Submission

on the

Issues Paper March 2015: Medicinal Cannabis

to the

Victorian Law Reform Commission

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1. Introduction

On 17 March 2015, the Victorian Law Reform Commission (VLRC) published an Issues Paper on Medicinal Cannabis after the Attorney-General Hon Martin Pakula MLC provided terms of reference on 19 December 2014.

The VLRC chair, Hon P D Cummins AM, notes in his Preface to the Issues Paper:

> *The Victorian Government has asked the Victorian Law Reform Commission to review and report on options for legislative change to allow people to be treated with medicinal cannabis in exceptional circumstances. The Commission has not been asked whether such a change is desirable, which is a matter for government. However, in reviewing options for legislative change, the Commission necessarily will examine the benefits, efficacy, risks and dangers involved in each.*
>
> *The Commission has not been asked the wider question of whether cannabis production and use more generally should be permitted. The review is confined to medicinal cannabis in exceptional circumstances. A central question in the review is the definition of what properly constitutes exceptional circumstances for this purpose.*
>
> *Developing options for legislative change is not merely a technical exercise in removing some of the existing prohibitions on possessing and using cannabis; it is also necessary to build an avenue of health care. Medicinal cannabis, if allowed, would need to be administered as an integral part of the treatment the patient receives, based on a safe and reliable supply, under the supervision of a health practitioner.*[1]

The broad purpose of the Issues Paper is to discuss two key questions. First, who should be eligible to use cannabis for medical purposes? Second, how extensive should any Victorian medicinal cannabis scheme be?[2]

Submissions are due by 20 April 2015.

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 the VLRC review.

2. General overview

As noted in the Introduction above, the VLRC Chair has pointed out that:

> *The Victorian Government has asked the Victorian Law Reform Commission to review and report on options for legislative change to allow people to be treated with medicinal cannabis*

> *in exceptional circumstances. The Commission has not been asked whether such a change is desirable…*

The evidence presented in the Issues Paper on the limited, unproven or negative health benefits of medicinal cannabis – contrasted with the serious mental health, cognitive and other risks associated with the use of cannabis for any purpose – indicates that such a change would not be desirable or in the public interest.

The Issues Paper also notes that: "Victoria is able to observe and consider the experience of other jurisdictions which have experimented with various systems and approaches to the regulation and supply of cannabis for medicinal purposes."[3]

Evidence from US states where medicinal cannabis has been legalised indicates that this law change has resulted in significantly increased non-medicinal cannabis use – possibly due to the sentiment that "if it's an approved medicine, it must be healthy".

This evidence of increased non-medicinal use – a negative impact of the legislative change – does not appear in the Issues Paper. The Paper tends to detail the legislation and regulations in these states, rather than the resulting impact on the community. Some of the relevant evidence is included in this submission.

The very rare "exceptional circumstances" that could justify the medicinal use of cannabis can be accommodated by existing Commonwealth legislation regulating the Therapeutic Goods Administration.

The 17 questions at the end of the Issues Paper presuppose that legalising or regulating the medicinal use of cannabis in the state of Victoria would be a good thing. Such a presupposition is unfortunate, given the Chair's words in the Preface quoted above.

Evidence for retaining the current state laws is outlined below.

3. The science is not settled

The Issues Paper notes that scientific trials of medicinal cannabis have often used invalid methodology.[4]

It is premature for Victoria to proceed with legislation authorising the medicinal use of cannabis while the evidence of its medicinal benefits and risks is far from conclusive.

President of the Australian Medical Association (Victoria) Dr Tony Bartone has said that 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.[5]

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.*[6] [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 trials:

> *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.*[7] [emphasis added]

In February this year, the RACP President challenged proponents of medical 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."[8]

In a submission to the 2014 , 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.*[9] [emphasis added]

4. Requirements for valid trials

Before Victoria legalises any production, supply, processing or distribution of cannabis in any form, proper clinical trials must be undertaken.

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.* [10]

Overseas trials of medicinal cannabis have not complied with this standard. The results of the NSW Government medicinal cannabis trials will not be available for up to five years.[11]

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!*[12]

5. Australia already has proven methods of drug regulation

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".[13]

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."[14]

The VLRC 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 completely new legislation.

However, cannabis is not comparable with 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 very few 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.*[15]

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.[16]

6. Medicinal cannabis is 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 undergoing chemotherapy);
- Dronabinol (Marinol) – a synthetic cannabinoid used in multiple sclerosis and pain patients;[17] and
- 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.

Under paragraph 4.10, the VLRC note its concern is not primarily with the above drugs, which are listed under Schedule 8 of the Commonwealth's *Standard for the Uniform Scheduling of Medicines and Poisons No 6 (SUSMP).* Rather, they are interested in legislating for other forms of cannabis, as under Schedule 9 of the SUSMP.

Substances classified under Schedule 8 are drugs that should be controlled. SUSMP explains Schedule 8 as:

> *Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.* [21]

Morphine, and the pharmaceutical cannabis products Nabilone, Dronabinol and Nabiximols are all classified under Schedule 8.

On the other hand, substances in Schedule 9 are prohibited:

> *Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.*[22]

It is irresponsible to promote the legalisation of substances capable of being "abused or misused", whose medicinal benefits are largely unproven.

7. 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 has reported as follows:

> *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.[23]

7.1. Vaguely worded US laws lead to abuse

Dr Whitehall has further documented abuse of US schemes:

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]

7.2. 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.

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]

7.3. Opposition from US medical associations

Drug Free Australia has reported that numerous US medical associations have expressed concern:

> *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]

8. Questions

8.1. Exceptional circumstances

> *1. Which of the following considerations should determine whether there are exceptional circumstances for medicinal cannabis to be made available to a patient:*
>
> *(a) the circumstances of the patient*
>
> *(b) the state of clinical knowledge about the efficacy or potential efficacy of using cannabis in treating the patient's condition*
>
> *(c) both of the above?*

Answer: (c). Both the circumstances of the patient and the state of clinical knowledge about the efficacy or potential efficacy of using cannabis in treating the patient's condition are important.

The circumstances and clinical knowledge should be assessed by the Commonwealth Therapeutic Goods Administration (TGA), as discussed in section 5 above.

The TGA assesses high risk medicines – and evidence suggests that medicinal cannabis is high risk – for quality, safety and efficacy.[27] Scientists and clinicians evaluate the data on a drug, taking "approximately 11 months to evaluate one new higher risk prescription medicine."[28]

8.2. Conditions for lawful use

> *2. For what conditions is there sufficient knowledge of the therapeutic benefits, dangers, risks and side effects of cannabis to justify allowing sufferers to use it lawfully in Victoria?*

The TGA is best placed to decide on the justification of the use of cannabis, as discussed in section 8.1, "Exceptional circumstances".

It is irresponsible for the VLRC to consider a separate scheme that might conflict with determinations made by the TGA.

8.3. Eligibility for lawful use

> *4. On which of the following should the law creating a medicinal cannabis scheme base a person's eligibility to use medicinal cannabis:*
>
> *(a) a list of medical conditions*
>
> *(b) a list of symptoms*
>
> *(c) a list of symptoms arising from certain medical conditions*
>
> *(d) evidence that all reasonable conventional treatments have been tried and failed?*

The TGA is best placed to assess and prescribe the circumstances in which a drug can be used, as discussed in section 8.1. "Exceptional circumstances".

8.4. Special cases for lawful use

> *5. Should there be a way to allow for special cases where a person who is otherwise ineligible may use medicinal cannabis? If so, what should that be?*

Again, the TGA is best placed to assess and prescribe the circumstances in which a drug can be used, as discussed in section 8.1, "Exceptional circumstances".

There is a mechanism for special uses of drugs already available under section 19 of the *Therapeutic Goods Act 1989* (Cth). The NSW Parliamentary Research Service explains the scheme:

> ***Special Access Scheme***
>
> *Under this scheme, certain categories of patients may obtain access to a drug. The controls applied depend on the category of patient for whom the drugs are intended.*
>
> - Category A (patients who are terminally or seriously ill with life-threatening conditions): *These patients do not have to obtain TGA approval to use/import the drug; in effect, the treating doctor approves the use.*
> - Category B (patients who are suffering from a life-threatening condition, even if they are not critically ill): *These patients need TGA approval to use. Drugs approved for use by*

> *patients in this category have generally been the subject of at least Phase 1 clinical trials in humans.*
>
> - Category C (patients who are suffering from a serious but not life-threatening illness): *These patients also need TGA approval to use the drug. Drugs approved for use by patients in this category must have been put through exhaustive clinical trials to test their efficacy and safety for human use. Normally the drugs would have been subjected to all the clinical trials needed to support a marketing application.*
>
> *It was under the Special Access Scheme that the synthetic cannabinoid, dronabinol, was imported and used for the treatment of HIV wasting syndrome. The NSW Working Party on the use of cannabis for medicinal purposes concluded that this was not a viable option to consider as the costs of obtaining access to such drugs was prohibitive for the majority of eligible patients.*[29]

Essentially, the TGA is properly and lawfully equipped to deal with "special cases". A parallel scheme is unnecessary.

8.5. Cultivation of medicinal cannabis

> *9. What mechanism should Victoria use to regulate the cultivation of medicinal cannabis?*

As discussed in section 6 "Medicinal cannabis is already available", section 19 of the *Therapeutic Goods Act 1989* provides for limited use under special circumstances of drugs that are not approved for general use in Australia.[30] The special circumstances include clinical trials, which if successful may lead to approval of the drug.

Drugs need to be approved by the TGA to be registered on the Australian Register of Therapeutic Goods (ARTG). Without being registered as a therapeutic product on the ARTG, cannabis may not be produced, prescribed, or marketed for use as a therapeutic product.[31]

It is not necessary for Victoria, or any juridistiction, to establish another scheme under which medicinal cannabis can be produced.

It will be years until valid clinical trials are conducted and use of cannabis is approved for a specific purpose by the TGA – if they approve any more uses at all.

8.6. Processing and distribution

> *10. What approach, or approaches, should Victoria take to regulating how medicinal cannabis is processed and distributed?*

A separate scheme is not necessary. Once a product is TGA approved, pharmacists can distribute the product. This is the normal and lawful approach for almost all drugs in Australia, and does not introduce problems which fall outside Victoria's jurisdiction as cited in paragraph 7.41.

As part of a clinical trial, medicinal cannabis could be manufactured under Part 3.3 of the *Therapeutic Goods Act 1989* (Cth). The TGA explains that:

> *Section 35 of the Act requires that medicines used in Australia must be manufactured by persons licensed to manufacture, or carry out a step in the manufacture, of medicines at licensed premises unless either the goods or person are exempt in relation to the manufacture of therapeutic goods. Also, manufacturers of medicines are required to comply with written manufacturing principles under Section 36 of the* Therapeutic Goods Act 1989*. In Australia,*

> *these principles include the* Australian Code of Good Manufacturing Practice for Medicinal Products*, 16 August 2002, as adopted by the TGA.*[32]

No Victorian scheme is necessary.

8.7. National law interaction

> *11. How should the Victorian medicinal cannabis scheme interact with the national arrangements for the control of therapeutic products under therapeutic goods legislation and narcotic drugs legislation?*

Any Victorian laws in relation to medicinal cannabis should defer to the national therapeutic goods legislation and narcotic drugs legislation. They should not seek to duplicate or bypass existing national laws.

It is arrogant of the VLRC to propose constructing a set of laws that might contradict the form and intent of the relevant Commonwealth laws.

8.8. Form of approved medicinal cannabis

> *16. In what form(s) should medicinal cannabis be permitted to be supplied and used?*

Ultimately, the TGA is best placed to decide the form(s) of medicinal cannabis for supply and use.

Some forms should obviously remain banned. The NSW Parliamentary Research Service reasons that:

> *Owing to the health risks associated with smoking, cannabis in smoked form is unlikely to ever comply with TGA requirements. Since cannabis is a crude plant product, even if it were administered in ways other than smoking, it would still be unlikely to comply with registration requirements under the Therapeutic Goods Act.*[33]

8.9. Keeping up to date

> *17. In what ways could Victoria's medicinal cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of cannabis and other changes in scientific knowledge, medical practices and technology?*

New drugs are continually approved by the TGA as new research becomes available. Using the current Commonwealth legislation, reviews of a separate Victorian scheme will not be necessary.

9. 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.

Victoria should await proper, valid clinical trials before seeking to legislate in favour of medicinal cannabis use.

10. Endnotes

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[19] Therapeutic Goods Administration, "Sativex Oromucosal Spray, nabiximols 80 mg/mL pump actuated metered dose aerosol": Public summary, Nov 2012, https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=80AE3C9BF0BDD408CA257AC2003CB6EF&agid=(PrintDetailsPublic)&actionid=1.
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