Submission

on the

Regulator of Medicinal Cannabis Bill 2014

to the

Senate Legal and Constitutional Affairs Committee

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1. Introduction

On 12 February 2015, Senator Richard Di Natale, Senator Ian Macdonald, Senator David Leyonhjelm, and Senator Anne Urquhart introduced the *Regulator of Medicinal Cannabis Bill 2014* in the Commonwealth parliament. On the same day the Senate referred the Bill to the Legal and Constitutional Affairs Legislation Committee for inquiry and report. Submissions are due by 13 March 2014.

The *Regulator of Medicinal Cannabis Bill 2014* (hereafter designated "the Bill") would establish a Regulator of Medicinal Cannabis to be responsible for formulating rules and monitoring compliance with those rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis. It would also provide for a national system to regulate the cultivation, production and use of medicinal cannabis products, and related activities such as research.

FamilyVoice Australia is a national Christian voice – promoting true family values for the benefit of all Australians. Our vision is to see strong families at the heart of a healthy society: where marriage is honoured, human life is respected, families can flourish, Australia's Christian heritage is valued, and fundamental freedoms are enjoyed.

We work with people from all major Christian denominations. We engage with parliamentarians of all political persuasions and are independent of all political parties. We have full-time FamilyVoice representatives in all states of Australia.

FamilyVoice Australia has a longstanding interest in promoting the health of Australian families and welcomes the opportunity to contribute to this inquiry.

2. Research on safety and efficacy of medicinal cannabis

Senator Di Natale rejects the need for more research on medicinal cannabis products, claiming there is "overwhelming" proof of their effectiveness:

> *Australian Greens health spokesperson and Co-convenor of the Parliamentary Group for Drug Policy and Law Reform, Dr Richard Di Natale, said today that a medicinal cannabis trial falls short of the reform we need. …*
>
> *"There is already overwhelming international evidence that medicinal cannabis can provide relief from conditions like nausea, pain and muscle spasms. Cancer patients undergoing chemotherapy have been needlessly denied access to this kind of medical relief for far too long.*
>
> *"Medicinal cannabis should be made available for those conditions where it has been proven to be effective now, without delay, without a trial.*[1]

But the allegedly "overwhelming" proof has not convinced professional medical associations.

Dr Tony Bartone, President of the Australian Medical Association (Victoria) said any new drug coming onto the Australian market, including forms of medicinal cannabis, should be tested by the Therapeutic Goods Administration (TGA). He rejected any legalisation of the crude plant form of cannabis for medicinal purposes, because its composition is so variable.[2]

Pharmaceutical Society of Australia President Grant Kardachi has been similarly cautious:

> *I believe we must ensure that any therapeutic products available for public use are assessed for safety and efficacy and this is a key challenge surrounding pharmaceutical cannabinoids and crude cannabis products.* ***The available research is confusing*** *with studies supporting and rejecting the benefits of medical use of cannabis so we must carefully assess this research when developing a position.*[3] [emphasis added]

President of the Royal Australasian College of Physicians (RACP) Professor Nicholas Talley welcomed NSW medicinal cannabis trials announced late in 2014 and cautioned against legalisation without them:

> *We have been urging Australian governments at all levels to* ***urgently support further clinical trials*** *into the use of medicinal cannabis. Without this evidence it is impossible to weigh the benefits and risks or be able to safely prescribe its use for patients.*
>
> *Good quality clinical research will provide doctors and decision-makers with clear and indisputable conclusions regarding the total health impacts of medicinal cannabis.*
>
> *Until then we must proceed with caution.*[4] [emphasis added]

In February this year, the RACP President challenged proponents of medicinal cannabis to consider the effects on patients. Patients rightly expect that their doctors prescribe good medicines. But he expressed great concern that "we just don't know" whether "medicinal cannabis will help … for many chronic conditions."[5]

In a submission to this inquiry, epidemiologist Professor Wayne Hall of the University of Queensland, who has worked with the Pharmaceutical Benefits Advisory Committee and the TGA, warns:

> *An informed policy towards the medical use of cannabinoids* ***requires much better evidence*** *than we currently have.*
>
> *First, we need clinical trials of the safety and efficacy of CBD and other cannabinoids in treating intractable epilepsy and chronic pain.* ***Evidence from these trials is essential*** *for rational decisions to be made about the medical use of cannabinoids.*[6] [emphasis added]

3. Requirements for valid trials

Dr John Whitehall, professor of paediatrics at the University of Western Sydney, has outlined the complex procedures needed for valid trials in an article published in *Quadrant* (October 2014). He said (in part):

> *Research on the medical value of a substance begins with pre-clinical consideration of biological plausibility, purification of product, standardisation of dose, understanding of absorption, bodily distribution, breakdown and excretion, and evaluation in animal studies.*
>
> *It then moves through ascending phases of complexity, beginning in a small cohort of healthy human volunteers to whom the drug is administered in increasing doses, then to a larger but restricted cohort of people affected by a diagnosed disease, and then, if results permit, to a broad cohort of a thousand or more patients in which the drug is usually compared with a placebo in a blinded, randomised, cross-over pattern.*
>
> *If the drug is known to lead to tolerance and dependency and to have side effects that accrue over time, the balance of benefit and side effect may be very difficult to assess, and the study will be prolonged. Ultimately, the proposed therapy must be compared with known alternatives.*[7]

Overseas trials of medicinal cannabis trials have not complied with this standard. The results of the NSW Government medicinal cannabis trials will not be available for up to five years.[8]

Dr Whitehall explains the need for such a high standard of testing:

> *This rigorous vetting process has evolved in order to prevent such tragedies as the effects of thalidomide on the unborn. It seemed a good idea at the time to give the drug to pregnant women because it reduced morning sickness. But no evaluations of unexpected complications had been performed, and babies were born without limbs. The vetting process is mandated in Australia by the Therapeutic Goods Act and protects against unwanted results from "good ideas". It also protects against vested ideological and financial interests.*
>
> *Many of the side effects of cannabis are already known, as is its popular ability to produce an altered mental state. But its anti-epileptic effect is unknown and ought to be submitted to the standard rigorous assessment. Particular difficulties for scientific analysis of the raw herb and epilepsy would involve its varying composition, the variety of molecular bases and the genetic predisposition of epilepsy, the unknown pharmacology in children (how much is absorbed, where does it accumulate, how fast is it destroyed and where?), the difficulty in measuring effect (convulsions range from "grand" to so "petit" they may not be obvious, and how do you count them at night?), the difficulty in measuring neurological and psychological effect (it can take hours to assess these, especially in a child with disabilities; how often should they be performed and by whom?), and the difficulty in assessing side effects (one anti-epileptic drug which appeared effective was discontinued when long-term follow-up revealed an unwanted effect on blood).*
>
> *Other difficulties result from the rarity of some epileptic diseases, which will make statistical assessment very difficult, as will their often contrary response to medication. Worse, sudden unexpected death is much more common than realised, with a reported six per cent of sufferers of Dravet Syndrome dying each year in ways not explained by convulsions themselves. Perhaps the molecular problem that predisposes to epilepsy exists in cardiac muscle as well as the brain.*
>
> *Another problem for rushed research on cannabis might be the opinion of "ethics committees" which must approve research in hospitals and universities. It would be interesting to see response to an application for a trial on children of a substance you could not chemically define, for effects that might not be obvious, with known ability to shrink a brain or precipitate madness, and create dependence in nine per cent, complicated by the expectation of sudden death, underpinned by contradictory effects on animals, and all because it seemed a wonderful idea to the media, and had the support of a few politicians!*[9]

4. The role of the Therapeutic Goods Administration

The Explanatory Memorandum states: "This Bill provides for a system of regulating medicinal cannabis that is entirely separate from the TGA."[10]

Yet the purpose of the Therapeutic Goods Administration (TGA) is to protect the Australian public from medicines with doubtful benefits and unacceptable risks. The TGA assesses medicines and medical devices to ensure that "the balance of benefits to risks is acceptable".[11]

The TGA assesses and regulates all of Australia's imports and exports, supply, manufacturing and advertising of medicines and medical devices.

The TGA already employs "highly qualified TGA staff [who] must read, analyse, question and evaluate thousands of pages of documentation to assess the quality, safety and efficacy of new, higher risk prescription medicines."[12]

Senator Di Natale provides no justification for a separate regulator to duplicate the role of the TGA for one type of drug.

The *UN Single Convention on Narcotic Drugs* and the *Narcotic Drugs Act* allow the regulation of opium and cannabis for medicinal purposes under strict conditions, as long as these drugs are banned for non-medicinal use.

In theory, the *Narcotic Drugs Act* could be amended to allow medicinal cannabis production and distribution to be controlled in Australia similar to the way opium is now. There would be no need to introduce a completely new legislation such as the Regulator of Medicinal Cannabis Bill.

However, cannabis is not analogous to opium in a very significant way.

Opium and its derivatives have a proven track record over many years in relieving severe pain. They have side effects of addiction and sedation, but if there are proper controls, authorities consider the side effects acceptable because of the drug's greater benefits.

By contrast, as discussed earlier, there is no valid evidence for the safety and efficacy of medicinal cannabis. There have so far been no properly conducted, large sample, double-blind, long-term trials with a matched control group using an alternative approved medication, for the use of cannabis or its derivatives in relieving specific conditions.

Such trials need to measure possible long-term effects including serious mental ill-health and cognitive impairment. It will be several years at least before valid evidence about the safety and effectiveness of synthetic or derived cannabis medicines are available. At present there is no justification for treating cannabis as a medicine under legislation similar to that relating to opium and its derivatives.

A NSW Legislative Council Committee recommended the legalisation of crude cannabis for medicinal use in 2013, but the NSW Government rejected the recommendation – instead supporting the use of cannabis products that had been approved by the TGA:

> *The Government supports the use of prescription pharmaceutical cannabis products that are approved and regulated by the Therapeutic Goods Administration (TGA) as these products have been assessed for quality, safety and clinical efficacy.*[13]

The NSW Government's response pointed out that:

- crude cannabis products cannot have guaranteed "potency and safety";
- there is limited evidence in support of the efficacy of crude cannabis; and,
- the Government has comprehensive pain relief options and palliative care.[14]

5. TGA-approved cannabis products already available

Senator Di Natale introduced the Bill by appealing to "peer reviewed and reputable medical and scientific journals supporting the use of medicinal cannabis under strict regulations."[15] He failed to acknowledge that some medicinal cannabis products are already available.

The TGA has approved the use of three synthetic or derived cannabis products under certain circumstances:

- Nabilone (Cesamet) – A synthetic cannabinoid used for treatment of anorexia and for its anti-vomiting effects (for example in cancer patients under chemotherapy);[16]
- Dronabinol (Marinol) – A synthetic cannabinoid used in multiple sclerosis and pain patients;[17]
- Nabiximols (Sativex) – A synthetic oral spray for use in patients with moderate to severe spasticity due to multiple sclerosis.[18,19]

Only medical practitioners may prescribe these drugs, after approval by the Secretary of the Commonwealth Department of Health and Ageing. Section 19 of the *Therapeutic Goods Act 1989* provides for the limited use under special circumstances of drugs that are not approved for general use in Australia.[20]

Thus patients can already access approved, properly controlled cannabis products to relieve certain medical conditions.

5.1. High cost of some medicinal cannabis

In Submission 2 to this inquiry, The Don Medicinal Cannabis company argues that Sativex is too expensive:

> *In New Zealand, an average annual prescription of Sativex costs about $16,000. Likewise, according to Professor Gavin Giovannoni of the London School of Medicine, Sativex has "not proven to be cost effective" in the UK, which has led to a large number of MS patients to continue using illegal forms of cannabis.*[21]

According to an estimate for Australia, Sativex would cost patients around $6-10,000 yearly.[22]

The Pharmaceutical Benefits Scheme subsidises certain drugs with proven safety and effectiveness. However as Professor Wayne Hall notes, "there are now much more effective drugs available." He says it is therefore "arguably unfair to subsidise" cannabinoids which are "at best modestly effective for some purposes", but "not to subsidise other pharmaceuticals for which there is better evidence of efficacy."[23]

6. International experience

Proponents of crude cannabis point to the growing number of countries or states that have legalised its medicinal use. But evidence from the USA suggests that the outcome is questionable at best:

Professor John Whitehall reports (edited):

> *We need to examine the US experience closely, because it contains great warnings. The push for medical marijuana began with compassionate attempts to relieve pain in dying patients, but has declined into mayhem. A time-honoured system of medical care is suffocating in "prescriptions" for cannabis.*
>
> *California legalised marijuana for the medical purposes of relieving pain, anorexia, vomiting, nausea and epilepsy in 1996. Since then, 22 other states have followed suit with many different laws and practices that function despite federal prohibition. The meanings of the words* doctor, patient care, prescription, dispensary and carer *in the US system of medical*

> *marijuana do not carry the Australian meanings. Nor do they carry the original meanings in the US.*
>
> *Essentially, the role of the doctor is merely to listen to the client's claim to have one or more of the several symptoms for which marijuana can be supplied. Without any legal or ethical obligation to question, examine, investigate or contact other physicians for past history, the doctor is merely obliged to check the patient's identification before signing a prescription for marijuana.*
>
> *The "prescription" does not carry our Australian meaning. It is merely a prescription the "patient" can produce to an inquisitive policeman to show that marijuana is possessed for medical reasons. In some states, the doctor must forward a minimum of information about the patient and his prescription to central authorities. For his services, the doctor will receive at least $100. Though the prescription will last for one year, there is no requirement to see the doctor again. At present, it can be renewed indefinitely by merely paying a $20 annual fee to the state.*
>
> *The "patient" then heads for a "dispensary", which is nothing like one of our pharmacies. Dispensaries are basically shops of varying attractiveness that cluster in suitable parts of the city to sell the marijuana herb and all its paraphernalia.*
>
> *The shop assistant (not the doctor) suggests the type and dose of marijuana suitable for the complaint, and is permitted by law to sell certain maximum quantities per visit. In Colorado it is two ounces, or six plants, three of which must not be mature. Under "special circumstances" the limit may be increased but, in any case, there is no limit to the number of regular purchases.*
>
> *The shopkeeper procures processed marijuana and plants from private growers who have been known to set up mobile "clinics" in caravans next to the "dispensary" on advertised days to ensure fresh and abundant supply. "Care givers" may be nominated to grow the herb on behalf of the patient and a "carer" may grow for more than one patient. Some have been found "caring" for as many as six patients. It is not surprising that produce has been diverted into the black market.*
>
> *Parents can apply on behalf of minors less than 18 years old. The only stipulation is that two doctors must sign the prescription. As of June 2014, 357 minors were registered in Colorado. According to registration data, 50 Colorado physicians were responsible for 85 per cent of the "prescriptions". A small group of 15 doctors was responsible for 49 per cent, with one single doctor registering six per cent of all patients. After its effective legalisation in October 2009, 163,856 people were registered for medical marijuana by 2011: over two per cent of the state's population.*

6.1. Vaguely worded US laws lead to abuse

Dr Whitehall continues:

> *Many of the doctors were "principally or exclusively" involved in this branch of medicine. The conflict of interest was obvious, especially as some doctors "practised" in a marijuana dispensary. The odour of corruption prompted the Colorado senate to legislate in 2010 against marijuana physicians from holding "an economic interest" in supply, and from practising within dispensaries. The Senate Bill 109 also sought to ensure a "bona fide" doctor-patient relationship, which would involve "full assessment of the patient's medical history and current condition", and availability for follow-up.*

> *But there is doubt that the system has changed. There is no obligation on the doctor to be educated about marijuana, to record failure of other treatments, to identify who might be harmed by the drug (such as pregnant women or the mentally ill) or who might be addicted to other drugs. Colorado is not unique. In Arizona, where doctors of osteopathy, homeopathy and naturopathy as well as medical physicians can issue marijuana certificates, only 24 doctors signed 73 per cent of the 28,977 registrations in an early year after legalisation. They comprised 17 naturopaths, one osteopath and only six of the state's 22,111 medical doctors. One survey of 520 physicians in Colorado revealed that 46 per cent did not support medical marijuana, and only 19 per cent believed doctors should prescribe it. Most agreed marijuana poses serious mental (64 per cent) and physical (61 per cent) risks. A minority believed it conferred physical (27 per cent) and mental (15 per cent) benefits. The media was a major source of education about marijuana for the physicians, with doctors complaining of a lack of formal education.*[24]

6.2. Child victims of medicinal cannabis

William Hurley from the Washington Poison Center, and Suzan Mazor of Seattle Children's Hospital reported on the dangers to children who have ingested the edible forms of medicinal cannabis available in states such as Colorado and Washington, in the JAMA *Pediatrics* journal in 2013.

After decriminalisation of medicinal marijuana in Colorado:

> *Accidental ingestion of marijuana by children [occurred through] attractive and palatable marijuana-infused solid and liquid products, including cookies, candies, brownies and beverages. …*
>
> *Ingestion of marijuana results in … hallucinations and illusions, followed by sedation. Toxic reactions are usually mild after acute accidental ingestion but can cause significant sedation in children. Respiratory insufficiency and the need for ventilator support are described in the article. In older children, the stimulatory phase and hallucinations can produce anxiety and panic episodes.*[25]

6.3. Opposition from US medical associations

Drug Free Australia reports that:

> *Peak organisations such as the Australian Medical Association, the American Medical Association, the American College of Physicians, the American Nurses Association, the American Cancer Society, the American Glaucoma Foundation, the National Multiple Sclerosis Society, the American Academy of Pediatrics and the American Society of Addiction Medicine all support the [Food and Drug Administration] approval process and have expressed either opposition to or concern over the use of smoked marijuana as a therapeutic product.*[26]

7. Uncertainty of regulation rules

The Bill's Explanatory Memorandum states: "The registration process and the register will have a number of rules … The Bill leaves detail, such as the manner in which the register is to be maintained, to the rules rather than setting it out in the Bill … to give the Regulator … flexibility…"[27]

Thus there is no way senators debating this Bill can know exactly what the rules are likely to be, or the validity of any of the Regulator's "flexible" approaches to regulation.

There is no requirement in the Bill to indicate that the regulator – which, according to section 34(4), must include a medical practitioner such as a GP, a member of the Australian Federal Police and a medicinal cannabis patient advocate – would insist on scientifically valid trials with the high standards specified above by Professor John Whitehall.

Indeed, the inclusion of a patient advocate/activist on the regulator could suggest that a lower standard of proof of the cannabis product's safety and effectiveness may suffice.

There is certainly no evidence that the regulator would insist on standards equal to or greater than those required by the TGA. The Bill is, in effect, a "pig in a poke". There is no way of knowing what its rules would be before the Bill is enacted.

8. Conclusion

Reliable and effective ways of addressing the regulation of medicinal cannabis – such as the Therapeutic Goods Administration – are already available.

The US experience of regulated medicinal cannabis use does not inspire confidence that a similar system would be safe or effective in Australia.

Recommendation:

Since the Regulator of Medicinal Cannabis Bill 2014 would bypass the Therapeutic Goods Administration, which already assesses the safety and efficacy of medicines, the Bill should be rejected.

9. Endnotes

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[2] Adrian Rollins, "Govts back historic cannabis trial", Australian Medical Association (28 Oct 2014): https://ama.com.au/ausmed/govts-back-historic-cannabis-trial

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[4] "NSW Government funding for medicinal cannabis trials will provide better health outcomes for patients", *Media Release*, Royal Australasian College of Physicians (22 December 2014): https://www.racp.edu.au/download.cfm?DownloadFile=6FF61978-BBFF-184F-A8F075F797C0D969.

[5] "Medicinal cannabis - a 'wicked problem'?", *Opinion piece*, Royal Australasian College of Physicians (25 Feb 2015), p 2: https://www.racp.edu.au/download.cfm?DownloadFile=C8846712-CC8C-25D8-03DC7D50AC2A949A

[6] Wayne Hall, "Regulator of Medicinal Cannabis Bill 2014: Submission 4", (3 Mar 2015), p 13: http://www.aph.gov.au/DocumentStore.ashx?id=78def552-f381-454f-afb5-9190691d4b5f&subId=304156

[7] John Whitehall, "The Comforting Myths of Medical Marijuana", *Quadrant*, Volume LVIII, No 10 (October 2014).

[8] "Clinical Trials: Medical Use of Cannabis", Fact Sheet, NSW Government (19 December 2014), p 1: http://www.health.nsw.gov.au/cannabis/Documents/fs-cannabis-trials.pdf accessed 12 Mar 2015.

[9] John Whitehall, "The Comforting Myths of Medical Marijuana", loc cit.

[10] The Parliament of the Commonwealth of Australia, "Regulator of Medicinal Cannabis Bill 2014: Explanatory Memorandum", 2014, p 1.

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[13] NSW Government, "NSW Government response to the Legislative Council General Purpose Standing Committee No 4 Report: The use of cannabis for medical purposes", 15 Nov 2013, p 2: http://www.parliament.nsw.gov.au/prod/parlment/committee.nsf/0/fdb7842246a5ab71ca257b6c0002f09b/$FILE/Government%20response%20-%20Use%20of%20cannabis.pdf

[14] NSW Government, "NSW Government response to the Legislative Council General Purpose Standing Committee No 4 Report: The use of cannabis for medical purposes", loc cit, p 2.

[15] Parliament of Australia, Senate Hansard, 27 Nov 2014, p 9507: http://parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansards/401b7784-0565-4469-9567-5d886c2a507c/0086/hansard_frag.pdf;fileType=application%2Fpdf

[16] Final Decisions & Reasons for Decisions by Delegates of the Secretary to the Department of Health and Ageing, Department of Health and Ageing, Jul 2011, p 1: https://www.tga.gov.au/scheduling-decision-final/reasons-scheduling-delegates-final-decisions-july-2011

[17] Ibid.

[18] Poisons Standard 2012, Schedule 8.

[19] Therapeutic Goods Administration, *Australian Public Assessment Report for Nabiximols*, Department of Health (September 2013).

[20] Poisons Standard 2012, Appendix D, Section 3.

[21] "The Don Medicinal Cannabis: Submission 2", (22 February 2015), p 2: http://www.aph.gov.au/DocumentStore.ashx?id=7b65288e-c7e3-4213-92c8-f210708534ac&subId=303577

[22] The Conversation, "Australia has no reason to disallow medical cannabis use", (26 Mar 2014), http://theconversation.com/australia-has-no-reason-to-disallow-medical-cannabis-use-24717.

[23] Wayne Hall, "Regulator of Medicinal Cannabis Bill 2014 Submission 4", loc cit, p. 12.

[24] John Whitehall, "The Comforting Myths of Medical Marijuana", loc cit.

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[27] Regulator of Medicinal Cannabis Bill 2014, Explanatory Memorandum, Part 2, p. 3.