Editorial

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MEDICINAL CANNABIS LAW REFORM IN AUSTRALIA

Attempts at medicinal cannabis law reform in Australia are not new. However, in historical perspective 2015 and 2016 will be seen as the time when community debate about legalisation of medicinal cannabis reached a tipping point in a number of Australian jurisdictions and when community impetus for change resulted in major reform initiatives. In order to contextualise the changes, the August 2015 Report of the Victorian Law Reform Commission (VLRC) and then the Access to Medicinal Cannabis Bill 2015 (Vic) introduced in December 2015 into the Victorian Parliament by the Labor Government are scrutinised. In addition, this editorial reviews the next phase of developments in the course of 2015 and 2016, including the Commonwealth Narcotic Drugs Amendment Act 2016 and the Queensland Public Health (Medicinal Cannabis) Bill 2016. It identifies the principal features of the legislative initiatives against the backdrop of the VLRC proposals. It observes that the principles underlying the Report and the legislative developments in the three Australian jurisdictions are closely aligned and that their public health approach, their combination of evidence-based pragmatism, and their carefully orchestrated checks and balances against abuse and excess constitute a constructive template for medicinal cannabis law reform.

INTRODUCTION

While cannabis has a long history of being utilised for what have been believed or asserted to be health applications,[1] the modern era (since the 1930s) has seen such applications criminalised by broad-based drug control legislation that has rendered use, possession, cultivation and trafficking of narcotic drugs such as cannabis illegal.[2] This has been regardless of the purpose of such conduct and whether it has been motivated by, or accomplished, a therapeutic objective. Unsurprisingly, this approach of undifferentiated prohibition has provoked controversy and has generated a level of non-compliance and civil disobedience with persons procuring cannabis for therapeutic purposes on the black market or by growing it themselves, and others, including "compassion clubs"[3] and "cannabis social clubs",[4] providing cannabinoid products for medicinal objectives.

A number of cannabinoid medications both derived from the cannabis plant, and from synthetic compounds, which mimic natural cannabinoids, have been developed and marketed by international

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[1] See Raphael Mechoulam (ed), *Cannabinoids as Therapeutics* (Springer, New York, 2005); Robert C Clark and Mark D Merlin, *Cannabis: Evolution and Ethnobotany* (University of California Press, Berkeley, 2013); Michael Backes, *Cannabis Pharmacy* (Black Dog & Leventhal, New York, 2014); David Bearman, *Drugs are not the Devil's Tools* (Blue Point Books, Santa Barbara, 2014); David Cassarett, *Stoned: A Doctor's Case for Medical Marijuana* (Penguin Random House, New York, 2015).

[2] See David E Smith, "Marijuana: A Fifty-Year Personal Addiction Medicine Perspective" (12 January 2016) J Psychoactive Drugs epub.

[3] See, for example, British Columbia Compassion Club Society, *Our Story* <https://thecompassionclub.org/about/215-2>.

[4] See Cannabis Social Club Australia, Submission No 15 to the Victorian Law Reform Commission, 27 March 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_15_Trich_Cannabis_Social_Club_Australia_27-03-15.pdf>.

pharmaceutical companies. The best known are Sativex (a nabiximol), Epidiolex, Canasol, Namisol, Cannador, Dronabinol, Nabilone and Rimonabant. All have proved controversial and some have manifested problematic side-effects.[5] As of early 2016 no such medications are available in Australia which have satisfied the requirements of the Therapeutic Goods Administration (TGA). The only product to have satisfied the TGA did not meet the requirements of the Pharmaceutical Benefits Scheme (PBS)[6] and to all intents and purposes cannot be obtained in Australia.[7] The consequence is that imported cannabinoid medications are currently not viable in Australia, so law reform initiatives have focused for the most part on other options for making cannabis available to patients for medicinal purposes.[8]

In Australia between 1999 and 2015 many attempts were made to secure legislative reform: Bills to enable access to medicinal cannabis were introduced into the federal,[9] New South Wales,[10] Western Australian,[11] South Australian,[12] Tasmanian,[13] Victorian[14] and Australian Capital Territory[15] Parliaments, while in the Australian Capital Territory,[16] Tasmania[17] and Victoria[18] reports on the issue were tabled in Parliament. This makes the three legislative initiatives of 2015-2016 in Victoria (the *Access to Medicinal Cannabis Bill 2015*), the Commonwealth (the *Narcotic Drugs Amendment Act 2016*) and Queensland (the *Public Health (Medicinal Cannabis) Bill 2016*) particularly significant, as it is clear that they represent the new phase of actual medicinal cannabis law reform.

When seen in historical perspective, 2015-2016 will be identified as a tipping point where there was a fundamental transition in the debate in relation to the legalisation of medicinal cannabis in Australia. In addition, pressures for reform continued to build in New Zealand. As often occurs, debate was driven by individuals – patients whose plight became publicly known and who engaged considerable sympathy and thereby galvanised the impetus for reform to the law. The lobbying for medicinal cannabis law reform in Australia, as in the United States and Canada, has been community-driven but energetic and often professionally constructed, latterly using social media extensively. Rallying for change in 2015 took place as a result of the campaigns waged by and in

[5] Victorian Law Reform Commission, *Medicinal Cannabis*, Issues Paper (2015) [2.50]-[2.77] <http://lawreform.vic.gov.au/sites/default/files/VLRC_Cannabis_Issues_Paper_1.pdf>.

[6] Pharmaceutical Benefits Scheme, *Nabiximols, Oral Spray, 10ml (90 Actuations of 100 Microlitres), Sativex* (July 2013) http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/nabiximols>.

[7] See Tony Moore, "MS Groups Welcome Medical Marijuana Treatments", *Brisbane Times*, 29 October 2015 <http://www.brisbanetimes.com.au/queensland/ms-groups-welcome-medical-marijuana-treatments-20151028-gkl24a.html>.

[8] Although there are mechanisms for access to imported drugs under clinical trials and for individual patients under the Special Access Scheme and Authorised Provider Scheme administered by the Therapeutic Goods Administration: see Department of Health, Australian Government, *Medicinal Cannabis* (10 December 2015) <http://www.health.gov.au/internet/main/publishing.nsf/Content/MC14-007515-medicinal-cannabis>, these measures provide access to medicinal cannabis to very few patients.

[9] *Regulator of Medicinal Cannabis Bill 2014* (Cth).

[10] *Drug Legislation Amendment (Cannabis for Medical Purposes) Bill 2014* (NSW).

[11] *Poisons Amendment (Cannabis for Medical and Commercial Uses) Bill 1999* (WA).

[12] *Controlled Substances (Medical Use of Cannabis) Amendment Bill 2003* (SA); *Controlled Substances (Palliative Use of Cannabis) Amendment Bill 2008* (SA).

[13] *Misuse of Drugs Amendment Bill 2014* (Tas).

[14] *Access to Medicinal Cannabis Bill 2015* (Vic).

[15] *Drugs of Dependence (Cannabis for Medical Conditions) Amendment Bill 2004* (ACT); *Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014* (ACT).

[16] Legislative Assembly for the Australian Capital Territory, *Report on the Medicinal Use of Cannabis* (2005).

[17] Legislative Council Government Administration Committee "A", Parliament of Tasmania, *Interim Report on Legalised Medicinal Cannabis* (2014) <http://www.parliament.tas.gov.au/ctee/Council/Submissions/gaa.inquiry.LMC.SIGNED%20INTERIM%20REPORT.19.11.14.pdf>.

[18] Victorian Law Reform Commission, *Medicinal Cannabis*, Report No 32 (2015) <http://lawreform.vic.gov.au/sites/default/files/VLRC_Medicinal_Cannabis_Report_web.pdf>.

memory of Dan Haslam who died of bowel cancer in northern New South Wales;[19] in Queensland by Lanai Carter whose son Lindsay used medicinal cannabis in the United States to advantage in relation to his inoperable brain tumour;[20] and in Victoria on behalf of two children with epileptic conditions, Cooper Wallace[21] and Tara O'Connell.[22] Each case evidently touched and engaged the commitment of Premier Mike Baird in New South Wales, Premier Annastacia Palaszczuk in Queensland and Premier Daniel Andrews in Victoria to reform.

In addition, the case of the Queensland child, Rumer Maujean, a child with neuroblastoma, who was treated by her father with cannabis oil generated extraordinary levels of attention when over 200,000 people put their name to a *change.com* petition after her father was arrested and charged in Brisbane with supplying a dangerous drug to a child under 16.[23] In New Zealand a rallying point was Paula Gray who contended that she had been compelled to purchase cannabis on the black market to obtain assistance with her fibromyalgia.[24]

By contrast, in South Australia, in 2014 the jailing by Judge Chivell of the District Court for a minimum of two years of Leon Ozolins, a man with leukaemia, for growing 23 cannabis plants for self-medication ignited calls for change to the law.[25] Earlier Ozolins had discovered that cannabis assisted his wife to endure the effects of chemotherapy before she succumbed to Hodgkin's lymphoma. A poll subsequently conducted by *The Advertiser* about whether cultivation of medicinal cannabis should be allowed yielded a 95.7% affirmative vote (n = 4557 votes), with 1.3% unsure (n = 62) and 3% against (n = 143).

In Western Australia, in July 2015 the Director of Public Prosecutions applied to freeze the assets of Nurse Miriam Down who had committed criminal offences, including cultivation of a narcotic drug, by treating her mentally ill 44-year-old son, George, with cannabis. The Western Australian Premier,

[19] See Scott Hannaford, "A Mother's Promise", *The Canberra Times*, 2015 <http://www.canberratimes.com.au/interactive/2015/a-mothers-promise>; James Robertson, "Dan Haslam, Who Changed Mike Baird's Views on Medicinal Cannabis, Dies of Cancer", *The Sydney Morning Herald*, 25 February 2015 <http://www.smh.com.au/nsw/dan-haslam-who-changed-mike-bairds-views-on-medicinal-cannabis-dies-of-cancer-20150225-13o6pk.html>. A very similar account was provided by Robert Wisbey in relation to his son Mason, who passed away from bowel cancer in 2015 but who, he maintained, received considerable assistance with his pain from medicinal cannabis: see Robert Wisbey, Submission No 65 to the Victorian Law Reform Commission, 21 May 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_64_Robert_Wisbey_21-04-15.pdf>.

[20] See Scott Sawyer, "Cannabis Treatment Helps Teen Fight for Life", *Sunshine Coast Daily*, 19 September 2014 <http://www.sunshinecoastdaily.com.au/news/cannabis-a-lifesaver/2392459/>; Christine Roussow, "Family Granted Approval to Import Cannabis to Help Save Son", *The Queensland Times*, 11 November 2015 <http://www.qt.com.au/news/finally-a-light-for-lindsay/2836210/>.

[21] See Rick Wallace, "High Hopes for Medical Marijuana Trials", *The Australian*, 23 October 2015 <http://www.theaustralian.com.au/news/inquirer/high-hopes-for-medical-marijuana-trials/news-story/cb4591e600bd9e02a006a7e0ae1dab20>; "One Family's Life in the Medical Marijuana Spotlight", *New Matilda*, 28 November 2014 <https://newmatilda.com/2014/11/28/one-familys-life-medical-marijuana-spotlight>. See too Cassie Batten and Rhett Wallace, Submission No 50 to the Victorian Law Reform Commission, 27 April 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_50_Cassie_Batten_%26_Rhett_Wallace_27-04-15.pdf>.

[22] See Annika Smethurst, "Desperate Parents Turn to Medical Marijuana in Last-Ditch Effort to Improve their Children's Lives", *Herald Sun*, 12 January 2014 <http://www.heraldsun.com.au/news/victoria/desperate-parents-turn-to-medical-marijuana-in-lastditch-effort-to-improve-their-childrens-lives/story-fni0fit3-1226799787147>; Joel Tozer, "Medical Marijuana Credited with 'Miracle' Recovery", *SBS*, 30 June 2014 <http://www.sbs.com.au/news/article/2014/06/30/medical-marijuana>. See also Cheri O'Connell, Submission No 51 to the Victorian Law Reform Commission, 5 May 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_51_Cheri_O%27Connell_05-05-15.pdf>.

[23] See Andy Rudd, "Adam Koesttler: Sick Daughter's Tumour Shrinking After He Was Arrested for Treating Her with Cannabis Oil", *The Mirror*, 23 January 2015 <http://www.mirror.co.uk/news/world-news/adam-koessler-sick-daughters-tumour-5028977>; "Intervene on Behalf of Adam Koesstler Arrested on 2nd January 2015", *change.com* <https://www.change.org/p/annastacia-palaszczuk-intervene-on-behalf-of-adam-koessler-arrested-on-2nd-january- 2015?just_created=true>.

[24] See Matt Rilkoff, "Taranaki Woman Sparks Debate on Medical Marijuana", *Taranaki Daily News*, 24 January 2015 <http://www.stuff.co.nz/taranaki-daily-news/news/65375931/Taranaki-woman-sparks-debate-on-medi>.

[25] See Antonio Bradley, "Cancer Patient Sent to Jail Over Cannabis", *Australian Doctor*, 2 April 2014; Tessa Akerman and Sean Fewster, "Leon Ozolins Jailed for Using Cannabis for Solace from a Form of Leukaemia Reopens Debate on Medicinal Marijuana", *The Advertiser*, 2 April 2014 <http://www.adelaidenow.com.au/news/south-australia/leon-ozolins-jailed-for-using-cannabis-for-solace-from-a-form-of-leukaemia-reopens-debate-on-medicinal-marijuana/story-fni6uo1m-1226849172150>.

Colin Barnett, conceded on Radio 720 ABC Perth that: "It does seem to be an unusual and compassionate case of a mother looking after a son."[26] By late 2015 the Western Australian Health Minister, the Honourable Kim Hames, said that he had sought advice about sourcing a cannabis product to be used in trials to be conducted at Princess Margaret Hospital so as to link in with the proposed national medicinal cannabis trials.[27]

There were developments too in relation to the conduct of patient trials, reports from parliamentary scrutiny of Acts committees in the Australian Capital Territory and Commonwealth Parliaments, and the promulgation of prosecutorial guidelines in New South Wales in relation to the preferring of charges related to the medicinal use of cannabis.[28] Most significantly, though, an issues paper and a final report on the subject were published by the Victorian Law Reform Commission (VLRC). These resulted in the introduction by the Labor Government into the Victorian Parliament of the *Access to Medicinal Cannabis Bill 2015* (the Bill) on 10 December 2015.

This editorial summarises the law reform developments of 2015, and reviews principal features of the Victorian and Queensland Bills, as well as the *Narcotic Drugs Amendment Act 2016* (Cth), referencing the arguments assembled by the VLRC in its August 2015 Report. It analyses the likely medico-legal impact of the three pieces of legislation and the direction which medicinal cannabis law reform is likely to take in Australia and, potentially, internationally if the reform approach of Victoria and Queensland, coupled with the Commonwealth legislation, is emulated.

EVENTS OF 2015

2015 saw an extensive series of significant but diverse developments in relation to medicinal cannabis law reform in Australia. The New South Wales Government established the Centre for Medicinal Cannabis Research and Innovation to which it dedicated A$12 million. The New South Wales Chief Scientist and Engineer, Mary O'Kane was appointed the inaugural Director of the Centre.[29]

In addition, New South Wales, Victoria and Queensland agreed to sponsor trials to explore the efficacy of medicinal cannabis. The New South Wales Government contributed A$9 million to the trials. The Australian Capital Territory Government announced it would work with New South Wales on the trials.[30] Tasmania[31] committed also to collaborating in them, while South Australia stated that it would not stand in the way of its residents participating in the trials.[32] Western Australia announced that it would examine options to link in with the trials.[33]

The first of the trials will be for children with severe, drug-resistant epilepsy (the Cooper Wallace category) and will involve up to 200 participants, commencing in mid-2016. The other two trials will be for adults (the Dan Haslam category) with terminal illnesses, focusing on improving quality of life

[26] See Emma Wynne, "Perth Mother Who Allegedly Grew Cannabis for Mentally Ill Son Could Lose Home Under Proceeds of Crime Law", *720 ABC Perth*, 17 July 2015 <http://www.abc.net.au/news/2015-07-17/perth-mother-could-lose-house-after-growing-cannabis/6627674>.

[27] See Rhiannon Shine, "WA Parents Treating Children with Medicinal Marijuana, Epilepsy Association of WA Says", *ABC News*, 7 November 2015 <http://www.abc.net.au/news/2015-11-07/epilepsy-group-says-wa-parents-using-marijuana-to-treat-epilepsy/6920892>.

[28] New South Wales Government, *Terminal Illness Cannabis Scheme* <http://www.nsw.gov.au/tics>.

[29] New South Wales Health, *Centre for Medicinal Cannabis Research and Innovation* (24 July 2015) <http://www.health.nsw.gov.au/cannabis/Pages/research-and-innovation.aspx>.

[30] Lisa Mosley, "ACT to Work with NSW on a Trial of Medical Cannabis Says Chief Minister Andrew Barr", *ABC News*, 21 April 2015 <http://www.abc.net.au/news/2015-04-21/act-will-work-with-nsw-on-medical-cannabis-trial/6409890>.

[31] Blair Richards, "Tasmania to Sign on to Medical Cannabis Trials", *The Mercury*, 10 December 2015 <http://www.themercury.com.au/news/politics/tasmania-to-sign-on-to-medicinal-cannabis-trials/news-story/40e3bea0c9c77c692a9b990ef6edfe52>.

[32] Jade Gailberger, "South Australians Could Participate in NSW's Medical Cannabis Trial with Help from Health Minister", *The Advertiser*, 20 October 2015 <http://www.adelaidenow.com.au/news/south-australia/south-australians-could-participate-in-nsws-medical-cannabis-trial-with- help-from-health-minister/news-story/9c145f31bb7d3635494e085629e89a01>.

[33] Andrew Tillett, "WA Keeps Eye on Cannabis Trial", *The West Australian*, 14 October 2015 <https://au.news.yahoo.com/thewest/lifestyle/a/29803337/wa-keeps-eye-on-cannabis-trial>.

and symptoms such as pain, nausea and vomiting; and for adults with chemotherapy-induced nausea and vomiting where standard treatment is ineffective.[34] In mid-2015 the University of Sydney received a donation of A$33.7 million from grandparents of a child with epilepsy for medicinal cannabis research.[35] The University will play a role in the trials. However, the results from the trials will not be available until 2018-2019.

New South Wales also established the Terminal Illness Cannabis Scheme which provides guidelines to police officers to help them determine whether to exercise their constabulary discretion not to charge adults with terminal illness who use cannabis to alleviate their symptoms and the carers who assist them.[36]

On 1 June 2015 cannabidiol (CBD) was rescheduled to Sch 4 in the *Standard for the Uniform Scheduling of Medicines and Poisons*.[37] This means that a medicine containing cannabidiol and two per cent or less of other cannabinoids may be made available on prescription. However, it must first be approved by the TGA. Given the small numbers of patients with paediatric epilepsy conditions, and commercial realities, this is unlikely to lead to availability of CBD medications for many years, if at all, in Australia.

In August 2015 the Australian Capital Territory Standing Committee on Health, Ageing, Community and Social Services tabled its report[38] in relation to the Greens' *Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014* (ACT). It recommended that the Australian Capital Territory Government reject the Bill and, instead, concentrate upon facilitating the interstate trials and achieving national law reform in the area.

On 11 August 2015 the Senate Legal and Constitutional Affairs Legislation Committee of the Parliament of Australia tabled a report[39] in relation to the Greens' *Regulator of Medicinal Cannabis Bill 2014* (Cth). It recommended a variety of significant amendments to the Bill, including changes "to ensure that medicinal cannabis products can be made available consistent with Australia's obligations, including under Articles 23 and 28 of the *Single Convention on Narcotic Drugs* (1961)" (Recommendation 4) and that "the Commonwealth government consult with its state and territory counterparts about the interrelationship of relevant laws to ensure a consistent approach to accessing medicinal cannabis and to facilitate compliance with any such access scheme and Australia's international obligations" (Recommendation 5). It also recommended amendment, if necessary, "to establish mechanisms by which scientific evidence about medicinal cannabis products can be assessed to determine their suitability for use in the treatment of particular conditions" (Recommendation 2).

On 6 October 2015 the August 2015 Report of the VLRC on *Medicinal Cannabis* was tabled in Parliament.[40] The terms of reference for the VLRC had required it:

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[34] New South Wales Health, *Clinical Trials: Medical Use of Cannabis*, Fact Sheet <http://www.health.nsw.gov.au/cannabis/Documents/fs-cannabis-trials.pdf>.

[35] Melissa Davey, "Medicinal Cannabis Research Gets $33m from Grandparents of Girl with Epilepsy", *The Guardian*, 12 June 2015 <http://www.theguardian.com/australia-news/2015/jun/12/medicinal-cannabis-research-gets-37m-from-grandparents-of-girl-with-epilepsy>.

[36] New South Wales Government, *Terminal Illness Cannabis Scheme*, Fact Sheet <http://www.nsw.gov.au/fact-sheet-adults-terminal-illness-and-their-carers>.

[37] See *Poisons Standard July 2015* (Cth) <https://www.comlaw.gov.au/Details/F2015L00844/Download>.

[38] Standing Committee on Health, Ageing, Community and Social Services, Legislative Assembly for the Australian Capital Territory, *Inquiry into the Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and Related Discussion Paper* (2015) <http://www.parliament.act.gov.au/__data/assets/pdf_file/0003/759270/8th-HACS-06-Cannabis-Medicnal-Bill-final.pdf>.

[39] Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Regulator of Medicinal Cannabis Bill 2014* (2015) <http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_ Cannabis_Bill/Report>.

[40] Victorian Law Reform Commission, n 18.

1. to review and report on options for changes to the *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations to allow people to be treated with medicinal cannabis in exceptional circumstances, and to make the recommendations for any consequential amendments which should be made to the:
   - *Therapeutic Goods (Victoria) Act 2010*
   - Any other relevant legislation.
2. In conducting its review, the Commission is asked to consider:
   - the operation of Victoria's *Drugs, Poisons and Controlled Substances Act 1981* and associated Regulations, and how this interacts with Commonwealth law, functions and any relevant international conventions.
   - medicinal use of cannabis in other jurisdictions.
3. The Commission is asked to appoint expert panels to assist in its review, specifically to examine:
   - Prescribing practices for medicinal cannabis, including eligibility criteria for access to medicinal cannabis and the role of doctors in managing the use of medicinal cannabis by patients
   - The regulation of medicinal cannabis manufacture and distribution, including which forms of medicinal cannabis should be permitted for use.

The VLRC Report was the product of an extensive inquiry, consultation throughout urban and rural Victoria on the basis of the Commission's April 2015 Issues Paper on the subject,[41] and 99 written submissions.[42] The response of the Andrews Labor Government was to accept 40 of the VLRC's 42 recommendations and to accept the remaining two recommendations in principle.[43]

On 2 December the federal Minister for Health, the Honourable Sussan Ley, announced that the federal government would create a nationally consistent licensing scheme regulating the controlled cultivation of cannabis for medicinal or scientific purposes via amendments to the *Narcotic Drugs Act 1967* (Cth).[44]

The next development occurred on 12 December 2015 when the Victorian Minister for Health, the Honourable Jill Hennessy (the Minister), determined not to await federal developments and introduced the Bill into the Legislative Assembly of the Victorian Parliament,[45] implementing the substance of the VLRC Report, as described above. The Minister maintained that:

> The law needs to change because families should not have to make the choice between obeying the law and treating their children … The current law is confusing and complex, and has not kept up with the views of the community, with surveys showing the overwhelming majority of Australians believe the use of cannabis for medicinal purposes should be legal.[46]

The Minister did not refer to a particular survey but her assertion about changing public opinion on the subject is correct. A ReachTel survey of more than 3,400 Australians in 2014 found that almost two-thirds supported legalisation of cannabis for medicinal purposes.[47] A 2015 survey result was even more pronounced with a Roy Morgan poll finding that 91% of Australians (n = 644) thought that medicinal cannabis should be legalised with strongest support in the 50-plus age group.[48] Only 7% of

[41] Victorian Law Reform Commission, n 5.

[42] Victorian Law Reform Commission, *Medicinal Cannabis – Received Submissions* <http://lawreform.vic.gov.au/projects/medicinal-cannabis/submissions/medicinal-cannabis-received-submissions>.

[43] Daniel Andrews, "Medicinal Cannabis to be Legalised in Victoria" (Media Release, 6 October 2015) <http://www.premier.vic.gov.au/medicinal-cannabis-to-be-legalised-in-victoria>.

[44] Sussan Ley, "Medicinal Cannabis to be Cultivated Through Single National Scheme" (Media Release, 2 December 2015) <https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley144.htm>.

[45] Second Reading Speech by Minister Jill Hennessy to the *Access to Medicinal Cannabis Bill 2015*: see Victoria, *Parliamentary Debates*, Legislative Assembly, 10 December 2015, 5528 <http://www.legislation.vic.gov.au/domino/Web_Notes/LDMS/PubPDocs.nsf/ee665e366dcb6cb0ca256da400837f6b/5973532394c874eeca257f150082d37d!OpenDocument>.

[46] Second Reading Speech, n 45, 5528.

[47] See Henrietta Cook and Bridie Smith, "Majority of Australians Support Medical Cannabis", *The Age*, 23 July 2014 <http://www.theage.com.au/victoria/majority-of-australians-support-medical-marijuana-20140723-zw56k.html>.

[48] Melissa Davey, "Legalised Medical Marijuana Opposed by Only 7% of Australians, Poll Shows", *The Guardian*,

respondents were opposed to cannabis being made legal for medicinal purposes.[49] Significantly, too, a 2014 survey of members of the Royal Australian Nursing Federation yielded a 95% level of support for the use of medicinal cannabis to treat terminal and life-threatening illnesses.[50]

Internationally, the end of 2015 brought a further development with Colombian President Juan Manuel Santos controversially signing a decree legalising and regulating medicinal cannabis.[51] The first national forum for discussion of legal use of cannabis for medicinal purposes, scrutinising the public health and addiction ramifications of such a change to the law was convened in January 2016 in Mexico in Cancun.[52] Debate on legalisation of medicinal cannabis continues in Chile,[53] in the aftermath of permitting cultivation for medical purposes in October 2014, while Uruguay legalised personal cultivation, consumption and sale of cannabis in 2013, and hopes were expressed late in 2015 that its regime might lead to important developments in cannabis research.[54]

In October 2015 the Queensland Minister for Health, the Honourable Cameron Dick, tabled in Parliament a letter responding to a petition in relation to the legalisation of medicinal cannabis. He confirmed Queensland's participation in an interstate clinical trial of a cannabis-derived product to treat children with severe drug-resistant epilepsy. He announced the Lady Cilento Children's Hospital as the likely Queensland trial site and observed that:

> The trial presents an opportunity to demonstrate that medicinal cannabis can be a safe and effective addition to existing treatments. This would be an important step in promoting further use of medicinal cannabis in Queensland.[55]

In early 2016 there were further developments. In Victoria the government announced that it would participate in a ground-breaking international clinical trial of a synthetic cannabinoid medicine being conducted by the United States pharmaceutical company, Insys Therapeutics Inc, to treat paediatric patients with refractory epilepsy. The trial will be led by a consultant to the VLRC, Austin Health's Director of Paediatrics, Professor Ingrid Scheffer, whose research group was the first to discover a gene for epilepsy.[56]

Two legislative initiatives followed.

The Commonwealth Government introduced and then promptly passed the *Narcotic Drugs Amendment Bill 2016* (Cth). The legislation was introduced on 10 February 2016, was passed on 24 February 2016, and received assent on 29 February 2016. It amends the *Narcotic Drugs Act 1967* (Cth) to give effect to various of Australia's obligations under the *Single Convention on Narcotic Drugs 1961*. The legislation is extensive but its effect is straightforward. The new s 7A of the *Narcotic Drugs Act 1967* asserts Commonwealth control over the granting of licences for the cultivation and production of cannabis for medicinal or related scientific purposes. It bears features that are very

26 October 2015 <http://www.theguardian.com/society/2015/oct/26/legalised-medical-marijuana-opposed-by-only-7-of-australians-poll-shows>.

[49] Compare Wendy Swift, Peter Gates and Paul Dillon, "Survey of Australians Using Cannabis for Medical Purposes" (2005) 2 *Harm Reduction Journal* 18.

[50] Royal Australian Nursing Federation (Victorian Branch), Submission No 75 to the Victorian Law Reform Commission, 4 June 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_75_Australian_Nursing_%26_Midwifery_Federation_Victorian_Branch_04-06-15.pdf>.

[51] See Paula Carrillo, "Colombia Legalizes Medical Marijuana", *Yahoo News*, 22 December 2015 <http://news.yahoo.com/colombia-legalizes-medical-marijuana-171023547.html>.

[52] "Cancun Will Host First National Marijuana Debate on Jan 26", *The Yucatan Times*, 13 January 2016 <http://www.theyucatantimes.com/2016/01/cancun-will-host-first-national-marijuana-debate-on-jan-26/>.

[53] Transnational Institute Drugs and Democracy, *Overview of Drug Laws and Legislative Trends in Chile* <http://druglawreform.info/en/country-information/latin-america/chile/item/202-chile>.

[54] "Uruguay's Radical Cannabis Plans", *BBC News*, 4 November 2015 <http://www.bbc.com/news/world-latin-america-34718278>.

[55] Letter from the Hon Cameron Dick MP to Neil Laurie, Clerk of the Queensland Parliament, 15 October 2015 <http://www.parliament.qld.gov.au/Documents/TableOffice/TabledPapers/2015/5515T1422.pdf>.

[56] Health Victoria, *Medicinal Cannabis* <https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis>.

closely aligned with the provisions for licensing in the Victorian Bill. For instance, it incorporates "fit and proper person" requirements for those who apply for licences (ss 8A, 8B) and it introduces a comprehensive licensing scheme for those wishing to cultivate or produce cannabis or cannabis resin for medicinal purposes (ss 8E-8P). It also provides for a medicinal cannabis permit system which allows permit holders to engage in activities authorised by the licence in accordance with the permit (ss 8P, 9B); there are two forms: a medicinal cannabis cultivation permit (s 9B(1)) and a medicinal cannabis production permit (s 9B(2)). A variety of offences and civil penalties are created (ss 11B-11E). A regime is also created for manufacturing licences and permits in respect of medicinal cannabis (ss 11G-13D), with an associated creation of criminal offences and penalties (ss 13E-13F). In addition, a regime is created for monitoring, investigation and enforcement of the various licences and permits via duly appointed inspectors (ss 13G-14G). The many decisions are internally reviewable and thereafter by the federal Administrative Appeals Tribunal (s 15L).

In the federal Minister for Health's Second Reading Speech, the Honourable Sussan Ley stated that:

> The *Narcotic Drugs Amendment Bill 2016* provides a clear national licensing scheme allowing the controlled cultivation locally of cannabis for medicinal and scientific purposes.
>
> Importantly this bill provides the critical "missing piece" for the Commonwealth to enable a sustainable supply of safe medicinal cannabis products to Australian patients in the future …
>
> It is imperative we have a clear national licensing system to ensure we maintain the integrity of crops for medicinal or scientific purposes. This national approach will allow the Commonwealth, acting with the states and territories, to closely manage the supply of cannabis products from "farm to pharmacy" …
>
> This bill to allow the cultivation of legal medicinal cannabis crops in Australia under strict controls strikes the right balance between patient access, community protection and our international obligations.[57]

Thus, the Commonwealth amendments to the *Narcotic Drugs Act 1967* create a licensing regime for cultivating and manufacturing medicinal cannabis which enables States and Territories to implement schemes by which medical practitioners and pharmacists can make medicinal cannabis available to patients.

On 29 February 2016 the *Public Health (Medicinal Cannabis) Bill 2016* (Qld) was made available for community input prior to planned introduction into the Queensland Parliament in April 2016. Its approach, which takes into account the Commonwealth amendments, is outlined below. The Queensland Premier, Annastacia Palaszczuk, maintained that: "This bill will create the most progressive laws in the country."[58]

THE VICTORIAN BILL

Medico-legal orientation

The orientation of both the VLRC Report and of the Victorian (and Queensland) Bill is to construct medicinal cannabis law reform overtly as a health initiative that comes into being through extensive legal and regulatory reforms that adhere to Australia's international obligations, maintain the preclusion on recreational use of cannabis, and introduce medicinal cannabis products into the therapeutic pharmacopoeia. The purpose of the Victorian Bill is stated, amongst other things, to be to establish a scheme "for supply to and treatment of Victorians with specified conditions with approved medicinal cannabis products of reliable quality and known composition" (cl 1(a)(i)).

[57] Second Reading Speech by Minister Sussan Ley to the *Narcotic Drugs Amendment Bill 2016* (Cth): see Commonwealth, *Parliamentary Debates*, House of Representatives, 10 February 2016, 13-15 <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansardr%2F7ef9bd10-ec92-4de4-9372-a92d6a12d7ef%2F0026%22>.

[58] See Cameron Atfield, "Queensland Medicinal Cannabis Legislation Set for April Debate", *The Brisbane Times*, 29 February 2016 <http://www.brisbanetimes.com.au/queensland/queensland-medicinal-cannabis-legislation-set-for-april-debate-20160229-gn6s16.html>.

Attempting to learn lessons from the Canadian experience where neither the medical profession nor human rights issues were effectively addressed in the initial versions of medicinal cannabis schemes,[59] the Bill focuses upon cannabis as a medicinal opportunity and upon the role of medical practitioners and pharmacists to function as gatekeepers to patients' access to it. The Minister observed that:

> It is important we get the balance right between helping people access medicinal cannabis safely, and minimising medical risk. The views of the medical profession are essential to the successful implementation of a medicinal cannabis scheme in Victoria.
>
> Consultations to date have been constructive with those involved from the medical profession, indicating a keen willingness to work with the government in the development and implementation of the framework.[60]

The formal response of the Australian Medical Association (AMA), Victorian Branch, has been qualified, recognising the potential of medicinal cannabis but expressing reservations about its immediate implementation:

> "This is an exciting development for a specific group of patients with specific conditions. However, AMA Victoria holds reservations as there is a lack of significant evidence and information on its side-effects, potential harms, and implications of long term use or use at a young age," AMA Victoria President Dr Tony Bartone said.
>
> The Victorian Government, on the recommendation of the VLRC, is not waiting for the results of further clinical trials, such as the NSW/ VIC/ QLD trials which are currently underway. This deviates from the usual process of how medications are approved for use in Australia, where there is either thorough international evidence and/or Australian evidence. Given this gap, we hope that the patients who are authorised to use medicinal cannabis under this new scheme are closely monitored on a comprehensive patient register.
>
> "We stated in our submission to the VLRC that more evidence is needed before there is a full roll out. This has not happened yet. We understand the distress and pain that some patients, and their families, with serious conditions like MS, cancer, epilepsy and seizures, HIV and those with chronic pain suffer. However, checks and balances, evidence, data, proof, risk analysis, warnings and quality control are always needed for medications and medical procedures. This step has been skipped here, and is an important part of good medical care," Dr Bartone said.[61]

However, most significantly, it is apparent that the reservations of the AMA do not constitute outright opposition and that there appears to be room for involvement by medical practitioners in the qualified scheme set out in the Bill. Importantly too, the submissions of the Royal Australian Nursing Federation (Victorian Branch)[62] and of the Law Institute of Victoria[63] expressed support for the approach ultimately adopted in the Bill.

Public health orientation

While it is impossible to preclude collateral and recreational usage of medicinal cannabis, a hallmark of the Victorian model is to reject the practice adopted in many States in the United States of making available smokable, dried leaf forms of cannabis for medicinal purposes.[64] The VLRC Report

[59] See Ian Freckelton, "Medicinal Cannabis Law Reform: Lessons from Canadian Litigation" (2015) 22 JLM 719.

[60] Second Reading Speech, n 45, 5528.

[61] AMA Victoria, *AMA Victoria's Response to the VLRC's Recommendation to Legalise Medicinal Cannabis* (6 October 2015) <https://amavic.com.au/page/News/AMA_Victoria_s_response_to_the_VLRC_s_recommendation_to_legalise_medicinal_cannabis>. See too submission of Royal Australian College of Physicians, Submission No 52 to the Victorian Law Reform Commission, 4 May 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_52_The_Royal_Australian_College_of%20_Physicians_04-05-15.pdf>.

[62] Royal Australian Nursing Federation (Victorian Branch), n 50.

[63] Law Institute of Victoria, Submission No 63 to the Victorian Law Reform Commission, 20 May 2015 <http://lawreform.vic.gov.au/sites/default/files/Submission_63_Law_Institute_of_Victoria_20-05-15.pdf>.

[64] See, for example, California Department of Public Health, *Medical Marijuana Program* <https://www.cdph.ca.gov/programs/MMP/Pages/default.aspx>; Marijuana Doctors, *California Medical Marijuana Qualification* <https://www.marijuanadoctors.com/medical-marijuana/CA/qualification>. See also Brian J Fairnman, "Trends in Registered Medical

identified problematic and consistent profiles of those gaining access to medicinal cannabis in a number of States in the United States and recommended a model that would avoid such pitfalls, and thus which is more consistent with contemporary approaches that are influenced by the need to integrate medicinal cannabis within an overall public health strategy.

The Bill adheres to contemporary Australian public health initiatives directed toward reducing the incidence of smoking and the various health problems associated with it.[65] Thus, the products to be made available under the scheme will be in the form of oils and tinctures, particularly suitable for children, and in tablet form, all of them labelled in a form which is well recognised for medications. This has the dual advantage of being in a therapeutic form, familiar in a medical context, and also enabling certainty about the amount of the product consumed by the patient. This latter consideration precludes self-medication and allows doctors to evaluate dose-response effect and monitor and address the emergence of any problematic side-effects.

No grow your own medicial cannabis

A number of submissions to the VLRC urged a model in which patients or their carers, or others, such as those running "compassion clubs", be permitted to grow stipulated amounts of cannabis for medicinal purposes. This would have involved decriminalising usage, possession, cultivation and trafficking cannabis for such purposes for those permitted to do so, for instance by a licensing system. However, the VLRC recommended strenuously against such an approach,[66] accepting submissions by medical practitioners, police and a number of carers and patients that too many adverse consequences would attach to such a scheme, including that it would in effect usher in legalisation of recreational use of cannabis.

First, it was observed that such a scheme effectively excludes therapeutic input from qualified health practitioners and that it encourages patients to self-administer the product. This means that medical oversight over administration would be absent and therefore its status as a medicinal product would be compromised and the risks attaching to its usage would be maximised. Secondly, the product itself is likely to be of unknown and highly variable constituency which is likely to impact adversely upon its therapeutic efficacy. Thirdly, it risks a variety of forms of anti-social and criminal activity with persons breaking into properties and houses to steal cannabis in order to divert it from its medicinal application to a recreational purpose. In addition, for many in need of the therapeutic effects of cannabis, growing it in the necessary quantities (which are substantial for the oil required by those with paediatric epilepsy) is not a feasible option. Some have neither the skills nor the inclination to undertake the task. Some do not live in a suitable environment. Some are too ill to do the cultivation. Finally, the VLRC noted reports of significant increases in the incidence of house fires in jurisdictions permitting home-grown cannabis as a result of accidents involving hydroponic equipment.

Therapeutic efficacy

In its Issues Paper and in its Report the VLRC undertook an extensive survey of contemporary clinical literature about the therapeutic efficacy of cannabinoids and also about their side-effects. It concluded that research into the therapeutic potential of cannabinoids, in particular THC (delta-9 tetrahydrocannabinol), CBD (cannabidiol), CBN (cannabinol), and CBG (cannabigerol) had only reached an early phase as of mid-2015. It observed that much of the literature was evangelistic and of poor scientific quality, reporting case studies and making claims which were not the product of randomised, double-blind, placebo-controlled trials. Such literature makes claims that cannabinoids,

Marijuana Participation Across 13 US States and District of Columbia" (25 November 2015) *Drug and Alcohol Dependency* epub.

[65] This has been a particular focus of health law reform in Victoria. See Health Victoria, *Tobacco Reforms* <https://www2.health.vic.gov.au/public-health/tobacco-reform>.

[66] Subsequent to the Victorian Law Reform Commission Report, see J Ablin et al, "Medical Use of Cannabis Products: Lessons to be Learned from Israel and Canada" (14 January 2016) *Der Schmerz* epub, arguing against the facility for home-growing of cannabis for medicinal purposes in Germany.

either individually or in combination (via what is often called the "entourage effect")[67] have remarkable curative powers for a wide array of medical conditions. However, the VLRC identified a modest number of conditions for which the evidence base was of reasonable strength and in respect of which randomised, placebo-controlled trials had been undertaken or in respect of which there were supportive meta-analyses of the research literature. It commented:

> A refrain of the credible scholarly literature is that further, suitably controlled, high quality studies need to be undertaken to evaluate whether the claims, anecdotes and aspirations for the efficacy of medicinal cannabis can be justified … It can be difficult to reconcile belief in medicinal cannabis with the strength of the clinical evidence. Views of the evidence for the efficacy of medicinal cannabis vary and perceptions based on faith, hope and experience with cannabis, on the one hand, can depart substantially from views based on the assessment of the clinical trials.[68]

This literature led the VLRC to identify five conditions in respect of which it could reasonably be said that as of 2015 the research literature established significant therapeutic potential:

- epileptic conditions (especially paediatric conditions such as Dravet syndrome and Lennox-Gastaut syndrome);
- multiple sclerosis (in respect of relief of contractures and the pain from them);
- nausea, vomiting and wasting caused by cancer or HIV, or their treatment (such as chemotherapy);
- acute pain from terminal conditions such as cancer and AIDS; and
- chronic pain (for which otherwise high levels of opiate medication are administered).

It noted that there was potential for efficacy to be demonstrated in respect of a number of other conditions (including glaucoma, post-traumatic stress disorder,[69] and various intestinal disorders) but that the emergence of supportive evidence as of mid-2015 was at an early phase.

The VLRC emphasised that medicinal cannabis is not a curative agent for any of the conditions in respect of which it recommended legalisation and that medical understanding about its efficacy in respect of symptom control for each of the conditions as of 2015 was still evolving. An example in this regard is the situation with the application of medicinal cannabis to address the symptoms of epilepsy. As of November-December 2015 the orthodox research position was reiterated by Schacter that "[w]hile existing published clinical studies of botanicals and seizure control are generally of inadequate quality to determine safety and efficacy, recent developments" may encourage further research and commercialisation of botanicals, such as cannabis.[70]

The evolving state of the research literature led the VLRC to consider whether it was appropriate for cannabinoid products to be made available to patients when they had not made their way through the rigorous evaluation processes of the TGA and the PBS and thus could be imported. It noted that, as exemplified with the experience with Sativex where the manufacturer has not proceeded with making the product available after having it rejected in 2013 by the PBS, it was likely to be some years before pharmaceutical companies invested the efforts and money necessary in the Australian marketplace to attempt to secure TGA and PBS endorsement for cannabinoid medications. However, in the meantime the evidence base in respect of at least the five identified conditions meant that a strong compassionate case existed for making such medicinal options available for patients who

[67] Ethan B Russo, "Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects" (2011) 163 Br J Pharmacol 1344.

[68] Victorian Law Reform Commission, n 18, [2.77]-[2-78].

[69] In May 2015 Yarnell, for instance, argued that, "While the literature to date is suggestive of a potential decrease in PTSD symptomatology with the use of medical marijuana, there is a notable lack of large-scale trials, making any final conclusions difficult to confirm at this time": Stephanie Yarnell, "The Use of Medicinal Marijuana for Posttraumatic Stress Disorder: A Review of the Current Literature" (7 May 2015) 17 Prim Care Companion CNS Disord epub; see also Margaret Haney and A Eden Evins, "Does Cannabis Cause, Exacerbate or Ameliorate Psychiatric Disorders? An Oversimplified Debate Discussed" (2016) 41 *Neuropsychopharmacology* 393.

[70] Stephen C Schacter, "Translating Nature to Nurture: Back to the Future for 'New' Epilepsy Therapies" (2015) 15 Epileps Curr 310. The debate remains live and contested. See, for example, Daniel Freidman and Orrin Devinsky, "Cannabinoids in the Treatment of Epilepsy" (2015) 373 N Engl J Med 1048.

wanted them and were made aware of the limited research base and thus the constraints upon knowledge about side-effects and efficacy. It accepted the proposition advanced by the AMA Victoria that compassion should not constitute a licence for undue latitude when important issues, including patient safety, are at stake, but concluded that this did not preclude a limited scheme for medicinal cannabis for the present.

Side-effects

A key and distinctive feature of cannabinoid medications is that their side-effects are of a modest order and for the most part can be monitored effectively by medical practitioners. The VLRC review of the clinical literature identified the now substantial body of research literature confirming a correlation between recreational use of cannabis and earlier onset of psychotic symptomatology (generally in respect of schizophrenia)[71] and the severity and frequency of relapses of psychotic illnesses. Since the publication of the VLRC Report, this was confirmed by a large Scandinavian study involving 1,119 patients which found a positive correlation between cannabis use and on average onset of schizophrenia spectrum disorders three years earlier.[72] In addition, there is a significant incidence of anxious and paranoid reactions in persons who use cannabis recreationally[73] and a correlation between cannabis use and an increased risk for several substance use disorders.[74] However, there is very little literature in respect of the nature and side-effects of medicinal cannabis usage, especially where it is monitored by medical practitioners. This includes information about longer term sequelae of usage of medicinal cannabis, and effects upon children and women who become pregnant.[75]

Insofar as cannabinoids function as alternative analgesics to opioids, they have fewer respiratory and cardiac depressant effects and do not generate the constipation, nausea and addiction that accompany administration of opioid painkillers. This raises the potential for them to function as part of the arsenal of agents for management of both acute and chronic pain, and as an alternative in some circumstances to opioid treatment.

The conclusion of the VLRC was that while it is important to recognise the reality of a diverse range of actual and potential side-effects from medicinal cannabis,[76] most arise from cannabis with a significant THC content and so do not apply to medications with a high CBD content, such as tend to be used to treat paediatric epilepsy. In respect of children with epileptic conditions that are not satisfactorily addressed by conventional medications, the stakes are very high in terms of threat to their health from their condition, so it is reasonable for parents to be able to authorise resort to medicinal cannabis, in spite of the absence of knowledge of long-term side-effects. In addition, attentive monitoring by medical practitioners should be able to enable careful titrating and adjustment of dosage so as to avoid dangerous or unpleasant side-effects for persons with terminal conditions, with multiple sclerosis, and with chronic pain,[77] and to address any issues arising out of the formation of any form of dependency. The Victorian (and Queensland) Bill makes no changes to road safety legislation or to legislation relating to the operating of heavy machinery so the ordinary law applies in

[71] See also Leon French et al, "Early Cannabis Use, Polygenic Risk Score for Schizophrenia and Brain Maturation in Adolescence" (2015) 72 JAMA Psychiatry 1002 arguing that "Cannabis use in early adolescence moderates the association between the genetic risk for schizophrenia and cortical maturation among male individuals. This finding implicates processes underlying cortical maturation in mediating the link between cannabis use and liability to schizophrenia."

[72] Siri Helle et al, "Cannabis Use is Associated with 3 Years Earlier Onset of Schizophrenia Spectrum Disorder in a Naturalistic, Multi-Site Sample (n – 1119)" (2016) 170 *Schizophrenia Research* 217.

[73] Victorian Law Reform Commission, n 18, [2.145]-[2.168].

[74] See Carlos Bianco et al, "Cannabis Use and Risk of Psychiatric Disorders: Prospective Evidence from a US Longitudinal Study" (17 February 2016) JAMA Psychiatry epub.

[75] See Cheryl K Roth, Lori A Satran and Shauna M Smith, "Marijuana Use in Pregnancy" (2015) 19 Nurs Womens Health 431.

[76] See recently to a similar effect Melvyn W Zeibin and Roger CM Ho, "The Cannabis Dilemma: A Review of its Associated Risks and Clinical Efficacy" (11 October 2015) J Addict epub.

[77] Victorian Law Reform Commission, n 18, [2.168]. See also Raphael Mechoulam, "Cannabis – The Israeli Perspective" (30 September 2015) J Basic Clin Physiol Pharmacol epub.

respect of persons under the influence of the THC in cannabis, whether it is medicinal or not. This is a further important public health and safety component of the legislation.

Medical practitioner and pharmacist involvement

The VLRC recommended that eligibility for patients should be based initially on the following conditions and corresponding symptoms:

(a) severe muscle spasms or severe pain resulting from multiple sclerosis;
(b) severe pain arising from cancer, HIV or AIDS;
(c) severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof);
(d) severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated side-effects that are intolerable for the patient;
(e) severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.[78]

The VLRC proposal contained three categories: it mandated "severity" of symptomatology from designated medical conditions, and in respect of epileptic conditions required also that other options not have proved effective or have generated intolerable side-effects, and in respect of chronic pain required also that *two* specialist doctors form the view that medicinal cannabis may overall provide better pain management than is available from other products. This deliberately places a significant bar in the way of access so as to avoid abuse.

The medicinal cannabis scheme proposed under the Bill implements only the fourth of these conditions initially. It is not known how many such patients there are but the numbers are modest.

The decision as to whether to include the remaining categories of patients, and others, within the category of "eligible patients" will depend upon which other categories in due course are prescribed by the Health Secretary on advice from the Independent Medical Advisory Committee (cl 12(3)). This mechanism ensures that there is significant medical input into the threshold issue of which categories of patients research suggests are likely to benefit sufficiently from medical cannabis. The view of the VLRC was that a reasonable research base existed as of mid-2015 in respect of the efficacy of medicinal cannabis (as well as in respect of paediatric epilepsy) to relieve terminal pain, to alleviate symptomatology of multiple sclerosis and to reduce wasting, vomiting and nausea in certain circumstances, including as a result of chemotherapy. However, the most fraught and contentious area of the VLRC's recommendations related to the use of medicinal cannabis for chronic pain. The view it expressed was that "further analysis needs to be undertaken before medical cannabis is made available as a first line or even an alternative form of treatment for patients who suffer or claim to suffer from chronic symptoms of pain".[79] It noted that as chronic pain is a long-term phenomenon, there was the risk that provision of medicinal cannabis could also be for a lengthy period, that there can be difficulties for medical practitioners in assessing the authenticity of assertions of pain, and that overseas experience suggests that numbers of patients desirous of cannabis for recreational purposes may abuse the system and place doctors under pressure for access to medicinal cannabis. This, and concerns about problematic aspects of North American schemes, led the VLRC to urge caution in respect of the chronic pain cohort of patients and to moot the option of the reasonably demanding requirement for two specialists' authorisation.

The proposed Victorian (and Queensland) legislation is predicated upon the pivotal role of a specialist medical practitioner. In Victoria the specialist applies to the Health Secretary for a "practitioner medicinal cannabis authorisation" for an "eligible patient" (cl 78(1)). Amongst other things, the authorisation must specify the medical condition in relation to which the authorisation is sought and the approved medicinal cannabis product or class of product that it is proposed to use to treat the patient (cl 78(2)). The specialist must be satisfied that the patient is eligible, namely with a condition falling within the designated category of conditions, that it is appropriate in all the

[78] Victorian Law Reform Commission, n 18, [3.100].

[79] Victorian Law Reform Commission, n 18, [3.89].

circumstances that the patient should be treated with the approved medicinal cannabis product, and that any prescribed additional criteria are met (cl 78(3)). The authorisation authorises the patient to obtain the product from a pharmacist and permits possession, storage and use of the product (cl 86). Other medical practitioners, usually general practitioners, will have the day-to-day responsibility for authorising medicinal cannabis access for patients, but the initial and threshold authorisation application must be by a specialist who in turn can nominate other medical practitioners to be authorised (cl 79(2)(g)).

An "eligible patient" is defined in the Bill as a patient who is under 18 years of age and "experiences severe seizures resulting from an epileptic condition in respect of which other treatment options have not proved effective or have generated intolerable side-effects" and meets the prescribed criteria for the condition (if any) and "a patient who has a prescribed medical condition" and who meets any prescribed criteria (cl 3(a)-(b)). The Explanatory Memorandum to the Bill makes it explicit that: "The definition also allows for further categories of eligible patients to be prescribed in regulations."[80] Such categories could include those recommended by the VLRC. It enables ongoing review by the Health Secretary on advice as to the evolving state of research knowledge.

Specific provision is made under the Bill for provision of medicinal cannabis to persons in "exceptional circumstances" (cl 80). A humanitarian application may be made in such a "fall-back situation" in respect of a particular patient setting out the exceptional circumstances that justify the patient (not being an "eligible patient") being treated with medicinal cannabis. The decision as to whether to grant such an exceptional licence is that of the Health Secretary (cl 81); if the decision is to decline such a licence, reasons must be provided (cl 81(5)).

Cultivation and manufacturing

The VLRC Report recommended a system whereby cultivation of medicinal cannabis and then manufacture of medicinal cannabis products be undertaken by those licensed to do so under strict supervision from the relevant government departments – the Department of Economic Development, Jobs, Transport and Resources in respect of cultivation, which already undertakes supervisory responsibilities in respect of the growing of poppy straw in Victoria, and the Health Department in respect of manufacture. Such a scheme would allow minimisation of any risk of diversion by the imposition of rigorous requirements as to those to be licensed as cultivators and manufacturers and also as to what happens with the product and the conditions subject to which the product is cultivated and manufactured. It would also promote suitable quality control by ensuring that contaminants not be used and that the quality of the product reaches the requisite standard and is consistent in its content and strength. Such an approach is utilised in Minnesota. This is important as what is envisaged is that a variety of products will be manufactured with different levels of THC and CBD content.

As a result of the passage of the amendments to the Commonwealth *Narcotic Drugs Act 1967*, the responsibility for licensing for growing and manufacturing medicinal cannabis will be pursuant to Commonwealth arrangements. Whether in practice this will involve the participation of State instrumentalities, as proposed by the VLRC and as set out in the *Access to Medicinal Cannabis Bill 2015* (Vic), remains to be seen but consequential amendments to the Victorian legislation will be required to ensure compatibility with the Commonwealth legislation.

Ongoing research

A key to ongoing adjustment to Victoria's medicinal cannabis law will be continuing research into the efficacy and side-effects of the various forms of medicinal cannabis. The Bill has built such developments into its structure. This occurs in multiple ways. The Health Secretary is obliged "to review research on the medicinal use of cannabis" (cl 9(b)) and is authorised to undertake research activities in relation to the manufacture of medicinal cannabis products (cl 18(e)). The Secretary to the Department of Economic Development, Jobs, Transport and Resources (the Resources Secretary) is

[80] Explanatory Memorandum, *Access to Medicinal Cannabis Bill 2015* (Vic) <http://www.legislation.vic.gov.au/domino/Web_Notes/LDMS/PubPDocs.nsf/ee665e366dcb6cb0ca256da400837f6b/5973532394C874EECA257F150082D37D/$FILE/581168exi1.pdf>.

empowered to undertake research activities in relation to the cultivation of cannabis, and the production of cannabis extract (cl 13(e)). A manufacturing licence can be specifically to enable the conduct of research (cl 44).

In addition, a specialist medical practitioner can apply for a practitioner medicinal cannabis authorisation for research purposes (cl 79) if satisfied that "(a) it is appropriate in all the circumstances that a participant should be treated with a medicinal cannabis product for research purposes; and (b) the prescribed additional criteria (if any) are met" (cl 79(3)). This enables the conduct of research trials with medicinal cannabis. To facilitate research and accountability, the Health Secretary is obliged to keep a publicly accessible register with an entry for each approved medicinal cannabis product (cl 71), as well as a register with an entry for each practitioner medicinal cannabis authorisation issued and each registered medical practitioner who is specified in a practitioner medicinal cannabis authorisation (cl 83).

Provision is made under cl 135 of the Bill for the Minister to cause an independent review to be conducted into the operation of the Act. This will be an important assessment to identify whether the expenditure of the Victorian Government continues to be justified by reference to the potential introduction of pharmaceutical cannabinoid agents pursuant to the TGA processes, and also by reference to the state of ongoing research and reports as to efficacy of the products made available during the first years of the Victorian scheme.

THE QUEENSLAND BILL

On 29 February 2016 the Queensland Government released the *Public Health (Medicinal Cannabis) Bill 2016* (Qld) for public discussion before proposed introduction of the Bill into Parliament during April 2016.[81] The Queensland Bill is overtly based upon the work of the VLRC and takes into account the Victorian Bill. It bears a number of features in common with the Victorian legislative initiative but has some important aspects which are distinctive.[82] It is intended to complement and be compatible with the amendments to the Commonwealth's *Narcotic Drugs Act 1967*.[83]

Like the Victorian legislation, the Queensland Bill is predicated on a medical practitioner applying for an approval to facilitate the treatment of a patient with medicinal cannabis (cl 13). An opinion from a specialist medical practitioner relating to the treatment of a patient with medicinal cannabis must accompany an application by a medical practitioner (cl 14). An approval process also applies to pharmacists who seek to dispense medicinal cannabis (cl 17), and also to applicants for a clinical trial approval (cl 19). It is the chief executive utilising an expert advisory panel who makes decisions about applications. The expert advisory panel will include experts from a variety of fields, including science, pharmacy or medicine, justice or law, ethics culture or sociology, and agriculture (cl 167).

The chief executive is able to grant approval if satisfied that:

(a) the applicant [medical practitioner] is a suitable person to hold the approval;
(b) the patient is a suitable person to undergo treatment with medicinal cannabis;
(c) the medicinal cannabis to which the approval will apply –
    (i) has, or will be, manufactured or imported under a law of the Commonwealth;
    (ii) is, or will be, able to be supplied, for the purpose of treating the patient, under a law of the Commonwealth. (cl 23(2)(a)-(c))

Arrangements are proposed for a carer to be authorised to obtain and possess "compliant medicinal cannabis" (cl 55) which is defined as "medicinal cannabis prescribed in accordance with the medicinal cannabis approval, and dispensed in accordance with the medicinal cannabis approval and

[81] <https://www.health.qld.gov.au/publications/system-governance/legislation/reviews/medicinal-cannabis/2016-02-18-bill.pdf>.

[82] See Queensland Health, *Cannabis in Queensland: Draft Public Health (Medicinal Cannabis) Bill 2016*, Discussion Paper (March 2016) <https://www.health.qld.gov.au/publications/system-governance/legislation/reviews/medicinal-cannabis/medicinal-cannabis-discussion-paper.pdf?>.

[83] Queensland Government, *Medicinal Cannabis in Queensland* <https://www.qld.gov.au/health/conditions/all/medicinal-cannabis/ queensland/>.

the prescription". An innovative component of the regulatory structure is its provision for a "medicinal cannabis management plan", which is a document that sets out a plan for managing known and foreseeable risks associated with the entity that performs an activity involving medicinal cannabis or which the entity is authorised to perform under the legislation (cl 64). A number of matters must be incorporated in such a plan:

(a) the day on which the plan starts;
(b) the relevant activity to be performed by the entity;
(c) the location where the medicinal cannabis will be stored or used to perform the relevant activity;
(d) details of known or foreseeable risks associated with the medicinal cannabis and the relevant activity;
(e) the measures to be taken to manage the risks mention in paragraph (d);
(f) the way in which the effectiveness of the plan will be monitored;
(g) the persons to whom the plan applies;
(h) the information, training and instruction to be provided to persons to whom the plan applies, including the way in which the persons are informed of changes to the plan;
(i) when and how the plan must be reviewed;
(j) the individual responsible for making, implementing and reviewing the plan. (cl 65(1))

The medicinal cannabis management plan must be written in such a way that it is likely to be understood by the persons to whom the plan applies and must be signed by the individual responsible for making, implementing and review the plan (cl 65(2)).

Another aspect of the scheme is the issuing of identity cards to persons who are authorised (cl 100). Lying behind the scheme is an elaborate apparatus for investigating potential abuses of the scheme with powers for search and seizure, and powers to require production of documents. Provision lies for appeals to the Queensland Civil and Administrative Tribunal against decisions under the Act after internal review mechanisms are exhausted (cl 175).

THE FUTURE

Momentum is growing inexorably for the medical use of cannabis. This is not confined to Australia.[84] After many years of political unresponsiveness to Bills introduced around Australia by the Greens, as of 2015-2016 governments in Australia, Labor and Coalition, are now competing for the political kudos of being seen as the first to champion the therapeutic benefits of medicinal cannabis and to promulgate schemes which circumvent the processes of the TGA and enable access to Australian-grown forms of the product. This change has been the product of lobbying from many quarters and has been responsive to the plight of a range of individuals whose circumstances have been adversely affected by the various criminalising laws which have prevented patients' access to medicinal cannabis.

The Victorian *Access to Medicinal Cannabis Bill 2015* and the Queensland *Public Health (Medicinal Cannabis) Bill 2016* provide templates for medicinal cannabis law reform throughout Australia, and even internationally. The approach to legalisation of cannabis from both Victoria and Queensland as a gradual, research-based process is a compassionate but pragmatic approach to law reform in the area. It combines provision of access to medicinal cannabis in exceptional circumstances with caution in respect of too ready availability of a drug whose properties are still not fully understood and which has the potential to be criminally diverted into the recreational marketplace. It avoids the exuberance and excesses of many of the North American reforms which have failed to achieve their therapeutic objectives and which have been undermined by commerciality and well-founded medical practitioner mistrust. Knowledge about the therapeutic properties of medicinal cannabis remains at a relatively early stage. Although a great many articles on the subject have been published, as of early 2016 the sound research base – from double-blind, placebo-controlled trials – remains relatively thin, although promising in many respects. This means that caution in the reform process is necessary from a medico-scientific point of view.

[84] See Chris McCall, "Momentum Grows for Medical Use of Cannabis" (2015) 386 *The Lancet* 1615.

While there is scope in respect of certain conditions to have resort for compassionate reasons to forms of medication that have not made their way through TGA and/or PBS assessment, this does not mean that orthodox means of assessment of therapeutic efficacy and safety should readily be jettisoned. It is important that care be exercised in respect of potential side-effects from medicinal cannabis, in a way that is comparable to the protections provided in respect of any other form of medication. It is also important that inflated expectations of cure or substantial remission or alleviation of symptoms not be created. Thus, the emphasis of the Victorian Bill upon introducing different categories of eligible patient, starting with those with paediatric epileptic conditions, has merit. There is less certainty in respect of the Queensland initiative, although it is likely that in that State also priority will be given in the initial phase to access for young patients with epilepsy.

The Medicinal Cannabis Advisory Committee in Victoria and the expert advisory panel in Queensland will be able to provide advice to the Health Minister and the Secretary respectively on other conditions for which medicinal cannabis should be made available for patients based upon review of the clinical literature and also emerging research evidence. In due course, information from the New South Wales trials, as well as from other research initiatives (to some of which both pieces of legislation give a fillip) will be able to feed into and enrich the evidence base, enabling informed decisions to be made in respect of a variety of cannabinoid compounds, as well as combinations of them. In addition, a fall back in respect of patients with unusual and particularly deserving circumstances is created in Victoria whereby medical practitioners can seek an "exceptional circumstances" authorisation (cl 76) and also research trial authorisations (cl 77). This provides flexibility for compassionate reasons when the circumstances are out of the ordinary, but subject to the assessment of the Health Secretary.

Medicinal cannabis will not be available for patients in Victoria until 2017 under the scheme and at first only for children with epilepsy. A similar situation is likely to obtain in Queensland. However, by setting the processes for cultivation and manufacture in train, and permitting time for trial crops and production, the potential for error is reduced and the likelihood of a sound broader based scheme is created.

For the Victorian and Queensland Bills to have a reasonable prospect of success, a number of considerations must be met. First, medical practitioners and also pharmacists have to be persuaded to engage with the scheme. If they decline to authorise and to dispense, the schemes will be unlikely to be successful and will be stigmatised and marginalised. The approach of incorporating medicinal cannabis from the folk into the orthodox pharmacopeia by confining closely the categories of eligible patients, by having it enabled by specialist medical practitioners and monitored by general practitioners, by ensuring that dose-response and side-effects can be effectively reviewed, and by ensuring that it will be available in conventional and labelled therapeutic forms – oils, tinctures and tablets – are measures that optimise the prospects of assuaging legitimate concerns that would otherwise be harboured by mainstream health practitioners. This is a lesson that has been sensibly learned from the Canadian and United States experiences where the Canadian Medical Association[85] and the American Medical Association[86] were not adequately engaged in the reform process and maintain their opposition to it.

[85] Canadian Medical Association, *CMA Statement Authorising Marijuana for Medical Purposes (Update 2015)* <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD15-04.pdf>: "The Canadian Medical Association has consistently opposed Health Canada's approach which places physicians in the role of gatekeeper in authorizing access to marijuana. Physicians should not feel obligated to authorize marijuana for medical purposes, Physicians who choose to authorize marijuana for their patients must comply with their provincial or territorial regulatory College's relevant guideline or policy."

[86] American Medical Association, *Cannabis for Medicinal Use* <https://www.ama-assn.org/ssl3/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=/resources/html/PolicyFinder/policyfiles/HnE/H-95.952.HTM>: "Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product."

Communication by the Office of Medicinal Cannabis in Victoria, and ideally by a comparable arrangement in Queensland, with both medical practitioners and members of the public will be very important to facilitate contemporary research-based knowledge about the clinical efficacy of cannabis and its potential side-effects and contra-indications. It is pertinent to acknowledge that most medical practitioners, to this point, have no informed knowledge about the clinical benefits and detriments of medicinal cannabis and are reliant upon the limited material that has been published in the research literature on the subject. This needs to be supplemented. So that they can discharge their duty of care to their patients in terms of information provision and oversight, and thereby be protected from medico-legal exposure, it will be incumbent upon government, through an entity such as the Victorian Office of Medicinal Cannabis, and also the learned colleges, to make the necessary information available. A model in this regard is the Canada Health documents, *Consumer Information – Cannabis (Marihuana, Marijuana)*[87] and *Information for Health Professionals: Cannabis (Marihuana, Marijuana, and the Cannabinoids)*[88] which are freely available on the internet. However, a disappointing attribute of the Canadian document for health professionals which should not be replicated is that as of March 2016 the information package is out-of-date; it had not been updated in three years. In a research environment where information in the area is evolving at a significant pace, this is not acceptable.

In addition, an approach which recognises that just as opiates and many other forms of medication are not a panacea, nor are cannabinoids, is best calculated to erode inflated and aspirational expectations. In the pain relief area, for instance, medicinal cannabis is likely to have a constructive role to play. However, it should best be viewed as playing such a role when incorporated as part of an overall, multi-modal, multi-disciplinary pain management regime.

Further, it is necessary that medicinal cannabis preparations be priced in a way comparable to those that have obtained PBS approval. Under cl 73 of the Victorian legislation the Health Secretary is able to set the maximum price at which a pharmacist may sell an approved medicinal cannabis product. This will mean that the State of Victoria will be required to underwrite a substantial percentage of the cultivating, manufacturing and other costs of medicinal cannabis. It is not possible to identify what this will cost until decisions are made about the categories of eligible patient and the costs per unit can be calculated. This constitutes another sound reason for the mandated review (cl 135) to be conducted within four years of the legislation coming into force so as to assess the cost-benefit impact of the legislation. Similar issues will arise under the Queensland scheme.

A criticism that could be made of the Bills are as to their comprehensiveness. The Victorian Bill is 142 pages in length and contains 188 clauses. The Queensland Bill is 133 pages in length and contains 218 clauses. Many of the Victorian provisions deal with licensing issues in relation to cultivation and manufacture, including detailed criteria for licences, and criminal offences for breach of obligations. These will now be able to be excised or reduced in extent. However, care will be needed in respect of the operation of the entities that engage in these tasks. Some entities may be equipped to do both, but this is likely to be the exception rather than the rule. Both phases need to be monitored effectively (probably at State/Territory level) to ensure quality control and product security and thereby to avoid diversion; this is essential for compliance with Australia's international obligations. In addition, given that the process is different from that which is orthodox and the subject of TGA oversight, the role and empowerment of inspectors from the relevant government departments are essential to ensure adherence to appropriate cultivation and manufacturing practice.

In summary, while there will be some who would wish that the draft legislation in both Victoria and Queensland went further and delivered medicinal cannabis to patients quicker, the comprehensive Bills before the Victorian Parliament and soon to be before the Queensland Parliament are the product of prudent compromise and have learned lessons from the schemes in existence in various States in the United States, and in Canada, the Netherlands and Israel. The prospects of collaboration in the medicinal cannabis schemes on the part of registered health practitioners are maximised by the

[87] (December 2015) <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/info/cons-eng.pdf>.

[88] (February 2013) <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf>.

carefully structured checks and balances within the legislation. This is consistent with what was recommended by the VLRC. In addition, the gradual introduction of categories of eligible patients on the basis of evolving research will ensure that medicinal cannabis products are not viewed as able to achieve more than is biochemically feasible. The regulation of cultivation and manufacture, together with the creation of a variety of criminal offences, under the amended *Narcotic Drugs Act 1967* (Cth) minimise the potential for organised crime to become involved in the industry and leverage off the successful poppy straw regimes which have operated well and lucratively for some years in both Victoria and Tasmania. The combination of the new Commonwealth legislation and the Victorian and Queensland Bills create interlocking schemes which are compliant with Australia's international obligations and avoid the perils of self-medication and lack of involvement from medical practitioners which have bedevilled "grow-your-own" schemes in other countries. They assure that a necessary cost-benefit assessment can be carried out within a modest timeframe and in Victoria set up a regime for generating and learning from ongoing clinical research.

The *Access to Medicinal Cannabis Bill 2015* (Vic) and the *Public Health (Medicinal Cannabis) Bill 2016* (Qld) are innovative examples of public health legislation. They have the potential to provide an additional form of quality-controlled and monitored pharmacotherapy that will benefit many persons for whom other forms of medication have not achieved the desired therapeutic objectives. There is much to be said for consistent medicinal cannabis regimes throughout Australia but given the politics of medicinal cannabis law reform this appears unlikely. The Victorian and Queensland Bills provide templates for law reform in Australia and have the potential to be internationally influential.