Inquiry into the Regulator of Medicinal Cannabis Bill 2014

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Sophie Dunstone
Committee Secretary

Dear Ms Dunstone

Thank you for the invitation to make a submission to your Committee concerning the regulation of cannabis for medical purposes. I have set out my submission as a statement of my relevant qualifications and disclosures, some definitions, a preamble, and a statement of my position.

My *qualifications* and *disclosures* in support of this submission are those of a now-retired chemical and clinical pharmacologist with some four decades of academic research, mainly in the disciplines of anaesthesia and pain medicine. I also write as the author or co-author of a number of peer reviewed papers on cannabis, including one that is seemingly Australia's first research paper on the chemical composition of cannabis.[1] In 2000, I served as a member of the Working Party convened by the Premier of NSW on the medicinal uses of cannabis and contributed to its report.[2] Since then, I have maintained a current knowledge of research and teaching about the medicinal uses of cannabis, and have made (unsuccessful) multidisciplinary applications for federal and state research grants to study cannabinoid pharmacotherapy of certain chronic neurological conditions. I have also made invited submissions to various state and territory inquiries held on this issue, and have published several reviews and commentaries on cannabis pharmacotherapy.[3 4 5 6 7 8 9] Since 2000, I have had sporadic communications about various aspects of medicinal cannabis with personnel of the British company GW Pharmaceuticals plc (originators of Sativex®: also known by the US Approved Name of nabiximols), and have given *pro bono* advice to the Australian company Tasman Health Cannabinoids concerning cannabis. I have no financial interests in the outcome of this or any other inquiry concerning cannabis.

Some definitions. Cannabis is one of a number of ancient herbaceous plants that have survived, along with others such as foxglove (containing digitalis-type cardiac glycosides), willow bark (containing salicin-type anti-inflammatory substances), and opium poppies (containing morphine-type alkaloids), to remain in medicinal use today. Various preparations from cannabis

[1] Cartwright L, Mather LE. Investigation of some samples of Australian grown cannabis. Australian Journal of Pharmaceutical Sciences 1: 49-51, 1972
[2] Report of the Working Party on the Use of Cannabis for Medical Purposes, August 2000; Volumes 1 to 3, August 2000; Volume 4 July 2001.
[3] Mather LE. Medicinal cannabis – hoax or hope? Reg Anesth Pain Med 26: 484-487, 2001
[4] Mather L. Cannabinoid pharmacotherapy: past, present and future. Minerva Anestesiologica 71: 405-412, 2005
[5] Mather LE, Rauwendaal E, Moxham-Hall V, Wodak A. (Re-)introducing medicinal cannabis. Medical Journal of Australia 199: 789-791, 2013
[6] Wodak A, Mather L. Australia has no reason to disallow medical cannabis use. The Conversation 26 March, 2014 http://theconversation.com/australia-has-no-reason-to-disallow-medical-cannabis-use-24717
[7] Mather LE, Wodak AD, Notcutt WG. Should doctors prescribe cannabinoids? Online response to Farrell M, Buchbinder R, Hall W. British Medical Journal 2014 Apr 23;348:g2737. doi: 10.1136/bmj.g2737
[8] Mather L, Wodak A. As politicians dither, patients and carers make their own cannabis rules. Sydney Morning Herald, November 18 2014
[9] Mather L, Wodak A. What is the evidence on medicinal cannabis? Sydney Morning Herald, November 21 2014

foliage and florets have been used for medicinal, dietary, fibre-making, religious, spiritual and recreational purposes for millennia. In drug parlance, cannabis is often also referred to by the American terminology as 'marijuana' or 'marihuana' to distinguish it from hemp, but this distinction is, these days, chemically moot - a result of extensive transport and hybridisation.[10] [11]. It is well known that medicinal preparations made from the cannabis plant typically contain several hundreds of known chemical substances, and many of these demonstrate activity in relevant pharmacological models. Moreover, these substances occur in varying concentrations in different strains of cannabis plants, with additional variations introduced by conditions of plant growing, harvesting, storage and processing.[12] Thus 'cannabis' cannot be regarded as a particular drug,[13] [14] and therein lies an issue for regulatory bodies and for intellectual property acquisition by pharmaceutical companies.

The widely used term 'cannabinoids' is problematic as it refers ambiguously to both the botanical substances with chemistry closely related to Δ9-tetrahydroccannabinol (THC, the most widely studied psychoactive, i.e., significantly affecting the central nervous system, substance in cannabis) as well as to a wide range of natural and synthetic substances that act on a particular family of 'G-protein coupled receptors', i.e., a family of proteins that change their electrical activity after contact with particular substances (that can be called 'drugs'), and thereby change or regulate some or other physiological function. These receptors, are presently designated subtypes CB1 and CB2. CB1 receptors are distributed throughout both the central and peripheral nervous systems, where they mediate physiological functions predominantly through inhibition of neurochemical transmitter release, along with mood modifying effects in association with a naturally occurring family of substances that have pharmacological similarities with THC.[15] These substances are referred to as endogenous cannabinoid agonists (pharmacologically, 'agonists' cause actions, as opposed to 'antagonists' that block actions). Broadly, CB1 agonism produces analgesia and other beneficial effects, but it is also associated with locomotor and cognitive impairments and, probably, abuse liability. Broadly, CB2 receptors predominantly occur on immune cells, and are associated with an antiinflammatory effect. Various synthetic or botanical cannabinoids may exhibit greater or lesser activity or selectivity for the receptor subclasses.

By way of *preamble*, I note that this Bill is concerned only with regulation of cannabis intended for medicinal uses, and I emphasise that this submission is concerned only with the medicinal use of cannabis (and/or preparations thereof). I believe that this is appropriate, and I maintain that the 'medicinal' and 'non-medical' (particularly 'recreational') uses of cannabis should be considered, sociologically, politically, legally, and even medically, as separate issues. Nonetheless, it is undeniable that the medical and 'recreational' uses of cannabis have been inextricably linked throughout history. Nevertheless, many highly valued contemporary drugs, immediately recognizable examples include fentanyl and ketamine, unfortunately, do get used

[10] Appendino G, Chianese G, Taglialatela-Scafati O. Cannabinoids: occurrence and medicinal chemistry. Current Medicinal Chemistry 18(7): 1085-1099, 2011
[11] Erkelens JL, Hazekamp A. That which we call *Indica*, by any other name would smell as sweet. Cannabinoids 9: 9-16, 2014
[12] Potter DJ. A review of the cultivation and processing of cannabis (Cannabis sativa L.) for production of prescription medicines in the UK. Drug Testing and Analysis 6(1-2): 31-38, 2014
[13] Hazekamp A, Fischedick JT. Cannabis - from cultivar to chemovar. Drug Testing and Analysis 4(7-8): 660-667, 2012
[14] Swift W, Wong A, Li KM, Arnold JC, McGregor IS. Analysis of cannabis seizures in NSW, Australia: cannabis potency and cannabinoid profile. PloS one, 8(7), e70052, 2013
[15] Pertwee RG. The pharmacology of cannabinoid receptors and their ligands: an overview. International Journal of Obesity 30: S13–S18, 2006

'recreationally'. Their medical use is not prohibited, but highly regulated. It is thus clear that legislative mechanisms and appropriate controls can be devised for such drugs. Regulating the medical use of cannabis ought not be different or present an insurmountable problem - should there be a will - a viewpoint that was reported by the 2000 NSW Premier's Working Party and also given in evidence to the 2013 NSW Legislative Council Inquiry.

My *position* is that, having studied a great deal of the relevant scientific and medical peer-reviewed published evidence about cannabis, I maintain that this evidence inarguably demonstrates cannabis to be a useful medication, and ought to be available to Australian patients in need. I thus maintain that the evidential literature strongly supports appropriate changes to the law, at both Federal and State levels, to enable cannabis and preparations thereof to be reintroduced into the range of medicines available for the treatment of an already identified number of medical conditions, with sufficient flexibility to enable future uses. I have previously written more extensively on this (see above), and have summarised the known and possible uses as reported in peer-reviewed medical/scientific literature in Table 1. I also accept that others may not share my level of acceptance of the evidence, perhaps due to different interpretations of the available material, or perhaps due to influences derived by views on the problems of 'recreational' use of cannabis. In any case, I maintain that projection of risks from 'recreational' use of 'street' cannabis to the medically supervised use of medicinal cannabis, as is commonly done, is quite inappropriate.

I further maintain that, through legislation, this Committee should work to more than permit but to encourage continuing research into the science and medicinal applications of cannabis and its preparations, for both humanitarian and business-related reasons, but I acknowledge that this aspect may bear only a peripheral relationship to the present Bill.

Table 1: Medicinal cannabis

Historically recognized uses for cannabinoid pharmacotherapy

- management of pain of migraine
- management of painful cramps of dysmenorrhoea
- glaucoma treatment (temporary relief)
- epilepsy treatment (and possible treatment for intractable seizures, e.g. in paediatric Dravet syndrome)
- bronchodilation (associated with asthma treatment)

Agreed and prospective uses for cannabinoid pharmacotherapy

- control of refractory nausea/vomiting (e.g. from cancer chemotherapy)
- appetite stimulation (e.g. in patients with HIV-related or cancer-related wasting syndrome
- control of muscle spasticity (e.g. from multiple sclerosis or spinal cord injury)
- pain management (analgesia, especially from neuropathic pain, and as an anti-inflammatory agent)
- anti-convulsant effects (e.g. from epilepsy)

Other investigations for cannabinoid pharmacotherapy

- antitumorigenic uses and direct (local) anticancer treatments
- endocrine-metabolic modification (e.g. in diabetes)
- treatment of post-traumatic stress syndrome
- delaying progression of neurodegenerative conditions (e.g. Alzheimer's disease)
- treatment of various forms of inflammatory bowel disease

The present Bill. This Bill is not a proposal to re-examine the evidence as to whether cannabis has a useful role in contemporary medicine and/or how it should be allowed – it is about how cannabis when used as a medicine should be regulated nationally. Whereas the former is an area within my specific expertise, I have only general expertise regarding the latter, and lean on the Simplified Outline of this Act and the Explanatory Memorandum in preparing this submission.

Present drug policy derives from the 1925 League of Nations summit that was implemented progressively in Australia, eventually leading to total bans on cannabis. By the 1950s and 60s, in a world of growing social drug abuse, the Single Convention of Narcotic Drugs was put in place to regulate cannabis, where it was placed, without research, among other medically-useful drugs that were also capable of abuse, such as cocaine and heroin. Cannabis is, of course, not a 'narcotic' drug (even by the definition of the day), but was seemingly included with the other drugs out of the high moral principles expressed in the Preamble to that Convention. Apart from its regulation according to international treaties and consequent Australian laws, the most serious complication affecting the use of cannabis as medicine lies in its composition, or rather the uncertainty in its composition. Unless selectively modified, cannabis is a variable mixture of natural products, and not a single substance for which purity and strength can be ascertained or be regulated by the operation of the Therapeutic Goods Administration.

In Australia, as elsewhere, many people, including some of whom are patients already under medical care, use cannabis as a medicine, despite its illegality.[16] [17] They do so to relieve distressing symptoms from a number of serious medical conditions, especially when the conventional medicines have been ineffective or accompanied by unacceptable side effects. This is not to say that cannabis is free from side effects – no medication is – but studies examining its side effects have reported that side effects, if occurring, are minimal and acceptable, especially when compared to the untreated symptoms of the condition or with the side effects of conventional medicines that may be used to treat the condition.

Despite its widespread use, and possibly because of it, there have been remarkably few studies that link the chemical composition of cannabis to its therapeutic outcomes. Therein lies a marked gap in our knowledge – and this gap is partly a consequence of the bias in research support (and consequent publication bias) arising from the intentional promotion of research into the harms of 'recreational' cannabis and the dearth of research into the benefits of 'medicinal' cannabis. Evidence in support of this viewpoint lies in the volumes of publications in the 'drug abuse' literature compared to those in the 'applied therapeutics' literature.

Is the fact that cannabis is a *mixture* of substances, as some would claim, a *preclusion* to its role as medicine? Medicinally – not necessarily. Ideologically – frequently.

Until some 50 years ago, pharmacists' formularies and pharmacopoeias were replete with both extemporaneous and proprietary preparations consisting of herbal medicines (e.g., tincture of opium, extract of belladonna). Nowadays, they largely contain totally synthetic substances, purified single substances, or semi-synthetic derivatives of substances extracted from some or other biological matrix (e.g., from animal parts, a mollusc, a fungus or a tree). Notwithstanding, contemporary pharmacists' shelves are replete with what we would commonly term

[16] Swift W, Gates P, Dillon P. Survey of Australians using cannabis for medical purposes. Harm Reduction Journal 2(1): 18, 2005

[17] Degenhardt L, Lintzeris N, Campbell G, Bruno R, Cohen M, Farrell M, Hall WD. Experience of adjunctive cannabis use for chronic non-cancer pain: Findings from the Pain and Opioids IN Treatment (POINT) study. Drug and Alcohol Dependence 147: 144-150, 2015

'complementary medicines', and very many of these are tinctures and extracts of various plants, albeit standardised to some or other degree.

After personal observations of its use in India, Dr William O'Shaughnessy introduced cannabis into European medicine, in 1842, to relieve pain, muscle spasm, convulsions of tetanus, rabies, rheumatism and epilepsy. Cannabis was soon taken into various pharmacopoeias that specified standards, through monographs on its properties and preparation. Its last appearance in the British Pharmaceutical Codex, for example, was in 1949 (BPC 1949).

Like other plants, cannabis contains many families of chemicals, in variable mixture, involved in plant growth and maintenance. Its botanical closest relative is hops. A particular chemical subset in cannabis is the terpenophenol family, and this contains the ingredients that give cannabis its well-known psychotropic effects. The BPC 1949 monograph specified standards for *Extractum Cannabis* and *Tinctura Cannabis* in terms of the total terpene and alcohol concentrations but did not specify any individual cannabinoids because of the absence of information about them and the inability to measure them. Indeed, this was a time when newer, mainly synthetic drugs in pure form were becoming available in large numbers, and these, it was thought, could supplant cannabis. As well, biopharmaceutical issues related to the inefficiency of the (oral) route of drug administration were starting to be appreciated. Cannabis, for which it was now being claimed that there was insufficient evidence to support its ongoing medical use, had become a pharmacotherapeutic casualty. The BPC 1949 monograph stated that "…Cannabis is too unreliable in action to be of value in therapeutics as a cerebral sedative or narcotic…". This statement contained the beginnings of the scientific argument for the demise of cannabis pharmacotherapy that was completed politically for reasons that were neither medical nor scientific.

Contemporary research has focussed on the pharmacological activity of two principal natural cannabinoids – the psychotropic tetrahydrocannabinol (THC), and the non-psychotropic cannabidiol (CBD) – out of the 100 or so known cannabinoids found in cannabis plants in proportions that vary mostly with the strain, but also with the preparation conditions. It is well known that strains have been developed for 'recreational use' and these generally have high THC and low CBD content; conversely, some strains being developed for treatment of neurological disorders have the reverse. Nevertheless, the activity of other natural components needs consideration also, and this is now being recognised. At present, overseas regulation, for example in the Netherlands,[18] [19] is leading to a number of cannabis plant preparations being made available for patient use, and these vary the proportions of THC and CBD to select a preferred mixture. The UK company GW Pharmaceuticals initially developed their product Sativex® (nabiximols) as an equi-part mixture of THC and CBD by blending extracts from two different cannabis strains, with the various minor components of the cannabis plant extracts remaining in the solution.[20] That company is now expanding its range of preparations to other mixtures.

The importance of regulation is thus abundantly clear.

[18] Hazekamp A, Fischedick JT. Cannabis - from cultivar to chemovar. Drug Testing and Analysis 4(7-8): 660-667, 2012
[19] Hazekamp A, Heerdink ER. The prevalence and incidence of medicinal cannabis on prescription in The Netherlands. European Journal of Clinical Pharmacology 69(8): 1575-1580, 2013
[20] Robson PJ. Therapeutic potential of cannabinoid medicines. Drug Testing and Analysis 6(1-2): 24-30, 2014

Contemporary research also is indicating that the mixture of ingredients of cannabis can have greater therapeutic advantage than any of the principal ingredients alone – for cannabis, this has been referred to as the 'entourage' effect.[21] Even more than the principal terpenophenol cannabinoids, others of the myriad noncannabinoid natural ingredients also contribute to the salutary actions attributed to cannabis. This is significant for several reasons.

Foremost, it has become a principle of contemporary pain management that combinations of analgesic substances in smaller dose are frequently more efficacious than larger doses of any one of the substances, and goes further to avoid the side effects of that substance: this principle is known as 'multimodal analgesia'.[22] The movement initiated during the 1980s to introduce THC as a pure drug substance (dronabinol) or various (minor) chemical modifications of THC (e.g. nabilone), was met with mixed success, more negatively reported than positively due to their oral route of administration being excessively variable and uncontrollable, and due, possibly, to the lack of natural adjunctive substances in the medicine. Additionally, the route of administration is an important variable, as it controls both the amount of the substances ultimately taken into the system for effect, and it controls the rate at which they are taken into the system. Transpulmonary administration through vaporisation would, at present, seem to be a suitable mode for such control, although other modes of administration such as oil extracts and 'tea' infusions can introduce blends of other components of the plant in different proportions. The lack of standardisation and regulation becomes immediately apparent, and folk-lore and the internet become the primary pharmacopoeias for such medicinal preparations.

This additionally impinges directly on some of the criticisms frequently aimed at medicinal cannabis – the dose. Indeed, what is the right dose? Cannabis is largely used to treat subjective symptoms – only the patient feels these symptoms and only the patient knows how well they are being treated. Take pain, as it is the prime example for lost productivity and financial burden to society, over and above the burdens imposed on the patients experiencing it, and the carers of those patients.[23] [24] [25] Pain is a major reason for medicinal cannabis use, in Australia as elsewhere.[26] [27] [28] [29]

Overall, the findings fit an emerging pattern that some, not necessarily all, patients may benefit from cannabinoid pharmacotherapy when conventional treatments have failed, and that the side effects in patients from cannabinoid pharmacotherapy are not a deterrent to its use. A pharmacotherapeutic consequence for neural injury and pain is that use of cannabinoids may reduce opioid use, may reduce opioid side effects, may increase efficacy and quality of pain

[21] Russo EB. Taming THC: potential cannabis synergy and phytocannabinoid‐terpenoid entourage effects. British Journal of Pharmacology 163(7): 1344-1364, 2011
[22] Young A, Buvanendran A. Recent advances in multimodal analgesia. Anesthesiology Clinics 30(1): 91-100, 2012
[23] Blyth FM, March LM, Brnabic AJ, Jorm LR, Williamson M, Cousins MJ. Chronic pain in Australia: a prevalence study. Pain 89(2): 127-134, 2001
[24] Blyth FM, March LM, Brnabic AJ, Cousins MJ. Chronic pain and frequent use of health care. Pain 111(1): 51-58, 2004
[25] Leeuwen MT, Blyth FM, March LM, Nicholas MK, Cousins MJ. Chronic pain and reduced work effectiveness: the hidden cost to Australian employers. European Journal of Pain 10(2): 161-161, 2006
[26] Campbell G, Nielsen S, Bruno R, Lintzeris N, Cohen M, Hall W, Larance B, Mattick RP, Degenhardt L. The Pain and Opioids IN Treatment study: characteristics of a cohort using opioids to manage chronic non-cancer pain. Pain 156(2): 231-242, 2015
[27] Bostwick JM. The use of cannabis for management of chronic pain. General Hospital Psychiatry 36(1): 2-3, 2014
[28] Lucas P. Cannabis as an adjunct to or substitute for opiates in the treatment of chronic pain. Journal of Psychoactive Drugs 44(2): 125-133, 2012
[29] Lynch ME, Campbell F. Cannabinoids for treatment of chronic non‐cancer pain; a systematic review of randomized trials. British Journal of Clinical Pharmacology 72(5): 735-744, 2011

management and may assist in more rapid patient rehabilitation.[30] [31] Although it can cause side effects, cannabis lacks life threatening acutely toxic effects even in large overdoses.[32] Cannabinoids offer moderate pain relief, perhaps limited by subjective side effects similarly to opioid analgesics. This allows self-determined individualisation of dosage, because the patient can detect the side effects which may be unpleasant but not potentially life-threatening side effects. In practical terms, the present methods of administration are restricted largely to transpulmonary administration by inhalation, or to oral administration, either by ingestion or by application to oral mucosal membranes of the mouth (as in Sativex®). As noted above, the route of administration affects the pharmacological response via the rate and extent of bioavailability of the agent(s) and/or their metabolites. Titration of dose to effect is facilitated by a minimal delay between dosage and perceived response – this is the "patient controlled analgesia" paradigm used in patients after surgery.

It is common for critics to claim that there is not enough evidence or that the evidence is weak or that there are already sufficient drugs that cater for the pharmacotherapy afforded by cannabis. The present complications of cannabis as a medicine are not due to a lack of evidence, as some would claim – the 'hard-backed' peer-reviewed published evidence supports the use of cannabis as, at least, a second line for numerous conditions that have been reported and analysed in various places, including Australian parliaments, the British House of Lords and the US Institute of Medicine. And it is widely acknowledged that, with continued research, its uses may expand, as there are number of emerging possibilities currently under research where cannabis may have new or particular medical applications not yet reported in the literature. Moreover, I venture to add that there are many drugs in current use, including some supported by PBS listing, for which the evidence of therapeutic efficacy is not as strong as that for cannabis, and this is reinforced when anecdotal evidence is admitted into the argument.

Thus, I maintain that the evidential literature strongly supports changes to the law, at both Federal and State levels, to enable cannabis and preparations thereof to be reintroduced into the range of medicines available for the treatment of an already identified number of medical conditions, with sufficient flexibility to enable future uses. I further maintain that this Committee should encourage strong support for continuing research into the science and medicinal applications of cannabis and its preparations, for both humanitarian and commercial reasons.

Various of the state and territory governments are presently examining the evidence concerning medicinal uses of cannabis, and how it should be dealt with by legislation. This includes whether and how it should be lawfully prescribed and dispensed as a pharmaceutical preparation, or at least lawfully allowed to be used, with the patient and/or carer being responsible for its acquisition and quality. However, it is proceeding in a state-by-state or territory basis, with notable differences, and this will inevitably lead to problems, unforeseen and otherwise.

How to permit and regulate cannabis and cannabis preparations for medicinal use has been a major stumbling-block to present state and territory governmental inquiries. If this Bill will allow a mechanism for the Federal production, regulation and permission of cannabis use as a medicine, including production and research, and to allow State and Territory governments to

[30] Notcutt W, Price M, Miller R, Newport S, Phillips C, Simmons S, Sansom C. Initial experiences with medicinal extracts of cannabis for chronic pain: results from 34 'N of 1'studies. Anaesthesia 59(5): 440-452, 2004
[31] Serpell MG, Notcutt W, Collin c. sativex long-term use: an open-label trial in patients with spasticity due to multiple sclerosis. Journal of Neurology 260(1): 285-295, 2013
[32] Robson P. Abuse potential and psychoactive effects of δ-9-tetrahydrocannabinol and cannabidiol oromucosal spray (Sativex), a new cannabinoid medicine. Expert Opinion on Drug Safety 10(5): 675-685, 2011

adopt the code of regulation afforded Federally, then surely this seems a beneficial way of precluding inharmonious local legislation and the errors of the past. A nation-wide code seems both sensible and economical.

In a recent *Perspectives* piece in the Medical Journal of Australia, respected physician Professor David Pennington wrote that "Cannabis can never be a pharmaceutical agent in the usual sense for medical prescription, as it contains a variety of components of variable potency and actions, depending on its origin, preparation and route of administration. Consequently, cannabis has variable effects in individuals. It will not be possible to determine universally safe dosage of cannabis for individuals based on a clinical trial."[33] This first part of this is true because cannabis is a mixture, and it can't be evaluated under the present working model of the TGA. The second part of this is also true, but only sort-of. All subjective symptom treatments are as variable as the patients and their conditions that warrant the treatment, and a reasonable preparation used with a route of administration that allows the patient to rapidly assess any benefits and side effects, minimises the risks of toxicity. This is significant because the toxicity of cannabis is largely subjective, and this compared favourably with the risk of fatality associated with many substances, e.g. opioid or nonsteroidal anti-inflammatory drugs, that might be used to treat the same conditions. Regardless, the Regulator would in large measure assist in standardisation of the cannabis substance, and a model such as that used in the Netherlands would be an efficient way of fulfilling the requirements.[34]

I note also that this Bill is acknowledging that research and development of medicinal cannabis is a growing field of science, and that it is important that research into types and strains of cannabinoids and medicinal cannabis be encouraged and furthered by the Regulator. I note that the experimental cannabis licensing scheme will allow authorised persons to develop, evaluate, test and improve cannabis products for medicinal purposes. The Regulator will also be responsible for issuing licences and prescribing a scheme for research and experiments with medicinal cannabis. These aspects are laudable.

I offer the additional comment that the Regulator, working in concert with academic or commercial laboratories, could go a long way to facilitating knowledge and safety by facilitating a laboratory enabled to analyse samples of cannabis associated with pharmacotherapy and toxicity.[35]

If this Bill will allow a mechanism for production and presentation of cannabis preparations at a cost affordable to Australian patients, either through PBS or non-PBS listing, whether by 'big pharma' companies or otherwise, then it will be a benefit to the Australian people, and I commend it.

END OF SUBMISSION

[33] Pennington DG. Medical cannabis: time for clear thinking. Medical Journal of Australia 202: 74-76, 2015
[34] CIBG Ministerie van Volksgezondheid, Welzijn en Sport Informatieclip: The Office of Medicinal Cannabis. BMC English. Available at http://youtu.be/hE60il2pI_k
[35] Atakan Z, Bhattacharyya S, Allen P, Martín-Santos R, Crippa JA, et al. Cannabis affects people differently: inter-subject variation in the psychotogenic effects of Δ9-tetrahydrocannabinol: a functional magnetic resonance imaging study with healthy volunteers. Psychological Medicine 43(06): 1255-1267, 2013