

Research Director, Health, Communities, Disability Services and
Domestic and Family Violence Prevention

Parliament House,
George Street,
Brisbane
Qld 4000.

18th July 2016

Attention:

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

Ms Leanne Linard MP, Member for Nudgee, Chair
Mr Mark McArdle MP, Member for Caloundra, Deputy Chair
Mrs Tarnya Smith MP, Member for Mount Ommaney
Mr Sid Cramp MP, Member for Gaven
Mr Aaron Harper MP, Member for Thuringowa
Mr Joe Kelly MP, Member for Greenslopes

Dear Secretary,

Re: Submission – Public Health (Medicinal Cannabis) Bill 2016

I am writing in response to the draft bill – Medicinal Cannabis Bill 2016.

Background:

I am the mother and carer of [REDACTED], a [REDACTED] patient with a Brain Tumor and associated epilepsy.

[REDACTED] is the first person in Australia and Queensland to be approved by the TGA for schedule 9 Botanical Medical Cannabis.

The TGA approval is for Cannabis oil in a specific formulation including THC/CBD and other cannabinoids for treatment of his brain tumor, epilepsy, pain, nausea/lack of appetite and he is approved for Indica bud for vaporization for pain, nausea/appetite and epilepsy.

[REDACTED] brain tumor causes intractable epilepsy which has not been able to be effectively controlled with anti - epileptic pharmaceutical medication and he has experienced a number of negative side effects from the pharmaceutical anti - epileptic medications.

[REDACTED] and I spent most of 2014 in the USA for his medical treatment. After approximately 1 month in the USA obtaining medical treatment [REDACTED] was recommended cannabis. He responded favourably to this treatment which controlled his epilepsy effectively. It also reduced his nausea, relieved his chronic headaches and assisted him with appetite stimulation.

The cannabis treatment has helped relieve debilitating symptoms so he could have a better quality of life. There has also been shrinkage and stability of his brain tumor when he is consistently on medical cannabis treatment. The treatment has also reduced the substantial Oedema (swelling around the tumor).

Since diagnosis with a brain tumor in 2013 [REDACTED] has lost a significant amount of weight. The medical cannabis is the only thing that helps to stimulate his appetite and enables him to eat most days. It has also helped him feel happier in general and able to cope better with his illness.

Unfortunately when [REDACTED] would return to Australia and have weeks without cannabis oil we witnessed growth of the tumor on the following scans, along with a return to increased seizures, headaches and nausea and difficulty with appetite. [REDACTED] has suffered up to a maximum of 20 seizures per day (witnessed during awake hours) when he was not on cannabis oil.

Cannabis has provided [REDACTED] quality of life which wasn't available to him prior to the commencement of the treatment.

[REDACTED] can now begin planning for a career and a life in the future with some level of independence instead of being reliant on a carer 24/7 because of seizures.

Consider the impacts from this Bill on patients and carers

The bureaucratic processes created by this bill caused delay, hardship and threat to my sons life and will continue to negatively impact other patients, carers' and their families if it is passed in its current format.

Whilst I understand that many politicians would consider that passing a bill for medical cannabis in Queensland may seem like a very positive, ethical and progressive thing to do I urge you to consider the true impact of how the conditions and processes as outlined in the bill will truly impact on patients, carers and families who are affected. Please try to understand this issue from the patient's perspective before making decisions in relation to this bill.

Please consider my comments carefully; I hope through explaining some of the challenges that we have faced I can highlight some of the issues, difficulties and hardship that this bill will potentially create for society and patients across this state from all demographics.

Processes outlined in this bill have directly impacted my son and our family:

Unfortunately many of the conditions from this bill were prematurely applied in the case of [REDACTED] ([REDACTED]) application. These conditions and processes were applied even well before this bill had been debated in parliament or even made lawful.

The application for [REDACTED] had already been sent by his doctor to the Therapeutic Goods Administration (TGA) in March last year. The TGA had already undertaken an extensive assessment of [REDACTED] application and reviewed the medical cannabis products being applied for.

Shortly after the TGA formal approval was granted to [REDACTED] doctor he notified Queensland Health of the approval. At this stage [REDACTED] doctor was advised by Queensland Health that a separate and new

application process (as outlined in the proposed Public Health Medical Cannabis Bill) was being imposed. This new separate application process was **in addition** to the TGA special access scheme application and approval. This process we were told would apply to [REDACTED] application and all future patients from Queensland who would receive approvals by the TGA for schedule 9 Medical Cannabis.

This state application process involved a complete duplication of the assessment process which had already been undertaken by the TGA at a federal level.

Below I have provided an overview of the duplication of processes between the TGA Assessment VS Qld Health Assessment processes to illustrate this duplication:

TGA – Special Access Scheme application assessment process	Qld Health Application and assessment process
Assessment of the patients diagnosis and suitability for medical cannabis treatment for specified condition	Assessment of the patients diagnosis and suitability for medical cannabis treatment for specified condition
Assessment of research material and supporting documentation regarding treatment for specific condition	Assessment of research material and supporting documentation regarding treatment for specific condition
Review of certificate of analysis and product data	Review of certificate of analysis and product data
Review of dosing recommendations	Review of dosing recommendations
Review of certifications, licencing requirements and manufacturing practices of the manufacturer/supplier of medical cannabis	Review of certifications, licencing requirements and manufacturing practices of the manufacturer/supplier of medical cannabis

It is shameful to think that state bureaucrats would develop such a convoluted and duplicative system. This process impacts directly on the health and wellbeing of patients and causes significant delays in access to critical medicine.

After months of waiting and literally hundreds of seizures later we were still no closer to [REDACTED] receiving the medical cannabis that had been specifically recommended for him in the USA.

At one stage after suffering a seizure and continual vomiting post seizure the hospital thought that [REDACTED] may have had a brain hemorrhage and rushed him urgently for a CT scan, this was an incredibly stressful experience for us, especially knowing that all that was delaying our sons access to medical cannabis in the recommended ratios was unnecessary bureaucratic processes.

Fortunately it was confirmed that [REDACTED] had not suffered a hemorrhage but our frustration levels were boiling over by this point and I was not prepared for my son's life to be in jeopardy just because of another "process". By this stage [REDACTED] second medical cannabis application was sitting at the Queensland State Health department. It was at this point that we decided to protest outside Queensland Health and then parliament house and commence a Change.org petition.

Further Duplication – more medical appointments

The TGA special access scheme and state process causes unnecessary stress and hardship on patients. One example is that Queensland patients would have to endure even more appointments with doctors and specialists to complete the state application process. Patients would have already had to previously consult with their doctors and specialists in order to complete the TGA process. Patients and carers are already currently overburdened with all of the medical appointments, care responsibilities and expense without more appointments being imposed.

In Queensland this proposed bureaucratic system of “processes” are a waste of taxpayers’ money and a drain on administrative and health resources that could be put to better use.

Disproportionate response

This process denies people the basic human right of access to medicine because the medicine is not being facilitated in a timely manner. The United Nations Human Rights Office of the High Commissioner website states “Nevertheless, for millions of people around the world, the full enjoyment of the right to health remains an illusive goal, including due to the obstacles to access to medicines of good quality, affordable and in a **timely** fashion”[emphasis added].¹

Consider this; In Queensland it only takes 1 day for a patient to be prescribed and dispensed a strong Opiate based medicine and yet according to the World Health Organisation statistics, there are 69,000 deaths per annum from Opiate overdoses (Organisation)² yet our state government is proposing that for cannabis (a medicine which one cannot overdose from) a more complex and convoluted process is created.

¹ <http://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx>

²² World Health organization – Management of Substance Abuse. Information sheet on opioid overdose
http://www.who.int/substance_abuse/information-sheet/en/

Proposed Application Timeframe:

Based on first - hand experience and the timelines outlined within the proposed Medicinal Cannabis Bill I would like to outline in the table below a realistic timeline of how long it may take for each stage of the process for a TGA Special Access Scheme (SAS) application. This illustrates the process from point of application to the medicine being ready to be dispensed at the pharmacy.

Please bear in mind that this is also illustrating the process if the medicine was coming from an overseas jurisdiction:

Activity or process	Estimated timeframe
TGA Special Access Scheme application and approval	14 days – 3 months
Qld State Application for Medical Cannabis (cannot be submitted until TGA approval is in place)	Up to 3 months
Application to Supply and Dispense Medical Cannabis (for pharmacist etc.)	1 – 2 months
Office of Drug Control – import permit issue (Cannot issue till both state approval and pharmacy approval is in place)	1 – 3 days
Import permit copy (original for exporter) to be sent to overseas supplier	1 week
Processing time of overseas authorities to issue export permit	6 – 8 weeks (this may vary depending on the jurisdiction and hopefully will become more efficient over time)
Shipping time for medical cannabis to be shipped to Australia, clear customs and be available at pharmacy for patient dispensing	1 – 2 weeks
TOTAL ESTIMATED TIME FROM APPLICATION TO DISPENSING UNDER TGA SPECIAL ACCESS SCHEME MODEL IN QLD WHEN MEDICAL CANNABIS IS COMING FROM OVERSEAS SUPPLIER	6 ½ - 10 ½ months approximately

██████ actual application timeframe:

In comparison I will also detail below a timeline of how long each of these processes took for ██████ application.

Please note that ██████ application was complicated by a few challenges, there were also delays because his application was the first of its kind for schedule 9 botanical cannabis in Australia. We also had to change suppliers and supply countries:

TGA Application Special Access Scheme timeline	
Submission to TGA by doctor	27 th March 2015
Request for exemption requested Queensland Justice (provided copy of TGA application)	27 th March 2015
Initial email sent by TGA to treating doctor on 2 nd April 2015	Sent to incorrect email address – not received by doctor
TGA requested further information	July 2015
Doctor supplied further information	July 2015
Met with Hon. Cameron Dick re: ██████ TGA Special Access Scheme application still outstanding and Medical Cannabis Advisory Group requests for changes to Health Drugs and Poisons Regulation	28 th July 2015
Approval decision provided to carer from TGA via email	28 th October 2015
Phone conference with TGA Doctors and carer	4 th November 2015
Email from carer to TGA requiring confirmation in writing of information discussed on phone conference	8 th November 2015
Letter sent from doctor to TGA with supporting documentation	Mid to late November 2015
Email follow up with the TGA by doctor	2nd December 2015
Response from TGA Doctor confirming that approval letter had been drafted however it would not be likely that products could be imported via the special access scheme from USA (another legal jurisdiction/country would need to be considered to source medical cannabis from)	3 rd December 2015

New supplier of Medical Cannabis being sourced from alternative country	
Doctor provided an amended TGA – SAS application for new products from Canadian supplier	Approx. 15 th February 2016
TGA approval for new products from Canadian supplier	29 th February 2016
TOTAL TIME TAKEN FROM APPLICATION TO APPROVAL FOR ██████████	339 days

I have provided an overview of the timeline involved in the state process for ██████████ application specifically. As stated previously the state health department wished to completely duplicate the entire process that had already been completed by the TGA over an 11 month period:

State Medical Cannabis Application process for ██████████

Copy of TGA federal approval sent to state Director General Health – ██████████	2 nd March 2016
Doctor sent a new Medical Cannabis Application form (Qld) to complete for patient	8 th March 2016
Pharmacist emailed copy of approvals for import permit to Office of Drug Control	3 rd March 2016
Pharmacist emailed copy of amended import application to office of drug control	11 th March 2016
Doctor sent state application for Medical Cannabis through to Qld Health (196 pages)	18 th March 2016
Approval granted by Qld Health for Medical Cannabis Oil	4 th May 2016
Approval granted by Qld Health for Indica Cannabis Bud for vaporisation	18 th May 2016
Approval granted to pharmacist for State Application to Supply and Dispense Medical Cannabis	8 th June 2016
Pharmacist received import licences from Office of Drug Control in the post	17 th June 2016

AS AT 18 th July 2016 [REDACTED] STILL HAS NO TGA APPROVED MEDICINE DUE TO UNECESSARY DELAYS AND PROCESSES!	138 days and counting still
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Personal Cost/hardship

Every time [REDACTED] and I would return from the USA we would hope that the laws may have changed in Australia or even in NSW so that we could simply move across the border and he would be able to obtain legal medical cannabis treatment but this was not an option.

When we returned from the USA we had already exhausted finances and options of obtaining legal treatment for [REDACTED]. We were not prepared to watch our son deteriorate further without access to treatment.

As a family unit we were struggling because we had been separated across two continents (my husband and younger son in Australia and [REDACTED] and I alone in the USA). This was a sacrifice we had made in order for [REDACTED] to get the medical treatment which was working for him. This was a difficult position to be in.

In Australia we could sense no urgency from the government in changing the laws. We were tired of the constant rhetoric by the government about doing something. There was plenty of talk and little action and by this stage we could know that even the announced trials (which were supposed to have started months ago now), would be unsuitable for our son.

We knew that the proposed trials for Qld and NSW would not include medical cannabis in the correct cannabinoid ratios or forms that had been recommended and proven for [REDACTED] to control his epilepsy, fight his tumor and manage his symptoms.

There was definitely a failure by the government to acknowledge the urgency of this matter for our son and all of the other patients suffering.

I notified the state justice and health departments in writing that [REDACTED] doctor would be applying for access to Medical Cannabis treatment to be imported from overseas for him through the TGA Special Access Scheme.

I told Qld Justice that we were not prepared to watch [REDACTED] tumor grow again without treatment. We were not prepared to watch his seizures, pain and nausea return and we notified justice that we would be sourcing cannabis locally until his TGA approval was in place and the approved medicine was available from overseas.

This was a very difficult time for our entire family. No parent should have to deal with the added burden or stress of breaking any law to just simply protect the life of their child, but [REDACTED] health and future was at stake here. We had already witness tumor growth, seizures and debilitating symptoms return when he had been off treatment between trips to the USA. I was not about to watch that happen again.

As a mother my desire was to do my absolute best to be upfront and honest with the justice and health departments as well as doing everything I needed to protect [REDACTED] health, life and future.

I knew at that time that I would never forgive myself if I didn't make that decision to fight for [REDACTED] life.

I faced the reality that politicians have more responsibilities on their hands than just the life of [REDACTED], to them he was just a number. I knew I was the only one who would truly fight for him. I was not prepared to wait for the government's timeline because if I took that risk that it may be too late.

Every day in [REDACTED] life mattered to us. Every day that passed without treatment would be another day I was at risk of losing him. We had already lost 2 years of his life and education prior to diagnosis with this debilitating illness; I could not bear to think of more time lost. At the point of the doctor putting the application in to the government [REDACTED] had already been suffering for almost 4 years.

Every day I would have to wait for his access to medical cannabis was another day where [REDACTED] tumor could be growing, another day that he could suffer up to 20 seizures in one day, another day where [REDACTED] would struggle to eat and lose weight because he had no appetite, another day where he would be suffering debilitating nausea and headaches. It was another day where he would miss vital education because his sickness was impacting on his quality of life and future opportunities. It was another day where our family life was turned upside down.

During the year whilst we waited for the TGA approval [REDACTED] suffered multiple seizures where he aspirated. The saliva he breathed into his lungs during these seizures ended up turning to pneumonia and then [REDACTED] lost even more weight as a result of that illness. As a family we were exhausted, so exhausted that we started even sleeping through his night time seizures.

As time progressed and delays occurred with the processes at a Federal and State level we commenced some legal processes and we also had to start petitioning and protesting. This was a very stressful time for me as [REDACTED] and carer and also for us as an entire family. I had surgery and was protesting within a week and a half of coming out of hospital.

I faced the reality that we may have to take the government to court and I realized that we could lose everything. It was an agonizing and stressful time, stress that we didn't need as a family but I continued to feel that this entire situation was unjust and wrong and was fully prepared to take this matter to court.

I did not want to see any patient, carer or family have to endure this kind of ordeal just to simply get medical treatment.

Timeline of events and Legal processes/action

March 2015:

- Application for TGA – Special Access Scheme submitted by doctor to Therapeutic Goods Administration.
- Request for medical exemption submitted to Queensland Justice, provided Queensland Justice with a copy of the TGA – Special Access Scheme paperwork.

- Provided Qld Health a copy of the application which had been sent to Queensland Justice requesting a medical exemption and also provided a copy of the TGA – Special Access Scheme paperwork.

September 2015:

- Commenced legal process with Qld Justice. Issued a Statement of Reason giving the Attorney General Justice 30 days to respond before this matter would go to Supreme Court as we had not received any correspondence from Justice after 5 months.

October 2015:

- Qld Justice requested extension of time, reassured us that they could not change health regulations for one patient they would need to change health regulations for all patients. Justice told us that cabinet was preparing to discuss the change to health regulation in Queensland.

November 2015:

- After numerous delays with TGA and no decision forthcoming after many months we commenced legal process with Sussan Ley Federal Health Minister – s60 Review of decision

8th March 2016

- After initial questioning of Qld health about why they would seek to completely duplicate the process that [REDACTED] application had already been through at the TGA, Qld Health confirmed that the application would be “going through the process as outlined in the newly proposed Medical Cannabis Bill” we issued a Take Notice letter to the Director General Health – [REDACTED] [REDACTED] threatening court action.

TOTAL TIME TAKEN AT THIS POINT- JUST UNDER 1 YEAR

Lobbying and petitioning

I participated in lobbying the Qld government with the Medical Cannabis Advisory Group and the group submitted a proposal to Qld Health in May 2015 proposing a change to the Health Drugs and Poisons Regulation and interim measures such as an Amnesty for patients and caregivers.

As a group we undertook 4 state petitions between March and December 2015 gaining over 9, 314 signatures in total, with 6,665 of those being paper petition signatures.

[REDACTED] application to the TGA was submitted in March 2015. After a 9 month process of working through the TGA special access scheme process and lobbying government with the Medical Cannabis Advisory Group for regulatory change to The Health Drugs and Poisons Regulation (regulation 270), Queensland government finally made a change to this regulation in December 2015.

We also conducted a Change.org petition in May 2016. This was in response to the duplicative processes being undertaken by Qld Health through the proposed Medical Cannabis Bill. We were also protesting because the processes within this bill were being applied to [REDACTED] application even though the Bill had not even been debated or passed.

We were petitioning against this proposed bill and the process outlined within. We knew it would create further unnecessary delays and risks for all patients who needed access to this medicine in a timely manner and was breaching patients' rights by not even allowing an appeal option.

Protests:

We also undertook two protests and one March as part of the Medical Cannabis Advisory Group Qld on Tuesday 19th April and Wednesday 20th April 2016 outside Qld Health and Parliament House.

Impact of the proposed Medical Cannabis Bill - 2016 on patients, carers and families

Most patients and carers are already under an enormous amount of stress physically, financially, emotionally and mentally without the added stress and pressure of having to work through a convoluted and repetitive application process that is draining on the patient and their carer/family.

By the time a patient gets to the point of a doctor applying for medical cannabis for them it's likely that they would already be suffering terribly with a debilitating or life threatening illness or may have exhausted treatment options or suffered adverse effects from previously recommended treatment.

Patients who are terminally ill may only have been given days, weeks or a few valuable months left. They do not want to be left waiting extended periods of time for medicine that comes too late to relieve them of their suffering. They do not want to waste time extending unnecessary energy on a process that could take weeks or months to complete before they have access to medicine. All patients who are suffering deserve access to medicine in an urgent manner.

Patients are often already exhausted and may find it difficult to leave the house and attend too many medical appointments.

This process at a federal and state level may require as many as 2 – 4 appointments with specialists/doctors. In [REDACTED] case I also estimate that the private medical and specialist appointments, transport and parking to attend specialist appointments in Queensland and interstate would have cost over \$2400 during the TGA and state applications.

I would describe this process as exhausting and inhumane on patients.

I would often question the intention of the government and wonder if they may be purposely make this process as difficult as possible for the patients in order to deter them from applying.

[REDACTED]

[REDACTED]

[REDACTED]

It was clear that this process would also cause unnecessary hardship which may inadvertently place patients and carers in a position where it may appear to be less stressful for them to turn to the illicit market instead of tackle such a convoluted and drawn out process.

If that is the case it is a very frustrating and insensitive situation.

I have to be honest and say that many patients who would consider this process would express concern surrounding their inability to undertake such a process because of their energy or stress levels or their financial situation.

Carers of terminally ill patients would sadly also express their concern that their loved one would pass before they would even have the opportunity to be able to be approved for the medical cannabis.

No Appeal Rights for Patients

It is unjust that there is no appeal rights proposed within this proposed Medical Cannabis Bill, this is another issue that needs to be rectified.

Inclusion of Synthetics in Bill

I note that there is an inclusion of synthetic cannabinoids in the Bill and I would like to express my concern surrounding Synthetic Cannabinoid treatments.

Many would not be aware of some recent trials in France of a synthetic Cannabinoid. The phase 1 trial aimed to evaluate the "safety, tolerance and pharmaceutical properties of the molecule" in healthy volunteers.

The French health ministry reported that a serious accident had occurred in relation to a synthetic medicine. The French health minister confirmed that the treatment acted on the body's endocannabinoid system.

As a result of this treatment one of the patients had been left brain dead and 5 were hospitalized. Pierre-Gilles Edan, head of the neurology department at Rennes hospital, told reporters that three of the patients could suffer "irreversible" disability as a result of brain injuries.⁴

My concern as a parent, is that the plant in its natural state has been proven over many years and that clearly the main purpose of a pharmaceutical company to develop a synthetic cannabinoid treatment would be so that they could patent the product and then potentially profit from it.

If these were healthy individuals that were participating in a trial of synthetic cannabinoids its very concerning to consider that synthetics may even be considered for trials on sick patients (including children) in Queensland or Australia or that synthetics would be considered as an alternative to the natural substances.

Medical Cannabis providing positive options for patients:

Medical Cannabis has provided positive outcomes for my son, including results with his brain tumor and other symptoms and for this we are very grateful.

⁴ <http://www.reuters.com/article/us-france-health-test-idUSKCN0UT131>

I often feel that many governments and medical professionals have not understood the full potential of cannabis as a medicine and also nutritionally. In Australia it seems that politicians are only touching the tip of the iceberg with their understanding of the potential scope of treatment with this plant.

Hopefully at some point in the not too distant future cannabinoids will also be used as a preventative and in nutrition to address the “endocannabinoid deficiency” that a number of scientists would say is the root cause of a number of chronic health conditions globally.⁵⁶

In Queensland there is a critical demand for patients requiring cannabinoid medicine for serious medical conditions. Recently I heard Federal Government representatives referring to the number of potential patients who may be requiring Medical Cannabis in Australia. They quoted projected figures of 20,000 – 100,000 patients nationally. I feel that this figure is grossly underestimating the true patient demand and I am talking about legitimate medical need, very separate to any labelled “recreational demand”.

The reality is that Cannabis as a medicine is already being utilised overseas successfully for far broader patient conditions than is being considered for in Australia.

Healthcare Cost Savings for the State

Queensland should consider the substantial cost benefits to health budgets.

A study released by the University of Georgia (USA) this month⁷ has highlighted the following benefits to bottom line of Medicare's prescription drug benefit program in states that have legalized its use for medicinal purposes,:

“The savings, due to lower prescription drug use, were estimated to be \$165.2 million in 2013, a year when 17 states and the District of Columbia had implemented medical marijuana laws. The results suggest that if all states had implemented medical marijuana the overall savings to Medicare would have been around \$468 million.

Compared to Medicare Part D's 2013 budget of \$103 billion, those savings would have been 0.5 percent. But it's enough of a difference to show that, in states where it's legal, some people are turning to the drug as an alternative to prescription medications for ailments that range from pain to sleep disorders.

Because medical marijuana is such a hot-button issue, explained study co-author W. David Bradford, who is the Busbee Chair in Public Policy in the UGA School of Public and International Affairs, their findings can give policymakers and others another tool to evaluate the pros and cons of medical marijuana legalization.

"The results suggest people are really using marijuana as medicine and not just using it for recreational purposes," said the study's lead author Ashley Bradford, who completed her bachelor's degree in sociology in May and will start her master's degree in public administration at UGA this fall.”

Government should also consider savings to hospital budgets.

⁵ <http://www.prohealth.com/library/showarticle.cfm?libid=10563>

⁶ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2241751/>

⁷ <http://news.uga.edu/releases/article/medical-marijuana-lowers-prescription-drug-use-0716/>

In ██████ case I estimate that 3 emergency visits per week which would be approximately the number of emergency visits he would require without any medical cannabis would cost the government at least \$224,640 annually. However during the year he was on medical cannabis in the USA consistently he did not require any emergency hospital visits.

Brain Cancer and Brain Tumours

As a mother of a brain tumor patient it's frustrating to think that there has been so many studies done over the years showing positive impacts from Cannabis in treatment of Brain Cancer specifically and that there has been a lack of advancement in this area.

In the USA ██████ treatment eventually was based around the ratios outlined in research conducted at the California Pacific Medical Center Research Institute which had been conducted on highly aggressive brain cancer Glioblastoma⁸.

"Cannabidiol Enhances the Inhibitory Effects of $\Delta 9$ -Tetrahydrocannabinol on Human Glioblastoma"

██████ response to treatment was quite promising and we hope that this treatment continues to provide him with positive outcomes.

I have provided some MRI images for your reference to highlight the impact of the treatment on his tumor and also the improvement of the Oedema surrounding the tumor.

You will note on these images the noticeable improvement after cannabinoid therapy and then worsening of the tumor when he was off the cannabis treatment and then improvement when he was on cannabis treatment again.

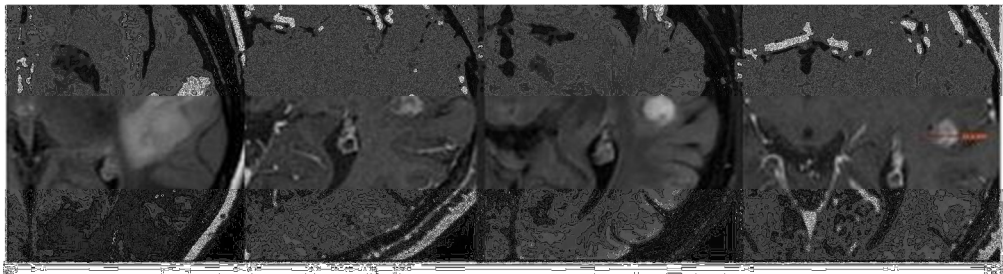


Image 1 - July 2013: Showing area effected at time of diagnosis, tumor and oedema

Image 2 - October 2014: Brain tumor after cannabinoid treatment in USA

Image 3 – March 2015: Brain tumor after 3 months without cannabinoid treatment in Australia
Showing growth again and oedema looking "conspicuous"

Image 4 – April 2015: Brain tumor reduction in size after only 1 month of being back on Cannabis oil

In ██████ case surgery was not recommended due to the significant risks of impacting critical function such as communication and learning.

⁸ <http://mct.aacrjournals.org/content/9/1/180.full-text.pdf>

Potential for Cannabinoid Therapy for Brain Cancer

In Australia brain cancer is the leading cause of cancer death for those under 39 years old and yet the status quo is that the medical profession is still continuing to use treatments from the 1800's or 1940's. It's disappointing to think that we seem to be stuck in these medical dark ages when there are thousands of lives being lost in Australia every year and quality of life lacking for so many suffering and terminal patients.

I quote from - Clin Oncol (R Coll Radiol). 2004 Dec;16(8):549-60⁹.

“The contribution of cytotoxic chemotherapy to 5-year survival in adult malignancies.

RESULTS:

The overall contribution of curative and adjuvant cytotoxic chemotherapy to 5-year survival in adults was estimated to be **2.3% in Australia** and 2.1% in the USA.

CONCLUSION:

As the 5-year relative survival rate for cancer in Australia is now over 60%, **it is clear that cytotoxic chemotherapy only makes a minor contribution to cancer survival. To justify the continued funding and availability of drugs used in cytotoxic chemotherapy, a rigorous evaluation of the cost-effectiveness and impact on quality of life is urgently required.**” [emphasis added]

This same study highlighted the 5 year survival rate of Brain Cancer patients after Cytotoxic chemotherapy was only **4.9%**. That is an incredibly low percentage and one has to wonder at the quality of their lives and the real impacts of a grueling regime of treatment on their families and the individual.

It is clear that even the authors agree that cytotoxic chemotherapy is only making a minor contribution and there are clearly issues raised about the quality of life impact from such treatments.

I am pleased that cannabinoid medicine is being considered at least for its benefits for terminal cancer patients and also chemo induced nausea but I feel this is falling far short of its therapeutic potential in respect to the cancers where there is specific research proving positive benefits from cannabinoid treatment.

There is a wealth of clinical research providing evidence for positive outcomes for brain cancers responding to Cannabinoids, I have provided a list of some of the relevant studies:

PLoS One. 2013;8(1):e54795. doi: 10.1371/journal.pone.0054795. Epub 2013 Jan 22.

Local delivery of cannabinoid-loaded microparticles inhibits tumor growth in a murine xenograft model of glioblastoma multiforme.

Hernán Pérez de la Ossa D1, Lorente M, Gil-Alegre ME, Torres S, García-Taboada E, Aberturas Mdel R, Molpeceres J, Velasco G, Torres-Suárez AI.¹⁰

⁹ <http://www.ncbi.nlm.nih.gov/pubmed/15630849>

¹⁰ <http://www.ncbi.nlm.nih.gov/pubmed/23349970>

Delta 9-tetrahydrocannabinol inhibits cell cycle progression by downregulation of E2F1 in human glioblastoma multiforme cells.

Galanti G1, Fisher T, Kventsel I, Shoham J, Gallily R, Mechoulam R, Lavie G, Amariglio N, Rechavi G, Toren A.¹¹

Childs Nerv Syst. 2011 Apr;27(4):671-9. doi: 10.1007/s00381-011-1410-4. Epub 2011 Feb 20.

Spontaneous regression of septum pellucidum/forniceal pilocytic astrocytomas--possible role of Cannabis inhalation.

Foroughi M1, Hendson G, Sargent MA, Steinbok P.¹²

Glia. 2010 Jul;58(9):1017-30. doi: 10.1002/glia.20983.

Cannabinoid and cannabinoid-like receptors in microglia, astrocytes, and astrocytomas.

Stella N1.¹³

Cannabinoids as potential new therapy for the treatment of gliomas

DOI:10.1586/14737175.8.1.37

Daniela Parolaro*a & Paola Massib

pages 37-49¹⁴

“Abstract

Gliomas constitute the most frequent and malignant primary brain tumors. Current standard therapeutic strategies (surgery, radiotherapy and chemotherapeutics, e.g., temozolomide, carmustin or carboplatin) for their treatment are only palliative and survival diagnosis is normally 6–12 months. The development of new therapeutic strategies for the management of gliomas is therefore essential. Interestingly, cannabinoids have been shown to exert antiproliferative effects on a wide spectrum of cells in culture. Of interest, cannabinoids have displayed a great potency in reducing glioma tumor growth either in vitro or in animal experimental models, curbing the growth of xenografts generated by subcutaneous or intratecal injection of glioma cells in immune-deficient mice. Moreover, cannabinoids appear to be selective antitumoral agents as they kill glioma cells without affecting the viability of nontransformed counterparts. **A pilot clinical trial on patients with glioblastoma multiforme demonstrated their good safety profile together and remarkable antitumor effects**, and may set the basis for further studies aimed at better evaluating the potential anticancer activity of cannabinoids”.

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Affordability of medical cannabis for patients

Affordability is a significant issue for patients. Daily costs for patients may range from less than \$5 per day to \$100 or more per day for specific medical conditions. Obviously this depends on the specific condition being treated and the recommended dosing.

Currently there will also be freight costs under the special access scheme as well as any customs clearance fees until there are licenced suppliers in Australia.

The 5 products from Washington State that were on [REDACTED] original application would have a retail cost of approximately \$8900 every 3 months when the current exchange rate was considered. These were products that [REDACTED] had responded well to in the USA.

Affordability will continue to be an issue for most patients. This is a major issue which will need to be resolved in the near future.

Any ongoing appointments, reporting and specific conditions within the approvals may add further expense and financial burden on patients.

Conclusion

So in summary I believe that it is realistic for the government to be able prescribe and dispense cannabis as efficiently as most other schedule 8 products. In other words being prescribed and dispensed on the same day or much faster than currently proposed.

There is simply no need for the duplication of both the TGA and State application processes.

Factors such as medical education for specialists, doctors and health care workers and affordability will need to be addressed as a priority.

This proposed bill and the processes outlined within it will cause unnecessary delay, stress, burden, expense and risk to the patient and their carers and is unjust.

Lanai Carter

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