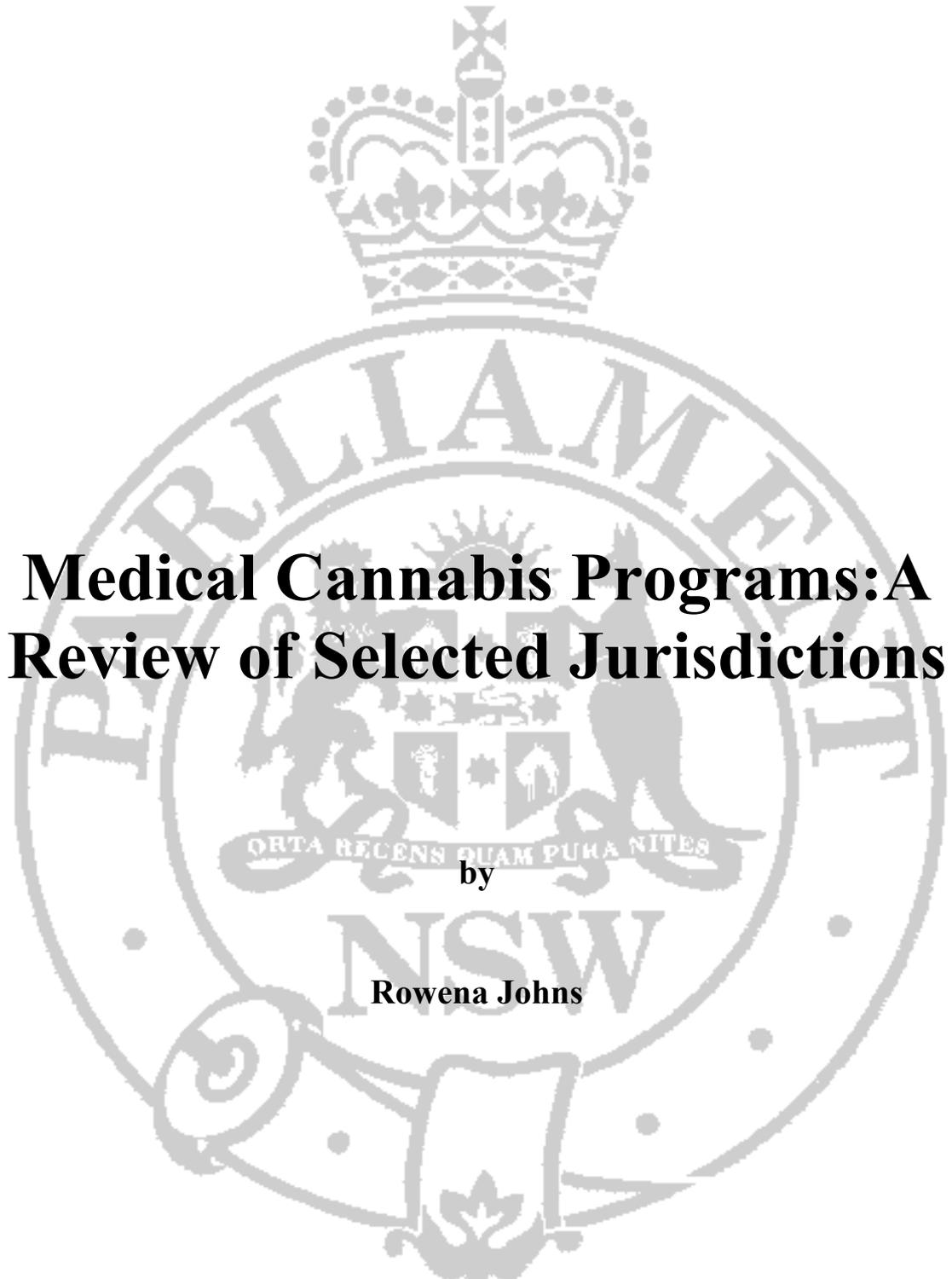


**NSW PARLIAMENTARY LIBRARY
RESEARCH SERVICE**



**Medical Cannabis Programs: A
Review of Selected Jurisdictions**

by

Rowena Johns

Briefing Paper No 10/04

RELATED PUBLICATIONS

- The Medical Use of Cannabis: Recent Developments by Gareth Griffith and Marie Swain, NSW Parliamentary Library Briefing Paper No 11/99

ISSN 1325-4456

ISBN 0 7313 1767 X

August 2004

© 2004

Except to the extent of the uses permitted under the *Copyright Act 1968*, no part of this document may be reproduced or transmitted in any form or by any means including information storage and retrieval systems, without the prior written consent from the Librarian, New South Wales Parliamentary Library, other than by Members of the New South Wales Parliament in the course of their official duties.

Medical Cannabis Programs: A Review of Selected Jurisdictions

by

Rowena Johns

NSW PARLIAMENTARY LIBRARY RESEARCH SERVICE

David Clune (MA, PhD, Dip Lib), Manager..... (02) 9230 2484

Gareth Griffith (BSc (Econ) (Hons), LLB (Hons), PhD),
Senior Research Officer, Politics and Government / Law (02) 9230 2356

Talina Drabsch (BA, LLB (Hons)), Research Officer, Law (02) 9230 2768

Rowena Johns (BA (Hons), LLB), Research Officer, Law (02) 9230 2003

Lenny Roth (BCom, LLB), Research Officer, Law (02) 9230 3085

Stewart Smith (BSc (Hons), MELGL), Research Officer, Environment . (02) 9230 2798

John Wilkinson (MA, PhD), Research Officer, Economics (02) 9230 2006

Should Members or their staff require further information about this publication please contact the author.

Information about Research Publications can be found on the Internet at:

www.parliament.nsw.gov.au/WEB_FEED/PHWebContent.nsf/PHPages/LibraryPublications

Advice on legislation or legal policy issues contained in this paper is provided for use in parliamentary debate and for related parliamentary purposes. This paper is not professional legal opinion.

CONTENTS

EXECUTIVE SUMMARY

1. INTRODUCTION	1
2. PRELIMINARY ISSUES	2
2.1 TERMINOLOGY	2
2.2 METHODS OF INGESTING CANNABIS	3
3. HEALTH EFFECTS OF CANNABIS USE	6
3.1 THERAPEUTIC EFFECTS	6
3.2 HARMFUL EFFECTS	8
4. NEW SOUTH WALES	14
4.1 DEVELOPMENTS FROM 1999 TO 2003	14
4.2 SITUATION IN EARLY 2004	17
4.3 RELEVANCE OF COMMONWEALTH LAWS	18
5. NETHERLANDS	22
5.1 CANNABIS ON PRESCRIPTION	22
5.2 CANNABIS ‘COFFEE SHOPS’	24
6. CANADA	25
6.1 LEGAL AND CONSTITUTIONAL BACKGROUND	25
6.2 MEDICAL CANNABIS PROGRAM	26
6.3 CANNABIS CLUBS	29
6.4 PROBLEMS AND CONTROVERSIES	29
7. UNITED STATES OF AMERICA	33
7.1 FEDERAL POSITION AND LEGAL CONFLICT WITH STATES	33
7.2 SUMMARY OF STATE MEDICAL CANNABIS PROGRAMS	39
8. UNITED KINGDOM	54
8.1 BACKGROUND	54
8.2 CANNABIS SPRAY CLINICAL TRIAL	56
9. CONCLUSION	59

EXECUTIVE SUMMARY

This briefing paper outlines the health benefits and detriments of cannabis use; summarises medical cannabis laws and programs operating in a range of overseas jurisdictions; and traces the development of a proposal to authorise the medical use of cannabis in New South Wales.

Preliminary issues (pages 2-5): Cannabis-related terminology is explained, from the basic question of the difference between ‘cannabis’ and ‘marijuana’, to the chemical composition of cannabis. Different methods of administering cannabis are then described, including smoking, eating, synthetic capsules, sub-lingual spray, and inhaling through a nebuliser, with some remarks on the advantages and disadvantages of each method.

Health effects of cannabis use (pages 6-13): There is evidence that herbal cannabis relieves the symptoms of: nausea experienced in cancer treatments; AIDS-related wasting; glaucoma; muscle spasms suffered in multiple sclerosis, epilepsy and spinal cord injuries; and chronic pain associated with other medical conditions. However, sustained cannabis use can impair memory, attention, and psychomotor skills, while smoking cannabis magnifies the risk of bronchial and respiratory problems and cancers of the lungs, oesophagus and mouth. There is also increasing evidence of a connection between cannabis use and mental health problems such as depression and schizophrenia.

New South Wales (pages 14-21): The Premier of New South Wales, Hon Bob Carr MP, has indicated his support for enabling cannabis to be legally available to patients suffering from serious illnesses. A Working Party on the Use of Cannabis for Medical Purposes completed a report in 2000, recommending that a trial be conducted. In May 2003, the Premier outlined some key elements of the plan, including the formation of an Office of Medicinal Cannabis, and stated that a draft exposure bill would be introduced at the earliest opportunity. Although the Carr Government has continued to affirm its support for the project, no further announcements have been made since May 2004. This chapter also outlines the Commonwealth requirements that New South Wales would have to meet if marijuana or cannabis medicines were to be imported from overseas.

Netherlands (pages 22-24): Dutch policy has been relatively tolerant towards cannabis possession for personal use since the 1970s, including allowing it to be easily purchased from cannabis ‘coffee shops’. This may have reduced the need to make specific laws authorising the use of medical cannabis. However, in 2003 the Netherlands became the first country to legalise cannabis on prescription for people suffering from serious illnesses. Patients who have a doctor’s prescription can buy 5 grams of dried marijuana from pharmacies. The Office of Medicinal Cannabis in the Ministry of Health, Welfare and Sport, licenses selected companies to grow cannabis on its behalf under strict conditions, and retains responsibility for distributing the product to pharmacies and hospitals.

Canada (pages 25-32): The Canadian Government began granting permits to individuals in 1999 to possess and cultivate cannabis for medicinal purposes. After the courts ruled that there were some constitutional deficiencies with the system, the Marijuana Medical Access Regulations were introduced in 2001. The Office of Cannabis Medical Access, in Health Canada, administers the scheme. Applicants must provide a statement from a medical

practitioner or specialist (depending on the type of illness) to obtain an Authorization to Possess a maximum of 30 days' supply of dried marijuana. Patients have three lawful sources of marijuana: gaining a licence to grow their own cannabis plants; arranging a designated person to be licensed to grow cannabis for them; or obtaining dried marijuana from Health Canada, which has licensed a company to cultivate cannabis on its behalf. An additional, unofficial channel of supply is through cannabis clubs and societies.

United States of America (pages 33-53): Unlike Canada's national program, there is no Federal approval of medical cannabis in the United States. A number of individual States have introduced their own medical cannabis laws, beginning with California in 1996, and most recently Vermont in 2004. None of the States supply marijuana to patients, instead allowing them to possess a certain quantity of dried marijuana and cannabis plants, acquired by their own means. These laws give patients, caregivers and doctors protection from State penalties, but some participants have been prosecuted and even imprisoned for contravening the Federal *Controlled Substances Act*. The latest constitutional challenge to the Federal Government's exercise of power in overriding State medical cannabis laws (*Raich v Ashcroft*) has been accepted for hearing by the U.S. Supreme Court.

United Kingdom (pages 54-58): In the late 1990s, the British Medical Association and the House of Lords Select Committee on Science and Technology expressed support for the therapeutic use of cannabis. The United Kingdom does not have a specific medical cannabis program but has been active in conducting clinical trials. A company named GW Pharmaceuticals developed an oral cannabis spray and applied for regulatory approval in 2003. A decision has not yet been made by the Medicines and Healthcare products Regulatory Agency.

1. INTRODUCTION

The Premier of New South Wales, Hon Bob Carr MP, has stated that a trial program will be conducted to allow marijuana to be lawfully used by people suffering from serious illnesses. A Working Party investigated the concept and reported in 2000 that, while further research was required, a trial should be conducted to enable more immediate compassionate action to be taken. In May 2003, the Premier foreshadowed that a draft exposure bill would be introduced, and outlined the broad features of the plan, including the formation of an Office of Medicinal Cannabis, eligible medical conditions, and excluded persons. As recently as May 2004, the Government has affirmed its intention to pursue the issue, while adverting to legal complexities that are delaying progress. No further developments had occurred by the end of July 2004.

The characteristics of the Carr Government's proposal reflect the influence of overseas medical cannabis programs in Canada, the Netherlands and the United States of America. But unlike Canada and the United States, the initial projections of a scheme for New South Wales do not envisage giving patients or their carers the option of growing their own cannabis plants. This reflects the reservations shared by the New South Wales Government and the Commonwealth Government about the smoking of marijuana. The development in the United Kingdom of a cannabis spray has been regarded as a likely alternative, but its approval and release has also encountered delays.

This briefing paper is concerned exclusively with the *medical use* of cannabis. It does not explore the issue of legalising *recreational use*. The focus of the research is on specific laws and policies that address the subject of medical cannabis. The paper does not attempt to review all criminal drug laws that affect cannabis or marijuana use. Readers should be aware that the jurisdictions examined may have decriminalised or exempted from prosecution the possession of small amounts of cannabis (or even the cultivation of a small number of plants) for personal use, and consequently that medical patients may also derive some relief from these measures.

2. PRELIMINARY ISSUES

2.1 Terminology

Analgesic – a pain-relieving drug.

Cannabis – 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 (ie. 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.’¹

Cannabis resin – an abundant sticky resin that is secreted by the female plant and covers the flowering tops and upper leaves.²

Cannabinoids – 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 cannabitol (CBN), cannabitol (CBT), and cannabidiol (CBND).³

Delta-9-tetrahydrocannabinol – the main psychoactive chemical in cannabis. Abbreviated as THC.

Dronabinol – synthetic delta-9-tetrahydrocannabinol (THC), taken in capsule form, and marketed under the brand name ‘Marinol’ in the United States of America.

Hashish – dried cannabis resin, formed into small blocks, ranging in colour from light brown to almost black.⁴

Immature/mature cannabis plant – 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

¹ Andrew Campbell, *The Australian Illicit Drug Guide*, 2001, Black Inc, Melbourne, p 51.

² Bruna Brands, Beth Sproule, and Joan Marshman (eds), *Drugs & Drug Abuse* (3rd ed.), 1998, Addiction Research Foundation, Toronto, p 225.

³ Marcello Spinella, *The Psychopharmacology of Herbal Medicine*, 2001, The MIT Press, Cambridge, Massachusetts, pp 396-397, 399-400; and Andrew Campbell, *The Australian Illicit Drug Guide*, 2001, Black Inc, Melbourne, pp 56-57.

⁴ Bruna Brands, Beth Sproule, and Joan Marshman (eds), *Drugs & Drug Abuse* (3rd ed.), 1998, Addiction Research Foundation, Toronto, p 226.

and buds. An immature plant has no observable flowers or buds.

Marijuana – the dried leaves and flowers (heads) of the cannabis plant. Marijuana is usually smoked in a cigarette (‘joint’) or using a water pipe (‘bong’).

Marinol – the brand name or trade name in the United States for dronabinol, a synthetic form of THC.

Nabilone – another synthetic cannabinoid, with similar effects to THC. It has been registered for therapeutic use in the United Kingdom.

Placebo – an inactive drug that is indistinguishable in appearance from the active drug with which it is being compared.⁵ 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.

THC – the common abbreviation for delta-9-tetrahydrocannabinol, the main psychoactive ingredient in cannabis.

Usable marijuana – 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.⁶

2.2 Methods of ingesting cannabis

There are a number of methods of absorbing cannabis or cannabinoids into the body. Government medical cannabis programs may take into account health effects, cost, quality, and political factors in choosing a particular option. It is conceivable that other methods could also be developed in the future, such as patches, gum or lozenges.

(i) Smoking

Smoking is the dominant method of marijuana consumption for recreational use. Smoking and inhaling marijuana through a hand-rolled cigarette or a pipe involves absorption of the delta-9-tetrahydrocannabinol (THC) into the bloodstream through the walls of the lungs. The effects of smoking marijuana begin almost immediately, peak after about 20 minutes and last 1-2 hours.⁷

⁵ Wayne Hall et al, *The Health and Psychological Effects of Cannabis Use*, Monograph Series No.44, 2001 (2nd edition), National Drug Strategy.

⁶ For example, the definition of usable marijuana in the *Vermont Statutes Annotated*, Title 18, Chapter 86 excludes the seeds, whereas the definition in the *Nevada Revised Statutes*, Title 40, Chapter 453A includes the seeds.

⁷ Andrew Campbell, *The Australian Illicit Drug Guide*, 2001, Black Inc, Melbourne, p 59.

Smoking is therefore one of the most direct methods of ingesting cannabis:

...oral administration is probably the least satisfactory route for cannabis owing to sequestration of cannabinoids into fat from which there is slow and variable release into plasma. In addition, significant first-pass metabolism in the liver, which degrades THC, contributes to the variability of circulating concentrations of orally administered cannabinoids, which makes dose titration more difficult and therefore increases the potential for adverse psychoactive effects. Smoking has been the route of choice for many cannabis users because it delivers a more rapid “hit” and allows more accurate dose-titration. Smoking may also change the chemical composition such that THC carboxylic acids are readily converted to THC by heating or baking. However, this route is not a viable option because of the potential for long-term side-effects from smoke inhalation. Delivery methods need to be developed for currently available and future compounds to allow better control of side-effects. One approach has been the development of a sublingual spray...⁸

(ii) Eating/drinking

Cannabis, particularly hashish, may be baked into food such as cookies or chocolate and eaten. Absorption occurs through the walls of the stomach and intestines. The effects of eaten cannabis take longer to manifest than smoking (1-2 hours depending on how much food is in the stomach) and peak more slowly, but the primary effects last 3-4 hours.⁹ Cannabis can also be mixed with alcohol, and the resulting tincture made into a tea.

(iii) Nebulisers

Nebulisers allow inhalation of marijuana without the negative health effects of smoking, because the nebuliser atomises the drug within the body of the device. A research scientist at the University of Sydney, Professor Laurence Mather, has undertaken research into developing an ultrasonic inhaler, which uses ultrasound to vibrate the cannabinoids into a breathable mist.¹⁰

(iv) Capsules

In the United States, synthetic THC in capsule form has been legally available on prescription under the brand name ‘Marinol’ since 1985.¹¹ ‘Nabilone’ capsules have been registered in the United Kingdom.

⁸ David Baker, Gareth Pryce, Gavin Giovannoni, and Alan J Thompson, ‘The therapeutic potential of cannabis’, *The Lancet Neurology*, Volume 2, Number 5, May 2003, p 291 at 297. Footnotes within the quote are omitted.

⁹ Andrew Campbell, *The Australian Illicit Drug Guide*, 2001, Black Inc, Melbourne, p 59.

¹⁰ Joshua Gliddon, ‘The Medicine Pot’, *The Bulletin*, 27 July 2004, p 20 at 22; and Karina Kelly, ‘Medicinal cannabis’, story on *Catalyst* program, ABC TV, 3 July 2003, transcript accessed at <www.abc.net.au/catalyst/stories/s888110.htm>

¹¹ Lester Grinspoon and James Bakalar, *Marihuana, the Forbidden Medicine*, 1993, Yale University Press, p 38.

There can be disadvantages associated with taking THC capsules. For example, they may be erratically or slowly absorbed into the bloodstream, or patients suffering from nausea or vomiting may be unable to keep the capsule down.¹²

(v) *Spray*

A cannabis spray has been developed in the United Kingdom. The spray mixes active cannabis ingredients into alcohol and is administered under the tongue ('sub-lingual'), from where it is absorbed into the bloodstream.¹³ The sub-lingual spray avoids the dangers of smoking raw cannabis, while still allowing for a controlled dose.

(vi) *Suppositories*

THC can also be converted to a hemisuccinate and administered as a rectal suppository. Dr Harold Kalant, Emeritus Professor in the Department of Pharmacology of the University of Toronto, has observed that, 'Absorption is quite good by this route, with much higher bioavailability than after oral administration. In addition, rectal absorption delivers the drug directly into the systemic circulation...'¹⁴

¹² Ibid, p 38.

¹³ Joshua Gliddon, 'The Medicine Pot', *The Bulletin*, 27 July 2004, p 20 at 22, 24.

¹⁴ Harold Kalant, 'Medicinal use of cannabis: History and current status', *Pain Research Management*, 2001, Volume 6, Number 2, pp 80-91.

3. HEALTH EFFECTS OF CANNABIS USE

This section deals with the negative and positive health consequences of cannabis use. A large amount of information exists on this topic, and the depth of analysis that can be undertaken here is limited. It should also be noted that long-term or potentially negative effects of cannabis may be relatively less compelling for people who seek immediate pain relief for terminal or serious illnesses. Furthermore, some types of side effects may only be associated with a particular method of consuming cannabis such as smoking.

3.1 Therapeutic effects

Cannabis is believed to have a wide variety of therapeutic properties.¹⁵ The evidence has been sufficient for several countries to embark on medicinal cannabis programs. A summary of the positive effects, and authorities for each, is reproduced here from the work of two drug policy advisers, Wayne Hall and Rosalie Liccardo Pacula.¹⁶ Further attention will be paid to therapeutic matters in the context of exploring each jurisdiction's program.

(i) Anti-emetic effects for cancer patients

There are cannabinoid receptors in the brain centres that control emesis (vomiting). Cannabis can therefore be an effective therapy for counteracting the nausea experienced by patients receiving chemotherapy and radiotherapy for cancer: United States Institute of Medicine, 1999.¹⁷

(ii) AIDS-related wasting

Patients with HIV or AIDS may experience nausea and weight loss, either while receiving anti-viral drugs to suppress HIV, or as a direct result of AIDS-related diseases. Cannabinoids and cannabis have been used to reduce nausea, stimulate appetite, and relieve pain in patients with HIV/AIDS wasting: U.S. Institute of Medicine, 1999.¹⁸ Dronabinol (synthetic THC) stimulates appetite in patients with AIDS-related wasting and it was registered for this purpose in the United States, but some patients suffer psychoactive side effects and have difficulty titrating the dose: U.S. Institute of Medicine, 1999.

¹⁵ For more information on the therapeutic history of cannabis see: Lester Grinspoon and James Bakalar, *Marihuana, The Forbidden Medicine*, 1993, Yale University Press, Chapter 1; and Martin Booth, *Cannabis: A History*, 2003, Doubleday, especially Chapters 9 and 24.

¹⁶ Wayne Hall and Rosalie Liccardo Pacula, *Cannabis Use and Dependence: Public Health and Public Policy*, 2003, Cambridge University Press, pp 146-152. Dr Hall is Director of the Office of Public Policy and Ethics at the Institute for Molecular Bioscience, University of Queensland, and Dr Pacula is a Research Fellow with the United States National Bureau of Economic Research.

¹⁷ United States Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, 1999, National Academy Press, Washington DC.

¹⁸ Ibid.

(iii) Glaucoma

Glaucoma occurs when intraocular pressure progressively impairs vision. If untreated, glaucoma may damage the optic nerve and cause blindness. Cannabis has been shown to reduce intraocular pressure in patients with glaucoma: Hepler and Petrus, 1970s.¹⁹ In 1976 Robert Randall, a glaucoma sufferer who was facing blindness, petitioned the United States Government for access to marijuana and, in a related court case, successfully raised the legal defence of ‘medical necessity’. He became the first individual to receive Food and Drug Administration (FDA) approval for the compassionate use of marijuana.²⁰

(iv) Reduction of muscle spasms

Cannabis has anti-convulsant properties that can assist in the treatment of epilepsy: U.S. Institute of Medicine, 1999. Some clinical studies and patient surveys report that cannabis reduces painful muscle spasms in patients with spinal cord injuries (U.S. Institute of Medicine, 1999; Glass et al, 1997)²¹ and multiple sclerosis: Clifford, 1983; Ungerleider et al, 1987; Consroe et al, 1997.²² Muscle spasms or ‘tics’ in persons suffering from Tourette’s syndrome may also be relieved: Mueller-Vahl et al, 1999.²³

The recent British ‘Cannabis trial in MS Spasticity’ (CAMS), which was funded by the Medical Research Council, generated mixed results.²⁴ The trial involved 600 patients from

¹⁹ For instance, R Hepler and R Petrus, ‘Marijuana smoking and intraocular pressure’, *Journal of the American Medical Association*, 1971, Volume 217, p 1392; R Hepler and R Petrus, ‘Experiences with administration of marijuana to glaucoma patients’, in S Cohen and R Stillman (eds) *The Therapeutic Potential of Marijuana*, 1976, Plenum, New York, pp 63-75.

²⁰ Lester Grinspoon and James Bakalar, *Marihuana, The Forbidden Medicine*, 1993, Yale University Press, pp 21, 42-52. However, the United States Institute of Medicine has argued that the effects of THC upon glaucoma are short-lived and that the high doses that are required to sustain it cause side effects: *Marijuana and Medicine: Assessing the Science Base*, 1999, National Academy Press, Washington DC.

²¹ M Glass, M Dragunow and R Faull, ‘Cannabinoid receptors in the human brain: a detailed anatomical and quantitative autoradiographic study in the fetal, neonatal and adult human brain’, *Neuroscience*, 1997, Volume 77, Number 2, pp 299-318.

²² D Clifford, ‘Tetrahydrocannabinol for tremor in multiple sclerosis’, *Annals of Neurology*, 1983, Volume 13, Number 6, p 669; J Ungerleider, T Andrysiak et al, ‘Delta-9-THC in the treatment of spasticity associated with multiple sclerosis’, *Advances in Alcohol and Substance Abuse*, 1987, Volume 7, Number 1, p 39; P Consroe, R Musty et al, ‘The perceived effects of smoked cannabis on patients with multiple sclerosis’, *European Neurology*, 1997, Volume 38, Number 1, p 44.

²³ K Mueller-Vahl, H Kolbe et al, ‘Cannabis in movement disorders’, *Research in Complementary Medicine*, 1999, Volume 6 (Supplement 3), p 23.

²⁴ ‘CAMS trial gives mixed message’, *Press Release*, 7 November 2003, Medical Research Council website at <<http://www.mrc.ac.uk>>. For details of the study’s findings see: John Zajicek, Patrick Fox et al, ‘Cannabinoids for treatment of spasticity and other symptoms related to multiple sclerosis (CAMS study): multicentre randomised placebo-controlled trial’, *The Lancet*, Volume 362, Number 9395, 8 November 2003.

33 neurology and rehabilitation centres across the United Kingdom. Whole cannabis extract and THC were tested for their effects on muscle stiffness, spasms, and other multiple sclerosis symptoms. For 15 weeks, trial participants took either oral THC capsules (206 patients), oral cannabis extract (211 patients), or an inactive placebo (213 patients) in addition to their standard medicine. The results of the CAMS study were released in November 2003. The medical scale used by the researchers to assess clinical spasticity found no change in patients receiving cannabinoids, and no detectable improvement in measures of general disability or wellbeing. However, the patients themselves reported significant pain relief and their walking times were faster. Two-thirds of those patients also said they felt their muscle control had improved, but interestingly so did half of the patients on the placebo drug.

(v) Analgesic effect on chronic pain

Positive evidence of the effects of cannabinoids on chronic pain has been provided by clinical studies of cancer patients with severe, persistent pain that resisted traditional analgesics: Noyes et al, 1975; Staquet et al, 1978.²⁵ These studies suggested that cannabinoids have analgesic effects equivalent to about 60 mg of codeine: Campbell et al, 2001.²⁶ Historically, there has also been anecdotal evidence of cannabis alleviating assorted conditions such as migraine, neuralgia, labour pain, and dysmenorrhoea (menstrual cramps): Grinspoon and Bakalar, 1993.²⁷

3.2 Harmful effects

The United Nations World Health Organization (WHO) advises that using cannabis can have acute health effects and chronic health effects:²⁸

Acute health effects of cannabis use

- Cannabis impairs cognitive development (capabilities of learning), including associative processes; free recall of previously learned items is often impaired when cannabis is used both during learning and recall periods;
- Cannabis impairs psychomotor performance in a wide variety of tasks, such as motor coordination, divided attention, and operative tasks of many types; human performance on complex machinery can be impaired for as long as 24 hours after smoking as little as 20 mg of THC in cannabis; there is an increased risk of motor vehicle accidents among

²⁵ R Noyes et al, 'Analgesic effect of delta-9-tetrahydrocannabinol', *Journal of Clinical Pharmacology*, 1975, Volume 15, p 139; M Staquet et al, 'Effect of a nitrogen analog of tetrahydrocannabinol on cancer pain', *Clinical Pharmacology and Therapeutics*, Volume 23, p 397.

²⁶ F Campbell, M Tramer et al, 'Are cannabinoids an effective and safe treatment option in the management of pain? A qualitative systematic review', *British Medical Journal*, 2001, Volume 323, Number 7303, p 13.

²⁷ Lester Grinspoon and James Bakalar, *Marihuana, The Forbidden Medicine*, 1993, Yale University Press, pp 106-114.

²⁸ World Health Organization, fact sheet on cannabis, accessed on WHO website at <http://www.who.int/substance_abuse/facts/cannabis/en/print.html>

persons who drive when intoxicated by cannabis.

Chronic health effects of cannabis use

- Selective impairment of cognitive functioning which include the organization and integration of complex information involving various mechanisms of attention and memory processes;
- Prolonged use may lead to greater impairment, which may not recover with cessation of use, and which could affect daily life functions;
- Development of a cannabis dependence syndrome characterized by a loss of control over cannabis use is likely in chronic users;
- Cannabis use can exacerbate schizophrenia in affected individuals;
- Epithelial injury of the trachea and major bronchi is caused by long-term cannabis smoking;
- Airway injury, lung inflammation, and impaired pulmonary defence against infection from persistent cannabis consumption over prolonged periods;
- Heavy cannabis consumption is associated with a higher prevalence of symptoms of chronic bronchitis and a higher incidence of acute bronchitis than in the non-smoking cohort;
- Cannabis used during pregnancy is associated with impairment in fetal development leading to a reduction in birth weight;
- Cannabis use during pregnancy may lead to postnatal risk of rare forms of cancer although more research is needed in this area.

In Australia, the National Drug Strategy has outlined similar health and psychological dangers of cannabis, under the categories of ‘major acute adverse’ effects and ‘chronic, heavy cannabis use’ effects, although some of the items appear under a different category than in the World Health Organization listings.²⁹

The research of Wayne Hall and Rosalie Liccardo Pacula provides a useful summary of health problems with cannabis, and accompanying authorities, as it did for therapeutic effects:³⁰

- *Psychomotor effects* – studies have shown that driving is impaired after taking cannabis but the effects of cannabis are less than alcohol: Peck et al, 1986; Smiley, 1999.³¹

²⁹ Wayne Hall, Louisa Degenhardt and Michael Lynskey (National Drug and Alcohol Research Centre, University of New South Wales), *The Health and Psychological Effects of Cannabis Use*, Monograph Series No.44, 2001 (2nd edition), National Drug Strategy, Executive Summary, p xxv.

³⁰ Wayne Hall and Rosalie Liccardo Pacula, *Cannabis Use and Dependence: Public Health and Public Policy*, 2003, Cambridge University Press, pp 38-100.

³¹ R Peck et al, ‘The effects of marijuana and alcohol on actual driving performance’, *Alcohol, Drugs and Driving*, 1986, Volume 2, p 135; A Smiley, ‘Marijuana: on road and driving simulator studies’ in H Kalant et al (eds), *The Health Effects of Cannabis*, 1999, Toronto, pp 171-191.

Driving after a combination of alcohol and cannabis significantly impairs performance: Ramaekers et al, 2000.³²

- *Carcinogenicity* – Cannabis smoke, rather than pure cannabinoids, may be carcinogenic. Cannabis smoke is therefore most likely to cause cancers in the parts of the body that receive the heaviest exposure to smoke – the lungs, mouth, tongue and oesophagus: MacPhee, 1999.³³
- *Respiratory system* – Cannabis smoking causes bronchitis, impairs functioning of the large airways and produces pathological changes in lung tissues that may be precursors of lung cancer: Tashkin et al, 2002.³⁴
- *Reproductivity* – controlled studies have associated cannabis use in pregnancy with reduced birth weight, even after statistically allowing for potential confounding variables: Fergusson et al, 2002.³⁵ However, there has been no consistent relationship between cannabis use and birth abnormalities.
- *Dependence and withdrawal* – In the 1960s and 1970s cannabis was not regarded as a drug of dependence. More recently, controlled studies have provided evidence of cannabis dependence and a withdrawal syndrome, with symptoms such as anxiety, insomnia, irritability and depression: Kouri and Pope, 2000; Budney et al, 2001.³⁶
- *Cognitive impairment* – Cannabis use does not produce gross cognitive impairment like that seen in heavy consumers of alcohol, but there is growing evidence that long-term daily cannabis use produces more subtle impairments in memory and attention: Solowij, 1998 & 1999.³⁷

³² J G Ramaekers et al, 'Marijuana, alcohol and actual driving performance', *Human Psychopharmacology – Clinical and Experimental*, 2000, Volume 15, Number 7, pp 551-558.

³³ D MacPhee, 'Effects of marijuana on cell nuclei: a review of the literature relating to the genotoxicity of cannabis' in H Kalant et al (eds), *The Health Effects of Cannabis*, 1999, Toronto, pp 291-309.

³⁴ D P Tashkin et al, 'Respiratory and immunologic consequences of marijuana smoking', *Journal of Clinical Pharmacology*, 2002, Volume 42, Number 11.

³⁵ D M Fergusson et al, 'Maternal use of cannabis and pregnancy outcome', *British Journal of Obstetrics and Gynaecology*, 2002, Volume 109, Number 1, p 21.

³⁶ E M Kouri and H G Pope, 'Abstinence symptoms during withdrawal from chronic marijuana use', *Experimental and Clinical Psychopharmacology*, 2000, Volume 8, Number 4; A J Budney and B A Moore, 'Development and consequences of cannabis dependence', *Journal of Clinical Pharmacology*, 2002, Volume 42, Number 11.

³⁷ N Solowij, *Cannabis and Cognitive Functioning*, 1998, Cambridge University Press; N Solowij, 'Long-term effects of cannabis on the central nervous system' in H Kalant et al (eds), *The Health Effects of Cannabis*, 1999, Toronto, pp 195-265.

- *Psychotic disorders* – THC is a psychoactive substance which produces some symptoms found in psychotic disorders, including euphoria, distorted time perception, and cognitive/memory impairments. There is epidemiological evidence that cannabis use exacerbates the symptoms of schizophrenia: Stahl and Muntner, 1996; Moore et al, 1999.³⁸ It is likely that cannabis use precipitates schizophrenia in persons who are vulnerable: Arseneault et al, 2002.³⁹ The most contentious issue is whether cannabis use can cause schizophrenia that would not have occurred in its absence.⁴⁰ On the positive side, the treated incidence of schizophrenia did not obviously increase during the 1970s and 1980s when there was a substantial increase in cannabis use among young adults in Australia and North America: Donnelly and Hall, 1994.⁴¹

The impact of cannabis use on the mental health of its users is a controversial subject that has become increasingly prominent in discussions about cannabis policy. According to Joseph Rey and Christopher Tennant, professors of psychiatry at the University of Sydney, ‘The explanation most accepted is that cannabis triggers the onset or relapse of schizophrenia in predisposed people and also exacerbates the symptoms generally.’⁴²

The numerous studies on cannabis and mental health in Australia and the Netherlands since the 1990s include:

- ***Linszen et al, Netherlands, 1994*** – The Psychiatric Center of the Academic Medical Center, Amsterdam, conducted a one year study which compared 24 cannabis-using patients (11 mild users and 13 heavy users) with 69 non-users.⁴³ Findings included:
 - Significantly more and earlier psychotic relapses occurred in the cannabis-using group.
 - In all but one patient, cannabis use preceded the onset of first psychotic symptoms for at least one year.
 - Cannabis, particularly heavy use, can be considered a stressor eliciting relapse in

³⁸ S M Stahl and N Muntner, *Essential Psychopharmacology: Neuroscientific Basis and Clinical Applications*, 1996, Cambridge University Press; H Moore et al, ‘The regulation of forebrain dopamine transmission: relevance to the pathophysiology and psychopathology of schizophrenia’, *Biological Psychiatry*, 1999, Volume 46, Number 1.

³⁹ L Arseneault et al, ‘Cannabis use in adolescence and risk for adult psychosis: longitudinal prospective study’, *British Medical Journal*, 2002, Volume 325, Number 7274.

⁴⁰ A study that asserts cannabis is a contributory cause of schizophrenia is: J Van Os et al, ‘Cannabis use and psychosis: a longitudinal population-based study’, *American Journal of Epidemiology*, 2002, Volume 156, Number 4.

⁴¹ N Donnelly and W Hall, *Patterns of Cannabis Use in Australia*, 1994, Australian Government Publishing Service.

⁴² Joseph M Rey and Christopher C Tennant, ‘Cannabis and mental health’, *British Medical Journal*, Volume 325, November 2002.

⁴³ D H Linszen, P M Dingemans and M E Lenior, ‘Cannabis abuse and the course of recent-onset schizophrenic disorders’, *Archives of General Psychiatry*, Volume 51, Number 4, April 1994.

- patients with schizophrenia, and is possibly a premorbid precipitant (ie. a cause of an illness prior to the onset of apparent signs or symptoms).
- No effect was found on the results of the study due to the presence of additional variables, for example, other street drugs.
- **Van Os et al, Netherlands, 2002** – A study was conducted of 59 Dutch subjects who had been diagnosed with a psychotic disorder.⁴⁴ Substance use was assessed at ‘baseline’ and followed up after one year and three years during 1997-1999. Findings included:
 - Baseline cannabis use predicted the presence at follow-up of psychotic symptoms.
 - More than 50% of the psychosis diagnoses could be attributed to cannabis use.
 - The effect of cannabis use was much stronger in those with a baseline diagnosis of psychotic disorder than in those without.
 - **Rey et al, Australia, 2002** – The study used data from a representative sample of 1261 adolescents aged 13-17 years who had participated in the National Survey of Mental Health and Wellbeing across Australia in 1998.⁴⁵ In addition, adolescents completed questionnaires and a self-rating depression scale, and their parents/caregivers were interviewed. Findings included:
 - One quarter of the adolescents in the sample had used cannabis (there were no gender differences). Cannabis use rapidly increased with age, and was more common in adolescents living with a sole parent.
 - Cannabis use was associated with greater behavioural and emotional problems, drinking alcohol and trying other drugs, and increased depression. For example, 14% of the male teenagers who had used cannabis qualified for a depressive disorder compared with 6% of the males who had not used it.
 - **Patton et al, Australia, 2002** – The study followed a sample of 1601 secondary students in 44 schools in Victoria, from the age of 14/15 years to 20/21 years. The study was conducted between 1992 and 1998.⁴⁶ Some key findings were:
 - 60% of participants had used cannabis by the age of 20 years.
 - Depression and anxiety increased with higher levels of cannabis use, and this pattern was clearest in female participants. Females who used cannabis daily had a fivefold increase in the odds of depression and anxiety (after adjustment for intercurrent use of other substances) than non-users.
 - Weekly cannabis use by females predicted an approximately twofold increase in the risk of depression and anxiety.
 - The authors deduced that self-medication was unlikely to be the reason for the association between depression/anxiety and cannabis use, because depression and

⁴⁴ J van Os, M Bak et al, ‘Cannabis use and psychosis: a longitudinal population-based study’, *American Journal of Epidemiology*, Volume 156, 2002.

⁴⁵ Joseph M Rey, Michael G Sawyer et al, ‘Mental health of teenagers who use cannabis’, *British Journal of Psychiatry*, Volume 180, 2002.

⁴⁶ George C Patton, Carolyn Coffey et al, ‘Cannabis use and mental health in young people: cohort study’, *British Medical Journal*, Volume 325, November 2002.

anxiety as a teenager did not predict later cannabis use.

- ***Veen et al, Netherlands, 2004*** – The purpose of the study was to assess the independent influences of gender and cannabis use on ‘milestones’ in the early course of schizophrenia among 133 patients. The milestones examined were first social and/or occupational dysfunction, first psychotic episode, and first negative symptoms.⁴⁷ Some key findings were:
 - Male patients were significantly younger than female patients at first social and/or occupational dysfunction, first psychotic episode, and first negative symptoms.
 - Cannabis-using patients were significantly younger at these milestones than were patients who did not use cannabis.
 - Cannabis use made an independent contribution to the prediction of age at first psychotic episode. Male cannabis users were a mean of 6.9 years younger at illness onset than male non-users.

⁴⁷

Natalie D Veen, Jean-Paul Selton et al, ‘Cannabis use and age at onset of schizophrenia’, *American Journal of Psychiatry*, Volume 161, March 2004.

4. NEW SOUTH WALES

4.1 Developments from 1999 to 2003

In October 1999, the Premier of New South Wales, Hon Bob Carr MP, announced that the Government would investigate the use of cannabis for medicinal purposes.⁴⁸ He referred to the Australian Medical Association's support for prescribing cannabis to people with cancer and AIDS, and the finding of a report by the House of Lords Select Committee on Science and Technology that cannabis could serve a therapeutic function.⁴⁹ 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, and included representatives of the NSW Cancer Council, the AIDS Council of NSW, the Law Society of NSW, the Australian Medical Association (NSW Branch), senior officials from the NSW Police Service, the Attorney General's Department, NSW Health, the Office of Drug Policy in the Cabinet Office, and medical professors. The Terms of Reference of the Working Party were:

- to assess the efficacy and safety of cannabis for medical purposes;
- to review the extant medical and scientific literature;
- to establish what further research is required;
- to establish if and how cannabis can be effectively administered with the least harm to patients;
- to establish if and how cannabis, or any cannabinoid substances, should be supplied for medical use and how diversion for recreational use or dealing or trafficking could be avoided in these circumstances;
- to identify legal, ethical, pharmacological, physiological, mental, general health and community implications and issues concerning the use of cannabis for medical purposes;
- to make recommendations to the Expert Advisory Group on Drugs.⁵⁰

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:⁵¹

⁴⁸ Premier of New South Wales, *News Release*, 'Government to consider cannabis for medicinal purposes', 19 October 1999.

⁴⁹ House of Lords, Select Committee on Science and Technology, *Report on Cannabis for Medical Purposes*, 9th Report, HL Paper 151, November 1998.

⁵⁰ *Report of the Working Party on the Use of Cannabis for Medical Purposes*, Volume II: Main Report, August 2000, Appendix B, p 113.

⁵¹ 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

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

The report made 24 recommendations, which followed two themes.⁵² Firstly, the report recognised the need for more authoritative scientific evidence on the medical benefits of cannabis and the development of more effective, safer means of delivering the therapeutic effects of cannabis than by smoking or consuming parts of the plant directly. Secondly, the recommendations recognised that because research would take time, more immediate action was necessary on compassionate grounds to relieve the suffering of seriously ill people who could be assisted by cannabis use. Therefore, a two year trial was proposed, whereby approved people with certain medical conditions would be exempted from criminal prosecution for possessing, growing and using cannabis for personal, medical purposes.

The Working Party's report was released for public comment on 1 November 2000, with submissions invited by 2 February 2001. Comment was also sought from organisations and individuals who had made submissions to the Working Party's original inquiry, key government agencies and advisory groups.

The Inquiry into the Use of Cannabis for Medical Purposes released its *Report on Consultation on the Findings and Recommendations of the Working Party on the Use of Cannabis for Medical Purposes* in July 2001. The report presents the viewpoints of the submissions received, rather than drawing any definite conclusions. Of the 117 submissions received (79 from private individuals and 38 from organisations), 72% supported the medical use of cannabis.⁵³ Overall, the main areas of concern raised by submissions were over the recommendations dealing with: developing alternative ways of using cannabis rather than smoking; introducing an interim compassionate regime; illnesses/conditions to be covered by the regime; whether patients should be able to grow cannabis plants; and the involvement of doctors to certify patients for medical cannabis.⁵⁴

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. .

⁵² Again, this interpretation is taken from the 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.

⁵³ Ibid, p 5.

⁵⁴ Ibid, p 16.

On 20 May 2003 the Premier, Hon Bob Carr MP, announced that a draft exposure bill would be introduced 'at the earliest opportunity' to provide for a four year trial of the medical use of cannabis:⁵⁵

Medical evidence supports the proposition that, although harmful in other respects, marijuana can relieve suffering in a number of cases. We have an obligation to minimise human pain and distress wherever we can. Under the proposal approved by Cabinet, patients will be able to access cannabis through a new Office of Medicinal Cannabis to be established within the New South Wales Department of Health. Eligibility will, of necessity, be tightly defined. Patients will be required to demonstrate that conventional treatment will not relieve their suffering.

Some of the features and requirements of the proposal outlined by the Premier were:

- Eligible medical conditions include wasting due to cancer or HIV/AIDS, nausea from chemotherapy, muscle spasticity due to multiple sclerosis, severe or chronic pain, and spinal cord injuries.
- Patients would be required to register annually with the Office of Medicinal Cannabis.
- Patients would need to obtain a certificate from a doctor and prove that they have a genuine and continuing medical relationship with that doctor.
- Excluded from participating are young people under 18 years of age, pregnant women, people convicted of an illicit drug offence in any jurisdiction (other than for a minor personal use offence), and offenders on parole. The Premier also conceded that scientific evidence of a link between heavy cannabis use and schizophrenia might warrant further exceptions: 'It could well be that proneness to a psychotic condition would be added to the list.'⁵⁶
- Offences and penalties will apply for contravening the provisions.

On the issue of the source of cannabis supply for registered medicinal users, Premier Carr stated that the Government would work with medical, pharmaceutical and research institutions to examine a variety of options.⁵⁷ The main possibilities outlined by the Premier included:⁵⁸

- Decriminalising the growing of cannabis plants or the possession of personal use

⁵⁵ 'Cannabis Medical Use', Questions Without Notice, *NSWPD*, 20 May 2003, p 697.

⁵⁶ Interview of Premier Bob Carr by Tony Jones, 'Cannabis trial won't lead to decriminalisation: Carr', *Lateline*, ABC TV, 20 May 2003. Transcript of interview obtained from ABC website at <<http://www.abc.net.au/lateline/content/2003/s859641.htm>>

⁵⁷ 'Cannabis Medical Use', Questions Without Notice, *NSWPD*, 20 May 2003, p 697.

⁵⁸ Interview of Premier Bob Carr by Tony Jones, 'Cannabis trial won't lead to decriminalisation: Carr', *Lateline*, ABC TV, 20 May 2003. Transcript of interview at <<http://www.abc.net.au/lateline/content/2003/s859641.htm>>

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 in cooperation with the British Government, if and when it becomes available.

In media interviews, the Premier clarified that the four year ‘trial’ was not intended to be a clinical trial, as there was already sufficient clinical evidence from overseas: ‘It’s been proven in the other jurisdictions [Canada, the UK and the USA]. It would repeat their experience if we were to say timidly this is only going to be a trial conducted by doctors.’⁵⁹

In response to the Government’s proposal, the Opposition Leader, John Brogden MP, was reported as saying he would support the idea if the cultivation and distribution of cannabis and the eligibility criteria for participants were tightly controlled. The president of the NSW branch of the Australian Medical Association, Dr Choong-Siew Yong, expressed the Association’s support for a trial because of the strong anecdotal evidence that cannabis eased the symptoms of certain diseases and could be more effective than the drugs available. However, Dr Yong emphasised the importance of properly controlling the dosage and using a method of delivery other than smoking cannabis, which he considered ‘as harmful or more harmful than smoking tobacco.’⁶⁰

4.2 Situation in early 2004

In the Legislative Council on 30 March 2004, Lee Rhiannon MLC (Greens) asked the Special Minister of State, Hon John Della Bosca MLC, a question without notice to ‘explain why the Government has continually pushed back the deadline for announcing the trial of cannabis for medicinal use?’ The Minister responded (in part):

...the Government has been exploring a number of options with regard to medicinal cannabis. This is a complex medical, legal and constitutional issue about which the Government has a responsibility to move, but it wants to move cautiously and to provide regulated access to medicinal cannabis. It is consulting agencies within government, including the Commonwealth Government, about this issue.⁶¹

On 12 May 2004 the Premier, Hon Bob Carr MP, further elucidated that:

...we have consulted governments that have medicinal cannabis schemes. We have also talked to the United Kingdom Home Office about the progress of an inhaler spray

⁵⁹ Interview of Premier Bob Carr by Tony Jones, ‘Cannabis trial won’t lead to decriminalisation: Carr’, *Lateline*, ABC TV, 20 May 2003. Transcript of interview at <<http://www.abc.net.au/lateline/content/2003/s859641.htm>>

⁶⁰ Nick O’Malley, ‘Marijuana to be trialled as pain drug’, *The Sydney Morning Herald*, 21 May 2003.

⁶¹ ‘Cannabis Medical Use’, Questions Without Notice, *NSWPD*, 30 March 2004, p 7648.

being developed by the firm G W Pharmaceuticals. Our advice is that this product—which has been the brightest hope for a cannabis-based pharmaceutical—will not be available for a few years. So we must look at alternatives, otherwise we would be asking people to suffer without considering one of these options.

New South Wales is opposed to any scheme that involves growing cannabis in backyards or requiring sick people to buy the drug on the black market. Therefore we need to work with the Commonwealth to resolve issues relating specifically to Commonwealth jurisdiction, including customs legislation and therapeutic drugs approvals. The remaining alternatives—and I confess to some personal reservations—could include the importation, under strict conditions, of standardised cannabis products from reputable sources such as the Canadian Government. I have therefore today written to the Prime Minister requesting the Commonwealth’s cooperation, in particular asking him to nominate a ministerial representative to work with New South Wales on this matter. In this regard, I am mindful of the Prime Minister’s encouraging comments from last year when he said:

Well, in principle, providing it's prescribed and people aren't allowed to grow it. ... I would in principle see merit in it for cases where there are no other conventional medicines available to reduce pain and to provide greater comfort.

He said that on 23 May 2003 on Radio 4BC, Brisbane. For those, like the Prime Minister and I, who detest illicit drugs and the evil they do, it is not easy to come to terms with the idea that cannabis can also have a valid therapeutic use in these cases. But the evidence says it can, and so I encourage the Prime Minister to take an evidence-based approach on the issue, setting aside any temptation to respond in a simplistic way that might deny hope of pain management and pain relief to hundreds of suffering Australians.⁶²

After Premier Carr’s remarks, the Opposition Leader, John Brogden MP, questioned whether the source of cannabis for a medical trial would have to be from overseas: ‘We should also trial the most effective way to manufacture and produce that [medical cannabis], and that may well be in a very refined laboratory environment, in New South Wales, or somewhere in Australia.’⁶³

4.3 Relevance of Commonwealth laws

Depending on the type of medical cannabis scheme favoured, the involvement or approval of the Commonwealth Government could be required. For example, the concept of importing cannabis/marijuana from overseas to dispense to medical patients in New South Wales would need to comply with the *Customs (Prohibited Imports) Regulations 1956* (Cth). Regulation 5 prohibits the importation of a drug (as listed in Schedule 4, including cannabis, cannabis resin and cannabinoids) into Australia unless a licence and permission to import drugs is granted. The Minister administering the *Therapeutic Goods Act 1989* may also, by notice published in the Commonwealth of Australia Gazette, approve the

⁶² ‘Cannabis Medical Use’, Questions Without Notice, *NSWPD*, 12 May 2004, p 8888.

⁶³ ‘Grow medicinal cannabis locally: Brogden’, ABC News online, 13 May 2004, <<http://www.abc.net.au/news/newsitems/s1107701.htm>>

importation into Australia of a drug specified in the notice. However, importing cannabis/marijuana from overseas could create further problems, as evidenced by the dissatisfaction over the quality of the marijuana produced under contract to the Canadian Government: see ‘**6.4 Problems and controversies**’.

Medical products imported into Australia or supplied in Australia, such as synthetic cannabinoid capsules or an oral cannabis spray, must comply with the Therapeutic Goods Administration requirements.⁶⁴ The Therapeutic Goods Administration (TGA) is a unit of the Commonwealth Government’s Department of Health and Aging. An application must be made for a medical product to be listed on the Australian Register of Therapeutic Goods. This register contained approximately 59,400 products as at 30 June 2003, including prescription medicines, non-prescription medicines and medical devices. The evaluation process may involve referral to the TGA’s expert advisory committee (the Australian Drug Evaluation Committee) or one of its sub-committees. There is no requirement for a clinical trial to be conducted in Australia for every medicine before a product can be approved, providing that trials have been conducted in accordance with international good clinical practice and ethical standards.⁶⁵ However, if clinical investigation of a product that is not on the Australian Register of Therapeutic Goods is conducted in Australia, the requirements for notification of clinical trials must also be met, as outlined in the *Therapeutic Goods Regulations 1990* (Cth).

It would seem to be legally possible for the New South Wales Government to grow its own cannabis crop within State borders, or authorise patients/their carers to grow a maximum number of plants. There is precedent in Australia for exempting certain drug use from the usual operation of the criminal law, such as the cannabis cautioning scheme in New South Wales, although this applies only to the possession (not cultivation) of small amounts of cannabis on a maximum of two occasions, and the caution is given at the discretion of the police.⁶⁶ Medical cannabis programs in Canada and the United States are usually conducted under the auspices of a government department of health or human services, but the co-operation of the police remains important.

However, the prospect of medical cannabis being grown in New South Wales, either on behalf of the government or by allowing patients to grow their own, seems an unlikely option given the views expressed thus far by the Carr Government. Some of the main potential problems with this option are: the possibility that supplies from the medical cannabis market could ‘leak’ into the recreational cannabis market; liability for health problems associated with smoking marijuana; lack of interest and waste of resources if the quality of government-supplied marijuana is lower (or the cost is higher) than ‘street’ marijuana; and the risk of a negative community reaction to official endorsement of

⁶⁴ Information was obtained from the Therapeutic Goods Administration website at <www.tga.gov.au>

⁶⁵ ‘Medicines – Prescription’, then ‘Australian regulation of prescription medical products’ on the Therapeutic Goods Administration website at <www.tga.gov.au>

⁶⁶ For more information see: NSW Parliamentary Library Briefing Paper No 7/04, *Drug Offences: An Update on Crime Trends, Diversionary Programs and Drug Prisons*, para 6.2.

growing or smoking marijuana for medical purposes as ‘going soft on drugs’.

Irrespective of the type of scheme, legislation can be expected to establish the framework for a medical cannabis program and/or to amend the *Drug Misuse and Trafficking Act 1985* (NSW) to protect patients, carers and physicians from prosecution for drug offences. Cannabis leaf, oil, plant, and resin are currently classified, along with all other prohibited drugs, under Schedule 1 of the Act. The obstacles that exist in the United Kingdom and the United States with needing to re-schedule cannabis under the *Misuse of Drugs Act* (UK) and the *Controlled Substances Act* (US) before its medical capacity can be recognised would not apply.

In the United States of America, constitutional questions have arisen regarding the power of Federal drug laws to override State laws. The commerce power of the U.S. Constitution, which has tended to be interpreted broadly to date by the courts, has been at issue in the Federal-State legal disputes over cannabis laws. The question of the U.S. Government’s constitutional power to regulate the use of cannabis for medical purposes within the States is to be considered in the near future in *Raich v Ashcroft*: see summary under ‘**7.1.4 Selected case law**’. The constitutional situation in Australia would appear to be less of a problem, even though the framing of the ‘trade and commerce power’ under s 51(i) of the Australian Constitution was influenced by the U.S. Constitution:

The United States provision, from which the Australian provision was largely taken, gives Congress power ‘To regulate Commerce with foreign Nations and among the several states and with the Indian Tribes’. It is by the use of what in Australia is called the incidental area of this power that Congress has in the last 50 years or so acquired power to control the entire economy of that country. The High Court of Australia has, in large part, regarded this trend as an example to be avoided rather than as a lead to be followed.⁶⁷

It is also the U.S. Government’s view that marijuana activities within a State contribute to – or are too difficult to separate from – the interstate marijuana trade. Statements of principle in the Federal *Controlled Substances Act* provide a pertinent example.⁶⁸ This reasoning reflects the ‘commingling’ doctrine in American constitutional law and has not been adopted in Australia:

Many of the Australian items [listed under s 51 of the Constitution]...spell out explicitly areas of power which in the United States emerged only through judicial exposition of what was implied in the “Commerce Clause”...The American expansion has depended in part on the “commingling” doctrine; that is, the idea that interstate

⁶⁷ Leslie Zines, *The High Court and the Constitution*, 1997(4th edition), Butterworths, p 55.

⁶⁸ The findings and declarations set forth by Congress in the *Controlled Substances Act* include: ‘Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances...Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate...Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.’ *U.S. Code*, Title 21, Chapter 13, section 801(4)-(6).

and intrastate trade are so commercially interdependent that congressional power to regulate the former must necessarily extend into the latter. By contrast, the High Court of Australia has consistently refused to espouse any such doctrine.⁶⁹

⁶⁹ Tony Blackshield and George Williams, *Australian Constitutional Law and Theory*, 2002 (3rd edition), Federation Press, p 670.

5. NETHERLANDS

Dutch law and policy has demonstrated tolerance towards cannabis for personal use since the 1970s. Under the revised *Opium Act 1976*, cannabis products were distinguished from ‘drugs presenting unacceptable risks’ and received lower penalties.⁷⁰ Currently, possession of up to 5 grams of cannabis for personal use is not prosecuted,⁷¹ which is of assistance to medical cannabis users. But the recent introduction of cannabis on prescription has specifically focused on medical needs.

5.1 Cannabis on prescription

In January 2003 the Netherlands became the first country to legalise the medical use of cannabis on prescription for people suffering from serious illnesses.⁷²

(i) Obtaining cannabis products by prescription

Dutch doctors are permitted to prescribe cannabis to treat conditions including: chronic pain; nausea associated with cancer and HIV/AIDS; multiple sclerosis spasms; and physical tics suffered in Tourette’s syndrome. From 1 September 2003, pharmacies could provide medical cannabis to patients with a prescription from a doctor. In addition to pharmacies, it was reported that 80 hospitals and 400 doctors would be authorised to dispense cannabis in 5 gram doses.⁷³

Two cannabis products were made available in 2003:

- ‘Bedrocan’ – Grown by Bedrocan B.V. and created by cross-breeding cannabis sativa and cannabis indica varieties. Bedrocan is the more potent product, containing approximately 18% dronabinol and 0.8% cannabidiol. The pharmacy selling price in December 2003 was €47.21 (incl. 6%VAT) per 5 gram tub.⁷⁴

⁷⁰ Working Party on the Use of Cannabis for Medical Purposes (New South Wales), *Report of the Working Party on the Use of Cannabis for Medical Purposes*, Volume II: Main Report, August 2000, Appendix G, p 142.

⁷¹ Jozica Kutin and Silvia Alberti, ‘Law Enforcement and Harm Minimisation’, in Margaret Hamilton et al (eds), *Drug Use in Australia: Preventing Harm*, 2004 (2nd ed.), Oxford University Press, p 155.

⁷² General sources of information are: the website of the Bureau voor Medicinale Cannabis (Office of Medicinal Cannabis) at <<http://www.cannabisbureau.nl>> and the website of the International Association for Cannabis as Medicine at <<http://www.cannabis-med.org/dutch/Regulations.htm>>

⁷³ (No author), ‘Dutch back prescription cannabis’, 1 September 2003, Reuters report, accessed on the CNN news website at <<http://www.cnn.com/2003/WORLD/europe/09/01/dutch.cannabis.reut>>

⁷⁴ Equivalent to \$AU 78.54 in December 2003, based on an exchange rate of 1 Euro = 1.66353 Australian Dollars: information from <www.x-rates.com/d/AUD/EUR/hist2003.html>

- ‘SIMM 18’ – also created by cross-breeding cannabis sativa and cannabis indica. Grown by the Stichting Institute of Medical Marijuana, it contains approximately 13% dronabinol and 0.7% cannabinal. The pharmacy selling price at December 2003 was €41.63 (incl. 6%VAT) per 5 grams.⁷⁵

These prices are more expensive than buying cannabis in coffee shops, but the quality is said to be superior.

(ii) Office of Medicinal Cannabis

The authority in charge of the cannabis on prescription program is the Bureau voor Medicinale Cannabis (BMC), translating as the Office of Medicinal Cannabis, in the Ministry of Health, Welfare and Sport. Since 1 January 2001 the BMC has acted as a government agency within the meaning of the UN Single Convention on Narcotic Drugs 1961. The BMC acts as a regulator for the cultivation of cannabis, the production of its preparations, and for clinical trials. The BMC effectively has a monopoly with regard to the import and export of cannabis, wholesale trade in cannabis, maintenance of stocks, and purchase of legally grown crops.

(iii) Licences to grow medical cannabis

An exemption from the drug prohibitions of the *Opium Act* may be granted under Article 8 for various reasons. One of the listed exemptions is for growing cannabis pursuant to an agreement with the Minister of Health, Welfare and Sport.

An application for an exemption to grow cannabis is directed to the BMC and will only be granted if the BMC concludes a contract with the party. The prospective grower will undergo extensive screening and be required to sell the entire harvest to the BMC; any unnecessary plants will be destroyed. Factors to be considered in granting a licence include whether a prospective grower is able to deliver a standardised product within a reasonable time, delivery terms and conditions, and security measures to prevent cannabis from disappearing into illegal markets. In addition, the BMC imposes quality standards upon prospective growers, aiming to ensure that the therapeutic properties of the product are consistent. The cannabis must be produced according to the Regulations for Cultivating Cannabis for Medicinal Purposes, which were derived from the general rules for good agricultural practice of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency.

Two companies in the Netherlands, Bedrocan B.V. and the Stichting Institute of Medical Marijuana, were initially granted licences to grow cannabis for the government. The BMC packages and labels the products and supplies them to pharmacies.

⁷⁵ Equivalent to \$AU 69.25 in December 2003.

5.2 Cannabis ‘coffee shops’

Another option for obtaining cannabis for medicinal purposes in an open manner, but without a prescription, is to buy it from a ‘coffee shop’. These establishments lawfully sell cannabis under strict guidelines.⁷⁶

The Dutch Government’s original intention in allowing coffee shops was to ‘keep the social environment of young people who use cannabis separate from those where the use of or trade in hard drugs occurs. In the 1970s, this ‘separation of markets’ formed the basis for the Justice Department to allow the sale of cannabis in youth houses by licensed dealers. Since the 1980s, so-called coffee shops have assumed this function on a commercial basis.’⁷⁷

Coffee shops cannot be established freely, and approximately 80% of municipalities do *not* have them.⁷⁸ A three party consultative body, comprised of the mayor, the public prosecutor, and the chief of police, decides whether a municipality may have one or more coffee shops. These three officials determine coffee shop policy within the guidelines of the Public Prosecutor’s Office. The mayor retains the authority to close coffee shops as a matter of policy, without any need for them to be causing a nuisance.

Exemptions from prosecution for the sale of cannabis only apply if the owner of the coffee shop meets certain criteria:⁷⁹

- not stocking quantities of cannabis in excess of 500 grams;
- not selling more than 5 grams per person per visit;
- not selling ‘hard drugs’, including ecstasy;
- not advertising drugs;
- not constituting a nuisance for surrounding businesses or residents;
- not selling ‘soft drugs’ to minors (under the age of 18 years) and not admitting minors to the premises.

Since 1995, the Dutch Government has sought to reduce the number of coffee shops. In 1997 there were an estimated 1179 coffee shops. By 2000, researchers identified 813, representing a decline of 31%.⁸⁰

⁷⁶ Information on cannabis coffee shops was obtained from: *Drug Policy in the Netherlands: Basic Principles and Enforcement in Practice*, International Public Series Health, Welfare and Sport No 18, September 2003, Ministry of Health, Welfare and Sport, The Hague. Accessed from the Ministry website at <www.minvws.nl>

⁷⁷ Ibid, p 9.

⁷⁸ Ibid, p 20.

⁷⁹ Ibid, p 19.

⁸⁰ Ibid, p 20.

6. CANADA

6.1 Legal and constitutional background

In June 1999 the Canadian Government began to issue permits under the authority of the Minister of Health, allowing individuals to possess and produce marijuana for medicinal purposes.⁸¹ In July 2000, the Ontario Court of Appeal held that a scheme that depended entirely on how the Minister of Health chose to exercise his or her discretion was unconstitutional: *R v Parker* (2000) 146 CCC (3d) 193. The court suspended its declaration for one year to allow the Canadian Government to address the constitutional deficiency.

The Government responded with the Marijuana Medical Access Regulations (under the *Controlled Drugs and Substances Act*), which came into force on 30 July 2001. The regulations divide applicants into three categories:

1. those with a terminal illness and a life expectancy of less than 12 months;
2. those who suffer from certain serious medical conditions, including multiple sclerosis, spinal cord injury/disease, cancer and HIV/AIDS;
3. those who have symptoms associated with other serious medical conditions, for which conventional treatments have failed to relieve the symptoms.

The original regulations required Category 1 applicants to supply a medical declaration by their medical practitioner; Category 2 applicants to supply a declaration by a specialist; and Category 3 applicants to supply declarations by a specialist and a second, supporting specialist.

Warren Hitzig, the co-founder of the Toronto Compassion Centre, and other individuals applied to the Superior Court of Justice for a declaration that the regulations were unconstitutional. In January 2003, Justice Lederman held that, because the regulations failed to provide a legal supply of marijuana for persons entitled to possess it for medicinal purposes, the regulations were constitutionally invalid and had no effect: *Hitzig et al v The Queen* (2003) 171 CCC (3d) 18. To enable the Government to act, Justice Lederman suspended the declaration of invalidity for six months. In July 2003, the Government implemented an interim policy, making available to approved medical users cannabis seeds and dried marijuana grown for the government. Meanwhile, the Canadian Government appealed Justice Lederman's decision.

On 7 October 2003 the Ontario Court of Appeal dismissed the Government's appeal: *Hitzig et al v The Queen* (2003) 177 CCC (3d) 449. Justices Doherty, Goudge and Simmons unanimously held that the absence of a legal supply of medical marijuana made the Marijuana Medical Access Regulations constitutionally defective. The court found that the scheme assumed, and indeed depended on, the existence of a black market. Such a scheme, that authorizes possession of marijuana by seriously ill individuals but drives them to the

⁸¹ This summary is drawn from the Ontario Court of Appeal's judgment in *Hitzig et al v The Queen* (2003) 177 CCC (3d) 449.

black market to meet their medical needs, undermines the rule of law and fails to create a constitutionally valid medical exemption to the criminal prohibition against possession of marijuana contained in section 4 of the *Controlled Drugs and Substances Act*.

Furthermore, the court found that the requirement in the regulations for Category 3 applications to be supported by a second specialist was an arbitrary barrier that added little or nothing to the assessment of medical need.⁸²

Consequently, the court struck down certain provisions of the regulations:

- the prohibition against compensating a designated person who is ‘licensed to produce’ marijuana for an authorized patient;
- the provision preventing a designated person from producing marijuana for more than one patient;
- the prohibition against a designated person producing marijuana in common with more than two other designated persons;
- the requirement for Category 3 applicants to provide medical declarations from two specialists.

The Ontario Court of Appeal’s reasoning would make it possible for ‘compassion clubs’ to be granted licenses by the government to produce marijuana for medical users, and to receive financial compensation for their efforts. At the time of writing, there was no indication of such developments occurring.

6.2 Medical cannabis program

The Office of Cannabis Medical Access, within Health Canada, administers and coordinates the development of the regulatory scheme permitting the use of cannabis for medical purposes.

(i) Eligibility to possess marijuana for medical purposes

An application for an ‘Authorization to Possess’ dried marijuana for medical purposes must be submitted to Health Canada using the official application forms and guidelines. A statement from a physician must accompany the application and recommend a specific dosage for the patient.

The Marijuana Medical Access Regulations (effective from 30 July 2001) set out three categories of individuals who can apply for an Authorization to Possess dried marijuana for

⁸² The Government’s reasoning was that different categories of applications warranted different levels of medical scrutiny. For example, long-term risks are virtually irrelevant for applicants with a terminal illness, justifying a lower level of medical scrutiny of Category 1 applications. By contrast, the Government considered that marijuana had a reduced potential benefit for Category 3 patients, so their applications should be vetted and supported by two specialists. The second specialist was supposed to confirm that he/she had reviewed the applicant’s medical file, discussed the case with the first specialist, and agreed that the use of marijuana to mitigate the symptoms would outweigh the risks.

medical purposes. The categories of applications and their current requirements are:

Category 1: for applicants who have a terminal illness and a prognosis of a life expectancy of less than 12 months. A medical practitioner must provide a declaration that conventional treatments have been reasonably tried or considered (but have failed to relieve the symptoms), and that the benefits of using marijuana outweigh the potential risks.

Category 2: for applicants who suffer from specific symptoms associated with certain serious medical conditions, namely, multiple sclerosis, spinal cord injury/disease, cancer, HIV/AIDS, severe arthritis, and epilepsy. A similar declaration must be provided as for Category 1, but from a medical specialist.

Category 3: for applicants who have symptoms associated with a serious medical condition, other than those described in Categories 1 and 2, but conventional treatments have failed to relieve symptoms. Examples include colitis, anorexia, and fibromyalgia.⁸³ The medical declaration required is the same as Category 2 (as amended in December 2003; previously declarations were required from two specialists).

A photograph identification card is issued to applicants who are authorized to possess dried marijuana, and can be shown to a police officer as evidence of entitlement. The Authorization to Possess is renewable every 12 months.

The amount of marijuana that can be produced and stored at any time depends on the daily dosage that has been prescribed by a physician, and whether the cannabis plants are grown indoors or outdoors. Holders of an Authorization to Possess dried marijuana may possess a maximum treatment supply of 30 days. For example, a patient whose daily dosage is three grams will be allowed to possess no more than 90 grams.

(ii) Sources of medical marijuana

Approved persons can lawfully obtain marijuana by:

- being granted a ‘personal-use production licence’ to produce their own marijuana (ie. to grow cannabis plants);
- being granted a ‘designated-person production licence’ to produce marijuana on behalf of a patient;
- ordering through Health Canada marijuana produced by a licensed company.

In December 2000, Health Canada contracted Prairie Plant Systems to cultivate and produce a standardised, homogenous supply of marijuana. The site where the cannabis is cultivated is a disused underground mine at Flin Flon, in Manitoba province.

⁸³ Colitis is a type of inflammatory bowel disease in the colon (large bowel): see Crohn’s and Colitis Foundation of Canada website at <www.ccfc.ca> Fibromyalgia, sometimes called fibrositis, is a chronic disorder that causes pain and stiffness throughout the tissues that support and move the bones and joints, particularly the neck, spine, shoulders, and hips: information from <www.immunesupport.com/library/fmdiagnosis.cfm>

A person who is authorized to produce will be issued with an identification card as well as the licence to produce. Cannabis plants can be grown indoors or outside, providing specific criteria are met. Holders of a licence to produce their own marijuana, or designated producers, must be 18 years of age or over, and ordinarily a resident of Canada.

In summary, some of the main features of the Canadian medical cannabis program are:

Responsible authority	Office of Cannabis Medical Access, in Health Canada.
Illnesses/conditions	3 categories of patients: (i) less than 12 months to live; (ii) serious conditions eg. cancer, HIV/AIDS, epilepsy, multiple sclerosis, spinal injury; (iii) other serious conditions.
Quantity	30 day supply, depending on dosage. eg. 3 gm daily dosage = maximum of 90 gm in total.
Means of supply	3 options: (i) obtain from Health Canada; (ii) grow own supply; (iii) designated person to grow on behalf of sick person.
Physician's role	Provides declaration to support application, stating that conventional treatments have been unsuccessful, and recommending a dosage for the patient.
Designated person	A designated person may be granted a licence to produce marijuana for a patient, provided he/she is at least 18 years old and has not been found guilty, within the 10 years preceding the application, of a drug offence.
ID cards	Yes, for patients and growers.
Children	Must be over 18 years to receive a licence to produce marijuana for self or others. The legislation/regulations do not prohibit children being patients.

(iii) Rates of use

Statistics from Health Canada demonstrate that the number of people registering for the medical cannabis program has slowly increased overall during 2004.⁸⁴ However, these figures reflect a very low participation rate, compared to the number of Canadians who use cannabis for therapeutic purposes: see '6.4 Problems and controversies' for further discussion.

Authorizations to possess or produce marijuana in 2004

	JAN	FEB	MAR	APR	MAY	JUN	JUL
Total persons 'authorized to possess' dried marijuana	710	717	715	750	734	763	781
Total persons with 'licence to produce' marijuana	532	537	535	549	542	563	572

⁸⁴

Statistics are available online from the Health Canada website at <www.hc-sc.gc.ca/hecs-sesc/ocma/whatsnew.htm>

6.3 Cannabis clubs

Cannabis clubs in Canada represent an alternative source of supply of medicinal cannabis to the government supply available through Health Canada. Some of the clubs are the Toronto Compassion Centre, Vancouver Island Compassion Society, and British Columbia Compassion Club Society. Like the cannabis clubs that operate in the United States, the basic concept is that applicants substantiate their medical condition with a statement from their doctor or other documentation to become a ‘member’ and receive cannabis from the society. Usually the location of the club is not advertised and members have to sign an agreement to observe conditions such as not re-distributing the drugs they obtain. The Canadians for Safe Access organisation claimed in April 2004 that ‘Canada’s compassion clubs and societies supply over 7000 critically and chronically ill Canadians with a safe and affordable source of cannabis (including over half of the Federal exemptees), all at no cost to the taxpayer.’⁸⁵

Health Canada has not licensed these clubs to supply cannabis, to date, which can lead to legal complications. Police have tolerated the operation of some clubs but retain the discretion to investigate activities and lay criminal charges. For example, the President of the Vancouver Island Compassion Society, Philippe Lucas, was charged with possession of marijuana for the purpose of trafficking, and pleaded guilty. Delivering sentence in the Provincial Court of British Columbia, Judge Higinbotham found that Lucas was not running a commercial operation in the sense that profit was not his motive, and that his actions were intended to ameliorate the suffering of others at minimal or no risk to society. Acknowledging ‘our need as a society to get this thorny issue resolved quickly by either Parliament or the Supreme Court of Canada’, Judge Higinbotham granted Lucas an absolute discharge: *Regina v Philippe Lucas*, Provincial Court of British Columbia, 5 July 2002.⁸⁶

On 27 May 2004, Vancouver Island Therapeutic Cannabis Research Institute, the production facility for the 400 members of the Vancouver Island Compassion Society, was raided by constables of the Royal Canadian Mounted Police. Cannabis plants were seized and destroyed.⁸⁷

6.4 Problems and controversies

There have been various difficulties and delays associated with the medical cannabis program in Canada. It is beyond the scope of this paper to document these in detail, but it is worth noting some of the problems that have arisen:

⁸⁵ Canadians for Safe Access, ‘30% of Health Canada’s medicinal cannabis customers are sending back the government pot’, *Press Release*, 29 April 2004, <<http://safeaccess.ca>>

⁸⁶ The judgment on sentence was accessed from the Vancouver Island Compassion Society website at <<http://thevics.com>>

⁸⁷ Canadians for Safe Access, ‘Compassion clubs lament RCMP raid of Vancouver Island Therapeutic Cannabis Research Institute’, *Press Release*, 9 June 2004, <<http://safeaccess.ca>>

- ***Lack of registrations to government scheme*** – The number of people who use marijuana for medical purposes is far greater than those who have registered with the government as medical marijuana patients. Health Canada estimates the number of Canadian medical marijuana users at 400,000, compared to 700 or so people who had registered by early 2004.⁸⁸
- ***Cost of government-supplied cannabis*** – The total quantity of cannabis dispensed by the government, as at 31 March 2004, was only 295 ounces, making its production much more expensive than illegal cannabis, which at that time cost about \$150-200 per ounce for high quality product.⁸⁹
- ***Dubious quality of government-supplied cannabis*** – Complaints about the low THC content of the cannabis cultivated for the Canadian Government were confirmed when tests performed by the Quebec National Institute of Public Health were made public in June 2004. The tests showed that the THC count of the cannabis produced by Prairie Plant Systems in Manitoba was 5%, compared to the 10.2% claimed on the package.⁹⁰ Philippe Lucas, the founder of the Vancouver Island Compassion Society, noted other problems with the quality of the government-supplied cannabis: ‘There’s visible stock and stem and it’s ground far too fine to actually roll so you’re forced to use it in a pipe and when you do it burns very black with dark, acrid ash.’⁹¹ The prospect of toxic contamination at the crop site is another concern.⁹² As at 31 March 2004, nearly a third of recipients of the government cannabis were sending it back to Health Canada, suggesting a substantial level of dissatisfaction with the product.⁹³
- ***Availability and distribution issues*** – Health Canada indicated in March 2004 that it is considering making marijuana produced under government contract more readily

⁸⁸ Philip Smith, ‘Canada plans to offer medical marijuana in BC pharmacies’, *Drug War Chronicle*, 26 March 2004, accessed on ‘News’ section of Canadians for Safe Access website at <<http://safeaccess.ca>>

⁸⁹ Canadians for Safe Access, ‘30% of Health Canada’s medicinal cannabis customers are sending back the government pot’, *Press Release*, 29 April 2004, <<http://safeaccess.ca>>

⁹⁰ Canadians for Safe Access, ‘Quebec National Institute of Public Health confirms that Health Canada cannabis below 6% THC’, *Press Release*, 18 June 2004, <<http://safeaccess.ca>>

⁹¹ Dennis Bueckert, ‘Activist: Ottawa’s pot not worth smoking’, *Halifax Herald*, 30 April 2004, accessed on ‘News’ section of Canadians for Safe Access website at <<http://safeaccess.ca>>

⁹² There have been accusations that the mining area in Manitoba in which the government cannabis is grown is highly polluted, and that elevated levels of toxic heavy metals such as arsenic and lead have been detected in the grown plants: Preston Peet, ‘You call this reform?’, 18 October 2003, article posted on Drug War website at <www.drugwar.com/pcanadarecrim.shtm> For environmental web sources and information about the Flin Flon mining area visit <<http://safeaccess.ca/research/flinflon.htm>>

⁹³ Canadians for Safe Access, ‘30% of Health Canada’s medicinal cannabis customers are sending back the government pot’, *Press Release*, 29 April 2004, <<http://safeaccess.ca>>

available to patients registered with Health Canada, by launching a pilot program to distribute it through pharmacies. Changes to the Marihuana Medical Access Regulations would be required to give pharmacists the authority to dispense marijuana. Consultation with pharmacists' associations and provincial authorities would also need to take place before a scheme could be implemented, possibly later in 2004. However, medical cannabis campaigners are concerned that there is little point in making it easier for patients to obtain government marijuana if its quality does not improve. Also, some would rather explore the licensing and registration of organisations such as compassion clubs that supply a much greater proportion of medical cannabis users than the government. But Health Canada's view is that international treaty obligations require the government to demonstrate commitment to the regulation of controlled substances and restriction of the medical cannabis market.⁹⁴

- ***Delays with clinical cannabis studies*** – In 1999, Health Canada created the Medical Marijuana Research Program and invited applications from organisations wishing to receive funding for research projects on therapeutic uses of marijuana. The Community Research Initiative of Toronto (CRIT) was scheduled to conduct the first Canadian study into whether smoked marijuana can alleviate nausea and weight loss associated with HIV/AIDS. After three years of preparations, CRIT's funding was terminated by Health Canada in March 2003.⁹⁵ The Health Canada website indicates (at the time of writing) that the Medical Marijuana Research Program has been suspended 'until further notice'.⁹⁶ Another study, which was initially announced in 2001, was to be a one-year pilot study on the effects of smoked marijuana on chronic neuropathic pain, conducted by the McGill University Pain Centre in Montreal. It was reported in December 2003 that Health Canada had given permission for marijuana to be released for use in the study. The project leader, Dr Mark Ware, has enrolled 32 patients suffering neuropathic pain to smoke specific doses and strengths of marijuana. Initial results from the study are expected in early 2005.⁹⁷
- ***Medical associations advising doctors not to sign declarations*** – There were reports in early 2004 that the Ontario Medical Association (OMA) and the Canadian Medical Protective Association were advising doctors and specialists not to sign the medical declaration forms for Category 2 and 3 patients until further research is conducted. The OMA's Director of Health Policy, Dr Ted Boadway 'said the medical declaration forms ask the impossible of doctors. With very little research available, there's no way a doctor can attest to the long-term benefits or negative effects of using cannabis medicinally. Drug potency also varies widely from batch to batch, making a

⁹⁴ Philip Smith, 'Canada plans to offer medical marijuana in BC pharmacies', *Drug War Chronicle*, 26 March 2004, accessed on 'News' section of Canadians for Safe Access website at <<http://safeaccess.ca>>

⁹⁵ 'Canada's first cannabis HIV/AIDS study suspended', Canada News Wire, accessed at <<http://www.newswire.ca/en/releases/archive/June2003/19/c5318.html>>

⁹⁶ Message at <<http://www.cihr-irsc.gc.ca/e/services/4628.shtml>>

⁹⁷ CBC Montreal online news, 23 December 2003, accessed at <<http://montreal.cbc.ca>>

recommended daily dosage difficult...’ Health Canada responded that it was working on changes to the declaration forms which are expected to be implemented by the fall (ie. September-November) of 2004.⁹⁸

⁹⁸ Lesley Bovie, ‘MS sufferer battles to get cannabis’, *Oshawa This Week* (Ontario), 5 May 2004, from ‘News’ section of Canadians for Safe Access website at <<http://safeaccess.ca>>

7. UNITED STATES OF AMERICA

A number of State jurisdictions in the United States of America permit the medical use of cannabis. In most of those States, voters initiated the reform process by ballot rather than the State legislature being the instigator. The medical cannabis laws give protection only from criminal prosecution under State law, and do not affect Federal powers.

(Note: American spelling which appears in laws and other material used for this chapter has been retained.)

7.1 Federal position and legal conflict with States

7.1.1 Introduction

There are no Federal laws that correspond to the laws in those States which authorize members of the public to use cannabis for medical purposes. The reasoning of State Governments to proceed with medical cannabis laws, notwithstanding the Federal Government's position, was recently articulated by the Vermont General Assembly:

...The general assembly would prefer for the federal government to permit marijuana to be prescribed by physicians and to be dispensed at pharmacies. However, the general assembly finds that the federal government has shown no indication that it will change federal policy with regard to medical marijuana, as evidenced by the federal government's reluctance to allow even FDA-approved clinical trials to move forward. ...According to the United States Sentencing Commission and the Federal Bureau of Investigation, more than 99 out of every 100 marijuana arrests are made under state law, rather than under federal law. Consequently, the general assembly finds that changing state law will have the practical effect of protecting from arrest the vast majority of seriously ill people who have a medical need to use marijuana. ...The general assembly finds that the state is not required to enforce federal law or prosecute people for engaging in activities prohibited by federal law. Therefore, compliance with this act [the Medical Marijuana Act] does not put the state in violation of federal law.⁹⁹

7.1.2 *Controlled Substances Act and other Federal laws*

The *Comprehensive Drug Abuse Prevention and Control Act 1970* consolidated Federal laws concerning narcotics and other illicit drugs. Title II was the *Controlled Substances Act*. The provisions of the *Controlled Substances Act* are incorporated into Title 21 (Food and Drugs), Chapter 13 (Drug Abuse Prevention and Control) of the *United States Code*.

The *Controlled Substances Act* categorises substances into five schedules, ranging from the most dangerous drugs in Schedule I, to the least dangerous in Schedule V. The reason for much of the inconsistency between Federal and State cannabis laws is that 'marihuana' and

⁹⁹ Medical Marijuana Bill 2003, Sec. 1, Findings and Purpose. 'FDA' stands for Food and Drug Administration, the Federal regulatory authority.

‘tetrahydrocannabinols’ are classified under Schedule 1. Three strict criteria are attached to Schedule 1 drugs:

- a high potential for abuse;
- no currently accepted medical use in treatment in the United States; and
- a lack of accepted safety for use under medical supervision.¹⁰⁰

As a consequence of being in Schedule 1, herbal cannabis (as opposed to synthetic cannabinoids such as ‘Marinol’) cannot be supplied on prescription or carried by pharmacies anywhere in the United States.

It is possible to re-schedule drugs in the *Controlled Substances Act*, or to add or remove drugs. A request may be instigated by a variety of methods including a petition to the Drug Enforcement Administration from an interested party such as a drug manufacturer, medical or pharmacy association, public interest group, or even an individual citizen.

The *Constitution of the United States of America* gives Congress the power, under Article I, section 8, to regulate interstate and foreign commerce. The broad interpretation of the ‘commerce power’ of Congress, to date, has extended to drug activities *within* the States. The *Controlled Substances Act* emphasises that, ‘A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce...’¹⁰¹ There is currently no exception for the medical use of cannabis.

There have been a number of proposals in recent years to encourage medical cannabis to be given a different status under Federal legislation. Some of these attempts have been made by State legislatures and others at the Federal level, but most have been instigated by representatives from California.

For example, in the California State Assembly on 10 March 2003, Assembly Member Mark Leno (Democrat-13th District) introduced Joint Resolution No.13, to urge the President and Congress of the United States to:

- enact legislation that secures a State’s right to regulate medical cannabis, allows individual patients to possess and consume it, and allows individuals deputised by States and localities to cultivate and distribute it;
- amend the *Comprehensive Drug Abuse Prevention and Control Act 1970* [ie. containing the *Controlled Substances Act*] to allow for a medical necessity defense in Federal cases;

¹⁰⁰ Section 812(b)(1) of the *United States Code*. The actual text of Schedule I appears after section 812(c). Marihuana and tetrahydrocannabinols are listed under Schedule I at (c)(10) and (c)(17) respectively.

¹⁰¹ Section 801(3) of the *United States Code*.

- cut budget allocations to the Drug Enforcement Administration, the US Attorney's Office, and other branches of the Federal Government that 'harass, intimidate, and prosecute Californians and others who are attempting to alleviate suffering through the legal and appropriate use of medical cannabis'.

The resolution was approved by a 42-32 vote of the California State Assembly in April 2003 and a 21-15 vote of the State Senate in June 2003. (Joint resolutions do not require the approval of the Governor.)

The concept of imposing funding restrictions on Federal bodies was also an aspect of a bipartisan proposal introduced in the U.S. House of Representatives by Congressman Sam Farr (Democrat-California) and Congressman Dana Rohrabacher (Republican-California). The intention was to block the U.S. Justice Department from using any of its funds to prevent States that have laws authorising the use of medical cannabis from implementing those laws. The proposal was defeated on 7 July 2004 by 268 to 148 votes. It would have involved amending the Commerce-Justice-State appropriations bill. A similar amendment was defeated in 2003.¹⁰²

Congressman Sam Farr also introduced the *Truth in Trials Act* (HR 1717) in the U.S. House of Representatives on 10 April 2003. This legislation would allow individuals accused of violating Federal drug laws to introduce evidence in Federal courts of the relevant State cannabis laws. Defendants could therefore be found 'not guilty' if the jury decided that they were merely following State medical cannabis guidelines. The law was referred to a number of House Committees, including the Committee on the Judiciary, but nothing further had happened at the time of writing.

7.1.4 Selected case law

(i) Classification of marijuana under the Controlled Substances Act

Jon Gettman and High Times Magazine v Drug Enforcement Administration

Jon Gettman, a marijuana campaigner, and 'High Times' Magazine petitioned the Drug Enforcement Administration to reschedule marijuana under the *Controlled Substances Act*. The petitioners appealed to the U.S. Court of Appeals for the District of Columbia Circuit to review the negative decision of the Drug Enforcement Administration.

In May 2002 the Court of Appeals dismissed the petition on the basis that the petitioners did not have standing to bring the action: *Jon Gettman and High Times Magazine v Drug Enforcement Administration*, 24 May 2002, No. 01-1182. The fact that Congress has given interested parties the right to petition a Federal agency to change a law, does not mean that those parties have judicial standing in the Federal courts under the U.S. Constitution.

¹⁰² Alan Fram, 'House opposes effort by States to allow medical use of marijuana', Associated Press, 7 July 2004, accessed on Find Law at <<http://news.findlaw.com>>

(ii) A ‘medical necessity’ exception for the therapeutic use of marijuana?*United States of America v Oakland Cannabis Buyers’ Cooperative*

In January 1998 the U.S. Government sought an injunction to prohibit the Oakland Cannabis Buyers’ Cooperative (OCBC) of California and its executive director, Jeffrey Jones, from contravening the *Controlled Substances Act* by cultivating cannabis and distributing marijuana to OCBC members. The U.S. District Court for the Northern District of California granted the injunction and subsequently found that the OCBC had violated the injunction by continuing to dispense marijuana. The District Court modified the injunction to permit the U.S. Marshal to seize the OCBC’s premises.

On 13 September 1999, the U.S. Court of Appeals for the Ninth Circuit remanded the case to the District Court to consider modifying the injunction to exempt the distribution of marijuana to seriously ill individuals who have a physician’s certification that they need marijuana for medical purposes: *United States v Oakland Cannabis Buyers’ Cooperative and Jeffrey Jones*, 190 F.3d 1109 (9th Cir. 1999). Following these instructions, the District Court modified the injunction to incorporate a medical necessity defense.

The U.S. Government petitioned the U.S. Supreme Court to review the Court of Appeals’ decision. On 14 May 2001, the Supreme Court held that under the *Controlled Substances Act* there is no medical necessity exception to marijuana offences: *United States v Oakland Cannabis Buyers’ Cooperative and Jeffrey Jones*, (2001) 532 US 483. The Act classifies marijuana as a Schedule 1 substance, and the only express exception to the prohibitions on manufacturing and distributing the drug is for Government-approved research projects. The statute expressly contemplates that drugs may have a useful medical purpose but does not include an exception for any medical use of marijuana.

(iii) Federal rules of evidence and sentencing guidelines*United States of America v Bryan Epis*

In March 1997, Bryan Epis founded the Chico Medical Marijuana Caregivers in California, serving approximately 40 medical marijuana patients. He also used marijuana himself to relieve pain for back injuries sustained in a car accident. Epis was arrested in June 1997 while growing 458 indoor plants at his home in Chico.

At the trial in the U.S. District Court for the Eastern District of California, Judge Damrell excluded testimony about medical use of marijuana and Proposition 215 (California’s compassionate marijuana law) under Federal rules of evidence. The jury convicted Epis for cultivating over 100 plants, and also conspiring to cultivate over 1000 plants, a charge which carries a 10 year mandatory minimum. As his home was within 1000 feet of a school, Epis was ineligible for an exemption from the mandatory minimum. In October 2002, Epis was sentenced to 10 years in a Federal prison.¹⁰³

¹⁰³ The judgment is not displayed on the website of the U.S District Court for the Eastern District of California. Information about the case up to the District Court result was obtained from the Americans for Safe Access website at <www.safeaccessnow.org>

In July 2004 the U.S. Court of Appeals for the Ninth Circuit remanded the case to the District Court for review of the conviction and sentence: *United States of America v Bryan Epis*, 12 July 2004, No. 02-10523. But first the Court of Appeals directed the District Court to await the outcome of the U.S. Government's appeal to the Supreme Court against the decision in *Raich v Ashcroft* (2003) 352 F.3d 1222: see the case summary below. If Epis's conviction remains intact, the Court of Appeals further ordered the District Court to re-sentence in a manner consistent with the Supreme Court's decision in *Blakely v Washington*, 24 June 2004, No.02-1632.¹⁰⁴ That case found constitutional problems with the sentencing guidelines of Washington State, implicitly affecting the Federal sentencing guidelines.

United States of America v Edward Rosenthal

In January 2003, a medical marijuana activist named Ed Rosenthal stood trial in the U.S. District Court for the Northern District of California on Federal charges of violating the *Controlled Substances Act*. The jury found Rosenthal guilty of growing more than 100 plants, maintaining a place for the manufacture of marijuana (an indoor growing facility in Oakland, California), and conspiring to grow more than 100 but less than 1000 marijuana plants.¹⁰⁵

Judge Breyer excluded evidence of California's marijuana laws. Nor was the jury allowed to know that Rosenthal was deputized to grow marijuana under the City of Oakland's medical marijuana program. The applicable mandatory minimum sentence was 5 years (60 months) imprisonment. However, Judge Breyer determined that a 'downward departure' from the mandatory minimum was appropriate because Rosenthal believed in good faith that he was immune from Federal liability due to the City of Oakland's purported designation of him as a city official for the purpose of cultivating marijuana. On 4 June 2003, Judge Breyer sentenced Rosenthal to a term of one day imprisonment, three years of supervised release, and a fine of \$1000.

(iv) Constitutional limits of Federal power: doctor-patient communications

Dr Marcus Conant v John P. Walters

In 1997 a group of physicians and patients initiated legal action to stop the U.S. Government from revoking the prescription licenses of doctors who recommended the use of marijuana to their patients as a form of medical treatment. The lead plaintiff, an AIDS specialist named Dr Marcus Conant, was one of the pioneers in addressing and treating HIV/AIDS in the United States. John P. Walters is the Director of the White House Office of National Drug Control Policy. The U.S. Government claimed that its authority to prevent

¹⁰⁴ *Blakely* will be reported at (2004) 542 US(page number pending).

¹⁰⁵ Details of the case were obtained from the 'Sentencing Memorandum' by Judge Breyer, dated 9 June 2003, available on the District Court's website at <www.cand.uscourts.gov> Further information can be found on the websites of Americans for Safe Access at <www.safeaccess.org> and Cannabis News at <www.cannabisnews.com>

physicians from distributing certain drugs extended to restricting physicians from advising their patients about marijuana as a treatment option.

The U.S. District Court for the Northern District of California found in favour of the plaintiffs. On appeal in 2002, the U.S. Court of Appeals for the Ninth Circuit enjoined the U.S. Government from either investigating or revoking the licenses of physicians who recommend the use of medical marijuana to ill patients. The Court of Appeals found that the Government's actions threatened to contravene the principles of freedom of speech under the First Amendment to the U.S. Constitution: *Conant v Walters* 309 F.3d 629 (9th Cir. 2002).

On 14 October 2003 the U.S. Supreme Court denied a petition to review the ruling, effectively upholding the decision of the Court of Appeals in the States within the Ninth Circuit that have medical marijuana laws, including California, Nevada, Oregon, Washington State, Alaska and Hawaii.¹⁰⁶

(v) Constitutional limits of Federal power: interstate commerce

John Ashcroft v Angel Raich

Two Californian women, Angel Raich and Diane Monson, used marijuana for medical purposes on the recommendation of their doctors, pursuant to California's *Compassionate Use Act*. Monson grew her own medical marijuana, while Raich was assisted in growing marijuana by the two remaining plaintiffs (referred to as John Doe Number One and John Doe Number Two).¹⁰⁷ The plaintiffs filed suit against the U.S. Attorney General, John Ashcroft, and the Administrator of the Drug Enforcement Administration, Asa Hutchinson, challenging the constitutionality of the *Controlled Substances Act* and seeking a declaration that the legal defense of medical necessity precluded enforcement of the Act against them. The U.S. Government argued that State laws making exceptions for medical marijuana are overridden by Federal drug laws.

The U.S. District Court for the Northern District of California ruled that the plaintiffs had not established a sufficient likelihood of success on the merits. The plaintiffs appealed to the U.S. Court of Appeals for the Ninth Circuit. In December 2003 the Court of Appeals ruled in favour of the plaintiffs/appellants by a 2-1 majority: *Raich v Ashcroft* (16 December 2003, No. 03-15481). The court held that the U.S. Government had exceeded its constitutional authority by raiding patients whose medical marijuana activities were not commercially-oriented and did not cross state lines. Judge Pregerson, delivering the majority judgment, found that cultivation, possession, and use of marijuana for medicinal purposes on the advice of a physician and not for exchange or distribution is not properly characterized as commercial or economic activity. Medical marijuana does not have a substantial effect on interstate commerce, and is therefore beyond the Federal 'interstate

¹⁰⁶ As the case did not proceed to a hearing, there is no published judgment.

¹⁰⁷ Details of the case are reproduced from the judgment of the U.S. Court of Appeals for the Ninth Circuit in *Raich v Ashcroft* (16 December 2003, No. 03-15481).

commerce' power in the U.S. Constitution.

In June 2004 the Supreme Court granted the U.S. Government's request for an appeal. The case is expected to be heard next winter (ie. late 2004/early 2005).¹⁰⁸

7.2 Summary of State medical cannabis programs

At least nine States had comprehensive medical cannabis laws at the time of writing. Additional States are considering the introduction of such laws, while others have made limited changes, for example, by diminishing the maximum penalty that can be imposed on a person who uses cannabis for medical purposes. Each regime has distinctive elements, although there are many broad features in common.

7.2.1 California

(i) Background

California was the first State to allow the medicinal use of marijuana. In November 1996 the majority of Californian voters approved Proposition 215. The enactment of the *Compassionate Use Act 1996* removed State legal penalties when marijuana was used on a doctor's recommendation to alleviate certain medical conditions. The *Compassionate Use Act 1996* is incorporated into Division 10, Chapter 6 of the *California Health and Safety Code*.

(ii) Main provisions

The intention of the compassionate law is to ensure that 'seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana': section 11362.5 of the *California Health and Safety Code*. The section also states an intention that marijuana patients, their primary caregivers, and their physicians are not subject to criminal prosecution or sanction, and that no physician in the State is denied any right or privilege for having recommended marijuana to a patient for medical purposes.

Eligible patients suffer from a 'serious medical condition', meaning AIDS, anorexia, arthritis, cachexia,¹⁰⁹ cancer, chronic pain, glaucoma, migraine, persistent muscle spasms (eg. multiple sclerosis), seizures (eg. epilepsy), severe nausea, and any other chronic or persistent medical symptom that either substantially limits the ability of the person to conduct one or more major life activities (as defined in the *Americans with Disabilities Act 1990*) or may cause serious harm to the patient's safety or physical or mental health: section 11362.7. This allows quite a broad scope of conditions compared to some other

¹⁰⁸ David Kravets, 'Supreme Court to hear case on medical pot', Associated Press, 28 June 2004, accessed on <www.washingtonpost.com>

¹⁰⁹ Cachexia means physical wasting resulting from illnesses or infections, and is often associated with HIV/AIDS.

jurisdictions. Patients may be under 18 years of age, but primary caregivers shall be over 18 years (with very limited exceptions). A primary caregiver may have multiple patients, as long as they all live in the same city/county as the caregiver.

A patient or caregiver may possess no more than eight ounces of dried marijuana per patient,¹¹⁰ and may maintain no more than six mature or 12 immature cannabis plants per patient: section 11362.77. These limits were introduced in 2003.¹¹¹ However, if a patient has a doctor's recommendation that the standard quantities do not meet the patient's medical needs, the patient/caregiver may possess an amount of marijuana consistent with those needs. Counties and cities may also enact medical marijuana guidelines allowing patients/caregivers to exceed the State limits. Marijuana is obtained through a person's own means, not supplied by the government.

Physicians must fulfil requirements including: possessing a license to practice medicine or osteopathy in California; taking responsibility for an aspect of the medical care, treatment, diagnosis, counselling, or referral of a patient; conducting a medical examination of the patient; and stating in the patient's medical record that the patient has a serious medical condition and that the medical use of marijuana is appropriate: section 11362.7.

Some of the limitations under the law are:

- Medical use of marijuana is not required to be accommodated at any place of employment or during working hours, or at a penal institution: section 11362.785.
- Medical marijuana patients cannot engage in the smoking of medical marijuana in any place where smoking is prohibited by law; or within 1000 feet of the grounds of a school, recreation center, or youth center; or in a school bus, a motor vehicle, or while operating a boat: section 11362.79.

In summary, the key provisions of California's medical marijuana laws include:

Responsible Department	Department of Health Services.
Illnesses/conditions	A wide range of 'serious medical conditions', from cancer and AIDS to any chronic or persistent medical symptom that causes serious harm or substantially limits the patient's life activities.
Quantity	Maximum of 8 ounces of dried marijuana per qualified patient, plus 6 mature or 12 immature marijuana plants. Obtain by own means.
Physician's role	An attending physician must state in their patient's medical record an assessment that the patient has a serious medical condition and the medical use of marijuana is appropriate.

¹¹⁰ Only the dried mature processed flowers of the female cannabis plant shall be considered when determining allowable quantities of marijuana.

¹¹¹ California Senate Bill SB420 clarified 'fair use' of medical marijuana. It added Article 2.5 to Chapter 6 of Division 10 of the *Health and Safety Code*, and was signed into law by the Governor of California in October 2003.

Primary caregiver	A person who has ‘consistently assumed responsibility for the housing, health, or safety’ of the patient. Must be over 18 years (except in very limited circumstances). May serve more than one patient, as long as the caregiver lives in the same city or county as their patients.
ID cards	Legislation makes provision for ID cards to be issued.
Children	Eligible as patients but not generally as caregivers.

(iii) Identification cards

When the use of medical marijuana was authorised in California in 1996, there were no requirements in the *Compassionate Use Act* for a statewide identification card system. Some counties or cities issued their own cards, beginning with the County Sheriff’s Department of Mendocino County. Some compassion clubs such as Oakland Cannabis Buyers’ Cooperative also issued identification cards.

California Senate Bill SB 420, introduced by Senator John Vasconcellos (Democrat - Santa Clara), outlines a medical marijuana identification card program. The Bill was signed into law in October 2003 by the then Governor of California, Gray Davis, and took effect on 1 January 2004. The law directs the California Department of Health Services to establish and maintain a voluntary program for the issuance of identification cards to qualified patients who satisfy the requirements. The program would be voluntary in the sense that patients and primary caregivers voluntarily apply for an identification card. There are to be separate photo identification cards for patients and primary care givers. Identification cards shall be valid for one year. Applicants for identification cards may be under 18 years of age, but the county health department or its designee shall contact the parent/legal guardian to verify the information given: section 11362.72.

The provisions state that no patient or primary caregiver ‘in possession of a valid identification card shall be subject to arrest for possession, transportation, delivery, or cultivation of medical marijuana in an amount established pursuant to this article [Article 2.5 Medical Marijuana Program] unless there is reasonable cause to believe that the information contained in the card is false ...’: section 11362.71(e) of the *California Health and Safety Code*. However, the section confirms that it is not necessary for a person to obtain an identification card in order to claim the protections of the compassionate cannabis law. At the time of writing, a State identification card system had not been implemented.

(iv) Cannabis clubs and cooperatives

A cannabis club is an establishment that dispenses cannabis to members in various forms, including buds, hashish, brownies, and tinctures (for tea). To join the club, applicants usually have to demonstrate a medical condition by showing documentation from a physician. The clubs often grow their own cannabis and may receive approval or support from city or county authorities. In California, cannabis clubs have operated in numerous locations such as Oakland, Berkeley and Hayward. In 1988 the city of Oakland proclaimed staff of the Oakland Cannabis Buyers’ Cooperative to be ‘officers of the city’, in an attempt to shield them from Federal prosecution. This was intended to utilise the provision in the *Controlled Substances Act* (US) that ‘city officers’ could not be prosecuted for selling

controlled drugs within the scope of their official duties. The Oakland City Manager's Office also issued business permits to a limited number of dispensaries.

However, the Federal authorities did not 'turn a blind eye' to the operation of cannabis clubs in California. The Drug Enforcement Administration raided various clubs and prosecuted their operators, while other clubs closed voluntarily.¹¹² One of the clubs that was raided was the Los Angeles Cannabis Resource Center (LACRC), which began operating on 4 November 1996, pursuant to a resolution of the City Council of West Hollywood and with the co-operation of the LA County Sheriff's Department and health care organisations.¹¹³ The client intake process involved provision of a doctor's letter and verification of the doctor's current license to practice.¹¹⁴ On 25 October 2001, the Drug Enforcement Administration raided and shut down the LACRC.¹¹⁵ At the time of the raid, the LACRC was reportedly serving 960 seriously ill patients, 80% of whom were HIV/AIDS sufferers. More than 450 physicians had referred patients to the LACRC for medical marijuana.¹¹⁶

Three former directors of LACRC, Scott Imler, Jeff Yablan and Jeffrey Farrington, entered a plea bargain with prosecutors and pleaded guilty to charges of maintaining a place where marijuana was manufactured and distributed. The defendants were sentenced on 24 November 2003 in the U.S. District Court for the Central District of California to one year on probation. Judge Matz departed downwards from the Federal sentencing guidelines because the defendants did not distribute the marijuana for money and had adhered strictly to the rules under Californian law. Judge Matz expressed concern that Federal agencies were wasting resources on prosecuting medical marijuana cases.¹¹⁷

¹¹² Ron Mackovich, 'Sorry...The Club is Closed', *Positive Living* newsletter, December 2001/January 2002 issue, AIDS Project Los Angeles (APLA), accessed on <<http://www.thebody.com/apla/apla.html>>

¹¹³ Information from the website of LACRC at <<http://www.lacbc.org/mission.html>>

¹¹⁴ Scott Imler, 'DEA Raids LA Cannabis Center' in Special Report of the LACRC newsletter, Autumn 2001, on LACRC website at <<http://www.lacbc.org>>

¹¹⁵ According to Scott Imler, one of the Directors of the LACRC: '30 agents from the federal Drug Enforcement Administration...detained eight patients for six hours and seized the center's collective garden, bagged marijuana and brownies, patient and doctor's records, computers and grow equipment...The search warrant's primary evidence stems from a visit in 1999 by two DEA agents to the club after the LACRC applied for a federal license [to manufacture marijuana for medical research] and invited the feds to inspect the operation.' Scott Imler, 'DEA Raids LA Cannabis Center' in Special Report of the LACRC newsletter, Autumn 2001, on LACRC website at <www.lacbc.org>

¹¹⁶ No author, 'Probation for Directors of West Hollywood Medical Marijuana Center', 24 November 2003, article on the website of Americans for Safe Access at <<http://safeaccessnow.org>>

¹¹⁷ Information on the judge's reasoning was obtained from the Associated Press report of the sentencing, on NBC Online News at <www.msnbc.com/news/997858.asp?cp1=1> The judgment is not available on the website of the U.S. District Court for the Central District of California at <www.cacd.uscourts.gov>

Recent amendments to the *California Health and Safety Code* addressed the protection of medical cannabis clubs under State law.¹¹⁸ Section 11362.775 of the Code states that qualified patients, persons with valid identification cards, and designated primary caregivers ‘who associate within the state of California in order **collectively or cooperatively to cultivate marijuana for medical purposes**, shall not solely on the basis of that fact be subject to state criminal sanctions...’ (emphasis added). However, this does not resolve the susceptibility of cannabis clubs to Federal prosecution.

7.2.2 Arizona

65% of Arizona voters approved Proposition 200 on 5 November 1996, which included one provision specific to the use of medical marijuana. It sought to allow doctors to prescribe marijuana to seriously ill patients. However, because Federal law ultimately prevents physicians from prescribing drugs that are listed in Schedule I of the *Controlled Substances Act*, Arizona physicians have not been using the law.¹¹⁹

7.2.3 Oregon

The *Oregon Medical Marijuana Act* was passed by Oregon voters on 3 November 1998 and came into effect on 3 December 1998.¹²⁰ The relevant provisions can be found in Title 37, Chapter 475 (Controlled Substances) of the *Oregon Revised Statutes* at 475.300-475.346.

The provisions are intended ‘to allow Oregonians with debilitating medical conditions who may benefit from the medical use of marijuana to be able to discuss freely with their doctors the possible risks and benefits of medical marijuana use and...to protect patients and their doctors from criminal and civil penalties...’: ORS 475.300(3).

A person engaged in, or assisting in, the medical use of marijuana is excepted from the criminal laws of Oregon for drug possession, delivery or production, if the person holds or has applied for a registry identification card and fulfils the other conditions: ORS 475.309. The requirements for claiming an affirmative defense for persons who do not possess an identification card are outlined in ORS 475.319.

Other features of the Oregon laws are:

Relevant Department	The Oregon Medical Marijuana Program is operated through the Oregon Department of Human Services.
Illnesses/conditions	‘Debilitating medical conditions’, including cancer, glaucoma, HIV/AIDS, cachexia, severe pain, severe nausea, seizures (eg.

¹¹⁸ As amended by California Senate Bill SB 420 in 2003.

¹¹⁹ Information from the NORML website at <www.norml.org/index.cfm?Group_ID=3391>

¹²⁰ Information about the Oregon program was obtained from the website of the Oregon Department of Human Services at <www.dhs.state.or.us/publichealth/mm/index.cfm>

	epilepsy), or persistent muscle spasms (eg. multiple sclerosis).
Quantity	A patient and their primary caregiver may collectively possess, at the location where the marijuana is produced, a maximum of 3 mature marijuana plants, 4 immature plants, and one ounce of 'usable marijuana' (dried leaves and flowers) per mature plant. When the patient/caregiver is elsewhere, one ounce of usable marijuana may be possessed.
ID cards	The law directs the Department to establish and maintain a program for the issuance of registry identification cards. The first ID cards were issued to patients and caregivers in May 1999.
Physician's role	The attending physician has 'primary responsibility for the care and treatment' of the patient. A patient's application for registration must be accompanied by written documentation from the attending physician, stating the diagnosis of a debilitating medical condition and that marijuana 'may mitigate' the symptoms or effects.
Designated primary caregiver	Must be 18 years or over and have 'significant responsibility for managing the well-being' of a patient.
Children	Persons under 18 years are eligible, subject to conditions, eg. their physician has explained the possible risks and benefits of medical marijuana; their parent/guardian consents and agrees to serve as the primary caregiver; the parent/guardian agrees to control the acquisition and use of marijuana.

Statistics kept by the Oregon Medical Marijuana Program showed that, at 1 April 2004, 8975 patients were holding current identification cards. This had risen to 10,196 by 1 July 2004. The most frequently qualifying medical condition at 1 July 2004 was 'pain' (8711 patients), with 'nausea' (2134 patients) and 'persistent muscle spasms' (2691 patients) also ranking highly.¹²¹

The Oregon Medical Marijuana Program (OMMP) demonstrates some of the legal complications or ambiguities that can arise in practice:

- ***There is no place in Oregon to legally purchase medical marijuana*** – Patients or their caregivers are expected to grow their own marijuana. The State does not supply patients with seeds or starter plants, nor give advice or information (at least not officially) on growing or obtaining marijuana.
- ***Applicants must list a 'grow site' on their application*** where the patient plans to grow the marijuana, or where the designated primary caregiver will grow it. Problems can be caused by this requirement. For example, if other people have access to the grow site, they will not be protected from criminal or civil penalties.
- ***If the patient lives near a school***, growing or possessing medical marijuana may be inconsistent with laws that create a drug free zone within 1000 feet of a school. The

¹²¹

Statistics posted on the website of the Oregon Department of Human Services at <www.dhs.state.or.us/publichealth/mm/data.cfm> Note that some patients have more than one qualifying medical condition.

OMMP website suggests that patients contact their local law enforcement agency for guidance.

- **Patients living in rented premises** could experience difficulties with their landlord if they grow the marijuana at their rented address. The *Oregon Medical Marijuana Act* does not specifically address whether a patient can be evicted in these circumstances, or whether participation in the OMMP affects entitlement to subsidized housing. The OMMP website states, ‘It is up to you to decide whether or not to tell your landlord that you are a patient in the OMMP’, and recommends obtaining advice from an attorney.
- **Employees who are subject to drug tests** may get into trouble from their employer. The *Oregon Medical Marijuana Act* states that employers are not required to accommodate employees who use medical marijuana. Therefore, an employer could regard medical marijuana like any prescription drug that may impair ability to function.
- **Patients may experience problems travelling to another State** in possession of medical marijuana, even if travelling with their identification card, or to a State that has its own medical marijuana laws. The *Oregon Medical Marijuana Act* is only recognised in Oregon.
- **Other limitations** – users of medical marijuana must not: drive under the influence of marijuana; engage in marijuana use in (or within view of) a public place, or in a correctional facility; manufacture marijuana at more than one address; or deliver marijuana for consideration (ie. reward) to any individual, including a person with an identification card.

7.2.4 Washington State

The majority of Washington voters approved the use of marijuana for medical purposes in November 1998.¹²² The relevant provisions appear at Title 69, Chapter 69.51A (‘Medical Marijuana’) of the *Revised Code of Washington*. The intention of the law is that, ‘Qualifying patients with terminal or debilitating illnesses who, in the judgment of their physicians, would benefit from the medical use of marijuana, shall not be found guilty of a crime under state law for their possession and limited use of marijuana’: s 69.51A.005.

The statute does not explicitly permit the possession of a certain number of plants, but the capacity to grow marijuana is implicit in the authorization of a qualifying patient and primary caregiver to collectively possess marijuana that is equivalent to a 60 day supply: s 69.51A.040.

Relevant Department	Department of Health.
Illnesses/conditions	‘Terminal or debilitating’ medical condition means: (a) cancer, HIV, multiple sclerosis, epilepsy/seizure disorders, spasticity disorders; (b) intractable pain, unrelieved by standard medical treatments; (c) acute or chronic glaucoma; or (d) any other medical

¹²² The *Medical Marijuana Act* was created by the passage of Initiative 692: website of the Washington State Department of Health at <www.doh.wa.gov> and Washington Citizens for Medical Rights at <<http://www.eventure.com/i692>>

	condition duly approved by the Washington State Medical Quality Assurance Commission. The Commission has approved Crohn's disease, Hepatitis C, and 'any disease, including anorexia, which results in nausea, vomiting, wasting, appetite loss, cramping, seizures, muscle spasms, and/or spasticity, when these symptoms are unrelieved by standard treatments.'
Quantity	Patients and their primary caregivers, in combination, may legally possess or cultivate no more than a 60 day supply of marijuana.
Physician's role	The patient's physician must provide a statement or copy of medical records stating that in the physician's professional opinion the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient.
Primary caregiver	Someone who is responsible for the 'housing, health, or care of the patient'. Family members, roommates or close friends are therefore prime candidates. Must be 18 years or over, and only caregiver to one patient at a time.
Children	Patients may be under 18 years of age but possession, production, acquisition, and decisions as to dosage and frequency of use shall be the responsibility of the parent or legal guardian.

Limitations of the law include:

- **Publicly displaying marijuana** – it is a misdemeanor to 'use or display medical marijuana in a manner or place which is open to the view of the general public'.
- **Employment, school etc** – the law does not require the medical use of marijuana to be accommodated in any place of employment, school grounds, school bus or youth center. Drug testing programs required by some employers and Federal agencies are unaffected by the law.
- **Driving a vehicle** – no person shall be entitled to claim the medical use of marijuana as a defense to endangering the health or well-being of a person through the use of a motor vehicle.

7.2.5 Alaska

A majority of voters approved a ballot in November 1998 to allow the medicinal use of marijuana. The law took effect on 4 March 1999 and the relevant provisions appear in Title 17 ('Food and Drugs') of the *Alaska Statutes*, at Chapter 17.37 ('Medical Uses of Marijuana').

A patient or caregiver registered with the Alaska Department of Health and Social Services under the medical marijuana laws has an affirmative defense to a criminal prosecution related to marijuana. Stricter criteria apply to primary caregivers in Alaska than some other States with medical marijuana laws.

Relevant Department	Department of Health and Social Services.
Illnesses/conditions	'Debilitating medical conditions' including cachexia, cancer, glaucoma, HIV/AIDS, severe nausea, severe pain, persistent

	muscle spasms, seizures/epilepsy.
Quantity	A patient and caregiver may not possess ‘in the aggregate’ more than one ounce of usable marijuana (seeds, leaves, buds and flowers), and more than 6 marijuana plants, of which no more than 3 may be mature.
Physician’s role	The physician must examine the patient and provide a signed statement that the patient has been diagnosed with a ‘debilitating medical condition’ and ‘might benefit from the medical use of marijuana’.
Registry/ID cards	In accordance with the statute, the Department created a confidential registry of patients who have applied for and are entitled to an identification card.
Primary caregiver	Must be at least 21 years of age, never convicted of a felony offense, and not currently on probation/parole. May only care for one patient at a time, except for relatives by blood/marriage.
Children	Patients may be minors, subject to conditions.

Limitations of the law under sec 17.37.040 include:

- **Public place** – A patient or caregiver may not engage in the medical use of marijuana ‘in plain view of, or in a place open to, the general public’ (this does not include transporting the marijuana in a closed container carried on the person).
- **Employment/jail/school etc** – The medical use of marijuana is *not* required to be accommodated by any place of employment, correctional facility, medical facility; or within 500 feet of school grounds; or within 500 feet of a recreation or youth center; or on a school bus.

7.2.6 Maine

A majority of Maine voters approved the medicinal use of marijuana in November 1999, and the law took effect on 22 December 1999.¹²³ The provisions currently appear at Title 22 (‘Health and Welfare’), Chapter 558, §2383-B of the *Maine Revised Statutes*.

The law allows eligible patients, and their designated caregivers, to possess marijuana for medical use. Senate Bill 611, signed into law on 2 April 2002, increased the amount of usable marijuana that was allowed to be possessed to 2½ ounces. Previously the lawful amount was 1¼ ounces. (The number of plants that could lawfully be possessed did not change.)

Illnesses/conditions	The listed categories of conditions are: persistent nausea, vomiting, wasting syndrome or loss of appetite as a result of AIDS or cancer; heightened intraocular pressure as a result of glaucoma; seizures associated with a chronic, debilitating
----------------------	---

¹²³

Information from the website of the National Organization for the Reform of Marijuana Laws at <www.norml.org/index.cfm?Group_ID=3391>

	disease, such as epilepsy; or persistent muscle spasms associated with a chronic, debilitating disease, such as multiple sclerosis.
Quantity	Patient is authorized to possess a maximum of 2½ ounces of harvested marijuana, and 6 marijuana plants, of which no more than 3 may be mature, flowering plants.
Physician's role	Patient must have written documentation from a physician (or a medical record) demonstrating that: the patient is under the continuing care of the physician; the physician has diagnosed the patient with an eligible condition; the physician has advised on the basis of the patient's condition and medical history that the patient might benefit from the medical use of marijuana.
Designated caregiver	Person over 18 years who is a family member or other person who has 'consistently assumed responsibility for the housing, health or safety' of the patient, or is a member of the same household as the patient; <i>and</i> is named in a written individual instruction or power of attorney for health care, or is the parent/legal guardian of the patient.
Children	Patients may be under 18 years, but must have written authorization from their parent/legal guardian, or be legally entitled to consent to medical/health care services.

7.2.7 Hawaii

Medical marijuana was permitted in Hawaii by an Act of the State legislature, rather than by a voter initiative process. The *Hawaii Medical Marijuana Act* was introduced by Governor Benjamin Cayetano, signed into law by him in June 2000, and took effect on 28 December 2000.¹²⁴ The relevant provisions appear in the *Hawaiian Revised Statutes* under Volume 6, Chapter 329, Part IX. The law protects patients, their primary caregivers, and physicians from prosecution for marijuana offences under Hawaiian law.

Relevant Departments	Department of Public Safety, and Department of Health.
Illnesses/conditions	'Debilitating medical condition', including cancer, glaucoma, HIV/AIDS, cachexia, severe pain, severe nausea, seizures (eg. epilepsy), severe and persistent muscle spasms (eg. multiple sclerosis, Crohn's disease), or any condition approved by the Department of Health.
Quantity	A patient and/or their primary caregiver may legally possess no more than one ounce of usable marijuana per mature plant, and may cultivate no more than 3 mature marijuana plants and 4 immature plants.
Physician's role	Medical records or a signed statement from the patient's physician must affirm the patient suffers from a debilitating condition and the 'potential benefits of the medical use of

¹²⁴

General information on Hawaiian developments was obtained from the website of the Drug Policy Forum of Hawaii at <www.dpfhi.org/docs/mmjbook.html>

	marijuana would likely outweigh the health risks.’ Written certification is valid for one year from signing.
Primary caregiver	A person aged 18 years or over ‘who has agreed to undertake responsibility for managing the well-being’ of a patient. May only be a caregiver to one patient at a time.
Registration	The law establishes a system for qualifying patients to register with the Department of Public Safety and receive a registration certificate. Qualifying patients who are not registered can still raise an affirmative defense to any marijuana charge.
Children	Patients can be under 18 years to participate, subject to conditions eg. primary caregiver must be parent/guardian.

Limitations under the Hawaiian medical marijuana law include:

- **School/public place** – The use of medical marijuana is prohibited on a public bus, school bus or any moving vehicle, in school grounds, in any public place (eg. park, beach), or at a youth or recreation center.
- **Employers** – The law prohibits the use of medical marijuana in the workplace but is silent regarding the employer’s rights and duties towards the patient. Employers can treat medical marijuana like any other prescription drug that might impair ability.
- **Tenants** – Any Federal laws or rules prohibiting the use of marijuana in Federally-subsidized housing would be likely to prevail over the Hawaiian law. The Drug Policy Forum of Hawaii recommends that people who wish to use medical marijuana in this situation, or in other rental premises, should seek legal advice.¹²⁵

7.2.8 Colorado

In the November 2000 general election, Colorado voters passed Amendment 20 of the Colorado State Constitution, and the Colorado Department of Public Health and Environment was tasked with implementing and administering the Medical Marijuana Registry Program. In March 2001, the State of Colorado Board of Health approved the Rules and Regulations pertaining to the administration of the program, and on 1 June 2001 the registry began accepting and processing applications for identification cards.¹²⁶

The relevant provisions can be found in Article XVIII (‘Miscellaneous’), section 14 of the Colorado State Constitution. The law provides that ‘it shall be an exception from the state’s criminal laws for any patient or primary care-giver in lawful possession of a registry identification card to engage or assist in the medical use of marijuana...’: section 14(2)(b). It would appear that if the patient or caregiver has not registered, and is charged with a violation of state criminal drug laws, he or she would still have an affirmative defense to

¹²⁵ The Drug Policy Forum of Hawaii, *The Medical Use of Marijuana: A guide to Hawaii’s law for physicians, patients and caregivers*, 2001, p 9, accessed at <www.dpfhi.org/docs/mmjbook.html>

¹²⁶ ‘Medical Marijuana Registry Program Update (as of April 30, 2004)’, on the Colorado Department of Public Health and Environment website at <www.cdph.state.co.us/hs/medicalmarijuana/marijuanaupdate.asp>

the allegation, provided they fulfil the requirements pertaining to diagnosis with a debilitating medical condition and possession of a permissible quantity of marijuana: section 14(2)(a).

Responsible authority	Medical Marijuana Registry in the Department of Public Health and Environment.
Illnesses/conditions	A 'chronic or debilitating disease or medical condition' including cachexia, severe pain, severe nausea, seizures, or muscle spasms.
Quantity	An authorised patient or a primary caregiver may possess no more than 2 ounces of a usable form of marijuana and no more than 6 marijuana plants, with 3 or fewer being mature, flowering plants that are producing a 'usable form of marijuana' (seeds, leaves, buds and flowers of the plant).
Physician's role	A patient who wishes to apply to the Medical Marijuana Registry must provide certification from a physician licensed in Colorado that the patient has been diagnosed with a debilitating condition that may be alleviated by the medical use of marijuana.
ID cards	Identification cards issued by the Medical Marijuana Registry authorise possession of marijuana for a patient or primary caregiver. The identification card must be re-applied for annually. ¹²⁷
Children	Persons under 18 years may apply, subject to conditions. However, it appears from the Registry's statistics that few, if any, young people have applied.

As at 30 April 2004, statistics from the Medical Marijuana Registry showed that:¹²⁸

- 455 applications had been received since the Registry began operating in June 2001.
- 364 patients possessed valid identification cards.
- 69% of approved applicants were male.
- Patients ranged in age from 18-76 years, with an average age of 45.
- The debilitating medical condition reported by 69% of patients was 'severe pain', followed by muscle spasms at 43%, severe nausea at 22%, seizures at 8%, 7% each for cancer and cachexia, 4% for HIV/AIDS, and 2% for glaucoma. (Note that some patients used marijuana for more than one condition.)

The Colorado Department of Public Health and Environment had received two petitions, up to 30 April 2004, to add Parkinson's disease and bi-polar (manic depressive) disorder to the current list of debilitating medical conditions. Both petitions were denied due to a lack of

¹²⁷ In addition to the legislative provisions dealing with the registry and identification cards, see the State of Colorado Board of Health Rules and Regulations Pertaining to Medical Use of Marijuana, accessible through the Department of Public Health and Environment website at <www.cdphe.state.co.us>

¹²⁸ 'Medical Marijuana Registry Program Update (as of 30 April 2004)', on the Colorado Department of Public Health and Environment website at <www.cdphe.state.co.us/medicalmarijuana/marijuanaupdate.asp>

scientific evidence that marijuana treatment may have a beneficial effect.

7.2.9 Nevada

In November 2000 a majority of voters approved amending the Constitution of the State of Nevada, adding section 38 to Article 4 (‘Legislative Department’), to direct the legislature to authorize the medical use of marijuana.¹²⁹ Assembly Bill 453 was passed by the Nevada Legislature on 5 June 2001 and was signed into law by Governor Kenny Guinn on 14 June 2001. The law took effect on 1 October 2001. The relevant provisions appear in the *Nevada Revised Statutes* at Title 40 (‘Public Health and Safety’), Chapter 453A (‘Medical Use of Marijuana’).

The law provides for the establishment of a program to issue identification cards to patients who have written documentation from their physician that marijuana may alleviate the patient’s chronic or debilitating condition. Holders of registry identification cards are specifically exempt from state prosecution for marijuana offences, provided that the quantity restrictions and other conditions are met.

Relevant Departments	Department of Human Resources (Health Division), and Department of Agriculture.
Illnesses/conditions	‘Chronic or debilitating medical condition’, including AIDS, cancer, glaucoma, cachexia, persistent muscle spasms (eg. multiple sclerosis) or seizures (eg. epilepsy), severe nausea, severe pain, or any other condition classified by regulation or approved by the Department of Human Resources (Health Div).
Quantity	A patient and his/her caregiver may collectively possess no more than one ounce of usable marijuana, 3 mature marijuana plants and 4 immature plants.
Physician’s role	A physician who has responsibility for the care and treatment of the patient must state in writing that the patient has been diagnosed with a chronic or debilitating condition, which may be mitigated by marijuana, and that the physician has explained the possible risks and benefits to the patient.
ID cards	Application forms for identification cards are issued by the Department of Agriculture. Patients who do not register (or who exceed the quantity limits) may argue the affirmative defense of medical necessity if they are charged with a drug offence.
Designated primary caregiver	Must be 18 years or older and have ‘significant responsibility for managing the well-being’ of the patient. Caregiver’s details must be registered.
Children	Patients may be under 18 years if parent/guardian gives consent, agrees to serve as primary caregiver, and controls the patient’s acquisition and use of marijuana.

¹²⁹

General information on Nevada was obtained from the website of the National Organization for the Reform of Marijuana Laws at <www.norml.org/index.cfm?Group_ID=3391>

A number of the usual limitations apply to the Nevada medical marijuana laws, such as not using medical marijuana in a public place, in a correctional facility, or while driving a vehicle: NRS 453A.300.

7.2.10 Maryland

Although it does not have a comprehensive medical marijuana program, Maryland's legislature passed a law in 2003 that requires a court in a marijuana-related State prosecution to consider a defendant's use of medical marijuana to be a mitigating factor. A maximum fine of \$100 applies to a medical marijuana user for possession of less than an ounce of leaf.¹³⁰

7.2.11 Vermont

Vermont recently permitted marijuana to be used for medical purposes when the State Senate passed the Medical Marijuana Bill in May 2004. Governor James Douglas announced that he would not support the bill by signing it into law, but nor would he exercise his power to veto it.¹³¹ Vermont is only the second State, after Hawaii, to have instigated such a change by the legislature rather than voter initiative. The *Medical Marijuana Act* amends the *Vermont Statutes Annotated*, inserting Chapter 86 (Therapeutic Use of Cannabis) into Title 18 (Health).

The law protects qualifying patients from being arrested, prosecuted, or penalised under State law for the use of an 'adequate supply' of marijuana.

Responsible Department	Department of Public Safety.
Illnesses/conditions	'Debilitating medical conditions', including cancer, glaucoma, HIV/AIDS, cachexia or wasting, severe pain, severe nausea, seizures (eg. epilepsy), severe and persistent muscle spasms (eg. multiple sclerosis or Crohn's disease).
Quantity	An 'adequate supply' of marijuana may be collectively possessed between the qualifying patient and primary caregiver. The amount of marijuana possessed shall not exceed 3 mature marijuana plants, 4 immature plants, and 3 ounces of usable marijuana.
Cultivation requirements	A patient or caregiver may elect to grow their own marijuana only if it is cultivated in a 'secure indoor facility', meaning a building or room equipped with locks or security devices, permitting access only to a person lawfully cultivating or possessing marijuana.
Physician's role	A qualifying patient is legally protected if they possess written

¹³⁰ Richard Willing, 'Attitudes ease toward medical marijuana', 22 May 2003, story on USA Today website at <www.usatoday.com/news/nation/2003-05-22-marijuana-usat_x.htm> See also the NORML website at <www.norml.org/index.cfm?Group_ID=3391>

¹³¹ David Gram, 'Vermont's Medical Marijuana Bill to be law', Associated Press, 20 May 2004, accessed on <www.marijuana.org>

	certification from a physician who has examined them, stating that the patient has a debilitating medical condition and the potential benefits of marijuana would likely outweigh the health risks. A copy of the certification must be submitted to the Department of Public Safety for the physician to be protected from prosecution, penalty or denial of any right or privilege under Vermont law.
Caregiver's role	A primary caregiver may only serve one patient at a time and must provide their written details to the Department of Public Safety.
Children	Patients may be under 18 years of age, subject to conditions.

The authorisation for the medical use of marijuana does not apply to:

- being under the influence of marijuana while operating a vehicle or heavy machinery;
- smoking marijuana in a public vehicle (including a school bus), in a place of employment, on school grounds, in a correctional facility, or in any public place.

7.2.12 Rhode Island

In February 2004, 'companion bills' on the medical marijuana issue were introduced in the State of Rhode Island House of Representatives and Senate. Supporters of the legislation included the Rhode Island Medical Society and the Rhode Island Nurses Association. The *Rhode Island Medical Marijuana Act* would protect seriously ill patients from prosecution for using or possessing medical marijuana with their doctors' approval. At the time of writing, the bills remained under consideration by the House Finance Committee and the Senate Judiciary Committee.¹³²

¹³²

Mark Silberstein, 'In pain, RN seeks legal relief from marijuana', *Warwick Beacon*, 17 June 2004; and the Rhode Island Patient Advocacy Coalition website at <www.ripatients.org>

8. UNITED KINGDOM

In the United Kingdom, cannabis is regulated under the *Misuse of Drugs Act 1971* and the *Misuse of Drugs Regulations 2001*. Schedule 1 of the Regulations contains cannabis, cannabis resin and cannabinoids, except for nabilone and dronabinol.¹³³

8.1 Background

In 1997 the British Medical Association published a report, *Therapeutic Uses of Cannabis*, which supported the notion that certain cannabinoids should be legalised for wider medicinal use.¹³⁴ The report influenced the House of Lords Select Committee on Science and Technology to examine the scientific and medical evidence to determine whether there was a case for allowing the medical use of cannabis. The Committee released a report in November 1998, titled *Cannabis: The Scientific and Medical Evidence*.¹³⁵ Some of the Committee's recommendations, and the corresponding Government responses, were:¹³⁶

Select Committee's recommendation	Government's response
Clinical trials of cannabis for the treatment of multiple sclerosis and chronic pain should be conducted as a matter of urgency.	The Government was willing to license medical research and clinical trials involving cannabis or cannabinoids, subject to conditions.
Research should be promoted into alternative methods of administering medicinal cannabis than smoking, to avoid its adverse health effects.	The Government accepted the recommendation.
The Government should take steps to transfer cannabis and cannabis resin from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations, to allow doctors to prescribe an appropriate preparation of cannabis (albeit as an unlicensed medicine), and to allow pharmacists and doctors to supply the drug prescribed.	The Government rejected the recommendation. The reasoning behind this was that substances in Schedule 1 to the Regulations were not generally acknowledged as having any therapeutic value.

¹³³ Dronabinol is in Schedule 2 because of its recognised therapeutic value. Nabilone is not a controlled drug, being a licensed medicine for use against nausea arising from chemotherapy. For definitions of substances see '2.1 Terminology' of this briefing paper.

¹³⁴ British Medical Association, *Therapeutic Uses of Cannabis*, November 1997, Taylor & Francis.

¹³⁵ House of Lords, Select Committee on Science and Technology, *Cannabis: The Scientific and Medical Evidence* (also sometimes referred to as the *Report on Cannabis for Medical Purposes*), HL Paper 151, (9th Report of 1997-1998 Session), November 1998.

¹³⁶ The Government's responses were reproduced in: Select Committee on Science and Technology, *Cannabis: Government Response*, HL Paper 39, (2nd Report of 1998-1999 Session), March 1999, Appendix 2.

If doctors are permitted to prescribe cannabis on an unlicensed basis, the medical professional bodies should provide firm guidance on how to do so responsibly, and safeguards must be put in place by the professional regulatory bodies to prevent diversion to improper purposes.	The Government was unwilling to allow cannabis to be prescribed on an unlicensed basis. If cannabis could be prescribed on a named patient basis, the doctor would take on full responsibility for the welfare of the patient and for allowing them to possess cannabis. The Government did not believe it would be reasonable to burden doctors with this responsibility.
The Government should raise the question of rescheduling the cannabinoids in Schedule 1 with the World Health Organisation.	If it becomes clear that any of the remaining cannabinoids in Schedule 1 have therapeutic potential, the Government would seek amendment of the 1971 UN Convention on Psychotropic Substances which would make it possible to place these substances in Schedule 2 of the Misuse of Drugs Regulations.
Cannabis and its derivatives should continue to be controlled drugs.	The Government agreed.

In response to the Government, the House of Lords Select Committee on Science and Technology released a short additional report in March 1999, entitled *Cannabis: Government Response*.¹³⁷ The Committee observed that the Government's main arguments against the recommendations in the original report were arguments that the Committee considered in the course of its inquiry and found unpersuasive.

In early 2001 the Select Committee on Science and Technology conducted a follow-up inquiry to examine: the current state of research into therapeutic uses of cannabis; the roles of the Home Office and the Medicines Control Agency (which was replaced by the Medicines and Healthcare products Regulatory Agency in 2003) in the licensing of cannabis-based medicines; and issues relating to the prosecution of therapeutic cannabis users.

The report, titled *Therapeutic Uses of Cannabis*, was released in March 2001.¹³⁸ Some of the views formed by the Committee were:

- The Government displayed a more encouraging attitude towards the licensing of therapeutic preparations of cannabis than the Committee previously detected;
- The Committee was advised that if the quality, safety and efficacy of an appropriate preparation of cannabis could be established, the Government would reschedule cannabis from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations. In other

¹³⁷ Select Committee on Science and Technology, *Cannabis: Government Response*, HL Paper 39, (2nd Report of 1998-1999 Session), March 1999, Appendix 2.

¹³⁸ Select Committee on Science and Technology, *Therapeutic Uses of Cannabis*, HL Paper 50, (2nd Report of 2000-2001 Session), March 2001.

words, once a cannabis-based medicine had been licensed by the Medicines Control Agency, the Government would actively co-operate in permitting it to be prescribed.

- The Medicines Control Agency's decision to insist on further toxicological studies on cannabidiol could delay the production of a cannabis-based medicine by GW Pharmaceuticals by two or three years: see description of this project below. The Committee considered this decision was flawed for a number of reasons. For example, the potential side-effects of cannabidiol which were of concern to the Medicines Control Agency (MCA) could be regarded as trivial compared to the serious illnesses suffered by patients.
- Both the MCA and the Home Office persisted in treating cannabidiol and cannabis oil as 'new medicines', whereas there is a long history of medicinal use of cannabis extracts containing significant quantities of cannabidiol, such as tincture of cannabis (cannabis oil in alcohol).
- Overall, cannabis-based medicines 'are not being dealt with in the same impartial manner as other medicines...a thorough and impartial reappraisal of the published scientific literature on the safety of [cannabidiol] and cannabis extracts should lead the MCA to reconsider their present overly cautious stance.'

8.2 Cannabis spray clinical trial

GW Pharmaceuticals is a company that was founded by Dr Geoffrey Guy in early 1998 to develop prescription medicines derived from cannabis. The company was first granted licences by the Home Office in June 1998, pursuant to section 7 of the *Misuse of Drugs Act 1971*, to cultivate, possess and supply cannabis for medical research purposes.¹³⁹ The cannabis plants used in the research are grown under computer-controlled conditions in secure glasshouses at a location in the south of England that has not been publicly divulged for security reasons. Cultivation aims to produce highly consistent plants with defined cannabinoid ratios. Strict Standard Operating Procedures (SOPs) are followed to ensure non-contamination by chemicals, infestation or fungal growth, consistency of content, and standards of harvesting, drying, primary extraction, and storage. Temperature, humidity, total light and photoperiod are all controlled by computer.

The broader product development process spans botanical research, cultivation, extraction, formulation into drug delivery technologies, clinical trials and regulatory affairs. The medical ailments that were identified for product development included multiple sclerosis, spinal cord injury, cancer pain and rheumatoid arthritis.

There are three phases to the clinical research:

¹³⁹

Information on the project was obtained from the website of GW Pharmaceuticals at <www.gwpharm.com> and the website of the Independent Drug Monitoring Unit Ltd (IDMU) at <www.idmu.co.uk> . The IDMU is a research consultancy which conducts large scale drug surveys and provides expert evidence for use in criminal court cases.

- *Phase I* – these are studies generally in healthy volunteers where the safe dose range of the drug is established. Subjects may be exposed to increasing doses of the drug whilst all bodily functions are closely observed and blood samples taken to assess blood levels of the drug.
- *Phase II* – generally carried out in small groups of patients to demonstrate the effect, if any, of the drug on defined endpoints and to establish a dose/response relationship if present.
- *Phase III* – having established an acceptable dose range and validated the clinical endpoint in a range of conditions and having shown therapeutic benefit in the smaller studies, larger scale studies are undertaken. Hundreds of patients may be entered into each study and may receive active or placebo drugs, in a random order. Special target patient groups are studied at this time.

By the end of 2002, GW Pharmaceuticals had completed various Phase I to Phase III trials. Further Phase III trials were ongoing in 2003.

GW Pharmaceutical's first product is an oro-mucosal spray, administered under the tongue. Its brand name is 'Sativex'. The company is also evaluating tablet and capsule formulations and is developing an inhaler. In March 2003, GW Pharmaceuticals submitted an application to the Medicines and Healthcare products Regulatory Agency (formerly the Medicines Control Agency) for Sativex.

A regulatory approval from the Medicines and Healthcare products Regulatory Agency (MHRA) would be followed by a change in British law allowing doctors to prescribe the medication. That is, the British Government would permit, subject to regulatory approval from the MHRA, cannabis-based medicines to be re-scheduled under the Misuse of Drugs Regulations so as to enable their general prescription. It is expected this change in law would have no direct consequence for the legal status of herbal cannabis for recreational use.

In June 2003, GW Pharmaceuticals announced that it had signed an exclusive agreement with Bayer to market Sativex in the United Kingdom and Canada. The agreement also provides Bayer with an option to expand the licence for Sativex to include Europe, Australia and New Zealand.

The application assessment process by MHRA continued during 2004. In January 2004, the Executive Director of GW Pharmaceuticals, Dr Geoffrey Guy, anticipated '...the timing of completion of this process is a matter of scheduling within the regulatory agency and is currently expected to occur during the second quarter of 2004.'¹⁴⁰ In June 2004, Dr Guy stated: 'We continue to make progress towards achieving UK regulatory approval for Sativex...In the next few weeks, we will be submitting further responses which are

¹⁴⁰

'Preliminary results for the year ended 30 September 2003', 21 January 2004, and 'Sativex regulatory update', 30 April 2004, *Press Releases*, available on the GW Pharmaceuticals website at <<http://www.gwpharm.com>>

intended to address the outstanding questions. We remain confident of a positive outcome to this approval process.¹⁴¹

However, in May 2004 the Premier of New South Wales, Hon Bob Carr MP, revealed that he had received advice from the Home Office that the cannabis spray would not be available for 'a few years'.¹⁴²

¹⁴¹ 'Interim results for the six months ended 31 March 2004', *Press Release*, 21 June 2004, accessed at <<http://www.gwpharm.com>>

¹⁴² 'Cannabis Medical Use', Questions Without Notice, *NSWPD*, 12 May 2004, p 8888.

9. CONCLUSION

Cannabis has a long history of therapeutic use, and was unrestricted in the United States, United Kingdom and Australia until the 20th century.¹⁴³ Those who support the concept of legally authorising cannabis use for medical purposes believe the law should accommodate compassionate circumstances:

It is widely accepted that communities have a moral imperative to reduce preventable suffering wherever it occurs but especially in patients suffering from distressing and potentially remediable symptoms due to a terminal illness. Patients using cannabis for a legitimate medical purpose should not be subject to the criminal justice system.¹⁴⁴

Numerous commentators have also pointed out the irony that alcohol and cigarettes are not as legally restricted as cannabis in western countries like Australia, yet they contribute to a significant proportion of deaths and represent a large cost to health services. Similarly, synthetic anti-depressant drugs such as Prozac are ‘prescribed almost with abandon and yet they are also mind-altering drugs with a risk of severe side effects.’¹⁴⁵ Perhaps then, cannabis has attracted a negative reputation, a moral stigma not necessarily connected to its scientific properties.

Those opposed to the authorisation of medical cannabis point to the physical and mental health dangers associated with cannabis, and argue that it would provide a ‘gateway’ for the legalisation of recreational use. There is concern, particularly from some religious and welfare organisations, that the ‘wrong message’ would be sent to young people and the wider community, creating a perception that cannabis is harmless. Another argument against allowing medical cannabis use is the difficulty of preventing fraud and abuse of the system, for example, by participants sharing marijuana with non-authorised persons.¹⁴⁶

A recent article in *The Bulletin* magazine was pessimistic about the prospect of the medical cannabis program eventuating in New South Wales:

¹⁴³ The *Marihuana Tax Act 1937* was the start of Federal regulation in the United States: Lester Grinspoon and James Bakalar, *Marihuana, the Forbidden Medicine*, 1993, Yale University Press, p 8. In the United Kingdom, cannabis was added to the schedule of the *Dangerous Drugs Act 1920* in 1928: Martin Booth, *Cannabis: A History*, 2003, Doubleday, p 186. Regulation in Australia also began in the 1920s: *Report of the Working Party on the Use of Cannabis for Medical Purposes*, Volume II: Main Report, August 2000, para 2.3.

¹⁴⁴ Alex Wodak and Timothy Moore, *Modernising Australia's Drug Policy*, 2002, University of New South Wales Press, p 65.

¹⁴⁵ Martin Booth, *Cannabis: A History*, 2003, Doubleday, p 332, referring to the views of Dr William Notcutt, Director of the Pain Relief Clinic at James Paget Hospital, UK.

¹⁴⁶ Submissions to the 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*, Office of Drug Policy (The Cabinet Office), July 2001, pp 11-15.

The NSW government's much-publicised decision to conduct a cannabis trial is mired in state, federal and international law. A representative for Special Minister of State John Della Bosca, whose ministerial office was given responsibility for administering the trial, says Premier Bob Carr has written to federal Health Minister Tony Abbott requesting a meeting about the issue, but it hasn't happened yet. Read between the lines and it's apparent that any sanctioned cannabis trial is essentially dead and buried.¹⁴⁷

This prediction may prove to be incorrect, but it is fair to say that there will be challenges in establishing and operating a medical cannabis program. Some of these are:

- **Financial cost** – Experience overseas has shown that high costs are involved in setting up a program, particularly if the government supplies the product. Expenditure can become disproportionate when only a small percentage of the population using cannabis for medicinal purposes registers with the government scheme.
- **Registration issues** – Patients may be disinclined to register in a medical cannabis program due to privacy concerns or for other reasons. The rate of applications is likely to be influenced by what the program offers, for example, whether proof of enrolment protects participants from arrest and prosecution, and whether there is a choice of options for obtaining cannabis.
- **Source/type of cannabis** – Legislation that simply authorises possession of a certain amount of cannabis by patients/carers and is silent on the source of supply effectively prompts people to engage in the illicit drug trade, or grow their own plants. This would entail the acceptance of smoking as a method of administering cannabis. If the government obtains raw cannabis or cannabis products from overseas, the cost would presumably be higher for Australian users than local cannabis, and any problems with quality would be more difficult to address.
- **Legal complications** – The disputes between the U.S. Government and the States that have medical cannabis laws illustrate the importance of State-Federal co-operation, although in Australia this is more likely to take the form of fulfilling Commonwealth requirements if New South Wales wishes to import cannabis or medications from overseas. Difficulties have also arisen in Canada and the United States with regard to the constitutional validity of laws, resulting in protracted court cases. However, the prosecution and imprisonment of Americans who were protected under State cannabis programs but contravened Federal drug laws should not occur in Australia, as the Commonwealth Government generally does not have the power or inclination to intervene in State criminal matters.
- **Involvement of medical practitioners** – The participation of the medical profession is vital if access to medical cannabis is dependent upon a statement from a doctor. Doctors need to be protected from criminal prosecution for drug offences, and also

¹⁴⁷Joshua Gliddon, 'The Medicine Pot', *The Bulletin*, 27 July 2004, p 22.

from incurring legal liability or suffering any loss of rights or privileges.

- ***Consequences for recreational use and criminal activity*** – Two politically sensitive concerns with legalising medical cannabis are whether it might cause an increase in recreational use or contribute to criminal activity. It is difficult to predict these factors in advance. The experience of overseas jurisdictions does not provide clear evidence of such negative trends.¹⁴⁸

148

Some studies have been conducted to examine whether the liberalising of cannabis laws in the Netherlands has led to greater recreational use, but the results have been mixed. For example, a study by MacCoun and Reuter, which compared cannabis usage among young people in the Netherlands and the United States, found that an increase in the Netherlands did coincide with greater commercial access to cannabis, but that usage also increased in the United States, despite cannabis being illegal in most States: Robert MacCoun and Peter Reuter, 'Interpreting Dutch cannabis policy: reasoning by analogy in the legalization debate', *Science*, 1997, Volume 278, Issue 533, p 47.