United in Compassion (UIC) Submission for Senate Inquiry into current barriers to patient access to medicinal cannabis in Australia.

Lucy Haslam *on behalf of United in Compassion Ltd.*

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I am happy for this to be made Public

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About UIC

United in Compassion is Australia's main Medicinal Cannabis (MC) advocacy body which initiated the 2016 legislative changes this inquiry is tasked with exploring. Founded in 2014 by retired registered nurse Lucy Haslam and her late son Daniel, UIC's main functions since then have been as a charitable organisation to promote education and knowledge around clinical uses of cannabis as well advocating for improved patient access to what, for many, can be a valuable quality of life and potentially life-saving medicine.

UIC has had ongoing contact with hundreds of medicinal cannabis patients and has advocated on behalf of several individual patients denied access or otherwise disadvantaged by the system. This is a position UIC regularly find itself in as they are contacted by very distressed and exasperated individuals who are suffering unnecessarily either physically or mentally or both, as a result of the inadequacies of the current system. Many times, UIC has attempted to bring this to the Government's attention via letters to the Health Minister and Prime Minister. The Government has consistently ignored or paid lip service to the plight of patients.

It became obvious early that there exists a large amount of misinformation about cannabis, particularly the exaggeration of harms and dismissiveness of the therapeutic benefits. UIC identified very early on that Australian attitudes were generally very backward when considered in a global context. Therefore, we focussed on providing educational events such as hosting several international medicinal cannabis symposia in 2014, 2016, 2018 and 2019. These events involved bringing international speakers (medicos and researchers) of repute from around the world to Australia to inform a largely ignorant audience of health professionals and general public. On every occasion, participation by decision makers from within the political and health areas was disappointing. This fact gives an insight into the attitude that has prevailed by many with a resulting negative impact for patients.

Australian patients are disadvantaged by a lack of medical and scientific knowledge about cannabis …. there is a 'knowledge vacuum.' Many decision makers (including professional medical bodies and MPs), DON'T WANT TO KNOW what they don't know. This educational arrogance has been very much to the detriment of genuinely sick Australians who, as a result, seek to access medicinal cannabis from the illicit sources without any medical supervision.

This is not an ideal situation and to have avoided acknowledging it speaks volumes about the attitude of the Australian Government and the Australian Health Ministry in particular. Even the fact the Government opposed this inquiry is politically arrogant and extremely disappointing. The Medicinal Cannabis Scheme in Australia operates at the expense of the wellbeing of patients.

UIC welcome the opportunity to contribute to this inquiry and provide a general overview of the failures of the existing system as observed predominantly through the lens of patients and carers and as they relate to several of the Terms of Reference. We feel that this inquiry is very needed and that it is long overdue.

UIC also recommends that all Senate Inquiry Committee members take the time to view the Documentary 'High as Mike' via video on demand https://www.highasmike.com/
This documentary was made to give a voice to the 'quiet Australians' to whom UIC dedicates their efforts.

- **The Appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS)Authorised Prescriber Scheme and clinical trials.**

In March 2015, Lucy Haslam along with many other patients, carers and academics presented to a Federal Senate Inquiry which, upon conclusion, **made recommendation for an Independent Medicinal Cannabis Regulator model for Australia** (as is the case for the vast majority of international jurisdictions which have an established legal medicinal cannabis program). Five prior inquiries held throughout Australia had already come to similar conclusions.

The proposal of an Independent Regulatory Body was accepted and widely supported across the political spectrum as the best option for Australia due primarily to the complex nature of the cannabis plant and the many cannabinoids and chemical compounds it contains.

A review of these half-dozen inquiries in general and the federal inquiry of 2015 in particular would, we argue, overwhelmingly demonstrate that, if the Government had been (or is) genuinely serious about making cannabis available for medical purposes to Australian patients it would regulate the drug outside of the Therapeutic Goods Act 1989.

Such a view was propounded by (among others) Emeritus Professor Laurence Mather of Sydney University in both his Public Submission to that Inquiry and in the oral evidence he provided to the 2015 Inquiry's Public Hearing in Sydney (one of three day's-worth of such events that were integral to the proceedings).

Here Professor Mather made clear:

'*Conventional regulatory bodies have no framework for examination and approval of potentially variable mixes of drugs. Conventional pharmaceutical companies have little to gain from investing in natural products that cannot be patented or bear an illegal drug label.'*

The argument for a separate regulator was made, won, and then rejected when in the last sitting week of Parliament in 2015 the Government intervened in the passage of the Regulator Bill and inserted a degree of political arrogance into the debate by instead choosing to pass an amendment to the Narcotic Drugs Act thus forcing cannabis into administration by the TGA (in direct contrast to the recommendations of the Senate Inquiry.)

That legislation passed on the first anniversary of Dan Haslam's death and involved a direct request from the then Health Minister Sussan Ley to Lucy Haslam to encourage her to personally appeal to the Labor Party and implore them not to require the Bill to go to Committee. The argument Minister Ley put forward was that if the Bill did not go to committee, the Legislation would pass on Dan's first anniversary. As a grieving mother this had a huge element of appeal and against better judgement that was what occurred. The Legislation passed without any regulations ready for public scrutiny or comment.

Upon reflection, and gaining better insight and understanding into parliamentary process, UIC believes that Minister Ley had taken advantage of Mrs Haslam at a very vulnerable time and misrepresented her intent in seeking her to directly to lobby the Labor Party so to avoid the Bill being taken to Committee. A heartfelt desire to expedite legalisation and the initial feeling of pride that Dan's campaign had paid dividends for the benefit of other suffering Australians was short lived once the regulations were written and enacted over the ensuing months. That pride soon turned to disappointment with the realisation that the 'system' was

either set up to fail or that the initial compassion that drove the political change was otherwise influenced and instead, a system designed more to impede than promote access was the result.

There appears no logic for going against the advice of these inquiries other than putting politics ahead of patients and possibly that of subsequent negative influence emanating from commercial competitors within the pharmaceutical industry and more particularly, the lucrative Australian poppy straw industry. Indeed, UIC was told very early on by a member of the Office of Drug Control, that the Australian Government would not jeopardise the domestic opiate industry. This seems particularly disturbing at a time when there is an opiate epidemic and many lives being lost to accidental opiate overdose worldwide when it is fast becoming recognised (at least internationally) that cannabis has a role in reducing dependence on dangerous medications including opiates. One is led to question if conflicting commercial interests had an impact on high level decision making.

Whatever the reason, the 'system' is a legislative failure because whilst the numbers of patients gaining legal approval to use cannabis is rising rapidly, (at around 15000 in Dec 2019 according to Freshleaf Analytics https://freshleafanalytics.com.au/reports/)which is a fact that the Government relies heavily on to demonstrate the success of the scheme, UIC believes that the rise in **number of patients seeking black market products is so enormous that the legal approvals fade into insignificance.**

Whilst UIC cannot provide actual figures around the number of patients accessing illicit supply we can confirm that our role in advocacy has led us to network with compassionate suppliers via the 'green market'. This interaction provides insight into the Australian reality that the parallel in numbers between illicit and licit supply is like a mountain to a mole hill.

UIC's focus is and has consistently been through the lens of the actual reality in Australia: the fact that, currently, possibly hundreds of thousands of sick Australians needing MC are accessing black market products of unknown provenance and completely without medical supervision, criminalising themselves in the process despite medicinal cannabis now being three years post legalisation.

This highly unsafe and grossly unsatisfactory situation – presumably - the exact opposite of what Governments and medical professionals should have wished to accomplish, has become exactly the position in which Australia now finds itself, largely as a result of the legislation under review. Failing or refusing to acknowledge this reality and its significance is to overlook arguably the single most important facet of the matter at hand – the context of things as they actually are for the 'quiet Australian's' accessing illicit cannabis for use as medicine and for whom it is not about 'getting high', but very much about 'getting well'. These Australians deserve a voice because their plight has been falling on deaf ears!

The fact that the recent Review of the Narcotic Drugs Act omitted any reference to patient access is indeed a red flag that the Government is taking a deliberate 'head in the sand approach'.

UIC also recognises the important fact that the number of approvals does not equal the number of patients. This fact becomes clearer when one looks into the problems that patients are describing:

It is too difficult for patients to locate doctors willing to prescribe. Some of the reasons relayed to UIC include the personal biases of doctors, time constraints involved for busy doctors, lack of education about cannabis and about navigating the Special Access Scheme,

limited numbers and geographical locations of Authorised Prescribers, lack of professional support, fear of being professionally ostracised, fear of having the legal responsibility of prescribing an unapproved medicine, and inability of doctors to be able to advertise their willingness to prescribe due to TGA restrictions around advertising.

Consequently, patients who do not want to break the law to access cannabis have to resort to research via word of mouth (often via internet), doctor shopping within and sometimes beyond their home locality, or using the specialist cannabis access clinics which in turn mean that the patient has significant additional costs (around $300 per application) to see a doctor who is not the patient's regular practitioner. This point alone would not fit with the better practice of continuity of care. The net result is that patients gravitate to the illicit market where the potential for harms are more significant and where that patients risks criminal conviction.

This strengthens the argument for an Independent Regulatory System which can be flexible and accommodating to the needs of the health workforce and patients and ensure that patients seeking access are readily able to find a prescriber and, that the best-case scenario has a greater chance and the prescribing doctor is the patient's regular GP.

***Navigating the process particularly of the Special Access Scheme Cat B is arduous* and negatively impacts on patients**. Patients are often too sick to go through the whole process of gaining approval which, for the most part requires a significant element of patient/carer driven research because of the lack of motivation and knowledge on the part of doctors. For the terminally ill and those with life threatening conditions, the sense of urgency is usually paramount and results in a preference for illicit product which is quicker to obtain.

While UIC acknowledges that some of the hurdles have been removed or lessened, (largely due to pressure exerted by organisations such as UIC, and by media highlighting patient struggles), one wonders why a system that creates barriers was adopted in the first place? The Special Access Scheme was designed for 'exceptional clinical circumstances.' Increasing volume of approvals itself is an indicator that the system is not fit for purpose, yet this is the main route for the majority of patients under a TGA administered model, clearly demonstrating that the majority of patients acquiring the medication via SAS B are not "exceptional" but rather, represent common illnesses and conditions being approved in rapidly increasing numbers.

Furthermore, the conscious removal of SAS Category A's inclusion of cannabis is the clearest indicator that the Government wanted to control access so tightly that it was prepared to punish the terminally ill group who had been recognised under the SAS A scheme of requiring expedited access. This to many is reprehensible.

These are arguments for an Independent Regulatory System that recognises that the SAS was never designed for the numbers of patients making application. We raise the question…. would a streamlined cannabis 'recommendation' scenario rather than a 'prescription' such as exists elsewhere provide a more appropriate model?

Below is a quote from Victorian Dr Karen Hitchcock about her experience. (Source "Drugs: on legalisation, medication and pleasure." The Monthly) It says a lot!

'I started looking into the matter seriously in April this year. In order to prescribe medicinal cannabis (MC) for a patient, I needed to submit a Special Access Scheme application to the TGA, nominating a specific cannabis preparation, justifying the need for the drug, and documenting that all other available treatments had been unsuccessfully trialled and why they were unsuccessful and that all the patient's treating doctors agreed with the trial. If approved, I then

needed to apply to the Victorian health department for its *approval. If the Victorian health department gave me that approval, I needed the patient to sign a consent document and agree to frequent follow-ups. At that point, I could finally write a prescription and send the patient off to the pharmacy of their choice. The pharmacist would (hopefully) order the product and (given MC is not subsidised under the Pharmaceutical Benefits Scheme) it would cost the patient anywhere between $150 and $350 for a month's supply.*

At the time, I was working in a busy, bulk-billed, public-hospital specialist clinic with a long waiting list of mostly unemployed patients. I estimated that completing the paperwork necessary to prescribe this treatment to a single patient (one who could afford it) would require at least four hours of my time. Prescribing enough opiates to kill them and their family, by way of comparison, would take me 30 seconds, max.

It was, however, theoretically possible to become an "authorised prescriber" and bypass this administrative load. And so, this was what I pursued. I completed a medicinal cannabis course and conducted and documented a major literature review of the current medical research. My final application to prescribe five different MC preparations for seven clinical indications, following the TGA template, stretched to 52 pages.

In order to submit the application to the TGA I needed an ethics committee to assess and approve it. My specialist college, the Royal Australasian College of Physicians, declined to do this, just as the Royal Australian College of General Practitioners and the Royal Australian and New Zealand College of Psychiatrists declined to assess the applications of two of my colleagues. They suggested we try a university or hospital ethics committee. I heard that the National Institute of Integrative Medicine (a not-for-profit education institution based in Victoria) had an ethics committee composed of doctors and scientists who were willing to assess such applications. I contacted them – they were knowledgeable, rigorous and supportive – and sent it in for their appraisal. (I was granted ethics approval. My application is now with the TGA.)'

Reliability of product supplied under the existing scheme. The Endocannabinoid System is unique to the individual and therefore responses to products are individualised. This means that patient's product needs vary. Patient have reported requiring products not readily available (as an approved product via SAS B).

Many patients are sourcing their medicines illegally via international sources and it is worth acknowledging that some patients have made the move overseas permanently because of the need to more easily access medicinal cannabis. As an example, a family of 6 children originally from Western Sydney, came to media attention in 2014 with the plight of their young daughter who has an intractable form of epilepsy. The child was being managed with illegally obtained cannabis at the time which placed the family at great risk of criminal prosecution. They bravely spoke out, received visits and comments from political figures promising a better outcome for the child but when nothing changed, they left Australia to reside permanently in Canada. In Canada access is a simple process and at a reasonable cost. They miss Australia but have no option but to remain in Canada because of the current system.

Some patients are forced to make frequent self-funded trips overseas to bring in short term supplies of the required product. An example is a young Queensland man with epilepsy caused by a brain tumour. The patient had successfully received cannabinoid treatment overseas but cannot successfully achieve access from within the Australian system despite making many representations to politicians. For him access is a matter of life or death. His

position remains ignored by politicians and his family remains under enormous financial and psychological pressure with frequent medication availability gaps.

Another example from a patient who reached out via email:

Message: Hello United in compassion
I am a medical cannabis refugee living in Spain. I had to leave Australia over four years ago in order to have safe access to cannabis, remain healthy and to live with some dignity and human rights.
As I use cannabis daily as medicine, to control the symptoms of my ulcerative colitis, it is not possible for me to re-enter Australia as I will criminalized for using or carrying this medication. It would be great if I could visit Australia again one day when I have the right to choose what i put in my body in order to maintain my health. I miss my family. March 19,2019

Other patients have described being prescribed a product via SAS B, procuring the product (at high cost) only to find that the product is unsuitable and hence another application, approval and payment is required. Some patients have reported being required to collect multiple bottles of product from the chemist at the time of initial dispensary. This puts an additional cost burden on the patient and if the product is not suitable, the patients is not necessarily able to return the product for refund. The approval is counted multiple times for the one patient giving rise to misleading approval figures. (regularly quoted by the Government as a measure of success).

Additionally, some patients have reported being unable to access their approved product due to supplier 'out of stock' issues. This requires the patient to either go without or get approval for another product type or supplier. This has even resulted in patients making the decision to resort to growing their own medicine and subsequent criminal conviction.

Actual patient example

"*I've given up……*

Was approved in Sept/Oct (2018), for which I waited a month, but which proved unsuitable. I got another approval in early Nov for something stronger and it's never arrived in the country."

Veterans are a group that seem particularly susceptible to the failures of the system with several making the decision to prioritise their mental health by using illicit product to manage symptoms of Post-Traumatic Stress Disorder (PTSD) when other treatments have failed them and/or caused them to become drug dependent. Some Veterans having gone so far as to grow their own cannabis with dire criminal consequences. At a time when Veteran suicide is very much on Australian minds, UIC believes that Veterans are being let down badly by the existing system. Whilst some Veterans are gaining approval for MC, others are declined. The struggle to obtain Department of Veteran's Affairs (DVA) funding of cannabinoid medications and device costs has also been arduous and inconsistent. This inconsistency puts further pressure on vulnerable people and exacerbates mental health trauma.

(UIC recommends watching the Documentary 'High as Mike' which depicts the access struggles of a Queensland Afghanistan Veteran and gives an expert opinion from Dr Sue Sisley USA into the treatment of PTSD with cannabis. https://www.highasmike.com/)

Amidst the general population, some of the most concerning reports have been cases where State Health Departments have determined that individual patients are only able to access

specific Government approved product despite that patient being previously managed by another product type entirely. This has sometimes been with dire health consequences.

UIC would argue the current system runs contrary to the National Medicines Policy which aims to '*meet medication and related service needs so that both optimal health outcomes and economic objectives are achieved for Australians', and includes the objective:*

Timely access to the medicines that Australian's need, at a cost individual and the community can afford

Lack of availability and continuity of supply under the existing system represent a case for argument for an Independent Regulatory System which is better able to manage and regulate product availability, choice and best practice in patient care including patient centred or personalised medicine.

- **The suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products.**
- **The significant financial barriers to accessing medicinal cannabis treatment**

Cost is possibly the biggest current factor that is negatively impacting patients and demonstrates that the system chosen is the wrong system.

The TGA regulations require that cannabis and cannabis products need to adhere to certain standards, including a Therapeutic Goods Order (number 93) which is specific to cannabis. By adhering to these standards, such products are clearly approved for use in Australia, yet at the same time none (except for Sativex) appears in the Australian Register of Therapeutic Goods - the ARTG - meaning they're simultaneously unapproved for use in Australia. This means we've literally got 'approved unapproved medicines' which is an absolute nonsense. Nor can unapproved medicines (i.e. those not on the ARTG) be subsidised under the Pharmaceutical Benefits Scheme (PBS) so now, despite TGA approvals increasing month by month we're hearing stories of people unable to afford their prescriptions. Although costs to patients have decreased over the past year, the cost to patients and particularly to epilepsy patients, is largely out of reach of most everyday Australians. Figures by FreshLeaf analytics (https://freshleafanalytics.com.au/report-q3-2019/) have put the costs at around $45-$50/day per epilepsy patient. Some patients have reported much higher costs at around $325 per 2.5 days for juveniles with intractable epilepsy. This of course is entirely worthwhile if it is preventing seizures and brain damage but not sustainable without subsidy.

When asked, how does the Government plan to lower costs, the standard reply given is that this will occur through competition as more suppliers come to market. This is an oversimplified and disappointing reply since the domestic industry is (as per the recent Review of the Narcotic Drugs Act demonstrated) struggling to get established amidst an overburden of bureaucracy and under resourced Office of Drug Control resulting in substantial waiting lists for any licencing, permit and product approvals. Indeed, there are even long wait times for academic organisations which are attempting to engage in the often called for 'research'. The regulatory burden to licenced producers and manufacturers has, as a consequence ensured that Australian produced products are likely to have a higher price point to those produced outside Australia.

As mentioned previously, cost is also impacted by additional dispensary costs (due largely to the regulatory burden imposed on pharmacists) and additional prescriber costs when patients are forced to consult with Specialist Authorised Prescribers and/or specialist Cannabis Clinics.

UIC was provided with a cost comparison by one family for their son with epilepsy. This comparison is based on personal requirement and relates to the individual, but we present these costs as an example:

- USA total patient cost per year US$14,600 if sourced from a dispensary (after currency conversion AU$21,132.)
- Canada total patient cost per year CA$48,172 if sourced from a licenced producer (after currency conversion AU$64,741.70.)
- Australia total cost per year $104,080 from licenced producer via pharmacy.

The Government has, in the past made the comment that any company can at any time apply to have their product registered on the ARTG which is again a form of lip service because they (the Government) know that it is highly unlikely that companies that will ever make the financial commitment required to invest in the clinical trials for a product that is difficult to patent. With clinical trial evidence a prerequisite to listing on the ARTG this becomes yet another example of a system set up to fail.

Unless matters such as cost are addressed, patients will continue to be at great risk as they criminalise themselves.

Patient example via email 10/03/2019;

Dear UIC

I'm a 70-year-old pensioner living alone in a small village in rural NSW. I have been taking assorted pharmaceutical drugs for chronic pain for approximately 18 years which have unfortunate side effects. When over-the-counter NSAIDs stopped being effective I was prescribed stronger NSAIDs such as Vioxx (now banned for increasing the risk of cardiovascular (CV) events like strokes and heart attacks), then Celebrex (similar, not sure if it's banned), then Mobic, but all messed with my stomach and I needed to take proton pump inhibitors (Omeprazole) for a while to help heal the gut.

Research shows that the long-term use of COX-2 inhibitors in NSAIDs increases the risk of CV issues and events such as heart attacks and strokes, and because these problems run in my family I absolutely believe it to be dangerous to take them any longer! So I have researched medicinal cannabis extensively and sourced a medicinal variety with a 1:1 ratio of CBD:THC at around 5 - 8% of each, and have been making tincture with it. Not only has this been amazingly successful at reducing pain and inflammation, it is kind to my gut and has no noticeable impact on my ability to go about life in an ordinary way day-to-day. One beer gives me a 'head' effect but this tincture does not! And to me the fact that it is safe and non-toxic with no side effects is a major benefit as well.

So I decided to grow 2 plants this summer in my vegetable garden in full sunshine to get maximum nutritional benefit since I also use the leaves in smoothies and in tea. I feel I should be able to grow this plant without hiding it even though I'm aware it is still a criminal offence in NSW. I don't want to break the law but I feel the law is unjust and that it is more important to do what I think is right so that I can live without fighting my own conscience.

Unfortunately my neighbours reported me to police and 2 officers arrived, removed my 2 plants and did a video interview for their charging purposes and have now issued me with the paperwork to appear in court in May. Although they were very polite and professional it still

felt traumatic since I have never been in a situation like this before! The officers said that things are starting to change regarding medical cannabis but I replied that it's too slow for people like me - I haven't got time to wait. Even if I obtained a legal prescription as a legal user, I wouldn't be able to pay for it. Not only am I on the age pension, I am also paying a mortgage, and when utilities and insurances etc are taken into consideration I am left with an amount that puts me well below the poverty line.

My best solution is to grow my own medicinal cannabis so that I can grow it organically and know exactly what I'm getting. I don't want to go looking for black market products since I have no idea on the ratios of cannabinoids in them or whether they are contaminated with chemicals or come from generally poor growing conditions. I have no idea how to even go about searching for such products! Anyhow, they are likely to have very little or no CBD at all and would not be suitable for my needs. Plus in the end I cannot afford them anyhow!

So that's my current predicament. I'm sure you've heard it many times before and I'm writing to you in the hope that you are keeping data on the number of people like me who are in trouble. I'm sure you would be getting endless emails similar to mine.

All the best for the upcoming conference which I wish I could attend but I have other commitments that weekend. Sincerely P

01/07/2019

Hi UIC
Thought I'd update you with the outcome of my "crime" of growing 2 plants. I was convicted, fingerprinted and fined $1000 plus expenses of $166, despite a letter from my doctor confirming my long term use of NSIADS that at my age and family history is no longer advisable and which explains why I grew medicinal cannabis at this late stage in life. The fingerprint part was crazy - aged skin which has lost collagen makes fingerprints much less distinct and so their machine kept rejecting mine! Each finger of each hand, both palms and edges of hands took a minimum of 6 attempts before the machine finally just accepted the best of a bad lot

So I now have a criminal record which may disadvantage me from various activities or obtaining insurance without penalties and possibly being unable to volunteer at our local school to help students with reading since they do police checks. I was asked by an insurance company whether I (or any member of my family) had been convicted of a crime in the past 5 years. Fortunately, it was before my case went to court.

It's all so absurd! (However, it's good revenue for the system) Keep fighting for us please.
Sincerely P

The very significant financial burden has far reaching social and psychological effects and is argument for an Independent Regulator where a complete overhaul of the system is applied to solve these complex cost issues. Cannabis should never be a medicine that only the rich can afford yet that is the system we have, and which is clearly ironic when patients can, and do grow their own cannabis for minimal financial cost…a situation which could be made much

safer by decriminalising home growing and allowing access to professional product testing in light of the excessive costs for Government approved products via the current system.

Lack of an educated workforce of prescribers is a problem that UIC has always sought to address in its own small way by providing symposiums, information via its website and provision of educational opportunities to health professionals. All this work done as a charitable organisation and without any government sponsored funding. The lack of education is not a simple problem and the causes are multiple including the fact that the Endocannabinoid System (ECS) is a fairly recent discovery (1990's) and that this discovery was set amidst the war on drugs and blanket prohibition of cannabis. There are also very few educational institutions that have added the ECS to their curriculum although some have and that gives some hope that the change in attitude will be generational and eventually based on science rather than propaganda.

Add to that the fact that cannabis was scheduled as a narcotic prior to the discovery of the ECS and that many of the peak medical bodies are funded by commercial competitors of cannabis, the fact that doctors in Australia have an over reliance on Randomised Controlled Trials (RCT's) as being the gold standard of evidence and the stigma attached to cannabis use whether medical or recreational and it is clear there exists a plethora of reasons why education amidst the health professionals is lacking. At the current time, UIC is investing its own funds into establishing an accredited online course for health professionals because there is such a general apathy to fund education.

We believe the attitude of the Government (including trying to regulate cannabis as any other pharmaceutical via the TGA and via a model reserved for unapproved medications considered as 'last resort") has compounded the negative attitude of many medicos who feel more comfortable turning desperate patients away rather than attempting to address their own knowledge gaps and personal biases.

On a positive note, those doctors who do obtain education about cannabis overwhelmingly tend to change their attitude, and often become new advocates willing to consider the treatment options cannabis provides.

An Independent Regulator would allow the opportunity for fresh attitudes and more positivity around medicinal cannabis by way of public information and health professional education. This would also assist with the attitudes of law enforcement and policy around criminal vs medical uses of cannabis and the future of MC users.

Clinical trials. Lack of evidence or an excuse to deny access?

Patients deserve much better than being constantly told that there is not enough evidence to justify the use of cannabis medicines. This is the patronising 'go to' reply that is thrown to patients by doctors and politicians even when those same patients are utilising illicit market products with good effect. The next throw -away remark is that any symptom relief is likely due to nothing more than the 'placebo effect'.

Patients need to be listened to, they deserve the right to have input and control over their own health care and from a scientific point of view, their individual responses and the existence of the Endocannabinoid System need to be acknowledged.

As mentioned previously, cannabis products are in a regulatory limbo…. unapproved because of the lack of clinical trial evidence, yet widely used because they are effective for a wide range of patients and conditions whether made legally available or not.

UIC therefore supports a potential solution for consideration which could be adopted under an Independent Regulator Model;

Previously the TGA has said 'Australia operates an evidence-based system of medicine, which provides for the best possible care and, importantly, protection of patients. The very fact that there is a great paucity of evidence, including that of safety, means that it would be inappropriate to allow access without appropriate clinical oversight and would risk the health and safety of patients.'

As has been highlighted by the TGA's statement above, Australia operates an evidence-based system of medicine, but what is confusing is that denying patients legal access due to lack of the highest levels of scientific evidence means many are left with the only option of tackling complex health problems alone and without appropriate clinical oversight by a licensed medical practitioner. Such policy seems to contradict itself and is risking the health and safety of patients by subjecting them to illicit, unregulated products. Is it not conceivably safer and within the scope of duty of care to medically monitor patient use of a regulated medicinal cannabis product for a condition with sub-optimal scientific evidence than to subject that patient by default to unregulated product and unsupervised care via illicit use?

According to the National Health and Medical Research Council (NHMRC), evidence comes in the form of systematic reviews (Level I), randomised controlled trials (Level II), pseudorandomised controlled trials (Level III-1), comparative studies with concurrent controls (Level III-2), comparative studies without concurrent controls (Level III-3) and case series with either post-test or pre-test/post-test outcome measures (Level IV). This 'hierarchy of evidence' underpins the clinical decision-making process of government departments, research institutes and universities as well as individual medical practitioners making informed clinical judgements for the health and wellbeing of their patients on a day-to-day basis.

Of particular relevance to this discussion is the N of 1 clinical trial, which fits within the hierarchy of evidence framework. This level of evidence considers an individual patient as the sole unit of observation in a study investigating efficacy or side-effect profiles of different interventions, with the goal being to determine the optimal intervention for an individual patient using objective data driven criteria and outcome measures.

Results of such studies can be collected and collated to ascertain proof of concept and establish a scientific rationale for treatment of a particular condition, which can then lead to more rigorous forms of evidence such as randomised, double blind, placebo controlled clinical trials being implemented.

UIC has publicly promoted the benefit of pursuing the use of open label N of 1 clinical trials for medicinal cannabis over recent years, and is ever hopeful that the Government and Health Professionals not only considers this a valid form of evidence in assessing the clinical justification of medicinal cannabis for SAS Category B applications, but may also openly finance and support such clinical research in Australia. Medically supervised case study evidence, based on a patient's previous use of illicit cannabis to manage a medical condition, may also be considered as a potential clinical justification, particularly in intractable cases where no current medical intervention is assisting the patient. After 70 years of cannabis prohibition, which has stifled scientific and medical research in this area, such concessions may provide a rational and balanced approach to the problem at hand. Instead, currently in Australia this opportunity is conveniently and deliberately ignored.

- **The interaction between State and Territory authorities and the Commonwealth including overlap and variations between states**.

When Medicinal Cannabis legislation was first introduced the variations in regulation across states caused an additional set of hurdles for patients on many levels. Hurdles ranged from creating confusion and difficulty for patients to interpret where they stood and what they needed to do to navigate the system, to downright interference by state health departments. On several occasions UIC sought the third-party help of legal firms to represent patients who for example were approved by the TGA only to be declined by the State appointed ethics committees.

UIC also had reports from some doctors who had written and phoned State Government funded advice lines and were actively discouraged and /or obstructed from prescribing cannabis for their patient. Instruction passed on sometimes included the requirement of the doctor to have the patient sign a document that they would not drive a motor vehicle while using cannabis whether it contained Tetrahydrocannabinol (THC) or not. This fact alone is an impediment to access that negatively impacts many patients and particularly those living rurally and remotely.

Example via Email from GP. This email raises serious concerns relating to patient rights to access treatment, patient privacy, and doctor's right to work without interference from Government.

Dear UIC
*I just had an interesting conversation this afternoon with **** from *** Health. I asked her about the requirements for prescribing cannabis in ***, as the information I received from *** Health appears to be different to Federal legislation.*

*She informed me that *** Health doesn't need to follow Federal Legislation because they follow their own "*** policy".*

*I asked where I could find a copy of the "*** policy" online, but she said that there is no copy of the policy available online.*

I asked her why there is no copy of the policy online and she stated that there is no requirement for the policy to be available online.

*I asked if she could send me a copy of the *** Health policy, but she said that I would need to write to the Chief Pharmacist and formally request a copy of the "*** policy" (which I have now done).*

*I asked her why the "*** policy" is kept hidden from health professionals and why we are asked to make applications without being able to know all of the details of the application process.*

*She informed me that the "*** policy" is not kept hidden, because "parts of it" were written into the letters I received after my applications were unsuccessful… :/*

Therefore, in summary:-

*1) There is a secret "*** policy", that is independent of Federal Legislation, hidden from doctors and the public.*

*2) *** Health assures me that the policy that they don't publish online, and won't freely provide to me, is not a secret.*

*3) To view the "*** policy", I need to formally request a copy from the Chief Pharmacist of ***, **********.*

*4) Doctors who make an application to *** Health currently need to follow rules of a policy we can't see, that is apparently different to Federal Legislation.*

*5) *** Health will only tell doctors if we have fulfilled the criteria for our application to be successful, after we have made an application - but we cannot see the criteria before or after making an application.*

*6) *** Health will not freely provide a copy of the policy but will mention parts of the policy in letters they provide to doctors after our application has been rejected.*

*7) For doctors receiving rejection letters from *** Health, there is no way of knowing which parts are "*** Policy", and which parts are just the opinion of the author of the letter.*

*8) *** Health state that they have no obligation to provide a copy of their policy online, but they will use the unseen policy as their basis for denying applications for medicinal cannabis*

*9) *** Health has no transparency with the application process and requires doctors and patients to wholeheartedly trust that they are doing the right thing.*

In addition...

I questioned why one of my patients needed to attain a letter from their psychiatrist in order to have medicinal cannabis prescribed for chemotherapy-induced nausea.

*I was informed by ******* that the patient was **not** asked to attain a letter from their treating psychiatrist, but that it was a requirement by *** Health to contact **all of the members of a patient's treating team** and inform them that the patient was being prescribed a drug under the Special Access Scheme. (NB - This doesn't explain why the patient's palliative care physician called me and told me that the application had been rejected by *** Health because they required a letter from his psychiatrist)*

*I stated that I didn't think that it was the role of *** Health to contact **all of the patient's treating team**, and that it was more appropriate for the patient's GP to inform and communicate with other members of the treating team.*

******* stated that due to reasons of "privacy", *** Health had the right to contact every health professional involved in the patient's care.*

Other patients have reported that they have been required to attend an excessive (sometimes daily or second daily) 'follow-up' schedule with the prescribing doctor, again setting cannabis patient treatment apart from other medications. This further demonstrates a climate of Government interference and active discouragement of access rather than facilitation of access.

There was also a huge blow-out in the time it took to successfully achieve an approval with some patients taking in excess of 18 months. The mental health burden this imposed on already sick people was enormous and accounted in part for the rapid rise in use of the black market. No patient wants to risk criminalisation but if the benefit outweighs the risk many have shown that they are willing to take the risk.

UIC lobbied hard around the issue of overlap and variation between states and territories and were relieved when the issue was taken to COAG by Minister Hunt and there was some consensus that the duplication and role of the States needed to be removed. Unfortunately not all states opted in to a program of streamlining and there continues to be several states which lag behind and the result of that continued interference and duplication is reflected in lower patient approval numbers in those states such as Tasmania, The Northern Territory and Western Australia which has only very recently made some much needed legislative changes.

UIC questions why third party 'ethics committees' are even involved in deciding whether any patient is able to obtain what has been prescribed for them by a qualified doctor. How can this be ethical?

The 'System' has affectively created a post-code lottery where the state you reside in dictates whether you have a mediocre outcome v's a terrible outcome. The Federal Government has been equally complicate in terms of their own policy guidances attracting scathing criticism from the more informed members of medical profession:

A/Professor David Caldicott, Author: The First Australian Medicinal Cannabis Course

'In just a decade's time, they (the Guidances) will be mocked as an example of the abuse of science. (They are) political, designed to arrive at conclusions that suit parties other than patients. The sad reality is these documents ...will do next to nothing to change the status quo – an illicit market of uncertain provenance, accessed by desperate people. They don't tally with the experience of tens of thousands in Australia – millions worldwide - and so will simply be ignored, even by doctors who choose to educate themselves, overseas and online, about the 'actual' pros & cons of medicinal cannabis.'

Related matter; Cannabis and Driving

UIC has been contacted by many patients concerned about advice and incorrect information given regarding driving. After receiving the email and attached Driving Agreement from the below patient UIC raised the issue with the appropriate State Health department who denied giving such advice to require patients to agree not to drive when taking CBD only preparations under lawful prescription. They later changed the wording on their website to remove the inference that the advice applied to CBD.

The wording on the agreement which the doctor said he was advised by the Health Department to make the patient sign before cannabis was prescribed (see attached Driving agreement) raises many questions around blatant discrimination and scaremongering and is yet another example of the propaganda machine being alive and well in Australia and embedded in the politicising of medicinal cannabis.

***'Subject:** Private and Confidential - CBD OIL Advice Required*

Dear UIC,

Would you be able to provide some advice on the attached document or would you know any lawyers or barristers who could provide some legal advice generally at no cost around the documents attached. I have been asked to sign the medical cannabis treatment agreement and the legal implications of signing such a document seem to me to be far too great to accept. I have chosen to decline treatment although I have minimal treatment options left for pain management.

*The main point that worries me are the restrictions imposed by the *** Ministry of Health on patients operating a vehicle.*

*I have attached the Ministries advice provided to doctors treating patients for your record. When I called the Ministry of Health Regulatory unit, they could not clarify how long the medication stays in your system and directed me to call my doctor. The advice I received was not to operate a car for a week to protect me from any legal risk while the medication is in my system. I am confused why the USA allows patients to drive, yet the ***Ministry of Health outline to many risks to even take the medication. It's just so disappointing and frustrating when I don't have anymore treatment options to try.'*

The whole driving subject including that of Drug Testing and the many issues that raises, such as false negatives, false positives, automatic loss of licence, disadvantage for rural and remote patients' needs to be reviewed urgently for obvious reasons.

The reality of the situation in Australia

Australia has been left with a chaotic and profoundly unsatisfactory situation that comprises:

- Tens if not hundreds of thousands of sick Australians continuing to be forced to use illicit products and being criminalised as a result;
- A medicinal cannabis 'programme' based on an assessment of regulatory change that did not meet the Government's Best Practice requirements at the time and leading to legislation that was hopelessly flawed from the outset;
- 'Medicinal cannabis' itself forever consigned to the void of 'regulatory limbo' (i.e. an 'approved unapproved medicine');
- 'Access pathways' which are wholly inadequate;
- Untenable and obscenely high prices of the limited choice of imported cannabis products available (if and when they can be accessed at all);
- An Australian 'Postcode Lottery' where such access is concerned;
- More than three and a half years on and still no (legal) Australian cannabis industry to speak of thus almost no domestic product grown or available;
- Patients having to move to States to source their medicines or even doing so by going overseas, sometimes relocating there;
- Patient deaths, including those of children.

In conclusion UIC asks the Committee to consider those that the legislation was intended to help by considering the following:

Is the Australian system promoting a safe environment where vulnerable patients feel encouraged to have medically supervised treatment and to access medicines that are safe, reliable and affordable, essentially to gravitate from the illicit market to the legal system? or Are they, as a result of the system chosen, exposed to a greater degree of harm and isolation by necessary dependence on a market with criminal and health risks but where the patients have determined the health benefits outweigh those risks?

UIC's experience tells us that the latter is true. Australia is following the global trend of everincreasing numbers of patients becoming aware of the effectiveness of medicinal cannabis treatments and they are seeking them out on mass. The need for compassion and common sense is now more critical than it ever has been. The TGA system has been trialled,

has failed and now it is time to make some meaningful changes based on putting human rights, patient needs and safety first.

Although probably outside the scope of this inquiry, Australia's hard-line approach of criminalising medical users for accessing cannabis illicitly, including home growing and driving must be examined urgently to ensure that genuine medical need is acknowledged and prioritised ahead of punishment and discrimination of otherwise law-abiding citizens. This should be a challenge that a compassionate Government would be willing to take.

1. Driving Agreement supplied by patient
2. Issues are addressed in more detail in the attachment United in Compassion Review of the Narcotic Drugs Act 1967.