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NSW Parliamentary Research Service

Medical cannabis

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1. INTRODUCTION

On 28 May 2014, *The Australian* reported that the NSW Greens MLC, John Kaye, would soon introduce a bill:

... that would allow people with a terminal illness to apply for a card that would prevent them from being prosecuted for possessing a small quantity of cannabis. The card would be issued by the Department of Health based on advice from the patient's treating doctor and would be "tightly monitored", Dr Kaye said. He said the measures would mean thousands of people in NSW would no longer have to make the "terrible choice" between breaking the law and suffering. "It is time for science and compassion to win out against prejudice and hysteria," he said.¹

On 29 May 2014, the NSW Nationals MP Kevin Anderson announced his intention to introduce a Private Members Bill to approve the use of cannabis by terminally ill patients. Mr Anderson said:

... "the Premier was sympathetic and listened intently while I explained the issue to him and the circumstances surrounding my decision to try and change the laws.

"I told him about the Haslam family from Tamworth and the heartbreaking circumstances facing 24 year old Dan Haslam who has terminal cancer and his use of cannabis for medicinal purposes.

"However the Premier joined with me in expressing grave concerns about the supply and the prescription of cannabis and the challenge in addressing those issues. It would need to be through a tightly controlled and regulated process.

"While the NSW Parliamentary Upper House Inquiry supported the use of cannabis for medicinal purposes, it did not address the supply.

"The work now begins on doing the research to solve those issues. It will be critical to get this bill right, and I will be working closely with the Chair of the NSW Upper House inquiry the Hon Sarah Mitchell and the Hon Trevor Khan to find those solutions.

"I strongly oppose the use of recreational drugs at every level and will continue to do so but through the Haslam family and my own research, I have a greater understanding of how cannabis can be used to alleviate the severe and distressing symptoms suffered by those who are dying and the need to provide comfort and relief when they need it most.

"I thank the Haslam family and the community for raising this issue with me and their determined push to help 24 year old son Daniel," Mr Anderson concluded.²

As reported in the Sydney Morning Herald on 30 May 2014:

Mr Baird said the government "will give careful consideration to Mr Anderson's bill, and I have nothing but sympathy for the Haslam family as they struggle with their son's illness".

The Australian, Bill would allow dying to smoke cannabis, 28 May 2014

² Kevin Anderson, <u>Anderson proposes historic Private Members Bill</u>, Media Release, 29 May 2014

A spokesman for Mr Baird said the matter would not be the subject of a conscience vote for Liberal MPs, as is often the case for social issues. This means the bill would require the support of the government to pass the lower house.³

In response to this development, John Kaye stated that he was willing to delay his own proposed bill to give Mr Anderson time to develop his legislation.⁴

The first half of this Issues Backgrounder considers the key legal issues that arise in relation to medical cannabis, in particular the relationship between Commonwealth and State laws. The second half sets out some of the key background parliamentary, scientific and legal sources.

The Parliamentary Research Service has previously published two papers on the subject of medical cannabis - R Johns, <u>Medical cannabis programs: a review of selected jurisdictions</u>, Briefing Paper No 10/2004 and G Griffith and M Swain, <u>The Medical Use of Cannabis: recent developments</u>, Briefing Paper No 11/1999. Also relevant is Briefing Paper No 3/1999, <u>The Drug Summit: Issues and Outcomes</u> by M Swain.

It should be noted at the outset that the issue of using cannabis solely for medical purposes is legally distinct from the decriminalisation or non-medical use of the plant.⁵

2. CANNABIS AND THE LAW IN NSW

CANNABIS AND THE CRIMINAL LAW

At present, cannabis is a prohibited plant in all Australian jurisdictions, and its possession, cultivation and trafficking is a criminal offence in all jurisdictions. In NSW, under Schedule 1 of the *Drug Misuse and Trafficking Act 1985*, the list of prohibited plants or drugs includes:

Prohibited plant or drug	Traffickable quantity	Small quantity	Indictable quantity	Commercial quantity	Large commercial quantity
Cannabis leaf	300.0g	30.0g	1 000.0 g	25.0 kg	100.0 kg
Cannabis oil	5.0 g	2.0 g	10.0 g	500.0 g	2.0 kg
Cannabis plant cultivated by enhanced indoor means	-	5 g	50 g	50 g	200 g
Cannabis plant –other	-	5 g	50 g	250 g	1 kg
Cannabis resin	30.0g	5.0 g	90.0 g	2.5 kg	10.0 kg

Sydney Morning Herald, NSW Premier Mike Baird open to supporting bill to decriminalise medical marijuana, 30 May 2014

⁴ Ibid.

Working Party on the Use of Cannabis for Medical Purposes, <u>Report of the Working Party on the use of cannabis for medical purposes</u>, <u>Volume 1</u>, <u>Executive Summary</u>, p. 17.

CANNABIS CAUTIONING SCHEME

Not all possession of cannabis results in criminal proceedings. The cannabis cautioning scheme was an initiative that resulted from the Drug Summit in May 1999 and introduced across New South Wales on 3 April 2000. It gave police the right to issue a caution to adults⁷ for minor cannabis offences involving personal use. The cannabis offences that are eligible for a caution are the possession or use of up to 15 grams of dried cannabis leaf, stalks, seeds, or heads, or possession of equipment such as bongs for the administering of cannabis. 15 grams is half the amount of a 'small quantity' (30 grams) of cannabis leaf under Schedule 1 of the *Drug Misuse and Trafficking Act 1985*. There is a limit of receiving cautions on two occasions.

CANNABIS AND MEDICAL/SCIENTIFIC RESEARCH

Although cannabis is a prohibited plant in all Australian jurisdictions, and cannabis and cannabinoid products are not listed as therapeutic goods under the Australian Register of Therapeutic Goods, the customs regime and the therapeutic goods regimes make provisions for limited exceptions in relation to accessing cannabis for medical, clinical or scientific research purposes. This is discussed below in a later section.

NSW WORKING PARTY AND LATER DEVELOPMENTS

In October 1999, Premier Bob Carr announced that the Government would investigate the use of cannabis for medicinal purposes. The Premier explained that a Working Party would first examine the feasibility of making cannabis available for therapeutic purposes. The Working Party was chaired by the then Executive Director of the National Drug and Alcohol Research Centre, Professor Wayne Hall. The Report of the Working Party on the Use of Cannabis for Medical Purposes was submitted to the Government in August 2000. The Working Party's key findings were that:

- Some cannabinoid substances may have value in the treatment of a limited range of medical conditions such as HIV-related wasting, nausea caused by chemotherapy for cancer, muscle spasm in some neurological disorders, and pain that is unrelieved by conventional analgesics.
- Research is required to better assess this therapeutic value.
- Crude cannabis cannot be, and is unlikely ever to be, prescribed in Australia.

for certain drug offences: see section 8.

NSW Drug Summit 1999, *Communique*, 21 May 1999, Recommendation 6.7. Related cannabis recommendations are outlined under '6. Breaking the Drugs and Crime Cycle' of the Communique.

Cautions and warnings are available to juveniles under the *Young Offenders Act 1997*, including

Premier of New South Wales, News Release, 'Government to consider cannabis for medicinal purposes', 19 October 1999.

The list of findings does not appear in exactly the same form in the *Report of the Working Party on the Use of Cannabis for Medical Purposes*, but reflects the content of Volume I: Executive Summary, '2. Key Findings of the Working Party', August 2000.The list is adopted from: Inquiry into the Use of Cannabis for Medical Purposes, *Report on Consultation on the Findings and Recommendations of the Working Party on the Use of Cannabis for Medical Purposes*, July 2001, Office of Drug Policy (The Cabinet Office), p 3.

 There are commercial and regulatory obstacles to the medical prescription of synthetic cannabinoid substances in Australia.

Following the publication of the findings of the NSW Working Party and the outcomes of the subsequent consultation on its recommendations, on 20 May 2003 the Carr Government announced its intention to introduce a draft exposure bill to provide for a four year trial of the medical use of cannabis. The main options being considered by the Carr Government for the design of the scheme were: 11

- Decriminalising the growing of cannabis plants or the possession of personal use quantities by eligible patients.
- Government regulating the supply and providing it to patients. The Government could buy the cannabis from an overseas jurisdiction such as Canada, or grow it under 'very carefully supervised conditions' in New South Wales.
- Obtaining Commonwealth Government approval to import the cannabis spray being developed in the United Kingdom, if and when it becomes available.

However, this trial was not pursued and in April 2004, the Carr Government announced that, despite having examined the various options, 'the preferred delivery method—a metered dose inhaler or spray—was years away from being available and the NSW (and federal) government opposed any means that allowed growing in backyards, i.e. decriminalization of cannabis cultivation or purchase on the black market'. ¹²

2013 LEGISLATIVE COUNCIL COMMITTEE REPORT

In November 2012, the Legislative Council's General Purpose Standing Committee No 4 received a referral to inquire into the use of cannabis for medical purposes, in particular:

- the efficacy and safety of cannabis for medical purposes;
- if and how cannabis should be supplied for medical use; and
- legal implications and issues concerning the use of cannabis for medical purposes

The Committee <u>reported</u> in May 2013, to which the Government <u>responded</u> in November 2013. According to the Chair's Foreword to the committee report, <u>The use of cannabis for medical purposes</u>:

The Committee has found that in general terms medical cannabis has potential as an effective treatment for some medical conditions with appropriate safeguards in place.

Bob Carr, 'Cannabis Medical Use', Questions Without Notice, *NSWPD*, 20 May 2003, p 697, cited in R Johns, *Medical cannabis programs: a review of selected jurisdictions*, p. 16.

R Johns, <u>Medical cannabis programs: a review of selected jurisdictions</u>, pp. 16-17.
 C Hughes, <u>The Australian (illicit) drug policy timeline: 1985-2011</u>, Drug Policy Modelling Program, National Drug and Alcohol Research Centre, last updated 12 September 2011, p.24.

Our reading of the evidence – including rigorous scientific evidence – is that cannabis products are emerging as a promising area of medicine, most notably in respect of a number of painful conditions that do not respond to existing treatments. Given this evidence, a compassionate approach is appropriate here. Such treatments will only be suitable for a small number of people in specific circumstances and under the supervision of medical practitioners with relevant expertise.

The Committee made a total of 5 recommendations, which are set out below:

Recommendation 1:

That the Minister for Health write to the Commonwealth Minister for Health and Ageing, expressing in principal support for:

- the timely, evidence based expansion of access to approved cannabis pharmacotherapies by additional patient groups, including those suffering from chronic pain for whom existing pain management is not effective
- further clinical trials of pharmaceutical cannabis products to continue to build this evidence base, and
- approved pharmaceutical cannabis products to be affordable to patients.

Recommendation 2:

That the NSW Government introduce an amendment to the *Drug Misuse and Trafficking Act 1985* to add a complete defence to the use and possession of cannabis, so as to cover the authorised medical use of cannabis by patients with terminal illness and those who have moved from HIV infection to AIDS. The features of this system would include:

- provision of a complete defence from arrest and prosecution for the use of cannabis and possession of up to 15 grams of dry cannabis or equivalent amounts of other cannabis products, and equipment for the administration of cannabis, by the patient
- provision of a complete defence from arrest and prosecution for the possession and supply of up to 15 grams of dry cannabis or equivalent amounts of other cannabis products, and equipment for the administration of cannabis, by the patient's carer
- that the defence be restricted to persons listed on a register of 'authorised cannabis patients and carers', with eligibility contingent upon certification by the patient's treating specialist medical practitioner that the patient is diagnosed with a specified condition
- the defence would only apply where the use and supply of cannabis does not occur in a public place, and
- a review of the amendment commence within three years of the date of commencement.

Recommendation 3:

That, consistent with Recommendation 2, the NSW Ministry of Health establish and administer a register of 'authorised cannabis patients and carers' certified by the patient's treating specialist medical practitioner and issue patients and carers on this register with a photo identity card verifying that they qualify for exemption from arrest and prosecution.

Recommendation 4:

That the NSW Ministry of Health and Department of Attorney General and Justice give further and detailed consideration to the issues surrounding lawful supply of crude cannabis products for medical purposes.

Recommendation 5:

That the NSW Ministry of Health implement an education strategy to accompany the legislative amendment set out in Recommendation 2 to inform the medical profession, community and relevant patient groups about the intentions and provisions made under the amendment. This should include information for patients about the harms that accompany smoking cannabis, and alternative forms of administration.

Responding on behalf of the Government, the Health Minister Jillian Skinner said that the Government supported Recommendation 1, but did not support the remaining recommendations. Noted in the Minister's response was the NSW Pain Management Plan 2012-2016, which is to "more broadly address the issue of pain relief". The Minister also noted the "limited evidence on the clinical efficiency of cannabis for medical purposes". In respect to recommendations 2 to 5, the Minister stated (in part):

The NSW Government acknowledges the use and supply of cannabis for medical purposes is a complex issue. However, the Government does not support the medical use of crude cannabis products that fall outside the existing regulatory and legal frameworks. The Government believes crude cannabis products are unlikely to be approved as medicines by the TGA while their quality and safety are uncontrolled.

3. THE RELEVANCE OF COMMONWEALTH LAWS

Options such as those initially considered by the Carr Government, as listed above, could trigger legal considerations at a number of jurisdictional levels, including international law, Commonwealth law and NSW State law. This section focuses on the legal issues that arise at the Commonwealth level. It also addresses the issue of federal impediments arising if NSW were to source its cannabis supply from within the State. A point to bear in mind is that the legislative impediments that may arise at the Commonwealth level in relation to a proposal by a State to introduce a scheme legalising the use of cannabis for medical purposes depends upon the nature of the scheme envisaged.

INTERNATIONAL OBLIGATIONS

Australia is a signatory to international agreements that aim to restrict production, manufacture, export, import, distribution, trade, and possession of narcotic drugs (including cannabis) for medical and scientific purposes. Two key agreements are relevant to the issue of medical cannabis:¹⁴

Report of the Working Party on the use of cannabis for medical purposes, Volume 1, Executive Summary, p. 17.

For a detailed discussion of legal and regulatory issues that may arise at all jurisdictional levels, see: Working Party on the Use of Cannabis for Medical Purposes, <u>Report of the Working Party on the use of cannabis for medical purposes</u>, <u>Volume II</u>, <u>Main Report</u>, pp. 66-109.

- the United Nations' Single Convention on Narcotic Drugs (1961) (the Single Convention), which aims to codify all existing conventions and the obligations of signatory states under those conventions; and
- the UN Convention Against Illicit Traffic in Narcotic Dangerous Psychotropic Substances (1988), which extended the provisions of the Single Convention to a range of behaviour and mood altering drugs but distinguished between those which are totally prohibited and those, such as cannabis, which may be used for restricted medical purposes.

As the Commonwealth is responsible for the implementation of international agreements that it enters into and has the power to override inconsistent State legislation to ensure national implementation of Australia's international obligations, the Commonwealth would have to be satisfied that any proposed State scheme would not place Australia in breach of its treaty obligations. ¹⁵

In reviewing the nature of the obligations imposed by the relevant instruments, the Working Party on the use of cannabis for medical purposes noted that international conventions aimed at limiting the use of narcotic drugs in the community recognised the possibility of there being exceptional circumstances in which the use of narcotic drugs may be necessary 'for medical and scientific purposes'. In the view of the Working Party, international legal commentary indicated that the term 'medical and scientific purposes' was sufficiently broad to encompass the prescription or certification of cannabis for the treatment of medical conditions. The Working Party concluded that—so long as proposals for the medical use of cannabis were grounded on evidence of their therapeutic value—the controlled availability of cannabis or cannabinoids for medical or scientific purposes would not place Australia in breach of any international treaty obligations. In

COMMONWEALTH LEGISLATION

Commonwealth legislation has a significant bearing on proposals to introduce a scheme legalising the use of cannabis for medical purposes, primarily with regard to the importation of cannabis and the regulation of therapeutic goods. The Commonwealth's ability to legislate in relation to such matters derives from its constitutional powers with regard to trade and commerce and external affairs. ¹⁸

The key pieces of Commonwealth legislation that are activated by proposals for the introduction of a scheme dealing with medical cannabis are listed below:¹⁹

- Criminal Code Act 1995 (Cth)
- Customs Act 1901 (Cth)
- Customs (Prohibited Imports) Regulations 1956 (Cth)

lbid., p.17; Working Party on the Use of Cannabis for Medical Purposes, <u>Report of the Working</u>

Party on the use of cannabis for medical purposes, Volume II, Main Report, p. 109.

¹⁶ Ibid.pp. 68-9

¹⁷ Ibid. p. 71.

¹⁸ Ibid., p. 72.

Report of the Working Party on the use of cannabis for medical purposes, Volume 1, Executive Summary, p. 18.

- Narcotic Drugs Act 1967 (Cth)
- Therapeutic Goods Act 1989 (Cth)
- Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990 (Cth)

Importation²⁰

The importation of cannabis for personal medical use is illegal under Commonwealth law.

Cannabis is listed as a "border controlled plant" under s.314.5, in Part 9.1 of the *Commonwealth Criminal Code Act 1995* (Cth). Under the *Criminal Code* it is an offence to:

- 1) import or export "border controlled drugs" or "border controlled plants" (sections 307.1-307.4)
- 2) possess unlawfully imported border controlled drugs or plants (sections 307.5-307.7)
- 3) possess unlawfully imported border controlled drugs or plants, reasonably suspected of having been illegally imported (sections 307.8-307.10)
- 4) import or export border controlled "precursors" intending, or believing that someone else intends, that it will be used to manufacture a controlled drug (sections 307.11-307.13).

Section 51A of the *Customs Act 1901* (Cth) provides that: substances or plants that are determined to be "border controlled" drugs, plants or a border controlled precursor under the Commonwealth *Criminal Code* are also taken to be prohibited imports under the *Customs Act*. Section 50(3) of the *Customs Act* allows the *Customs (Prohibited Imports) Regulations 1956* (Cth) to establish a system of licences and permissions in relation to the importation of prohibited goods.

The Customs (Prohibited Imports) Regulations 1956 (Cth) (the Regulations) establishes a system of licenses and permissions to enable the authorisation of the importation of cannabis for medical or scientific purposes.

Under regulation 5(1) a person wishing to import a drug must apply in writing for both a licence (r.5(1)(a)(i)), and a permission (r.5(1)(a)(ii)) from the Secretary of the Department of Health and Aged Care (Cth)(r.5(4)). Examples of potential licensees include drug companies, universities, police and government departments.

Schedules to the *Customs (Prohibited Imports) Regulations* designate categories of prohibited imports. Opioids, including cannabis, cannabinoids and cannabis resin,

The following information is taken from: Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the use of cannabis for medical purposes, Volume II, Main Report*, pp. 72-76; and, R Douglas, 'Import/export offences', *The Laws of Australia*, Thomson Reuters, 2009.

are listed in Schedule 4. The *Regulations* treat cannabis in the same way as other drugs listed in Schedules I or II of the Single Convention. For drugs listed in Schedule I and II of the Single Convention (including cannabis) a permission to import must specify a quantity of a drug that, together with already authorised and anticipated imports, "exceeds the amount that, in accordance with the requirements of the Single Convention, has been determined to be the maximum amount of that drug that may be imported into Australia during the relevant year" (r.5(12)).

This maximum amount is determined by the Department of Health and Aged Care (Cth) in accordance with Australia's obligations under the Single Convention and is notified annually to the International Narcotics Control Board (INCB). One of the reasons for this notification is to prevent a build up of stocks in excess of those required for medical and scientific purposes.

For cannabis to be legally imported into Australia, the Department of Health and Aged Care (Cth), would have to notify the INCB of an estimated maximum amount for cannabis and the INCB would notify other parties to the convention. According to a report published by the INCB, as of September 2011, Australia had notified the INCB of an estimated maximum amount of 1,500grams of cannabis.²¹

The Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990 is intended to implement the provisions of the 1988 convention in relation to trafficking in narcotic drugs and psychotropic substances. The Act criminalises certain defined activities that constitute an offence against a law of the Commonwealth, a State or Territory, or a foreign country (s.9). As it is "not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory" (s.5(1)), it should not affect lawful activities involving cannabis or cannabinoids.

Therapeutic Goods Act 1989 (Cth)²²

Under Part 4(A) (s.31) of the *Poisons and Therapeutic Goods Act 1955* (NSW), Commonwealth therapeutic goods laws apply in NSW. Hence, the Commonwealth has extensive powers in relation to the use of therapeutic goods within NSW. Cannabis as a crude plant product is very unlikely to ever be registered as a therapeutic good in Australia. Without being registered as a therapeutic product on the Australian Register of Therapeutic Goods (ARTG), cannabis may not be produced, prescribed, or marketed for use as a therapeutic product.

The Therapeutic Goods Act establishes the ARTG, which records therapeutic goods approved for supply. The Act also makes special provision for unregistered goods that are intended for use in clinical trials. Effective from February 2014 there is one cannabis or cannabinoid product registered on the ARTG; this is Sativex Oromucosal Spray, which is <u>described</u> as "a mouth (oromucosal) spray formulated from two chemical extracts derived from the cannabis plant and contains delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD)". According to the summary for

International Narcotics Control Board (INCB), <u>Estimated World Requirements</u>, of Narcotic drugs in grams for 2011 (September update), 2011, p. 1.

The following text is largely taken from: Working Party on the Use of Cannabis for Medical

The following text is largely taken from: Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the use of cannabis for medical purposes, Volume II, Main Report*, pp. 76-80.

ARTG entry, Sativex is "indicated as treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy".

Under therapeutic goods legislation, before any product can be marketed in Australia it must be registered on the ARTG. Consequently, a product containing any cannabinoid from a natural or synthetic source would have to be registered. To obtain approval for registration, the application must provide pharmaceutical, toxicological and clinical information. This information is carefully evaluated by the Therapeutic Goods Administration (TGA) to establish the quality, safety and efficacy of the product put forward for registration. As this is an expensive and lengthy process applications are not usually lodged unless the sponsor considers the product commercially viable. Owing to the health risks associated with smoking, cannabis *in smoked form* is unlikely to ever comply with TGA requirements. Since cannabis is a crude plant product, even if it were administered in ways other than smoking, it would still be unlikely to comply with registration requirements under the Therapeutic Goods Act.

The NSW Working Party on the use of cannabis for medicinal purposes provided the following reasons as to why cannabis was unlikely to comply with requirements under the Therapeutic Goods Act.

- Drugs cannot be registered except on application from a pharmaceutical company and it is unlikely that any pharmaceutical company would seek to register a natural plant product that cannot be patented;
- There are very few data from controlled clinical trials on the efficacy of cannabis for treating the recommended conditions;
- There are serious concerns about the safety of smoked cannabis, especially in the treatment of chronic medical conditions;
- Quality is also problematic, because crude forms of cannabis contain variable amounts of THC and other cannabinoids.

The Working Party concluded that, as a result, it would not be possible to manufacture cannabis products for use as a therapeutic good.

Under s.19 of the *Therapeutic Goods Act 1989* (Cth) there are two ways the Secretary of the Department of Health and Aged Care may authorise the importation and/or use of a drug not registered on the ARTG. These are: the Personal Import Scheme and the Special Access Scheme.

Personal Import Scheme

Under this scheme individuals may import for medical uses (and at their own expense) a drug that is not registered on the ARTG. They may import no more than 3 months' supply at the maximum dose and must have a doctor's prescription for the medication, where this is required by State law. Since, however, narcotic, psychotropic and other drugs subject to the Customs (Prohibited Imports)

Regulations may not be imported under the Personal Import Scheme, this is not a viable option.

Special Access Scheme

Under this scheme, certain categories of patients may obtain access to a drug. The controls applied depend on the category of patient for whom the drugs are intended.

- Category A (patients who are terminally or seriously ill with life-threatening conditions): These patients do not have to obtain TGA approval to use/import the drug; in effect, the treating doctor approves the use.
- Category B (patients who are suffering from a life-threatening condition, even if they are not critically ill): These patients need TGA approval to use. Drugs approved for use by patients in this category have generally been the subject of at least Phase 1 clinical trials in humans.
- Category C (patients who are suffering from a serious but not life-threatening illness): These patients also need TGA approval to use the drug. Drugs approved for use by patients in this category must have been put through exhaustive clinical trials to test their efficacy and safety for human use. Normally the drugs would have been subjected to all the clinical trials needed to support a marketing application.

It was under the Special Access Scheme that the synthetic cannabinoid, dronabinol, was imported and used for the treatment of HIV wasting syndrome. The NSW Working Party on the use of cannabis for medicinal purposes concluded that this was not a viable option to consider as the costs of obtaining access to such drugs was prohibitive for the majority of eligible patients.

SUPPLY OPTIONS FOR THE NSW GOVERNMENT IN LIGHT OF EXISTING COMMONWEALTH LAW

The NSW Working Party concluded that it was not clear whether some or all of the legislative impediments at the Commonwealth level could be overcome if the cannabis being used were to be sourced and supplied in New South Wales alone. In addition to importing cannabis products by fulfilling requirements under the *Customs (Prohibited Imports) Regulations 1956* (Cth) and applying to access cannabis products through the Special Access Scheme under the *Therapeutic Goods Act 1989* (Cth), it may be possible for the NSW Government to:

- i) Licence companies/authorities to cultivate cannabis for medical and research purposes. The 1961 Single Convention permits parties to cultivate cannabis under the control of government agencies (act 28(1)). As cannabis is not currently registered on the ARTG, licensed cultivation could only be legally sanctioned under the Therapeutic Goods Act regime if it were part of a clinical or scientific trial. However, the cost of establishing a regulatory body to oversee the licensing of cannabis cultivation for medical and research purposes would be considerable.
- ii) Decriminalise privately cultivated amounts of medical cannabis that neither threaten the "public health and welfare" nor contribute to the "illicit traffic", without placing Australia in breach of its international obligations under the

Single Convention. Australia's international treaty obligations would not necessarily be compromised if a regulatory model giving legal exemptions to individuals with certain medical conditions to grow their own cannabis plants were to be adopted in New South Wales. If such a model were adopted, it would need to focus on distinguishing between cultivation for medical or recreational purposes. For example, to qualify for exemption, individuals might be required to present medical documentation (e.g. certification from medical practitioner) diagnosing a condition for which cannabis is an effective treatment and stating that the person may benefit from its use. In addition, the number of plants allowable per person should be restricted to the number considered necessary for them to maintain treatment of a specified health condition. A legislative framework would have to be developed to provide exemptions for specific individuals or class of individuals requiring cannabis or cannabinoids for personal therapeutic use. Consideration may also need to be given to the issue of whether legislative exemptions should be extended to carers or concerned individuals.

supply by cannabis dispensaries ("buyers" or "compassion" clubs) to patients without remuneration (the supply of cannabis on a commercial basis as a therapeutic good would contravene the Therapeutic Goods Act as cannabis is not a registered therapeutic good). The NSW Working Party also concluded that in order to preserve the distinction between recreational and medical use of cannabis, as a matter of public policy, government regulation is the most responsible and appropriate way of sanctioning the supply of cannabis to those in need.

While, in theory, the legal options outlined above may be available to a State government, until a scheme is legally tested, it is not clear whether a State scheme would survive legal challenge or legislative attempts to override from the Commonwealth. The NSW Working Party concluded that the Commonwealth could in theory legislate (for example, using its external affairs powers) to proscribe any such State model and penalise its participants. Whether the Commonwealth would in fact act on that power is another matter.

4. AUSTRALIAN PARLIAMENTARY AND GOVERNMENT SOURCES ON MEDICAL CANNABIS

For a timeline for all Australian jurisdictions see the <u>Australian (illicit) drug policy timeline: 1985-2012</u>

COMMONWEALTH

Commonwealth of Australia, *Legislative Options for Cannabis Use in Australia*, Monograph No.26, 1994, pp.96

Maurice Rickard, <u>The Use of Cannabis for Medical Purposes</u>, Department of the Parliamentary Library, Research Note No.13, 15 September 2003

AUSTRALIAN CAPITAL TERRITORY

Standing Committee on Health and Community Care, <u>Cannabis Use in the ACT</u>, Report No.7, December 2000, pp.81

In 2004, the <u>Drugs of Dependence Amendment Bill 2004</u> was introduced in the ACT with the backing of the Greens and Democrats. The Bill, which was defeated, would have allowed eligible medical users or nominated caregivers to grow cannabis. A key argument against the Bill was that the proposed system did not establish a supply source for the growing of cannabis. Concern was also expressed about the costs involved in regulating such a scheme.

In his speech to the Legislative Assembly, Simon Corbell, the Minister for Health, stated that:

Mr Speaker, I'm please to indicate to members that if the government is returned at the October election, it would be prepared to provide a detailed report to the new Assembly within six months of the Assembly sitting to examine in detail the threshold issues which I have outlined today. However, Mr Speaker, at this stage the government cannot support the legislation.²³

On 18 October 2005, Simon Corbell tabled the <u>Report on the Medicinal Use of Cannabis</u> in the ACT Legislative Assembly.

SOUTH AUSTRALIA

Drug and Alcohol Services Council South Australia, <u>Therapeutic Uses of Cannabis</u>, May 1998, pp.51

On 23 July 2008, the <u>Controlled Substances (Palliative Use of Cannabis)</u> <u>Amendment Bill 2008</u> was introduced in the South Australian Legislative Council. The Second Reading can be found here (page 3582). The Bill was not passed.

WESTERN AUSTRALIA

In 1999, two Private Members Bills were introduced by the Hon. Dr Christine Sharp, both titled the Poisons Amendment (Cannabis for Medical and Commercial Uses) Bill 1999 – (Bill No. 20 & Bill No. 68). The Second Reading of Bill No. 68 may be found here. Neither Bill was passed.

5. SOURCES ON MEDICAL CANNABIS IN SELECTED OVERSEAS JURISDICTIONS

USA

Selected US resources include:

- The White House, Office of National Drug Control Policy Marijuana;
- Federal Drug Enforcement Agency The DEA Position on Marijuana;

Legislative Assembly for the ACT, Minutes of Proceedings, 25 August 2004

- US National Library of Medicine Marijuana;
- National Conference of State Legislatures <u>State Medical Marijuana Laws</u>
- The RAND Drug Policy Research Center;
- The Multidisciplinary Association for Psychedelic Studies <u>medical marijuana</u> <u>research timeline</u>; and
- University of California, San Diego <u>Center for Medicinal Cannabis</u> Research.

Selected State Medical Marijuana Programs:

- California;
- Connecticut;
- Delaware;
- Massachusetts;
- Oregon; and
- · Washington.

A US website – <u>ProCon.org</u> – provides a Table summarising the legalisation of medical cannabis in 22 US States and the District of Columbia (see below). Further details, including hyperlinks to the legislative measures introduced to legalise the use of cannabis for medical purposes, can also be found on the <u>website</u>.

Table 1: Medical Cannabis in the USA: 22 States and the District of Columbia²⁴

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. DC	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. Oregon	1998	Ballot Measure 67 (55%)	\$200/\$60	24 oz usable; 24 plants (6 mature, 18 immature)	No
21. Rhode Island	2006	Senate Bill 0710 (52-10 House; 33-1 Senate)	\$75/\$10	2.5 oz usable; 12 plants	Yes
22. Vermont	2004	Senate Bill 76 (22-7) HB 645 (82-59)	\$50	2 oz usable; 9 plants (2 mature, 7 immature)	No
23. Washington	1998	Initiative 692 (59%)	No fee	24 oz usable; 15 plants	No

Notes: **(a) Residency Requirement** - 20 of the 22 states require proof of residency to be considered a qualifying patient for medical marijuana use. Only Oregon has announced that it will accept out-of-state applications. The Illinois law does not appear to have a residency requirement, but it is unknown whether the program rules will address this matter.

(b) Home Cultivation - <u>Karen O'Keefe, JD</u>, Director of State Policies for Marijuana Policy Project (MPP), stated the following in a May 29, 2014 email to ProCon.org:

"Some or all patients and/or their caregivers can cultivate in 15 of the 22 states. Home cultivation is not allowed in Connecticut, Delaware, Illinois, Maryland, Minnesota, New Hampshire, New Jersey, or the District of Columbia and a special license is required in New Mexico. In Arizona, patients can only cultivate if they lived 25 miles or more from a dispensary when they applied for their card. In Massachusetts, patients can only cultivate if they have a hardship waiver. In Nevada, patients can

²⁴ ProCon.org., <u>22 Legal Medical Marijuana States and DC</u>, 2014 [online – accessed 6 June 2014]

cultivate if they live more than 25 miles from a dispensary, if they are not able to reasonably travel to a dispensary, or if no dispensaries in the patients' counties are able to supply the strains they need. In addition, Nevada patients who were growing by July 1, 2013 may continue grow until March 31, 2016."

(c) Patient Registration: Mandatory vs Voluntary - <u>Karen O'Keefe, JD</u>, Director of State Policies for Marijuana Policy Project (MPP), stated the following in a May 29, 2014 email to ProCon.org:

"Affirmative defenses, which protect from conviction but not arrest, are or may be available in several states even if the patient doesn't have an ID card: Rhode Island, Maryland, Michigan, Colorado, Nevada, Oregon, and, in some circumstances, Delaware. Hawaii also has a separate 'choice of evils' defense. Patient ID cards are voluntary in Maine and California, but in California they offer the strongest legal protection. In Delaware, the defense is only available between when a patient submits a valid application and receives their ID card.

The states with no protection unless you're registered are: Alaska (except for that even non-medical use is protected in one's home due to the state constitutional right to privacy), Arizona, Connecticut, Montana, New Hampshire, Vermont, Minnesota, New Mexico, and New Jersey. Washington, D.C. also requires registration."

- (d) Maryland Laws Prior to Legalization Prior to Maryland becoming the 21st state to legalize medical marijuana, it had passed laws that, although favorable to medical marijuana, did not legalize its use. Senate Bill 502, the "Darrell Putman Bill" (Resolution #0756-2003) was approved in the state senate by a vote of 29-17, signed into law by Gov. Robert L. Ehrlich, Jr. on May 22, 2003, and took effect on Oct. 1, 2003. The law allows defendants being prosecuted for the use or possession of marijuana to introduce evidence of medical necessity and physician approval, to be considered by the court as a mitigating factor. If the court finds that the case involves medical necessity, the maximum penalty is a fine not exceeding \$100. The law does not protect users of medical marijuana from arrest nor does it establish a registry program. On May 10, 2011, Maryland Governor Martin O'Malley signed SB 308, into law. SB 308 removed criminal penalties for medical marijuana patients who meet the specified conditions, but patients are still subject to arrest. The bill provides an affirmative defense for defendants who have been diagnosed with a debilitating medical condition that is "severe and resistant to conventional medicine." The affirmative defense does not apply to defendants who used medical marijuana in public or who were in possession of more than one ounce of marijuana. The bill also created a Work Group to "develop a model program to facilitate patient access to marijuana for medical purposes." Maryland passed two medical marijuana-related laws in 2013. HB 180, signed into law by Governor O'Malley on Apr. 9, 2013, provides an affirmative defense to a prosecution for caregivers of medical marijuana patients. HB 1101, signed into law by Governor O'Malley on May 2, 2013, allows for the investigational use of marijuana for medical purposes by "academic medical centers." The University of Maryland Medical System and Johns Hopkins University indicated they would not participate.
- **(e) United States Attorneys' Letters to Legal States** Several states with legal medical marijuana received letters from their respective United States Attorney's offices explaining that marijuana is a Schedule I substance and that the federal government considers growing, distribution, or possession of marijuana to be a federal crime regardless of the state laws. An Aug. 29, 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to "address marijuana activity through enforcement of their own narcotics laws."
- **(f) Symbolic Medical Marijuana Laws, 1979-1991** Between Mar. 27, 1979 and July 23, 1991, five US states enacted laws that legalized medical marijuana with a physician's prescription, however, those laws are considered symbolic because federal law prohibits physicians from "prescribing" marijuana, a schedule I drug. The five states were <u>Virginia</u> (Mar. 27, 1979), New Hampshire (Apr. 23, 1981), Connecticut (July 1, 1981), Wisconsin (Apr. 20, 1988), and Louisiana (July 23, 1991).

A further eight US States have recently passed Cannabidiol Bills:

Cannabidiol is one of the 400+ ingredients found in marijuana and is not psychoactive.

1. On Mar. 21, 2014, **Utah** Governor Gary Herbert signed <u>HB 105</u>, known as "Charlee's Law," which allows the use and possession of marijuana extract, under certain conditions, by people with intractable epilepsy who have a statement signed by a neurologist. The extract must be composed of less than 0.3% tetrahydrocannabinol

(THC) and at least 15% cannabidiol (CBD) by weight, and may not contain any other psychoactive substance. The law goes into effect on July 1, 2014. The extract must be obtained in a sealed container from a laboratory that is licensed in the state where it was produced, with a label stating the extract's ingredients and origin, and transmitted by the laboratory to the Utah Department of Health. The Utah Department of Health is required to determine the details of the registration program.

Kristen Stewart of the *Salt Lake Tribune* wrote in her article "Utah Families Celebrate Passage of Cannabis 'Charlee's Law,'" dated Mar. 25, 2014:

"HB105 gives Utahns with epilepsy trial access to a non-intoxicating, seizurestopping cannabis oil. But it doesn't take effect until July 1, 2014, and until then, Utahns can't legally possess cannabis oil.

And obtaining it after that date will still risk violating federal law — and require jumping through a set of still-vaguely defined hoops.

Currently, patients will need to travel to states where medical marijuana is legal and import cannabis oil themselves. Doing so remains technically a violation of federal law."

- 2. On Apr. 1, 2014, **Alabama** Governor Robert Bentley signed <u>SB 174</u>, known as "Carly's Law," which allows an affirmative defense against prosecution for CBD possession by people suffering from a debilitating epileptic condition. The law states that "a prescription for the possession or use of cannabidiol (CBD) as authorized by this act shall be provided exclusively by the UAB [University of Alabama at Birmingham] Department for a debilitating epileptic condition." Since marijuana is illegal under federal laws, doctors are not allowed to write "prescriptions" for it. The states that have legal medical marijuana allow doctors to "recommend" it.
- 3. On Apr. 10, 2014, **Kentucky** Governor Steve Beshear signed <u>SB 124</u>. The law excludes from the definition of marijuana the "substance cannabidiol, when transferred, dispensed, or administered pursuant to the written order of a physician practicing at a hospital or associated clinic affiliated with a Kentucky public university having a college or school of medicine."
- 4. On Apr. 16, 2014, **Wisconsin** Governor Scott Walker signed <u>AB 726</u>, which states that "any physician may provide an individual with a hard copy of a letter or other official documentation stating that the individual possesses cannabidiol to treat a seizure disorder if the cannabidiol is in a form without a psychoactive effect." A release from the Governor's office characterizes the law as "clearing the way for a new treatment for children suffering from seizure disorders, pending FDA approval."
- 5. On Apr. 17, 2014, **Mississippi** Governor Phil Bryant signed <u>HB 1231</u>, known as "Harper Grace's Law," which allows for cannabis extract, oil, or resin that contains more than 15% CBD and less than 0.5% THC. "The CBD oil must be obtained from or tested by the National Center for Natural Products Research at the University of Mississippi and dispensed by the Department of Pharmacy Services at the University of Mississippi Medical Center." The law also provides an affirmative defense for defendants suffering from a debilitating epileptic condition who accessed the CBD oil in accordance with the requirements set forth in the bill and is effective July 1, 2014.

Governor Bryant released the following statement to the media on Apr. 17, 2014:

"The bill I signed into law today will help children who suffer from severe seizure disorders. Throughout the legislative process I insisted on the tightest controls and regulations for this measure, and I have been assured by the Mississippi Bureau of Narcotics that CBD oil is not an intoxicant. The outcome is a bill that allows this substance to be used therapeutically as is the case for other controlled prescription medications. I remain opposed to any effort that would attempt to legalize marijuana or its derivatives outside of the confines of this bill."

- 6. On May 16, 2014, **Tennessee** Governor Bill Haslam signed <u>SB 2531</u> into law. The bill allows the use of cannabis oil containing cannabidiol (CBD) that has less than 0.9% THC "as part of a clinical research study on the treatment of intractable seizures when supervised by a physician practicing at... a university having a college or school of medicine." The study is authorized for four years.
- 7. On May 30, 2014, **lowa** Governor Terry Branstad signed <u>SF 2360</u> into law, saying "This bill received tremendous support and truly shows the power of people talking to their legislators and to their governor about important issues to them, to their families and to their children." The bill allows the possession or use of cannabidiol that has less than 3% tetrahydrocannabinol [THC] for the treatment of intractable epilepsy with the written recommendation of a neurologist. The bill states that the cannabidiol must be obtained from an out-of-state source and "recommended for oral or transdermal administration" (non-smoked).
- 8. On June 2, 2014, **South Carolina** Governor Nikki Haley signed <u>S 1035</u> into law. "Julian's Law" pertains to people who obtain a written certification signed by a physician "stating that the patient has been diagnosed with Lennox-Gastaut Syndrome, Dravet Syndrome, also known as 'severe myoclonic epilepsy of infancy', or any other severe form of epilepsy that is not adequately treated by traditional medical therapies and the physician's conclusion that the patient might benefit from the medical use of cannabidiol." Those patients may use CBD oil that is less than 0.9% THC and more than 15% cannabidiol, which is to be provided by the Medical University of South Carolina in a study to determine the effects of CBD on controlling seizures.²⁵

CANADA

The current position in Canada appears to be in flux and is best explained by reference to the Health Canada website, which states:

Since 2001, Health Canada has granted access to marihuana for medical purposes to Canadians who have had the support of their physicians. Once approved under the <u>Marihuana Medical Access Regulations</u> (MMAR), individuals have three options for obtaining a legal supply of dried marihuana: 1) they can apply under the MMAR to access Health Canada's supply of dried marihuana; 2) they can apply for a personal-use production licence; or 3) they can designate someone to cultivate on their behalf with a designated-person production licence.

In response to concerns from stakeholders that this system was open to abuse, and after extensive consultations, the Government of Canada introduced the new *Marihuana for Medical Purposes Regulations* which were published in *Canada Gazette*, Part II on June 19, 2013. The new regulations aim to treat marihuana as

²⁵ ProCon.org., <u>22 Legal Medical Marijuana States and DC</u>, Note (d), 2014 [online – accessed 6 June 2014]

much as possible like any other narcotic used for medical purposes by creating conditions for a new, commercial industry that is responsible for its production and distribution.

During the transition period, the new *Marihuana for Medical Purposes Regulations* and the current Program will operate concurrently. Authorized individuals have the option to remain with the current Program until March 31, 2014, or to switch to a licensed producer as soon as they become available. The production of marihuana for medical purposes in private residences will end March 31, 2014, as will the Health Canada supply.

As of April 1, 2014, the *Marihuana Medical Access Regulations* will be repealed and the only way to access marihuana for medical purposes will be through commercial, licensed producers. At this time the Marihuana Medical Access Program will also end.

The same <u>website</u> explains:

Under the MMAR, Health Canada issues individuals an **Authorization to Possess** and/or a **Licence to Produce** (either a **Personal-Use Production Licence** or a **Designated-Person Production Licence**) so that they may possess and/or produce marihuana for their own medical purposes if this is supported by their physician or, in the case of a Designated-Person Production Licence, produce marihuana for the medical purposes of the authorized person.

Once approved, the legal documentation issued to clients of the program is a large pink-coloured document that describes the activity (either possession or production) that the named individual is permitted to conduct. Only individuals who hold this documentation are considered authorized/licensed by Health Canada, and only the person whose name appears on the document is considered authorized/licensed to access and care for plants and/or dried marihuana at the production and storage sites listed on the document.

Depending on the specifics of the authorization and/or licence issued to an individual and the province in which they reside they **may** be permitted to:

- Possess marihuana
- Use marihuana;
- Produce marihuana;
- · Store marihuana; and
- Transport or ship marihuana domestically.

Regardless of the specifics of the authorization and/or licence issued to an individual and the province in which they reside they are **not** permitted to:

- Let others to use their marihuana; or
- Import to, or export from, Canada any marihuana or marihuana seeds.

Additionally, Health Canada has the ability to revoke an authorization and/or a licence to produce for any reason under $\underline{s.62}$ and $\underline{s.63}$ of the MMAR.

And further:

The new *Marihuana for Medical Purposes Regulations*, sets up a new system whereby individuals, who have their health care practitioner's support, would access marihuana for medical purposes from licensed producers.

Licensed producers will have to meet strict security and quality standards and notification of local police is a requirement of the application to become a licensed producer. Health Canada will have a list of licensed producers and the proof of authority to possess marihuana for medical purposes will either be the label on the packaging or a separate document accompanying the shipment of dried marihuana provided by the licensed producer.

The maximum amount that may be possessed by those holding this authorization is 30 times the daily amount as indicated by their licensed health care practitioner, to a maximum of 150 grams.

Individuals who access marihuana for medical purposes are **not** permitted to:

- Let others use their marihuana;
- Grow marihuana;
- Import to, or export from, Canada any marihuana or marihuana seeds; or
- Produce derivatives of marihuana such as hashish, hash oil, resin, etc.

But note that the new system appears to be subject to legal challenge, as set out in this CTV News 21 March 2014 article, which states:

The Conservative government's plan to move medical marijuana plants out of patients' basements and into commercial facilities was dealt a significant setback Friday, after a Federal Court judge ruled anyone already licensed to grow the drug may continue to do so.

And see this <u>article</u> from Global News and one from <u>The Huffington Post</u>. For a summary of the legal history see this Wikipedia website.

ISRAEL

Israel has a medical cannabis scheme, under which medical cannabis is supplied to patients who are approved by the Israeli Ministry of Health through licensed growers in Israel who cultivate cannabis plants on a not-for-profit basis. Some information is available on the Ministry of Health website. A broader overview, historical and contemporary, is found on this ENCOD website. An article from The New York Times of 1 January 2013 setting out recent developments in Israel can be found here.

On 5 June 2014 The Times of Israel reported:

The Health Ministry has commissioned a comprehensive study into the effects and effectiveness of medical marijuana. The study, which is being carried out by the Israeli National Institute for Health Policy Research, will track up to 2,000 patients using medical cannabis over a two-year period, Haaretz reported on Sunday.

NEW ZEALAND

An authoritative overview is found in the April 2011 report by the New Zealand Law Commission titled, *Controlling and Regulating Drugs: A Review of the Misuse of Drugs Act 1975*. It states (page 19):

Cannabis and cannabis-based products have historically been used for medicinal purposes. There is continuing debate about the nature and extent of their therapeutic benefits. However, a number of jurisdictions, particularly in North America, now authorise the use of cannabis for some therapeutic purposes.

In New Zealand, the current licensing scheme and exemptions from prohibition appear to adequately deal with cannabis-based medicines. The more difficult issue is whether there should be greater access to unprocessed cannabis for therapeutic uses. Cannabis-based medicines can be expensive (if they are not publicly funded) and may not be considered effective for all those who could benefit medically from cannabis use.

There are significant differences of opinion on whether unprocessed cannabis should be available for therapeutic use. Until randomised control trials are undertaken we do not think it will be possible to resolve the differences of view about the safety or efficacy of raw cannabis. As a matter of principle, we take the view that cannabis should not be a special case, but should be treated in the same way as other controlled drugs that can be used medicinally. It should therefore be subject to the same evidence-based testing as other controlled drugs before being made available to the public as a medicine.

Given the strong belief of those who already use cannabis for medicinal purposes that it is an effective form of pain relief with fewer harmful side effects than other legally available drugs, we think that the proper moral position is to promote clinical trials as soon as practicable. We recommend that the Government consider doing this.

In the meantime, while trials are being conducted, we think that it would be appropriate for the police to adopt a policy of not prosecuting in cases where they are satisfied that cannabis use is directed towards pain relief or managing the symptoms of chronic or debilitating illness.

In May 2014 the <u>New Zealand Parliament's Health Committee</u> published a report, <u>Petition 2011/41 of William Joseph Rea</u>. Mr Rea's petition was in support of the Law Commission's Recommendation 134 that "the Government should consider undertaking or supporting clinical trials into the efficacy of raw cannabis by comparison to synthetic cannabis-based products as a treatment for pain relief".

The majority committee report noted that:

The Ministry of Health is reluctant to treat raw cannabis differently from other controlled drugs that may have medicinal properties. It also has concerns about the use of raw cannabis as a medicine. It noted that raw cannabis varies greatly in chemical composition and strength, and that no credible assurance could be given at present that medicinal cannabis would be free of chemical contaminants or mould.

The majority committee report concluded:

We recommend that the Ministry of Health continue to review world literature on the use of cannabis and its derivatives as a medicine.

We also recommend that Pharmac continue to assess whether there is positive evidence from countries that subsidise medicinal cannabis as to whether it provides a useful option for managing chronic pain, particularly with terminally ill patients.

The Green Party's minority view was that (in part):

Green Party members welcome Mr Rea's petition, and the Law Commission's report on which it was based. We believe that a much more positive and proactive stance should have been taken by the committee.

The <u>Voxy.co.nz</u> website reported on 23 May 2014 that:

News that the Associate Health Minister is considering allowing a clinical trial of low-THC cannabis on New Zealand patients, is welcomed by the Aotearoa Legalise Cannabis Party. ALCP deputy leader Abe Gray said Charlotte's Web cannabis oil had already shown promising results for children with a severe form of epilepsy called Dravet's syndrome.

"Clinical trials for medical cannabis were recommended by the Law Commission's report into the Misuse of Drugs Act," Mr Gray said. "New Zealand could become a world leader in the field if our scientists can begin using cannabis for medical research."

ALCP has allocated \$100 million for clinical trials of medical cannabis in its shadow budget as well as a further \$40 million for research scholarships. Trials will include treatments for chronic pain, cancer, epilepsy, nausea, depression, eating disorders and skin conditions. Cannabis has also shown promise in the fight against MRSA and other superbugs.

Mr Gray said Harvard Medical School had described cannabis as "the wonder drug of the 21st century", so New Zealand could not afford to be left behind on the issue.

"Not only can cannabinoids be used to treat a wide variety of illnesses, they can also be used to create customised medications tailored to each patient," he said. "Replacing hospital bedding with hemp fabric could also reduce infections."

UNITED KINGDOM

Prohibited drugs are classified as Class A, B and C depending on their likely capacity to cause harm. In January 2009 cannabis was reclassified from Class C to Class B (see this <u>article</u>). The penalties relevant to each class and the drugs contained therein are set out on this UK Government website.

Between 1997-98 and 2001-02 three relevant parliamentary reports were published, as follows:

- House of Lords Science and Technology Committee, <u>Ninth Report</u>, Session 1997-98.
- House of Lords Science and Technology Committee, <u>Second Report</u>, Session 2000-01.

• House of Commons Home Affairs Committee, *Third Report*, Session 2001-02.

The law in respect to the medical use of cannabis does not appear to have altered substantially since that time.

For the views of advocacy groups see this Release website and this CLEAR website.

CZECH REPUBLIC AND OTHER EUROPEAN COUNTRIES

On 16 February 2013 it was <u>reported</u> in *The New York Times* that legislation had been passed in the Czech Republic making it legal to use cannabis for medical treatment:

The legislation had been approved by both houses of Parliament. It allows marijuana to be imported and later grown locally by registered firms licensed for such activity, which had been illegal. Patients will need a prescription from a doctor to get the drug at pharmacies, and the treatment will not be covered by health insurance.

Further information about the legislation and its operation can be found on this website.

For a summary of the position in other European countries see this <u>Medical Marijuana.org website</u>, which states:

Medical marijuana is currently legal or decriminalized in the Czech Republic, Finland, the Netherlands, Portugal and Spain. Possession of (small amounts of) marijuana is generally tolerated or not penalized in Belgium, Croatia, Estonia, Italy, and Switzerland. While Germany has theoretically decriminalized medical marijuana, the rules are applied so stringently that it is effectively impossible to get approved as a medical marijuana patient.

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8. GLOSSARY

Analgesic: a pain-relieving drug.

<u>Cannabis</u>: most botanists consider that there are three distinct species of cannabis: cannabis sativa, cannabis indica, and cannabis ruderalis. An alternative view is that cannabis indica and cannabis ruderalis are particular varieties within the cannabis sativa species (i.e. cannabis sativa var. indica and cannabis sativa var. ruderalis). The Australian Illicit Drug Guide recognises the three distinct species and states that, 'Cannabis sativa is the species cultivated for marijuana, hashish and hash oil. It contains a higher concentration of the psychoactive agent known as THC.'

<u>Cannabis resin:</u> an abundant sticky resin that is secreted by the female plant and covers the flowering tops and upper leaves.

<u>Cannabinoids:</u> there are approximately 400 chemicals in the cannabis plant, 61 of which may be called cannabinoids. It is the cannabinoid receptors in the brain that mediate the psychoactive effects of cannabis. The major psychoactive cannabinoid is delta-9-tetrahydrocannabinol (THC). Cannabidiol (CBD) is another example of a cannabinoid, but it does not have the same psychoactive effects as THC. Others include cannabinol (CBN), cannabitriol (CBT), and cannabinidiol (CBND).

<u>Delta-9-tetrahydrocannabinol:</u> the main psychoactive chemical in cannabis. Abbreviated as THC.

<u>Dronabinol:</u> synthetic delta-9-tetrahydrocannabinol (THC), taken in capsule form, and marketed under the brand name 'Marinol' in the United States of America.

<u>Hashish:</u> dried cannabis resin, formed into small blocks, ranging in colour from light brown to almost black.

<u>Immature/mature cannabis plant</u>: most of the jurisdictions in the United States that allow patients or their caregivers to grow cannabis for medical purposes specify the maximum number of 'mature' plants that may be possessed. This usually means a plant with flowers and buds. An immature plan has no observable flowers or buds.

<u>Marijuana:</u> the dried leaves and flowers (heads) of the cannabis plant. Marijuana is usually smoked in a cigarette ('joint') or using a water pipe ('bong').

<u>Marinol:</u> the brand name or trade name in the United States for dronabinol, a synthetic form of THC.

<u>Nabilone:</u> another synthetic cannabinoid, with similar effects to THC. It has been registered for therapeutic use in the United Kingdom.

<u>Placebo:</u> an inactive drug that is indistinguishable in appearance from the active drug with which it is being compared. A 'placebo-controlled' clinical study means that a proportion of participants are unknowingly taking a substance with no active ingredient. A 'placebo effect' occurs when patients feel improvement because they think they are receiving treatment.

<u>THC:</u> the common abbreviation for delta-9-tetrahydrocannabinol, the main psychoactive ingredient in cannabis.

<u>Usable marijuana:</u> this expression appears in numerous medical cannabis laws in the United States, to describe the quantity of marijuana that may be possessed for medical purposes. It refers to the dried leaves and flowers of the plant, and usually excludes the stalks and roots of the plant. Seeds may be included or excluded as usable marijuana, depending on the jurisdiction.

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