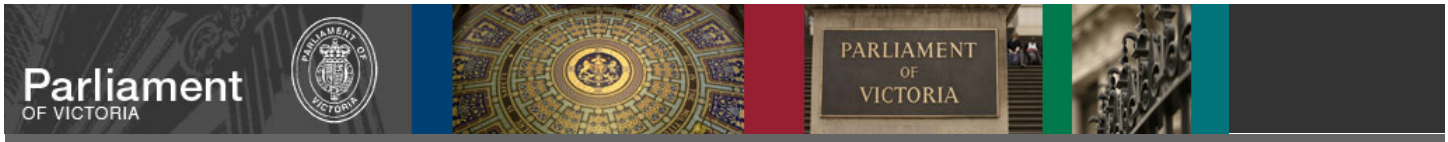

RESEARCH PAPERS

Drugs, Poisons and Controlled Substances Amendment (Clinical Trials) Bill 2014

Introduction

On 28 August 2014 the Coalition Government announced the introduction of a Bill to facilitate clinical trials of medical cannabis.[footnote 1] The Minister for Health, the Hon David Davis stated that 'The issues surrounding the use of cannabis compounds for treatment of medical conditions are extremely complex, requiring regulatory and legislative changes, but most importantly, sound medical advice'.[footnote 2] The Coalition Government indicated an intention to establish an expert advisory committee of clinical and regulatory experts to investigate the related clinical and ethical issues and ensure trials are properly governed.[footnote 3]

The Health Minister has also signalled that the government would consider further amendments to legislation to allow regulated cultivation of cannabis for use in clinical trials.[footnote 4] In addition, the Minister gave 'in principle' support for Victorians to take part in an international trial of Epidiolex, a pharmaceutical cannabis product being tested overseas in children with epilepsy.[footnote 5]

Opposition Leader, the Hon. Daniel Andrews had previously announced on 24 August 2014 that, if elected, the Labor Party would put the issue to the Victoria Law Reform Commission, with the aim of finding a path to legalisation of cannabis for medical purposes.[footnote 6]

Cannabis

§ Cannabis is a generic term for drugs made from any of the genus cannabis plants, including *Cannabis Sativa* and *Cannabis Indica*.

§ Drugs derived from cannabis are usually produced in three main forms: marijuana (dried leaves and flowering tops of the plants), hashish (cannabis resin) and cannabis oil.

§ When consumed, cannabis can result in users experiencing an alteration in mood and a feeling of 'high'. The psychotropic and psychoactive effect of cannabis were grounds for the inclusion of cannabis as a controlled drug in the United Nations *Single Convention on Narcotic Drugs in 1961*.

§ Cannabis is an illicit drug in Australia under Commonwealth and state laws.

§ Cannabis is the most widely used illicit drug in Australia.

Cannabinoids

§ Cannabis consists of over 400 chemical substances, and over 60 of these are cannabinoids. When ingested, cannabinoids activate the cannabinoid receptors in the body, producing a range of effects on movement, appetite, emotion, memory and cognitive functions.

§ Principal cannabinoids found in the cannabis plant are Delta-9-Tetrahydrocannabinol (THC) and Cannabidiol (CBD). THC produces the psychoactive effects of cannabis, but can also have therapeutic effects on reducing pain, nausea and vomiting, and stimulating appetite. CBD is non-psychoactive and may reduce the unwanted psychoactive effects of THC.

§ The combination and strength of cannibinoids in cannabis plants can vary depending on plant strain and conditions of growth and storage, as well as chemical contamination (eg. from pesticides, heavy metals, fungus and mould).

§ Cannabinoids can be manufactured in pharmaceutical laboratories as pharmaceutical drugs. Three pharmaceutical cannibinoids are:
dronabinol – a synthetic THC, approved for the treatment of nausea and vomiting in chemotherapy patients, as well as AIDs related weight loss. Dronabinol is taken as oral capsules and marketed as Marinol.
nabilone – a synthetic analogue of THC, licensed for use in treating chemotherapy-induced nausea and vomiting. Nabilone is taken as oral capsules and marketed as Cesamet.
nabiximols – a 1:1 ratio of THC and CBD from cannabis plants, approved to treat spasticity in patients with multiple sclerosis. Nabiximols is an oral spray known under the trade name of Sativex.

§ Dronabinol and nabilone have been granted approval for use in the United States of America, Canada and the United Kingdom, but have not been marketed in Australia. Nabiximols (Sativex) has been approved to treat spasticity for patients with multiple sclerosis in Canada, the United Kingdom, Spain, New Zealand, and recently in Australia as a controlled drug available on prescription for multiple sclerosis patients.

Administration

§ Smoking (via joints or water pipes) – offers a rapid effect and allows patients to self-titrate (measure their own dosage), but has been linked to health risks including cardiovascular and respiratory disease and cancer.

§ Inhalation through a vaporiser – offers a rapid effect, allows for self-titration and may avoid health risks of smoking.

§ Ingestion via food or drink – a slower effect, more difficult to self-titrate and not suitable for patients with nausea and vomiting.

§ Taken as oral capsules (for cannibinoids such as dronabinol and nabilone) – a slower effect and swallowing may be problematic for patients with nausea and vomiting

§ Application to skin as a cream

§ Taken orally in tincture form – liquid drops placed under the tongue

§ Taken in oral spray form (eg. nabiximols Sativex) –considered to be the best controlled dosage form, slower effect yet avoids unwanted feeling of 'high', suitable for patients with nausea and vomiting.

Summary based on General Purpose Standing Committee No. 4 (2013) *The Use of Cannabis for Medical Purposes,* final report, New South Wales, Parliament, Legislative Council, 15 May, pp. 3-6.

Background

History of medical cannabis

There is a long history of cannabis use for medical purposes in various locations, including India, China, Greece, Egypt and the Middle East, dating back up to 4,000 years.[footnote 7] The earliest documented medicinal use dates back to 4,000 BCE in China.[footnote 8] Cannabis has been used to treat a variety of conditions, such as pain, nausea, spasms, insomnia, appetite loss and other conditions. Western medicine took on cannabis during the nineteenth century, primarily in tincture form.[footnote 9] The twentieth century saw the development of other more effective analgesic drugs, and this, combined with the difficulty in standardising cannabis for medical purposes, resulted in a marked decrease in the medical use of cannabis.[footnote 10]

In 1961, the United Nations' *Single Convention on Narcotic Drugs* included cannabis as a controlled drug. Australia is a signatory to this and other international conventions, such as the *United Nations Convention on Psychotropic Substances 1972* and the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988,* which restrict the cultivation, supply, possession and use of cannabis, however these restrictions do not apply to cannabis used for medical or scientific purposes.[footnote 11]

From the late 1990s, several international medical institutes published research into the potential medicinal use of cannabis, including the Health Council of the Netherlands, American Medical Association House of Delegates, British Medical Association and World Health Organisation. The two most prominent reports of this period were produced by the House of Lords Select Committee on Science and Technology in the United Kingdom in 1998 and the Institute of Medicine in the United States in 1999.[footnote 12]

History of medical cannabis in Australia

Similarly in Australia, there were calls from the late 1990s to approve cannabis use for medical purposes. NSW Premier Hon Bob Carr established a Working Party on the Use of Cannabis for Medical Purposes in October 1999,[footnote 13] whose subsequent report in August 2000 concluded that some cannabinoids may be useful in the treatment of wasting in AIDS patients, nausea related to chemotherapy, muscular spasms in certain neurological disorders and pain which did not respond to conventional treatments.[footnote 14] The report expressed the view that crude cannabis could not, and was unlikely to ever be, prescribed in Australia, and acknowledged the commercial and regulatory challenges to prescribing synthetic cannabinoids for medical use in Australia.[footnote 15] The report made 24 recommendations to the NSW Government, including recommendations to conduct further research, identify safer ways to administer cannabis other than smoking or consuming the plant directly, develop a compassionate scheme in the short term to provide access to cannabis for seriously ill patients, and a two year trial of medical cannabis where approved people with certain medical conditions could possess, grow and use cannabis without prosecution.[footnote 16] These recommendations were in line with those made by the reports by the Institute of Medicine and the House of Lords Select Committee on Science and Technology.[footnote 17]

Following the release of this Working Party report, a subsequent NSW Government report in 2001 showed that 72 per cent of responses from the public supported the use of cannabis for medical purposes.[footnote 18] In May 2003, Premier Carr announced his proposal to launch a four-year trial of the medical use of cannabis, including the establishment of an Office of Medicinal Cannabis to regulate supply and use and to register eligible patients.[footnote 19] The proposed trial did not proceed. Professor Wayne Hall, former chair of the Working Party, later suggested a range of factors prevented the Government from proceeding with their authorised supply approach, including the high cost to government of controlling cultivation, supply, oversight and distribution of the cannabis.[footnote 20]

In May 2008, the Hon Morris Iemma (Premier Carr's successor) requested permission from the Commonwealth Government for the importation of Sativex to Australia.[footnote 21] Sativex was subsequently included in the Australian Register of Therapeutic Goods as a controlled drug in November 2012, available on prescription to treat spasticity in patients with multiple sclerosis.[footnote 22]

Sativex

Sativex is a nabiximol in oral spray form which has been approved or is recommended for approval in 21 countries, including Canada, Denmark, Czech Republic, Germany, New Zealand, Spain, Sweden and the United Kingdom.

Currently GW Pharmaceuticals has been conducting an international clinical trial of Sativex, including 11 Australian sites (eg Royal Melbourne, Peter MacCallum and John Hunter Hospitals). The trial investigates the efficacy of using Sativex to relieve pain associated with cancer, and the expected completion date is December 2015.

The cost of Sativex is estimated to be $500 per month in New Zealand, totalling around $6,000 per year.

Many stakeholders have advocated for Sativex and other pharmaceutical cannabis products to be made more affordable through listing it on the Pharmaceutical Benefits Scheme.

Summary based on General Purpose Standing Committee No. 4 (2013) *The Use of Cannabis for Medical Purposes,* final report, New South Wales, Parliament, Legislative Council, 15 May, pp. 32, 38-9.

2013 NSW Legislative Council Committee Report

A recent report by a committee of the New South Wales Legislative Council provides a useful overview of medical and legal issues relating to medicinal cannabis, as well as drawing some noteworthy conclusions. In November 2012 the New South Wales Legislative Council's General Purpose Standing Committee No. 4 was asked to look into the efficacy and safety of medical cannabis, issues relating to possible supply for medical use, as well as legal implications. The Committee published its report in May 2013, and concluded that there was sufficient evidence to indicate that cannabis products can be effective in treating certain conditions.[footnote 23] In their report, the Committee

§ acknowledged that certain attitudes may have prevented the recognition of cannabis for its therapeutic potential in Australia;[footnote 24]

§ understood that, despite being illegal, the use of crude cannabis products for medical purposes is 'fairly widespread among people with serious illness';[footnote 25]

§ agreed that provisions should be made for 'a very small and specific group of patients' to legally use crude cannabis products for medical purposes.[footnote 26] This was in light of the lengthy approval process through the Therapeutic Goods Administration (TGA), the potentially high cost of pharmaceutical cannabis without subsidy under the Pharmaceutical Benefits Scheme and the varied effectiveness of cannabis products for individuals, all of which may lead some patients to use crude cannabis;

§ recognised the significant problem of supply;[footnote 27]

§ acknowledged the arguments for cannabis use in treating chronic pain, but did not recommend provision of cannabis products to patients with chronic conditions, citing a lack of evidence examining the long term effects of prolonged cannabis use;[footnote 28]

§ expressed the view that the risk of diversion was minimal and that the community would be prepared to tolerate this small risk on compassionate grounds;[footnote 29]and,

§ did not believe legalising medicinal cannabis would normalise cannabis use more broadly, or 'glamourise cannabis use to potential recreational users'.[footnote 30]

The Committee made the following five recommendations –

§ that the NSW Government express in-principle support for the use of medicinal cannabis for relevant patient groups, further clinical trials and addressing the affordability of pharmaceutical cannabis products (Recommendation 1);

§ that a complete defence from prosecution be established for the use and possession of cannabis for medical purposes by people with terminal illness and AIDS, covering use and possession of up to 15 grams. This defence would be extended to carers. However, the use and supply must not occur in a public place. This amendment should be reviewed after three years (Recommendation 2);

§ that a register of authorised patients and carers be established and administered by the NSW Ministry of Health (Recommendation 3);

§ that further consideration be undertaken by the NSW Ministry of Health and the Attorney-General into the matter of legal supply for crude cannabis for medical use (Recommendation 4); and,

§ that the NSW Ministry of Health develop and implement an education strategy to inform medical professionals, the community and patients of relevant issues surrounding medical cannabis, such as the harms of smoking cannabis and other methods of administration (Recommendation 5).[footnote 31]

Apart from recommendation 1, the NSW Government did not support these recommendations.[footnote 32] It has, however, made recent moves towards a clinical trial of medical cannabis, see 'Other Jurisdictions' on page 21.

The medicinal use of cannabis

Efficacy

Several reviews of evidence for medical cannabis have supported its use for certain conditions.[footnote 33] One such review is a 2012 German medical review which found that controlled trials were predominantly favourable towards the use of cannabis to treat a variety of conditions, including –

§ Spasticity in multiple sclerosis (nine favourable trials, three unfavourable)

§ Nausea and vomiting related to chemotherapy (40 favourable, one unfavourable)

§ HIV/AIDS-related wasting (seven favourable, none unfavourable)

§ Cancer-related wasting (three favourable, one unfavourable)

§ Chronic neuropathic pain (12 favourable, two unfavourable)

§ Other chronic pain, eg. cancer, rheumatism, fibromyalgia (11 favourable, two unfavourable).[footnote 34]

Safety

Side effects

In clinical trials, patients using cannabinoids reported a variety of side effects, including dizziness, dysphoria (a state of feeling unhappy or unwell), hallucinations, depression, paranoia and impairment in cognitive functions and physical movement (psychomotor performance).[footnote 35] Some studies show side-effects appear to be low and use of medicinal cannabis may be sufficiently safe in the short term.[footnote 36] A 2008 review of side effects of medical cannabis found that side effects when using cannabis or cannabinoids were minor, [footnote 37] and supported a previous finding by the US Institute of Medicine that the use of medical cannabis was 'within the risks tolerated for many medications'.[footnote 38]

Potential health risks from long-term use

§ *Cardiovascular or respiratory diseases or cancer*

Cannabis smoke contains similar harmful carcinogens to those in tobacco, which can cause damage to the lungs and respiratory system if used in large quantities over a long period of time.[footnote 39]

§ *Dependence*

There is also a concern that a long term effect of using medical cannabis is dependence. However, studies on cannabis dependence vary. Some studies suggest cannabis dependence and withdrawal syndrome can occur.[footnote 40] Other studies suggest dependence is more psychological than physiological.[footnote 41] In a 2011 review of Sativex, it was found that cannabis abuse or dependence 'is likely to occur in only a very small proportion of recipients'.[footnote 42]

§ *Psychotic disorders*

Much research has been conducted into the effects of cannabis on mental health and its potential links to psychotic disorders. Evidence suggests the use of cannabis may trigger psychotic disorders in young people or people with a predisposition or history of psychiatric conditions,[footnote 43] yet it has not been shown that cannabis causes psychotic disorders in people who would not have developed such conditions in the absence of cannabis.[footnote 44] A report by the Mental Health Council of Australia in 2006 raised concern about the use of cannabis by young people between 12 and 19 years old, who are at a stage of life when their brain is still developing.[footnote 45]

Toxicity

Cannabis has low toxicity and a higher 'margin of safety' (the margin between a safe therapeutic dose and a toxic dose) than many other potent drugs.[footnote 46] The side effects of using cannabis are considered milder than those of opioid analgesics or antidepressants, and milder than the effects of serious medical conditions left untreated.[footnote 47] Cannabis has not been shown to cause immediate life-threatening side effects, even if consumed in large quantities.[footnote 48]

Use of medical cannabis in Australia

It is difficult to gain an accurate picture of the extent of medical cannabis use in Australia. In 2001, Hall et al. estimated that in NSW there could be up to 18,900 people who have used medicinal cannabis for chemotherapy-induced nausea, wasting related to cancer or HIV, chronic pain or spasticity.[footnote 49] If medicinal cannabis were to be legalised, it is unknown how many people may use it.[footnote 50]

One of the few surveys conducted in Australia to date is by Swift et al., who undertook a small survey of 128 people in Australia who used cannabis medicinally.[footnote 51] Respondents used various forms of administration, though smoking was most common. The health risks of smoking cannabis were a concern to respondents, but it was a preferred means of administration due to its rapid effect and the ability to measure doses, as well as its lower cost compared to other cannabis products.[footnote 52] A high level of satisfaction was reported among the respondents regarding the effects of cannabis on their symptoms or medical conditions,[footnote 53] which is consistent with other international surveys.[footnote 54] However, many of these surveys show a skewing towards patients who favour medical cannabis use and these self-reported patient perceptions may not be considered evidence of efficacy.[footnote 55] The Australian survey by Swift et al. also found 27 per cent of respondents stated they had been arrested, cautioned or convicted for their use of medicinal cannabis.[footnote 56] Concern about the illegal status of cannabis was reported by 76 per cent of respondents and 60 per cent feared being arrested.[footnote 57] The majority of respondents also reported that the quality and effectiveness of their cannabis supply was variable.[footnote 58]

Supply

The question of how medical cannabis may be supplied in Australia has been much debated when considering law reforms in this area.[footnote 59] Australia's ratification of international conventions does not prevent the use of cannabis for medical or scientific purposes, but the 1961 convention did include an international system of controls on cultivation of cannabis plants.[footnote 60] According to the Australian National Council on Drugs, it would be necessary for Australia to establish a new body or assign a current government agency to regulate cannabis cultivation for medical or scientific purposes.[footnote 61] Approved growers would need to be licensed, and legislative changes would be needed as cannabis plants cannot legally be sold in Australia.[footnote 62]

Importing cannabis would require Australia to give advance specifications to the International Narcotic Control Board detailing the amount of cannabis products to be imported each year.[footnote 63] Importers would also require licences. Importing cannabis products is likely to be more costly than cultivating cannabis in Australia and state and territory laws may need to be amended accordingly.[footnote 64]

Cultivation of cannabis plants for medical purposes by licensed growers would not contravene the 1988 Convention, so therefore it would be possible for patients growing their own supply to be exempt from prosecution, though this would require an appropriate legislative framework to be established. [footnote 65]

Supply—Stakeholder views

There has been much discussion of various models for the supply of medical cannabis. The Australian Drug Law Reform Foundation proposed a model similar to that operating in the Netherlands, where the government licensed growers to produce standardised cannabis which would be prescribed by doctors and dispensed by pharmacists.[footnote 66] An expert panel would determine the eligibility of patients to access the cannabis products. Former Members of the Working Party, Professor Lawrence Mather of the University of Sydney and Professor Wayne Hall of the University of Queensland Centre for Clinical Research also endorsed the Netherlands model, though Professor Hall noted that this highly regulated approach would be costly to run. [footnote 67]

The HEMP Party proposed licensed operators grow and dispense cannabis products for medical use to patients with a doctor's letter, similar to the model operating in California. [footnote 68] Other commentators view the Californian model as too liberal.[footnote 69]

Supply models are often based on registration of approved patients who are allowed to grow, obtain, possess and use cannabis for medical purposes. Issues which have arisen in relation to a registration model include the development of two classes of people for whom different laws apply, privacy concerns regarding the disclosure of patient information to law enforcement agencies, registration being extended to patients who may not benefit, and difficulty in identifying conditions for which patients can be registered to access medicinal cannabis.[footnote 70]

Options for legal changes—state level

There appear to be three options for legal reform at the state level which would not be in conflict with Commonwealth law—allowing access to cannabis products through clinical trials, amending legislation to exempt a certain group of people from prosecution for the possession and use of cannabis for medical purposes, and enabling prescription of cannabis products through the Australian Register of Therapeutic Goods.[footnote 71]

The Commonwealth *Criminal Code Act 1995* provides that it is a defence to drug offences under the Code if the conduct is justified or excused under State or Territory law (this excludes import/export offences).[footnote 72] Therefore a defence at state level legislation would also apply at the federal level.

However, while state legislation can cover a patient cultivating and using medical cannabis without Commonwealth legislative involvement, a person supplying seeds, plants, equipment and instructions to a patient or their carer who are cultivating medical cannabis may be in breach of the *Therapeutic Goods Act 1989.* This would therefore require reform at the federal level.[footnote 73]

Current Situation

Regulation of cannabis

Australia

As a signatory to international agreements by the United Nations which place restrictions on the use of cannabis, including the *Single Convention on Narcotic Drugs (1961)* and the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988),* the Commonwealth must only allow cultivation, trade and use of cannabis for medical or scientific purposes. All other cultivation, possession and use of cannabis plants or pharmaceutical cannabis is illegal in all Australian states and territories, with the exception of Sativex by prescription and other cannabis products through the Special Access Scheme (see below).[footnote 74]

Relevant Commonwealth legislation includes:

§ *Criminal Code Act 1995;*

§ *Customs Act 1901;*

§ *Customs (Prohibited Imports) Regulations 1956;*

§ *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990;*

§ *Narcotic Drugs Act 1967; and,*

§ *Therapeutic Goods Act 1989.*[footnote 75]

The *Therapeutic Goods Act 1989* establishes the requirements for including therapeutic goods in the Australian Register of Therapeutic Goods (ARTG), which records all goods approved for therapeutic use in Australia.[footnote 76] Currently, Sativex is the only cannabis product listed on the ARTG. It is classified as a controlled drug, available only on prescription from a medical practitioner authorised by the Secretary of the Commonwealth Department of Health.[footnote 77]

The Special Access Scheme provides for patients with serious medical conditions or those at the end stage of their life to request access to cannabis products and other unapproved therapeutic goods through the TGA.[footnote 78] However, there can be high costs associated with importing specific drugs.[footnote 79]

In the federal parliament, Greens Senator Richard Di Natale, who is also chair of the cross-party Parliamentary Group for Drug Policy and Law Reform, has announced plans to introduce a private member's Bill to legalise medical cannabis.[footnote 80] Senator Di Natale has stated the Bill would include provisions for the licensing of cannabis growers, quality control standards, as well as requirements for processing and distribution.[footnote 81] The system would be designed to mirror the regulation of the cultivation of poppies for use in medical opiates.[footnote 82] Senator Di Natale said he would prefer the establishment of a new independent statutory authority to regulate the drug, but that this role could also be performed by the Department of Health[footnote 83]. The Prime Minister Tony Abbott has also made recent comments in support of the use of cannabis for medical purposes.[footnote 84]

Victoria

It is an offence to possess, cultivate or distribute cannabis in Victoria under the *Drugs, Poisons and Controlled Substances Act 1981*[footnote 85]. However Victoria Police have the discretion to issue up to two cautions against a person possessing less than 50 grams of cannabis under the Cannabis Cautioning Scheme.[footnote 86]

Currently, under the *Drugs, Poisons and Controlled Substances Act 1981*[footnote 87], medical practitioners must apply to the Secretary for a permit to administer, supply and prescribe Schedule 8 or 9 poisons on an individual patient basis.[footnote 88]

What the Bill proposes

According to the second reading speech, this Bill amends the *Drugs, Poisons and Controlled Substances Act 1981* to make is easier for a medical practitioner to conduct clinical trials using cannabis or other controlled substances.[footnote 89]

Clause 4 of the Bill inserts three new definitions – 'approved clinical trial', 'clinical trial participant' and 'clinical trial permit'. The definition of a clinical trial is a trial conducted in accordance with the Commonwealth *Therapeutic Goods Act 1989*. This means the trial would need to be conducted under either the Clinical Trial Notification Scheme or the Clinical Trial Exemption Scheme, as administered by the Therapeutic Goods Administration. Approval for the clinical trial from a recognised human research ethics committee would also be necessary.

Clause 5 of the Bill inserts a new Division 10B into Part II to provide for applications for clinical trial permits for Schedule 8 and Schedule 9 poisons to be administered, supplied or prescribed to one or more participants. A point of difference between the application for trials of Schedule 8 and Schedule 9 poisons is that a medical practitioner or nurse practitioner is able to apply for a clinical trial permit involving Schedule 8 substances, whereas only a medical practitioner is allowed to apply for a clinical trial permit involving Schedule 9 substances.

Approval of permits to conduct clinical trials rests with the Secretary of the Department of Health and may be subject to any other terms, conditions, limitations or restrictions as the Secretary sees fit, such as the provision of specific documentation, the destruction of remaining poison at the conclusion of the trial or notification of any contraindications apparent during the trial. The clinical trial permit remains in force for the time specified for the trial, unless the permit is suspended or revoked sooner. The Secretary has the power to refuse, amend, suspend or revoke a clinical trial permit at any time. A person who feels aggrieved by a decision by the Secretary to refuse, suspend or revoke a clinical trial has the right to appeal to the Magistrates' Court within six months, under section 37 of the Principal Act.

Proposed subsection 36J of the new Division 10B creates two new offences for practitioners who administer, supply or prescribe Schedule 8 or 9 poisons to participants outside of the period covered by the clinical trial permit unless otherwise authorised (100 penalty units).

Clinical trial participants and anyone involved in conducting a clinical trial is authorised to possess a Schedule 8 or 9 poison in line with the relevant clinical trial permit, under proposed subsection 36K.

Schedule 8 and Schedule 9 Poisons

The Standard for the Uniform Scheduling of Medicines and Poisons lists all scheduled poisons, and is produced by the Australian Committee for Chemical Scheduling in the Therapeutic Goods Administration (TGA). Schedule 8 poisons are 'Controlled Drugs' which have a high potential for abuse, misuse and dependence. Schedule 9 poisons are 'Prohibited substances' which may be abused or misused and are the most highly regulated poisons.

Cannabis is a Schedule 9 prohibited substance, meaning that it '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'. Pharmaceutical products containing cannabinoids may still be used medicinally if they are registered with the TGA and rescheduled.

Certain pharmaceutical cannabis products such as nabilone, nabiximols (Sativex) and dronabinol are Schedule 8 controlled drugs. Nabilone and dronabinol have never been used in Australia and are unregistered, but are included as Schedule 8 drugs to enable patients to access them via the Special Access Scheme. Similarly, nabiximols (Sativex) was included as a Schedule 8 drug in 2010 and was registered in 2012 for use in Australia to treat spasticity in patients with multiple sclerosis.

Summary based on Australian National Council on Drugs (2014) *Medicinal Use of Cannabis: Background and Information Paper,* ANCD, 25 August, pp. 3-4.

Clause 6 provides for the Governor in Council to make regulations regarding the administration, supply or prescription of Schedule 8 or Schedule 9 poisons to participants in clinical

trials.

Stakeholder views

There appears to be significant community support for the medicinal use of cannabis. In the 2010 National Drug Strategy Household Survey by the Australian Institute of Health and Welfare, around 69 per cent of respondents supported a change in legislation permitting the use of marijuana for medical purposes, and 74 per cent of respondents were in favour of clinical trials into medical marijuana (see Table 1).[footnote 90]

Table 1: Support* for measures relating to cannabis use in medical settings, people aged 14 years or older, 2004 to 2010 (per cent)

	Persons		
Measure	**2004**	**2007**	**2010**
A change in legislation permitting the use of marijuana for medical purposes	67.5	68.6	68.8
A clinical trial for people to use marijuana to treat medical conditions	73.5	73.6	74.0

* Support or strongly support (calculations based on those respondents who were informed enough to indicate their level of support). Source: 2010 National Drug Strategy Household Survey

According to the survey, among the states and territories, the ACT had the highest proportion of respondents supporting the medical use of marijuana, whereas Victoria was fractionally higher than the national average (see Table 2).

Table 2: Support* for measures relating to cannabis use in medical settings, people aged 14 years or older, by state/territory, 2010 (per cent)

Measure	**NSW**	**Vic**	**Qld**	**WA**	**SA**	**Tas**	**ACT**	**NT**	**Aust.**
A change in legislation permitting the use of marijuana for medical purposes	68.6	69.1	67.0	71.2	69.2	70.0	72.4	70.1	68.8
A clinical trial for people to use marijuana to treat medical conditions	73.6	74.1	72.8	75.5	74.0	75.4	81.7	74.9	74.0

* Support or strongly support (calculations based on those respondents who were informed enough to indicate their level of support). Source: 2010 National Drug Strategy Household Survey

Arguments for the legalisation of cannabis for medical purposes

The following section outlines general arguments for the legalisation of cannabis for medical purposes.

Medical cannabis as distinct from recreational cannabis

Stakeholders have argued that the issue of medical cannabis has become politically entangled with the recreational use of cannabis, and that this has held back the development and acceptance of cannabis as a medical treatment.[footnote 91]

Control potential harms

As noted by President of the Australian Drug Law Reform Foundation Dr Alex Wodak during the 2013 NSW inquiry, all medicines are potentially harmful, and these potential harms must be balanced against the potential benefits of the medicine when determining its potential for therapeutic use.[footnote 92] Dr Wodak argued potential harms can be better controlled in a regulated therapeutic context.[footnote 93]

Dr Graham Irvine, whose PhD thesis studied the medicinal use of cannabis, went further to state that 'Cannabis is a particularly safe drug. In the annals of medical history there has never been a death attributable to cannabis alone and the adverse effects are relatively trivial'.[footnote 94]

A moral obligation to patients at the end of life

There was a broad recognition among participants in the 2013 NSW inquiry that people at the end of their lives should be treated compassionately and allowed to access treatments as required.[footnote 95] Some commentators have argued that restricting medical cannabis is 'morally problematic', as it goes against our moral obligation to avoid causing unnecessary suffering.[footnote 96]

Arguments against the legalisation of cannabis for medical purposes

Broad arguments against the use of crude cannabis for medical purposes are outlined in the following section.

Risk of normalising cannabis use

Some stakeholders have raised concerns about whether legalising cannabis for medical use would normalise its use as a recreational drug. During the 2013 NSW Inquiry, Christian advocacy group FamilyVoice Australia argued that legalising medical cannabis would normalise drug-taking behaviour, and could result in problems on an individual and social level. [footnote 97]

Health risks

Some stakeholders have raised concerns about the potential health risks of prolonged use of crude cannabis, including links to cardiovascular and respiratory diseases from smoking cannabis[footnote 98], as well as potential cognitive impairment, particularly in the developing brains of young people.[footnote 99] The link between cannabis use and mental health is controversial, with stakeholders expressing differing views on this issue. The National Cannabis Prevention and Information Centre emphasised potential risks of mental health disorders,[footnote 100] while Professor Michael Farrell, Director of the National Drug and Alcohol Research Centre, argued that mental illness was not a critical issue for medical cannabis use by adults and that such effects should be compared with the long term health risks of other medications.[footnote 101]

Risks of diversion

Stakeholders such as FamilyVoice Australia have expressed concern about the risk of medical cannabis products being diverted for recreational use.[footnote 102] Other stakeholders including the Australian Drug Law Reform Foundation argued that there was very little evidence that diversion has taken place in other jurisdictions where medical cannabis has been legalised.[footnote 103]

Stakeholder views on the Bill

The Coalition's Bill focusing on clinical trials has received mixed reaction. Some stakeholders have welcomed the Bill's facilitation of clinical trials into medical cannabis.[footnote 104] The Victorian branch of the Australian Medical Association (AMA) has expressed its support. AMA President Dr Tony Bartone stated that international studies has shown medical cannabis can have an effect on relieving symptoms in a range of conditions including epilepsy and muscle spasticity, but stressed that more research was needed.[footnote 105]

Prominent psychiatrist Professor Patrick McGorry, who plans to trial the use of cannabidiol (CBD) to treat psychosis, believes clinical trials in cannabis products should already be possible, especially if the products are synthetic.[footnote 106]

Police Commissioner Ken Lay welcomed the Coalition's announcement of clinical trials, stating that the use of medicinal cannabis use is best addressed as a medical issue, rather than a law enforcement issue.[footnote 107]

Chief Executive Office of Lower Murray Medicare Local, Lydia Senior, expressed support for controlled trials, stating that 'it's what patients want'.[footnote 108]

However, some stakeholders have questioned the focus on further trials and whether the provisions of the Bill will be meaningful in the short term for patients and families.[footnote 109] President of the Australian Drug Law Reform Foundation Dr Alex Wodak argued that the Coalition's plan for clinical trials will have little effect. 'It sounds good, but if you look at the small print, it's really nothing. This might benefit 10 people in Victoria in five years' time.'[footnote 110]

Pharmaceutical cannabis and crude cannabis

There has been much discussion surrounding what form of cannabis should be legalised for medical purposes. Questions have arisen about whether pharmaceutical cannabis should be the only cannabis products to be legalised for medical use, or whether patients should also have legal access to crude cannabis.

Pharmaceutical cannabis

The primary focus of the current Bill is on clinical trials of pharmaceutical cannabis products. As the Minister for Health, the Hon David Davis stated in the Second Reading, 'This Bill ensures that only bona fide cannabis-based products of known and standardised quality from recognised pharmaceutical companies that are already approved for medical use overseas or in Australia, or that are currently undergoing that process, can be considered for clinical trials'.[footnote 111]

The advantages of pharmaceutical cannabis products include:

§ standardisation;

§ dosage control;

§ minimisation of unwanted effects;

§ personal acceptability to patients; and,

§ differentiation from unlawful cannabis products.[footnote 112]

The disadvantages of pharmaceutical cannabis products include:

§ the costs of developing and registering synthetic drugs. Australia represents a small market for pharmaceutical cannabis products and may not justify the cost for pharmaceutical manufacturers;[footnote 113]

§ the cost to patients, for example, the cost of Sativex is estimated at $500 per month in New Zealand, totalling around $6,000 per year;[footnote 114] and,

§ the lengthy process of registering products with the TGA.[footnote 115]

Crude cannabis

Arguments in favour of legalising crude cannabis for medical use include the following:

§ A pharmaceutical cannabis-only approach leaves no provision for compassionate access to cannabis until pharmaceutical products have been approved for use. Seriously ill patients may not have time to wait;[footnote 116]

§ Pharmaceutical cannabis products which are not listed on the Pharmaceutical Benefits Scheme may be prohibitively expensive for patients.[footnote 117] Crude cannabis is cheaper, reportedly costing $50 per week or $2,600 per year;[footnote 118]

§ Synthetic forms of cannabis may not be as effective as natural whole plant based cannabis;[footnote 119]

§ It is objectionable to criminalise seriously ill people who do choose to use crude cannabis for medicinal purposes;[footnote 120] and,

§ It would be preferable to have use of crude cannabis operating under controlled medical supervision.[footnote 121]

Arguments against legalising crude cannabis for medical use include the following:

§ Natural cannabis products cannot be easily patented, so it would be unlikely that cannabis plant products could be registered with the TGA;[footnote 122]

§ Cannabis plants can be of uncertain composition and may contain contaminants;[footnote 123] and,

§ There are health risks associated with smoking crude cannabis over long periods, such as cardiovascular and respiratory disease.[footnote 124]

Other Jurisdictions

Australia

New South Wales

Premier Michael Baird announced on 16 September 2014 that a clinical trial into the use of cannabis to treat terminally ill patients would take place.[footnote 125] The trial will be devised by a working party, which will report back at the end of 2014. The Premier also announced that new guidelines would formalise police discretion not to charge terminally ill patients who use cannabis to treat their medical conditions. A register of terminally ill patients and carers would be established as part of this reform. This follows an earlier announcement by Nationals MP Kevin Anderson that he would introduce a private member's Bill to legalise medical cannabis.[footnote 126]

Australian Capital Territory

Chief Minister Katy Gallagher has made a request for the ACT to be involved in the NSW clinical trial of medical cannabis.[footnote 127] However, Ms Gallagher has expressed a preference for a nationally coordinated response and has written to federal Health Minister Peter Dutton, proposing an Australia-wide clinical trial.[footnote 128]

A committee of the ACT Legislative Assembly is also considering a bill from Greens Minister Shane Rattenbury to allow terminally and chronically ill patients in Canberra to grow and use cannabis for their medical treatment. The committee's report is expected by June 2015. [footnote 129]

Western Australia

A national approach has been favoured recently by the Western Australian Government, with Health Minister Kim Hames writing to federal Health Minister Peter Dutton to recommend a national trial of medicinal cannabis. Mr Hames stated 'As a doctor myself, I want to see the best outcomes for patients. But we don't want a situation where we give a blanket OK to medical cannabis that works for some but puts others in intensive care because of the side effects.'[footnote 130]

Tasmania

A committee of the Tasmanian Legislative Council is currently conducting an inquiry into the possible legalisation of cannabis for medical use in Tasmania.[footnote 131] The report is expected to be released next year.[footnote 132]

International jurisdictions

Netherlands

The most liberal system of regulation regarding cannabis exists in the Netherlands.[footnote 133] While cannabis remains an illegal substance, possession of up to 5 grams per person for personal use is tolerated and not prosecuted.[footnote 134] Cannabis can be purchased and consumed in special 'coffee shops', designed to separate recreational cannabis use from the hard drugs trade.[footnote 135]

Regarding cannabis for medical purposes, from 2003 the Dutch Government has regulated the cultivation, production and supply of medicinal cannabis through the Bureau voor Medicinale Cannabis (BMC). Cannabis growers are licensed by the BMC and required to sell their whole harvest to the BMC and to destroy any leftover plants. Patients with serious medical conditions can obtain cannabis in crude plant form from pharmacies and hospitals, though they are warned against smoking the cannabis and advised to either use a vaporiser to inhale it or drink it as herbal tea.[footnote 136]

Canada

Cannabis is an illegal substance in Canada, however in 2001 the *Marihuana Medical Access Program* was introduced, providing for patients to request permission to possess and use crude cannabis as a medical treatment.[footnote 137] Patients were certified by an approved medical practitioner as having certain serious medical or end of life conditions, where other conventional treatments have proven ineffective or inappropriate. Once approved, patients could purchase cannabis from the government, grow their own or ask someone else to grow it on their behalf.[footnote 138]

Following concerns that this system could be abused, the Canadian Government introduced the new *Marihuana for Medical Purposes Regulations* in 2013, which aimed to treat marijuana like any other narcotic used for medical purposes by creating conditions for a new, commercial industry for its production and distribution.[footnote 139]

The new *Marihuana for Medical Purposes Regulations* and the current Program operated concurrently until 31 March 2014, when the production of marijuana for medical purposes in private residences ended, as well as the government supply.[footnote 140]

From 1 April 2014, the Marihuana Medical Access Program ended and the only way to access marijuana for medical purposes is through commercial, licensed producers.[footnote 141] However, there have been some legal challenges in the courts regarding the rights of people already licensed to grow their own cannabis supply to continue doing so.[footnote 142]

United States of America

While cannabis is illegal at the federal level, 23 US states and the District of Columbia have legalised cannabis for medical use.[footnote 143] Regulations vary between states regarding the source of supply, medical assessment requirements, approved medical conditions and limitations on use and possession (see Appendix A). Pharmaceutical cannabis products including dronabinol and nabilone have been legal for medical use since 1985, while Sativex is being trialled as a pain treatment for cancer patients.[footnote 144]

Several issues have arisen in the US model, including inconsistency between state and federal laws meaning that cannabis suppliers may be open to federal charges, difficulty for patients in sourcing legal cannabis, difficulty for medical practitioners in prescribing an appropriate amount of cannabis in the absence of sufficient medical studies, and cannabis use by people who do not have cancer or serious neurological conditions.[footnote 145]

Israel

Patients can be licensed to grow their own supply of cannabis. Cannabis is also available from other licensed growers who distribute cannabis products centrally.[footnote 146]

Appendix A – Legalised Medical Cannabis in the USA

State	Year Passed	How Passed (Yes Vote)	Fee	Possession Limit	Accepts other states' registry ID cards?
1. Alaska	1998	Ballot Measure 8 (58%)	$25/$20	1 oz usable; 6 plants (3 mature, 3 immature)	No

2. Arizona	2010	Proposition 203 (50.13%)	$150/$75	2.5 oz usable; 0-12 plants	Yes
3. California	1996	Proposition 215 (56%)	$66/$33	8 oz usable; 6 mature or 12 immature plants	No
4. Colorado	2000	Ballot Amendment 20 (54%)	$15	2 oz usable; 6 plants (3 mature, 3 immature)	No
5. Connecticut	2012	House Bill 5389 (96-51 House, 21-13 Senate)	$100	One-month supply (exact amount to be determined)	No
6. District of Columbia	2010	Amendment Act B18-622 (13-0 vote)	$100/$25	2 oz dried; limits on other forms to be determined	No
7. Delaware	2011	Senate Bill 17 (27-14 House, 17-4 Senate)	$125	6 oz usable	No
8. Hawaii	2000	Senate Bill 862 (32-18 House; 13-12 Senate)	$25	3 oz usable; 7 plants (3 mature, 4 immature)	No
9. Illinois	2013	House Bill 1 (61-57 House; 35-21 Senate)	TBD*	2.5 ounces of usable cannabis during a period of 14 days	No
10. Maine	1999	Ballot Question 2 (61%)	No fee	2.5 oz usable; 6 plants	Yes
11. Maryland	2014	House Bill 881 (125-11 House; 44-2 Senate)	TBD*	30-day supply, amount to be determined	No
12. Massachusetts	2012	Ballot Question 3 (63%)	$50	60-day supply for personal medical use	unknown
13. Michigan	2008	Proposal 1 (63%)	$100/$25	2.5 oz usable; 12 plants	Yes
14. Minnesota	2014	Senate Bill 2470 (46-16 Senate; 89-40 House)	$200/$50	30-day supply of non-smokable marijuana	No
15. Montana	2004	Initiative 148 (62%)	$75	1 oz usable; 4 plants (mature); 12 seedlings	No
16. Nevada	2000	Ballot Question 9 (65%)	$100	1 oz usable; 7 plants (3 mature, 4 immature)	Yes
17. New Hampshire	2013	House Bill 573 (284-66 House; 18-6 Senate)	TBD*	Two ounces of usable cannabis during a 10-day period	Yes
18. New Jersey	2010	Senate Bill 119 (48-14 House; 25-13 Senate)	$200/$20	2 oz usable	No
19. New Mexico	2007	Senate Bill 523 (36-31 House; 32-3 Senate)	No fee	6 oz usable; 16 plants (4 mature, 12 immature)	No
20. New York	2014	Assembly Bill 6357 (117-13 Assembly; 49-10 Senate)	$50	30-day supply non-smokable marijuana	No
21. Oregon	1998	Ballot Measure 67 (55%)	$200/$60	24 oz usable; 24 plants (6 mature, 18 immature)	No
22. Rhode Island	2006	Senate Bill 0710 (52-10 House; 33-1 Senate)	$75/$10	2.5 oz usable; 12 plants	Yes
23. Vermont	2004	Senate Bill 76 (22-7) HB 645 (82-59)	$50	2 oz usable; 9 plants (2 mature, 7 immature)	No
24. Washington	1998	Initiative 692 (59%)	No fee	24 oz usable; 15 plants	No

*TBD – To Be Determined Source: ProCon.org (2014) '23 Legal Medical Marijuana States and DC: Laws, Fees, and Possession Limits', ProCon.org website.

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[footnote 90] Australian Institute of Health and Welfare (2011) *2010 National Drug Strategy Household Survey,* AIHW, p. 177. 'More than 26,000 people aged 12 years or older participated in the survey, in which they were asked about their knowledge of and attitudes towards drugs, their drug consumption histories, and related behaviours. Most of the analysis presented is of people aged 14 years or older, so that results can be compared with previous reports' (p. x). It is unclear how many of the 26,000+ respondents were aged 14 years or older.

[footnote 91] Hall & Farrell (2013) op. cit., p. 4, as cited in General Purpose Standing Committee No. 4 (2013) op. cit., p. 23.

[footnote 92] A. Wodak (2013) Evidence to the Inquiry, 11 March 2013, p. 61, as cited in General Purpose Standing Committee No. 4 (2013) op. cit., p. 26.

[footnote 93] ibid.

[footnote 94] G. Irvine (2013) Submission to General Purpose Standing Committee No. 4, *Inquiry into the Use of Cannabis for Medical Purposes,* February, New South Wales, Parliament, Legislative Council, p. 2.

[footnote 95] General Purpose Standing Committee No. 4 (2013) op. cit., p. 37.

[footnote 96] For example, P. Lucas (2009) 'Moral regulation and the presumption of guilt in Health Canada's medical cannabis policy and practice', *International Journal of Drug Policy,* 20, pp. 296-303, as cited in Australian National Council on Drugs (2014) op. cit., p. 10.

[footnote 97] FamilyVoice Australia (2013) Answers to questions on notice taken during evidence, 18 March 2013, Question 1, p. 2, as cited in General Purpose Standing Committee No. 4 (2013) op. cit., pp. 54-55.

[footnote 98] National Cannabis Prevention and Information Centre (2013) Submission to General Purpose Standing Committee No. 4, *Inquiry into the Use of Cannabis for Medical Purposes,* February, New South Wales, Parliament, Legislative Council, p. 7.

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[footnote 102] G. Mitchell, State Officer (NSW and ACT), FamilyVoice Australia (2013) Evidence, 18 March 2013, p. 46, as cited in General Purpose Standing Committee No. 4 (2013) op. cit., p. 60.

[footnote 103] E. Rauwendaal, Member, Australian Drug Law Reform Foundation (2013) Evidence, 11 March 2013, p. 66, as cited in General Purpose Standing Committee No. 4 (2013) op. cit., p. 60.

[footnote 104] For example, Editorial (2014) 'Marijuana trials a great step forward', *Bendigo Advertiser,* 29 August.

[footnote 105] J. Medew, J. Gordon & H. Cook (2014) op. cit., p. 6.

[footnote 106] ibid.

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[footnote 108] WIN TV Albury News (2014) News Story, 17 September 2014.

[footnote 109] For example, Editorial (2014) 'Medical marijuana needs brave course', *Sunday Age,* 31 August, p. 24.

[footnote 110] J. Medew, J. Gordon & H. Cook (2014) op. cit., p. 6.

[footnote 111] D. Davis, Minister for Health (2014) 'Second reading speech: Drugs, Poisons and Controlled Substances Amendment (Clinical Trials) Bill 2014', op. cit., p. 3092.

[footnote 112] General Purpose Standing Committee No. 4 (2013) op. cit., p. 28.

[footnote 113] Australian National Council on Drugs (2014) op. cit., p. 11.

[footnote 114] K. Charlesworth, Advisor to Mullaways Medical Cannabis (2013) Evidence, 11 March 2013, p. 32, as cited in General Purpose Standing Committee No. 4 (2013) op. cit., p. 38.

[footnote 115] Australian National Council on Drugs (2014) op. cit. p. 11.

[footnote 116] Australian Drug Law Reform Foundation (2013) Submission to General Purpose Standing Committee No. 4, *Inquiry into the Use of Cannabis for Medical Purposes,* February, New South Wales, Parliament, Legislative Council, p. 12.

[footnote 117] ibid.

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[footnote 120] See General Purpose Standing Committee No. 4 (2013) op. cit., p. 50.

[footnote 121] ibid.

[footnote 122] Working Party on the Use of Cannabis for Medical Purposes (2000) op. cit., as cited in Australian National Council on Drugs (2014) op. cit., pp. 11-12.

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