling and access under jurisdictional laws and the Special Access Scheme (SAS). Members agreed to create a Schedule 8 entry for this specific formulation, in conjunction with an Appendix D, paragraph 3 listing to facilitate its use within the various jurisdictions.

Nabiximols: October 2009 included *nabiximols* (a specific THC:CBD extract) as a Schedule 8 listing with specific reference to buccal sprays after an issue was raised that some jurisdictions were unable to allow SAS access to the substance as it was captured under Schedule 9.

Nabiximols: May 2010 included in Schedule 8 and Appendices D and K. The Appendix D, Part 3 entry was made to limit access through the SAS. The Appendix K entry was agreed due to its sedating effects.

Nabiximols: March 2013 change in the Appendix D entry from Paragraph 3 to Paragraph 1 with the requirement for specialist oversight for safe prescribing of the drug.

Cannabidiol: (CBD) - 2015 included in Schedule 4 in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis.
An exemption exists for processed hemp fibre and its products containing 0.1 percent or less of tetrahydrocannabinol.

Rescheduling and registration of cannabis

The TGA have made an interim decision to reschedule Cannabis (including seeds, extracts and derivatives of extracts) and Tetrahydrocannabinols (being extracts, or derivatives of extracts, of cannabis) from Schedule 9 to Schedule 8 with an Appendix D[54] Item 1 entry and new Appendix K[55] entry where the cultivation, production and manufacture of the substances in Australia is only under the *Narcotic Drugs Act 1967*, and where the substances are imported into Australia under the *Customs (Prohibited Imports) Regulations 1956*, with any further production or manufacture of the substances in Australia being under the *Narcotic Drugs Act 1967*, if required. The rescheduling does not apply to cannabis when listed separately in Schedule 8 (*nabiximols*) or Schedule 4 (*cannabidiol* (CBD)). Use outside of the specific schedule entries will make the substances Schedule 9.

- The proposed Schedule 8 entry **does not include synthetic** Tetrahydrocannabinols.
- Supply and import of products is still required to comply with the *Therapeutic Goods Act 1989*.
- Any product not on the Australian Register of Therapeutic Goods will still need an exemption or approval to be legally supplied under the *Therapeutic Goods Act 1989* ie Special Access Scheme, and authorised prescriber.

The proposed implementation date was 1 June 2016.[56]

[54] Appendix D Item 1 entries for Cannabis and Tetrahydrocannabinols place an additional control on the substances such that the substances will only be *"available from or on the prescription or order of an authorised medical practitioner"* where the medical practitioner has been authorised by the "appropriate authority" as defined in Part 1 paragraph 1(1) of the SUSMP which are generally senior health executives of the states and territories.
[55] The new Appendix K entries for Cannabis and Tetrahydrocannabinols are because of the potential sedation effect of these substances and place a requirement for products including these substances to be labelled with a warning regarding their sedation potential.
[56] At the time of writing the final decision had not been published.

TGA's reasons for the decision

- There is some evidence to support the use of cannabinoids in the treatment of some conditions when these conditions are not adequately treated by other medications.

- The current Schedule 9 listing produces barriers to clinical trials being undertaken in some states and by creating Schedule 8 entries their availability for clinical trials is improved, within the restrictions of Schedule 8 substances.

- In some states the current Schedule 9 entries preclude individuals from being able to access appropriate cannabinoid products for appropriate clinical justified conditions except through clinical trials in the states where they can be conducted. By creating the Schedule 8 entries and the Appendix D Item 1 entries individuals will be able to have appropriate cannabinoid products including these substances prescribed where the medical practitioner is an authorised prescriber.

Effect of TGA rescheduling

When botanical cannabis is rescheduled from Schedule 9 to Schedule 8 in the SUSMP, doctors should also be able to use the Category A notification system, and if using the Category B treatment approval pathway, only need to notify the chief executive if they have been treating a patient with cannabis for more than 2 months, as they would any other Schedule 8 medicine.

TGA Access to Unapproved Medicines in Australia

In circumstances where patients need access to therapeutic goods that are not on the ARTG, the *Therapeutic Goods Act 1989* provides for a number of exemptions and special use provisions for patient access to unapproved medicines[57] For example section 18 provides for exempt goods, section 18A provides for exemptions because of emergency, and section 19 provides for exemptions for special and experimental use.

Exemption and special use schemes

In Australia, the TGA manages a number of exemptions for special use and experimental schemes that allow for patient access to unapproved medicines by way of:

- Special Access Scheme Category A[58]
- Special Access Scheme Category B[59]
- Authorised Prescriber[60]
- Personal importation[61]
- Clinical Trials (CTN scheme)[62]
- Clinical Trial (CTX scheme)[63]

According to TGA policy, any registered doctor is eligible to supply unapproved medicines via the special access scheme, authorised prescribers and the personal importation scheme. In addition there are no restrictions on the classes of medical practitioners that can be approved by the TGA to be authorised prescribers because the way in which a doctor prescribes a treatment for an individual in a particular clinical setting is a matter of good medical practice and the TGA does not regulate medical practice. However, as the TGA administers supply of therapeutic goods including access to unapproved therapeutic products in Australia there is a significant degree of oversight to ensure that the appropriate mechanism is used in any given circumstance. Therefore a registered doctor in Queensland may prescribe and supply potentially any unapproved therapeutic cannabis good as long as the manufacture, possession, sale or use is allowed under State or Territory law.[64]

[57] See section 19 of the *Therapeutic Goods Act 1989*
[58] *Therapeutic Goods Act 1989,* section 18, Subsec 31A(2), Reg 12A
[59] Section 19, esp, 19(1)(a), Subsec 31B(1)
[60] Subsection 19(5), Subsection 31B(3), Reg 12B
[61] Subsection 18(1), Reg 12(1), Schedule 5 item 1
[62] Subsec 18(1) , Subsec 31A(1), Reg 12 & Schedule 5A, item 3
[63] Section 19, esp 19(1)(b), Subsec 31B(1) & 31B(2) , Regs 12AA-12AD
[64] For more information about accessing unapproved medicines see the Therapeutic Goods Administration website at https://www.tga.gov.au/accessing-unapproved-products

Special access scheme (SAS)

Under the Commonwealth Special Access Scheme (SAS), [65] a registered medical practitioner may treat a single patient with an "unapproved" therapeutic good, on a case-by-case basis under a range of circumstances such as:

- early access for terminally ill patients to almost any product including experimental and investigational products;
- access to products withdrawn from the Australian market for commercial or other reasons;
- access to products provided initially to patients through a clinical trial while a marketing application is being processed; and
- access to products available overseas but not marketed in Australia.

Patients are grouped into two categories under the scheme:

- Category A is a notification scheme[66] for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment. Does not include access to Schedule 9 cannabis.

- Category B[67] provides for approvals to treat all other patients that do not fit the Category A definition including access to Schedule 9 cannabis.

The choice of which category is used lies with the prescribing doctor,[68] and not the TGA or the State however the TGA monitor for incorrect or misuse of the category's especially Category A as doctors do not need TGA approval as it is a notification only scheme. Sponsors of unapproved products supplied under the SAS are required to notify the Therapeutic Goods Administration any information that has an important bearing on the benefit-risk assessment of the unapproved product, particularly any information that may lead to changes to the usage of the product under the SAS.[69]

Authorised prescribers

A medical practitioner may apply to the TGA to be granted authority to become an authorised prescriber[70] to prescribe a specified unapproved cannabis good or class of unapproved cannabis goods to specified patients or classes of patients. To be an Authorised Prescriber the medical practitioner must:

- have the training and expertise appropriate for the condition being treated and the proposed use of the product;
- be able to best determine the needs of the patient; and
- monitor the outcome of treatment.

Once a medical practitioner becomes an 'Authorised Prescriber' they do not need to notify the Therapeutic Goods Administration when they are prescribing the unapproved product, however they must report to the Therapeutic Goods Administration the number of patients treated on a six monthly basis.[71]

[65] Special Access Scheme at https://www.tga.gov.au/form/special-access-scheme.
[66] Section 18 of the *Therapeutic Goods Act* and Regulation 12A of the Regulations, medical practitioners can supply unapproved medicines to Category A patients but the TGA must be notified.
[67] Subsections 19(1) to 19(4) of the *Therapeutic Goods Act,* approval can be given by a delegate in the TGA or a delegate outside the TGA (known as an external delegate) to a medical practitioner to supply unapproved medicines to Category B patients.
[68] Therapeutic Goods Administration Publication: *"Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, page 11 at https://www.tga.gov.au/sites/default/files/access-sas-guidelines.pdf
[69] SAS Guidelines at pp 9 -10
[70] Sections 19(5) and 41HC of the *Therapeutic Goods Act 1989*
[71] For further information on authorised prescribers see the Therapeutic Goods Administration website at https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers.

Personal importation scheme

An individual can either bring a therapeutic good into Australia on their person or arrange from within Australia for a therapeutic good to be sent to them from an overseas supplier without the goods being entered on the ARTG under the following criteria:

- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person; and
- the goods do not contain a substance which is a prohibited import under the C(PI) Regulations, and
- the quantity imported does not exceed three months' supply per importation and the total quantity imported per year does not exceed 15 months' supply at the manufacturer's recommended maximum dosage; or
- importation of the goods is approved under regulation 5 of the C(PI) Regulations or the goods are included in a gazetted class approved for importation under regulation 5; and
- in the case of prescription medicines the goods are the subject of a prescription issued by a State/Territory registered medical practitioner. Medicines carried by a passenger on a plane or ship are an exception to this requirement, however, an import licence is still required in the case of medicines in Schedule 4 of the C(PI) Regulations if the passenger does not have a prescription. [72]

Clinical research trials

According to the TGA "there is no requirement that applications to the TGA to register medicines on the ARTG must contain data from clinical trials conducted in Australia, and that the Australian Schemes only provide benefits by providing the momentum to research and develop new medicines locally, and creating an environment of scientific research, and by providing early access for patients to new therapeutic developments."

"Drug manufacturers engage researchers to conduct clinical trials to answer questions about the safety and efficacy of their product," and use the data to apply to the TGA for registration on the ARTG for product approval for marketing purposes which can cost hundreds of thousands of dollars for TGA assessment and registration fees. It is about getting commercial products to market for profit and gain, as registration is also needed market the products in Australia, and to apply to have the product subsidised by the government on the PBS. The TGA have two separate schemes under which clinical trials using unapproved therapeutic goods may be conducted in Australia:

- Clinical Trial Notification Scheme
- Clinical Trial Exemption Scheme

A clinical trial is described by the TGA as an "experiment conducted in (sic) humans in order to assess the effects, efficacy and/or safety of a medicine, medical device, or a procedure or intervention, and therefore it is necessary that the trial be conducted using appropriate experimental designs to obtain valid data without exposing people to unnecessary risks." The primary responsibility for monitoring a clinical trial rests with the sponsor of the unapproved medicine, the institution in which the trial is being conducted and its Human Research and Ethics Committee, and the investigator.

Informed consent

Individuals using unapproved medicines must be made aware that in many cases the quality, safety and efficacy of the products may not have been evaluated or may have only undergone minimal testing. If patients suffer adverse consequences redress may be difficult to obtain so they must be prepared to accept any risks associated with the use of the unapproved products.

The patient should also have adequate knowledge about his or her condition and its consequences, other treatment options, and the likelihood of recovery and long-term prognosis. The doctor should specifically inform the patient of the following:

- that the product is not approved in Australia;
- the possible benefits of treatment and any risks and side effects that are known;

[72] Subsection 18(1) of the *Therapeutic Goods Act*, see also Regulation 12(1), and Schedule 5 item 1

- the possibility of unknown risks and late side effects; and
- any alternative treatments using approved products which are available.[73]

Therefore it is always a condition with the supply of unapproved medicines that the patient or the patient's legal guardian must be in a position to make an informed decision about the treatment. Informed consent should be freely given in writing to the medical practitioner or sponsor in line with good medical practice.

Patient privacy and release of information

Medical practitioners are only required to provide the patients initials and date of birth to the TGA. No other personal or contact details are required. Explicit consent to the disclosure of the patient's identity to the TGA must be sought. Therefore information provided to the TGA concerning the use of unapproved therapeutic goods is treated as strictly confidential[74] and may only be released in circumstances consistent with Privacy[75] and FOI legislation.[76]

Conditions of a TGA approval

Should approval be granted, that approval will almost always be granted subject to certain conditions placed on the medical practitioner. The legislation requires the conditions to be met. The types of conditions imposed by the TGA may include:

- "the maximum dose and duration of treatment for a medicine.
- that should treatment be discontinued before the end of the treatment period approved, the TGA is to be notified of the reasons for discontinuation within 6 weeks of the treatment being discontinued.
- the use of an unapproved product should be regarded as an experimental use. The principles set out in the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research 2007* should be observed.
- the patient is to give their written informed consent to the doctor, and the doctor and patient, or patient's guardian, accept responsibility for any adverse consequence of treatment. The Commonwealth accepts no responsibility for any defects in the product whatsoever, including defects related to manufacture, distribution, directions for use and dosage.
- on completion of the treatment all remaining supplies of the product should be returned to the supplier.
- any special conditions appropriate to the specific patient and product.
- the period for which the approval is valid, particularly in cases where importation is required. (eg: for up to 18 months from the date of the decision).
- that the total quantity imported and supplied is not to exceed that required for the treatment of the particular patient; and
- the approval is for supply for use only by the particular patient"

[73] The Australian Government, Department of Health and Ageing Publication, Access to unapproved therapeutic goods via the Special Access Scheme, November 2009 at https://www.tga.gov.au/sites/default/files/access-sas-guidelines.pdf at page 9
[74] Section 61 of the *Therapeutic Goods Act 1989* prescribes which information may be released.
[75] The *Privacy Act 1988* places limits on disclosure of personal information. Parties cannot disclose personal information about an individual to a person, body or agency other than the individual concerned except under certain circumstances.
[76] The *Freedom of Information Act 1982* (FOI Act) governs access to information. Section 27 of the FOI Act requires that consultation occur between the TGA and the owner of the information prior to release of documentation.

Queensland Legislation

The following gives a brief overview of the legislation that governs the making of legislation, and the use of cannabis in Queensland.

- *Constitution of Queensland 2010*
- *Health Act 1937 (QLD)*
- *Health (Drugs and Poisons) Regulation 1996 (QLD)*
- *Health Regulation 1996 (QLD)*
- *Criminal Code 1899 (QLD)*
- *Drugs Misuse Act 1986 (QLD)*
- *Criminal Law (Rehabilitation of Offenders) Act 1986*
- *Legislative Standards Act 1992*

Constitution of Queensland

The Constitution was amended in 2010 to include a preamble acknowledging that the people of Queensland, who are "free and equal citizens" of Australia, intend through the Constitution to foster the "peace, welfare and good government" of Queensland; by adopting the principle of the sovereignty of the people, under the "rule of law," and the system of representative and "responsible government," and acknowledge the achievements of our forebears, who overcame "adversity and injustice," and whose efforts were bequeathed to us, and future generations, as a realistic opportunity to strive for "social harmony," and resolve to nurture our inheritance, and "build a society based on democracy, freedom and peace.'"

The preamble was a Queensland aspiration to enshrine in law the principle of popular sovereignty so as to set an example for other Australian states as a way forward to a future republican federated Australia, and says something about the values and ideals of the Queensland community and the political process that was used to bring into force the amendments to the Constitution.

Queensland did not adopt the *Therapeutic Goods Act*

Queensland along with Western Australia are the only states that did not enact legislation that adopted the *Therapeutic Goods Act* as a law in their respective jurisdictions.[77] Due to constitutional limitations the *Therapeutic Goods Act* only applies to corporations operating in Queensland. The *Therapeutic Goods Act* does not apply to State agencies, sole traders, small business and cooperatives registered under Queensland law that trade or operate only within the State of Queensland, and does not regulate the medical profession, pharmacists or hospitals in Queensland.

Queensland's History of Opposing Commonwealth Health Standards

Queensland has a long history of being opposed to adopting Commonwealth health standards and laws that are not adequate or in the public interest for Queensland. On 3 June 1952, Vince Gair the then Premier of Queensland responded to the Prime Minister's request for Queensland to adopt national standards, and noted the limitations of the Commonwealth's powers to the importation and exportation of therapeutic substances. In reply Premier Gair indicated that Queensland would be represented at a National Health Conference but continued:

> *"You will understand that any recommendations made by the conference will not necessarily be accepted by my Government. Under no circumstances will this State agree to the acceptance of uniform standards which are not considered to be adequate in the public interest ….. I mention that there is power under the existing Health law of this state to prescribe standards for therapeutic substances, and insofar as Queensland is concerned fresh legislation would not be required."*[78]

[77] Regulation 3 of the *Therapeutic Goods Regulations 1990 - Poisons and Therapeutic Goods Act 1966* (NSW); *Poisons and Therapeutic Goods Regulation 2008* (NSW); *Therapeutic Goods (Victoria) Act 2010* (Vic); *Controlled Substances Act 1984* (SA); *Controlled Substances (Poisons) Regulations 2011* (SA); *Therapeutic Goods Act 2001* (Tas); *Therapeutic Goods Regulations 2002* (Tas); *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT); *Medicines, Poisons and Therapeutic Goods Regulation 2008* (ACT).

[78] Therapeutic Goods Administration, Commonwealth of Australia publication, *'A History of Therapeutic Goods Regulation in Australia,'* John McEwan at p 20

Health Act 1937 currently in force

The cultivation, manufacture, supply, possession, prescription, sale, dispensing and use of medicines and poisons is regulated and controlled under the state *Health Act* 1937 (QLD) and the *Health (Drugs and Poisons) Regulation* 1996 and *Health Regulation 1996.* These legislative instruments have adequate regulating powers and prescribing standards that can provide for, the safe and effective regulation and control of all aspects of cannabis for medical purposes in Queensland.[79]

The *Health Act* contains a range of regulation-making powers that cover the regulation and control of medicines, drugs, poisons and cannabis for medical purposes in Queensland from cultivation and manufacturing licences and practices to possession, supply, prescribing, dispensing, investigation, monitoring, and enforcement. The *Health Act* does however adopt the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) or the Poisons Standard.

The SUSMP is not law and is only recommendations to the states and territories regarding the classification of medicines and poisons into Schedules and provisions about containers and labels.

Under the *Health Act* there are two pieces of subordinate legislation that provide for a range of controls over cannabis, for medical use and drugs and poisons in Queensland.

Section 180 Head regulating power

Section 180 (1) of the *Health Act* provides that the Governor in Council (Premier and Cabinet) may make regulations under the Act. Regulations are far more flexible than provisions under an act as they can be made or amended by the Premier and Cabinet rather than the need for an amending Bill to go before Parliament for debate and passed by both houses of Queensland Parliament.

Part 4 - Drugs and other articles

Section 101 to 133 contains provisions for regulations to be made about manufacturing, packaging and labeling requirements and advertising.

Section 132 provides for a number of Regulations to be made about about drugs, articles, substances and appliances including the following:

- Section 132(a) provides for regulations to be made about standards for the composition, strength, weight, quantity, purity, or quality of any drug or article, or of any ingredient or component part thereof, or for the nature or proportion of any substance which may be mixed with or used in the preparation or preservation thereof, or prohibiting the addition of any article to any drug or article.

- Section 132(t) provides for regulations to be made about prescribing poisons, restricted drugs, controlled drugs and biological preparations.

- Section 132(u) provides for regulations to be made about controlling and, as deemed necessary, prohibiting or restricting the ownership, possession, manufacture, cultivation, sale, distribution, supply, use, lending, dispensing, prescribing, or giving away of, or forging and uttering of prescriptions for or any other dealing with poisons, restricted drugs, controlled drugs, biological preparations …… or goods for therapeutic use under and within the meaning of the Therapeutic Goods Act 1989 (Cth).

Part 4 A - Monitoring, Investigation and Enforcement Powers

Sections 134 - 153 contain a raft of provisions for regulations to be made about monitoring, investigation and enforcement including the appointment of inspectors, appointment conditions and limits on power, identity cards, powers of inspections including entry of places, search and seizure, stopping motor vehicles, power to seize, and power to obtain information and warrants.

[79] The *Health Act* 1937 (QLD) and *Health (Drugs and Poisons) Regulation* 1996 (QLD).

Health (Drugs and Poisons) Regulation 1996 (QLD) currently in force

Imposes a wide range of controls over substances listed in the Standard for the Uniform Scheduling of Medicines and sets out requirements for approvals and endorsement holders and obligations around the manufacture, supply, prescription, storage, record keeping and sale and use of medicines, drugs and poisons in Queensland.

Regulation 77: approved drug dronabinol (*delta*-9-tetrahydrocannabinol) synthetic THC

Dronabinol, a synthetic THC listed on the ARTG, has been in Queensland law for several decades, and can only be imported via the SAS.

Regulation 120: treatment with and dependence on controlled drugs

A doctor or nurse practitioner, or pharmacist is only required to notify Queensland Health if they dispense, prescribe or supplies, or intends to administer, dispense, prescribe or supply, a controlled drug in the treatment of a patient for more than 2 months; or reasonably suspects a patient has been treated with a controlled drug by another doctor or nurse practitioner for more than 2 months and the doctor or nurse practitioner intends to administer, dispense, prescribe or supply a controlled drug in the treatment of the patient. After 2 months of treatment or supply the doctor or nurse practitioner must immediately give the chief executive a written report in the approved form about the circumstances of the patient's treatment.

Regulation 122: approval only needed for treating drug dependent patients with S8 drugs

If a relevant practitioner reasonably believes a person is a drug dependent person, they must not, without an approval dispense or prescribe a controlled drug for the person; or administer or supply a controlled drug to or for the person; or give an oral or written instruction to supply a controlled drug to or for the person.

If the chief executive is reasonably satisfied that, for the welfare of the drug dependent person or class of drug dependent persons, it is necessary for the relevant practitioner to treat the person or persons with a controlled drug, the chief executive may give the relevant practitioner written approval to administer, dispense, prescribe, supply a controlled drug, or give an oral or written instruction to supply a stated quantity or volume of the controlled drug, or an oral approval to administer, dispense, prescribe, supply or give an oral or written instruction to supply a stated quantity or volume of the controlled drug to or for the person or persons, the chief executive may give the oral approval. If the chief executive gives the relevant practitioner an oral approval, the chief executive must give the relevant practitioner written confirmation of the approval as soon as possible after giving the oral approval.

relevant practitioner means a doctor, nurse practitioner or surgical podiatrists.

Current medical cannabis regulations in force

The Premier and Cabinet have made several amendments and new medical cannabis regulations in the *Health (Drugs and Poisons) Regulations* since November 2015, and are able to approve these at weekly Cabinet meetings without the need for a Bill to go to Parliament. Cabinet has adequate regulating powers under the *Health Act 1937* to implement a State medical cannabis program discussed further below.

New Regulation 78 A: Nov 2015 nabiximols Schedule 8 FDA approved controlled drug

In November 2015, Cabinet made changes to the *Health (Drugs and Poisons) Regulations* to include approval provisions for Schedule 8 *nabiximols* ie Sativex was listed in the SUSMP since 2009, and registered on the ARTG the same year, however Queensland has restricted prescribing to specialists in the fields of neurology and rehabilitation, even though the TGA does not have these restrictions. The only *nabiximol* registered on the ARTG is Sativex.

Regulation 270 A amended: Dec 2015 removed prohibition for human use

In December 2015 the Queensland Government removed the full prohibition on the use of Schedule 9 cannabis for human therapeutic use in Queensland through an amendment to Regulation 270A of the *Health (Drugs and Poisons) Regulation* 1996, and the addition of Regulation 270B, however provisions were only made for access via the SAS and research trials. The Government failed to make any regulations to cover how access was to be regulated, or for cultivation, supply and access under a State program.

270A Approval must not be granted for therapeutic use of S9 poisons Subject to section 270B, the chief executive must not grant an approval to a person to manufacture, obtain, possess or use an S9 poison for human therapeutic use.

270B Approval for cannabis
The chief executive may grant an approval to a person to administer, dispense, manufacture, obtain, possess, prescribe, supply or use an S9 poison if

(a) the S9 poison is cannabis; and
(b) the approval is for or connected with
    (i) an approved clinical trial; or
    (ii) an approval, for the supply of cannabis for use in the treatment of a person, given under the *Therapeutic Goods Act 1989* (Cwlth), section 19(1).

New Regulations 78 B-P: June 2016 medicinal cannabis provisions inserted

On 1 June 2015, 6 months after Regulation 270A was amended, regulations were inserted to provide for the regulatory framework for a single patient prescriber, and patient class prescriber approvals, and research approvals, and dispensing approvals to prescribe, dispense, possess, manufacture, supply and obtain cannabis for patient access via TGA research trials, SAS Category B, and authorised prescribers. However the State provisions are inconsistent with the TGA as discussed in more detail below. As can be shown these short provisions provide for the regulatory framework for cannabis via the TGA as opposed to over 100 pages with this complex Bill.

Part 3A of the *Health (Dugs and Poisons) Regulation:* Regulations 78B – 78P contain the current medical cannabis provisions that are being used for patient access to unapproved medicines via the TGA's SAS, authorised prescribers and research trials. The provisions as set out below are almost identical to the provisions in the proposed Bill, which over almost 140 pages.

Definitions

approved good means a registered good or a listed good within the meaning of the *Therapeutic Goods Act 1989* (Cwlth).

cannabis product means any product

(a) that is or was any part of a plant of the genus *Cannabis*, whether living or dead; or
(b) otherwise derived, wholly or in part, from any part of a plant of the genus *Cannabis*, whether living or dead; or
(c) that has, or is intended by the manufacturer of the product to have, a pharmacological effect that is substantially similar to the pharmacological effect of a product mentioned in paragraph (a) or (b).

carer, for a patient, means an adult who has responsibility for the immediate care and safety of the patient.

compliant, for medicinal cannabis, means the medicinal cannabis has been—
(a) prescribed, for the treatment of, or use by, a patient, in accordance with this part; and
(b) dispensed in accordance with this regulation, including a prescription under this regulation; and
(c) if the medicinal cannabis is the subject of a medicinal cannabis approval—prescribed and dispensed in accordance with the approval; and
(d) manufactured or imported in accordance with the applicable law of the Commonwealth; and
(e) approved, or authorised to be supplied, for the purpose of treating the patient, in accordance with the applicable law of the Commonwealth.

medicinal cannabis means a cannabis product that is—

(a) not an approved good; and
(b) used, or is intended by the manufacturer of the product to be used, for human therapeutic purposes; and
(c) is a controlled drug, other than a regulated controlled drug.

medicinal cannabis approval see section 78E(1).

patient-class prescriber means—

(a) a specialist health practitioner in the specialty of medical oncology, paediatric neurology or palliative care medicine; or
(b) a registrar in medical oncology, paediatric neurology or palliative care medicine working under the supervision of a specialist health practitioner in the specialty of medical oncology, paediatric neurology or palliative care medicine.

single-patient prescriber means a doctor who is the holder of a medicinal cannabis approval.

78C Purpose of part

The purpose of this part is to provide for regulated access to medicinal cannabis in Queensland through—

(1) The chief executive may grant an approval (a ***medicinal cannabis approval***) to a doctor to facilitate the treatment of a particular patient of the doctor with medicinal cannabis.

(i) the prescription of medicinal cannabis, under a system of medicinal cannabis approvals, by single-patient prescribers; and
(ii) the prescription of medicinal cannabis, without medicinal cannabis approvals, by patient-class prescribers; and

(2) A medicinal cannabis approval is an endorsement until the expiry of this part under section 78P.

Note— See chapter 1, parts 5 and 6 for provisions relating to endorsements.

78D Application of part

(1) To the extent of any inconsistency between a provision of this part, and another provision of this regulation, the provision of this part prevails.

(2) A number of provisions do not apply to medicinal cannabis-sections 52 and 54; 56; 58; 58A(3) and (4); 58B; 59A; 61 and 62; 64 to 64A; 66; 69; 70A and 71; 74(3); and section 81.

Division 2 Medicinal cannabis approvals

78E Grant of medicinal cannabis approval

(1) The chief executive may grant an approval (a ***medicinal cannabis approval***) to a doctor to facilitate the treatment of a particular patient of the doctor with medicinal cannabis.
(2) A medicinal cannabis approval is an endorsement.

Division 3 Dealing with medicinal cannabis

78F Patient-class prescribers

(1) If a patient-class prescriber is satisfied a patient the patient-class prescriber is treating (the ***patient***) needs medicinal cannabis for therapeutic use as a part of the patient's medical treatment, the patient-class prescriber is authorised to write a prescription for the—
(a) issue or supply of medicinal cannabis for the purpose of treating the patient; or
(b) administration of medicinal cannabis to the patient.

(2) The patient-class prescriber is authorised to obtain and possess compliant medicinal cannabis if the patient-class prescriber is temporarily possessing the medicinal cannabis—
(a) until the patient can be treated with, or use, the medicinal cannabis; and
(b) only for the purpose of treating the patient.

(3) The patient-class prescriber is authorised to do the following in accordance with the prescription—
(a) supply the medicinal cannabis to the patient;
(b) issue the medicinal cannabis to a carer for the patient;
(c) administer the medicinal cannabis to the patient.

78G Single-patient prescribers

(1) A single-patient prescriber, for a medicinal cannabis approval, is authorised to write a prescription for the—
(a) issue or supply of the medicinal cannabis for the purpose of treating the patient to whom the medicinal cannabis approval applies (the ***approved patient***); and
(b) administration of the medicinal cannabis to the approved patient.

(2) The single-patient prescriber is authorised to obtain and possess compliant medicinal cannabis if the single-patient prescriber is temporarily possessing the medicinal cannabis—
(a) until the approved patient can be treated with, or use, the medicinal cannabis; and
(b) only for the purpose of treating the approved patient.

(3) The single-patient prescriber is authorised to do the following in accordance with the prescription—
(a) supply the medicinal cannabis to the approved patient;
(b) issue the medicinal cannabis to a carer for the approved patient;
(c) administer the medicinal cannabis to the approved patient.

78H Patients

(1) This section applies if a single-patient prescriber or a patient-class prescriber has, in accordance with this regulation, written a prescription for the administration, issue or supply of medicinal cannabis for the treatment of a patient.

(2) The patient is authorised to obtain, possess or self-administer compliant medicinal cannabis in accordance with the prescription.

(3) The patient is also authorised to issue the medicinal cannabis to the following persons—
(a) the doctor who wrote the prescription for the purpose of administering the medicinal cannabis to the patient;
(b) a carer for the patient.

78I Pharmacists

(1) A pharmacist is authorised to obtain medicinal cannabis and possess the medicinal cannabis at the pharmacist's dispensary if the pharmacist is possessing the medicinal cannabis for the purpose of—
(a) selling or supplying the medicinal cannabis to patients to whom section 78H applies; or
(b) selling or issuing the medicinal cannabis to carers for patients to whom section 78H applies or other persons authorised to obtain and possess the medicinal cannabis.

(2) The pharmacist, when at the dispensary, is authorised to do the following in accordance with a prescription for medicinal cannabis—
(a) sell or supply medicinal cannabis to patients to whom section 78H applies;
(b) sell or issue medicinal cannabis to carers for patients to whom section 78H applies or other persons authorised to obtain and possess the medicinal cannabis.

78J Carers

(1) A carer, for a patient to whom section 78H applies, is authorised to obtain and possess compliant medicinal
(a) until the patient can be treated with, or use, the medicinal cannabis in accordance with this part; and
(b) only for the purpose of treating the patient.

(2) The carer is authorised to—
(a) if the patient is able to self-administer the medicinal cannabis—supply the medicinal cannabis to the patient; or
(b) administer the medicinal cannabis to the patient in accordance with a prescription for the medicinal cannabis; or
(c) issue the medicinal cannabis to a single-patient prescriber or patient-class prescriber treating the patient, for administration to the patient.

78K Clinical trials

The chief executive may grant an approval to a person to administer, dispense, manufacture, obtain, possess, prescribe, supply or use medicinal cannabis if the approval is for or connected with an approved clinical trial.

Division 4 Obligations of prescribers and pharmacists

78L Requirement for prescribers to notify chief executive

(1) A patient-class prescriber or a single-patient prescriber (each the ***prescriber***) must notify the chief executive in writing when the prescriber prescribes, supplies, issues or administers medicinal cannabis to a patient.

(2) The notice must state—
(a) the name and date of birth of the patient; and
(b) the medical condition, or associated symptoms, of the patient;
(c) the pharmacy from which the patient intends to obtain medicinal cannabis prescribed by the prescriber.

78M Conditions applying to prescribers

(1) The chief executive may, by written notice to a patient-class prescriber, or a single-patient prescriber, (each the ***prescriber***) impose conditions on the prescriber's authority to deal with medicinal cannabis under this part.

(2) A condition under subsection (1) may, for example—
(a) impose requirements relating to the prescription of medicinal cannabis; or
(b) impose requirements relating to the monitoring or reporting of the condition, or associated symptoms, of patients being treated with medicinal cannabis by the prescriber; or
(c) require the prescriber to comply with a stated code, guideline, protocol or standard.

(3) For single-patient prescribers, the chief executive's power to impose conditions under subsection (1) is in addition to the chief executive's power to impose conditions on a medicinal cannabis approval under chapter 1, part 5.

78N Requirement for pharmacists to notify chief executive

A pharmacist must notify the chief executive in writing when the pharmacist dispenses, sells, issues or supplies (each a ***relevant activity***) medicinal cannabis to a patient within 24 hours of carrying out the relevant activity.

78O Conditions applying to pharmacists

(1) The chief executive may, by written notice to a pharmacist, impose conditions on the pharmacist's authority to deal with medicinal cannabis under this part.
(2) A condition under subsection (1) may, for example—
(a) impose requirements, in addition to requirements under this regulation, relating to the storage and dispensing of medicinal cannabis; or
(b) require the pharmacist to comply with a stated code, guideline, protocol or standard.

78P Expiry of part

This part expires on the earlier of the following
(a) the commencement of the *Public Health (Medicinal Cannabis) Act 2016*; or (b)1 January 2017.

Health Regulation 1996 (QLD)

Sets out standard operating procedures for dispensing and dispensaries and imposes controls over the advertising, promotion and labelling of therapeutic substances in Queensland.

Drugs Misuse Bill 1985 not to target actual users

When the Drugs Misuse Bill was introduced into the Queensland Parliament in 1985 the Honourable W.H. Glasson said in his second reading speech:

> "The Drugs Misuse Bill was introduced under tough new measures to combat drug trafficking in Queensland ... quite contrary to what some media commentators have stated and printed over the last week, the principal thrust of **the Bill is not aimed at actual users of drugs…**. the Bill is aimed at protecting our young people from the greed of those who live off the drug habits that their unfortunate victims develop. Drug-traffickers in this filthy trade and I do not care who they might be are nothing but parasites on today's young people and society in general, extracting millions of dollars from those who are addicted. These are the people that this Bill is intended to catch not their victims. By the introduction of this Bill it is intended to make Queensland a most unpopular place, in fact the most unpopular place in Australia for hard drug dealers or traffickers. "[80]

Queensland cannabis capital - statistics arrests of actual users v traffickers

In contrast key findings from the Australian Crime Commission's Illicit have consistently earned Queensland the tile of "Cannabis Capital" of Australia. The Drug Date Report 2012-13[81] shows that over half of all illicit drug arrests in Queensland relate to cannabis, and Queensland accounted for the greatest number of **cannabis arrests,** with an increase of 3.6 per cent from 17,733 in 2011–12 to 18,365 in 2012-13, with only 2,034 being supplier arrests.

Consumer arrests[82] accounted for **16,331 or 86.7** per cent of all cannabis related arrests in Queensland.

Drugs Misuse Act 1986

The *Drugs Misuse Act 1986 (QLD)* (DMA) provides for a range of criminal offences and defences, and must be read with the Criminal Code. Cannabis is classified as a dangerous drug under the DMA.

Offences

A person may be found guilty of an offence if the person '*unlawfully'* carries out any of the following:

- trafficking in dangerous drugs
- supplying dangerous drugs includes the offence of aggravated supply of cannabis to a minor under 16 years of age.
- producing dangerous drugs includes cultivation, manufacture or production of cannabis, cannabis resin or cannabinoids
- publishing or possessing instructions for producing dangerous drugs
- possession of dangerous drugs
- possessing things including things used to administer, cultivate or produce cannabis or cannabinoids
- permitting use of place to produce, cultivate or supply cannabis.

[80] Honorable H.W. Glasson, Drugs Misuse Bill, Note 14, pp 3472-3481.
[81] Australia Crime Commission, Illicit Drug Date Report 2012-13, https://www.acic.gov.au/sites/g/files/net1491/f/2016/06/illicit_drug_data_report_2013-14.pdf?v=1467242385
[82] Note: 'Arrest' incorporates recorded law enforcement action against a person for suspected unlawful involvement in illicit drugs. It incorporates enforcement action by way of arrest, summons, diversion program, and 'notice to appear.' Some charges may have been subsequently dropped or the defendant may have been found not guilty.

Harsh penalties can apply to a person found guilty of committing an offence. The offence of aggravated supply of a dangerous drug to a child under the age of 16 carries a maximum penalty of 25 years imprisonment. Matters not involving commercial quantities and where there is no evidence of trafficking or supply may be dealt with in the Magistrates Court. In the majority of cannabis cases a guilty plea is entered, and the use of cannabis for medical purposes is only raised as a mitigating factor on sentencing.

First time offenders who plead guilty may be given drug diversion, and in other cases penalties range from a fine, community service to a suspended sentence and imprisonment. For a first offence and under some other circumstances no conviction may be recorded, however the charge is always on the persons criminal record and can impact on a person, for example in some areas of employment, or overseas travel where a person must declare both charges and convictions when applying for a visa to travel to some countries.

Authorisation, exemptions and defences

The definition for '*unlawfully'* in the DMA, and the Criminal Code means: *"without authorisation, justification or excuse by law* and as mentioned above the DMA must be read with the Criminal Code. The principle of authorisation is used as the underlying legal concept to allow an eligible person to be granted approval to be authorised to '***lawfully***'[83] undertake activities, which would otherwise be an offence under the *Drugs Misuse Act,* and provides the person with a complete exemption from criminal charges and prosecution. If a person acts outside the conditions of their approval or exemption they come under the scope of the *Drugs Misuse Act.* There are also several defences available for people who do not have an approval but have justification or excuse for breaking the law.

Authorisation

There are a number of provisions in the DMA and health legislation that provide for a person to be granted an endorsement or approval to be 'authorised' to carry out specified activities involving the use of cannabis for medical or other purposes that would otherwise be a criminal offence. Under recent changes to the *Health (Drugs and Poisons) Regulations* doctors can now be given approval to prescribe, and supply cannabis via the Special Access Scheme or in research trials, and a pharmacist may be given an approval to obtain, possess, supply and dispense cannabis.

Justification or excuse

The availability of the defence of justification and excuse in the DMA, and as set out below in the Criminal Code, implies that in certain circumstances the law may excuse a person from breaking the law where there is sufficient evidence to show that the person committed the act in order to save himself or herself or another person, from serious harm or detriment threatened to be inflicted by some person in a position to carry out the threat.

Criminal Code 1899

The Queensland Criminal Code applies to the *Drugs Misuse Act* and must be read with the Act. The Code contains the defences of 'justification and excuse' and 'extraordinary emergencies.' Justification and excuse is also referred to as the common law defence of necessity. The defences in the Criminal Code may apply to a person who may have no alterative but to break the law out of necessity or in an extreme emergency to prevent harm or danger to life or health. The Code also provides for a number of legal duties to provide another person in their care, the necessaries of life. This duty may extend to a carer, legal guardian or health professional.

Defence of justification and excuse

"A person is not criminally responsible for an act or omission, if the person does or omits to do the act under any of the following circumstances, that is to say when

(i) the person does or omits to do the act in order to save himself or herself or another person, or his or her property or the property of another person, from serious harm or detriment threatened to be inflicted by some person in a position to carry out the threat; and

[83] The definition of *unlawfully* in the DMA means without "*authorisation, justification or excuse by law.*'

(ii) the person doing the act or making the omission reasonably believes he or she or the other person is unable otherwise to escape the carrying out of the threat; and

(iii) doing the act or making the omission is reasonably proportionate to the harm or detriment threatened."[84]

Defence of extraordinary emergency

"Subject to the express provisions of this Code relating to acts done upon compulsion or provocation or in self-defence, a person is not criminally responsible for an act or omission done or made under such circumstances of sudden or extraordinary emergency that an ordinary person possessing ordinary power of self-control could not reasonably be expected to act otherwise."[85]

Duty to provide necessaries of life

"It is the duty of every person having charge of another who is unable by reason of age, sickness, unsoundness of mind, detention, or any other cause, to withdraw himself or herself from such charge, and who is unable to provide himself or herself with the necessaries of life, whether the charge is undertaken under a contract, or is imposed by law, or arises by reason of any act, whether lawful or unlawful, of the person who has such charge, to provide for that other person the necessaries of life; and the person is held to have caused any consequences which result to the life or health of the other person by reason of any omission to perform that duty." [86]

Duty to provide for the necessaries of life for the child

"It is the duty of every person who has care of a child under 16 years to provide the necessaries of life for the child; and take the precautions that are reasonable in all the circumstances to avoid danger to the child's life, health or safety; and take the action that is reasonable in all the circumstances to remove the child from any such danger; and he or she is held to have caused any consequences that result to the life and health of the child because of any omission to perform that duty."[87]

Failure to supply necessaries of life

"Any person who, being charged with the duty of providing for another the necessaries of life, without lawful excuse fails to do so, whereby the life of that other person is or is likely to be endangered or the other person's health is or is likely to be permanently injured, is guilty of a misdemeanor, and is liable to imprisonment for 3 years.[88]

Common law defence of medical necessity

The English Courts introduced the concept of necessity as early as 1551. *In Reninger v Fagossa*[89] the court stated that:

> "A man may break the law, and yet not break the law itself …. where the words of them are broken to avoid a greater inconvenience, or through necessity, or by compulsion." [90]

In 1765 William Blackstone recognised that the necessity defence was founded upon the theory that individuals should not be punished when they are not acting out of free will and that "the law ought to promote the achievement of higher values at the expense of lesser values, and that sometimes the greater good for society will be accomplished by violating the literal language of the criminal law." [91] Blackstone also 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." [92]

[84] Section 31(1)(d) of the Criminal Code
[85] Section 25
[86] Section 285
[87] Section 286
[88] Section 324
[89] [1551] 1 Plowden, 75 English Reports
[90] See also Criminal Code 1899 QLD ss 22 and 31(1)(d).
[91] See William Blackstone, Commentaries on the Laws of England at p 28.
[92] Ibid at p 134.

In Australia the necessity defence has been articulated in several cases,[93] and referred to Queensland in cases involving the defense of extraordinary emergency, however there are no recorded cases where it has been successfully raised in relation to the cultivation or possession of cannabis, however there are medical cannabis cases that have resulted in no convictions recorded, or the matters dismissed before proceeding to hearing.[94]

In Australia the medical use of cannabis is generally raised as a mitigating factor in sentencing rather than pleading and raising it as complete defence. There have been a number of unreported cases where the defence has been successfully raised in Australian courts however in the majority of cases the person pleads guilty.

The availability of a defence does not protect a person from being charged in the first instance. Unless a police officer uses discretion not to arrest or charge a person, or the Director of Public Prosecutions makes a decision not to prosecute the matter on public interests grounds or because of lack of evidence, a person charged with an offence is required to raise a defence in his or her Court proceedings.

This involves a criminal hearing or trial, which is a lengthy, complex and stressful process. To successfully raise a defence, a person would be required to produce expert testimony from a doctor, which can be quite costly. In many cases, while doctors are prepared to provide a letter or medical certificate for his or her patient, most are unwilling to provide an expert affidavit and attend Court as an expert witness.

Industrial cannabis hemp licenses

Part 5B of the *Drugs Misuse Act* contains provisions for the industrial cultivation and use of cannabis. Cultivation of the plant is restricted to 1% THC content or 3% or more for research purposes. Section 4a also provides that any products made from it must be in a form that cannot be used for human consumption.

Director of Public Prosecutions (DPP)

The decision to prosecute a matter is a two-tiered test:

- is there sufficient evidence, and
- does the public interest require a prosecution

The DPP have discretion on whether to prosecute cases that are not in the public interest. If there is insufficient evidence, or if it is not in the interests of the public that a prosecution should be initiated or continued, then it should not be pursued. The scarce resources available for prosecution should be used to pursue, with appropriate vigour, cases worthy of prosecution, and should not be wasting taxpayers monies pursuing inappropriate cases that are not in the public interest.

Response: Government's Policy Objectives and Reasons

Comment: imports and supply via TGA pathways v State program for all patients

As mentioned above the chief executive may only grant a medicinal cannabis approval if the chief executive is satisfied that the cannabis has been imported, cultivated, or manufactured in accordance with the Commonwealth *Customs Regulations, Narcotics Drugs Act* and *TGAct*; and supplied in accordance with the *Narcotics Drugs Act* and *TGAct* ie: access is only via TGA approved SAS, authorised prescribers and research trials.

There are no provisions for:

- an amnesty
- state program for patients who are not eligible for research trials
- state program for patients who cannot afford imports via the TGA pathways
- approvals for patients who are growing their own cannabis

[93] For cases involving the necessity defence see *R v Loughnan* [1981] VR 443 at [448]; *R v Cairns* [1999] 2 Crim App Rep 137[1981] VR 443 at [448]; and *R v Rogers (1996)* 86 A Crim R 542.
[94] See for example *R v Patel* (No 7) [2013] QSC 65; *Carter v Attorney General for the State of Queensland* [2013]; QCA 140; *Wilkinson v Stevenson* [2000] QDC 426; *State of Qld v Alyssa Nolan & Anor* [2001] QSC 174; *Moores v Pearce* [2013] QDC 32.

- approvals for patients who are obtaining their cannabis from the illicit market
- patients to have their own cannabis tested
- approvals for cannabis to be cultivated and supplied under Queensland law from not for profits and small business, and no provisions for home growing.

Comment: funding trials for a minority v funding a state program for all patients

Current policy to only fund and allow for research trials using synthetics or isolated single constituents of a traditional herbal medicine to treat symptoms where there is already more than adequate evidence to support immediate cultivation, access and supply has nothing to do with patient safety and more to do with Orwellian health policy, vested interests, and prejudice, as mentioned above in this submission.

Only a very small number of patients will be able to access cannabis using the TGA pathways, due to the Commonwealth restrictions on cultivation and manufacturing, and the complex TGA/State process as well as costs involved for patients purchasing cannabis, specialist reports, ongoing costs for monitoring and testing, and costs of importing, just to mention some of the costs.

Comment: TGA no requirement for trials v funding research for vested interests

The TGA do not restrict the conditions that can be treated, and it is not necessary for cannabis supplied by the TGA SAS or authorised prescribers to have undergone research trials. According to the TGA "there is no requirement that applications to the TGA to register medicines on the ARTG must contain data from clinical trials conducted in Australia, and that the Australian Schemes only provide benefits by providing the momentum to research and develop new medicines locally and creating an environment of scientific research, and by providing early access for patients to new therapeutic developments."

The TGA cannot compel a company to conduct research trials in Australia, or compel a company to register a therapeutic good on the ARTG, and state that medical practitioners should not use clinical trials primarily as a means for obtaining an unapproved product for a particular patient and advise that they should consult information on the other mechanisms for access to unapproved therapeutic goods, and as we have shown, the other access pathways such as the SAS and authorised prescribers do not work in the interests of the patient. [95]

Comment: creating illusion of reform v replacing identical laws and eliminating rights

The Government have created the illusion of reform, in stating that it's policy position is ***"to allow greater use"*** and so ***"a more comprehensive regularity framework is needed to effectively regulate the use of medicinal cannabis products."***

However there is no greater use or access to cannabis under this Bill to what patients can access now under the **current medical cannabis provisions** in the *Health (Drugs and Poisons) Regulations.* This Bill is only amending and replacing the existing regulations with ones in an Act that are almost identical in substance to the regulations that the Bill propose to replace, and in the process of replacing the regulations with this Bill, the State is eliminating fundamental legal rights.

Section 212 of the Bill provides for consequential amendments that will amend the *Health Act 1937* and the *Health (Drugs and Poisons) Regulation 1996,* and show that this 143 page Bill will only repeal and replace the current 8 pages of medical cannabis approval provisions in the *Health (Drugs and Poisons) Regulation 1996,* which are almost identical to the Bill. Section 213 of the Bill provides for transitional provisions for existing medicinal cannabis approvals.

Legal rights breaches in Queensland legislation have increased in recent years because of the sheer amount of legislation passed, and in many cases rushed through the Queensland Parliament in an attempt to reform the law; or to create the illusion of reform, but in reality the Government is only amending and replacing existing laws and regulations with new ones that are very similar or identical in substance to the laws and regulation they replace, and in the process of these amendments and laws replacing other laws, eliminating fundamental legal rights.

[95] Therapeutic Goods Administration, *'Access to unapproved therapeutic goods – clinical trials,'* October 2004, p 10

Comment: State objectives inconsistent with well established Commonwealth schemes

In respect to the two pathways, the Bill and the current medical cannabis provisions in the Regulations are in direct conflict with Commonwealth law and interfere with a well-established legal process that provides for a patient's right to access unapproved medicines in Australia that are not registered on the ARTG. Medical practitioners have used the SAS for decades to access unapproved medicines for their patients, and there are also many doctors who have become authorised prescribers for other medicines far more toxic than cannabis.

Now without any justification, and only in respect to cannabis, the State has put in place so many unnecessary, complicated and time consuming processes and barriers at a state level that only serve to delay and obstruct access to cannabis medicines that are needed by terminally ill patients, patients with a life threatening condition and patients with chronic and disabling medical conditions.

Comment: Commonwealth TGA approval v unnecessary intervention from the State

All that is needed from in respect of patients who already hold TGA approvals is a simple to use online register for doctors to notify the State that they are treating their patients with unapproved cannabis via the SAS, or as TGA approved prescribers, and not an inquisition, and a complicated time consuming State process that most doctors will not even use because it will take up too much of their time.

- the doctor has already determined that their patient may benefit from cannabis,
- the doctor has explained the risks and benefits of the treatment
- the choice of product and supplier has been determined
- a cannabis treatment plan has already been developed
- the patient has given the doctor their written informed consent assuming full liability for any adverse outcomes
- the patient has to pay for the cannabis as it is not subsidised, and is also responsible for all other costs including, package and handling, customs and shipping fees, and pharmacist dispensing fees
- the TGA has assessed the patient, doctor and product, and have given the doctor a treatment and supply approval, in respect of the specified product type including its form, the quantity, dosage and route of administration.

Rather than obstruct this process the State should be concerning itself with implementing a state program that is just and provides for the needs of all patients, and training its own doctors and pharmacists in the public health system, and providing funding so that patients on low incomes can also afford to access cannabis medicines through the SAS.

Comment: State restrictions on conditions v TGA no restrictions

This Bill only proposes to facilitate patient access to unapproved medicines via the TGA exemption and special use schemes, and the TGA does not have any restrictions on the types of conditions that can be treated under these schemes. Therefore any restrictions imposed by the State on the types of conditions that can be treated with cannabis are inconsistent with Commonwealth law and an abuse of process. If a doctor determines there is clinical justification to treat his or her patient with cannabis, and has prescribed it in accordance with good medical practice guidelines, and has approval from the TGA to prescribe and supply the cannabis, then the State has no right to put any restrictions on what conditions doctors can treat.

Comment: State restricts access to pediatric neurology, oncology, palliative care v TGA allows any doctor to apply

The current regulations only provide for specialists in paediatric neurology, oncology and palliative care can apply to be patient class prescribers, and the Health Department have made it almost impossible to access cannabis using the SAS. The restrictions and conditions imposed by Queensland Health are a breach of fundamental rights, and inconsistent with the TGA's SAS, and authorised prescribers scheme, as the TGA allow any doctor to apply to use the SAS or be an authorised prescriber. Imposing restrictions, and placing barriers to access causes harm and delays access. It will be unjust for many patients who come under their GP or a specialist not listed. It is also unjust for doctors who are interested in treating a number of patients rather than on a case by case basis.

Response: Use of Controls in Drugs Misuse Act

As mentioned above the Government states: "In Queensland, the controls in the *Drugs Misuse Act 1986 operate to* ***prevent harm to the community from the use of illicit drugs,*** and make it an offence to produce, possess and supply cannabis *without authorisation, justification or lawful excuse*,[96] and its policy position is to allow ***greater use*** of ***medicinal cannabis*** *products* under ***certain circumstances*** and ***for specific patients***."

Comment: arrests of actual users inconsistent with objectives of Drugs Misuse Act

Arresting people who use drugs including cannabis is inconsistent with the objectives of the *Drugs Misuse Act 1986.* The reports to the Drugs Misuse Bill 1985 when it was introduced into Queensland Parliament make clear it's objectives were not to apply to people who use cannabis for medical purposes, or for that matter any actual user of any drug, and makes no mention of its effect overriding fundamental health and human rights,. Queensland has failed opportunity to rectify this situation following legal challenges in 2008 submitting that the offences in Part 2 Drug Trafficking only applied to drug traffickers, and not to patients who used cannabis for medical purposes, however the State changed the heading to read Drug Offences.

Comment: Drugs Misuse Act does not prevent harm to the community

The State's out-dated law enforcement policy wastes billions of taxpayers monies and does nothing, if very little to prevent harm to our community and is used in breach fundamental rights, as police primarily target members of the community who are the actual users of cannabis, and not the intended target, drug traffickers who avoid arrest and conviction as they can afford expensive lawyers.

This indiscriminate and unlawful use of the *Drugs Misuse Act* by the State to wrongly target, arrest, convict, and imprison the actual users of cannabis, as well as other drugs, rather than only targeting drug traffickers has allowed the black market to flourish for the benefit of the drug traffickers who pay no taxes and make substantial profits from preying on the sick and dying, and some of the most vulnerable members of our communities.

The State must ensure that its police only arrest drug traffickers rather than misappropriating taxpayers monies to ***unlawfully*** arrest, charge, prosecute, punish and incarcerate patients and carers who cultivate, possess, supply and use cannabis for medical purposes. The State must also stop targeting the actual users of other drugs and start concerning itself with only targeting traffickers in heroin and ice as these drugs are causing great harm to our community.

Comment: law enforcement, courts and prisons v untaxed profits for traffickers

Although this submission does not go into details about the economic costs to the community it is well documented that it costs the State billions for police services, court and prisons services for implementing a failed drug law enforcement and punishment policy. Arresting patients and carers is a waste of taxpayers monies, and only serves the traffickers who pay no taxes and make millions. Patients and carers are saving the State money on reduced hospital admissions, and a reduction in State funded drugs and medicines, ambulance costs, and disability services. These savings will increase substantially if the State provides for a medical cannabis program that actually works in the interests of the patients, and the community. The not for profit, farmers and small business in Queensland will also benefit rather than large overseas corporations.

Comment: Bill does not prevent harm but causes harm

The Bill causes substantial harm to Queensland patients and carers, as it does not protect the health and welfare of patients and carers by including provisions for patients and carers who grow their own cannabis, or who are forced to obtain it from the black market; it does not provide for patients who cannot afford imported cannabis via the SAS; or the patients who are not eligible for research trials; or who entered trials and found the product unsuitable; and there are currently no TGA authorised prescribers and the Bill will restrict these to limited specialists; and it will not assist patients who will not be able to afford commercial prices of cannabis grown locally under the federal licenses. It will also discriminate against patients who have criminal records; and who have been wrongly charged and convicted; or charged with minor drug offences, or who have spent convictions as discussed further below.

[96] Explanatory Notes to the Public Health (Medicinal Cannabis) Bill 2016, p 1.

The Bill does nothing, if very little to prevent harm to our community, as police primarily target members of the community who are the actual users of cannabis, and not the intended target, drug traffickers who pay no taxes and prey off vulnerable members of our communities, and avoid prison as they can afford expensive lawyers.

Response: Inconsistency with Commonwealth Therapeutic Goods Act

The Bill is inconsistent with a number of provisions in the Commonwealth *Therapeutic Goods Act* (TGAct) that provide for access to unapproved medicines in Australia as set out in the exemption and special use pathways administered by the Therapeutic Goods Administration (TGA), and is also inconsistent with almost identical medical cannabis provisions in the *Health (Drugs and Poisons) Regulations* that are currently used for the same purpose, and in contrast with provisions used for Schedule 8 controlled drugs in which a doctor only needs to notify Queensland Health that he or she is treating the patient. The Bill also fails to provide access in a timely manner, is inconsistent with privacy provisions under the TGAct, and also fails to include any review rights for patients and carers who are adversely affected by a decision made by the chief executive in accordance with the TGAct.

As mentioned above the Commonwealth Health Minister Sussan Ley said in February this year, that the Commonwealth Department of Health and the Therapeutic Goods Administration were "well-advanced" in considering downgrading cannabis to a "controlled substance" class, putting it in the same category as morphine, and *"This will in turn reduce any barriers to access, no matter what state a patient lives in."* [97] Last year Sussan Ley also said in the Commonwealth Parliament of Australia that she would make the Special Access Scheme work for the patients. The State should ensure that access to unapproved cannabis from the Commonwealth schemes is consistent with the TGA pathways.

Comment: medical practitioners v specialists

Contrary to what is proposed in the Bill, under the TGA any registered medical practitioner can facilitate patient access to unapproved medicines using either the SAS Category A or B pathways or the authorised prescriber pathway. It should also be noted that according to the TGA, the doctor determines which SAS category his or her patient comes under, not the TGA or the State, and the way in which a doctor prescribes a treatment for an individual in a particular clinical setting is a matter of medical practice and the TGA does not regulate medical practice. However, as the TGA administers supply of therapeutic goods including various avenues of access to unapproved therapeutic products in Australia there is a degree of oversight to ensure that the appropriate SAS pathway is used in a given circumstance.

Comment: TGA unapproved medicines prescribing pathways v State prescriber pathways

The proposed prescriber pathways as set out in the Bill itself, and as proposed to be further regulated in the regulations to the Bill, are inconsistent with Commonwealth law and processes, as the Bill does not provide access to unapproved cannabis in accordance with the SAS Categories A and B, and the authorised prescriber scheme. The inconsistencies with the prescriber pathways in the Bill as compared to each of the TGA pathways administered by the TGA are discussed in more detail below.

Comment: TGA authorised prescriber v state patient class prescriber

The Bill is inconsistent with the provisions for authorised prescribers under the TGAct, as it restricts approvals to patient class prescribers to a list of specialists in the regulations. Currently under the *Health Drugs and Poisons Regulations* these are limited to oncology, pediatric neurology, and palliative care specialists whereas under the TGAct any medical practitioner may apply to the TGA to be granted authority to become an authorised prescriber to prescribe a specified unapproved cannabis good or class of unapproved cannabis goods to specified patients or classes of patients.[98] To be an Authorised Prescriber the medical practitioner must:

[97] Jane Lee, Sydney Morning Herald, http://www.smh.com.au/federal-politics/political-news/senate-passes-medicinal-cannabis-legislation-20160224-gn2gjk.html, 24 February 2016.
[98] Sections 19(5) and 41HC of the *Therapeutic Goods Act 1989*

- have the training and expertise appropriate for the condition being treated and the proposed use of the product;
- be able to best determine the needs of the patient; and
- monitor the outcome of treatment.

Once a medical practitioner becomes an 'Authorised Prescriber' under the TGA they do not need to notify the TGA when they are prescribing the unapproved product, however they must report to the TGA the number of patients treated on a six monthly basis.[99]

Comment: TGA Category A: notification only not provided in Regulations or Bill

The Bill fails to make any provision for a *single patient prescriber* to facilitate access to unapproved cannabis in accordance with the SAS Category A notification pathway that provides access to unapproved cannabis to a terminally ill patient or patient with a life threatening illness.

According to the TGA, the Category A pathway provides access to unapproved cannabis medicines for those patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.

A doctor is only required to **notify** the TGA (within 28 days) that they are treating the patient with an unapproved medicine listed in Schedule 4 or 8 of the SUSMP. There is no need for doctors to seek prior approval from the TGA for the use of an unapproved product in a Category A patient. The treating registered medical practitioner is in effect the approving authority in that he/she is prepared to prescribe the product in question.

The way the definition of Category A was intended to be interpreted can be gained by reference to the discussion in the Senate of the Australian Parliament at the time the definition was being framed for inclusion in the TGAct. The following statement was offered:

> "when people are confronting the certainty of death and have a terminal ***or*** life-threatening illness, special provisions clearly ought to be made to help them psychologically face that prospect by giving them assurance that virtually ***whatever they wish, by way of administration of a drug of which they have learnt, can be undertaken."***[100]

Patients in this category have the right, in consultation with their medical practitioner, to use any therapeutic good, except medicines listed in Schedule 9 of the *SUSMP.*[101] A medical practitioner who forms the view that his/her patient is Category A can ***import and supply*** (emphasis added) an unapproved therapeutic good ***without approval from the TGA*** in accordance with the limitations and requirements as outlined below.[102]

How a doctor notifies the TGA of supply of an unapproved therapeutic good under Category A

The practitioner is only required to complete the "Category A Form Special Access Scheme" and send it to the sponsor of the product. This provides the sponsor with the legal authority to supply the product.

The practitioner must send a copy of the completed "Category A Form Special Access Scheme" to the TGA within 4 weeks of the date of signature on the Form.[103]

[99] For further information on authorised prescribers see the Therapeutic Goods Administration website at https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers.
[100] Hansard, Senate 12 December 1991, Senator Tate; Therapeutic Goods Administration Publication: "*Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, p 11
[101] See Regulation 12A(1) of the *Therapeutic Goods Regulations*
[102] Therapeutic Goods Administration Publication: *"Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, p 11
[103] ibid p 12, Failure to do so is an offence that carries a financial penalty.

The "Category A Form Special Access Scheme" requires the practitioner to certify that he/she:

- has reached the conclusion that the patient is Category A; and
- has obtained the informed consent of the patient, or patient's guardian, to the product being given to the patient; and
- will prescribe the product in accordance with good medical practice. [104]

If the cannabis can be supplied from within Australia, the doctor sends the form direct to the supplier, and the form gives the supplier authority to supply the medicine without the need for TGA approval. If the cannabis needs to be imported, either a doctor or a pharmacist sends the Category A form to the Office of Drug Control section of the TGA with an application for an import licence and permit. This is generally a formality and can be processed the same day.

Note: Any registered medical practitioner can use the Category A notification pathway. It is not restricted to specialists however access using this pathway is restricted to access to Schedule 4 and 8 medicines only, and is not available for Schedule 9 medicines.

Therefore according to the TGAct, if a Category A patient wishes to use an unapproved medicine that the patient has learnt about - their doctor can prescribe and supply Schedule 4 cannabidiol (CBD) and Schedule 8 cannabis (nabiximols) without seeking TGA approval. Doctors seeking to use Schedule 9 medicines to treat a Category A patient must apply for approval under the Category B pathway.

Comment: TGA Category B application v single patient prescriber

The Bill proposes to duplicate the TGA process, and also has a number of other provisions that are not in Commonwealth or State law now for cannabis or any other medicine, ie: requirement for criminal history checks and consideration of the patients personal circumstances just for a patient to undergo treatment:

- criteria for suitability of patient to undergo treatment,
- criminal history checks at the expense of the patient
- chief executive can consider the personal circumstances of the patient
- 90 days for the chief executive to provide a response
- chief executive can refer applications to an expert specialist panel
- chief executive can request further information
- no limits to the number of requests for further information
- no review or appeal rights for patients or carers adversely affected by a decision or failure to make a decision
- disclosure of patient information in breach of privacy provisions

Comment: TGA assessment process

A doctor must obtain approval from the TGA to treat a patient who does not fit the Category A definition ie all other patients who do not fit the Category A. This includes patients with a terminal illness or a life threatening illness who require access to Schedule 9 cannabis. Approval is given on a patient-by-patient basis to reflect the needs of different patients.

Category B applications need to address criteria relating to the suitability of:

- the patient,
- the product
- the prescriber

Doctors can also provide any other information they consider important. The TGA consider the quality and extent of the information provided by the doctor and balances the position in relation to each of the criteria. Approval will not be given unless each of the criteria has been met.

[104] Ibid p 12

Criterion 1 - the patient

The doctor needs to provide adequate clinical justification for the use of the unapproved product, including an outline of the seriousness of the patient's condition, details of past treatment and an appraisal of the expected benefits from the use of the unapproved product, and justification for the use of the unapproved product in preference to approved treatments. [105] The doctor needs to provide the following information on a 1-page application form as opposed to the 4 page State form currently in use:

Patient details:	Initials only Date of birth (or age) Sex Patient ID or unit record number Diagnosis If applying for an extension of use under SAS - previous approval number, if available

Criterion 2 - the product

The doctor needs to indicate how the product is to be used and include an appraisal of the efficacy and safety of the proposed use of the product including the following:

Product details:	Active ingredient Trade name Company/supplier (sponsor) Dose form
Administration regime:	Dosage Route or method of administration Duration of treatment

Efficacy/Safety Data

Efficacy and safety data needs to be provided to support the proposed use of the product including a copy of the reference articles from which the data has been obtained. References can range from published randomised controlled trials and non-randomised trials and case reports to consensus opinion. The level of evidence required from reference articles depends on the seriousness of the condition. [106]

Outcomes of Treatment, Monitoring and Reporting Adverse Reactions

The doctor also needs to provide the TGA with details of the techniques that are to be used to determine the outcome of treatment and the occurrence and severity of any adverse reaction and this can be done in terms of clinical, biochemical, hematological and/or immunological monitoring throughout treatment and in some cases for a period thereafter. If a doctor requests an extension of use under SAS, outcomes of monitoring, including measures of patient response and safety parameters are required.

Criterion 3 - the Prescriber

A doctor needs to provide his or her qualifications and/or expertise appropriate to the condition being treated and the proposed product:

Prescriber details	Name Postal address Qualifications Hospital and hospital department, if applicable Phone number Fax number, if available

[105] Therapeutic Goods Administration Publication: "*Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, p 15
[106] ibid p 15-16

How the TGA assess the criteria

The TGA provide a general guide on how the issues impacting a decision may be balanced in accordance with a hierarchy of evidence of efficacy and safety of the product, and evidence based on the seriousness of the patient's condition, and evidence of the doctor's qualifications.

The product hierarchy differentiates between:

- Products not approved in Australia but approved in countries with a regulatory standard comparable to that in Australia (ie, USA, UK, Sweden, Canada, The Netherlands for medicines,
- Products not approved in Australia but approved in countries other than those with regulatory standards comparable to Australia;
- Products currently under evaluation by TGA;
- Products not approved anywhere and still undergoing clinical trials.

These products may be further classified according to the types of evidence available from

- published randomised controlled trials [highest level of evidence]
- published non-randomised trials
- individual case reports
- consensus opinion of specialist colleges and societies [lowest level of evidence].

Efficacy and safety data to support of the application is weighed against the seriousness of the patient's condition. The less serious the clinical need, the higher the degree of evidence is required to support the use of the unapproved product. For example, a product approved in a country with a regulatory system comparable to Australia is likely to be approved for a condition for which it has already been approved for in that country.

If the only evidence available is obtained from published case reports, it is unlikely that use of the product would be approved for anything but the most serious almost life-threatening conditions, and the prescriber also needs to demonstrate that other conventional therapies are clinically unacceptable.

If another product has already been evaluated and approved by the TGA, the level of evidence to support the use of an unapproved product instead of the new product is higher, especially for products with the same active ingredient or with active ingredients in the same therapeutic class.

It should also be noted that:

1. The TGA provide phone requests reserved for cases where there is an urgent medical need for access to the product.[107]

2. The TGA have appointed a limited number of delegates outside the TGA in hospitals with respect to a small number of medicines, and could do the same for cannabis.[108]

Comment: TGA Australia wide database of approved cannabis products and doctors

The TGA have a SAS database of unapproved products that have previously undergone the TGA SAS assessment. The TGA delegate is also responsible for undertaking a limited search for information, such as the status of overseas products. The TGA may also have information about products and suppliers based on previous SAS applications from the other states and territories, and research trials that are not available to Queensland Health. Clinical justification needs to show why a newly approved product is not acceptable on medical grounds and not because of cost or convenience.[109]

[107] Therapeutic Goods Administration Publication: "*Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, p 37
[108] ibid p 37
[109] The TGA state, this requirement is imposed in part because it is the TGA's responsibility to encourage at all times the availability of approved (fully evaluated) products. To do otherwise would remove the incentive for a sponsor to seek registration of the unapproved product or for other sponsors to seek registration of alternative products for treatment of the indication.

Comment: effect of TGA rescheduling

When botanical cannabis is rescheduled from Schedule 9 to Schedule 8 in the SUSMP, doctors should also be able to use the Category A notification system and Category B treatment approval pathway as they would any other Schedule 8 medicine.

Comment: TGA investigation and monitoring powers

The TGA have adequate investigation and monitoring powers to prevent inappropriate prescribing, and to prevent misuse and diversion. The TGA can require the treating medical practitioner to provide information or documents about the condition of the patient, and the supply and handling of an unapproved medicine in relation to that patient. The TGA can also request information or documents about the supply and handling of a medicine, including information about the unapproved product itself, to clarify the intended use of the product or to obtain information concerning patient diagnosis.[110] The Act includes penalties for failing to comply with a request.[111]

In some cases, after obtaining information or documents from a treating medical practitioner, TGA staff may informally discuss the appropriateness of Category A with the medical practitioner, as another avenue of exemption may be more appropriate.[112] The TGAct also allows information to be released to State or Territory bodies that have functions relating to therapeutic goods or that are responsible for the registration of medical practitioners or pharmacists. If the TGA believes that a medical practitioner is using the Category A provisions inappropriately, and the medical practitioner continues to do so, information concerning such use may be provided to State and/or Territory authorities, such as a Medical Board and/or Medical Complaint Units.[113]

Response: Health (Drugs and Poisons) Regulations - current process

The doctor is required to go through a State process on a case-by-case basis after undergoing the TGA process to obtain Category B treatment and supply approval. However all the TGA import section needs to be able to issue an import licence to a doctor or pharmacist is notice from the State that the cannabis can be legally possessed, administered and supplied within the State's jurisdiction.

Comment: unnecessary interference by the State

- the doctor has already determined that their patient may benefit from cannabis,
- the doctor has explained the risks and benefits of the treatment
- the choice of product and supplier have been determined
- a cannabis treatment plan has already been developed
- the patient has given the doctor their written informed consent assuming full liability for any adverse outcomes
- the patient has to pay for the cannabis as it is not subsidised, and is also responsible for all other costs including, package and handling, customs and shipping fees, and pharmacist dispensing fees
- the TGA have assessed the patient, doctor and product, and have given the doctor a treatment and supply approval, in respect of the specified product type including its form, the quantity, dosage and route of administration

Queensland Health - current assessment process

The current application form and process being used by Queensland Health under the medical cannabis approval provisions in the *Health (Drugs and Poisons) Regulations* requires the doctor to complete a 5 page application form, and include all TGA documents, followed by an assessment process that can take up to 3 months, and can be referred to a an expert panel. The State process not only duplicates the TGA's 1 page form and 1-5 day approval, it puts in place a number of other barriers that delay access. Applications must also be sent to Queensland Health by POST as they do not accept applications online or by fax or email.

[110] See for example section 31A(2) of the *Therapeutic Goods Act 1989*
[111] See the Therapeutic Goods Administration Publication: "*Access to unapproved therapeutic goods via the Special Access Scheme,*" November 2009, p 12
[112] ibid p 12
[113] ibid 13

As can be shown in [redacted] case the State process duplicates the TGA process, and is complex, time consuming and causes delay and harm. The chief executive can take up to 90 days to give a decision. The doctor will only be notified by mail if the chief executive grants approval as there are no online facilities or phone approvals. The chief executive may also refer the application to a specialist panel for review to assist in his (sic) decision. A doctor needs to provide information in regard to the following:

- details of the doctor including contact details
- a copy of the TGA approval
- a full copy of the application to the TGA including all supporting documentation
- details of the patient including full name, address, date of birth, town and country of birth
- details of carer/s as above as well as telephone and mobile number
- whether the doctor is satisfied that the carer is a fit and proper person to manage the patients care with medical cannabis
- copies of all and any supporting specialists reports that support diagnosis and the treatment with the medical cannabis
- diagnosis
- prognosis
- medical history
- full details of the product/s approved by the TGA
- relevant safety and consumer information including evidence the products meet Good Manufacturing Practice
- supporting clinical or research evidence of the use of the unapproved product for treatment of the nominated condition
- types and amount of current cannabis that the patient is cultivating or using and the supply source

The State application also includes a declaration to be signed by the doctor that includes:

- the doctor agrees to comply with conditions set out in the TGA approval
- the doctor accepts responsibility for any adverse consequences of treatment
- the doctor has obtained full informed consent from the patient or their legal guardian
- details of any adverse drug reactions are to be reported to the chief executive
- the chief executive is to be immediately notified on completion of treatment
- the doctor accepts responsibility for any defects in the drug supplied related to its manufacture, distribution, or its direction for usage, including dosage.

Comment: TGA only cannabis via TGA research trials, SAS and authorised prescribers

Like the Bill, and as mentioned above the chief executive may only grant a medicinal cannabis approval if the chief executive is satisfied that the cannabis has been imported, cultivated, or manufactured in accordance with the Commonwealth *Customs Regulations, Narcotics Drugs Act* and *TGAct*; and supplied in accordance with the *Narcotics Drugs Act* and *TGAct* ie: access is only via TGA approved SAS, authorised prescribers and research trials. There are no provisions for cannabis to be cultivated and supplied under Queensland law from not for profits and small business, and no provisions for home growing.

Lengthy treatment with controlled drug

Section 120 of the *Health (Drugs and Poisons) Regulation* provides that a doctor is only **required to give Notice if the treatment is with controlled drugs such as morphine, or pethidine,** and only applies if a doctor or nurse practitioner administers, dispenses, prescribes or supplies, or intends to administer, dispense, prescribe or supply, a controlled drug in the treatment of a patient for more than 2 months; or reasonably suspects a patient has been treated with a controlled drug by another doctor or nurse practitioner for more than 2 months. The doctor or nurse practitioner must immediately give the chief executive a written report in the approved form about the circumstances of the patient's treatment. The chief executive may ask the doctor or nurse practitioner to give the chief executive additional information about the treatment of the patient within a stated reasonable time.

Approval needed for treating certain drug dependent persons with controlled drugs

Section 120 provides that a relevant practitioner is only required to apply for an approval to treat a patient with a controlled drug, or supply or dispense a controlled drug if the practitioner reasonably believes that a person is a drug dependent person. A relevant practitioner includes, a doctor, nurse practitioner or a pharmacist.

The practitioner must give the chief executive a report in the approved form about the circumstances of the person's treatment; or if the relevant practitioner proposes to treat a class of drug dependent persons—the class of drug dependent persons the relevant practitioner proposes to treat and the proposed treatment of the persons. The chief executive may only then ask the practitioner to give stated additional information within a stated reasonable time. The relevant practitioner must comply with the request, unless the relevant practitioner has a reasonable excuse for not complying with it.

If the chief executive is reasonably satisfied that, for the welfare of the drug dependent person or class of drug dependent person, it is necessary for the relevant practitioner to treat the person or persons with a controlled drug, the chief executive may give the relevant practitioner written approval to administer, dispense, prescribe, supply or give an oral or written instruction to supply a stated quantity or volume of the controlled drug, or an oral approval to administer, dispense, prescribe, supply or give an oral or written instruction to supply a stated quantity or volume of the controlled drug to or for the person or persons, the chief executive may give the oral approval. If the chief executive gives the relevant practitioner an oral approval, the chief executive *must* give the relevant practitioner written confirmation of the approval *as soon as possible* after giving the oral approval.

Response: Public Health (Medicinal Cannabis) Bill – proposed process

As outlined above the chief executive is seeking power in this Bill to undertake an approval process that is currently provided for in the *Health (Drugs and Poisons) Regulations,* and also duplicates the TGA process in breach of fundamental rights. In addition the chief executive also seeks to impose harsher provisions that breach more fundamental legal rights.

Comment: TGA only cannabis via TGA research trials, SAS and authorised prescriber

The Bill changes nothing and only allows for the same access to unapproved cannabis via the TGA pathways that the patients have now under the *Health (Drugs and Poisons)* Regulations as the the chief executive may only grant a medicinal cannabis approval if the chief executive is satisfied that the cannabis has been imported, cultivated, or manufactured in accordance with the Commonwealth *Customs Regulations, Narcotics Drugs Act* and *TGAct*; and supplied in accordance with the *Narcotics Drugs Act* and *TGAct* ie: access is only via TGA approved SAS, authorised prescribers and research trials.

Patients will only be able to access imported cannabis through the TGA for some years to come, and even when cannabis is available locally access will still be restricted through the TGA pathways and also be expensive. There are no provisions for cannabis to be cultivated and supplied under Queensland law from not for profits and small business, and no provisions for home growing.

Comment: Bill criteria for grant of medicinal cannabis approval v opiates, methadone

In breach of fundamental rights the chief executive can take up to 90 days to respond to an application and may have regard to, and consider the following after the doctor already has TGA approval:

- whether the applicant is a suitable person to hold the approval;
- whether the patient is a suitable person to undergo treatment with medicinal cannabis;
- the patient's medical condition and associated symptoms of the medical condition;
- the form and dosage of medicinal cannabis for which the applicant intends to give a lawful direction under the approval;
- whether treatment with medicinal cannabis can be integrated into the patient's existing medical treatment;
- any opinion of a specialist medical practitioner given to the chief executive
- alternative treatments suitable for the patient's medical condition or associated symptoms;
- the patient's criminal history, personal circumstances, and history of drug dependence, if any, including current use of cannabis;

- discriminatory and excessive definitions and terms not used for any drugs including opiates and methadone, and benzodiazepines
- any other matters the chief executive reasonably considers relevant to deciding the application.

Comment: Other Schedule 8 controlled drugs no approval required v cannabis

The current medical cannabis approval provisions in the *Health (Drugs and Poisons) Regulations* and the assessment process the doctor is required to undergo after they have already undergone the TGA process to obtain Category B treatment and supply approval is inconsistent with the long standing provisions in the *Health (Drugs and Poisons) Regulations* for lengthy treatment with addictive controlled drugs such as opiates, and methadone. There are also a number of other inconsistences and breach of fundamental legal rights with the use of cannabis that are not imposed with the use of far more toxic and dangerous and addictive drugs as discussed further below.

Comment: TGA v State pathways

As shown above approval is not required for treatment or dispensing of any other unapproved medicines, or registered medicines under the *Health (Drugs and Poisons) Regulations* including controlled drugs of addictive and dangerous drugs such as opiates and benzodiazepines unless the doctor determines that the patient is a drug dependent person.

Therefore the provisions for access to cannabis under the single *patient prescriber* and the patient class prescriber as set out in the Regulations and the Bill are unreasonable, as they do not apply to any other medicine or drugs, and are excessive and inconsistent with fundamental legislative principles (FLP's), and discriminate against patients because the treatment being used is cannabis.

If a doctor has an exemption under Category A or an approval under Category B of the SAS, the doctor should only be required to notify the chief executive that they are treating their patient with cannabis.

We have also demonstrated in [redacted] case that trying to access cannabis via the SAS Category B is already a very convoluted, expensive, complex and time consuming process for doctors and patients to navigate without all the added processes and conditions that the State is imposing.

As also shown above, the Bill is inconsistent with provisions in the TGA as it fails to provide access to unapproved medicines in accordance with Category A, Category B or the authorised prescriber pathways. In respect to patients with a terminal illness or a life threatening illness they should be able to have ***whatever they wish, by way of administration of a drug of which they have learnt."***[114]

As also mentioned above patients in this category have the right, in consultation with their medical practitioner, to use any therapeutic good they wish, except medicines listed in Schedule 9 of the *SUSMP.*[115] If the doctor forms the view that his/her patient is Category A they can ***import and supply*** (emphasis added) an unapproved therapeutic good ***without approval from the TGA*** in accordance with the limitations and requirements as outlined above and should not be obstructed by the State.[116]

The TGA have in place adequate provisions to monitor and investigate doctors who are misusing the SAS and authorised prescriber schemes, as well as adequate provisions to release any such information to Queensland Health and other state bodies such as medical and pharmacy boards.

[114] Hansard, Senate 12 December 1991, Senator Tate; Therapeutic Goods Administration Publication: "*Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, p 11
[115] See Regulation 12A (1) of the *Therapeutic Goods Regulations*
[116] Therapeutic Goods Administration Publication: "*Access to unapproved therapeutic goods via the Special Access Scheme,"* November 2009, p 11

Response: Specific Terms and Clauses in Breach of Fundamental Legal Principles

Comment: clause 5 definition of synthetics v TGA SUSMP

The definition of ***cannabis product*** clause (c) has, or is intended by the manufacturer of the product to have, a pharmacological effect that is substantially similar to the pharmacological effect of a product mentioned in paragraph (a) or (b) whereas the TGA Schedule 8 entry for Tetrahydrocannabinols extracted from, or derived from the extracts, of cannabis does not include synthetic Tetrahydrocannabinols.

To ensure there is no confusion with the prescription, sale, supply or dispensing of synthetic cannabis products as opposed to botanical cannabis, all provisions for synthetic cannabis products should be listed separately in the *Health (Drugs and Poisons)* for example under Part 3 Regulated controlled drugs, section 77 that provides for the approved drug dronabinol (*delta*-9-tetrahydrocannabinol), which is a synthetic form of THC.

Comment: clause 10 suitability of patient to undergo treatment

In deciding whether a patient is a suitable person to undergo treatment with medicinal cannabis under a medicinal cannabis approval, the chief executive may have regard to the following:

(a) the information in the application for approval;
(b) the **patient's personal circumstances**;
(c) the **patient's criminal history** but only to the extent it is relevant to the application;
(d) the advice of the expert advisory panel;
(e) the advice of a specialist medical practitioner;
(f) whether the patient, in the chief executive's reasonable opinion, will be able to comply with
    (i) this Act; and
    (ii) the conditions proposed to apply to the approval.

The definitions, and criteria that the chief executive proposes to assess a patent on, to decide whether or not to grant an approval, when the doctor already has TGA approval, is not in any other law for patient access to any type of medicine including opiates, and methadone here in Queensland or Australia, or the world for that matter.

It is entirely inappropriate to allow bureaucrats who are so far removed from the care and responsibility of the patient to intervene in the doctor patient relationship in such a discriminatory and irrelevant manner. It is the patient's right in consultation with his or her own doctor to determine whether or not they will undergo treatment and what type of treatment is best suited to their individual medical needs.

Specific definitions in this clause, and the requirement for criminal history checks are addressed separately below.

Comment: clause 5 definition of drug dependence

The definition for ***drug dependence*** is discriminatory, ambiguous and has been changed as compared to the long-standing definition that is currently used under Section 5 of the *Health Act 1937.*

drug dependence for a person, means repeated administration to the person of a drug resulting in the person
(a) demonstrating any of the following over the person's continued use of the drug
(i) impaired control;
(ii) drug-seeking behaviour that suggests impaired control;
(iii) social impairment related to continued use of the drug;
(iv) continued use of the drug despite the known harms of the continued use; and
(b) suffering, or likely suffering, mental or physical distress or disorder when the administration to the person of the drug ceases.

Whereas the long-standing definition that is currently in use under Section 5 of the *Health Act 1937* reads:

> ***drug dependence*** means a person
>
> (a) who, as a result of repeated administration to the person of controlled or restricted drugs or poisons
> (i) demonstrates impaired control; or
> (ii) exhibits drug-seeking behaviour that suggests impaired control; over the person's continued use of controlled or restricted drugs or poisons; and
> (b) who, when the administration to the person of controlled or restricted drugs or poisons ceases, suffers or is likely to suffer mental or physical distress or disorder. [117]

Comment: clause 5 no definition of personal circumstances for patient to undergo treatment

The meaning of personal circumstances is not defined in the Bill, and it is not defined how the chief executive can consider a patient's personal circumstances, and what information is to be provided or what information can be requested. This provisions is intrusive in breach of fundamental rights, and will target the homeless, the poor, indigenous patients, and patients who have been classified in the past as drug dependent or as having mental health conditions and under treatment orders, and patients in prison etc.

Comment: clause 5 no definition of social impairment for patient to undergo treatment

drug dependence for a person, means repeated administration to the person of a drug resulting in the person (a) demonstrating any of the following over the person's continued use of the drug …….. **(iii) social impairment related to continued use of the drug;**

There is no definition for social impairment in the Bill, and there is no explanation of how the chief executive can consider a patient's social impairment in respect to the patient's suitability to undergo treatment. Social impairment generally relates to medical conditions such as autism, PTSD, and anxiety, and has been defined as:

> "a distinct dissociation from and lack of involvement in relations with other people. It occurs with various mental and developmental problems such as autism, schizophrenia and severe anxiety disorders. It can also be a result of medical issues that cause disfigurement, such as acne or the loss of a limb or problems with teeth."

and further:

> "Autism spectrum disorders can mean that the person's focus is more on things than people, resulting in some social impairment. Children with autism exhibit a marked withdrawal from interactions with family members or caretakers. Asperger's syndrome is a mild form of autism characterized by a lack of normal social functioning, although intelligence is usually average or above. It is often seen as social awkwardness, little or no eye contact, obsessive interests and a tendency to miss social cues.
>
> Social anxiety and phobias can cause very severe avoidance behaviors. Generally people with social phobias recognize that their fear is unreasonable, but they are hard-pressed to change it, so they avoid situations that may trigger a panic attack. In the case of disorders like agoraphobia, they may never go out at all. Post-traumatic stress disorder (PSTD) can cause social impairment in adults who cannot maintain normal interactions due to persistent anxiety, flashbacks, and a sense of detachment from others who did not experience the same trauma."[118]

[117] *Health Act 1937*, Queensland legislation at http://www.legislation.qld.gov.au/legisltn/current/h/heala37.pdf
[118] See Quora website at https://www.quora.com/What-are-examples-of-social-impairment; and the Autism Network, at https://iancommunity.org/cs/autism/impairments_in_social_interaction.

Comment: clause 10 personal circumstances for suitability of patient to undergo treatment

There is no definition for personal circumstances, therefore this is open to abuse as personal circumstances could relate to irrelevant factors from income, housing, employment, education, through to marital and social relationships. In addition, this criteria does not exist in any Commonwealth or Queensland or other State law for treatment with cannabis or any other medicines or drug. It is excessive, discriminatory, and irrelevant, and should not be a factor to consider just for a patient to undergo treatment.

Comment: Division 5 process for deciding applications

Information in the application, and advice from a specialist only seeks to duplicate the TGA process as Queensland Health is requesting this information after the patient in consultation with his or her doctor has already determined the treatment plan, cannabis supplier, what product is to be used, and how it is to be used, and the patient has given the doctor their written informed consent, and the doctor has already obtained Category B treatment approval from the Therapeutic Goods Administration.

Comment: clause 21 expert panel

Referral to an expert panel is unnecessary and only serves to obstruct and delay access, and cause unnecessary suffering for patients and carers when the doctor already has TGA approval. As set out above to obtain TGA approval a doctor is required to address criteria in the SAS Category B application relating to the suitability of the patient to undergo treatment with the product, and the suitability of the prescriber.

The doctor must also include adequate clinical justification for the use of the unapproved product, with an outline of the seriousness of the patient's condition, details of past treatment and an appraisal of the expected benefits from the use of the unapproved product, justification for the use of the unapproved product in preference to approved treatments, and must indicate how the product is to be used and also give an appraisal of the efficacy and safety of the proposed use of the product.

Comment: clause 22 requirement for doctor to seek specialist advice

As mentioned above this is an unnecessary requirement as the doctor already has TGA approval, and as part of the TGA criteria, and the TGA assessment process, the doctor is required to provide specialist reports, and the TGA can also request further information including an updated specialist report. This provision only serves to obstruct and delay access, and cause unnecessary suffering to patients and carers, and will be an added financial burden to patients, as there can be significant waiting times for specialist appointments, and significant costs as most specialists do not bulk bill.

Comment: clauses 31, 32 up to 90 days to make a decision, extensions for complex applications

In breach of fundamental rights clause 31 gives the chief executive power to extend the period for considering the application by the reasonable number of days the chief executive considers necessary to decide the application; and considers that, because of the complexity of the matters to be decided for an application, the chief executive needs extra time to consider the application. The chief executive must give the applicant notice of the day the extended period ends.

Section 32 gives the chief executive up to 90 days to make a decision, and the application is taken to be refused after that time has expired if the chief executive fails to make a decision. This is inconsistent with the TGA who states a SAS application should only take 1 – 5 days. A renewal application can take up to 30 days; or another application 60 days after receiving the application.

After 90 days if the chief executive has refused to grant an approval, the chief executive must give the applicant an information notice for the deemed refusal.

Comment: clause 84 register disclosing patient identity v TGA non disclosure

The TGA only require the doctor to provide the initials of the patient, and his or her DOB. In breach of privacy, and fundamental legal rights, the Bill proposes that Queensland Health keep a register of all patients who have been approved to be prescribed and supplied cannabis via the TGA pathways, as well as the carers.

The register must contain the following particulars for each approval: any identification number allocated to the approval; the name of the approval holder; for a medicinal cannabis approval the name of the patient for the approval; and the dispensing pharmacy; and any carers for the approval; for a dispensing approval - the name of any secondary dispenser for the approval; the type of the approval; the term of the approval.

A State register can be used for patients who grown their own cannabis or who obtain from the illicit market.

Response: Criminal history just to undergo treatment

Comment: definition of criminal history v Criminal Law (Rehabilitation of Offenders) Act

The definition in respect to criminal history in the Bill is a breach of fundamental legal rights, and is inconsistent with provisions in the *Criminal Law (Rehabilitation of Offenders) Act 1986.* Criminal history should only be considered in respect to applications for licenses to cultivate, manufacture or supply cannabis, and under those circumstances the *Criminal Law (Rehabilitation of Offenders) Act 1986* should apply as set out below.

Conviction

In the Bill Schedule 1 Dictionary ***conviction*** includes a plea of guilty or finding of guilt by a court even though a conviction is not recorded.

In contrast the *Criminal Law (Rehabilitation of Offenders) Act 1986 provides:*

> ***conviction:*** means a conviction by or before any court for an offence, whether recorded, in Queensland or elsewhere, before or after the date of commencement of this Act.

Criminal history

In the Bill ***criminal history***: of an individual, means all of the following:

> (a) ***every conviction*** of the individual for an offence, in Queensland or elsewhere, whether before or after the commencement of this Act;
> (b) ***every charge*** made against the individual for an offence, in Queensland or elsewhere, whether before or after the commencement of this Act.

In contrast the *Criminal Law (Rehabilitation of Offenders) Act 1986 provides:*

> ***criminal history***: in relation to any person, the convictions recorded against that person in respect of offences.

In addition the *Criminal Law (Rehabilitation of Offenders) Act 1986 and other legislation* provides for a number of matters that are to be excluded from criminal history as discussed below.

Comment: Clauses 10, 27, 28, 29: criminal history report suitability to undergo treatment

This type of criteria is in breach of fundamental principles, discriminatory and irrelevant and is not in any other law for patient to have to disclose a criminal history report to access any type of medicine including opiates, and methadone. It is entirely inappropriate to allow bureaucrats to intervene in the doctor patient relationship in such a manner.

In deciding whether a patient is a suitable person to undergo treatment with medicinal cannabis under a medicinal cannabis approval, the chief executive may have regard to the following:

(c) the patient's criminal history but only to the extent it is relevant to the application;

Comment: matters to be excluded Criminal Law (Rehabilitation of Offenders) Act

In contrast section 5 of the *Criminal Law (Rehabilitation of Offenders) Act 1986* also provides for **matters to be excluded from criminal history.** (1) It is declared that a conviction that is set aside or quashed and a charge **are not** part of the criminal history of any person. (2) A person shall not be required or asked to disclose and, if so required or asked, shall not be obliged to disclose for any purpose a conviction that is not part of the person's criminal history or of the criminal history of another person or a charge made against the person or another person.

Comment: rehabilitation period Criminal Law (Rehabilitation of Offenders) Act

The *Criminal Law (Rehabilitation of Offenders) Act 1986,* section 6 provides for a rehabilitation period

(a) a conviction upon indictment recorded against a person who was not dealt with as a child
  (i) a period of 10 years commencing on the date the conviction is recorded; or
  (ii) (ii) where an order of a court made in relation to the conviction has not been satisfied within that period of 10 years - a period terminating on the date the order is satisfied; whichever period is the later to expire; or

(b) in relation to a conviction recorded against a person where paragraph (a) does not apply (i) a period of 5 years commencing on the date the conviction is recorded; or (ii) where an order of a court made in relation to the conviction has not been satisfied within that period of 5 years - a period terminating on the date the order is satisfied.

Comment: non-disclosure upon expiration of rehabilitation period Criminal Law (Rehabilitation of Offenders) Act

The *Criminal Law (Rehabilitation of Offenders) Act 1986* also provides for non-disclosure of convictions upon expiration of rehabilitation period where the rehabilitation period has expired in relation to a conviction recorded against any person and the conviction has not been revived in respect of the person, neither that person nor any other person, if the person knows that the rehabilitation period has expired, shall disclose the conviction unless (a) being the person against whom the conviction is recorded - the person wishes to disclose the conviction; or (b) the person makes the disclosure under the authority of a permit granted under section 10 in accordance with the conditions (if any) of the permit; or (c) the person makes the disclosure in circumstances that constitute an exception to the operation of section 9(1) or that are expressed by section 9(2) to be a case to which the provisions of section 9(1) do not apply.

Comment: minor cannabis offences to be struck out Drugs Misuse Act

The *Drugs Misuse Act*,[119] and *Police Powers and Responsibilities Act*[120] provide for minor cannabis offences involving the possession of not more than 50 grams of cannabis, or the possession of a thing for inhaling cannabis to be struck out in cases where the person pleads guilty, and is eligible to complete a drug diversion program.

Comment: Supreme and Distinct Court indictable v summary convictions

There are no official figures involving patients in Queensland who use cannabis for medical purposes, and were charged for cannabis offences not involving trafficking or supply, and who have Supreme Court convictions due to the practice of some solicitors requesting the prosecution to elect to indict matters to the Supreme Court for offences that could have been heard summarily in the Magistrates Court.

[119] See 122 A, B and C of the *Drugs Misuse Act*
[120] Section 379 and Schedule 6 to the *Police Powers and Responsibilities Act 2000*

This issue was raised in several cases involving medical use and not drug trafficking, and the Supreme Court Judiciary initiated an inquiry, which resulted in a number of changes being made to the *Drugs Misuse Act.* Now cases involving not more than 15 years imprisonment or allegations of commercial supply may only be heard summarily in the Magistrates Court.

Comment: impact of disclosure of criminal history

Criminal history checks for cultivation licenses are clearly in the public interest, but there is no relevance to the these excessive and discriminatory requirements in this Bill for history checks just for a patient to undergo treatment with cannabis. Individuals with a criminal history already face significant barriers to some employment, and with overseas travel, and to exclude them from being treated with cannabis is particularly unfair as criminal records only provide limited information.

People who have already completed their punishment are effectively being punished again by the State. Access to health services is vital for reintegrating people who have criminal records into society, and preventing reoffending by providing legally prescribed cannabis, benefitting the individual, the community and the economy.

Requirement for criminal history checks for a patient to undergo treatment is unjust and will only delay access. A person reading a criminal history will rarely get the full facts, especially as ALL charges and ALL convictions have to be disclosed.

This will capture patients who have been wrongly charged and convicted, and those charged with a minor offence and that have undergone drug diversion and have had the matter struck off the record. It will also impact where a patient has been charged but the DPP did not proceed with the case, or if a court finds the patient is not guilty and on appeal the conviction has been quashed.

The spent conviction provisions in the Queensland *Criminal Law (Rehabilitation of Offenders) Act 1986* were introduced in recognition that criminal records are not an accurate indicator of current or future behavior.
Stigmatisation and discrimination because of criminal history should not be tolerated as it leads to entrenched disadvantage and exclusion from the community, especially experienced by aborigines who are over-represented in the criminal justice system. Criminal history should not be a barrier to receiving adequate health care.

Response: Other Breaches of Fundamental Legislative Principles (FLP)

The Office of Queensland Parliamentary Counsel (OQPC) whose function it is to advise on the application of fundamental legislative principles to proposed legislation. state that the Bill "does not raise any Fundamental Legislatives Principles (FLP) issues likely to be of any real concern to a parliamentary committee, and most FLP issues raised at the Authority to Prepare stage have been addressed during drafting."

Comment: in breach of legal rights of individuals

Fundamental legal rights have evolved over hundreds of years, and in Australia predominately originate from the English legal system, and have been further developed through the Commonwealth and States legal systems. In Queensland the *Legislative Standards Act* [121] sets out the principles relating to legislation, and upholds fundamental legal rights of the individual, and the institution of Parliament that underlie a parliamentary democracy based on the rule of law. The principles require that legislation has sufficient regard to:

(a) the rights and liberties of patients and carers; and

(b) the institution of Parliament.

[121] *Legislative Standards Act (QLD) 1992*

This submission has not covered the full extent to which fundamental legal rights and liberties of patients and carers are abrogated, however we have found that a serious problem exists with respect to fundamental legislative principles as there are numerous provisions that remove or undermine fundamental rights and liberties of patients and carers; and the institution of Parliament.

- makes rights and liberties dependent on administrative power that is not sufficiently defined or subject to review[122]
- is inconsistent with the principles of natural justice[123]
- allows delegation of administrative power in inappropriate cases and to inappropriate persons[124]
- reverses the onus of proof in criminal proceedings without adequate justification[125]
- fails to provide protection against self-incrimination[126]
- adversely affects rights and liberties, and imposes obligations retrospectively[127]
- confers immunity from proceeding or prosecution without adequate justification[128]
- is ambiguous and not drafted in a sufficiently clear and precise way[129]
- is inconsistent with Commonwealth law as outlined above
- is inconsistent with International law as outlined above

Comment: makes rights dependent on administrative power that is not sufficiently defined

The Bill makes rights and liberties of the patient dependent on administrative powers that are not only excessive, but are not sufficiently defined. The prescriber pathways and the approval processes in the Bill are inconsistent with the TGA pathways in the first place, and it is only through these TGA exemption and approval pathways that a doctor must first obtain approval from, to prescribe and supply cannabis. There are also a number of other powers and provisions that are not sufficiently defined or defined at all, and the legislation has been drafted in an ambiguous and unclear way. This contributes to making the Bill difficult to define some of the powers for example:

- prescriber pathways v TGA pathway are not consistent and uniform
- as the Bill is not uniform it is not sufficiently defined to what extent the Bill gives the chief executive excessive powers over doctor's clinical judgments
- it is not clear what conditions can be imposed
- misleading and not sufficiently defined how the State gives the chief executive excessive power over TGA decisions
- not sufficiently defined how the State is duplicating the TGA approval process
- not sufficiently defined how the Bill only facilitates cannabis only supplied via TGA approvals and exemption pathways
- not sufficiently defined how or why the chief executive has excessive power to interfere with a decision for an approval already granted that is made under a Commonwealth
- no definition for personal circumstances and how these can be considered, and what documents can be requested
- no definition on how social impairment is considered
- time to grant approvals
- not sufficiently clear how criminal history will be considered and part of the definitions for criminal history is in section 5 and the definition for conviction for example is in the Dictionary at end of Bill

Comment: rights and liberties dependent on administrative power not subject to review

The *Therapeutic Goods Act* provides for an application to be made by or on behalf of **any** person or persons whose interests are affected by a decision for an internal review to the Commonwealth Minister for Health, or for external review to the Australian Administrative Appeal Tribunal under the *Australian Administrative Appeal Act 1975* and this includes the patient or a carer in respect to decisions about the SAS applications including decisions that are delayed.

---

[122] *Section 3 (a) of the Legislative Standards Act (QLD) 1992*
[123] *Section 3* (b)
[124] *Section 3* (c)
[125] *Section 3* (d)
[126] *Section 3* (f)
[127] *Section 3* (g)
[128] *Section 3* (h)
[129] *Section 3* (k)

A patient or their carer whose interests are affected by a decision of the chief executive should also have the right to an internal review or an appeal to QCAT, which is a far less costly and complex process than a review to the Supreme Court under the *Judicial Review Act.*

Comment: in breach of natural justice and procedural fairness

The Bill eliminates the right to natural justice and procedural fairness as it fails to afford patients and carers an opportunity for a review of a decision or appeal against a decision, and an opportunity to respond to any adverse decisions made by the chief executives or expert panel during the decision making process, or disclosure and whether any irrelevant material was taken into account, or whether there was a failure to take into account relevant material.

Comment: in breach of privilege against self-incrimination

The Bill fails to give patients and carers the privilege against self-incrimination, in cases where details of their current use of illicit cannabis is disclosed to their doctor, or for example in blood and urine tests, and in cases where the chief executive may also request information about what type and how much cannabis the patient is using from the Australian illicit market, as what is happening now in [redacted] case, as the Director General requested this type of information.

Patients and carers need to be able to have an open and honest relationship with their doctor and should be able to discuss their current use including the forms and types of cannabis they are currently using, the strength and amount, duration, and the benefits that they receive from using it to assist their doctor in helping them making an informed decision if they are seeking to change over to a legal supply of cannabis.

Comment: in breach of delegated administrative powers in an Act v Regulations

This Bill proposes to give the chief executive excessive and discriminatory powers in the act itself as opposed to powers in the regulations. Once an act is passed by Parliament it can be very difficult to change, as it requires an amending Bill to go before both houses of parliament, whereas it is a relatively more straightforward and less costly process for Cabinet to amend and make regulations.

Comment: delegation of administrative power is inappropriate and to inappropriate persons

The linkedin profile of the present Director General, Mike Walsh shows Mr Walsh is not patient focused, and is more concerned with organisational power and control. The Director General is far removed from the health care of patients, and has not practiced in medicine, and has only held senior executive roles in government across economic and social portfolios over the past 17 years, with executive management experience in eHealth, organisational change and design and portfolio, program and project management, and can *craft* innovative strategies. [130]

The chief executive is so far removed from the patient's care, and should not be given licence to use power that comes between the doctor patient relationship, or excessive powers that breach fundamental legal rights, or that are inconsistent with Commonwealth laws and processes. Regard for fundamental legal rights is necessary and must be upheld to ensure the state provides safeguards against injustice; and to prevent unjust outcomes by using unjust drug laws against patients and carers, and bureaucratic health processes that have already been shown to cause harm, and will continue to cause even greater harm, and deny patients access.

Response: Review and Appeal Rights

The *Therapeutic Goods Act* provides for an application to be made by or on behalf of **any** person or persons whose interests are affected by a decision for an internal review to the Commonwealth Minister for Health, or for external review to the Australian Administrative Appeal Tribunal under the *Australian Administrative Appeal Act 1975* and this includes the patient or a carer in respect to decisions about the SAS applications including decisions that are delayed. A patient or their carer whose interests are affected by a decision of the chief

[130] Linkedin profile at https://au.linkedin.com/in/michael-walsh-52a23738

executive should also have the right to an internal review or an appeal to QCAT, which is a far less costly and complex process than a review to the Supreme Court under the *Judicial Review Act.*

Response: Alternative Ways of Achieving Policy Objectives

The explanatory notes to the Bill state there are "***no alternative ways of achieving the policy objectives*** as the use of cannabis needs to be strictly controlled and monitored through legislation in conjunction with the Commonwealth legislation."

We reject the proposition that there are no alternatives to this Bill. There are several alternatives models that the State could also adopt in conjunction with the Commonwealth schemes, and that will uphold fundamental legal rights instead of breach of rights; and that will prevent diversion, and foster a local cannabis industry for Queensland.

State program

- Implement an immediate amnesty similar to our amnesty program
- Continue to use the *Health (Drugs and Poisons) Regulation* rather than the Bill
- Uphold fundamental legal rights
- Stop arresting, and charging patients who grow or possess cannabis out of necessity
- Stop discriminating against patients, and their carers or cannabis
- Do not give excessive discriminatory powers to the chief executive or any other person
- Establish a patient focused State program that works for the patient
- Provisions for doctors recommendation as opposed to prescription via the TGA pathways
- Grant approvals to patients who have a doctors recommendation to grow their own cannabis
- Grant approvals to patients obtaining cannabis from illicit market
- Approvals for not for profits and small Queensland businesses to cultivate, manufacture and supply
- Approvals for dispensaries to supply a range of cannabis products instead of TGA imports
- State application to the Commonwealth for cultivation licenses
- Change the *Drugs Misuse Act* and allow for hemp foods to be made from low THC hemp

State consistency with Commonwealth TGA schemes

- A doctor who already has obtained a TGA approval need only notify Queensland Health that they are prescribing cannabis via the TGA pathways without the need to undego a bureaucratic State process
- Make amendments to ensure that the *Health (Drugs and Poisons) Regulation/* or the Bill is consistent with and complies with the TGAct and the TGA pathways
- Stop imposing unreasonable conditions ie use of TGA approved vaporisers when the TGA do not impose that condition.

Fund ground breaking research trials

- Fund research on patients using their own or locally grown cannabis
- Do not fund research for the benefit of researchers and overseas companies
- Fund a state program rather than access via the TGA pathways

State's Powers: Constitution of Queensland for peace, welfare and good government

The State retains power under its Constitution to implement laws for the "peace, welfare and good government" of Queensland, and also retains the power to reject laws and standards that are not adequate or in the public interest. The State can no longer ignore this important public health issue or the health and welfare of thousands of patients, carers and other family members by leaving them in a situation where they have no choice but to break an unjust law, and in doing so risk criminal prosecution rather than die or suffer needlessly. Patients and carers have a fundament legal right to be afforded protection from criminal charges, and alternative options to access and use an affordable supply of cannabis as shown throughout this submission.

Patient and community demand

Patients, carers, medical practitioners, politicians and community organisations have voiced their support through the media, polls, petitions, advocacy, and being involved in community forums requesting a compassionate access and supply of botanical cannabis for medical use where there is clinical justification on the grounds that the standard treatments have either been trialled for appropriate periods of time without sufficient therapeutic benefit, or the standard treatments are not tolerated by the patient or are contraindicated for the patient without waiting on trials or waiting years for phamaceutical cannabis from the federal model.

Mandate from the community

The Queensland Government and Parliament both have a mandate from the people with almost 30,000 people signing petitions calling for an amnesty, calling for local supply of botanical whole plant cannabis under a State medical cannabis program with approvals for patients to cultivate their own cannabis, and provisions for cultivation and manufacturing approvals for the not for profit sector and small business under State law.

There was no mandate for this Bill, or for the State to keep criminalising patients and carers under the *Drugs Misuse Act*, or to only allow access via the TGA pathways through overly bureaucratic administrative processes, or for patients to have to rely on expensive imports from overseas for years to come. There was no mandate to use taxpayers monies to conduct research trials for overseas companies, or to use synthetics, and there was no mandate to give the chief executive discriminatory and excessive powers to obstruct access and to have power and control over the lives of patients and doctors and to come between the doctor and patient relationship.

State's Powers to make medical cannabis health Regulations

Part 3A of the *Health (Drugs and Poisons) Regulation* contains the current medical cannabis provisions that are being used for patient access to unapproved medicines via the TGA's SAS, authorised prescribers and research trials. As mentioned above, the 8 pages of Regulations are almost identical to the provisions in the proposed Bill, which is almost 143 pages. The Premier and Cabinet could approve more new regulations for a State medical cannabis program with adequate health and safety standards, which would allow greater access than the Bill, and prevent diversion as outlined below.

Continue to use the State's *Health Act* to make more regulations

The State can continue to use existing standards and regulating powers in the *Health Act* for Cabinet to provide a regulatory framework in the *Health (Drugs and Poisons) Regulations* that will provide for a State medical cannabis program as set out in our proposal and below. As Queensland has not adopted the TGA as a law of Queensland, it does not require a new Bill or complex amendments to State health and criminal laws like the other states that have adopted the TGA into state law.

Section 180 Head regulating power

Section 180 (1) of the *Health Act* provides that the Governor in Council (Premier and Cabinet) may make regulations under the Act. Regulations are far more flexible than provisions under an act as they can be made or amended by the Premier and Cabinet rather than the need for an amending Bill to go before Parliament for debate and passed by both houses of Queensland Parliament,

Part 4 - Drugs and other articles

Section 101 to 133 contains provisions that can be used to make regulations about cultivation, manufacturing, packaging and labeling requirements and advertising in relation to cannabis.

Section 132 provides for a number of Regulations that could be used to make more than adequate regulations about cannabis under a state program including the following:

- Section 132(a) can provide for regulations to be made about standards for the composition, strength, weight, quantity, purity, or quality of any cannabis product, or of any ingredient or component part thereof, or for the nature or proportion of any substance which may be mixed with or used in the preparation or preservation thereof, or prohibiting the addition of any article to any cannabis product.

- Section 132(t) can provide for regulations to be made about prescribing cannabis.
- Section 132(u) can provide for regulations to be made about controlling and, as deemed necessary, prohibiting or restricting the ownership, possession, manufacture, cultivation, sale, distribution, supply, use, lending, dispensing, prescribing, or giving away of, or forging and uttering of prescriptions for or any other dealing with cannabis within Queensland or cannabis goods for therapeutic use under and within the meaning of the Therapeutic Goods Act 1989 (Cth).

Part 4 A - Monitoring, Investigation and Enforcement Powers

Sections 134 - 153 contain a raft of provisions for regulations to be made about monitoring, investigation and enforcement including the appointment of inspectors, appointment conditions and limits on power, identity cards, powers of inspections including entry of places, search and seizure, stopping motor vehicles, power to seize, and power to obtain information and warrants.

Amnesty and State register for patients

Patients and carers disclosing to their medical practitioners and Queensland Health details of the activities they are currently undertaking or propose to undertake to use cannabis "out of necessity" for medical purposes do so in good faith. Patients should be able to have an honest relationship with their doctors about their health care and should also be afforded their fundamental legal rights to immunity against arrest and self-incrimination.

Patients and carers who are otherwise honest and law abiding citizens should be protected by the State and afforded their rights, to come under a State medical cannabis program. Patients should be able to register as a matter of urgency under an interim amnesty program. Patients and carers need a guarantee from the Queensland Government that they will not be prosecuted by the State for cultivation, possession, supply or use. Parents need a guarantee that they will not be subjected to the intervention of child services.

Home growing rights and affordable and compassionate supply and access

Patients are already struggling trying to cope with the costs of living with a disability and don't need the further burden and stress of living under the threat of criminal prosecution or trying to source their medicine from criminals. This situation is having a detrimental impact not only on the patient's physical and mental health and well-being but on carers and the family unit as a whole. Patients and carers who grow their own cannabis or obtain if from the black market need an immediate exemption from criminal charge and prosecution, and need access to support services. More details of how this can be implemented are outlined in our submission that was submitted to the State last year.

Patients right to chose strain, form, dose, route of administration, and vaporiser

The form, type, strain, of cannabis and the dose, route of administration, duration of cannabis treatment and the type of device used to vaporise cannabis should be left between the patient in consultation with his or her doctor, not bureaucrats who are so far removed from the patient's health and well being.

The method of consumption has a determining effect on the way the cannabis treatment will affect symptoms, and the methods differ in the dose required for each patient, the amount of time it takes to feel the effects of the treatment and the amount of time the effects last.

The appropriate dose for each patient can needs to be determined by taking into consideration any medications the patient is on, their weight and energy level, symptoms they have and their intensity, and according to the consumption methods and strains that are combined. In some cases it is possible to treat a disease and symptoms with lower cannabis doses than the doses that generate psychotropic side effects.

Patient should be advised to start slow and increase in small amounts only until the optimal dose is reached as you would for other medications. During the first few weeks of treatment the dose can be titrated and increased slowly until the optimal amount is reached. Once an optimal dose is achieved a patient can wait until the symptoms start to increase before taking another dose. Patients should be advised not to take two doses simultaneously to make up for a missed dose, and to be patient as sometimes it can take one to two months of dose adjustments until the optimal dose is achieved and to obtain the full effects and benefits of the treatment.

Every patient's needs and circumstances are different, and different strains also have different effects on patients. Treatment needs to be tailored to meet their individual needs and specific circumstances of the patient, and not dictated by bureaucrats far removed from patient care and treatment, researchers, or pharmaceutical companies that are only interested in making profits, and it certainly should not be dictated by the media, and uninformed and prejudicial views from uneducated and ignorant people who don't understand the use of cannabis for medical purposes.

Access to State laboratories to test cannabis for health and safety reasons

In the interests of the health and safety of patients the State can make available the State Analytical Services[131] to patients and carers for a small fee so that they can test samples of their cannabis, cannabis oils and tinctures for potency, heavy metals, homogeneity, solvents, microbes, mold, pesticides and other contaminants. Patients and carers of children regard this as an important aspect of medical cannabis treatment and care, especially in the case of patients using concentrated cannabis oils to treat life threatening or serious conditions such as cancer and epilepsy, and who may also be receiving treatment with pharmaceutical drugs.

Prevention of diversion and misuse

We acknowledge the State must strike a balance between a patient's right to choose to use botanical cannabis and the State's responsibility to ensure that there are adequate safeguards in place to prevent the diversion of cannabis to the illicit market or access and abuse by minors.

Approvals can be given under strict guidelines, and on the condition that a patient has a doctors recommendation, cannabis treatment plan; and has given their informed consent to his or her doctor assuming full responsibility for the use of the cannabis; and provides an undertaking to Queensland Health by way of a Statutory Declaration that they will adhere to strict guidelines and conditions. Provisions for patients and carers to grow their own cannabis are not intended to undermine the role of law enforcement agencies from targeting drug traffickers. The scope of a state program can be constrained by specific conditions and monitoring, enforcement and investigative powers to ensure compliance.

Overall benefits

The overall net benefits from a State medical cannabis program will provide for patient safety, health and well-being, and will far outweigh any risks for diversion and misuse as these can be mitigated with adequate safeguards and monitoring provisions. A State program can also separate the use of cannabis for medical purposes from the traffickers and will give the Queensland Government the opportunity to receive specific information and feedback about the patients and carers in the community who are using cannabis and what types of support services they require. A number of overall benefits have been identified as follows:

Patients and Carers

- afforded protection from criminal prosecution
- not living under constant fear and threat of criminal prosecution
- parents not living under constant fear and threat of child protections services
- no longer be forced to deal with or be exploited by the black market
- afforded a quality of life and can save lives
- live with dignity and respect as other members of the community
- cannabis can be grown safely and at reasonable standards
- patient can have access to an affordable and guaranteed supply of cannabis
- patients will be able to trial different strains and forms of cannabis
- cannabis and cannabis oils can be tested for safety and quality
- treatment can be tailored to suit the specific and individual needs of the patient
- patients can have an open relationship with their doctor
- patients will be monitored by their doctor
- access to education and support services, and
- carers can tend to the other needs of the patient and family.

[131] Queensland Health, Forensic and Scientific Services, Archerfield at http://www.health.qld.gov.au/qhcss/qhss/fss/chem- analysis.asp.

Health Services

- patients will be properly monitored by health professionals
- reduction of patient hospitalisation
- reduction of overdose and adverse reactions to pharmaceutical drugs
- reduction in the use of allied services such as ambulance
- resources can be used for disability services.

Statistical Information

- age and number of patients using cannabis for medical purposes
- the number of parents or carers supplying cannabis to children
- the conditions and symptoms being treated
- forms, types and amount of cannabis cultivated, produced, supplied, possessed and used
- security and responsible use measures being used by patients and carers
- medical practitioners willing to recommend and monitor cannabis treatment
- number of patients and carers and types of support services required.

Law Enforcement

- police can easily identify individuals who are using cannabis for medical purposes
- police can use resources to target drug traffickers in dangerous drugs
- there will be a reduction in profits for criminals

Economic

- police resources can be used to combat drug trafficking in far more dangerous drugs
- a reduction and savings in prosecution, legal aid and court time and costs
- law enforcement savings can be used for education, housing and look after the elderly and vulnerable
- volunteers can obtain training with not for profits associations and small business
- creation of employment opportunities for Queenslanders
- will give small local industry an opportunity to build from the ground up
- small industry will not be at disadvantage against large corporations or entities in other states
- good for other local industry as small businesses often buy supplies from other local small business
- licence and registration fees can go towards the costs to run the program
- revenue from licenses and fees can go back into the local community for education and housing

Brief Overview of State Program for Patients and Carers

Implementation and Commencement

It is proposed that a state program should be implemented that allows for approvals to be given to patients and carers to undertake permitted activities as set out below.

A patient or carrer could be granted approval on the date the person lodges an application in the approved manner and form, and should receive a notice that the application has been received.

A patient, carer or a nominated carer must register under the state program to carry out the permitted activities that would otherwise be an offence under the *Drugs Misuse Act.*

A person could be granted provisional registration from the date of approval of the application.

Permitted Activities

Approval for a person to undertake permitted activities will allow an eligible person to '***lawfully'*** undertake activities, which would otherwise be an offence under the *Drugs Misuse Act* by providing an exemption from criminal prosecution. Permitted activities could be as follows:

- cultivation of no more than 12 cannabis plants, with no more than 6 in flower at any one time
- possession of no more than 1 months supply of dried cannabis and cannabis resin
- possession of no more than 3 months supply of cannabis oil and tincture
- producing no more than 3 months supply of cannabis resin, oil and tincture
- supplying/administering no more than the dosage of cannabis, cannabis resin, cannabis oil or tincture as set out in the patient's cannabis treatment plan
-

Exceptional circumstances must exist for cultivation of more than 12 plants.

Eligible Person

To be eligible a person must be a Queensland resident and provide evidence of residency in the approved form. The following persons may apply as an eligible person to register:

- Patient
- Carer
- Nominated Carer

Patients

To register a patient must be a Queensland resident, attained the age of 18, and must be using cannabis solely for medical purposes and undertake the following:

- obtain a letter from his or her medical practitioner certifying that he or she has a life threatening or chronic and disabling medical condition, or suffers from chronic and disabling symptoms from a medical condition, and

- prepare an approved cannabis treatment plan and discuss with his or her doctor their cannabis use, and

- provide a written informed consent in the approved form to his or her medical practitioner assuming full responsible for any and all adverse outcomes of his or her treatment with the use of cannabis, and

- provide an undertaking to Queensland Health by way of a Statutory Declaration in the approved form, and

- submit application and supporting documents to Queensland Health in the approved manner and form.

Children

A parent or a primary carer may register a child if the child has a life threatening or chronic and disabling medical condition, suffers from a medical condition or a symptom from a life threatening or chronic and disabling medical condition. Two (2) medical practitioners (one of whom is the child's specialist in the relevant field) must certify that the child has a serious medical condition, and cannabis would be a beneficial treatment, and one of the child's medical practitioners undertakes to oversee the cannabis treatment, and report on its effectiveness to Queensland Health. Examples of serious conditions may include cancer, childhood leukemia and epilepsy.

Carers

A carer is a person nominated by a patient to be a carer or is the legal guardian of the patient.

In the case of a child a carer may only be the parent or legal guardian of the child, and who is a person who has consistently assumed full responsibility for the housing, health, education and safety of the child. Each parent

may register as a carer if they are both involved with the child's cannabis treatment, and must indicate what activities they each undertake. If the child's parents are separated or reside at separate residences, both parents may be eligible to register as carers for the purpose of administering cannabis to the child.

Nominated Carers

A registered patient or primary carer may nominate another person to be a nominated carer solely for the purpose of cultivating or producing cannabis and cannabis oils for the patient. To register as a nominated carer, the person must be a Queensland resident, and must have attained the age of 18 years of age to administer/supply cannabis to a patient.

To register as a nominated carer, for the purpose of cultivating cannabis and or producing cannabis cannabis oils the person must be a Queensland resident, and must have attained the age of 21 years of age (unless exceptional circumstances exist), and must provide an undertaking to Queensland Health in the approved form.

A patient may nominate 3 carers to administer the cannabis.

A carer may nominate two other carers to administer the cannabis.

A patient or carer may only nominate 1 carer to cultivate and produce the cannabis.

A nominated carer may only be a carer for up to 3 patients.

Patient or Carer - Nominated Carer Relationship

Another person nominated by a patient, carer or legal guardian to cultivate and or produce cannabis, cannabis oil for supply to a patient is serving a health need for the patient, and is a person who is merely maintaining a source of cannabis for the patient and does not automatically become the party "who has consistently assumed responsibility for the housing, health, or safety" of that patient.

Specific conditions could be as follows:

- a nominated carer may only receive compensation for actual expenses, including reasonable compensation incurred for actual out-of-pocket expenses incurred relating to the patient-nominated carer relationship and shall not, on the sole basis of that fact, be subjected to prosecution for trafficking or other related offences.

- a nominated carer must keep and maintain receipts for actual expenses incurred.

- a nominated carer must immediately notify the patient, carer and Queensland Health if they are unable to carry out the permitted activities as a nominated carer, or if they have reason to believe they will not be able to carry out the permitted activities as a nominated carer for the full term of the agreement between the parties.

- a nominated carer must immediately notify a patient or carer of any loss, attempted theft or theft of the patient's cannabis, cannabis resin or cannabis oil.

It is the responsibility of the patient or primary carer to ensure that a nominated carer is eligible to register as a nominated carer, and is reliable, responsible and qualified to perform or undertake all of the requisite and necessary activities expected of them including supplying and or administering the cannabis, or cultivating and/or producing cannabis, cannabis resin or oils.

The patient's medical practitioner and Queensland Health are not liable for any non-performance or part performance of the nominated carers contractual responsibilities between a patient or carer and a nominated carer.

The patient's medical practitioner and Queensland Health are not liable for any adverse outcome whatsoever that may arise at any time from the patient/carer - nominated carer relationship.

Conditions of Registration

Patients and carers willing to register must undertake the following:

- obtain a letter from his or her treating medical practitioner, or in the case of a child 2 medical practitioners, one of which must be the child's treating specialist; and
- develop a Cannabis Treatment Plan with his or her medical practitioner; and
- provide written informed consent to his or her medical practitioner assuming full responsibility for all and any adverse outcomes from the use of the cannabis; and
- sign and have witnessed a Statutory Declaration in the approved form

All documents must be completed, signed and witnessed and in the approved form.

Cannabis Treatment Plan

It is proposed that a cannabis treatment plan could provide for a patient or carer to disclose his or her personal and medical details, how the cannabis is to be used, safe and responsible use, security and safety, and the unlawful activities the person is undertaking or proposes to undertake from which registration is required to exempt the person from criminal prosecution under the *Drugs Misuse Act*.

The following is an example of some of the details to be provided:

- name, address, DOB, contact details, and any other relevant details
- name of medical practitioner
- name of specialist medical practitioner in the case of a child
- medical condition/s being treated
- forms and amounts of cannabis proposed to be used
- safe and responsible use measures
- activities carried out or proposed to be carried out
- security and safety measures
- other information for statistical purposes.

Examples of Security and Safety Measures

- cultivation or production of cannabis is to be carried out in a locked room or fenced area away from children and out of public view
- all cannabis and cannabis oils to be kept out of reach of children
- use of child resistant bottles for cannabis oils with label clearly marking patients name, form of cannabis, warning notice and other details if available
- cannabis oils to be kept in a locked safety box in the fridge or a bar fridge used for the patient's medicines
- grow journal to be kept with details of quantity, strain, nutrients used, methods of cultivation of plants, yield
- no neighbourhood nuisance such as proximity, smell or noise
- not to be sold to another person
- any theft, attempted theft to be reported immediately to nearest police station and Queensland Health
- no theft of or tampering with electricity.

Examples of Safe and Responsible Use Measures

- for authorised patient use only
- use of vaporiser
- not to be inhaled in the presence of minors
- any adverse effects or reactions to be reported immediately
- no use of illicit substances

- no driving of a motor vehicle, boat or operating machinery if affected from use
- not to be used in public non smoking areas.
-

Informed Consent and Access to Unapproved Medicines

In accordance with access to unapproved medicines that have not been evaluated for safety and efficacy by the Therapeutic Goods Administration[132] or Queensland Health,[133] a patient or a carer must sign an informed consent form stating that they will be using his or her own cannabis as set out in the cannabis treatment plan and will assume full responsibility for any and all risks associated with the use of the cannabis. Annexure 'B' includes a sample informed consent form that follows standard informed consent guidelines issued by Queensland Health with minor changes to include the use of botanical cannabis.

The patient must acknowledge that they understand the risks, including the risks that are specific to them, and that his or her doctor has explained to them the following:

- their medical condition/s other relevant procedures or treatment options and their associated risks
- their prognosis and the risks of not having the other treatment
- that cannabis is an unapproved medicine and has not been evaluated for safety and efficacy by the Therapeutic Goods Administration or Queensland Health
- the doctor is only responsible for monitoring the medicinal aspect of the cannabis treatment.
- no guarantee was made to them that the cannabis treatment will improve the condition
- if adverse reactions or events happen during the treatment, they will notify the doctor immediately
- they were able to ask questions and raise concerns with the doctor about their condition, the medicinal aspect of the cannabis treatment, its risks and potential benefits and other treatment options available
- will notify the doctor if they change their mind or cease using cannabis
- will not seek to use any cannabis outside the scope of their Cannabis Treatment Plan approval.

Assessing Applications

Applications should generally be assessed in the order they are received at Queensland Health, and on a case-by-case basis and according to the quality and extent of the information provided with the application. However priority should be given to applications for registration of children under the age of 18, terminally ill patients and patients with serious medical conditions. These applications could be assessed and processed as a matter of urgency by an expert panel of doctors, patient advocates and health and law enforcement representatives.

Patients or carers should also be able to provide any other information they consider important or relevant to the application.

Any state program should allow for an appeal process.

---

[132] Australian Government Department of Health and Ageing, 'Access to unapproved therapeutic goods via the Special Access Scheme' November 2009 at p 9.
[133] Queensland Health Publication, 'Guide to Informed Decision Making' at pp. 53-54.

Monitoring and Reporting by Medical Practitioners

Medical practitioners who provide letters for their patients would only be required to keep a copy of the informed consent form and the patient's cannabis treatment plan.

A patient should attend for regular check ups to allow his or her doctor to monitor the progress of the medicinal aspect of the treatment. A medical practitioner could provide a report to the Chief Executive of Health within 3 months of commencement of treatment for patients under the age of 18 and at 12 months for other patients if requested.

Statutory Declaration

A patient or carer and a nominated carer must also provide an undertaking to Queensland Health in the approved form and by way of a Statutory Declaration[134] and will adhere to the conditions of a state program, his or her Cannabis Treatment Plan and any other conditions imposed by Queensland Health (See Annexure 'C').

Other Conditions

A person registered under a state program must adhere to the following guidelines:

- immediately notify Queensland Health if they have been charged with any drug offence under Queensland or Commonwealth legislation
- maintain a journal of activities undertaken and produce his or her documents for presentation to health or law enforcement officials if requested.
- immediately report any loss, attempted theft or theft of cannabis to the nearest police station and Queensland Health. A written copy of the police report is to be provided to Queensland Health within 5 days.
- immediately notify Queensland Health of any change in circumstances
- immediately notify Queensland Health if a patient dies, or is hospitalized or institutionalised or is likely to be hospitalised or institutionalised for any substantial period of time but in any case longer than 4 weeks

Offences

The trafficking, sale or supply of cannabis, cannabis resin or cannabis oils for commercial profit or personal gain is prohibited. If a registered patient, carer or nominated carer does something outside the scope of their approval, the *Drug Misuse Act (QLD)* will apply in full force, and the person dealt with under provisions of that legislation and registration may be cancelled.

Breach of Program

Registration should provide for circumstances where the person has a reasonable excuse for performing the activity. For example a patient or carer may need an unregistered carer who is a family member or close family associate to perform an activity such as administering cannabis to a patient or tending to the cannabis plants due to an emergency situation i.e. illness, hospitalisation or a work commitment.

A minor breach of the program may include that a person has inadequate security due to relocating residence however a person will not be in breach if the person takes all steps and measures to mitigate any harm, loss or theft or risk for diversion, and has in place measures to secure the cannabis within a reasonable time frame. If warranted further conditions could be imposed for breaches that may compromise the integrity of the program.

[134] *Oaths Act 1867* (QLD)

Monitoring, Enforcement and Investigation

A patient, carer or a nominated carer will be required to consent to reasonable inspections or monitoring by Queensland Health or law enforcement officers if requested.

Registration Fee and Analytical Services Charge

It is proposed that a basic annual registration fee could be imposed to cover costs of the program. If available, a patient or carer may elect to pay a charge to be able to access the Queensland State Analytical Services if required.

Review

An annual review may be conducted.

Response: Public Consultation

Just as the Commonwealth has excluded patient advocacy groups, from the consultation and decision making process, the State has also excluded patients and carers from the decision making process even though we we're advised that we would be included.

There was no consultation about how the changes to Regulation 270A of the *Health (Drugs and Poisons) Regulation,* were going to be implemented, and since the changes there has been no or inadequate public notice and awareness about the changes, as there are patients and doctors in the community who are still unaware about the inclusion of *Nabiximols*, and how THC cannabis can be accessed via the TGA pathways now.

There was also no consultation with patients that this Bill was even being prepared, and in fact the release of this Bill, and the committee inquiry has caused confusion in the community, and misled the public into thinking that the Bill needs to be passed before Queensland patients can assess cannabis. The promotion of this Bill has also been misleading, and to make it look like the Government was doing something when in fact it's not, and all this Bill is doing is replacing identical medical cannabis provisions that are already in *Health (Drugs and Poisons) Regulation*, and in the process of replacing the health regulations, the Government is in fact eliminating existing rights, and putting in new provisions that are discriminatory and in breach of fundamental legal rights of the patients and other stakeholders.

This Bill should not be rushed through Parliament to make it look like the State is doing something, or that what is being done is for the benefit of the patients, when in fact it's not, and in its current form, patients will be far worse off under this Bill, than what they are now under the *Health (Drugs and Poisons) Regulation* because of inconsistencies with Commonwealth law and excessive and discriminatory powers in gross breach of fundamental rights and liberties of the patients and other stakeholders.

Response: Consistency with Other Jurisdictions

Last year Sussan Ley also said in the Commonwealth Parliament of Australia that she would make the Special Access Scheme work for the patients. On 24 February this year, Commonwealth Health Minister Sussan Ley said that the Department of Health and the Therapeutic Goods Administration were "well-advanced" in considering downgrading cannabis to a "controlled substance" class, putting it in the same category as morphine, and *"This will in turn reduce any barriers to access, no matter what state a patient lives in."* [135]

Although the Commonwealth has the main responsibility over the import, export, and the manufacture of medicines in Australia, as well as responsibility for access to unapproved medicines via the SAS, authorised prescribers, research trials, and that most states and territories also adopt the TGA into their respective state health laws, as well as the SUSMP.

[135] Jane Lee, Sydney Morning Herald, http://www.smh.com.au/federal-politics/political-news/senate-passes-medicinal-cannabis-legislation-20160224-gn2gjk.html, 24 February 2016.

Comment: No uniformity or consistency with the Commonwealth or the States and Territories

There have never been uniform laws across the states and territories when it comes to patient access to either a TGA registered, or unapproved medicines via the TGA pathways or illicit drugs, as each state and territory has very different health and drug laws.

Therefore there will never be consistency with the Commonwealth, and Queensland or between the other jurisdictions in respect to access to cannabis. Some states are already taking very different approaches to patient access to cannabis, for example Victoria passed laws earlier this year for patient access, and the State has started to grow it's own cannabis, however access is not until 2017, and will start with children with epilepsy, whereas in Queensland the Premier and Cabinet were able to amend the *Health (Drugs and Poisons)* Regulations, however only made provisions for patient access via the TGA pathways, and now have this Bill that proposes to do the same, and there are no provisions for cultivation.

Tasmania is proposing a state access scheme and have stated that they do not need to change laws, and will use existing laws, whereas New South Wales have invested almost $10 million in trials but have now said they have an authorised prescriber approved by the TGA who will prescribe CBD epidiolex that the State has purchased from overseas firm, GW Pharmaceuticals. New South Wales have also issued state cultivation licenses before the federal changes were made, and have also recently been approved by the ODC to hold a State cultivation licence. There are also some states that have not even commenced making changes to allow for patient access, and Western Australia has recently stated they are waiting on the Commonwealth and to see how the New South Wales trials go.

The inconsistencies have a lot to do with politics and the administration in state health departments, and medical boards, and also because the TGA decisions in the SUSMP are only recommendations to the states and territories, and are not law, and each state and territory has always had it's own state health legislation, and has control over the cultivation, manufacture, possession, supply, sale, prescribing, dispensing, and use of licit and illicit drugs and medicines within their own jurisdictions through state health and drug laws.

So even though most states have adopted the TGA as a state law, it has been adopted into some very old legislation that has undergone extensive amendments over the decades, especially around substances that are classified in Schedule 8 and 9. Queensland and Western are the only two states that did not adopt the *Therapeutic Goods Act* and could introduce state programs without the need for new Bills or complex amendments because the TGA has also been integrated into law.

Key Recommendations

The following are some of our key recommendations for the committee's due consideration.

1. Health Drugs and Poisons Regulations v Bill

Continue to use the existing medical cannabis provisions in the *Health Drugs and Poisons Regulations* and ensure that this works in the interests of the before wasting any more public monies on complex legislation that only serves to strip away the fundamental and human rights of the patients and other stakeholders. The Premier and Cabinet to make further regulations pursuant to Section 180 and Part 4 and Part 4A of the *Health Act* as mentioned above, and as outlined in our key recommendations and our proposal that was submitted in May last year, for a state medical cannabis program with provisions for approvals for patients and carers growing their own cannabis or obtaining it from the illicit market, and provisions for not for profit associations and sole traders, and small business that are registered under Queensland laws and operating only within Queensland.

2. Fundamental legal rights and liberties

Ensure that any legislation relating to cannabis has regard for the fundamental legal rights and liberties of all patients, carers, doctors, pharmacists, and not for profits, and small business, and any other stakeholder who may come under the scope of a State medical cannabis program or access via the TGA.

3. Powers in regulations and remove excessive powers

If the Bill should proceed, provisions for approvals or licenses to cultivate, manufacture, possess, sell, supply, prescribe, recommend, dispense, or use cannabis should be made as Regulations to the Bill, as they currently provide for in the *Health Drugs and Poisons Regulation* rather than giving excessive and discriminatory powers to the chief executive in the head Act. This will ensure that the power and flexibility to make amendments to regulations or to be able to make new regulations remains with Cabinet and the people as opposed to an amending Bill needing to go to Parliament if urgent provisions need to be made or if amendments are needed to be made in the future.

4. State program: approvals for patients and carers to grow own cannabis

Include provisions for approvals for patients who have a doctor's recommendation in Queensland by including approvals to be granted to patients and carers who are growing their own cannabis or obtaining it from the illicit market a outlined above. An approval under the health laws allows for the principle of authorisation to be used as the underlying legal concept, as a person granted approval to be authorised to '***lawfully***'[136] undertake certain activities such as cultivation, and possession of cannabis and possession of things used to administer cannabis such as vaporizers, under the health legislation will automatically be exempt from criminal charges and prosecution under the *Drugs Misuse Act*.

5. Doctors recommendations

Include provisions for approvals for doctor's to provide recommendation certifying the patient may benefit from the use of cannabis for medical purposes under a State program in accordance with our submission.

6. Approvals for patients to test their own cannabis

In the interests of the health and safety of patients and to assist them make informed choices, insert provisions that allow for patients to be able to access the State Analytical Services so that they can have their own cannabis tested for potency, heavy metals, homogeneity, solvents, microbes, mold, pesticides and other contaminants.

7. State program: Approvals for Queensland organisations and support with funding

Provide support and funding for Queensland industry and include provisions for approvals for not for profit associations and sole traders, and small business that are registered under Queensland laws and operating only within Queensland and supplying Queensland patients.

8. Low THC hemp for food edibles and raw juicing

There needs to be provisions for farmers, and not for profits to be able to cultivate cannabis to be made into whole plant food products, and hemp seed oil products. All states in the US, Canada, and most of the EU countries have had hemp seed oil products for decades, and more recently whole plant cannabis food products.

9. No unnecessary restrictions or conditions

No restrictions on patient access to treatment, and no unnecessary conditions imposed such as the use of approved vaporisers, or unnecessary and expensive testing and monitoring requirements.

[136] *Drugs Misuse Act 1986* (QLD) - Definitions provides that unlawfully means without "*authorisation, justification or excuse by law.*'

10. Definitions synthetics

Section 5 Definitions – Remove the definition of ***cannabis product*** clause (c) has, or is intended by the manufacturer of the product to have, a pharmacological effect that is substantially similar to the pharmacological effect of a product mentioned in paragraph (a) or (b) as the TGA Schedule 8 entry for Tetrahydrocannabinols extracted from, or derived from the extracts, of cannabis does not include synthetic Tetrahydrocannabinols.

To ensure there is no confusion with the prescription, sale, supply or dispensing of synthetic cannabis products as opposed to botanical cannabis, all provisions for synthetic cannabis products should be listed separately in the *Health (Drugs and Poisons)* for example under Part 3 Regulated controlled drugs, section 77 that provides for the approved drug dronabinol (*delta*-9-tetrahydrocannabinol), which is a synthetic form of THC.

11. Definitions drug dependence

Section 5 Definitions - Remove the discriminatory and ambiguous definition for ***drug dependence*** that reads***:***

> for a person, means repeated administration to the person of a drug resulting in the person (a) demonstrating any of the following over the person's continued use of the drug (i) impaired control; (ii) drug-seeking behaviour that suggests impaired control; (iii) social impairment related to continued use of the drug; (iv) continued use of the drug despite the known harms of the continued use; and (b) suffering, or likely suffering, mental or physical distress or disorder when the administration to the person of the drug ceases.

If there is to be a definition for drug dependent person then insert the long-standing definition that is currently used under Section 5 of the *Health Act 1937* that reads:

> ***drug dependence*** means a person— (a) who, as a result of repeated administration to the person of controlled or restricted drugs or poisons—
> (i) demonstrates impaired control; or
> (ii) exhibits drug-seeking behaviour that suggests impaired control; over the person's continued use of controlled or restricted drugs or poisons; and
> (b) who, when the administration to the person of controlled or restricted drugs or poisons ceases, suffers or is likely to suffer mental or physical distress or disorder.

12. Definitions criminal history

The definitions, terms and exemptions in the *Criminal Law (Rehabilitation of Offenders) Act 1986* should apply.

13. Personal circumstances

Remove provisions for chief executive to enquire about a patient's personal circumstance to undergo treatment.

14. Patient prescriber v TGA Category A

Amend and insert provisions that recognise a separate *single patient prescriber A* in strict accordance with SAS Category A that provides for patients with a terminal illness or a life threatening illness. Provisions should include that doctors only need to notify Queensland Health within 28 days that they are treating a patient with cannabis that has been prescribed and supplied in accordance with the Commonwealth Category A pathway.

15. Patient prescribers v TGA Category B

Approval from the State should be a formality not an inquisition. The doctor should only have to notify Queensland Health that they are treating their patient with cannabis under a SAS approval and provide details of the approval. Approval should only be required if the doctor determines that the patient needs to be monitored more closely or if the State establishes a State program and cannabis is to be supplied upon a doctors recommendation from a local supply source rather than through the TGA pathways, for example supply from a not for profit incorporated associations, or small business.

16. Patient class prescribers v TGA authorised prescribers

Provisions for the patient class prescribers should be in strict accordance with the TGA authorised prescribers. Any medical practitioner can apply to the TGA to be approved to be an authorised prescriber, and should not be restricted by the State to only a small cohort of specialists determined by the chief executive.

17. Criminal history checks approval only for cultivate, manufacture or supply

A criminal history report should only be required if a person is applying for approval or a licence to cultivate, or manufacture or supply cannabis, and in accordance with the exemptions, and spent convictions in the *Criminal Law (Rehabilitation of Offenders) Act 1986* as outlined above.

18. Definitions, clauses 10, 27, 28, 29: criminal history report for patient to undergo treatment

Remove all provisions that relate to criminal history reports just for a patient to undergo treatment with cannabis.

19. Clauses 11, 24, 27, 28, 29: suitability of a patient to undergo treatment

Remove all provisions and reference to the suitability of a patient to undergo treatment with medicinal cannabis. It is entirely inappropriate to allow bureaucrats who are so far removed from the care and responsibility of patient to intervene in the doctor patient relationship in such a discriminatory and irrelevant manner.

20. Clauses 13, 14, 15, and 16: applications

Insert provisions for the State to grant approvals for a person to cultivate, manufacture and supply cannabis in Queensland to patients who are registered under a State program.

21. Clause 21 - expert advisory panel

Remove consideration by expert advisory panel. It is not necessary for either Category A patients or for Category B applications that have already been given TGA approval to be delayed or obstructed by this process. Referral to an expert panel should only be necessary under exceptional circumstances or if the doctor wishes to seeks advice themselves from an expert panel, or if cannabis was available for supply from State approved local suppliers. An expert advisory panel or steering committee should be transparent with patient advocates and members appointed who are experienced with the cultivation, and use of cannabis, and who are capable and willing to facilitate the introduction of a State medical cannabis program that has provisions to cater for all patients.

22. Clause 30: exceptions to criminal history disclosure requirements

Change to read the *Criminal Law (Rehabilitation of Offenders) Act 1986* applies, and this only applies to a person applying for approval to cultivate, manufacture or supply, and not to a patient to undergo treatment.

23. Clause 31: time to decide applications

Persons who have a TGA exemption (Category A), or have been approved by the TGA (Category B) and authorised prescribers should only need to notify Queensland Health that they are treating a patient with cannabis, and if an approval is necessary, response should be on the same day, and no more than 3-5 days for complex applications. Time to make decisions for the not for profit and small business sector for approvals for cultivation and manufacture, supply should be capped at 28 days, and urgent phone approvals need to be available.

24. Legislation to be unambiguous and drafted in a clear and precise way

As mentioned above there is a lot of unambiguity throughout the 143 pages Bill, compared to the 8 pages of almost identical provisions in the *Health (Drugs and Poisons) Regulations.* It is too complex for the average person to follow or understand, and hides a number of breaches of fundamental legal rights.

Definitions and terms need to be very clear, and in accordance with the TGAct, and other key recommendations. This Bill should clearly define where relevant, that those provisions are only for TGA approved cannabis via TGA pathways. The state prescribers pathways needs to be clearly defined in accordance with the TGA pathway provisions in TGA law, and not with so many unjust restrictions and barriers to access.

It is very lengthy, with a lot of sub headings and sub sections, which are unnecessary, and there are provisions split over several sections, throughout the Bill. Definitions are also split between the definitions section at the beginning of the Bill, throughout the Bill, and in the back in the dictionary. The TGA law and processes are convoluted enough without the State making its laws and processes even more complex and difficult and impossible to read or navigate.

25. Uniformity and consistency with TGA and other jurisdictions

Provisions needs to be uniform and consistent with the TGA, and with medical cannabis provisions in the other states, but only if they are more advanced or have regard to fundamental rights. There also needs to be reciprocal rights in Queensland law for patients and carers travelling to the state from interstate and overseas.

26. Review rights and appeals

Review and appeal rights need to be included for patients and carers whose interests are adversely affected by a decision of the chief executive.

27. Expert panel with patient advocates

Include provisions for patient advocates to be appointed to any expert panel or working groups to ensure that fundamental rights are upheld, and so that patients have representation, and are part of the decision making process.

28. Separate medical cannabis office and working groups

There needs to be a separate office and working group outside of the Health Department with representation from health and other government departments such as agriculture, police, treasury, patient groups, and industry to oversee legislation and provisions for a state program that will meet the needs of all patients and the community.

29. Public Consultation

There needs to be wider public consultation and community forums. Patient advocacy groups must be included in the decision making process to ensure legal rights are upheld, and to prevent discrimination, and exclusion and any adverse outcomes for the patient. Adequate notice needs to be given to all stakeholders, so that the public has time to participate in the process and respond to any adverse material or decisions.

30. Promotion in the public

There needs to be more ongoing promotion in the media, government websites, and through social media with more **factual** information and media statements, and not in a way that misleads the public or causes any confusion. Adequate notice needs to be given to all stakeholders, so that the public has time to participate and respond.

31. Consultation with the Commonwealth and the other states and territories

There needs to be more consultation with the TGA and ODC to ensure that access through the State laws and processes are not in conflict with the TGA pathways, and to ensure that there is not a duplication at a state level of the TGA process. The state needs to make access achievable, and so that access to cannabis from the TGA pathways is not blocked at a state level, and can be completed in 1 – 2 days, not months, years or not at all.

There also needs to be more consultation with the other states to ensure uniformity between the jurisdictions, and reciprocal rights need to be put in place for patents traveling to and from interstate or overseas.

32. Online applications

Insert provisions for online services rather than POST.

33. Funding and training for doctors

The Queensland Government needs to make a commitment to provide funding for training of doctors, and to train their own doctors and pharmacists in the public system, for the patients who are unable to afford private doctors.

Funding also needs to be allocated to establish a State medical cannabis program with funding and grants for patient support groups, not for profits, and for small business to foster a local industry in Queensland.

There also needs to be funding for online services for doctors and pharmacists, and adequate staff that are well trained to ensure that applications are processed on the same day, or within an acceptable time frame but no more than 5 days.

There also needs to be funding to assist patients on low incomes to obtain cannabis from overseas in the interim or from local suppliers when available.

Conclusion

We do not support this Bill. The Bill is unnecessary, discriminates against patients who use cannabis for medical purposes, and is inconsistent with existing Commonwealth and State laws. It is also in breach of the fundamental legal rights and liberties of patients, carers and other stakeholders in the community.

We are strongly opposed to the State giving discriminatory and excessive powers to bureaucrats and placing barriers between the doctor and patient relationship and the supply of cannabis to patients who can benefit from using it, and we are equally opposed to any forms of discrimination against a patient based on their medical condition, or their personal circumstances including their socio-economic circumstances, history of drug dependency, or past criminal history.

The key justification for upholding fundamental legal rights in this case is to constrain the State and the Executive from using excessive, discriminatory and unlawful powers against patients who use cannabis for medical purposes, as well as their doctors, pharmacists, and other persons who are involved in the care of the patient. Regard for fundamental legal rights is necessary and must be upheld in this instance to ensure that the state provides safeguards against any injustices that have been raised throughout our submission and this inquiry.

It is necessary to prevent the State from producing unjust outcomes from:

- the use of the *Drugs Misuse Act, and*
- through unjust bureaucratic health processes in the Public Health (Medicinal Cannabis) Bill 2016 *that replace identical medical cannabis provisions in the Health (Drugs and Poisons Regulations) !996*

The States health and criminal laws, and administrative processes have already been shown to cause significant harm to patients and carers, and will continue to cause even greater harm, by denying lawful access and a lawful supply of cannabis for the overwhelming majority of patients who are currently using cannabis, or who are considering using it.

[redacted] approvals show that both the Commonwealth and the State have recognised the benefits of cannabis for treatment of these conditions, however there is a lack of political will to effect real and meaningful change.

The problem is access and no local supply because of conflicting powers between the Commonwealth and the State, in the respective health departments.

The Commonwealth and State have both failed patients and carers and need to do more to provide alternative options for supply and access that will meet the individual needs and circumstances of all patients rather than only providing access and supply via the complex and convoluted TGA schemes and limited places in research trials.

It is unjust to continue to use the *Drugs Misuse Act* against patients and carers and force them into the illicit market, and to not provide an amnesty, and provisions for patients to grow their own cannabis.

We thank the Committee for the opportunity to present our submission, and look forward to the committee having due regard to the issues that we have raised in our submission, and to our alternative proposals for a state program and other measures, and the key recommendations that we have outlined above.

Several of our members who have extensive experience with and decades of using cannabis for medical purposes are also available to give evidence to the committee in person.