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# Legalisation of medicinal cannabis in New South Wales

Graham Irvine  
*Southern Cross University*

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# Legalisation of Medicinal Cannabis in New South Wales

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Thesis submitted in fulfilment of the requirements for a  
Doctorate of Philosophy award within the  
School of Law and Justice,  
Southern Cross University

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# STATEMENT OF SOURCES

I certify that the work presented in this thesis is, to the best of my knowledge and belief, original, except as acknowledged in the text, and that the material has not been submitted, either in whole or in part, for a degree at this or any other university. I acknowledge that I have read and understood the University's rules, requirements, procedures and policy relating to my higher degree research award and to my thesis.

I certify that I have complied with the rules, requirements, procedures and policy of the University (as they may be from time to time).

Signed:

Graham Irvine

Date:

## Other publications by candidate on matters relevant to thesis

Graham Irvine, 'The North Coast NSW Long Term Cannabis Users Survey', Conference paper, Nimbin Mardi Grass Organising Committee, Nimbin Town Hall, 2<sup>nd</sup> May 1997.

Graham Irvine, 'Medicinal cannabis use and the criminal defence of necessity: *R v Quayle & Ors*' Attorney General's reference (no 2 of 2004) 1 All ER988 [2005] *Southern Cross University Law Review* SCULR10 243.

Graham Irvine, *Hitzig & Others v Canada* [2003] O.J. No. 3873 SCULR 7 326.

Graham Irvine, 'Rural doctors' attitudes to and knowledge of medicinal cannabis' (2006) 14(1) *Journal of Law & Medicine* 135.

# ABSTRACT

Ever since cannabis pharmaceuticals were removed from official pharmacopeias in the Western world in the mid-twentieth century there have been ongoing campaigns to re-legalise medicinal cannabis. This political and social struggle for legalisation tends to be cyclical, with its proponents and detractors fluctuating between characterising its use as a form of deviance through to viewing it as a legitimate response to serious medical conditions.

This thesis poses the research question, ‘Is there a case for reform of the law to allow for the use of cannabis for medicinal purpose in New South Wales?’

The thesis is written for the thousands of seriously ill people who could benefit greatly from medicinal cannabis if it were legal and available. It addresses the what, who, how and why of the topic, only omitting ‘when’ which is a function of political timing beyond the scope of this study. Throughout it utilises forms of risk/benefit analysis, mindful of the potential hazards of the drug while being cognisant of its unique properties. It is designed to function as an evidentiary base for use by health care advocates, activists and reformist politicians seeking to raise the issue of medicinal cannabis with a view to initiating legislation, initially in the state of New South Wales and subsequently in all Australian states and territories.

Adopting a multi-disciplinary triangulated methodology, the thesis sets out to assess the evidence for medicinal cannabis legalisation. This includes a narrative of my own experiences with Parkinsons disease, the jurisprudential and criminological issues raised, whether there is sufficient evidence of the efficacy of medicinal cannabis to warrant its legalisation and whether there is a large enough constituency of potential medicinal cannabis users to render legalisation politically feasible.

After examining the history of medicinal cannabis use both overseas and in Australia, the study examines overseas and Australian legislation and case law, dissects three case studies explaining some pitfalls of drug research, a legal defence for medicinal cannabis arrestees and an ethical and safer source of medicinal cannabis. The remaining chapters draw out the implications of the data for the preparation of proposed New South Wales’ legislation.

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# INTRODUCTION

As one authority puts it, ‘... the history of drug law ... may be represented as a perpetual cycle of attempts at legal repression, which, being incomplete, lead to resistance, adaptation and further attempts at repression [because] drug law is not ‘evidence based.’<sup>1</sup> This is despite the fact that:

[s]ince the middle of the twentieth century drug offences have been the driving force propelling the criminal justice system ... [d]rugs have been effectively quarantined as a specialist area of criminal law and practice ... [and] little or no attention is paid to broader policy questions such as: the rationale or justification for criminalisation; the historical evolution of drug laws; the relationship of criminalisation to other regulatory strategies and options for law reform.<sup>2</sup>

In 1995 I was the principal interviewer in a study of 356 long term cannabis users for the National Drug and Alcohol Centre and conducted some 250 ninety-minute interviews for the study. While conducting these interviews I was struck by the large number of users who were using the drug for medicinal purposes and who carefully titrated their dosage to avoid any untoward side effects of consumption.

However I had no other involvement in cannabis issues until 2002 when I was approached by the Medical Cannabis Information Service to analyse the results of a survey they had undertaken amongst people with serious medical conditions who had approached them for support in taking medicinal forms of cannabis for their conditions. This analysis was subsequently written up as a report submitted to the then Special Minister of State, John Della Bosca, who had Ministerial authority for the issue.<sup>3</sup>

I was shocked by the results of this survey because it showed that there is a significant group of seriously ill patients in our community for whom only medicinal cannabis relieves their symptoms and yet these people are being denied access to this medication. I decided it was a sufficiently important medico-social legal issue to warrant applying to the Southern Cross University Graduate Research Centre to research it as a PhD project. The particular facts that concerned me were that the survey seemed to indicate that there were potentially a significant

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<sup>1</sup> S Bronitt and B McSherry, *Principles of Criminal Law* (2<sup>nd</sup> ed, 2005) 788.

<sup>2</sup> *Ibid* 786–787.

number of seriously ill patients who had tried all the available licit drugs to treat or to overcome the side effects of their condition/s and whose only form of efficacious relief came from using cannabis. As a lawyer, my concern of course, was that, by using cannabis, they were exposing themselves and their families to the risk of criminal prosecution for using or dealing in an illicit drug.

Upon further inquiry I discovered that several United States' states as well as Canada had already legislated to approve the use of the cannabis herb for the treatment of a variety of medical conditions and symptoms. Despite the obvious dangers of legalising cannabis in the same raw form as is used by recreational users, these jurisdictions, faced with two unpalatable options clearly concluded the preservation of life and the amelioration of symptoms among the seriously ill to be more important than the Federal United States' 'War on Drugs'.

I began to wonder if the situation of medicinal cannabis users in Australia was similar in terms of their numbers, distribution and range of illnesses. By conducting and analysing surveys of doctors and patients and comparing these results with overseas surveys I found that the same medicinal cannabis users' cohort also exists in Australia. It then became necessary to demonstrate that the size of this cohort is sufficiently large and well-distributed as to be a politically significant constituency, which this research answers in the affirmative.

Next I conducted an indicative survey to ascertain whether this cohort has the support of the medical stakeholders and drew on another survey to see if they have the support of their friends and families. The results of these surveys indicate that they do have such support at a high level in the community, which adds to their political importance.

I've tried to keep my writing accessible for laypeople in the hope that law reformers and activists will find some of it useful. Although written to the specifications of academic conventions, it is also addressed to drug law reformers. To this end the chapter titles are largely self explanatory, but to put them into the context of the thesis, I will now briefly describe each chapter and the function it serves in the overall argument.

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<sup>3</sup> Letter from G Irvine [GI] to NSW Special Minister of State, John Della Bosca, forwarding *Preliminary report on findings of a survey of medicinal cannabis users*, 25 February 2003.

Chapter 1 of the thesis begins with Section 1.1 which investigates some ethical and jurisprudential issues potentially concerning medicinal cannabis and the intellectual lineage of these issues. In Section 1.2 I present my own personal autoethnographic medical dossier which documents the evolution of my Parkinson's disease. Section 1.3 gives a description of and rationale for the research methods used in this study.

Section 1.4 considers the medicinal cannabis issue from criminological and political perspectives, detailing my effort to raise the medicinal cannabis issue with legislators and bureaucrats.

The first section of Chapter 2 examines whether there is sufficient evidence to justify medicinal cannabis use, based on the burgeoning clinical and scientific literature on the topic, while Section 2.2 looks at whether a significant constituency of medicinal cannabis users exists in New South Wales. Sections 2.3 and 2.4 report and discuss the results of quantitative surveys, the first designed to further articulate the medicinal cannabis user cohort and its differences and similarities within New South Wales and between Australia and Britain. The second survey, of general practitioners on the New South Wales North Coast, was designed to check whether there is sufficient evidence of doctors' knowledge and willingness to prescribe medicinal cannabis.

In Chapters 3 and 4 I have contextualised the debate on medicinal cannabis by examining the history of medicinal cannabis use around the world, and in particular in the four jurisdictions which have made most of the running in the current debate – the United States of America, the United Kingdom, Canada and The Netherlands, before tracing the history of medicinal cannabis in Australia generally and in New South Wales specifically.

This is followed in Chapter 5 by a detailed consideration of relevant current legislation and case law in the United States, United Kingdom and Canada and in Chapter 6 by a similar examination of current New South Wales and Australian legislation.

Chapter 7 is made up of three critiques. In Section 7.1 I critically review the findings and recommendations of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes, and in Sections 7.2 and 7.3 I critique the conduct and methods used by drug control institutions when they contribute to the debate over legalising

cannabis medicine. Here I grapple with and elucidate some of the contradictory aspects of the debate and the political forces which have shaped the various policy positions of decision makers both in Australia and abroad.

The next chapter, Chapter 8, begins with an interview with two of the principal volunteers operating the Medicinal Cannabis Information Service, a not-for-profit group supplying medicinal cannabis to patients referred by their doctors. The remainder of the chapter analyses the common law necessity defence and its utilisation in cases of medicinal cannabis use in three jurisdictions – the United States, United Kingdom and Canada, with a view to utilising the defence in an Australian jurisdiction.

In Chapter 9, Section 9.1 I draw conclusions from the implications of the findings in earlier chapters relevant to the provisions necessary for a Bill for a Medicinal Cannabis Act.

The thesis culminates in Section 9.2 with the draft bill for a Medicinal Cannabis Act, the provisions of which are drawn from the earlier findings of this research. It is my intention to submit the Bill to the New South Wales government as an action plan for the introduction of legislation to legalise medicinal cannabis in New South Wales.

# Chapter 1

## MY CASE

### 1.1 *Ethical and jurisprudential perspectives*

I have long been drawn to philosophies which afford a central role for the operation of reason in everyday life. This has led me to an appreciation of a line of philosophers often collectively called ‘consequentialists’ because they based their evaluation of an action on what the consequences of that action would be. Perhaps the first of these is the ancient Greek Epicurus who taught that the greatest good came from the achievement of happiness and the avoidance of pain<sup>1</sup> – a viewpoint clearly apposite to a study such as this which advocates the minimisation of pain for the seriously ill.

This optimisation of happiness is the central doctrine of J.S. Mill and forms the essential underpinning and ethical basis of my case for legalisation of medicinal cannabis. One of his best known principles of political practice is expressed in his proposal that the only purpose for which power can rightly be exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral is not a sufficient warrant.<sup>2</sup>

The corollary of this – that governments should aim in their policies to cause the least harm to the fewest citizens – is the central tenet of the branch of utilitarianism known as ‘negative utilitarianism’ – a term and concept devised by philosopher Karl Popper. He argued that we should aim to act so as to minimise suffering rather than maximise happiness,<sup>3</sup> because ‘Philosophers should consider the fact that the greatest happiness principle can easily be made an excuse for a benevolent dictatorship’.

Utilitarianism has much in common with Buddhist teachings. However whereas Buddhism teaches that ‘dukkha’ or the existential state of being in which we are all permanently

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<sup>1</sup> Stanford Encyclopaedia of Philosophy 2009 <<http://www.plato.stanford.edu/entries/epicurus>> (accessed 25 February 2010).

<sup>2</sup> S Shaw Miller, *On Liberty* (2002) (New Haven CT: Yale University Press) at 81.

<sup>3</sup> *Karl Popper and Negative Utilitarianism* <<http://www.utilitarianism.com/Karl-Popper.html>> (accessed 18 February 2010).

unsatisfied with this life is permanent, unchanging and universal, some contemporary idealist utilitarians, the ‘paradise engineers’ or ‘abolitionists’, see the potential of bioengineering and medicine to eliminate pain and physical suffering on a global scale.

The value of utilitarianism to studies like this thesis is summed up by Charlotte Laws who claims that, ‘despite periodic misuse, utilitarianism has a critical role to play in society. Utilitarianism allows undiscovered evidence and improved arguments to emerge. It is our best hope for an improved future, and we should recognise it as such.’<sup>4</sup>

For the purposes of this research, I have adapted a Millian viewpoint which argues that worthwhile progressive reform can be achieved through Parliament via changes to the laws.

The closest Mill came to the issue of the individual’s right to take the medication of their choice is in ‘On Liberty’, where he points out that:

If poisons were never bought or used for any purpose except the commission of murder, it would be right to prohibit their manufacture and sale. They may however be wanted not only for innocent but for useful purposes, and restrictions can not be imposed in the one case without operating in the other.<sup>5</sup>

However, Mill’s view of the contemporary Western governments of his day was that:

There is also in the world at large an increasing inclination to stretch unduly the powers of society over the individual ... and ... this encroachment is not one of the evils which tend spontaneously to disappear but, on the contrary, to grow more formidable.<sup>6</sup>

This observation was extended by Thomas Szasz in several studies beginning in the 1950s. Szasz claims that the role taken by the United States government in particular in relation to drugs amounts to the imposition on society of ‘pharmakracy’ – rule mainly by means of drug control.<sup>7</sup>

Since the beginning of this century through a combination of medical licensure and direct drug control regulation, the American government has assumed progressively more

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<sup>4</sup> C Laws, Jun 21, 2007 in The Simon  
<[http://www.thesimon.com/magazine/articles/telling\\_stories/01407\\_guess\\_whos\\_coming\\_dinner\\_controversial\\_peter\\_singer.html](http://www.thesimon.com/magazine/articles/telling_stories/01407_guess_whos_coming_dinner_controversial_peter_singer.html)> (accessed 18 February 2010).

<sup>5</sup> Miller, *ibid* n 2, 58.

<sup>6</sup> *Ibid* 84.

<sup>7</sup> T Szasz, *Ceremonial Chemistry* (1973) 139.

authority over the drug trade and the community's drug use. The ostensible aim of these restrictions is to protect people against incompetent doctors and unsafe drugs. The actual result is loss of personal freedom, without the gain of the promised benefits.<sup>8</sup>

Szasz compares the 'War on Drugs' with the extirpation of witchcraft in the Middle Ages and sees the conflict between stakeholders as:

... a struggle between individuals aspiring to care for themselves by contracting for their own healing and collectivities or states insisting upon caring for their members by subjecting them to procedures they define as therapeutic.<sup>9</sup>

In 'Our Right to Drugs' he summarises his ethical position thus:

When the state deprives us of our right to drugs and justifies it as drugs controls, we ought to regard ourselves not as patients receiving state protection from illness, but as victims robbed of access to drugs.<sup>10</sup>

In jurisprudential terms, the individual's right to their physical integrity is one of ancient lineage, being mentioned in Blackstone's Commentaries.<sup>11</sup> However although the ascription of criminality is central to the debate on medicinal cannabis it has not attracted significant attention from criminologists. For example Bronitt and McSherry claim that:

Most strikingly, unlike other areas of the criminal law dealing with 'consensual harm', liberal and moral philosophical ideas have not significantly informed legal debate about the purpose, scope and limits of drug offences ... and the criminal law remains remarkably resistant to external sources of knowledge – whether scientific, historical, sociological, cultural or public health – about the drugs themselves and the unintended effects of criminalisation.<sup>12</sup>

One commentator, the constitutional lawyer J.Bessie Hill, believes that '[a] right to protect one's health by making medical treatment decisions has already been recognised by the United States Supreme Court but that its application has largely been clouded by the problem of deference.'<sup>13</sup> She separates the United States case law into two categories – 'public health' cases in which individuals' rights are subordinated to the right of the community and 'autonomy' cases where the individual's rights prevail.

<sup>8</sup> T Szasz, *Our Right to Drugs: The Case for a Free Market* (1992) 7.

<sup>9</sup> Ibid 61.

<sup>10</sup> Ibid.

<sup>11</sup> W Blackstone, cited in *Abigail Alliance for better access to developmental drugs v Eschenbach*, 445 t 3d 470, 480 (DC Cir) 2006).

<sup>12</sup> S Bronitt, and B McSherry, *Principles of Criminal Law* (2<sup>nd</sup> ed, 2005) 786.

<sup>13</sup> B J Hill, 'The Constitutional Right to Make Medical Treatment Decisions' 86 *Texas Law Review* 277, 282.

Hill traces the ‘autonomy’ case law back to *Union Pacific Railway Co. v Botsford*<sup>14</sup> where the Court ruled that a plaintiff in a personal injury suit could not be ordered to undergo a surgical procedure. An early manifestation of the ‘public health’ line of cases was in 1905 in *Jacobson v Massachusetts*,<sup>15</sup> in which the Court refused to exempt the plaintiff from compulsory vaccination.

*Botsford* was followed by *Griswold*, which ‘concerned the right to protect one’s health through medical choices made autonomously and without government interference ...’,<sup>16</sup> while the 1958 case of *England v Louisiana State Board of Medical Examiners*<sup>17</sup> declared that, under the Fourteenth Amendment, ‘the State cannot deny to any individual the right to exercise a reasonable choice in the method of treatment of his illness.’<sup>18</sup>

In *Washington v Glucksberg*<sup>19</sup> the issue was whether one had the right to suicide. While rejecting this notion the court ‘appeared to recognise at least a limited right to make medical treatment decisions’.<sup>20</sup> Five of the judges ‘suggested that they would recognise a right to obtain medication from one’s physician in a quantity sufficient to alleviate physical suffering, even if it would hasten the patient’s death’.<sup>21</sup>

A 1979 United States case saw the rejection of the plaintiff’s assertion that he had a constitutional right to access Laetrile, an anti-cancer drug. In dissent, the Chief Justice opined that:

So long as there is no clear evidence that Laetrile is unsafe to the users I believe each individual patient has a right to obtain the substance from a licensed physician who feels it appropriate to prescribe it to him.<sup>22</sup>

So in the United States there is a significant line of case law upholding the citizen’s right to take decisions as to their choice of medicine.

<sup>14</sup> *Union Pacific Railway Co. v Botsford*, 141 US 250 (1891).

<sup>15</sup> *Jacobson v Massachusetts*, 197 US (1905).

<sup>16</sup> Hill, above n 13 281.

<sup>17</sup> *England v Louisiana State Board of Medical Examiners*, 375 US 411 (1964).

<sup>18</sup> *Ibid* 420.

<sup>19</sup> *Washington v Glucksberg*, 521 US 702, 737 (1997) .737

<sup>20</sup> *Ibid*.

<sup>21</sup> *Ibid* 741.

<sup>22</sup> *People v Privetera* 591 2pd Col 1979 at p. 927(2000) 146 C.C.C. (3d) 193.

In Canada, a number of cases such as *R v Parker*<sup>23</sup> and *Hitzig & Ors. v Canada*<sup>24</sup> upheld patients' rights to access medicinal cannabis as a human right guaranteed by the Canadian Charter of Rights. Yet in Australia no such Bill of Rights exists at the Commonwealth level and so any medicinal cannabis case will have to be fought according to human rights law or common law principles such as necessity.<sup>25</sup>

In fact these human rights are supported by all the signatory nations to the Universal Declaration of Human Rights ('Declaration') and Article 12 of the International Covenant of Economic Social and Cultural Rights ('Covenant'), including Australia.

Article 25 of the Declaration reads '[e]veryone has the right to a standard of living adequate for the health and wellbeing of himself ... including ...medical care.'<sup>26</sup> It could well be argued that the denial of medicinal cannabis means that a patient does not enjoy an adequate standard of living adequate for their health and wellbeing.

The relevant reference in the Covenant is at Article 12, reading, 'The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'<sup>27</sup>

The Covenant's drafting committee laid down guidelines to assist policy-makers at a national level. These comprise the elements of availability, acceptability, accessibility and quality.<sup>28</sup>

Again it can be argued that the present embargo on medicinal cannabis in Australia breaches, at the least, availability and accessibility since patients in need of medicinal cannabis do not have it available to them and have little or no access to supplies of medicinal cannabis.

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<sup>23</sup> *Hitzig & Ors. v Canada*[2003] OJ No. 2873.

<sup>24</sup> *People v Privitera* 591 P 2d 919 (Cal 1979).

<sup>25</sup> See Chapter 8.

<sup>26</sup> *Universal Declaration of Human Rights*, GA res. 217A (III), U.N. Dec A/810 at 71 (1948).

<sup>27</sup> *International Covenant on Civil and Political Rights*, G.A. res 2200A (XXI) (1966).

<sup>28</sup> *Ibid* General Comment 14.

Thus, although New South Wales ('NSW') citizens have no such instrument of human rights, the possibility would seem to exist for invoking the above United Nations Covenants since Australia as a signatory to them is bound by them, even though these rights have not been enshrined in Australian legislation.

## 1.2 *Personal dossier*

The following narrative is an experiential autoethnographical account of the evolution of my disease and the changes in my life that it has precipitated.

'My' disease is Parkinson's Disease ('PD') although, since I inherited it from my father, it is older than I am. A dictionary definition of PD is, 'a progressive disease of the brain and nervous system marked by trembling, muscular rigidity and slow, imprecise movement.'<sup>29</sup>

Looking back on my life, I realise that early signs of PD were occurring from my earliest years. For example, I have always had trouble in getting keys into locks due to already poor fine motor skills. But it can be, and is for me, much more. My doctors explain that there are twenty or so symptoms of PD, of which most patients have five to ten. However each individual manifests different symptoms from the complete suite of symptoms so that treatment options can be quite complicated. In my case symptoms include extreme fatigue, akinesia, illegible handwriting, atrophy of fine motor skills, muscle pain and spasms, cramps, insomnia, dyskinesia, dystonia, constipation and more. I take five medicines six times a day to control these symptoms – sometimes they work and sometimes they do not and I never know this until after I have taken the dose. Then there are the side effects of these drugs, which for me include involuntary muscle spasms, difficulty in concentrating, speech difficulties and incontinence. Since I am by profession a university lecturer, it is obvious that these symptoms and side effects are having a debilitating effect on my work.

The scientific literature on PD has it that exposure to certain environments can trigger the disease and so it was, I believe, with me. For three consecutive years in the mid-70s I worked and lived for three months near a wheat silo where toxic heavy chemicals like Malathion were routinely, copiously and frequently sprayed onto the wheat and anything that came in contact with it. To this day I recall its purple colour and most of all its sickly

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<sup>29</sup> C Soames (ed), *Pocket Oxford Dictionary* (9<sup>th</sup> ed, 2002) 650.

sweet smell. The PD literature contains many clinical studies of other pesticides but I am unaware of any evidence directly implicating Malathion.

The second trigger for me arose from the extreme pressure of work and responsibility of running a sole practitioner law practice in a small country town. My partner in the fledgling business withdrew leaving me to carry on the practice alone. As I was less than five years out from graduating I felt enormous pressure not to make errors among the many complexities of legal processes. After some months I began to notice that I had developed a tremor in my right leg, hand and foot very much like Dad's.

I realised I had to have my condition assessed and so consulted a neurologist who examined me for five minutes and then baldly stated, 'Yes, you've got it.' From that day I have kept an intermittent record in diaries of my medications and symptoms as well as my dealings with politicians and bureaucrats. Throughout the remainder of this narrative I have drawn on extracts from this body of material which contrasts the antipathy of the bureaucrats and politicians who will be discussed in Chapter 1.4 with the emotive accounts of my hopes, fears and feelings, in this present chapter.

'Tuesday 14<sup>th</sup> May 2002: first diagnosis by neurologist Dr A.' On my second appointment with him I was much better prepared to ask about my situation and had six questions I wanted him to answer. However he seemed to resent my queries and so I never went to see him again.

Through my general practitioner I found Dr C, whom I continued to consult until 2005 when I first met my current treating neurologist, Dr F. Dr A had explained to me that I should avoid taking dopamine medications for as long as possible to maximise the time I had left before its side effects became worse than its benefits brought. However Dr C's attitude was 'live for today' while you can and prescribed the dopamine drug Madopar along with Comtan.

During 2004 I tried chiropractic and physiotherapy as treatment modalities but to no apparent change. As a measure of my desperation I bought CD's by an American healer who claimed that PD could be overcome just by listening to a recording of what seemed to

be white noise with occasional bells tolling. This did not work for me but doesn't seem to have done any damage.

On 15<sup>th</sup> December 2004 I listed my symptoms as:

Weakness in hands after digging garden; writing difficult for hour after digging; involuntary clenching of buttocks, pain in toes; poor urinary flows; shuffling gait; right hand tremor with every bodily movement, breathy, croaky voice; stickiness of feet when trying to initiate movement; shortness of breath when speaking; weakness in legs and arms, drooling, stiff neck.

The involuntary clenching of muscles I report here is symptomatic of dystonia and was included in my doctor's application to the Therapeutic Goods Administration ('TGA') to import Sativex. which will be covered in detail in Chapter 1.3.

In those early years I did not keep a diary and my first diary entry was on, 'April 1<sup>st</sup> 2005. Taking 4 x ½ a 200mg Comtan and 4x ½ Madopar x 200mg.' The next day I felt 'very shaky in legs' and the next, 'tired and shaky; trembling in class moderately severe. Almost no leg or arm twisting the last three or so weeks after taking ½ a Madopar and a 1/2 Comtan.' Thus, as early as my third year of PD, I was experiencing dystonia as a side effect of levadopa medication.

During April 2005 I kept a particularly detailed diary which reveals that I was then dosing myself with Madopar and Comtan four times a day but was still suffering tremors, freezing in the right leg and tremor in the right hand. Around mid-April Dr F put me on Stalevo in place of the Madopar but I began to experience adverse reactions. For example on 13 April I reported 'very bad leg tremor'; on April 16 'violent tremor in bed'. So I went back on to Madopar and Comtan.

By May 2005 my condition had worsened with reports such as that of 20<sup>th</sup> May, when I had 'severe right leg tremor for more than one hour', leading up to 31<sup>st</sup> May when I had 'overnight leg and arm tremor first time ever and at night heaviness in bed, weakness, feeling that I am going to collapse.' (For the uninitiated, 'tremor' is a trembling of the hand, arm, leg or foot which continues until consciously halted but can then resume seconds later. Usually it vanishes after several minutes but can last for hours). 'Freezing' or akinesia occurs when, in a standing position, suddenly there seems to be no power or

strength in that leg to move so that the leg appears to be stuck to the floor. To regain movement it is necessary to wobble the body until the leg lifts off the floor and some momentum can be worked up to start to walk again.

The weakness, extreme fatigue and feelings of imminent collapse are symptoms of dyskinesia which, when they arise, make it hard to stand, sit or even lie in one position for more than a few minutes at any one time. The heaviness in bed is part of akinesia, meaning that I do not have the strength to move my position in the bed and lack the muscle power to change position. This is an alarming phenomenon as you feel paralysed.

Throughout 2005 I continued to have bad insomnia. I unsuccessfully tried every medication prescribed for me, including Stillnox, Effexor, Tramyl and melatonin. In 2006 I did not keep a diary – I do not know why except that I do not like wallowing in my own misery, it depresses me. I was now back on the dopamine agonist, the pseudo dopaminic agent called Cabaser, the first PD drug I took, along with the Madopar and Comtan. I was also attending an acupuncturist and a chiropractor, neither of whom gave me any apparent symptomatic relief after six months' treatments.

My diaries reveal that in 2007 I was still subject to daily freezing and tremors. In addition I had begun to experience micrographia, which produces small and almost illegible handwriting. As an academic the ability to write is crucial. I also have great difficulties in word processing as the PD has diminished my fine motor skills to the point where I cannot attain sufficient accuracy to hit one key without also hitting its neighbour and positioning the cursor in the right place is often a problem. By October 18<sup>th</sup> I had had 'my worst night ever; severe hand tremor lasting on and off for an hour; shaky, slow and freezing'. In a note dated 3<sup>rd</sup> June 2007 I listed my symptoms as, 'tremor and micrographia 9–11am; usually symptom-free until 4.30pm tremor when awake at night; freezing slightly during day, worst early evenings; taking  $\frac{3}{4}$  Madopar and Comtan at 7.15am, 10.45am and two Cabaser at 6.30pm.'

Early in 2008 I decided to detail my nightly and daily routines so as to elucidate what it is like to live with P.D. I wrote:

The first ritual is checking that the lamp switch is within reach, as with T-shirt and socks, should I get cold. Then, as my feet get sore if I lay them on the bed, I have to position myself in the centre of the bed with my feet hanging out the end. So I need to carefully fold the blankets lengthwise, and then fold them back over me.

By positioning my pillow to cradle the crook of my neck and pulling the bedclothes over my shoulders, I can usually sleep three to four hours. I usually wake between two and four but not always. I usually wake with pain in my upper left, and sometimes my right arm and shoulder, and also with lower back pain. Although there is usually some pressure on my bladder I try to ignore it and regain some sleep. This rarely works and, if so, only for about two hours when I finally have to urinate. This involves untangling myself from the bedclothes and getting out of bed. When I return I have to repeat my folding of the bedclothes and pillow adjustment. This usually triggers trembling of the right arm and a leg and can continue for an hour or more. Sometimes I get back to sleep, but usually not and so I lie there and pray to sleep until sunrise when I begin a new day on my feet.

On bad days I have trouble in dressing, shoes and clothes. Every day I try to begin with a bowel movement, usually unsuccessfully. I then wash my hands and go straight to the spare bedroom to do exercises for about half an hour before taking my first medicines and supplements and eating a banana. I put on my track shoes and head off up the hill. My hill climb takes about 30 minutes and is sufficiently steep that it has me heavily breathing on the way up. I try and do this walk every day as it helps the spirit as well as the mind and body.

On returning to the house, breakfast is two slices of toast and butter, one of these with jam, a fried egg and a bowl of muesli yoghurt and goats milk. I usually then read the newspaper for 10 to 20 minutes before starting the work of the day, and taking my second round of medicine.

The amount and quality of my work varies with how much sleep I've had. The worst-case scenario finds me feeling weak in the legs, and being unable to stand for more than a few minutes. Within an hour or so, my head is dropping from sleepiness, and my body is trying to get some sleep. I find myself drooling involuntarily and my handwriting going off the wall. After two or so hours I cannot any longer bear the pain in my back and have to lie down for half to one hour. When speaking to people, my voice is throaty, and I have difficulty in preserving enough breath to finish a sentence.

In July 2008 I wrote three 'condition reports' which attest to the evolution of my disease.

The first read:

Woke up this morning, slow to dress. It is getting harder to climb the ridge every day. Last night I retired at 10.30, early for me and I think that as a consequence, I awoke at 2 or so. Very pronounced tremor in hand, leg and foot. I continue to have good and bad days which seem to coincide with good or bad sleep the night before. Last night my neck was especially sore and my lower back also, though the left hip, which had been bothering me, was OK today. These days I frequently wake at night with a painfully sore left shoulder. The acute pain usually lessens after I take a toilet break. My arms are very weak and I have trouble pushing a computer mouse, while after an hour I cannot sit comfortably at a desk.

On 10 July 2008 my symptoms were:

1. right leg tremor at 6:15 a.m. upon arising and also yesterday from 9:30 a.m. for 15 minutes
2. right arm tremor, intermittent
3. right hand tremor from 8:30 a.m. until 9:30 a.m.
4. right hand and arm freezing, 11:00 a.m. to 12:30 p.m.
5. freezing intermittently
6. constipation
7. incontinence
8. walking up the hill is hard because muscles stiffer each day
9. fine motor skills , dressing ,word processing more difficult
10. back pain at night, especially bad in early morning
11. neck pain, especially bad at night
12. freezing and leg weakness intermittent throughout the day
13. left shoulder pain so bad I woke at 2:30 a.m. and had to take two aspirin to get back to sleep as I had the previous night also.

This list was followed by another condition report on 21<sup>st</sup> July 2008 which added some detail to the preceding report:

I reckon my overall condition has worsened by 20% over the past two weeks. I am hoping it is temporary. I am overwhelmed by fatigue and the increase in frequency and severity of right arm and leg tremors, unrelated to the timing of my medication. My whole body aches and all the muscles are tight and often cramp despite daily stretching exercises. My neck is constantly painful. Then there is the recurrence of the head tremor I experienced when I took four Symmetrel in one day, following doctor's advice. This is unnerving as it feels like my brain is trying to separate from my skull. I also have frequent momentary freezing and continual slowness of movement.

By this time my condition was rapidly deteriorating as reflected in my diary and my writing of more frequent condition reports, like these following three:

Last Thursday forgot to take my 10:30 a.m. and 1:30 p.m. medication. As my GP had told me that by taking nutritional supplements, I might be able to decrease the amount of Parkinson's drugs I have been taking, I decided to see what would happen if I kept taking supplements, but stopped Parkinsons medications. I lasted until Saturday morning and have not been the same since. It is now Tuesday, and the severe akinesia, and dyskinesia I've experienced since Saturday shows few signs of abating.

Yesterday, I drove to University and ran my class without much trouble, but my akinesia and dyskinesia increased from 2:00 p.m. onwards, and I had some difficulty in driving home. Last night akinesia and dyskinesia was moderate and my movement very slow. When I tried to move my position on the bed, my right arm and right leg tremors started up and my muscles are and were sore from bearing my full body weight as my legs could not do so.

I put the lights out at 11:30 p.m. and was still getting right arm and right leg tremor, but was surprised that I fell asleep quite quickly, and only made one toilet stop at 2:30 a.m. when I had to change the two blankets for a doona as I was too cold.

This morning I woke at 5:45 a.m. My movements in dressing were extremely slow. My lower back and legs were sore and painful. Although I had taken one Coloxyl tablet last night, I could not manage a bowel movement. Before taking my supplements at 6:45 a.m. and PD drugs at 7 a.m., I was extremely weak and fatigued in the legs. Then I started shaking, which lasted till about 8 a.m.

On 14 September 2008:

My condition has gravely worsened over the last three weeks. I am symptom-free perhaps 60% of the day and 20% of the night when awake, compared with 80% and 80% before that.

Last night I slept between 11:15 p.m. and 4:15 a.m., but woke for half an hour, three times. This morning at 6:30 a.m. it was difficult to move my body to get up. Every movement triggered right-hand and right leg tremor at the rate of two every second and strong. My back and shoulders are sore, though the pain in my right shoulder has eased in the last week.

Very slow to get to my feet. I had to lift myself by pulling on the door handle and then it took a long time to dress myself. I woke with a tired hangover, which has been washing through my brain all day.

When sitting at my computer, my lower back is unbearably painful and my arms ache and the right arm exhibits bradykinesia, making it difficult to move the mouse, and with acute pain above my right kidney at the back. At the table, my lower back, and back muscle above the kidney make it impossible to sit for more than two hours.

When standing in the kitchen preparing food I experience bradykinesia and akinesia, feeling my legs so sore and fatigued that I might collapse. Standing puts pressure on lower back.

My only relief used to come from occasional ingestion of a cannabis cookie, which eased the pain for one or two hours, but had undesirable side-effects. I took Symmetrel for six weeks and can't say it made any difference and the same for Sinemet and Cabaser. However I changed my dose of Madopar by increasing it from three doses per day to four or five doses per day. Irritability and weepiness also afflict me.

In a condition report from 23 October 2008 I stated:

Yesterday seemed to mark another unfortunate milestone in the progression of my condition. My right hand has started to flap violently whenever I wake up at night. Sometimes it is so severe that it triggers r/l tremors as well as echoes in my l/leg and foot. This hand flapping is going on all day along with moderate akinesia (a/a) and dyskinesia (d/a).

Meanwhile I can't sit in most chairs for more than a few minutes w/o getting a raging bad back and buttocks. Standing for more than a few seconds is painful and my legs often seem about to collapse and this triggers a/a.

The upshot of this flapping is that I don't think I can safely drive which in turn means that I'll have to leave home.

I've noticed a strange head-tightening sensation that I put down to amantadine ('Symmetrel') for it was this that gave me similar but stronger sensations when I was taking 3 X 2 tabs a day. I'm now on 1 x tab 2 in mornings.

Other symptoms include drooling, constipation (improved), hypersexuality and irritability and petty rages.

In a condition report dated 15 November 2008, I reported that:

I've just returned from a three day workshop in Canberra. Having 'hit the wall' about a month ago I was wary of attending but as I was feeling quite well in the preceding weeks, I went.

The hotel I stayed at had no fresh air and the centralised air conditioning system did not maintain the temperature low enough to aid sleep onset. I had to strip the bedclothes and lay naked under one sheet to get off to sleep. As soon as I got into bed I experienced moderate to severe right arm and leg tremors which continued each night for an hour before I arose and took another dose of Madopar and Comtan.

Both in the daytime and at night I was experiencing a twitching of the scalp and jaw and tongue tremors. During the day I had moderate dyskinesia, dystonia and akinesia and was unable to write lecture notes or to manage food and drink without spillage. I was constantly fatigued and was so shaky I found it hard to retrieve tablets from my purse. Fortunately I was relatively symptom-free when driving to and from Lismore and on the 'plane flights. The whole journey has left me fearful and depressed as I am now clearly totally dependent on my medications.

Throughout 2009 my condition has fluctuated. I wrote: on 13<sup>th</sup> January, 'severe right hand tremor on waking and after 11am medication'; 15<sup>th</sup> January, 'For about three months now I've been getting mini-blackouts, sudden brain fades for a second which have only been occurring since my change of medication.' During a trip to Launceston, Melbourne and Sydney in February I was relatively symptom-free, though in the last few days I was experiencing moderate akinesia, dyskinesia and dystonia.

In February 2009 I hit the wall: 'Constant akinesia and dyskinesia since waking. Extreme fatigue, drooling. Started on Sifrol x 3 morning, noon and night.' On 15<sup>th</sup> February I '[f]elt great on walk from 10–11am and then got severe tremors from 11:30 am on.'

Right through January, February and into March I reported head, jaw and tongue twitches. By the end of March I had seen some improvement in my condition but then:

over the last few days the symptoms are slowly returning – right hand and foot tremor lasting several minutes and tremor upon waking during nights; though I seem to sleep longer I do not feel any better for it during the day and often have to lie down for an hour or so.

On March 17 I reported twitching all night, woke twitching, first time in months. Twitching still at 9am after first medications at 6:15 am. Twitching scalp and clenched jaw on and off all day. But Friday 27 March had me entering in my diary that:

the lack of entries reflects the general improvement in my condition. However in the past few days I've been experiencing dizziness and light headedness when I rise from a seated position. It only lasts a second but is quite unnerving.

Moving into April I was feeling OK but on April 14<sup>th</sup> 2009 I recorded dyskinesia, and bradykinesia. There is a gap of two weeks after the last entry indicating I was OK, but the akinesia was coming back again, with right leg tremors, hand freezing, insomnia, and fatigue. Similar symptoms experienced over the next few days and on Friday 17<sup>th</sup> I reported, 'I've taken a turn for the worse this week, with much fatigue, leg weakness, tremors and extreme back pain ... though I have not altered my medication ... .' On the following Saturday – 'Haven't had right leg and right arm tremors like this for months. 'Today I start on Sifrol on Dr O's advice.'

On Monday April 20<sup>th</sup> I recorded:

Akinesia comes at any time whether or not I've recently taken medication. Still much worse than the week before last. Akinesia and dyskinesia occur when dressing and recur any time I change clothes. Right arm and leg tremors also present at seemingly random intervals.

A week later I wrote:

This is the second week of a downturn in my condition.' Now I never know if or when these symptoms may recur. My akinesia is present all the time. It is hard to get out of a car, out of bed, or from a sitting position. My micrographia disables me from writing and typing and I have to wait until the tremors lessen which may not be for hours. I am always very fatigued and have to sit down every few minutes.

Then there is another break in diary entries from 24<sup>th</sup> May to 3<sup>rd</sup> June. These breaks seem to occur roughly every month but just when I think I am improving I get a day like June 24<sup>th</sup> – 'Worst day in weeks or months – had akinesia, dyskinesia, bad back, stiff leg muscles, difficult to move computer mouse.' Then there was a large gap and some gratefully received respite from the end of June until August 10<sup>th</sup>.

On 31<sup>st</sup> August, after taking Stalevo for two weeks, on Dr O's advice, I've changed back to Madopar and Comtan on Dr F's advice for Stalevo did not seem to help my condition at all. So far most of my symptoms have abated – no micrographia, no dystonia so I thought it may be useful to go back a year in my diary, see what symptoms were troubling me then and compare them with my present symptoms. My entry for 10<sup>th</sup> July 2008 revealed a list of thirteen symptoms of which I have nine today, 21<sup>st</sup> August 2009, namely right leg

tremor, right hand tremor, freezing, constipation, disabled fine motor skills affecting dressing and word processing, neck pain, leg weakness, left shoulder pain. In addition I am becoming more and more irritable and constantly become frustrated at my inability to perform many simple daily tasks. When home alone I often shout at myself or at whatever inanimate object is causing my frustration. This can happen six times a day and can be accompanied by my hitting or throwing something. I am also becoming weepy especially at times when hearing music.

One of the hardest issues confronting doctors and seriously ill patients is how to deal with side effects of the medications taken. It is sometimes unclear whether the side effects experienced stem from one or several medications. In an attempt to investigate these phenomena for myself, I went back through all the patient information pamphlets I had been given to see how many of the listed side effects of each medicine were occurring for me – this is what I found:

Madopar 200mg (levadopa and benserazide): abnormal involuntary jerking movements of the body; mental changes including illusions; constipation; tiredness; sleeplessness; poor muscle tone; cramps; changes in sex drive – that is nine of the nineteen listed.

Sifrol (Pramipexole hydrochloride): constipation; drowsiness; dry mouth; hallucinations; abnormal uncontrolled movements; fatigue, light headedness; insomnia; change in sex drive, (9 of 23).

Symmetrel (Amantadine hydrochloride): light headedness; constipation; dry mouth; fatigue difficulty in concentrating; incontinence, hallucinations; weakness; shakiness; trembling; disturbed sleep, (12 of 28).

Comtan (Entacapone) stomach pain, constipation, dry mouth, light headedness, tiredness, shakiness, aches and pains, leg cramps, difficulty sleeping, increased sexual urges, (10 of 20).

Sinemet CR (Levodopa and carbidopa) abnormal uncontrolled movements, light headedness, dry mouth, sleepiness, weakness, increased desire for sex, (6 of 10).

My doctors all know about my side effects yet seem powerless to mitigate them. Meanwhile my hallucinations are worsening and I am beginning to experience phenomena like seeing a dot on a wall as moving when it is not.

Since I am soon due to submit my PhD thesis these may be the last entries in my diary, so to sum up I don't think I'm doing badly after seven years of PD although I am still plagued by fluctuations in my condition. After 14 months I received the Sativex I had been waiting for, which I hoped would lessen my insomnia and back pain. On the 4<sup>th</sup> September 2009, I sent off a cheque for the Sativex which cost me \$A797. So I was hoping to be able to insert an addendum to this chapter to say that I have received the Sativex and it is working well, but after trialling it for 2 weeks I don't feel any effects though I have experienced side effects like light headedness and smokers' cough.

### 1.3 *Battling the bureaucrats: Political perspectives*

On 1 February 2005 I wrote my first letter to the Experimental Drugs Section (EDS) of the Therapeutic Goods Administration's (TGA's) Drug Safety and Evaluation Branch. It struck me as bizarre that cannabis could be thought of as an 'experimental' drug, since my research in Chapter 3 dates its medicinal use from circa 2500 years BC. In my letter I asked whether the TGA would entertain an application for approval to import Sativex under the Special Access Service (SAS) which is discussed in Chapter 6.<sup>30</sup> In reply Dr Jonathon Rankin wrote that, although Marinol (dronabinol), a synthetic cannabinoid, is categorised as a Schedule 8 drug and thereby prescribable, cannabis, being categorised in Schedule 9 is not prescribable. 'Finally,' he wrote, 'unless amendment is made to the SUSDP [Standard for the Uniform Scheduling of Drugs and Poisons], Sativex would be considered cannabis and in schedule 9 ....'<sup>31</sup> It is interesting to note that Dr Rankin in this email estimates that an SAS Category B application 'typically takes a few days to consider and provide a written decision to the applying medical practitioner',<sup>32</sup> whereas the application, made on my behalf, was lodged on 31 July 2008 but we waited until 29 October before receiving their written decision.

So a synthetic cannabis medicine, Marinol, can be prescribed for my condition but Sativex, an extract from the cannabis plant, cannot. This contradictory conundrum was my introduction to the health industry bureaucracy. Then, in a letter I cannot now find, I wrote

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<sup>30</sup> Letter from Gaham Irvine to Therapeutic Goods Administration, 1 February 2005.

<sup>31</sup> Email from Dr Jonathon Rankin, Head, Experimental Drugs Section email to Graham Irvine 8 February 2005.

<sup>32</sup> Ibid.

to Bayer, the multinational pharmaceutical corporation which holds the rights to Sativex in Australia. I asked if they had plans to market Sativex here and, whilst they would not divulge their marketing plans, it was made clear that its marketing was not imminent.

In 2006 I stepped up my earlier correspondence with the New South Wales and Commonwealth governments but largely to no avail. I wrote to the New South Wales Health Minister on 24<sup>th</sup> February<sup>33</sup> regarding the Government's 2003 announcement that they would conduct a medicinal cannabis trial.

The Minister replied on 9 March, stating that:

Sativex certainly holds promise for people suffering a range of conditions ... [but] given the time it would take before Sativex could be available in New South Wales due to lengthy clinical testing and approvals processes associated with allowing this sort of product to be marketed the government investigated other solutions to help patients suffering from certain medical conditions and sought the Commonwealth Government's cooperation. We have been awaiting a reply from the Prime Minister and the Minister for Health and Ageing to letters written last year.<sup>34</sup>

Although Minister Della Bosca claimed that he had referred my letter to the then Health Minister, John Hatzistergos, I received no reply from him and so wrote next to the then Premier, Maurice Iemma<sup>35</sup> to which his Director-General, Roger Wilkins answered:

As the matter you have raised primarily concerns the administration of the Minister for Health ... the Premier has arranged to bring your approach to the Minister's attention ... You may be sure that your comments will receive close consideration.<sup>36</sup>

From that day to this I have not heard from the Health Minister despite several letters and representations by The Greens' Lee Rhiannon on my behalf.

On 20 May 2006 I wrote to Prime Minister Howard, asking him to approve the import of Sativex and facilitate the New South Wales trial. The response was completely negative.

Objections were raised about:

the regulatory framework for the trial, particularly in relation to restricting access; determining eligibility, and ensuring adequate supervision of participants. Furthermore, at this stage the government has not been given sufficient information by the New South Wales government to provide reassurance that the potential benefits of such a trial would outweigh the risks of proceeding. In addition, the government has

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<sup>33</sup> Letter from Graham Irvine letter to NSW Health Minister J Della Bosca, 24 February 2006.

<sup>34</sup> Letter from NSW Health Minister J Della Bosca to Graham Irvine, 9 March 2006.

<sup>35</sup> Letter from Graham Irvine to NSW Premier Maurice Iemma, 6 June 2008.

<sup>36</sup> Letter from Roger Wilkins to Graham Irvine, 2 July 2008.

noted recent national and international research that associates cannabis use with increases in depression, suicidal behaviour and psychopathic illness and may bring forward the onset of schizophrenia. ... the weight of evidence points in the direction of early and regular cannabis use having substantial negative effects on psychosocial functioning. Given this, any proposed future trial would need to be established in such a way as to ensure that broader community risks are not introduced.<sup>37</sup>

It should be noted that this same government conflated similar objections to the New South Wales safe injecting room scheme for heroin users which has now become an international exemplar. I have quoted from this letter at length because it is so similar to the current Rudd Government's take on medicinal cannabis and because it (deliberately?) confuses Sativex with raw cannabis. By analogy the fact that opium can cause serious physical and psychological problems does not alter the fact that, used in a medicinal form, it is an invaluable drug.

In September 2007 my treating neurologist, Dr F, wrote to his colleague and Parkinson's disease (PD) specialist Dr O for his advice on any further treatment he would suggest. Inter alia he commented that:

There were muscle spasms in his feet and buttocks ... At times he gets dystonic reactions in his right leg and this has affected his driving at times. At the end of 2005 he was trialled with Stalevo but this caused dyskinesia in the mornings and then he is fine in the afternoons. By the end of 2006 he was having on/off effects which were becoming increasingly unpredictable ... This year he has had trouble with sleep due to back pain and stiffness. More recently pain in both his shoulders. His sleep is becoming quite disturbed which is having an impact on daytime functioning.<sup>38</sup>

On 22 January 2008 I wrote to Prime Minister Rudd asking him to 'expeditiously give serious consideration to approving Sativex on prescription.' After two and a half months I had a reply from a staffer. Hers was a completely negative response, similar to that of a Mr Sperling, advisor to Prime Minister Howard two years earlier. Ms. Hart gives two reasons why medicinal cannabis will not be approved. Firstly she claims that, '... if cannabis were allowed for medical purposes it could be diverted to non-medicinal purposes, contravening United Nations Conventions to which Australia is a signatory.' Yet none of the nations that have legalised medicinal cannabis has reported law enforcement problems with medicinal cannabis being diverted to recreational use and none has been accused of breaching the United Nations conventions. Indeed Ms. Hart herself acknowledges that the conventions

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<sup>37</sup> Letter from Perry Sperling, Senior Advisor (Social Policy), Office of the Prime Minister to GI, 7 July 2006.

<sup>38</sup> Dr O'Sullivan, letter to Dr Fairfull-Smith, 17 September 2007.

do ‘permit the use of cannabis ‘for scientific and medicinal purposes.’ She then trots out a list of alleged harms which she attributes to cannabis, conveniently staying silent that these harms are all related to recreational and *not* medicinal uses. On 11 April 2008 I replied:<sup>39</sup>

Dear Minister

If your Ms Hart’s letter of 2 March 2008 is an accurate description of your Department’s knowledge of medicinal cannabis, then you have been ill-advised.

Hart claims that cannabis for medicinal use ‘could be diverted to non-medicinal purposes contravening United Nations conventions to which Australia is a signatory’. However this possibility was intensively studied by Canada, the United Kingdom and the Netherlands, all of which have not raised such diversion as being a problem in law enforcement of their medicinal cannabis regimes or in breaching the same UN conventions to which we are signatory.

In any case her statements are misleading in two respects – that here she is referring to the raw cannabis plant NOT the pharmaceutical ‘Sativex’ about which I asked. Secondly, she herself states that, under these conventions, the use of cannabis for medicinal purposes is sanctioned.

Similarly, her list of so-called ‘health effects’ applies, if at all, only to raw smoked cannabis NOT to the Sativex medicine. Moreover this list of health risks attributed to cannabis is not generally accepted by the weight of scientific medical research and none of these studies has reported any of the effects as problematic.

Moreover her letter has not answered my question, which was ‘What hope can you give me and my fellow sufferers that your Government will expeditiously give serious consideration to following the lead of other countries in making this invaluable medicine available to those who need it.’

I write again to ask you to refer my letter to someone who has more knowledge of this subject to answer this question and to detail what, if any, policy your Government has regarding medicinal cannabis.

Yours sincerely

Graham Irvine

Like my doctor and I, the state government had been waiting for a reply to a letter they had sent to the Commonwealth government in 2007. Such delay has characterised most of my correspondence with the Prime Minister and the Minister for Health, whereas my letters to the New South Wales Premier and to the Health Minister are often not answered at all.

In February 2008 later my treating neurologist applied to the Pharmaceutical Services Branch of the New South Wales Health Department to authorise him to prescribe Sativex for me.<sup>40</sup> He appended a list of medications and therapies I had tried to relieve my insomnia and back pain, thus indicating that I was seeking Sativex as a drug of last resort. He added that, ‘I have recently consulted with Dr John O’Sullivan, a neurologist

<sup>39</sup> Letter from Virginia Hart, Assistant Secretary, Drug Strategy Branch, Commonwealth Department of Health and Ageing to Graham Irvine 2 April 2008.

<sup>40</sup> Letter from Dr Hugh Fairfull-Smith to Chief Pharmacist, NSW Health Department, 22 February 2008.

specialising in PD in Brisbane. He is supportive of this application.’ This approval was granted in a letter dated 17 June 2008.<sup>41</sup> It authorises Dr F under clauses 105 and 166 of the *Poisons and Therapeutic Goods Regulation 2002*, ‘to obtain and supply Sativex oromucosal spray ... to Mr Graham Irvine of Falls Road, Nimbin, for the treatment of pain associated with PD.’ So now my doctor and I had won over the first line of bureaucracy but there were more to come as, although my doctor could now legally prescribe Sativex, he still needed Commonwealth approval to use it and to import it.

With the advent of a new state Health Minister I wrote to her, asking her to clarify the procedures by which I could seek the approval of my doctor to authorise prescription. However, like her predecessors in the portfolio I received no reply from her or her department.

New South Wales Health Minister Reba Meagher announced on 19 May 2008 that she was setting up a clinical trial of medicinal cannabis ‘as soon as possible.’<sup>42</sup> I wrote to her, asking to be considered as a participant in the trial, pointing out that I already had the support of my three doctors in requesting approval to prescribe Sativex for me.<sup>43</sup> I have heard nothing from her or her successors.

When, on October 29 2008, Dr F received a letter informing him that his application for Category B status under the SAS had been refused, I, as a person affected by this initial decision determined to appeal the decision and informed the Therapeutic Goods Administration of this in a letter of 17 January 2009 to which I appended a document setting out the grounds and evidence for my appeal, which I reproduce here in full:

My appeal under Section 60 of the *Therapeutic Goods Act 1989*

The basis for this appeal is that the decision maker has misunderstood the nature of the application and failed to give due weight to my medical conditions and personal circumstances.

Despite the statement in the rejection letter that, ‘The TGA has a responsibility to determine each request to supply an unapproved product on a case by case basis, taking into account the need of the patient and the properties of the product.’ (Dr Ray Cook letter to Dr Fairfull-Smith, 29 October 2008), the decision maker has apparently ignored or overlooked the nature of the application and the evidence provided to him.

<sup>41</sup> Letter from Acting Chief Pharmacist, NSW Health Department to Dr Hugh Fairfull-Smith, 17 June 2008.

<sup>42</sup> K.Sukova, ‘Medical Use of Cannabis Re-opens Drug Debate’, *Daily Telegraph* (Sydney), 19 May 2008, p 5.

<sup>43</sup> Letter from Graham Irvine to Minister for Health NSW, 21 May 2008.

## PERSONAL CIRCUMSTANCES

In this appeal I have the support and backing of my general practitioner, treating specialist and consulting neurologist, all of whom have conducted thoroughgoing physical and medical history examinations on me before reaching their conclusions. Thus they have taken into account my needs as a patient in a way that the Therapeutic Goods Administration has not.

Dr O’Sullivan advised, ‘For a number of years he has been bothered by low back pain, consistent with painful dystonia which is a complication of advancing Parkinson’s Disease and which can be difficult to treat. As Mr Irvine has tried a number of medications for his pain without success, and as the pain is causing considerable distress, particularly overnight, I consider a trial of Sativex to be an appropriate treatment strategy for Mr Irvine’s pain.’ (Dr J O’Sullivan ‘To Whom It May Concern’, 6 May 2008). In fact I have unsuccessfully tried all the available medicines for my conditions, making Sativex the medicine of last resort.

The Applicant, Dr Fairfull-Smith wrote, ‘Specifically he is troubled by night time dystonic pain’ (Dr H Fairfull-Smith, letter to Chief Pharmacist, Pharmaceutical Services Branch, NSW Health, 2 February 2008) while in my letter to Dr Cook (24 September 2008) I wrote that ‘I have enclosed several papers illustrating the potential of Sativex to alleviate dystonia and dyskinesia.’

Despite their advice it seems that the decision-maker’s rejection was based ‘on the basis of lack of submitted evidence supporting the safe and effective use of Sativex in Parkinsonism and/or in pain associated with Parkinsonism’ (Dr R Cook letter to Dr Fairfull-Smith 29 October 2008, p.1) but he has not specifically considered dystonia, dyskinesia and insomnia in his determination.

One of the studies provided well describes my position – ‘Although initially successful, within five years of initiating levodopa treatment, up to 80% of patients will experience severe side effects such as loss of efficacy and marked unpredictable fluctuations in motor activity, including dyskinesia’ (Lastres-Becker, I, ‘An overview of Parkinson’s Disease and possible benefits of cannabinoid-based treatments’ (2006) 13 *Current Medical Chemistry* 3705–3718, at 3715).

I was diagnosed with Parkinson’s disease eight years ago and, because my principal medication has been levodopa I am now experiencing the above mentioned severe side effects. This has now reached the stage that I will be obliged to inform my employer that I will not be available to work in 2009 which in effect would permanently terminate my working life.

## THE EFFICACY AND SAFETY OF SATIVEX IN THE TREATMENT OF DYSTONIA, DYSKINESIA AND INSOMNIA

Scientific reports of cannabinoids reducing dystonia go back at least to 1986 when Consroe et al. found that when patients were dosed with 100 to 600mg/kg of cannabidiol, (one of the two active ingredients in Sativex), ‘Although there were individual differences in the response to CBD, improvement of the dystonic disability was generally dose related with maximal improvement ranging from 20 to 50%.’ (Consroe, P, Sandyk, R and Snider, S R, ‘Open label evaluation of cannabidiol in dystonic movement disorders’ (1986) 30 *International Journal of Neurosciences* 277–282, at 278).

In 2001 a double blind randomised, placebo controlled crossover design study by Sieradzan et al. reported that Nabilone, [a synthetic cannabinoid] significantly reduced total levodopa-induced dyskinesia compared with placebo.’ (Sieradzan, K et al, ‘Cannabinoids reduce levo-dopa-induced dyskinesia in Parkinson’s disease: a pilot study’ (2001) 57 *Neurology* 2108–2111, at 2110).

Subsequently a 2002 study confirmed that, ‘Co-administration of levodopa and the cannabinoid receptor Nabilone (at 0.1 mg/kg) resulted in significantly less total on-period dyskinesia ... than levodopa.’ (Fox, S et al, ‘Stimulation of cannabinoid receptors reduces levo-dopa-induced dyskinesia in the MPOTP-lesioned nonhuman primate model of Parkinson’s disease’ (2002) 17(6) *Movement Disorders* 1180–1187, at 1182).

A 2004 large scale survey of Parkinson’s patients revealed that, of the 25% of 399 patients who had used cannabis, 45.9% of these reported benefits, including 145 who reported improvement in levodopa-induced dyskinesia (Venderova, K et al, ‘Survey on cannabis use in Parkinson’s disease: subjective improvement of motor symptoms’ (2004) 19 (9) *Movement Disorders* 1102–1106).

The 2006 study by Lastres-Becker (above at 3715) concluded that ‘cannabinoid-based medicines ... might modulate behavioural effects of levodopa and Parkinson’s Disease motor symptoms themselves.’

Lately, a 2008 paper reasoned that, ‘cannabinoid agonists may attenuate the actions of dopaminergic drugs including levodopa-induced dyskinesias (LID), i.e. anti-dyskinetic effect. Dyskinesias (involuntary movements) together with response fluctuations are motor complications that commonly develop during long-term levodopa therapy of PD.’ (Papa, S, ‘The cannabinoid system in parkinson’s disease: multiple targets to motor effects’ (2008) 211 *Experimental Neurology* 334–338, at 335).

The evidence of Sativex’s efficacy in treating insomnia is examined in a recent study which reported that in six of the nine studies they reviewed, which included subject numbers ranging from 20 to 507, Sativex was found to significantly improve objective and subjective quality sleep (Russo, E, Guy, G and Robson, P, ‘Cannabis, pain and sleep: lessons from therapeutic clinical trials of Sativex, a cannabis-based medicine’ (2007) 4 *Chemistry and Biodiversity* 1729–1743).

The results of comparative tests of other cannabinoid medicines show the consistent efficacy of Sativex over other cannabis-based pharmaceuticals, (eg see Russo et al, above at pp 1734–1735 and 1738–1739) in the treatment of a range of conditions. Both they (at 1739) and McCarberg and Barkin (2007) 14(5) *American Journal of Therapeutics* 475–483, at 480) maintain that this is due to its different formulation in containing almost equal parts of THC and cannabidiol, the latter concluding that, ‘the interaction of THC with CBD appears to improve the risk/benefit profile of a THC-containing cannabinoid product.’ (McCarberg, above, at 480). Although I am not aware of any studies directly comparing the efficacy of Sativex and Nabilone in treating dystonia and dyskinesia, the consistent superiority of Sativex in pain treatment in a range of other conditions indicates its likely superiority in treating these conditions also.

I should state here that I have no financial or any other ties with GW Pharma, the manufacturer of Sativex and my advocacy of it is solely based on its superiority in clinical tests over Nabilone and other synthetic cannabinoid medicines.

There is now available data on the long term effects of Sativex as recently several studies into the uses of Sativex have failed to find significant tolerance or dependence among patient groups. (Budney, A J et al, ‘Review of the validity and significance of cannabis withdrawal syndrome (2004) 161 *American Journal of Psychiatry* 1967–1977; Russo, E and Robson, P, ‘Abrupt interruption of long-term treatment with Sativex was not associated with a withdrawal syndrome’ *XV Symposium on the Cannabinoids*, Clearwater 2005, Abst 45; Russo, E ‘Sativex and tolerance: Sativex cannabis-based medicine provides long-term clinical efficacy without dosage increases or withdrawal’, *American Public Health Association 133<sup>rd</sup> Annual Meeting and Exposition*, Philadelphia 2005 , Abst. 106317). ‘The existence of a clear-cut physical dependence syndrome is much less convincing on the basis of the published literature.

If it exists at all it is probably mild and fleeting ...’ (Guy, G W et al (eds), *The medical uses of cannabis and cannabinoids*’ (2004), Pharmaceutical Press, Salisbury, UK, at 252). In a long term study of 404 MS and chronic pain patients, ‘Patients treated for one year had sustained improvements in symptoms ... with no evidence of treatment tolerance’ (Perez, J ‘Combined cannabinoid therapy via an oromucosal spray’ (2008) 42(8) *Drugs of Today* 495–503, at 500).

As to safety, ‘[c]annabis has an exceptional record of safety (Grinspoon, L and Bakalar, J B, *Marihuana the forbidden medicine* (1997) New Haven, Yale UP). It is virtually impossible to kill animals with acute doses and there are no substantiated deaths from ingestion of cannabis.’ (Guy et al, above at 450)

Finally, in a United Kingdom government regulatory agency’s report on Sativex, a group of independent experts provided by GW Pharma, the manufacturer of Sativex, concluded, ‘In summary, we note that all the elements which are required to conclude that Sativex is providing worthwhile clinical benefit at low risk are present in the data we have seen ... Long term use confirms maintenance of the treatment effect without the emergence of new adverse events and with no evidence of tolerance’ (United Kingdom Medicines and Healthcare Regulatory Agency, ‘*Public Information Report*’, UK/H/961/01/DC, pp 43–44).

I am confident that Sativex will alleviate my conditions because I have successfully treated them using herbal cannabis. However its side effects and illegality rule it out as a viable option.

#### PROPOSED TRIAL DETAILS

Dr O’Sullivan in his 6 May 2008 letter suggests a three month trial of Sativex.

The proposed monitoring regime would be for me to be seen by my general practitioner every second fortnight; to see Dr Fairfull-Smith every month and to consult Dr O’Sullivan before and after the trial. The appropriate dosage regime for the proposed trial is based on the Sativex Product Monograph (enclosed) which states, ‘Your regular daily dose is determined by increasing your dose gradually over the first few weeks of taking Sativex. The starting dose for an adult is not more than one spray every four hours on the first day ... The average dose of Sativex is five sprays per day. ... These doses should be spaced out evenly throughout the day. When you have found your regular daily dose, you may adjust the timing of your dose depending on how you feel.’ (‘Sativex Product Monograph, GW Pharma, Salisbury, UK, 13 April 2005, at 37).

#### CONCLUSION

Whilst the clinical evidence is not voluminous the enclosed references do indicate that much evidence is forthcoming in the near future. Given the exceptional safety record of cannabis in general and Sativex specifically; the support of my three doctors and specialists and the urgency of my need I seek a reversal of the initial decision in this matter.

Then, a few days short of the 90 day statutory time limit for replies to Section 60 applicants, I received a seven-page document informing me that the result of my appeal

was that the reviewing officer had decided, ‘to revoke the initial decision in relation to Dr Fairfull-Smith’s application and make a fresh decision in this matter.’<sup>44</sup> This decision was:

Pursuant to subsection 19(1) of the *Act* I approve the use of Sativex for the indication of pain associated with your Parkinson’s disease, with the monitoring regimen in place as outlined in your appeal letter dated 17 January 2009.

The letter goes on to list those of my appeal arguments which he has accepted:

Dr Fairfull-Smith does state that you have undergone investigations to rule out some possible underlying causes of the pain you have experienced. I also note in Dr Fairfull-Smith’s letter to Dr John O’Sullivan dated 21 September 2007, he relates that ‘current symptoms are chiefly insomnia as a result of back and shoulder pain, which causes a debilitating insomnia that may be caused by Parkinson’s-related dystonia and ... he believes a trial of Sativex is warranted, given that you have trialled, in your own words, all other medications for pain relief and the subsequent interference with activities of daily living ... Dr Fairfull-Smith feels that your pain may be caused by Parkinson’s-related dystonia and ... he believes a trial of Sativex is warranted, given that you have trialled, in your own words, all other medications for pain relief.’<sup>45</sup>

Dr Cook’s conclusion was, ‘The safety and efficacy of Sativex in Parkinson’s disease and/or in pain associated with Parkinson’s disease has not been established.’ I [Dr. Rankin] concur with the above conclusions of Dr Cook.<sup>46</sup> In reaching his decision, Dr Rankin took into account, inter alia, ‘you are under specialist care and have been for several years; You propose a monitoring regimen in your appeal letter over a three month period; I am satisfied your condition results in significant morbidity caused primarily by postulated dystonic pain and subsequent insomnia. I am satisfied that there is some evidence in relation to the drug’s efficacy in the symptomatology you describe, although none in patients with Parkinson’s disease ... ; I am not satisfied there is adequate evidence to suggest Sativex will have any efficacy in the treatment of pain associated with Parkinson’s disease; I am satisfied that Dr Fairfull-Smith has specialist knowledge as well as an intimate knowledge of your condition, and that he is willing to supervise an initial trial.’<sup>47</sup>

In his conclusion, Dr Rankin states that:

The SAS scheme requires a risk/benefit assessment of a proposed use of an unapproved good, taking into account any information in relation to efficacy and safety for the proposed use, along with the individual circumstances of the patient. ... I believe it remains uncertain whether you will benefit from any such trial of this medication, and the safety profile of this drug does raise my concerns for you. However, given that the use of the drug will be for an initial three month period, under a specified monitoring regimen, I think that in your individual case the risk benefit assessment is favourable.

<sup>44</sup> Letter from Dr Jonathon Rankin, Delegate of the Minister for Health to Graham Irvine, 12 March 2009, p 1.

<sup>45</sup> Ibid p 4.

<sup>46</sup> Ibid 5–6.

<sup>47</sup> Ibid 6–7.

## 1.4 Methodology

The ethical standpoint adopted in this thesis is based both on an inversion of a Millian rationale and a re-working of the radical libertarian position in relation to the individual's right to determine how s/he uses her/his body. This standpoint is supported by three discrete bodies of work.

The first theoretical underpinning draws on an inversion of the Millian axiom of the greatest good for the greatest number by positing its opposite, being the least harm to the fewest number.

The second is partly informed by the work of Thomas Szasz and proceeds from the widely acknowledged human rights principle that all individuals have the right to control and maintain their own body.<sup>48</sup>

The third perspective draws on the work of Conrad and Schneider who posit that the operation of political, social and economic forces results in the perception that drug policy changes over time in a cyclical motion from criminalisation to medicalisation and back again.<sup>49</sup>

The methodological techniques used in this study include quantitative interview surveys, content analysis of relevant documents, autoethnography, case studies, comparative analyses and literature reviews.

This is avowedly policy research which has been characterised as the very elusive process of 'conducting research on, or analysis of, a fundamental social problem in order to provide policy makers with pragmatic action-oriented recommendations for alleviating the problem.'<sup>50</sup>

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<sup>48</sup> T Szasz, *The Myth of Mental Illness* (1976) and T Szasz, *The Theology of Medicine: The Political-Philosophical Foundations of Medical Ethics* (1977).

<sup>49</sup> P Conrad and J Schneider, *Deviance and Medicalization: From Badness to Sickness* (1992) and J London, *Demedicalization and Criminalization of Marijuana: a Study of Changing Deviance Directions* (PhD thesis, University of Colorado 2006).

<sup>50</sup> A Majchrzak, *Methods for Policy Research* (1984) 12, cited in T Hutchinson, *Researching and Writing in Law* (2<sup>nd</sup> ed, 2006) 62.

I describe this multi-methodological approach to the subject matter here as a triangulated study, meaning that different methodological forms have been utilised to capture the richness of the data. ‘The combination of multiple methodological practices ... in a single study is best understood, then, as a strategy that adds rigor, breadth, complexity, richness, and depth to any inquiry.’<sup>51</sup>

Although my introduction to the chapters comprising these methods often addresses the methodology employed in those chapters, it is appropriate here to expand on their nature and on why I have used them in the particular contexts in which they have been employed.

### *Survey*

In Chapter 2 I address the issue of whether there is a constituency for medicinal cannabis users, that is whether there are enough of them to constitute a viable cohort for research and policy action. Having concluded that there is, it was then necessary to discover if the level of support for medicinal cannabis use is sufficiently strong among the key stakeholders to make a regulatory system function effectively. The survey was also prompted by the findings from the literature review that, in some states of the United States and Canada, such support was initially so low that it threatened to render the local medicinal cannabis use legislation ineffective.

This afforded the opportunity to undertake a small quantitative survey of general practitioners in one region of New South Wales as to their knowledge of and willingness to prescribe medicinal cannabis if it were legalised. As Chapter 2.4 explains, the survey had the full support of the local chapter of the national general practitioners association.

The validity of the study was addressed by choosing a sufficiently large and randomised sample of informants from the total population of general practitioners on the Association’s database.

The process of recruiting interviewees took place in three stages. First I sent a letter to all the region’s general practitioners inserted into their association’s newsletter explaining the reason for the survey and explaining that I would be writing to all general practitioners in

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<sup>51</sup> N Denzin and V Lincoln (eds), *Handbook of Qualitative Research* (2<sup>nd</sup> ed, 2000).

the sample to invite them to volunteer as interviewees. In the second stage these letters were sent, giving the recipients the option of making themselves available for interview if a mutually convenient time could be arranged or, alternatively, posting or telephoning back their refusal to participate.

The geographical extent of the region and time-poor lifestyle of the practitioners necessitated that many of the interviews were carried out by phone and often I had to ring several times before being able to arrange an interview.

Questions used in the survey were based on earlier surveys and vetted by medical experts. The questionnaire was piloted and pre-tested with three local general practitioners who were not part of the sample.

As a result of these strategies and techniques I can be confident that the resulting data are both valid and reliable.

### *Case studies*

Two case studies are included in this thesis to try to convey to the reader some idea of the political forces arrayed for and against medicinal cannabis, both overseas and in Australia.

The first of these, Chapter 7.2, is a forensic examination of a large-scale study conducted among long-term cannabis users in the Northern Rivers region of New South Wales. By comparing the words and contexts of questions asked in the survey with the authors' interpretations of those questions and the statistical use made of them, I hope to have demonstrated how policy research can be corrupted by political considerations and how research bodies can fall captive to their funding sources.

The second case study, Chapter 7.2, firstly employs a modified form of citation analysis to compare and contrast the references used in three major recent works on medicinal cannabis before continuing to a rebuttal of a document issued by the United States Drug Enforcement Administration. The study is designed to show how it is possible for different researchers to arrive at diametrically opposed conclusions by the selective use of the references they use to build a case.

### *Action research*

As Hutchinson puts it, action research is ‘self research [in which] action researchers identify an issue or problem in a working environment. Their objective may be to change the environment and perhaps attempt to change practice.’<sup>52</sup> Another writer insists that ‘action research is not done on some one or some group or; it is done with people who can benefit from the actions and findings and the changes that result.’<sup>53</sup>

Thus I have taken advantage of my personal medical condition to become both the subject and the researcher in an attempt to examine the processes of drug regulation and how they operate at the bureaucratic and grassroots levels. By presenting myself to the politicians and policymakers as a potential patient rather than an academic researcher, I have sought to convey the complexity of the drug regulation system and to work through this to achieve a breakthrough which will enable many thousands of patients access to a drug which could afford them significant relief from their suffering.

This action research consists on the one hand of the development of a series of correspondences with politicians and bureaucrats with a view to convincing them of the worthwhileness of medicinal cannabis legislation. On the other hand, it comprises a paper trail of applications made to the regulatory authorities for approval to import, to prescribe and to use medicinal cannabis. Had these applications failed to obtain approval, I had briefed the Public Interest Advocacy Centre to file suit for me in an administrative law case to challenge the Minister's decision on several grounds of unreasonableness and failure to take account of relevant considerations.

### *Comparative research*

In Chapter 2.3 I utilise comparative research to broaden the inquiry of the thesis and to demonstrate the relevance of overseas data to conditions in Australia. In the literature review of the history and current regulation of drug policies in the jurisdictions examined, I have sought out comparisons and contrasts between them, hoping thereby to draw out implications which may be useful in the development of the New South Wales medicinal

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<sup>52</sup> M Wilkinson, *Action Research: for People and Organisational Change* in T Hutchinson, *Research and Writing in Law*, (3<sup>rd</sup> ed, 1996) at 105.

<sup>53</sup> H Gutteridge, *Comparative Law: An Introduction to the Comparative Method of Legal Study and Research* (2<sup>nd</sup> ed, 1999) 73.

cannabis legalisation regime. Whilst it is pertinent to heed Gutteridge’s warning that ‘like must be compared with like; the concepts, rules or institutions under comparison must relate to the same state of legal, political and economic development’,<sup>54</sup> I believe that these preconditions are met in the jurisdictions examined due to their common history and development.

### *Autoethnography*

Autoethnography has recently been defined as, ‘autobiographies that self-consciously explore the interplay of the introspective, personally engaged self with cultural descriptions mediated through language, history and ethnographic explanation.’<sup>55</sup> This ‘explanation’ aspect makes autoethnography transcend autobiography by connecting the personal to the cultural.<sup>56</sup>

Chang identifies four typologies of autoethnographic writing – ‘descriptive realistic; confessional emotive, analytical interpretative and imaginative creative.’ My dossier in Chapter 1.1 is an example of analytical interpretation in that, ‘essential features transcending particular details are highlighted and relationships among data fragments are explained. The analytical discourse, grounded in specifics, shows your ability to see interconnectedness within the case.’<sup>57</sup>

My autoethnographic account is a narrative of the interplay between my PD with my bodily and mental condition and my consequential dealings with the medical and regulatory systems. It consists of extracts from my medical diaries and ‘Condition Reports.’ One of the aims of that chapter is to give the reader an impression of what it feels like inside to live with PD. Another aim is to afford readers the opportunity of

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<sup>54</sup> Ibid 66.

<sup>55</sup> C Ellis and A Bochner, ‘Autoethnography, Personal Narrative and Personal Reflexivity’ in Denzin and Lincoln above n 49, 742.

<sup>56</sup> Ibid 739.

<sup>57</sup> H Chang, *Autoethnography As Method* (2008) 9.

eavesdropping on an important current debate in Australia through the medium of my experience.

## Chapter 2

# THE EVIDENCE FOR MEDICINAL CANNABIS

### 2.1 *Efficacy*

#### *Complicating factors*

Several factors make it difficult to assess the many scientific studies of medicinal cannabis and thus to assess its efficacy in treating different medical conditions.

Firstly, the results of tests of efficacy vary widely according to whether cannabis is smoked or other delivery systems of ingestion are used. There is already a scientific consensus that the many substances in smoked cannabis produce a synergistic effect that does not occur when synthetic cannabis formulations are employed<sup>1</sup>. This sometimes results in findings where smoked cannabis is efficacious for certain conditions while the synthetics are not or are less so. Furthermore, different results have been reported due to the use of different cannabis synthetics, eg nabilone and dronabinol (Marinol) in otherwise identical research.

Secondly, placebo studies with smoked cannabis are problematic especially with experienced cannabis smokers who can readily detect placebo ‘joints’ due to the lack of the characteristic smell and taste of combusted cannabis.<sup>2</sup>

Thirdly, dosage rates, especially with test animals, are extremely variable and can be associated with aberrant results especially since several studies have found that the therapeutic dose of medicinal cannabis is quite specific within a narrow range – that is, too much or too little can eliminate its effects, as can including or excluding ingredients.

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<sup>1</sup> M Eddy, ‘Medical Marijuana: Review and Analysis of Federal and State Policies’ (Congressional Research Service, Library of Congress, CRS Report for Congress, 29 December 2005) 22 and see L Grinspoon, ‘Opinion: Marijuana as Wonder Drug’, *Boston Globe* (Boston), 1 March 2007.

<sup>2</sup> M ben Amar, ‘Cannabinoids in Medicine: A review of Their Therapeutic Potential’ (2006) 105 *Journal of Ethnopharmacology*, 1–25 and L Iversen, *The Science of Marijuana* (2000) 14–18, Table 4.

For example Table 4 in the recent review of ben Amar lists one study of the efficacy of oral THC (tetrahydrocannabinol, a component of cannabis) with 20% CBD (Cannabidiol) which found ‘no benefits on spasticity’<sup>3</sup> whereas another study in Table 4, using THC with 50% CBD, reported ‘Statistically significant reductions in spasticity.’<sup>4</sup> Similarly, a study by Vaney et al.<sup>5</sup>, using 2.5 mg THC and 0.0 mg CBD found, ‘no beneficial effects of cannabinoid extracts on spasticity’ while Wade et al.<sup>6</sup> in a 2004 study using 2.7mg THC and 22.5 CBD reported a, ‘statistically significant reduction in spasticity.’<sup>7</sup> This is backed up by a more recent study, which claimed that ‘the combination of cannabinoid and non-cannabinoid compounds, as present in [plant-derived] extracts provide significant advantages in the relief of neuropathic pain compared with pure cannabinoids alone.’<sup>8</sup> Lately, in studying the effects of medicinal cannabis on insomnia, the researchers found that a dose of 15mg THC was sedative whereas 15mg CBD increased waking activity.<sup>9</sup>

Fourthly, it has been reported that:

Cannabinoids can exert opposite actions at the cellular level and at the level of the circuitry within a nucleus or in between nuclei. They inhibit or excite neurons and oppose excitatory and inhibitory input transmission within the same nucleus ... Similar complexity in actions is observed after systemic administration of cannabinoids where relatively low doses enhance motor output while relatively high doses inhibit movement and furthermore induce catalepsy.<sup>10</sup>

Fifthly, a significant factor impeding large-scale clinical studies in the United States has been the obstructionism of the Bush presidency and its federal government agencies which threatened, raided, arrested and prosecuted medicinal cannabis users. The result of this is that it has been extremely difficult for researchers there to obtain large enough sample populations of medicinal cannabis users for effective testing of medicinal cannabis’s efficacy. The Bush government’s hypocrisy is demonstrated by its claims that there were not sufficient

<sup>3</sup> ben Amar, above n 2, 1–25.

<sup>4</sup> D Wade et al, ‘A Preliminary Controlled Study to Determine Whether Whole-plant Cannabis Extracts Can Improve Intractable Neurogenic Pain.’ (2003) 17 *Clinical Rehabilitation* 21–29.

<sup>5</sup> C Vaney C et al, ‘Efficacy, Safety and Tolerability of an Orally Administered Cannabis Extract in the Treatment of Spasticity in Patients with Multiple Sclerosis’ (2004) 10 *Multiple Sclerosis* 417–424.

<sup>6</sup> D Wade, et al, ‘Do Cannabis-Based Medicinal Extracts Have General or Specific Effects on Symptoms of Spasticity in Multiple Sclerosis?’ (2004) 10 *Multiple Sclerosis* 424–441.

<sup>7</sup> Ibid 440.

<sup>8</sup> P Comelli et al, ‘Anti Hyperanalgesic Effect of a Cannabis Sativa Extract in a Rat Model of Neuropathic Pain’ (2007) 22 *Phytotherapy Research* 1017–1924, 1022.

<sup>9</sup> P Nicholson et al, ‘Delta9 Tetrahydrocannabinoid and Cannabidiol on Nocturnal Sleep and Early Morning Behaviour in Young Adults’ (2007) 24 *Journal of Clinical Psychopharmacology* 305–314, 313.

<sup>10</sup> Sanudo-Pena, M Clara and E Fride, ‘Marijuana and Movement Disorders’ in S Onaivi (ed), *Endocannabinoids: the Brain and Body’s Marijuana and Beyond* (2006).

epidemiological studies to justify legalising medicinal cannabis,<sup>11</sup> when, for many years the United States governments refused all applications to conduct the very research which could provide the evidence which they claimed was lacking. It remains to be seen what, if any, policy changes will be made by the United States' Obama administration.

Although the United States' drug war czar General Barry McCaffery stated in August 1996 that '[t]here is not a shred of scientific evidence that shows that smoked marijuana is either useful or needed',<sup>12</sup> and the Drug Enforcement Administration (DEA) continues to claim that, 'Marijuana has no medical value that cannot be met more effectively by legal drugs',<sup>13</sup> its own Independent New Drug (IND) Compassionate Access Program, which has provided low-grade government-supplied medical marijuana to a select group of patients since 1978, 'would seem to affirm that marijuana has medical value and can be used safely.'<sup>14</sup>

A thoroughgoing and rigorous health study of four of the seven remaining 1978 IND patients concluded, *inter alia*:

1. Smoking, even of a crude, low-grade product, provides effective symptomatic relief of pain, muscular spasms and intraocular pressure elevations in selected patients failing other modes of treatment;
2. These clinical cannabis patients are able to reduce or eliminate other prescription medicines and their accompanying side effects.
3. Clinical cannabis provides an improved quality of life in these patients...<sup>15</sup>

Sixthly, and related to the fifth point is the oscillating presentation of evidence in the scientific literature, such that '[a]n initial apparently damning report was followed by a great deal of research that largely failed to support the initial claims.'<sup>16</sup> This can be demonstrated in relation to the issue of the role of cannabis, (in this case smoked cannabis), in the pathology of adolescent schizophrenia. Initial reports in 2002 drew mixed conclusions, such as 'cannabis use is associated with an increased risk of developing schizophrenia, consistent with a causal

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<sup>11</sup> US Department of Justice, Drug Enforcement Administration, 'Marijuana Scheduling Petition', 57 Federal Register 10499, 26 March 1992, 10506 <<http://www.us.doj.gov/dea/ongoing/marijuanap.html>> (accessed 2 June 2006).

<sup>12</sup> Drug Enforcement Administration, 'Exposing the Myth of Medical Marijuana: the Facts' <[www.justice.gov/dea/ongoing/marijuana.html](http://www.justice.gov/dea/ongoing/marijuana.html)> (accessed 2 June 2006).

<sup>13</sup> *Ibid.*

<sup>14</sup> E Russo et al, 'Chronic Cannabis Usage in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis' (2005) 2 *Journal of Cannabis Therapeutics* 1, 51.

<sup>15</sup> *Ibid.*

<sup>16</sup> Iversen, above n 2, 68.

relation’<sup>17</sup> compared with another study which found that ‘[t]here is no evidence that cannabis is a causal factor in schizophrenia.’<sup>18</sup> By 2005 the journal *Psychiatric Research* had reported that ‘the onset of schizotypal symptoms generally precedes the onset of cannabis use. The findings do not support a link between cannabis use and schizotypal traits.’<sup>19</sup>

### *The current state of evidence of the efficacy of medicinal cannabis*

Until recently it could fairly be claimed that there was not sufficient hard evidence to justify policy-makers to responsibly legalise medicinal cannabis.

However in the last twenty years there has been what one scientist has called an ‘explosion of scientific information on cannabis.’<sup>20</sup> He speaks of ‘thousands of researchers moving into the cannabinoid field ... and hundreds of presentations on cannabis every year’ and claims ‘[t]here is no reason to believe that the increase in scientific interest in cannabis will level off in the coming decade.’<sup>21</sup>

Nevertheless the value of cannabis as a medicine is still disputed. Whilst a major review by Zimmer and Morgan concluded that ‘marijuana’s therapeutic uses are well-documented in the modern scientific literature’<sup>22</sup>, another contemporaneous study claimed that:

The medicinal properties of cannabis are still mainly delineated by the anecdotal reports of those who believe their symptoms are relieved by its use and these accounts are often dismissed as wishful thinking or even mischievous.<sup>23</sup>

However it is submitted that no longer are the medicinal properties of cannabis still only delineated by anecdotal reports. In an expansive survey the United States lobby group Medical Marijuana ProCon’s publication<sup>24</sup> examined 29 studies divided into double blind human studies, other human studies and animal studies, assessing these as either pro cannabis or anti cannabis. Among the double blind papers 46.7% were pro cannabis, 40% were neutral

<sup>17</sup> S Zammit and P Allebek, ‘Cannabis Use is a Risk Factor for Schizophrenia’ (2002) 325 *British Medical Journal*, 1199.

<sup>18</sup> A Johns, ‘Psychiatric Effects of Cannabis’ (2001) 178 *British Journal of Psychiatry* 116 – 122, 119.

<sup>19</sup> J Schiffman et al, ‘Symptoms of Schizotypy Precede Cannabis Use’ (2005) *Psychiatric Research* 134 (1) 37, 42.

<sup>20</sup> P Smith, *Cannabis on the Brain* (2002) 9.

<sup>21</sup> Ibid.

<sup>22</sup> L Zimmer and J Morgan, *Marijuana Myths, Marijuana Facts* (2002) 127.

<sup>23</sup> Smith, above n 20.

<sup>24</sup> *Peer-Reviewed Scientific Studies involving cannabis and cannabis extracts 1990 –2008* Medical Marijuana ProCon.org, <<http://medicalmarijuana.procon.org/viewresource.asp?resourceID=884>> (accessed 5 September 2009).

and 13.3% con. In the other human studies, the respective percentages were 42.9% pro, 35.7% neutral and 21.4% con. The animal studies were 100% pro. The overall percentages across all the studies were 47.6% pro, 34.4% neutral and 18% con. While their assessments may be questioned as to the rating criteria used, the general trend of the studies was clearly substantially more favourable to a pro cannabis position than to a neutral or negative stance.<sup>25</sup> Since that study there have been several large collections of articles in books edited by Onaivi<sup>26</sup> and Guy et al.,<sup>27</sup> all of which are favourable to cannabinoid treatment.

So what does the current scientific literature tell us about the efficacy of cannabis? Adopting, for the sake of this exercise, the medical conditions and symptoms recommended by the NSW Working Party on the Use of Cannabis for Medical Purposes as being effectively treated with medicinal cannabis, the recent scientific evidence for its efficacy is presented here.

### *Chronic pain*

The conclusions drawn from the two exhaustive reviews of the literature on the analgesic properties of medicinal cannabis were highly favourable as to its efficacy. Walker et al. found that ‘...synthetic cannabinoids are equal to morphine in potency and efficacy...[and have] high efficacy...in models of chronic pain.’<sup>28</sup> Similarly Vaughan and Christie concluded that ‘cannabinoids warrant urgent study as therapeutic agents’.<sup>29</sup>

Two comprehensive review articles in 2006 both endorsed the value of medicinal cannabis as an analgesic,<sup>30</sup> the former quoting Blake et al.<sup>31</sup> who found that, ‘Sativex produced statistically significant improvements in pain on movement, pain at rest, quality of sleep and disease activities.’ The latter concluded:

<sup>25</sup> Ibid at 1.

<sup>26</sup> Onaivi, above n 10; E Onaivi (ed), *Marijuana and Cannabinoid Research: Methods and Protocols* (2006) and Grotenhermen in F Grotenhermen and E Russo (eds), *Cannabis and Cannabinoids: Pharmacology, Toxicology and Therapeutic Potential* (2005).

<sup>27</sup> G Guy et al, *The Medical Uses of Cannabis and Cannabinoids* (2004), and a comprehensive review by J Walker et al, ‘Pain Modulation by the Release of the Endogenous Cannabinoid Anandamide’ (1999) *Proceedings of the National Academy of Sciences (USA)* 96, 12198–12203.

<sup>28</sup> J Walker, above n 27, 12198–12203, and see J Walker J and S Huang ‘Cannabinoid Analgesia’ (2000) 95 (2) *Pharmacology and Therapeutics* 127–135.

<sup>29</sup> C Vaughan and J Macdonald, ‘Mechanisms of cannabinoid analgesia’, Chapter 5 in Grotenhermen and Russo, above n 26.

<sup>30</sup> P Pacher et al, ‘The Endocannabinoid System as an Emerging Target of Pharmacotherapy’ 58 *Pharmacology Review* 389–462, 405–407 and ben Amar M, above n 2, 9–11.

<sup>31</sup> D Blake et al, ‘Preliminary Assessment of the Efficacy, Tolerability and Safety of a Cannabis-based Medicine (Sativex) in the Treatment of Pain Caused by Rheumatoid Arthritis’ (2006) 45 *Rheumatology* 1, 50–52, 51.

to the extent that pain and inflammation accompany many of the disorders discussed in the rest of this review cannabinoids would be expected to provide significant benefits due to their analgesic and anti-inflammatory properties.<sup>32</sup>

A series of clinical trials run by GW Pharma and others demonstrated the superior efficacy of Sativex in treating neuropathic pain, concluding that, ‘these early studies have involved significant numbers of patients and their results have been positive with regard to relief of spasticity and pain.’<sup>33</sup> This was backed up by another specialist’s conclusion that, ‘these early studies have involved significant numbers of patients and the results have been positive with regard to relief from spasticity and relief of pain.’<sup>34</sup>

Finally a review of 134 studies in late 2006 led its author to conclude:

there is an overwhelming body of research ... supported by a vast number of recent laboratory studies on animal and human models to demonstrate the increased tolerance of pain from administration of cannabis or individual cannabinoids including THC.<sup>35</sup>

### *Nausea*

Nissar Darmani, a researcher who has contributed significantly to research into the use of cannabinoids in treating nausea, sums up the dominant current scientific view that ‘significant evidence supports the selective use of ... cannabinoids for the treatment of nausea and vomiting in some patients treated with chemotherapy.’<sup>36</sup>

He goes on to report:

a recent MEDLINE search yielded 194 titles on the anti-emetic properties of marijuana and cannabinoids. This list suggests that delta 9 THC is a useful anti-emetic for nausea and vomiting associated with cancer chemotherapy.<sup>37</sup>

Similarly, Robson states that ‘Cannabis and THC are very effective appetite stimulants.’<sup>38</sup>

<sup>32</sup> Pacher, above n 30, 407.

<sup>33</sup> M Barnes, ‘Sativex: Clinical Efficacy and Tolerability in Treatment of Symptoms of Multiple Sclerosis and Neuropathic Pain’ (2006) 7 *Expert opinion of Pharmacotherapy* 5, 607–615, 614; J Perez, ‘Combined Cannabinoid Therapy via an Oromucosal Spray’ (2006) 42 *Drugs of Today* 8, 495–503, and D Wade et al. ‘Long Term Use of a Cannabis Based Medicine in the Treatment of Spasticity and Other Symptoms in Multiple Sclerosis’ (2006) 12 *Multiple Sclerosis* 639–645, 644.

<sup>34</sup> Barnes, above n 33, 614.

<sup>35</sup> M Atha, *Cannabis and Pain Relief: a Literature Review* (2006) London UK, Independent Drug Monitoring Unit, <<http://www.idmu.co.uk/>> (accessed 1 May 2007).

<sup>36</sup> N Darmani, ‘Anti-emetic Action of Deltahydrocannabinoid and Synthetic Cannabinoids in Chemo-Therapy Induced Nausea and Vomiting’ Chapter 5 in Onaivi, above n 10.

<sup>37</sup> Ibid 3.

<sup>38</sup> P Robson, ‘Cannabis and RHC are Effective Appetite Stimulants. Therapeutic aAspects of Cannabis and Cannabinoids’ (2001) 178 *British Journal of Psychiatry*, 107–115, 110.

In ben Amar's compendious review of the therapeutic potential of medicinal cannabis and its synthetic analogues, he lists 31 studies of its use as an anti-emetic, of which 29 were assessed as significantly superior to placebo or other drugs.<sup>39</sup> The other literature review in 2006 concluded that, 'THC (delta9tetrahydrocannabinol) has gained acceptance as a highly efficacious therapeutic agent, often effective in cases resistant to other more conventional medications.'<sup>40</sup>

### *Spasticity*

While there have been fewer studies of multiple sclerosis focussing on spasticity rather than neuropathic pain, by 2006 three teams of researchers were advocating cannabinoids for the treatment of spasticity. One stated:

In conclusion, controlled clinical trials with cannabinoids have demonstrated their efficacy in eliciting symptomatic improvements in MS patients. These results suggest that there is place for the use of cannabis in the treatment of MS, which should be confirmed in further larger-scale clinical trials.<sup>41</sup>

The second study found:

[t]here is a compelling neuropharmacological rationale to support the use of CBM [cannabis based medicines] in the relief of spasticity in multiple sclerosis with evidence from both human and animal studies.<sup>42</sup>

The third study concluded that earlier trials had 'involved significant numbers of patients and the results have been positive with regard to the relief of spasticity and relief of pain.'<sup>43</sup>

### *Appetite and wasting*

Cancer and HIV/AIDS patients are prone to cachexia, wasting and loss of appetite. It is notorious among herbal recreational cannabis users that the herb stimulates appetite and hence it was to be expected that a 1986 study found that, '[s]moked marijuana can produce significant increases in food intake....'<sup>44</sup> Two more studies using THC found that it stimulates

<sup>39</sup> ben Amar above n 2 .

<sup>40</sup> Pacher, above n 30, 420.

<sup>41</sup> Ibid 398.

<sup>42</sup> C Collin et al, 'Randomised control trial of cannabis based medicines in spasticity caused by multiple sclerosis' (2007), 14 *European Journal of Neurology* 3, 290–296, 296.

<sup>43</sup> Barnes, above n 33, 614.

<sup>44</sup> R W Foltin et al, 'Behavioural Analysis of Marijuana Effects on Food Intake in Humans' (1986) *Pharmacology, Biochemistry Behaviour* 25(3) 577.

appetite associated with cancer and HIV/AIDS.<sup>45</sup> More recent studies with THC have confirmed the earlier conclusions.<sup>46</sup> In a more recent literature review of seventy-two controlled studies, the conclusion reached was that:

cannabinoids exhibit an interesting therapeutic potential as anti-emetics and appetite stimulants in debilitating diseases (cancer and AIDS), analgesia, as well as in the treatment of multiple sclerosis, spinal cord injuries, Tourette's syndrome, epilepsy and glaucoma.<sup>47</sup>

### *Neurological disorders*

This category of serious medical conditions includes Multiple Sclerosis, Motor Neuron Disease, Parkinson's Disease and Tourette's Syndrome and has been researched using Sativex and several of the synthetic cannabinoids. Recently Pacher et al.<sup>48</sup> in an extensive review of multiple sclerosis cited 24 studies of multiple sclerosis patients, 19 of which produced positive results. Two of these studies<sup>49</sup> employed Sativex and one used Cannador.<sup>50</sup> Two of those three reported improvement in spasticity and pain relief. Plant-derived cannabinoids, in a series of clinical trials conducted by Muller-Vahl on Tourettes patients, were found to be effective in treating tics and behavioural problems.<sup>51</sup> Another extensive review of 135 research studies concluded that '[s]ince 1998 scientific investigation of the effects and causes of cannabinoid action on multiple sclerosis has exploded with the vast majority of studies and reviews showing a potential therapeutic effect.'<sup>52</sup> It should be noted that multiple sclerosis is accepted by the United Kingdom, Canada and several United States states as a medical

<sup>45</sup> L Hollister, 'Hunger and Appetite After Single Doses of Marijuana, Alcohol and Dextroamphetamine' (1971) 12 *Clin Pharmacol Ther* Jan-Feb (1) 44–49 and E Regelson et al, *The Pharmacology of Marihuana* (1976).

<sup>46</sup> See J Beal et al, 'Dronabinol as a Treatment for Anorexia Associated with Weight Loss in Patients with AIDS' (1995) Feb 10(2) *J of Pain and Symptom Management*, 89–97.

<sup>47</sup> Smith above n 20, 12.

<sup>48</sup> Pacher, above n 30.

<sup>49</sup> Killestein et al, 'Cannabinoids in Multiple Sclerosis: Urgent Need for Long Term Trials' (2002) 58 *Neurology*, 1404–1407 and D Wade et al, 'A Preliminary Controlled Study to determine whether whole plant cannabis extracts can improve intractable neurogenic symptoms' (2003) 17(2) *Clin Rehabil* 21–29.

<sup>50</sup> J Zajicek et al, 'Cannabinoids for Treatment of Spasticity and Other Symptoms Relating to Multiple Sclerosis' (2003) 362 *The Lancet* 9395, 1517–1526.

<sup>51</sup> K Muller-Vahl et al, 'Gilles de la Tourette Syndrome: Effect of Nicotine, Alcohol and Marihuana on Clinical Symptoms' (1997) 68 *Nervenarzt* Dec (12), 985–989; K Muller-Vahl et al, 'Cannabinoids Possible Role in Pathophysiology and Therapy of Gilles de la Tourette Syndrome' (1998) 98 *Acta Psychiatrica Scandinavica* (6) 502–506; K Muller-Vahl et al, 'Treatment of Tourettes Syndrome with delta9tetrahydrocannabinol' (1999) 35 *Pharmacopsychiatry*, 57–61; K Muller-Vahl et al, 'Delta9tetrahydrocannabinol (THC) is Effective in the Treatment of Tics in Tourette syndrome' (2003) 64 *J of Clinl Psychiatry* (4), 459–465; K Muller-Vahl et al. 'Treatment of Tourette's Syndrome with delta9tetrahydrocannabinol (delta9 THC): No Influence on Neuropsychological Performance' (2003) *Neuropsychopharmacology*, 384–388.

<sup>52</sup> Atha, above n 35.

condition warranting the prescription of medicinal cannabis.under those jurisdictions’ medical marijuana laws.

### *The issues of tolerance and dependence*

The mechanics of ascertaining tolerance and dependence are explored in some detail in Chapter 7.2. The concepts are raised here as they obviously relate to the efficacy of medicinal cannabis. In Chapter 7.2 I raise concerns that the interpretation of test results of tolerance and dependence may be distorted by the researchers’ policy objective of persuading government to set up cannabis clinics to treat ‘dependent’ cannabis users. However, even the most enthusiastic acolytes of the dependence hypothesis acknowledge that, ‘it is uncertain whether the risk of dependence in regular recreational users can be applied to patients using cannabinoids for therapeutic reasons.’<sup>53</sup>

As to tolerance they concede that ‘some reports indicate that patients achieve stabilization of dose and persistence of therapeutic benefit.’<sup>54</sup> Former concerns regarding the long term effects of the use of Sativex were allayed by the findings of Wade et al. that, ‘[S]ativex can be used in the long term without tolerance or intoxication and with maintenance of subjective symptomatic relief.’<sup>55</sup>

More recently, several studies of the use in treatment of Sativex have failed to find significant tolerance or dependence among patient groups. In a long term study of 404 multiple sclerosis or chronic pain patients, ‘[p]atients treated for one year had sustained improvements in symptom scores, with no evidence of treatment tolerance.’<sup>56</sup> Although 46% of these patients exhibited some symptoms of withdrawal they did not meet the criteria which would warrant their characterisation as withdrawing from cannabinoids.<sup>57</sup>

<sup>53</sup> W Swift and W Hall, ‘Cannabis and Dependence’, Chapter 23 in Grotenhermen and Russo, above n. 26, 263.

<sup>54</sup> Ibid.

<sup>55</sup> Wade, above n 33, 644.

<sup>56</sup> Perez, above n 33, 500.

<sup>57</sup> M Serpell et al, ‘Sativex in the Treatment of Pain of Neurological Origins or Symptoms of Multiple Sclerosis’ (2005) *24<sup>th</sup> Annual Sci Society Meeting*, Boston USA Abstract 722 and Serpell et al, ‘Sativex for the Treatment of Pain of Neurological Origin or Symptoms of Multiple Sclerosis’, *8<sup>th</sup> Congress of the European Federation of Neurological science*, Paris, France Abstract 1431.

There is now further available data on the long term effects of Sativex, as recently several studies into the uses of Sativex have failed to find significant tolerance or dependence among patient groups.<sup>58</sup>

### *The different cannabis-based pharmaceuticals*

By one count, there are 27 different cannabis-based pharmaceuticals available around the world.<sup>59</sup> However in this thesis I have only advocated one – Sativex. This preference is based on an evidence-based judgement that Sativex has proved superior in efficacy over the other cannabinoid formulations.

The two earliest cannabis-based medicines are Dronabinol marketed by Solvay Pharmaceuticals in the USA under the name Marinol and Nabilone, produced by the United States' Valeant Pharmaceuticals and marketed as Cesamet. While these medicines have had some success in the treatment of weight loss and as anti-emetics, and Marinol has shown some promise in some neurological conditions, in general their efficacy is low and their price high. The Los Angeles Cannabis Resource Center has estimated that the cost of one year's treatment using Marinol would amount to \$US8.260.<sup>60</sup> Excessive cost is also the reason it is not widely prescribed in Australia.<sup>61</sup>

Another North American synthetic cannabinoid – Cannador – which contains other cannabinoids has been trialled for the treatment of neurological disorders but without much success.<sup>62</sup> Rimonabant is a cannabinoid receptor agonist used to treat obesity but its

<sup>58</sup> A Budney et al, 'Review of the Validity and Significance of Cannabis Withdrawal Syndrome (2004) 161 *American Journal of Psychiatry*, 1967–1977; E Russo and P Robson, 'Abrupt Interruption of Long-term Treatment with Sativex Was Not Associated with a Withdrawal Syndrome' *XV Symposium on the Cannabinoids*, Clearwater 2005, Abst 45; E Russo, 'Sativex and Tolerance: Sativex Cannabis-based Medicine Provides Long-term Clinical Efficacy Without Dosage Increases or Withdrawal' *American Public Health Association 133<sup>rd</sup> Annual Meeting and Exposition*, Philadelphia 2005, Abst. 106317. 'The existence of a clear-cut physical dependence syndrome is much less convincing on the basis of the published literature. If it exists at all it is probably mild and fleeting ...'; Guy, above n 27, 252. In a long term study of 404 MS and chronic pain patients, 'Patients treated for one year had sustained improvements in symptoms ... with no evidence of treatment tolerance' (J Perez, above n 33500). As to safety, '[c]annabis has an exceptional record of safety' (L Grinspoon and J Bakalar, *Marihuana the Forbidden Medicine* (1997). 'It is virtually impossible to kill animals with acute doses and there are no substantiated deaths from ingestion of cannabis.' (Guy, above n 27.)

<sup>59</sup> Pacher, above n 30, 441.

<sup>60</sup> K Zwier and J Ahrens, *Calvin College, Chimes*, Michigan (2005) V 100 (7)  
<<http://www.cannabisnews.com/thread21214.shtml>> (accessed 6 October 2008).

<sup>61</sup> M Kyriagis, 'Just what the doctor ordered?' (1997) 20 *University of New South Wales Law Journal*, 594.

<sup>62</sup> E Russo and G Guy, 'A Tale of Two Cannabinoids' (2006) 66 *Medical Hypotheses* 234–246,239.

manufacturers were denied approval by the Food and Drug Administration to market in the United States due to neurological side effects.<sup>63</sup>

The results of comparative tests of other cannabinoid medicines show the consistent efficacy of Sativex over other cannabis-based pharmaceuticals<sup>64</sup> in the treatment of a range of conditions. Both Russo et al.<sup>65</sup> and McCarberg and Barkin maintain that this is due to its different formulation in containing almost equal parts of THC and cannabidiol, the latter researchers concluding that, ‘the interaction of THC with CBD appears to improve the risk/benefit profile of a THC-containing cannabinoid product.’<sup>66</sup>

But what distinguishes Sativex from these other products is its success in ongoing clinical trials and its unique formulation which balances the psychoactivity of delta 9 THC with the non-psychoactive cannabidiol. However, it is to be hoped that eventually an Australian cannabis-based pharmaceutical will be available to Australian patients.

The efficacy of medicinal cannabis in the treatment of the medical conditions examined in this chapter are only those for which there is a substantial and/or growing body of evidence in support of efficacy. However there are many more conditions for which medicinal cannabis has been successfully used though there is as yet insufficient evidence to satisfactorily claim efficacy. These include (in no particular order) cachexia, anorexia, neurotoxicity, stroke, neurotrauma, Parkinson’s disease, Tourettes syndrome, Huntington’s disease, amyotrophic lateral sclerosis, epilepsy, schizophrenia, anxiety, depression, insomnia, nausea, emesis, opiate, nicotine, cocaine and alcohol addiction, hypertension, circulatory shock, myocardial reperfusion injury, atherosclerosis, asthma, glaucoma, retinopathy, cancer, inflammatory bowel disease, hepatitis, liver cirrhosis, arthritis, and osteoporosis.<sup>67</sup>

Many states of the United States with medical marijuana laws include a provision to include new qualifying conditions as the evidence to support their inclusion grows. *the New South Wales Parliamentary Inquiry into the use of cannabis for medical purposes Report on*

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<sup>63</sup> United States Federal Drugs Administration 2007  
<[http://en.sanofi-aventis.com/Images/20070613\\_Rimonabant\\_AD\\_Comm\\_EN\\_tcm24-16868.pdf](http://en.sanofi-aventis.com/Images/20070613_Rimonabant_AD_Comm_EN_tcm24-16868.pdf)> (accessed 6 October 2008).

<sup>64</sup> eg see Russo, above n 14, 1734–1735 and 1738–1739.

<sup>65</sup> McCarberg and Barkin, ‘The Future of Cannabinoids as Analgesic Agents’ (2007) 14 *American Journal of Therapeutics* 5, 475–483, 480.

<sup>66</sup> Ibid.

*Consultation on the findings and recommendations of the Working Party on the use of Cannabinoids for Medical Purposes* recommended that, ‘as this list [of approved conditions] may need to be amended in the light of further medical research, it should be specified by regulation rather than by primary legislation.’<sup>68</sup>

### *Adverse effects*

It would be remiss not to include, in this review of efficacy, reports of the adverse effects of medicinal cannabis. A recent Canadian study which reviewed the medicinal cannabis literature found 31 relevant studies which collectively reported 4779 adverse effects of which 4615 (99.6%) were not serious. Of the 164 serious adverse events, the most common were relapse of multiple sclerosis, (12.8%) and vomiting (9.8%). The authors concluded that short term medicinal cannabis use increased the risk of non-serious adverse events. Long term medicinal cannabis use risks were ‘poorly characterized’ and they urged more research trials to address safety concerns.<sup>69</sup>

The rates of non-serious adverse events were higher in the group taking medicinal cannabis than in the control group but there was no significant difference between the two groups as to the rate of serious adverse events.<sup>70</sup> In a response to this review, Degenhardt and Hall raise the issue of a possible association between cannabis use and psychosis. However they point out that the evidence for this association comes from recreational users and, ‘there are currently no data on the extent of risk for psychotic symptoms among medical users. ...’<sup>71</sup>

They conclude that:

the findings of Wang and colleagues’ review suggest that, based on the current data, the risk of adverse events associated with short term medical use of cannabinoids and cannabis extracts are minor.<sup>72</sup>

<sup>67</sup> Pacher, above n 30, 389–390.

<sup>68</sup> ‘Report of the Working Party on the Use of Cannabis for Medical Purposes’, vol II, Main Report, Office of Drug Policy, New South Wales Government, August 2000, 39.

<sup>69</sup> T Wang et al, ‘Adverse Effects of Medicinal Cannabinoids: a Systematic Review’ (2008) 178 *Canadian Medical Association Journal* (3) 1669–1678, 1669.

<sup>70</sup> Ibid 1669.

<sup>71</sup> L Degenhardt and W Hall, ‘The Adverse Effects of Cannabinoids: Implications For Use of Medical Marijuana’ (2008) 178 *Canadian Medical Association Journal*.

<sup>72</sup> Ibid.

## Conclusion

On 13 December 2007 the British drug regulatory agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), published a Public Information Report on Sativex which contains an Experts' Report stating:

More than 1200 patients have been prescribed Sativex in the UK. In a recent postal survey of UK physicians who have prescribed Sativex to at least two of their patients, 80% of physicians indicated that Sativex provided useful clinical benefits to their patients and 88% regarded Sativex as a useful addition to their therapeutic options.

A carefully constructed questionnaire was also sent to patients who have been receiving Sativex over a period of at least one year. The results of this questionnaire confirm that relevant functional improvements are being achieved, and these improvements are independently confirmed by their carers. A remarkable 19% of patients report a reduced need for either supportive equipment or specific assistance to improve their mobility. 94% of respondents report an improvement in general life benefits from the improvement they have experienced on Sativex. These reports are exactly what doctors rely on when assessing the clinical relevance of treatments for spasticity, and indicate that Sativex does produce relevant benefits and functional improvements. A notable 71% of carers report that night-time care of the patient is less burdensome.

In summary, we note that all the elements which are required to conclude that Sativex is providing worthwhile clinical benefit at low risk are present in the data we have seen. Controlled clinical trials show statistical significance, and analyses of the improvement seen, especially in responders, show clear evidence of clinical relevance. Long-term use confirms maintenance of the treatment effect without the emergence of new adverse events, and with no evidence of tolerance. Questionnaire responses confirm that independence is improved in long term use, a view expressed by patients and confirmed by carers. Prescribers overwhelmingly agree that Sativex provides them with a valuable treatment option. We conclude that Sativex meets a currently unmet medical need in patients where there is no other conservative treatment option. It is our view that Sativex should be licensed and become available on prescription for patients with spasticity due to multiple sclerosis, and we urge the Medicines and Healthcare Products Regulatory Agency (MHRA) to do so.<sup>73</sup>

Given that this favourable evidence comes in addition to the support for medicinal cannabis' efficacy by the United States National Institute of Medicine<sup>74</sup> and the British Medical Association<sup>75</sup> it is submitted that, 'The case for relaxing current regulations to make cannabis and cannabis-based medicines more widely available to patients who want them seems overwhelming.'<sup>76</sup>

<sup>73</sup> United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), *Public Information Report on Sativex*, Ministry of Health, 2007.

<sup>74</sup> J Joy, *Marijuana and Medicine: Assessing the Science Base* (1999), Executive Summary at 10.

<sup>75</sup> British Medical Association, *Therapeutic Uses of Cannabis* (1997) 78–79 and the Australian Medical Association 79 Australian Medical Association, *Report on Consultation on the Use of Cannabis for Medical Purposes*, Office of Drug Policy, NSW Government, July 2001, 2.

<sup>76</sup> Iversen, above n 2, 264.

## 2.2 *The medicinal cannabis constituency*

Realistically it could only be expected that politicians would be motivated to introduce medicinal cannabis legislation if they were convinced that a sufficiently significant constituency of electors wanted it.

However this presents a dilemma for researchers attempting to establish whether or not such a constituency exists due to the current illegality of medicinal cannabis use in NSW. This prohibition means that any patient admitting to its use is also confessing to breaking the law.

Consequently it is mainly the brave and the desperate who are prepared to volunteer their medicinal cannabis use, leaving an unknown and possibly unknowable cohort of clandestine current users. Nevertheless it is a testament to their courage on this issue that so many have been prepared to admit to their medicinal cannabis use in the surveys so far conducted in NSW.<sup>77</sup>

Given the current illegality of medicinal cannabis in Australia it is difficult to accurately estimate the number of potential legal medicinal cannabis users in NSW.

In a Canadian nationwide telephone survey 1.9% of respondents reported medicinal cannabis use in the previous year,<sup>78</sup> whilst a Health Canada poll reported 4% of the Canadian population over 15 used cannabis for medical purposes without government permission.<sup>79</sup>

In those thirteen states, as of June 2009, of the United States where cannabis has been legalised for medicinal use, the proportions of those states' populations who have registered to use medicinal cannabis range from 3.2 registered medicinal cannabis patients per 100,000 general population in Colorado to 79 in Oregon.<sup>80</sup> However these figures are drawn from only five states which, as of 2003, had mandatory registration requirements for medicinal cannabis

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<sup>77</sup> P Didcott et al, *Long Term Cannabis Use on the New South Wales North Coast*, Sydney Australia, National Drug and Alcohol Research Centre Monograph No. 30, 1996; G Irvine and A Kavasilas, *A Survey of Medicinal Cannabis Users* Nimbin, Australia, Medical Cannabis Information Service 2002; and W Swift et al, *Survey of Australians Using Cannabis for Medical Purposes* (2005) Sydney, Australia National Drug and Alcohol Research Centre.

<sup>78</sup> A C Ogbourne et al, 'Self-reported Medical Use of Marijuana: a Survey of the General Population' [2000] *Canadian Medical Association Journal* 162(2),1685–1686.

<sup>79</sup> 'Most 'medical' cannabis use illegal', *Ottawa Citizen* 2002.

<sup>80</sup> D Gieringer, 'The Acceptance of Medical Marijuana in the United States' (2003) 3(1) *Journal of Cannabis Therapeutics* 53.

users. Up until 2003, the figures for states without mandatory registration programmes included 89 patients per 100,000 population in California, 45–51 in British Columbia, Canada and 39 in Washington state.<sup>81</sup>

All jurisdictions with a legal medicinal cannabis system have recorded successive annual increases in numbers. In Canada for example, medicinal marihuana registrants' numbers rose from 1807 in September 2005 to 2854 in September 2006 and in Oregon registrations in the state-run medical marijuana scheme rose from 1,691 in February 2002 to 19,646 on January 1, 2008.<sup>82</sup> However there is reason to believe that such numbers seriously underestimate the real size of the medicinal cannabis constituency in NSW. Statistics from the 1999 National Marijuana Strategy reveal that some 70% of the national and NSW populations have at some time used cannabis for any purpose.<sup>83</sup>

Although other evidence indicates that most of these cannabis consumers were reporting recreational smoking of the drug, results from the 1995 the National Drug and Alcohol Research Centre (NDARC) survey of NSW North Coast long term cannabis users showed that 73% of women and 56% of men in their sample had used cannabis for medical purposes.<sup>84</sup>

A figure of 16,000 potential medicinal cannabis users in NSW has been suggested, though Premier Carr doubted the number was that high. However this is discrepant with an earlier figure he gave of 27000.<sup>85</sup> Using data from NSW patient associations, Hall, Degenhardt and Curnow estimated in 2000 that:

The total estimate of about 19,000 (Box) [sic] is likely to be an upper limit on the number of medicinal cannabis users who would be eligible to receive medicinal cannabis under the NSW's Working Party on Medicinal Cannabis's recommendations.<sup>86</sup>

<sup>81</sup> Ibid 55, table 1.

<sup>82</sup> Canadian Office of Medical Marihuana website <[http://www.hc-sc.gc.ca/home\\_acceuil/contact/hecs\\_dgsesc/mma-amm-eng.php](http://www.hc-sc.gc.ca/home_acceuil/contact/hecs_dgsesc/mma-amm-eng.php)> and Oregon Medical Marihuana Program <<http://www.oregon.gov/DHS/ph/ommp/data.shtml>> (accessed 29 January 2007).

<sup>83</sup> National Drug Strategy Survey: first results, Australian Institute of Health and Welfare, 1999, (Drug Statistics Series; AIHW catalogue no. PHE15.) 5.

<sup>84</sup> Didcott, above n 77, 43.

<sup>85</sup> ABC 'Interview with Premier Bob Carr', *Lateline*, 20 May 2003, 10.30pm c.f. Premiers Department, NSW Government, 'Government to Consider Cannabis for Medicinal Purposes' (News release, 19 October 1999).

<sup>86</sup> W Hall, L Degenhardt and D Curnow, 'Allowing the Medical Use of Cannabis' (2001) 175 *Medical Journal of Australia* 39–40.

But the Hall et al. paper goes on to state that:

The number of people who would be permitted under these recommendations to use cannabis for medical purposes is less than 2.5% of the 820,000 NSW adults estimated to have used cannabis for non-medical purposes in 1998.<sup>87</sup>

However their figure does not appear to include multiple sclerosis patients who numbered 5,330 as at 30 June 2008<sup>88</sup> and even if they are correct in their estimate of 2.5% of the cannabis-using population in 1995, this still yields a figure in excess of 10,000.

My own enquiries revealed that, as well as multiple sclerosis patients, there were 34,227 people in NSW diagnosed with some form of cancer in 2005, with 37,550 estimated for 2007,<sup>89</sup> plus 221,602 patients alive who were diagnosed between 1980 and 2003.<sup>90</sup> Furthermore there were 14,814 NSW HIV/AIDS patients diagnosed in 2008 alone, excluding the 5,330 who died in 2008.<sup>91</sup> While Sativex would not be needed or useful in many of these cases, in many others it may be. Hence the estimates given for potential users of Sativex may be way too low.

Older United States studies of HIV/AIDS patient populations found that 46% of Alabaman patients were currently using medicinal cannabis in 1997,<sup>92</sup> and 37% of a Hawaiian cohort had at some time used medicinal cannabis to treat their conditions.<sup>93</sup>

Roughly extrapolating these figures to NSW yields the approximate numbers of current MS medicinal cannabis users as being almost 7,000. But this is likely to be a considerable underestimate of current NSW medicinal cannabis users because medicinal cannabis legislation has since been introduced to Hawaii and moreover, the two studies are over ten years old. Also, none of the above population estimates include the numbers of patients suffering from other serious conditions who would potentially be eligible to receive medicinal cannabis if it were to be legalised for such patients as those with motor neuron disease,

<sup>87</sup> Ibid.

<sup>88</sup> Telephone interview with Neil at Multiple Sclerosis Centre (Sydney, 30 June 2008).

<sup>89</sup> T Baker et al, 'Cancer in NSW: Incidence, Mortality and Prevalence Report' (2005) *Cancer Institute of NSW*, November 2005.

<sup>90</sup> Ibid 12.

<sup>91</sup> Telephone interview with Jessica, ACON (NSW Sydney, 30th June 2008).

<sup>92</sup> D Dansak, 'Medical Use of Recreational Drugs by AIDS Patients' (1997) 16(3) *Journal of Addictive Drugs* 25–30, 26.

<sup>93</sup> D Wesner, 'Marijuana Use in HIV Positive and AIDS Patients' (2001) 1 *Journal of Cannabis Therapeutics*, 3–4.

Tourette's syndrome and others. Above all, though, the above figures do not reflect the growth in absolute patient numbers since the cited studies were reported.

Such speculation concerning the numbers of medicinal cannabis users is strengthened by general population opinion polls which show a high level of support amongst the general public for the right to use cannabis medicinally in Canada, (93%),<sup>94</sup> and in Australia, where 68% support a change in legislation to permit cannabis use for medical purposes and 74% supported a clinical trial of medicinal cannabis.<sup>95</sup>

These figures are more consistent with the speculative numbers above than, for example, with the numbers of medicinal cannabis users registered in United States' and Canadian programs for several reasons.

Firstly, the likelihood is that many medicinal cannabis users do not register because the jurisdictions still allow for an affirmative defence for genuine medicinal users if they are charged; secondly, the cost, complexity and recurrent nature of the registration process is a deterrent; thirdly, unknown numbers refuse to register on principle as they see their use as a human and/or constitutional right to be allowed to protect their own health and fourthly, the published data reported above cover only the first few years of operation of the medical marijuana programs and numbers have substantially increased since then.<sup>96</sup>

Nevertheless, extrapolating from the numbers of registered medicinal cannabis users in US states with legal medicinal cannabis programs, where average percentages of 0.5% of the total population are users.<sup>97</sup> New South Wales could have thousands of patients in need of medicinal cannabis. But whatever the correct number, it is clearly big enough to still constitute a meaningful cohort in terms of public health policy in Australia.

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<sup>94</sup> M Harris, 'Most Canadians OK with Medicinal Marijuana: poll' (2006) *Ottawa Citizen* (2 November) 3.

<sup>95</sup> Welfare AloHa, 'National Drug Strategy, Household Survey: First Results' (2004) Canberra, Australian Institute of Health & Welfare, 5.

<sup>96</sup> Oregon Medical Marijuana Program, <<http://www.oregon.gov/DHS/ph/ommp/data.shtml>> (accessed 29 January 2007).

<sup>97</sup> Gieringer, above n 80, 15.

## 2.3 A preliminary comparative analysis of three surveys of medicinal cannabis use<sup>98</sup>

### *Introduction*

The purpose of this comparative analysis is to provide a further check on the validity and reliability of the data in the Medical Cannabis Information Service (MCIS) survey of medicinal cannabis users, referred to in the Introduction, by comparing its results with those of an overlapping cohort in the National Drug and Alcohol Research Centre (NDARC) survey, also mentioned in the Introduction, and again with a completely separate sample of British medicinal cannabis users.

This analysis compares and contrasts three sample surveys of the use of medicinal cannabis in several states of Australia and in the United Kingdom. Within the limitations of differences in sampling, questions asked and answer categories devised, the analysis explores commonalities between the studies with a view to making generalisations about populations of medicinal cannabis users in countries where the taking of medicinal cannabis is illegal. It is precisely because medicinal cannabis is illegal that it has been difficult until now to draw any firm conclusions about the nature of its users and so this analysis is intended as a preliminary attempt to characterise some of their attitudes and behaviour.

Comparisons and contrasts between some of the issues explored in the three data sets will be drawn, followed by a short conclusion and discussion section which will draw out implications for further research on the topic.

### *The surveys' methodologies*

All three samples were self-selected and their questionnaires self-administered. Both Australian studies' respondents were predominantly from New South Wales. In the National Drug and Alcohol Research Centre (NDARC) study, 57.8% were from NSW and in the Medicinal Cannabis Information Service (MCIS) study, 68.2 were from NSW. The UK sample drew on respondents from all over the United Kingdom. Sample sizes varied from 45

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<sup>98</sup> Swift n 77; Irvine and Kavasilas, above n 77, Paper presented to John Della Bosca, New South Wales Special Minister of State, 13 December 2002; M Ware et al, 'The Medicinal Use of Cannabis in the UK: Results of a Nationwide Survey' (2005) 59(3) *Int Clin Pract* 291.

(MCIS), to 128 (NDARC), to 2969 (UK). In the UK sample, only 947 had used cannabis medicinally at some time.

Respondent recruitment for NDARC was:

primarily ... from media stories conducted opportunistically between November 2003 and August 2004, in newspapers, on radio and television',<sup>99</sup> supplemented by publicity generated by the MCIS and 'several GPs who said they would inform certain patients of the study.'<sup>100</sup>

People responded by email or telephone, were screened by telephone and posted questionnaires with stamped, self-addressed envelopes for their return eliciting an 87.1% response rate.

The MCIS sample comprised existing medicinal cannabis users who had voluntarily written to the organisation to support its campaign for legalisation of medicinal cannabis who were posted stamped, self-addressed questionnaires and asked to return them completed. Although no count of the response rate was ever conducted, the Director of the MCIS, who sent out the questionnaires, recalls that almost all those sent questionnaires were returned, estimating a response rate of over 80%<sup>101</sup>

In the UK study, 'Patients were identified by word of mouth and through patients' support groups',<sup>102</sup> and questionnaires were posted to them with a stamped, self-addressed envelope for return. This process elicited an 81% response rate from 2969 volunteers. However, only 947 of these reported ever having used cannabis for medical purposes.

**Table 2.1 Response Rates (%)**

<b>National Drug &amp; Alcohol Research Centre (NDARC)</b>	<b>87.1</b>
<b>Medicinal Cannabis Information Service (MCIS)</b>	<b>c. 80</b>
<b>Ware et al (UK)</b>	<b>&gt;75</b>

<sup>99</sup> Swift, above n 98, bid 2.

<sup>100</sup> Ibid 7.

<sup>101</sup> Interview with Andrew Kavasilas, Medical Cannabis Information Service (Nimbin, 19 July 2005).

<sup>102</sup> Ware, above n 98, 292.

*Currency of use*

The eligibility criterion for inclusion in all three surveys was that respondents had used cannabis for medical purposes at some time in their life but a limitation to the usefulness of the data from all three was that no distinction in answers was made between those still using cannabis medicinally and those not. Nevertheless NDARC reported 85.2% still using, compared with MCIS = 95.5% and UK = 57.3%.

The UK survey gives a figure of 18.3% as still using medicinal cannabis but this figure is a percentage of the total sample, which includes ‘ever’ users and ‘never’ users, whereas the Australian surveys’ percentages are based on ‘ever’ users. Even so, the UK figure is significantly lower than that in the other surveys.

**Table 2.2 Currency of use (%)**

<b>NDARC</b>	<b>85.2</b>
<b>MCIS</b>	<b>95.5</b>
<b>UK</b>	<b>57.3</b>

*Demographics*

In terms of demographic features, the NDARC and MCIS samples were similar, with 62.5% and 63.6% being respectively male respondents, but for the UK only 46.4% were male. Whilst 30.5% of NDARC’s sample were over 50 years old, the figures for MCIS and UK were 37.7% and 40%. For those 60 and over the figures were NDARC 9.4%, MCIS 8.8% and UK 11%.

**Table 2.3 Demographics (%)**

	<b>Males</b>	<b>Age 50+</b>	<b>Age 60+</b>
<b>NDARC</b>	<b>62.5</b>	<b>30.5</b>	<b>9.4</b>
<b>MCIS</b>	<b>63.6</b>	<b>37.7</b>	<b>8.8</b>
<b>UK</b>	<b>46.4</b>	<b>40.0</b>	<b>11.0</b>

### *Patients' reported medical conditions*

Each of the surveys included different medical conditions as answer categories in their questions on patients' medical conditions. The MCIS survey merely asked what conditions the respondent had been diagnosed with rather than which they had treated with cannabis. The most frequently reported medical conditions were similar in ranking for the Australian surveys, though the overall percentages clearly differed, for example depression, NDARC = 56% compared to MCIS = 42.2% and chronic pain, 57% compared to 44.4%, though other less frequently reported conditions scored much the same, for example arthritis 35% (NDARC) compared to 35.5% (MCIS); migraine, 21.9% (NDARC) compared to 22.2% (MCIS); weight loss, 21.1% (NDARC) compared to 20% (MCIS); persistent nausea, 19.5% (NDARC) compared to 20% (MCIS). Though the UK's list of conditions was much longer than the others, chronic pain, depression, arthritis and migraine were again the most frequently reported conditions. Unfortunately, lack of data and lack of congruity between the surveys make it difficult to extrapolate more detailed and accurate information comparing the reported medical conditions of respondents and which of those they were currently treating with cannabis.

**Table 2.4 Reported medical conditions (%)**

	Depression	Chronic pain	Arthritis	Migraine	Nausea	Multiple sclerosis
NDARC	60.2	53.1	37.5	21.9	19.5	–
MCIS	42.2	44.4	35.5	22.2	20.0	10.7
UK	8.0	11.0	7.2	3.5	–	11.6

### *Duration of use*

Duration of use was generally similar in the Australian samples, though the MCIS inclusion of non-numerical answers, for example 'many years' or 'years' probably contributed to the large difference between the 20+ years category, where 21.11% (NDARC) compared to 6.6% (MCIS) and the 6–10 years category, 20.3% (NDARC) compared to 13.3% (MCIS). The UK study unaccountably did not report overall duration of cannabis use but did give median durations of use for individual conditions, ranging from two years for respondents with genitourinary conditions to 9.5 years for spinal paralysis patients, with most conditions reporting 4+ years of use.

**Table 2.5 Duration of use (%)**

	< 1 yr	1–5 yrs	6–10 yrs	11–15 yrs	16–20 yrs	>20 yrs
NDARC	12	27	20	9	10	21
MCIS	8.8	35	15	15	12.5	7.5*
UK	–	–	–	–	–	–

\* When the responses ‘years’ and ‘many years’ are added, this totals 22.5%

### *Frequency of use*

The NDARC and MCIS frequency of use results were remarkably similar, for example users in the ‘several times a day’ category were 38.9% and 37.7% respectively. The UK data did not include this category. In the ‘6–7 days a week’ category the responses were 23.8% , 37.7% and 35% respectively for the NDARC, MCIS and UK studies.

**Table 2.6 Frequency of use (%)**

	>Daily	Daily	3–5 days p wk	1–2 days p wk	< Weekly	As required + other
NDARC	39	24	14	2	4	20
MCIS	36.9	23.9	15.2	4.6	4.6	17.4
UK	–	35	23	15	8	19

### *Usual routes or modes of administration*

Usual routes or modes of administration were similar in the NDARC and UK samples, with ‘eating’ accounting for 48.8% and 43% respectively but it is speculated that there were special factors influencing the MCIS figure of 91.1%. However these results are not directly comparable because the question asked of the NDARC respondents was: ‘In what form have you usually taken cannabis for medical purposes? (*please tick **one** only*)’, whereas the MCIS question was, ‘In what ways have you taken cannabis?’ and respondents were not restricted to one response category. It is not recorded what question the UK respondents were asked but it is obvious from the percentage responses that multiple responses were permitted.

**Table 2.7 Usual administration methods (%)**

	<b>Eat</b>	<b>Joint</b>	<b>Chillum</b>	<b>Bong</b>	<b>Tea</b>	<b>Vaporiser</b>
<b>NDARC</b>	16	31	10	33	2	6
<b>MCIS</b>	33.3	25.6*	–	21.5	6.6	5
<b>UK</b>	43	82	–	–	28	–

\* includes dry pipes, (chillums)

### *Overall effects of cannabis*

The overall effects of cannabis were comparable between all three surveys, for example ‘great relief’ was reported by 85.8% in the NDARC study, 77.2% in the MCIS study and 68% in the UK study. However it should be noted that the UK answer categories differed in speaking of ‘much/a little better/worse’. It is also salutary to note that, as all three surveys achieved a high response rate there may be grounds for surmising a highly motivated sample which might bias results concerning the efficacy of cannabis by exaggerating its effectiveness and minimising its adverse effects.

**Table 2.8 Overall effectiveness of medicinal cannabis (%)**

	<b>Much better/great relief</b>	<b>A bit better/a little relief</b>	<b>No difference</b>	<b>Worse</b>
<b>NDARC</b>	86	14	0	0
<b>MCIS</b>	77.3	20.5	0	0
<b>UK</b>	68	27	4	0.8

### *Comparative side effects of cannabis and other medications*

Results on the comparison of the undesirable effects of cannabis and other medications were broadly similar and the form of the answer categories was the same, for example for ‘cannabis produced much worse effects than other medications’ responses were; NDARC 0.8%, MCIS 1.6% and UK 0.6%; for ‘other medications produced much worse effects than cannabis’ responses were 40.8%, 27.4% and 34% respectively though the UK study had no category of ‘I have no undesirable effects from cannabis’. In the NDARC and MCIS studies the responses to this question were 31.2% and 37% respectively. For the return of symptoms following discontinuance of cannabis the responses were 71% NDARC and 76.8% for MCIS.

**Table 2.9 Comparative Side Effects of Cannabis and Other Medications (%)**

	Cannabis much worse	Cannabis somewhat worse	Same	Others somewhat worse	Others much worse	No bad effects from cannabis
NDARC	1	2	8	16	41	31
MCIS	1.6	0	3.2	24.2	27.4	37
UK	0.6	2.6	6.2	30.0	34.0	–

### *Comparative effectiveness of medicinal cannabis and other medications*

Comparison of the relief provided by cannabis and other medicines is very noteworthy as the questions asked in all three surveys were very similar, and with the exception of the dosage variable, the effect of the medication as a parameter of whether or not medicinal cannabis is needed by some patients is relatively standard across these populations and cultures. For example, for ‘other medicines work much better than cannabis’ responses were 2.5% (NDARC), 4.3% (MCIS) and 0.9% (UK). For ‘cannabis works much better than other medicines’ responses were 54.2% (NDARC), 63% (MCIS) and 45% (UK), though the UK did not include this category, ‘only cannabis gives me relief from my condition’ for which the responses were 15.3% (NDARC) and 15.2% (MCIS).

**Table 2.10: Comparative effectiveness of medicinal cannabis and other medications (%)**

	Others much better	Others a bit better	Same	Cannabis a bit better	Cannabis much better	Only cannabis effective
NDARC	3	3	9	13	54	15
MCIS	4.3	2.2	2.2	13	63	15.2
UK	1	2	5	28	45	–

### *Respondents’ concerns*

In the Australian surveys there was a similar high level of concern among patients about the illegal status of cannabis, even though the question asked was different. NDARC asked, ‘Have you ever felt concerned about your use of cannabis for medical reasons?’, with answer categories of ‘no/its illegal status/possible health effects/risk of dependence/cost/other.’ MCIS asked the question directly – ‘Are you concerned about the illegal status of cannabis?’. Both the NDARC and MCIS samples were asked, ‘Do you worry about being arrested?’, and the

responses were NDARC 59.8% ‘Yes’ and MCIS 57.7% ‘Yes’. No such question was asked in the UK survey.

The other set of attitudinal questions asked by NDARC and MCIS showed the MCIS sample to be considerably more in favour of the provision of medicinal cannabis to patients in all the asked circumstances, eg for those without a consistent supply = NDARC 75% c.f. MCIS 88.8%; to those incapable of growing cannabis = 71.9% c.f. 86.6%. Such questions were not asked of the UK sample.

### *Support for medicinal cannabis use*

The great majority of respondents in the Australian surveys had told health workers, family and friends about their use of medicinal cannabis and the great majority of those told were supportive.

**Table 2.11 Support for medicinal cannabis use (%)**

	<b>General Practitioners</b>	<b>Specialists</b>	<b>Nurses</b>	<b>Family and friends</b>
<b>NDARC</b>	<b>75</b>	<b>74</b>	<b>81</b>	<b>71</b>
<b>MCIS</b>	<b>86.8</b>	<b>92.5</b>	<b>83.3</b>	<b>72.9</b>
<b>UK</b>	–	–	–	–

Recreational use in the Australian samples was similar – ‘ever used recreationally’. Responses were 79.7% (NDARC) compared to 82.2% (MCIS), with the UK reporting 56.9% and recreational use in the last year was 54.3% (NDARC) and 56.5% (MCIS) with no figure from the UK.

### *Changes in amount of medicinal cannabis used*

Results for changes in the amount of cannabis used over time were very similar for NDARC and MCIS – ‘I now have a stable level of use’ responses were 22% (NDARC) and 19.2% (MCIS) and for ‘I need about the same as when I started’ responses were 17.3% (NDARC) and 15.7% (MCIS). When these two categories are combined, (as they apparently were in the UK sample), the results are 39.3% (NDARC), 34.9% (MCIS) and 66% (UK). Figures for those

needing much or a little more: 11.8% (NDARC), 15.7% (MCIS) and 28.9% (UK) and those needing much less or a little less response rates were 5%, 10.5% and 4.8% respectively.

**Table 2.12 Changes in amount of medicinal cannabis used (%)**

	More now	Stable/Unchanged	Less now	Depends on condition
NDARC	12	39	5	35
MCIS	15.7	34.9	10.5	35.1
UK	28.9	66.1	4.8	–

### *Amounts of medicinal cannabis used*

Two questions asked in the MCIS and UK surveys but not in NDARC also yielded quite similar results – amounts of smoked cannabis used, at a level of 10+ grams per day were 2.2% (MCIS) 1.9% (UK); and for 1–2 grams per day the results were: 27.2% (MCIS) and 27.1% (UK).

**Table 2.13 Amounts of medicinal cannabis used (%)**

	10+ gms p day	5–9 gms p day	3–4 gms p day	1–2 gms p day	Several p wk	Several p mth	When needed
NDARC	–	–	–	–	–	–	–
MCIS	3.5	11.4	13.6	27.3	–	3.5	43.3
UK	1.9	6.5	11.6	27.1	16.7	11.7	24.2

### *Discussion and conclusion*

This analysis has demonstrated regular similarities in survey results across samples and questions asked. Clearly, a more rigorous statistical analysis is called for but it would appear that the finding of so many similar results is not mere coincidence. Nevertheless, it is salutary to heed Ware et al’s warning concerning the possible presence of a significant selection bias which:

may also have the effect of excluding cannabis non-responders, persons who have tried cannabis and for whom it has not been of any use. This is a difficult group to target, and only randomly selected large-scale surveys would be able to identify the extent of this.<sup>103</sup>

<sup>103</sup> Ware, above n 98, 294.

Since surveys of medicinal cannabis users are still in their infancy, some speculations about the underlying factors influencing the results may be useful in pointing to some directions for future research.

Some of the discrepancies in amount, frequency and duration of use and usage drop-out rates between the UK and Australian users may indicate a relative lack of availability, higher cost and lower quality of medicinal cannabis in the UK. This might be predicted by the climatic differences which enable cannabis to grow more readily, potently and prolifically outdoors in Australia. Moreover, it might be surmised that users in Australia are more likely than those in the UK to have (especially outdoor) space in which to grow their own cannabis.

Where climatic and economic considerations are not a factor – such as overall effects of cannabis; comparison of efficacy and side effects and return of symptoms – the UK results are similar, and in many cases, very close to the Australian statistics.

These discrepancies and similarities might suggest that supervening factors like those mentioned above may be controlled for in future studies, which could establish whether the suppositions made here are real or artefactual.

In terms of the wider issue of whether there is a need for medicinal cannabis, perhaps this analysis, like the UK study, ‘lends support to ongoing efforts to make cannabis-based medicines available for research purposes and lends credence to changes in public policy on compassionate grounds.’<sup>104</sup>

## *2.4 Rural doctors’ attitudes to and knowledge of medicinal cannabis*

### *Introduction and rationale*

As part of research investigating the need for and viability of medicinal cannabis legislation in NSW, an exploratory survey was conducted among general practitioners (GPs) in the Northern Rivers region of NSW to ascertain their knowledge and attitudes towards medicinal cannabis. I was the researcher who undertook the survey.

The importance of GPs' support for any legalised medicinal cannabis regime is demonstrated by the opposition of physicians' groups in some American states and in Canada<sup>105</sup>. There, partly due to those jurisdictions' legalising of smokeable cannabis for medicinal purposes and partly to the bureaucratic burdens imposed on practitioners by governments, their regulatory systems have been considerably hamstrung by the lack of doctors willing to participate.

Countries which have already legislated such regimes use a variety of models and regulations to determine a person's eligibility to be prescribed medicinal cannabis. However, since this eligibility is based on a medical decision, it is doctors who must function as 'gatekeepers' in allowing or denying patients' access to medicinal cannabis for their conditions.

In May 2004 New South Wales Premier Bob Carr announced a four-year clinical trial of the use of medicinal cannabis in the treatment of a range of serious medical conditions. The implication of such a trial was that if it were successful, the government might introduce legislation to make medicinal cannabis generally available under some form of regulatory regime. But the trial never eventuated.

Although the NSW Branch of the Australian Medical Association has conditionally endorsed the medicinal use of cannabis<sup>106</sup>, it is the GPs practising in the community who would be key players in any legal prescription regime and without whom such a system could not effectively function. Therefore it follows that, as key stakeholders, GPs' views on any proposed legislation should be canvassed and their support sought.

As a preliminary step in this direction, the support of the NSW Northern Rivers Division of General Practice (the NRDGP) was sought and granted for the conduct of a stratified random sample interview survey of its members concerning their knowledge of and attitudes to the prescription of medicinal cannabis.

The Northern Rivers region was chosen as the locale for the survey because previous research had found that there were significant levels of self-medicated cannabis users in the Northern

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<sup>104</sup> Ibid.

<sup>105</sup> See, eg, S Wharry, 'CMPA warns doctors..?' (2002) *Canadian Medical Association Journal* 166 (1) 5.

<sup>106</sup> 'AMA & Society Agree on Cannabis Use for Palliative Care' (1999) 37 (10) *New South Wales Law Society Journal* 79.

Rivers, their GPs were often confidants, and because the region was manageable given the resources of the sole researcher who is also a long-term resident of the area.

Initially, the Division expressed some concerns about possible media ‘bad press’<sup>107</sup> which it feared might lead to patients pressuring their doctors to prescribe cannabis. It also had doubts as to whether their typically busy members would have the time to participate.

However, following a formal written request to the NRDGP for its endorsement of the project, they appointed one of their board members to liaise with me. Over the course of an exchange of emails, the Division’s concerns were addressed and allayed. With the assistance of the board’s liaison person and others, the questionnaire was edited and streamlined to minimise the time it would take doctors to answer. The research proposal was also submitted, vetted and approved by the Southern Cross University Human Ethics Committee and the NRDGP itself.

### *The sample*

Using the NRDGP’s database of 187 members located in the NSW Northern Rivers region, from Byron Bay to Maclean and west to Casino and Kyogle, a stratified random sample of 25 interviewees was selected. However, the number of volunteers in all stratified sub-groups enabled a final sample of 32 interviewees.

As a general methodological precaution, (since it is common knowledge that attitudes and knowledge may vary with age and gender cohorts) separate sub-samples were derived for males and females in three age categories – up to 44 years of age; 45 to 54 years and 55 years and over, as an age breakdown of the sample indicated that the GP population comprised approximately equal numbers in each of these age categories.

Thus the whole sample was broken down into six sub-samples stratified by age and gender. The database was divided into these categories with all of the practitioners in each listed, from which a target number for interview was derived. This target was attained and exceeded for all sub-samples.

The administrative procedure for obtaining interviewees began with a mail-out by the NRDGP to all its members in May 2005 of a flier providing the background and explaining the need for the research. It stressed that the researcher wanted to ascertain the views and knowledge of all opinions amongst GPs and not just those predisposed to favourable opinions of medicinal cannabis. The flier explained that the researcher would send a letter to all GPs on the NRDGP's database, informing them of the survey and inviting them to volunteer as subjects by faxing back their consent to be interviewed, having read, agreed to and signed the Informed Consent part of the letter in the form stipulated by the Southern Cross University Human Ethics Committee.

These letters were posted early in June 2005 and, besides restating the rationale and aims of the research, invited recipients to volunteer or to notify the researcher that they did not want to take part. This letter resulted in 24 volunteers and 25 refusals contacting the researcher by telephone or facsimile. After a period of some two weeks, I phoned doctors in the sample to try to make appointments with them to undertake the interview.

Despite offering to meet with potential interviewees in person, it was found in practice that this was overly difficult – for the doctors because they found it hard to predict when they would have the time available and, for me, because the survey area was large and there was usually no way to arrange several interviews in the same location in the one day, thus necessitating multiple, sometimes long, car trips to interview doctors one at a time.

This arranging of interview appointments proved to be the hardest and lengthiest stage in the research. It was often necessary to phone doctors' receptionists several times, over two or three weeks before the appointment could be made and the interview conducted, either to remind them or because they had not responded to earlier contacts. As most of the mail-out recipients had not responded, either to the offer to volunteer or to refuse an interview, this stage was also characterised by numbers of refusals. However most of these refusals were due to lack of time rather than lack of interest or disapproval, and, of the 131 contacted only 35 said they 'were not interested.'

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<sup>107</sup> Email from Dr D Ewald, Manager Northern Rivers Division of General Practice to Graham Irvine, 13 February 2005.

*The questionnaire*<sup>108</sup>

The questions used were specifically designed and worded for this particular survey and drew on the expert knowledge of Dr David Helliwell, from Riverlands Drug and Alcohol Rehabilitation Centre, Lismore and Dr Dan Ewald, GP and board member of the NRDGP, both of whom have extensive local clinical experience and are familiar with the medicinal cannabis issue and its local application.

The questionnaire also drew on previous surveys conducted by the National Drug and Alcohol Research Centre<sup>109</sup>, in which the researcher participated as questionnaire designer and interviewer; a survey conducted by the Nimbin Hemp Embassy and reported by Dr D Helliwell<sup>110</sup> and a mail survey of New Zealand GPs and some specialists by the New Zealand Greens Party.<sup>111</sup>

Every effort was made to write and ask the questions in a value-neutral manner. After discussions with the abovementioned doctors, which resulted in some amendments to the questions, the questionnaire was pre-tested and piloted with three local GPs, after which a few further rewordings were made.

In Question 1, the list of the most clinically accepted medicinal cannabis-treatable conditions was derived from a number of sources but principally from the reports cited on Showcard 1, (see Questionnaire, page 1) which was read to or read by interviewees. This list was refined by reference to the medical conditions listed in Canadian and American states' medicinal cannabis legislation and finalised by discussions with the abovementioned clinical advisers. This question was intended to ascertain respondents' knowledge of which medical conditions are widely accepted in the clinical literature as being treatable with medicinal cannabis.

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<sup>108</sup> Reproduced in Appendix 1.

<sup>109</sup> Didcott, above n 77.

<sup>110</sup> Dr D Helliwell 'GPs Key Confidants in Medicinal Cannabis Survey' <<http://www.conference.nrdgp.org.au/clinical/drug&alcohol/drug&alcohol290.html>> (accessed 15 May 2008).

<sup>111</sup> Green Party of Aotearoa New Zealand *Medical Cannabis Survey* (2005) <[www.greens.org.nz](http://www.greens.org.nz)> (accessed 13 March 2006).

With Question 2 each medical condition was put to the respondent in turn, so that s/he could estimate the number of their patients seen in 2004 with that condition. The intent of this question was to gauge the potential extent of the need for medicinal cannabis in the survey area.

Question 3 sought to ascertain the general hypothetical attitude of GPs towards the prescription of medicinal cannabis in the event that it were legalised; that clinical research had scientifically established its efficacy for the specified conditions and that its use was supported by the medical profession.

So as to minimise ‘response set’<sup>112</sup> in Question 4, this question was alternately asked as, ‘Would you disapprove ...’ and, ‘Would you approve ...’ The reference to government sponsored research was intended to avoid the possible perceptions that such clinical trials might lack credibility if they were conducted by advocacy groups or pharmaceutical firms which could have vested interests in favourable results.

Question 5 was designed to determine whether GPs would be prepared to act on their favourable attitude to medicinal cannabis prescription by applying to prescribe it if such prescription was carried out within the framework of a legal regulatory trial scheme.

In addition to the five questions in the survey, respondents were also given the opportunity to make their own comments on the topic of medicinal cannabis and many did so.

Interviews were conducted between the 8<sup>th</sup> and 29<sup>th</sup> of June 2005, with most during the week beginning 20 June. Four were face to face interviews and all the rest were conducted by telephone. Interview durations ranged from four to twelve minutes, with most lasting six minutes. All interviews were conducted by the researcher.

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<sup>112</sup> ‘Response set’ is a form of interview bias which may operate to pre-dispose positive or negative answers from respondents, according to whether a question is framed positively or negatively.

*The results*

**Question 1:** The most widely known application of medicinal cannabis among respondents was in palliative care, closely followed by chronic pain, then AIDS-related wasting, chronic nausea and vertigo, multiple sclerosis and muscle spasticity and then, a long way behind, seizures and Crohns Disease – see Table 2.14.

**Table 2.14 Percentages of GPs knowing about usage of medicinal cannabis for various conditions**

Condition	% know	L95%CI	U95%CI
palliative care	81.3	74.4	88.2
AIDS wasting	59.4	50.7	68.1
multiple sclerosis	37.5	28.9	46.1
Crohn's disease	9.4	4.2	14.6
chronic pain	78.1	70.8	85.4
chronic nausea	50.0	41.2	58.8
Seizures	18.7	11.8	25.6

The following significant differences in the probability of respondents knowing of an application of medicinal cannabis among age categories were observed:

- AIDS wasting: 25% of up to 44 years age group, 82% of 45–50 age group, 62% of 51+ age group ( $\chi^2 = 6.24, p = .044$ )
- Crohn's disease: 0% of up to 44 years age group, 27% of 45–50 age group, 0% of 51+ age group ( $\chi^2 = 6.32, p = .042$ )

No significant differences were observed between genders.

**Question 2:** By a majority of almost 4:1, the most populous group of patients with medicinal cannabis-treatable conditions was chronic pain patients. After that came seizure, palliative care and chronic nausea and vertigo patients, followed by much smaller still groups of multiple sclerosis/ muscle spasticity and of AIDS-related wasting patients – see Table 2.15.

**Table 2.15 The numbers of patients seen with various medical conditions who consulted respondent doctors in 2004:**

Numbers of patients seen with:	Mean	Std. Deviation	Median
palliative care needs	8.8	11.1	5
AIDS wasting	1.7	3.1	0
multiple sclerosis	1.4	1.3	1
Crohns disease	2.4	1.9	2
chronic pain	36.7	49.6	20
chronic nausea/vertigo	6.5	8.2	3
seizures	9.3	8.2	7

No significant differences were observed among either age categories or genders.

**Question 3:** Overwhelmingly respondents would consider prescribing medicinal cannabis in circumstances where it was legal, supported by their peers and based on good quality clinical research evidence – see Table 2.16.

**Table 2.16 Percentages of respondents approving medicinal cannabis prescription, clinical trials and trial scheme**

Approve of:	Don't know	No	Maybe	Depends	Yes	L95%CI	U95%CI
prescription	0.0	0.0	25.0	NA	75.0	67.3	82.7
clinical trial	NA	0.0	0.0	NA	100	–	–
trial scheme	6.3	12.5	NA	3.1	78.1	70.8	85.4

No significant differences were observed between either age categories or genders.

**Question 4:** 100% of respondents would approve of government sponsored research for the treatment of the abovementioned medical conditions – see Table 2.16.

**Question 5:** Approximately 75% of the sample indicated that they would be prepared to prescribe medicinal cannabis to suitable patients under the hypothesised regulatory scheme – see Table 2.16. However a significant number were concerned that the involvement of the public health bureaucracy would result in unwanted burdens of more red tape and extra paper

work. A few were worried that they may be overburdened with patients seeking prescriptions for cannabis if it became known that they were licensed to do so.

Other general comments included respondents who reported that they had anecdotal evidence from some of their patients that they had successfully smoked cannabis for the treatment of chronic pain, nausea, palliative care and appetite stimulation, and one who would have prescribed it for a case of scleroderma had it been legal.

Some interviewees felt that there is not sufficient evidence or that the evidence is too equivocal to prescribe medicinal cannabis, whilst others would only prescribe it on the advice of a specialist with more knowledge of its efficacy for particular conditions. Others emphasised the need for GPs wishing to prescribe medicinal cannabis to undergo training similar to that conducted for methadone providers. One respondent stressed the need for uniform legislation across Australia to prevent jurisdiction-shopping and another pointed to possible problems with overdose of a liquid preparation and the potential danger of children using it.

### *Discussion and conclusion*

Whilst it is claimed that the survey is representative of NSW Northern Rivers GPs, there is some evidence to suggest that these GPs are more favourably disposed towards medicinal cannabis prescription than the national GP population.<sup>113</sup>

The New Zealand Greens' survey found a strong correlation between doctors' knowledge of medicinal cannabis and favourable attitudes to its prescription,<sup>114</sup> and so, given the recognition of the NSW North Coast as 'a centre for cannabis cultivation and use'<sup>115</sup> it might be expected that both knowledge of, and favourable attitudes to medicinal cannabis among the local GPs would be higher than elsewhere and that their attitudes to its prescription would be more approving.<sup>116</sup>

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<sup>113</sup> Didcott, above n 77; D Helliwell, n 110 'GPs Key Confidants in Medicinal Cannabis Survey', *Medicine Australia*, <<http://www.medicine.au.net.au/clinical;/drug&alcohol/drug&alcohol2>> (accessed 15 May 2008).

<sup>114</sup> Greens Party of Aotearoa New Zealand 'Medicinal Cannabis Survey of Registered Doctors', <[www.greens.org.nz](http://www.greens.org.nz), 2005> (accessed 27 May 2009).

<sup>115</sup> Didcott, above n 77.

<sup>116</sup> *Ibid* n 77 and Helliwell, above n 110.

Nevertheless the very high rates of NSW Northern Rivers GPs' willingness to prescribe and to participate in a trial regulatory scheme would suggest that there would also be a substantial majority in favour of these proposals among GPs across Australia. If this speculation is correct, the implications for policy-makers would be, even in a worst-case scenario that GPs would not actively oppose a carefully regulated trial system of medicinal cannabis prescription.

The survey results would appear to indicate that (Northern Rivers) GPs have a strong commitment to evidence-based medicine and an openness to consider prescription of medicinal cannabis if scientific and social criteria are met.

## Chapter 3

# THE INTERNATIONAL HISTORY OF MEDICINAL CANNABIS

### 3.1 *The history of medicinal cannabis*

The history of medicinal cannabis is characterised by cycles of pro- and anti-cannabis ascendancy in Western nations, ranging from its universal use to its complete prohibition. The use of the plants *cannabis sativa* and *cannabis indica* for medicinal purposes stretches back to the dawn of recorded history and encompasses Asia, Africa, America, and Europe. By the twenty-seventh century BC, the Chinese cultivated ‘ma’ (cannabis hemp) for fibre, medicine and herbal use.<sup>1</sup> It is mentioned in the oldest known pharmacopeia, the Chinese Pen-ts’ao Ching, dated to 2737 BC.<sup>2</sup> In India, the Atharva Veda (c 1400 BC) advocated the use of cannabis for ‘freedom from distress’ and traditional Aryurvedic medicine has thousands of uses for it.<sup>3</sup> In Europe, its medicinal uses were recorded by Galen, c 160AD as appetite stimulation and analgesia among others.<sup>4</sup> In Egypt, its uses as medicine were recorded on papyrus scrolls in the sixteenth century BC.<sup>5</sup>

In medieval times in the Middle East, recreational hashish use was punishable by a flogging so severe it left the recipient crippled for life whereas its medicinal use was sanctioned as a diuretic, analgesic and digestive.<sup>6</sup> In Africa, the cannabis plant was medicinally used for snakebite, aiding childbirth, malaria, anthrax and asthma.<sup>7</sup> One source refers to cannabis being an ingredient of an Anglo-Saxon ‘holy salve’ in about the 10<sup>th</sup> Century<sup>8</sup> whilst Parkinson, the English King’s herbalist in 1640, recommended it for jaundice, gout, worms

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<sup>1</sup> J Green, *Cannabis* (no date circa 2005) 240.

<sup>2</sup> Ibid.

<sup>3</sup> M Aldrich ‘The History of Therapeutic Cannabis’ in M Mathre, *Cannabis in Medical Practice* (1997) 37.

<sup>4</sup> M Booth, *Cannabis* (2003) 48.

<sup>5</sup> J Zias et al, ‘Early Medical Use of Cannabis’ (1993) 363 *Nature* 215.

<sup>6</sup> Mathre, above n 3, 40.

<sup>7</sup> Ibid 41.

<sup>8</sup> Ibid 42.

and more.<sup>9</sup> An earlier Portuguese herbal also listed appetite stimulation as being one of its properties.<sup>10</sup>

The French were among the first in 19<sup>th</sup> Century Europe to experiment with cannabis and in 1840 Louis Aubert-Roche used it to treat plague.<sup>11</sup>

In the West, its use reached a peak in the latter half of the nineteenth century when:

cannabis extract was one of America's three most regularly prescribed drugs and by 1890 the British doctor J. R. Reynolds prescribed it for epilepsy, migraine, asthma and depression. It was sold by some of the world's largest drug companies such as Parke Davis, Eli Lilly and Squibb.<sup>12</sup>

It was first listed in the official United States Pharmacopeia in 1850<sup>13</sup> and it remained listed until 1941, whilst in the United Kingdom it remained in the British Pharmacopeia until 1954. In Australia, tincture of cannabis was used until the mid-1960s and was included in the Pharmacopeia until 1977.<sup>14</sup>

One of the first of many official enquiries into cannabis was the Indian Hemp Drugs Commission in 1894. 'The findings, consisting of 3500 pages ... were specifically unpartisan and objective and remain to the present day the most thorough official study of cannabis ever conducted.'<sup>15</sup> It's main recommendation [was] that 'the long-term consumption of cannabis in moderate doses has no harmful effects ...'<sup>16</sup>

The Indian inquiry was followed by a plethora of official inquiries, most of which acknowledged, to a greater or lesser degree, the efficacy of cannabis as medicine. They included: the Panama Canal Zone Military Investigations, 1916–1929; the New York La Guardia Committee Report 1944; the British Wootton Report, 1968; the Canadian Le Dain Commission, 1972 and the United States' Shafer Commission of 1972 and subsequent inquiries which will be referred to later.

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<sup>9</sup> M Fankhauser, 'The History of Cannabis in Western Medicine' in F Grotenhermen and E Russo (eds), *Cannabis and Cannabinoids* (2002).

<sup>10</sup> Mathre, above n 3, 42.

<sup>11</sup> R Bonnie and W Whitebread, *The Marijuana Conviction: A History of Marijuana Prohibition in the United States* (1974) 4.

<sup>12</sup> Green, above n 1, 186.

<sup>13</sup> Booth, above n 4, 139.

<sup>14</sup> A Caswell, 'Marijuana as Medicine' (1992) 156 *Medical Journal of Australia* 497–498.

<sup>15</sup> Booth, above n 4, 168.

By the end of the nineteenth century, medicinal cannabis's popularity as a panacea had waned and that of opium waxed owing to opium's water solubility, injectability and quicker effect and the difficulties of standardising cannabis dosages. 'The status of cannabis was compounded by the increasingly severe quality control problems with material imported from India.'<sup>17</sup> Nevertheless, by the 1930s both Eli Lilly and Parke Davis were marketing uniformly effective extracts and tinctures.<sup>18</sup> However, early in the twentieth century the arrival of synthetic drugs, especially aspirin, supplanted the popularity of cannabis which has never regained its once pre-eminent position of drug-of-choice.

### *The history of international drug conventions in the twentieth century*

The other development around this time which led to increasing restrictions on medicinal cannabis use was the advent of a series of international conventions on drugs. This development marked the emergence of fear as a motivating policy force in the enactment of laws governing cannabis use and Kirby J has characterised the degree of international cooperation on drugs as 'exceptional'.<sup>19</sup>

The first fifteen years of the twentieth century were crucial in shaping American drug policy. ... The United States became involved in several international conferences ... [which] served to help influence new federal legislation and led directly to ... the *Harrison Act* of 1914 [which] was to shape federal anti-drugs policies for the next fifty years<sup>20</sup>

The first of these conventions was the Shanghai International Opium Commission of 1909, convened by the United States but the delegates were not authorised to enter into a treaty and so a second convention was held in The Hague in 1911, while the League of Nations set up the Advisory Committee on the Traffic in Opium and Other Dangerous Drugs to oversee international controls on drugs. Although the United States, South Africa and Italy pressed for the inclusion of cannabis in the regulatory regime proposed for the international opium trade at the 1911 Convention, this did not occur until the third International Opium Conference in Geneva in 1925. This conference was the first to formally consider cannabis in a sub-committee which recommended the imposition of controls over extracts and tinctures of cannabis; import and export controls over hemp and resin; prohibition of export to countries

<sup>16</sup> Green, above n 1, 137.

<sup>17</sup> E Russo, 'Cannabis in India' in R Mechoulam (ed), *Cannabinoids as Therapeutics* (2005) 9 and see above n 4, 142–145.

<sup>18</sup> Booth, above n 4, 142, and Fankhauser, above n 9, 467.

<sup>19</sup> M Kirby, 'Drugs: an International Prohibition' (1992) 18(1) *Commonwealth Law Bulletin* 312–320, 312.

<sup>20</sup> S Belenko, *Drugs and Drug Policy in America: a Documentary History* (2000) 29.

where it was illegal and prevention of the illicit international trade in cannabis and especially in cannabis resin.<sup>21</sup> It also set up an ongoing Permanent Central Opium Board to oversee regulation and established the International Convention on Narcotics Control, prohibiting the non-medical uses of opiates, cocaine and cannabis.<sup>22</sup> ‘Thus began cannabis prohibition, from ‘the top down’, in the western world.’<sup>23</sup> This series of conferences and conventions ‘created a going concern ... [whereby] the drug question became a permanent feature of international relations. ... Yet the control regime suffered from numerous defects.’<sup>24</sup>

The *Narcotics Limitation Convention* of 1931 applied controls to all stages between manufacture and the ultimate consumption of manufactured drugs.<sup>25</sup> It required participating nations to provide annual estimates of the quantities of their expected scientific and medicinal needs of the proscribed drugs to the Permanent Central Opium Board as a means of tracing and limiting international trade in those drugs. In 1933 the Advisory Committee on trafficking in opium, set up by the Convention, became concerned that trafficking in cannabis was becoming more widespread and so established a sub-committee on Indian Hemp which investigated for several years but never issued a report.<sup>26</sup> The system was tightened to strengthen the penalties for trafficking in the 1936 *Convention for the Suppression of the Illicit Trade in Dangerous Drugs*.<sup>27</sup> At this convention, the United States’ Federal Bureau of Narcotics chief, Henry Anslinger, ‘urged the international control of cannabis but other countries rejected his approach on the grounds that there was insufficient evidence to support his claims of the drug’s iniquity.’<sup>28</sup>

After the end of the League of Nations came the establishment of the United Nations which set up the Commission on Narcotic Drugs and transferred all the League’s former drug control organs and functions under the 1946 *Geneva Protocol*. This was followed in 1948 by the Paris Protocol which authorised the World Health Organisation to impose international controls over any dependence-producing drug.<sup>29</sup>

<sup>21</sup> A Mead, ‘International Control of Cannabis’ in G Guy et al (eds), *The Medicinal Uses of Cannabis and Cannabinoids* (2004) 388.

<sup>22</sup> Booth, above n 4, 170–172.

<sup>23</sup> Mead, above n 21, 388.

<sup>24</sup> W McAllister, *Drug diplomacy in the Twentieth Century* (2000) 77.

<sup>25</sup> H Anslinger and W Tompkins, *The Traffic in Narcotics* (1953) 36.

<sup>26</sup> Mead, above n 21, 387–388.

<sup>27</sup> Anslinger and Tompkins, above n 25, 37.

<sup>28</sup> Ibid.

<sup>29</sup> R Fox and I Matthews, *Drugs Policy: Fact, Fiction and Future* (1992) 72.

Next in the line of international conferences and conventions and of prime importance among them was the United Nations *Single Convention on Narcotic Drugs* in 1961. The document drawn up as a result of this Convention has been ratified by over a hundred nations and is still partly in force today. It codified and replaced the eight earlier treaties and extended the reach of international drug regulation to the cultivation of drug-producing plants. Fox and Matthews claim ‘it did introduce for the first time internationally a prohibition and a strong one at that respecting cannabis.’<sup>30</sup> However this ‘prohibition’ has been disputed by another writer who points out that Article 4(1)(c) reads, ‘Subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes, the use and possession of drugs.’ He points out that

One of the provisions relevant to its interpretation is clearly article 30 which provides, inter alia, that medical prescription must be required for the supply or dispensation of drugs ... to individuals. However that requirement need not apply to such drugs as individuals may lawfully obtain use, dispensation or administration in connection with their duly authorised therapeutic functions.<sup>31</sup>

Similarly, Dawkins argues that Article 22 ‘does not oblige parties to impose criminal sanctions on the private cultivation of small quantities of cannabis for personal use.’<sup>32</sup> and that:

It is clear both from the drafting history and terms of the provision that a party may discharge its general obligation under art 28(3) without criminalising activities involving small quantities of marijuana leaves for personal use.<sup>33</sup>

If this is correct then the treaty would presumably not apply to pharmaceuticals such as Sativex.

The 1971 *Vienna Convention on Psychotropic Substances* extended the provisions of the 1961 treaty to psychotropics but nevertheless retained the 1961 Convention’s exclusion from the general provisions of drugs for scientific and medical research. In 1972 a protocol was agreed upon to amend the 1961 *Single Convention* by strengthening its treatment of illicit use, production and trafficking of narcotics. In 1988 the United Nations General Assembly voted to request its Economic and Social Council to draft a convention to complement those of 1961 and 1971 and this is known as the *Convention Against Illicit Traffic in Narcotic Drugs and*

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<sup>30</sup> Ibid 74.

<sup>31</sup> H Woltring, ‘The 1988 UN Convention – Help or Hindrance?’ (1990) 1(4) *Criminology Australia* 19–20, 20.

<sup>32</sup> K Dawkins, ‘International Law and Legalising Cannabis’ (1997) *New Zealand Law Journal* 281–284, 282.

<sup>33</sup> Ibid 281.

*Psychotropic Substances*. It further refined the provisions of the earlier treaties and, together with the 1961 and 1971 treaties, forms the current international law as it stands today.

### *The history of official enquiries into drugs in the twentieth century*

Over the course of the twentieth century several influential officially-appointed investigative enquiries have been held in Western countries. The first of these was the *Panama Canal Zone Report* which was prompted by the United States' Army's discovery that many of its soldiers stationed in the Zone smoked cannabis. However, a panel of civil and military experts who carried out an exhaustive study with hundreds of witnesses concluded that, 'there is no evidence that Marihuana, as grown and used [in the Canal Zone] ... has any appreciable deleterious influence on the individual using it.'<sup>34</sup> Therefore they recommended that the sale or use of marijuana should not be prevented by the Zone authorities.

In 1944 the New York Mayor, Fiorello LaGuardia, commissioned a report titled *The Marijuana Problem in the City of New York*, better known as the *La Guardia Report*. This report was the outcome of six years' research by more than two dozen experts and officials appointed by the mayor with the assistance of the New York Academy of Medicine. It found that 'the practice of smoking marijuana does not lead to addiction in the medical sense of the word [and] does not lead to morphine or heroin or cocaine addiction.'<sup>35</sup> The researchers declared that 'the publicity concerning the catastrophic effects of marijuana smoking in New York City is unfounded.'<sup>36</sup>

The United Kingdom set up a sub-committee of the Advisory Committee on Drug Dependence in 1968 to report on policy options for hallucinogens, headed by the respected sociologist Baroness Wootton and reporting to the Home Secretary. Its members comprised a senior police officer, a psychiatrist, a magistrate, a pharmacologist and others. Their hearings ran from April to July 1968 in seventeen sessions and their report was delivered in January 1969. It came to the conclusion that:

having reviewed all the material available to us we find ourselves in agreement with the conclusion reached by the Indian Hemp Drugs Commission ... and the New York Mayor's Committee on Marijuana ... that the long-term consumption of cannabis in 'moderate' doses has no harmful effects.<sup>37</sup>

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<sup>34</sup> *Panama Canal Zone Report* cited in Green, above n 1, 139.

<sup>35</sup> *The Marijuana Problem in the City of New York* cited in Green, above n 1, 148.

<sup>36</sup> *Ibid.*

<sup>37</sup> *Wootton Report* cited in Green, above n 1, 153.

It recommended that the personal use and small scale supply would not usually result in custodial offences.<sup>38</sup> However by the time of its release, the political will for change to the drug laws had weakened and the Report was effectively shelved by the new Home Secretary, the socially conservative James Callaghan.

Canada established its Commission of Enquiry into Non-Medical Use of Drugs, (the Le Dain Commission), in 1970. It produced two reports in 1972 arguing for the decriminalisation of possession of cannabis for personal use but recommending that distribution continue to be prohibited, commenting that the debate on the non-medical use of cannabis, ‘has all too often been based on hearsay, myth and ill-informed opinion about the effects of the drug.’<sup>39</sup>

The 1970 United States *Comprehensive Drug Abuse Prevention and Control Act* made provision for the establishment of the National Commission on Marijuana and Drug Abuse, later known as the Shafer Commission after its chairman Raymond Shafer. The Commission conducted and commissioned research into the dangers of cannabis going back fifty years. But in its report it found no conclusive evidence that marijuana caused crime, insanity, sexual aberration, promiscuity or other drug use. It reported:

a careful search of the literature and testimony by health officials has not revealed a single fatality in the United States, proven to have resulted solely from the use of marijuana.<sup>40</sup>

It too concluded that marijuana for personal use was not a sufficiently serious problem to be subject to criminal penalties.

The above official enquiries demonstrate the cyclical nature of the ongoing debate over cannabis, with the whipping up of ‘moral panic’ leading to the establishment of official enquiries, all of which have dismissed the claims of the morally panicked. In later chapters the same cyclical nature of the debate will be observed within the research community.

Two points arise from the above analysis – the extent over time and cultures of the use of cannabis in treating much the same serious illnesses as it is prescribed for today. Secondly all of the large-scale official enquiries mentioned in this chapter recommended its medicinal use.

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<sup>38</sup> Booth, above n 4, 376.

<sup>39</sup> *Le Dain Report* cited in Green, above n 1, 247.

<sup>40</sup> [The *Shafer Report*] *National Commission on marijuana and drug abuse, 1<sup>st</sup> report* (1972) Washington, US Government Printing Office, cited in Booth, above n 4, 340.

### 3.2 *United States’ medical marijuana history and regulation in the twentieth century*

For convenience this section will be subdivided into subsections following the structure adopted by London in his ordering of the nine ‘core legislative events’ which shaped the United States’ regulation of drugs in general and of cannabis in particular in his attempt to understand why ‘the United States has declared war on a simple plant.’<sup>41</sup>

The first core event was the enactment of the *Pure Food Act 1906* (The Wiley Act), which set quality and labelling standards. Although it did not specifically include cannabis, it made possible (but did not cause) the classification scheme of marijuana to change from an herbal and legal remedy to a deviant and harmful drug.<sup>42</sup>

[I]t was the first step toward the erosion of some of Americans’ [sic] most closely guarded civil liberties. Contemporary scholars such as Thomas Szasz now view the 1906 Act as ‘the foot in the door of paternalistic statist protectionism’.<sup>43</sup>

The *Harrison Narcotics Act 1914* was London’s second core legislative event. The Act was:

one of the most influential acts ever passed concerning drugs ... [and] was to become ... the basis of narcotic regulation in the United States for the next fifty years.. It was based on the constitutional authority of the Federal Government to ‘raise revenue and to tax amend regulate the distribution and sale of narcotics’.<sup>44</sup>

It required all people who imported, manufactured, produced, compounded, sold, dispensed, or otherwise distributed drugs to register with the Treasury Department and to keep records of all transactions.<sup>45</sup> By setting the level of the tax at a high rate, the Act could thereby end any legal trade in its nominated drugs by making them prohibitively expensive.

The third event was the passage of the *Uniform Narcotic Drug Act 1932* (UNDA) which the Federal Government had passed so as to conform with the 1931 *Geneva Narcotics, Manufacturing and Distribution Limitation Convention* but, by the end of 1934, only ten states had passed it.

<sup>41</sup> J London, *The Criminalization and Medicalization of Marijuana: A Study of Changing Deviance Designations* (PhD thesis, Department of Sociology, University of Colorado, 2006) 60.

<sup>42</sup> Ibid 63.

<sup>43</sup> Ibid quoting T Szasz, *Our Right to Drugs: The Case for a Free Market* (1992) 38–39.

<sup>44</sup> J Inciardi, *The War on Drugs Heroin, Cocaine, Crime and Public Policy* (1986)(PhD thesis, West Coast Universities, Mountain View, California, 1992) 18 London above ibid 83.

But as Mexican migration increased... a fear developed... that marijuana use would increase...As a result twenty-two states restricted marijuana to medical channels... Yet because marijuana use was primarily a lower class phenomenon the middle class was generally unaware of the proposed legislation... Quickly and with neither consideration nor dissent, the laws were enacted.<sup>46</sup>

The fourth event, the *Marihuana Tax Act*, was modelled on the *Harrison Act* and, like that Act, did not ban cannabis outright but imposed onerous tax levels and ‘made medical use of cannabis difficult because of the extensive paperwork required of doctors who wished to use it’<sup>47</sup> and thus its effects were much the same:

This Act was the introduction of the federal prohibition of medicinal marijuana, but the process of medicinal marijuana criminalization had entered in through the back door, to avoid any constitutional safeguards that might be made for an awkward exchange of legitimacies.<sup>48</sup>

It is noteworthy that, almost alone, the American Medical Association opposed the Act and its spokesperson, Dr. James Woodward, informed the Senate Finance Committee that:

There is no evidence, however, that the medicinal use of these drugs [cannabis and its preparations and derivatives] has caused or is causing cannabis addiction. As remedial agents they are used to an inconsiderable extent, ... the prevention of the use of the drug for medicinal purposes can accomplish no good end whatsoever.<sup>49</sup>

Presciently, he added, ‘how far it may serve to deprive the public of the benefits of a drug that on further research may prove to be of substantial value, it is impossible to foresee.’<sup>50</sup>

Herer claims that the passage of the Act owed much to a conspiracy between big business and the Congress. He mentions the newspaper tycoon William Randolph Hearst, Andrew Mellon, Gulf Oil founder and Secretary of the Treasury and Lamont Du Pont, President of Du Pont chemical company and alleges that their motive was to promote the newly invented synthetic fibre nylon at the expense of cannabis hemp.<sup>51</sup> In the public hearings preceding the passage of the Act, its proponents relied on three major sources of evidence to support assertions that marijuana caused insanity, crime and death – firstly, lurid newspaper articles read aloud by Anslinger and others with headings like ‘Marihuana makes fiends of boys in 30 days:

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<sup>45</sup> Ibid.

<sup>46</sup> R Bonnieand and W Whitebread ‘*The Marijuana Conviction: A History of Marijuana Prohibition in the United States*’ (1974) 56 *Virginia Law Review* 1010–1970, 1027–8.

<sup>47</sup> L Grinspoon and J Bakalar, *Marihuana: The Forbidden Medicine* (1983) 8.

<sup>48</sup> London, above n 41, 71.

<sup>49</sup> US Congress, Senate Committee on Finance, *Taxation of Marihuana Hearing* on HR 6906, 75<sup>th</sup> Congress, 1<sup>st</sup> Session, 12/7/37, Washington GPO 11937, 33.

<sup>50</sup> Ibid.

hasheesh goads users to blood lust’; studies by the New Orleans District Attorney, Eugene Stanley purporting to show links between marijuana and imprisonment, and a man who had studied marijuana use in dogs.<sup>52</sup>

It was the establishment in the United States of the Federal Narcotics Bureau, the appointment of Henry Anslinger as its Commissioner, and the passage of the *Marihuana Tax Act* in 1937 which were to have the most significant effect in suppressing the use of cannabis both medicinally and recreationally throughout the Western world. Anslinger led a personal crusade against cannabis, discouraged any unbiased scientific investigation and even prevented marijuana from being provided to respectable research institutions for the purpose of research. This discouragement of research was reinforced by his efforts in persuading state legislatures to enact the *Uniform State Narcotic Acts*, which culminated in thirty-six states adding cannabis to their most dangerous drugs lists under these Acts.

The *Marihuana Tax Act* of 1937 transformed marijuana from a legal substance into a criminal substance almost overnight.<sup>53</sup> The *Marihuana Tax Act* was followed a year later by the *Food, Drug and Cosmetic Act 1938* which required all drugs not on the market prior to its enactment to prove their safety. A 1951 amendment, the Durham-Humphrey Amendment, divided drugs into two categories – those that could be used safely by patients without medical supervision and bought without a prescription and those that required a prescription and medical supervision, allowing for greater control of the latter.

The fifth event was the passing of the *Boggs Act 1952*:

Under the *Boggs Act*, for the first time at the federal level, marijuana was included with all the other narcotics with uniform penalties for drug offenders. Within the context of the *Boggs Act*, marijuana received the definition and treatment of a narcotic drug.<sup>54</sup>

The public hearings preceding the Act were dominated by Anslinger and his associates who justified the draconian penalties by promulgating the ‘Stepping Stone Theory’, later known as the ‘Gateway Theory’, which held that marijuana use was the precursor to harder drug usage.<sup>55</sup> The Act increased penalties involving possession of cocaine, cannabis or any opiate

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<sup>51</sup> J Herer, ‘The Emperor Wears No Clothes’ (1985) 29 and London, above n 41, 72–76.

<sup>52</sup> Bonnie and Whitebread, above n 46, 1056.

<sup>53</sup> London, above n 41, 77.

<sup>54</sup> Ibid 82.

<sup>55</sup> Booth, above n 4, 250.

to 2–5 years' gaol for a first offence; 5–10 for a second and 10–20 for a third, with no parole for second or subsequent offences. As Booth points out, even serial killers were eligible for parole.<sup>56</sup>

The sixth key legislative event was the *Narcotics Control Act 1956* which ratcheted up penalties for drug use even higher, increasing maximum sentences to ten, twenty and thirty years gaol respectively. No distinction was made between low level users and high level traffickers. The Act also augmented the powers of the Federal Bureau of Narcotics (FBN), including sanctioning them to carry guns.<sup>57</sup>

The seventh event was the *Controlled Substances Act (CSA) 1970* which codified more than fifty acts and regulations and remains the basis of the US regulatory framework today. It was instigated by the Nixon Administration's alarm at the burgeoning use of cannabis and other street drugs. In 1969 the President asked Congress to enact legislation to deal with this perceived problem, resulting in Congressional hearings and a conference whose report was tabled in October 1970.<sup>58</sup>

...the Act merged more than fifty separate portions of existing and fragmented drug laws. The Act was an effective and efficient law that has brought about the consolidation of many different federal drug policies into one coherent document.<sup>59</sup>

Its purpose was to set an anti-marijuana agenda that was supposed to be easy to understand and implement. Included in the new law was the *Controlled Substances Act (CSA)*. This omnibus act was designed to control the licit drug market and restrain the importation and distribution of illicit drugs. It created five schedules of drugs, ranging from Schedule I, containing the most dangerous drugs, to Schedule V, the least dangerous.

The categorisation into schedules is based on three criteria – how dangerous a drug is; its potential for abuse and addiction; and whether it has legitimate medical value. Schedule I includes cannabis, along with heroin and hallucinogens because they are deemed to have no accepted medical utility but a substantial potential for abuse.

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<sup>56</sup> Ibid.

<sup>57</sup> Ibid 251.

<sup>58</sup> US Congress, Conference Committees, '*Comprehensive Drug Abuse Prevention and Control Act of 1970 Conferences Report to accompany HR 18583*', (1970) 91<sup>st</sup> Congress, 2<sup>nd</sup> Session, H-Rept 91-1603 Washington GPO.

The Act empowers the Attorney General to, ‘remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.’<sup>60</sup> The Attorney General exercises his authority through the Drug Enforcement Agency (DEA) which can re-schedule or de-schedule any drug in the schedules on its own initiative or on that of any other body or person. Additionally, Congress or the courts may pass legislation or make a ruling instructing the DEA to make a change to the scheduling.

This re-scheduling is an exhaustive ten-step administrative process involving a review of recent scientific research and including the right to a judicial review by the court of appeals. The pro-cannabis activist group, the National Organisation for the Reform of Marijuana Laws (NORML), filed a petition to have marijuana re-scheduled in 1972 and its final rejection occurred in 1994. Another activist, Jon Gettman, filed in 1995 and is still waiting for a final decision.<sup>61</sup>

Schedule I drugs cannot be prescribed unless the physician and the patient are participants in a research project approved by the Food and Drug Administration (FDA) and the DEA. If approved, physicians are granted licences. After the drug has been available on the market for some three years, the producer may formally apply to the FDA to have its status changed from prescription only availability to over the counter sale. The producer must prove to the FDA, *inter alia* that the drug is safe for use by a patient without medical supervision.

However, given the implacable opposition of successive federal governments to relaxing the restrictions on medicinal cannabis, the above mechanisms for re-scheduling have never been exercised in relation to cannabis and the FDA and DEA retain their policy of ‘zero tolerance’ to medicinal cannabis. In the context of medicinal marijuana it is notable that the CSA makes no distinction between medicinal and recreational cannabis use, such that, under federal law, possession of a small amount of cannabis for personal use can carry a year in gaol and up to \$100,000 in fines for a first offence, whilst growing cannabis is deemed as manufacturing, carrying a sentence of up to five years’ gaol and \$250,000 fine for one plant as a first offence.

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<sup>59</sup> London, above n 41, 91, *Ibid* at 94.

<sup>60</sup> Booth, above n 4, 249–250.

By the early 1970s the groundswell of support for medicinal cannabis had spawned a number of medicinal cannabis advocacy groups, the most important of which was NORML the National Organization for Reform of the Marijuana Laws for which medicinal cannabis was and is of secondary concern to its main aim of legalising the recreational use of cannabis. It was NORML that petitioned the Bureau of Narcotics and Dangerous Drugs, (the successor to the Federal Bureau of Narcotics) in 1972 to re-schedule cannabis into Schedule 2 of the Act, thus enabling doctors to legally prescribe it. This initiated a long drawn-out legal battle which culminated in the DEA issuing a final rejection of all applications for re-classification in 1994.<sup>62</sup>

However, partly due to the adverse publicity arising from a glaucoma patient prosecuted by federal authorities for growing and using medicinal cannabis to ease his symptoms<sup>63</sup> the federal government began a small Individual Patient Investigational New Drug Program which allowed physicians to prescribe marijuana as part of a strictly controlled scientific trial. But only eight patients were ever prescribed cannabis under this scheme between 1975 and 1992.<sup>64</sup> In May 1999 the Federal Department of Health and Human Services announced the creation of a new mechanism to provide research grade marijuana and set up an ad hoc public health service committee to:

review non-NIH [National Institute of Health] funded clinical studies and [to] assess them both for scientific quality and the likelihood that they will yield data capable of meeting the FDA's standard for drug approval. ... [The] new procedure does not signal any change in HHS's view on the therapeutic efficacy of marijuana but rather a way to enable more objective research to be done to evaluate the potential merits of marijuana for medical uses.<sup>65</sup>

Meanwhile Nixon had set up the Drug Enforcement Agency ('DEA') in 1973 to 'co-ordinate all federal efforts related to drug enforcement ... [so as to put] ... an end to the interagency rivalries that have undermined federal drug law enforcement ...'<sup>66</sup> Since then its staff has grown from 2,775 and a budget of \$65.2 million to 1,894 and \$2.141 billion in 2005.<sup>67</sup>

<sup>61</sup> J Gettman, *Re-Scheduling Cannabis* (2004) Drug Science Org <[http://www.drugscience.org/lib/lib\\_H.html](http://www.drugscience.org/lib/lib_H.html)> (accessed 20 January 2009).

<sup>62</sup> J Himmelstein, *The Strange Case of Marijuana* (1983) 57–58.

<sup>63</sup> Robert Randall: *United States v Randall* 101 Wash.L.Rep. 2249 (DC Super.Ct. 1976).

<sup>64</sup> W Hall and R Pacula, *Cannabis Use and Dependence* (2003) 229.

<sup>65</sup> US Department of Health, *Investigating Possible Medical Uses of Marijuana* (2002) <[www.hhs.gov/news/pkss/2002/marijuana.htm](http://www.hhs.gov/news/pkss/2002/marijuana.htm)> (accessed 22 August 2008).

<sup>66</sup> DEA Online History, cited in London, above n 41, 93.

<sup>67</sup> US Dept. of Justice, cited in London, above n 41, 94.

The combination of the seventies' upsurge in interest in medicinal cannabis and the intransigence of the federal government in refusing to approve its prescription had the effect of galvanising medicinal cannabis supporters to turn to the state legislatures to enable patients to obtain cannabis. Following the lead of New Mexico in 1978, 33 states enacted laws to make cannabis available for medical use by the early 1980s and by 2001, the figure was 30, with five states' laws having expired or been repealed.<sup>68</sup>

Following the passage of the *Controlled Substances Act*, Congress requested the President to set up a special Presidential Commission to produce a comprehensive assessment of the drug problem. This, the Schafer Commission or the National Commission on Marijuana and Drug Abuse was established in 1971 and issued its final report 1972. This was 'the most definitive look at marihuana that the US Government had ever produced.'<sup>69</sup> The Report recommended decriminalisation for marijuana possession with no criminal or civil penalties under state or federal laws.

The eighth core event was the *Comprehensive Crime Control Act of 1984* which aimed to empower the DEA to regulate medically legitimate drugs which were being diverted or misused and to increase asset disposal and forfeiture laws and penalties.<sup>70</sup>

London's ninth and final historical event was the *Anti-Drug Abuse Act 1986* and its 1988 amending act. The former restored mandatory prison sentences for large-scale distribution of cannabis, amongst other things, while the latter again dramatically raised penalties so that possession of one hundred marijuana plants carried the same sentence as possession of one hundred grams of heroin and introduced offences of 'attempting' and 'conspiracy' which were punished as if they were completed acts. Moreover the conspiracy offence operated so that:

[if]a college student who introduced two people who began dealing in marijuana later, the said college student becomes liable for all of the marijuana the two people ever grew or distributed together.<sup>71</sup>

Consequently, drug offenders in federal prisons increased by 300% in six years.<sup>72</sup>

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<sup>68</sup> Marijuana Policy Project, *State by State Medical Marijuana Laws* (2007) State Policies Dept, Washington DC, 12.

<sup>69</sup> DEA Online History, cited in London, above n 41, 93.

<sup>70</sup> London, above n 41, 94

<sup>71</sup> Ibid 101–102.

*Recent United States regulatory history of medicinal cannabis*

In 1985 Marinol, the brand name given to dronabinol, (a synthesised form of delta-9-tetrahydrocannabinol, known as THC) became the first synthetic cannabis pharmaceutical drug to be approved by the FDA for nausea and vomiting associated with cancer chemotherapy in patients who had failed to benefit from other anti-emetics. In 1992 the FDA also approved it for use in the treatment of anorexia associated with weight loss among AIDS patients and in 1999 it was moved from Schedule 2 to Schedule 3, ‘after a DEA and Department of Health and Human Services (HHS) review found little illicit abuse of the drug’.<sup>73</sup>

In 1997 the highly respected National Institute of Health conducted a workshop of experts on medical marijuana who recommended further research into its use for pain, neurological and movement disorders, cancer chemotherapy, nausea, anorexia associated with AIDS weight loss and appetite as well as glaucoma.<sup>74</sup>

In September 1998 the federal House of Representatives passed a resolution<sup>75</sup> declaring support for the existing federal drug approval process which determines the safety and effectiveness of drugs in the USA. They also included a statement of their opposition to any move to circumvent this regulatory process by altering the scheduling of marijuana.<sup>76</sup>

The year 1999 saw the Director of the Office of National Drug Policy commission the National Institute of Medicine (IOM) review the scientific evidence on the possible risks and benefits of medical marijuana and its constituents. Their 257 page report was one of the most comprehensive and influential official documents ever produced on the subject. Not only did it review published studies but called public hearings and conducted consultations with experts and lay people throughout the US. It found sufficient data to recommend further research into the use of medical marijuana for the treatment of cancer or AIDS appetite

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<sup>72</sup> Ibid 102.

<sup>73</sup> M Eddy, *Medical Marijuana: Review and Analysis of Federal and State Policies* (2005) Congressional Research Service, Library of Congress, CRS Report for Congress, 9.

<sup>74</sup> *Workshop on the Medical Utility of Marijuana: Report to the Director* (1997) Ad Hoc Group of Experts, National Institute of Health, <<http://www.nih.gov/news/medmarijuana/MedicalMarijuana.htm>> (accessed 15 February 2010).

<sup>75</sup> HJ Res. 117.

<sup>76</sup> Eddy, above n 73, 6.

suppression, pain and nausea but concluded that more research was needed on effective and safe delivery systems as it opposed the smoking of marijuana as a medication.<sup>77</sup>

During the 108<sup>th</sup> Congress of 2003–2005, representatives Hinchey and Rohrbacher introduced a bi-partisan amendment to the Commerce, Justice, State appropriations bill for the 2004 fiscal year which would have prevented the Department of Justice from employing this funding to interfere with the operation of states' medical marijuana laws. However the bill was twice defeated by margins of 121 and 102 votes. Also introduced into this session was the Steve McWilliams Truth in Trials Bill (HR 4272, Farr) which did not progress past the committee referral stage but would have established an affirmative defence allowing medical marijuana defendants to produce evidence of their medicinal use of cannabis.<sup>78</sup>

The 2005 109<sup>th</sup> Congress was presented with a more specific bill to end federal action against states' medical marijuana laws. This, The Rights to Medical Marijuana Bill<sup>79</sup> sought to move marijuana from Schedule 1 to Schedule 2 and to amend the CSA and the *Food, Drug and Cosmetics Act* so that they could not restrict physicians or pharmacists from recommending or prescribing medical marijuana or prevent individual patients from obtaining, possessing or using medical marijuana if prescribed or recommended by their physician. The Bill also attempted to restrain the federal government from preventing a state from growing or distributing cannabis under its medical marijuana law but the Bill was never referred to a committee hearing.<sup>80</sup>

### 3.3 *The history of Canadian drug laws*

The evolution of policy on medicinal cannabis in Canada is instructive for Australia and New South Wales because of the oft-quoted similarities between the two nations.

It is therefore surprising to compare the legal state of medicinal cannabis in the two jurisdictions. Canada today has one of the most compassionate medicinal cannabis regulatory

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<sup>77</sup> Ibid 10–11.

<sup>78</sup> Ibid 9.

<sup>79</sup> The Rights to Medical Marijuana Bill HR 2087, (Frank) 9

<sup>80</sup> Eddy, above n 73.

regimes in the world whilst Australia and New South Wales continue to subscribe to a watered down ‘zero tolerance’ policy.

Like Australia, Canadian drug legislation has gone through several phases. The Report of the Senate Special Committee on Illegal Drugs, September 2002, titled ‘Cannabis: Our Position for a Canadian Public Policy’ divides that drug legislative history into three periods.<sup>81</sup>

The first period, from the 1908 *Shanghai Conference on Opium* to the passing of the *Narcotic Control Act 1961*, the Committee characterises as ‘hysteria’. As in Australia, this period was marked by a fear of Chinese immigration and their use of opium and by attempts by doctors and pharmacists to protect their position, which in Canada led to the enactment of the *Opium Act 1908* and later to the *Opium and Narcotic Drugs Act 1911*. Again, like Australia, the emphasis in public concern and its legislative response was on opium and not cannabis which was not added to the list of drugs controlled by the Act until 1923 with the introduction of the *Act to Prohibit the Improper Use of Opium and other Drugs*.

Yet another parallel between Australian and Canadian drug policies is that, at the time of the addition of cannabis to the list of prohibited substances to the Act, ‘there [was] no problem of cannabis in Canada and its use was not a problem.’<sup>82</sup>

The *Act to Amend the Opium and Narcotic Drugs Act 1920* set up a system of controls for the legal trade in otherwise prohibited drugs for medical and scientific purposes through the mechanism of permits issued by the Health Department to pharmacists, physicians and businesses. It covered matters such as importing, exporting, packaging, labelling, manufacturing, sale and distribution.

In 1955 the Senate set up a Special Committee on the Traffic in Narcotic Drugs, which, although hearing evidence on cannabis was ‘preoccupied by ... how to eliminate both the supply and demand for [other] drugs.’<sup>83</sup>

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<sup>81</sup> Senate Special Committee on Illegal Drugs, *Cannabis: Our Position for a Canadian Public Policy* (2002) Ottawa, 247.

<sup>82</sup> P Giffen et al, *Panic and Indifference: The Politics of Canada’s Drug Laws* (1991) Ottawa: Canadian Center on Substance Abuse, 179.

<sup>83</sup> Ibid.

The second period of Canada's drug legislation began with the passage of the *Narcotic Control Act 1961*, which followed on the heels of Canada's endorsement of the United Nations *Single Convention*. It saw a continual ramping up of criminalisation and law enforcement provisions over a progressively expanded list of recreational drugs but does not seem to have made substantive changes to the regulation of otherwise prohibited drugs for medicinal purposes.

The third period of legislation began with the 1969 appointment by the Trudeau government of the Commission of Inquiry into the Non-Medical Use of Drugs, the Le Dain Commission which presented its final report in 1973.<sup>84</sup> Although the Commission's mandate did not include the medical uses of drugs, it did indirectly affect medicinal cannabis users when the government adopted its majority recommendation of moving the regulation of cannabis from the *Narcotic Control Act* to the *Food and Drugs Act 1974*, which provided for permits to cultivate cannabis in certain circumstances.

In 1990 the Canadian Senate set up a committee to examine options for policy on cannabis. Over a period of two years it heard from over a hundred witnesses and commissioned its own research. Like the Le Dain Report before it, the committee found that:

The [Le Dain] Commission concluded that the criminalization of cannabis had no scientific basis. Thirty years later we confirm this conclusion and add that continued criminalization remains unjustified based on scientific data on the danger it poses.<sup>85</sup>

After Le Dain, the most significant reform of Canada's drug legislation came in 1996 with the enactment of the *Controlled Drugs and Substances Act (CDSA)* which remains in force today as the primary legislative instrument for the administration of Canada's drug policy. This Act and the *Medical Marihuana Access Regulations [MMAR]* made under it are examined in some detail in Section 5.3.

The *CDSA* and *MMAR* established a cannabis regulatory regime unique in the world in which the federal government licenses a private company to grow and process cannabis which the government then sells direct to individuals whom they have authorised to use it. The system also provides for the licensing of individual patients to grow their own cannabis. Medical

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<sup>84</sup> Government of Canada, *Report of the Canadian Government Commission of Inquiry into the Non- Medical use of Drugs* (1973) Ottawa, Canada, Information Canada.

evidence that a patient suffers from one or more of a list of medical conditions must be provided by the patient's doctor. However the system has been fraught with problems since its inception with clients complaining of inferior quality, bureaucratic ineptitude and inflated prices.<sup>86</sup>

On 19 April 2005 the federal government approved the use of Sativex as an adjunctive treatment for neuropathic pain in multiple sclerosis patients. As Sativex is not included in the Canadian health care program, it costs some patients \$1,000 Canadian a month while some consumers claim it is less effective than herbal cannabis.<sup>87</sup>

### 3.4 *The regulatory history of medicinal cannabis in the United Kingdom*

In Britain the first major official interest in both recreational and medicinal cannabis came with the government's appointment of the Indian Hemp Drugs Commission in 1893 which was required to examine all aspects of the issue. The Commissioners travelled widely, interviewed more than a thousand witnesses and produced a 3,500 page report which confirmed the medical efficacy of cannabis and concluded that its long term recreational use 'in moderate doses, has no harmful effects.'<sup>88</sup> Notwithstanding this, the government largely ignored the Commission's work, despite it being regarded by one historian as the most comprehensive study ever into cannabis.<sup>89</sup>

In common with other Western nations, the U.K. attended the 1911 Hague Conference and agreed to legislate against drug trafficking and in 1920 enacted the *Dangerous Drugs Act*, which, in effect, created two classes of drugs – medical and criminal, though cannabis was initially not included in either category. However on 28 September 1928 it was added to the 'criminal' schedule to comply with the 1925 Geneva Convention. The Act was amended in

<sup>85</sup> Government of Canada *Canada: Our Position for a Public Policy* (2002) Report of the Senate Special Committee on Illegal Drugs Summary Report 35.

<sup>86</sup> D Beeby, 'Health Canada Mark-up on Government Certified Dope, 1500% Documents', *Canadian Press* (Canada), 15 April 2007; B Clarke, 'Government Pot Sucks: FOI Request Confirms', *Victoria News* (Canada) 5 May 2004; D Beeby, 'Marihuana Users More Than \$500,00 in Arrears with Health Canada', *Canadian Press* (Canada) 13 April 2008.

<sup>87</sup> S T Martin, 'Marihuana Medicine Tests Pot's Potential', *St Petersburg Times*, 1st August 2005, p 1 <[http://www.sptimes.com/2005/08/01/worldandnation/Marijuana\\_medicine\\_te.shtml](http://www.sptimes.com/2005/08/01/worldandnation/Marijuana_medicine_te.shtml)> (accessed 29 August 2008).

<sup>88</sup> Green, above n 1, 137.

<sup>89</sup> Booth, above n 4, 168.

1965, when it included cannabis in the schedule for opiates and though not banned for medical uses it was steadily losing ground as an analgesic to newer more potent synthetic analgesics.<sup>90</sup>

By this time, recreational cannabis use had become widespread among the young and, following several well-publicised arrests of pop stars for cannabis possession, in 1968 the government set up a sub-committee of the Advisory Committee on Drug Dependence to report to the Home Secretary about hallucinogens. This sub-committee's report, (the Wootton Report, named after its head, Baroness Wootton), also concluded that:

Having reviewed all the material available to us we find ourselves in agreement with the conclusion reached by the Indian Hemp Drugs Commission ... and the New York Mayor's Committee (1944) that the long term consumption of cannabis in 'moderate' doses has no harmful effects.<sup>91</sup>

Again, the government largely ignored the Report and instead brought in the *Misuse of Drugs Act 1971*. This set up three categories of drugs, later expanded to five in the 1985 Regulations to the Act, which lumped in cannabis with raw opiates and LSD and prohibited its prescription except in exceptional cases. Following another commission, the Independent Inquiry into the *Misuse of Drugs Act 1997*, chaired by and named after Viscountess Runciman, which recommended placing cannabis in Schedule Two of the Act, thus allowing its medical use, the Home Secretary announced in 2001 that possession of cannabis should no longer be an arrestable offence and that it would be re-classified under the Act in Class C. The *Misuse of Drugs Act 1971* and its Regulations remain as the regulatory instruments over drugs in the United Kingdom today.

The British Medical Association published a report in 1997, 'Therapeutic Uses of Cannabis'<sup>92</sup>, which supported legalisation of medicinal cannabis use. This report prompted the House of Lords Select Committee on Science and Technology to examine the case for legalisation.<sup>93</sup> Among the Committee's recommendations were advocacy of clinical trials and research into non-smokeable forms of cannabis.

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<sup>90</sup> Ibid 260.

<sup>91</sup> Green, above n 1, 153.

<sup>92</sup> British Medical Association, *Therapeutic Uses of Cannabis* (1997).

<sup>93</sup> House of Lords Select Committee on Science and Technology, *Cannabis: The Scientific and Medical Evidence*, HL Paper 151, November 1998.

However:

[t]he Government was not persuaded that even on compassionate grounds there was a case for setting aside the controls which exist to protect the public and allowing doctors to prescribe even on a named patient basis, raw cannabis with unknown standards of safety, quality and efficacy.<sup>94</sup>

It believed that allowing raw cannabis as a medicine would seriously blur the distinction between misuse and therapeutic use. ... On the other hand, if a medicinal form of the drug were available it would be possible to retain a clear difference between the two forms. The risk of diversion of the medicinal form to the illicit market would be no greater than it is for current medicines which contain controlled drugs.<sup>95</sup>

While the government rejected some of the recommendations, it did agree to the licensing of clinical trials and to researching non-smokeable forms of cannabis. In 1999 and again in 2001, the Committee released two more reports, the first of which criticised the government's approach to its 1998 Report and the second of which made a number of observations on the issue, including that the government was prepared to re-schedule cannabis from Schedule 1 to Schedule 2 if it could be advised of the quality, safety and efficacy of a non-smokeable form of medicinal cannabis. It criticised the Medicines Control Agency's decision to insist on further studies of cannabidiol, on the basis that it had been extensively researched over the long history of medicinal cannabis research and that, overall, 'cannabis based medicines are not being dealt with in the same impartial manner as other medicines ...'.<sup>96</sup>

Meanwhile, in 1998 the government had licensed GW Pharmaceuticals, pursuant to section 7 of the *Misuse of Drugs Act* to cultivate, possess and supply cannabis for medical purposes. Since that time the company has undertaken and completed several clinical trials of their sub-lingual spray 'Sativex' on multiple sclerosis, spinal cord injury and rheumatoid arthritis patients but, at the time of writing, final official approval for the general prescription of Sativex has not yet been forthcoming. However, after the licensing of Sativex in Canada, the UK government approved the importation of Sativex from there for use by individual multiple sclerosis patients on the prescription of and under the responsibility of their treating physicians.<sup>97</sup> It issued a Wholesale Dealer's Licence to GW and has also issued a general licence permitting any doctor wishing to prescribe Sativex to do so under the Act. This

<sup>94</sup> G Griffith, 'The Medical Use of Cannabis: Recent Developments', (1999) NSW Parliament Briefing Paper 11/99, Sydney, 10.

<sup>95</sup> Ibid 11.

<sup>96</sup> R Johns, 'Medicinal Cannabis Programmes: A Review of Selected Jurisdictions' (2004) *NSW Parliamentary Library Research Service Briefing Paper 10/04*, Sydney, 55–56.

<sup>97</sup> BBC News, *Cannabis Drug Available in the UK* (15 November 2005) BBC News <<http://news.bbc.co.uk/2/hi/health/4438498.stm>> (accessed 15 February 2010).

licence also permits pharmacists to dispense Sativex and permits patients to use it if dispensed in accordance with a bona fide prescription.<sup>98</sup>

Although the United Kingdom multiple sclerosis community has generally welcomed the introduction of Sativex, recent reports contain the same complaints about expense as had previously surfaced in Canada.

### 3.5 *The Netherlands medicinal cannabis regime and its history*

Largely in response to the 1925 Geneva *International Convention on Narcotic Control*, the Dutch government enacted the *Opium Act 1928* which was subsequently amended in 1976 and 2002 as its primary instrument of drug regulation and control.

In conformity with the 1961 *Single Convention on Narcotic Drugs*, Article 3 of the Act listed drugs in two different categories and declared that any form of dealing in one of them, which included cannabis, was illegal.

Article 3(c) provided for exemptions from the general prohibitions of the Act; Article 4 exempted some prescriptions; Article 5 exempted certain pharmacists, doctors and veterinarians and Article 8 provided for exemptions ‘in the interests of public health’ where the applicant is engaged in research or for instructional purposes. These exemptions covered preparation, processing, selling, supplying, manufacturing, providing, treatment and growing.<sup>99</sup>

Unlike the mistaken characterisation of cannabis as a narcotic in the drug schedules of the International Conventions and, subsequently, of Australia and other Western countries, Holland’s 1976 revised *Opium Act* excluded cannabis from drugs considered to present ‘unacceptable risks’ and consequently imposed more lenient penalties for its possession and

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<sup>98</sup> GW Pharmaceuticals website 2007 <<http://www.gwpharm.com>> (accessed 6 August 2005).

<sup>99</sup> *Opium Act* after the Act of 13 July 2002 to amend the *Opium Act* (Staatsblad [Bulletin of Acts and Decrees] 2002, 520) and the Decree to Actualise Lists I and II of the *Opium Act* (Staatsblad 2002, 623), Articles 2, 3.

use. These included non-prosecution for possession of 30 grams or less, subsequently revised down to 5 grams or less.<sup>100</sup>

The NSW Working Party on the use of Cannabis for Medical Purposes characterised this policy approach as ‘a compromise between total prohibition and de jure decriminalisation.’<sup>101</sup> Part of the rationale for this was the Dutch desire to avoid any allegation that they were in breach of either of the International Conventions of 1961 and 1976. They partially justified the absence of any prohibition on the possession or use of cannabis on the ground that neither convention mandates the criminalisation of these acts, whilst formally retaining supply, possession and use offences so as to conform with the conventions. They also relied on the fact that the conventions do not impose any obligations relating to enforcement.<sup>102</sup>

This interpretation of the international conventions radically differs from that of Australia and other nations recognising its authority and represents a plausible rationale for the implementation of similar laws in NSW which could permit medicinal cannabis use for those in extreme need.

In 2001, the Dutch government set up the Office of Medicinal Cannabis, (Bureau voor Medicinale Cannabis, or BMC) as the responsible regulator of medicinal cannabis under Articles 2.3 and 2.8 of the 1988 *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*. It has an effective monopoly over the import, export, trade and distribution of medicinal cannabis and also coordinates research.

On 1 September 2003, the Netherlands became the first nation to legalise medicinal cannabis use on prescription for patients with serious illnesses. In September 2003 the government extended the BMC’s powers to include responsibility for selling raw cannabis on behalf of the government and for auditing the crops of cannabis grown for the government for quality and contamination and for licensing growers and manufacturers and distributors.

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<sup>100</sup> ‘Report of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes’, Main Report, August 2000, Appendix G, 142.

<sup>101</sup> Ibid.

<sup>102</sup> Dawkins, above n 32, 84.

The new legalised cannabis regime allows Dutch doctors to prescribe cannabis to treat conditions including Tourette's syndrome tics, chronic pain or nausea associated with HIV/AIDS or cancer chemotherapy, multiple sclerosis, other spasticity and chronic neuropathic pain. However doctors can prescribe medicinal cannabis for other conditions though they are answerable to the Medical Council for their prescriptions.

From 1 September 2003, many pharmacies, hospitals and doctors were authorised to supply medicinal cannabis in 5 mg. doses on a doctor's prescription.<sup>103</sup> Initially two authorised strains of cannabis were made available – a crossbred plant comprising both *cannabis sativa* and *cannabis indica* comprising approximately 8% dronabinol and 0.8 % cannabidiol, costing \$E 46.91 per 5gm and another crossbred strain with approximately 13% dronabinol and 0.7% cannabidiol, selling for \$E41.39 per 5gm.<sup>104</sup>

Under the longstanding exemptions provided for under Article 8 of the *Opium Act*, the BMC can grant licences to grow cannabis for medicinal purposes. Prospective growers are extensively screened and must sell their whole crop to the BMC which imposes quality and cultivation standards on all growers. There are currently two licensed growers – Bedrocan BV and the Stichtig Institute of Medical Marijuana.<sup>105</sup>

Another unique Dutch initiative, although designed primarily for recreational cannabis users, provides another option for the supply of medicinal cannabis to medical users. This scheme has been operating since the 1970s with the aim of segregating the cannabis market from that of hard drugs by allowing youth entertainment venues and more recently coffee houses to sell cannabis whilst banning the sale of 'hard' drugs. In 2001 there were estimated to be 1,200 to 1,500 coffee shops in the Netherlands.<sup>106</sup>

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<sup>103</sup> Reuters, *Dutch Back Prescription Cannabis* (1 September 2003) International CNN, <<http://edition.cnn.com/2003/WORLD/europe/09/01/dutch.cannabis.reut/index.html>> (accessed 15 February 2010).

<sup>104</sup> Netherlands Office of Medical Cannabis, <[www.cannabis-med.org/dutch'Regulations.htm](http://www.cannabis-med.org/dutch'Regulations.htm)> <<http://www.cannabisoffice.nl/leg/>> (accessed 26 March 2007).

<sup>105</sup> Johns, above n 96, 10/04, NSW Parliamentary Library Research Service, August 2004, 22–23.

<sup>106</sup> R McCoun, and P Reuter NY Cup *Drug War Heresies* (2001) 241.

Although these coffee houses are commercial businesses they can only be set up with the sanction of a municipal consultative committee comprised of the Mayor, Chief of Police and Police Prosecutor who lay down the policy to be followed by the shops and set limits on their operation. Among these limits are no selling of cannabis to those under 18 or allowing minors in the shops; no selling of hard drugs; no advertising of drugs; limiting stock to 500 grams of cannabis and not selling more than 5 grams of cannabis per person per visit. In addition the shops are enjoined from creating a nuisance to surrounding premises and can be summarily closed on the Mayor's initiative.<sup>107</sup>

Whilst there has been some interest in establishing similar coffee shops in NSW for recreational and medicinal users,<sup>108</sup> I am unaware of any proposal to use them as supply points for medicinal cannabis users and the decline in the numbers of these shops in Holland may suggest that they are not particularly successful in regulating either recreational or medicinal use.<sup>109</sup> In addition, the much smaller and less dense population in NSW would militate against the commercial viability of such shops. For these reasons, the coffee shop policy is not further explored in this thesis. Moreover the supply system instituted under the Netherlands' medicinal cannabis regime has experienced problems in its operation,<sup>110</sup> which may be seen as further reasons not to set up a similar scheme in NSW.

A 2003 survey of Dutch general practitioners and physicians revealed a large majority in favour of medicinal cannabis prescription, but after the Medical Insurance Council decided not to reimburse medical spending on medicinal cannabis, many adopted 'a critical and negative attitude.' An unexpected result of this was that illegal cannabis distributors took the opportunity to increase their market share and to spread rumours about the high price of the legal cannabis. This led to a majority of patients purchasing their cannabis from these illegal sources. A Dutch official claims that ... This results in a loss on the BMC's sales and endangers the continuation of the legal production and distribution. The same people who

<sup>107</sup> Netherlands Ministry of Health, Welfare and Sport, *Drug Policy in the Netherlands; Basic Principles and Enforcement in Practice*, International Public Series in Health, Welfare and Sport No. 18, The Hague, Netherlands, Sept. 2003.

<sup>108</sup> D Helliwell, *GPs Key Confidants in Medicinal Cannabis Survey*, Medicine Australia, <<http://www.medicine.au.net.au/clinical/drug&alcohol/drug&alcohol12>> (accessed 25 November 2005).

<sup>109</sup> Netherlands Ministry of Health, Welfare and Sport n 107, 20.

<sup>110</sup> M van de Velde, *Two Years of Experience with Legal Production and Distribution of Medicinal Cannabis in The Netherlands*, Abstract of Paper Presented to the International Association of Cannabis as Medicine, Leiden, Netherlands, 2006.

once lobbied for legalisation of medicinal cannabis successfully are now killing its production.<sup>111</sup>

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<sup>111</sup> Ibid 6.

# Chapter 4

## MEDICINAL CANNABIS IN AUSTRALIA

### 4.1 *Australian medicinal cannabis history*

As in Europe and America, the use of cannabis for medical purposes was very common in Australia in the nineteenth and the first half of the twentieth century. ‘It was one of the most important medicines of the time and was used for a wide variety of illnesses.’<sup>1</sup>

It was usually made up by pharmacists as a tincture combined with other ingredients such as opium, chloroform and morphine. Cannabis cigarettes such as ‘Joys’ were popular until after World War Two especially in the treatment of asthma, as were lozenges like Walco’s Linseed, Liquorice and Chlorodyne Jubes.<sup>2</sup>

Although there had been attempts by state parliamentarians to ban or restrict the legal use of cannabis as medicine going back to the 1900s, medicinal cannabis remained legal in New South Wales until the passage of the *Police Offences Amendment (Drugs) Act 1954* (NSW),<sup>3</sup> which in turn was repealed and replaced by the *Poisons Act 1966* (NSW). This 1966 Act introduced even harsher penalties for the use of cannabis in any form, whether for medicinal purposes or otherwise.<sup>4</sup> After its enactment cannabis was reclassified as a ‘prohibited drug’.<sup>5</sup>

This regulation of cannabis stemmed from the Commonwealth Government’s subscription to the 1925 *Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare*, and the 1931 *Narcotics Manufacturing and Distribution Limitation Convention* both in Geneva which added cannabis to the lists of illegal substances for non-medical uses and resulted in the proscription of the import and export of cannabis under the *Commonwealth Customs (Prohibited Imports) Proclamation 1926*.

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<sup>1</sup> No author listed, ‘Medical Cannabis in Australia: The History’, Nimbin Hemp Embassy, no date, p 3.

<sup>2</sup> Ibid 6–7.

<sup>3</sup> A Caswell, ‘Marijuana as Medicine’ (1992) 156 *Medical Journal of Australia*, 497–8.

<sup>4</sup> Section 21(1)(g).

<sup>5</sup> *NSW Government Gazette* No. 77, 5 August 1966.

However medicinal cannabis was not a public issue through the 1920s and '30s until, in 1938, *Smiths Weekly* began an anti-cannabis campaign which 'changed Australian drug policy from a medical to a law enforcement model ... mark[ing] the beginning of the Americanisation of cannabis policy in Australia ... based not on medical knowledge, but on misinformation and tabloid hysteria'.<sup>6</sup>

In 1967 Australia ratified the *United Nations Single Convention on Narcotic Drugs 1961*, Article 2(5) of which refers to cannabis as a 'particularly dangerous' narcotic, though it is not chemically a narcotic at all. The Convention's provisions were enacted in the *Narcotic Drugs Act 1967* (Cth), the effect of which was to establish Commonwealth control over the manufacture of cannabis-based drugs as manufacturers now needed to obtain a licence from the Minister, a permit from the Comptroller of Customs as well as permission under New South Wales laws. The *Narcotic Drugs Act* marked the beginning of a bureaucratic turf war which continues to this day, between the federal health and customs departments and the various state departments and agencies.

Under the *Customs Amendment Act No. 2, 1971* (Cth), because the importation of cannabis was absolutely prohibited, anyone found in possession of any form of cannabis was automatically in breach of this provision, without actual proof because it was always reasonable to suspect, which was the standard of proof required under the Act, that the cannabis had been illegally imported. Instead of the prosecution having to prove illegal importation, the accused had to prove s/he had not illegally imported.<sup>7</sup> This provision:

extend[ed] the authority of the [Customs] department far beyond the customs barrier from which its constitutional authority is derived'.<sup>8</sup> Drug law was becoming a special case in which the normal principles of proof and normal levels of punishment did not apply.<sup>9</sup>

In New South Wales the *Poisons (Amendment) Act 1970* introduced provisions whereby possession of a 'prescribed quantity' of cannabis was deemed to be for the purposes of supply or sale, irrespective of intent.<sup>10</sup>

<sup>6</sup> J Jiggins, *Marijuana Australiana: Cannabis Use, Popular Culture and the Americanisation of Drugs Policy in Australia, 1938–1988* (PhD thesis, Queensland University of Technology, Brisbane, Queensland (2004) 166.

<sup>7</sup> *Customs Amendment Act*, s 7, inserting *Customs Act 1901–1971* (Cth), s 231B(1 and s 233B(10).

<sup>8</sup> D Manderson, *From Mister Sin to Mister Big*, (1993) 160.

<sup>9</sup> *Ibid.*

<sup>10</sup> Section 21(2)(a) and 45(a).

In 1971 the *United Nations Convention on Psychotropic Substances* extended the reach of the *Single Convention* and although both *Conventions* allow the use of cannabis for ‘medical and scientific purposes’, the restraint to which cannabis is subject to under them ‘is due more to international politics than chemistry.’<sup>11</sup>

The 1961 *Single Convention* and the 1972 *Protocol* amending the 1961 *Convention* significantly increased the powers of the International Narcotics Control Board by, inter alia, enabling it to control the flow of drugs into a signatory nation independently of that country if it believed that the country’s statistics on drug imports were misleading. Provisions from the 1972 *Protocol* were enacted in the *Psychotropic Substances Act 1976* (Cth).

In response to a recommendation from the Australian Labor Party’s New South Wales Central Executive, the Wran Government set up the ironically named ‘Joint Committee Upon Drugs’, so named because its members were drawn from both sides of both Houses of Parliament. Although I made a submission to the Inquiry, I do not recall that its report had any practical effect on the legality of medicinal cannabis.

Later still, Australia ratified the *United Nations Convention Against the Illegal Traffic in Narcotic Drugs and Psychotropic Substances 1988* in 1992 and enacted its provisions in the *Crimes (Traffic in Narcotic and Psychotropic Substances) Act 1988* (Cth). This Act perpetuated the fiction that cannabis is a narcotic which has ‘contributed to the confusion about cannabis and its effects because it is unjustifiably identified with other dangerous drugs.’<sup>12</sup> Another writer concurs that ‘[t]his classification has been important in shaping public and political perceptions – that cannabis is dangerous to personal health and public safety.’<sup>13</sup>

In the last twenty years there have been several parliamentary, governmental and judicial inquiries and reports into recreational use of cannabis but most of these did not focus on medicinal cannabis. However in 1994 an Australian Capital Territory private member’s bill was introduced into the House of Assembly which sought, inter alia, to provide a defence to the offence of possessing small quantities of cannabis if a medical practitioner engaged in

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<sup>11</sup> R Fox and I Matthews, *Drug Policy: Fact, Fiction & Future* (1992) 699 cited in; M Kyriagis ‘Marijuana-Just What The Doctor Ordered?’ (1997) 20 *UNSWLJ* 594 at 635.

<sup>12</sup> *Ibid* 637.

research certified that the cannabis was being used for medical purposes. Yet, despite its passage through the House, it was never enacted.<sup>14</sup>

A report released in 1994 by the National Drug Strategy Committee, titled ‘The Health and Psychological Consequences of Cannabis Use’ concluded that:

there is good evidence for the therapeutic potential of a pure synthetic form of cannabis in treating cancer patients, reasonable evidence that cannabis is efficacious for glaucoma and that other potential uses, e.g. as an analgesic, anti-asthmatic, anti-spasmodic and anti-convulsant warrant further research.<sup>15</sup>

In 1998, a report titled ‘Therapeutic Uses of Cannabis’ was written by the South Australian Services Council for the Ministerial Council on Drug Strategy. Its conclusions included that the greatest potential for the therapeutic use of cannabis lay in appetite stimulation, pain management and as an anti-emetic. Generally, the report saw the value of cannabis as an ‘adjunct to conventional treatment to improve aspects that are currently resistant to, or inadequately resolved by conventional treatment.’<sup>16</sup> However, in contrast to the National Drug Strategy Committee, it cast doubt on the efficacy of cannabis in the treatment of multiple sclerosis and other neurological conditions and glaucoma due to its claim that the required dosage rate in the long term would be so high as to outweigh any benefits.<sup>17</sup>

## 4.2 *The recent history of medicinal cannabis in New South Wales*

Late in 1999, the then Premier of NSW, Bob Carr, issued a news release stating that his government would examine the feasibility of using cannabis for medicinal purposes.<sup>18</sup> He referred to the House of Lords Select Committee’s conclusion that cannabis could be therapeutically efficacious and also mentioned the Australian Medical Association’s support for its use in the treatment of AIDS and cancer. This initiative led to the establishment of the

<sup>13</sup> M Kyriagis n 11 at 635.

<sup>14</sup> G Griffith and M Swain, ‘The Medical Use of Cannabis: Recent Developments’ *New South Wales Parliamentary Library Briefing Paper 11/9932*.

<sup>15</sup> W Hall, *The Health and Psychological Consequences of Cannabis Use*, National Drug Strategy Committee, Canberra, Monograph No. 25, 1994, 109.

<sup>16</sup> L Gowing et al, ‘Therapeutic Uses of Cannabis: Clarifying the Debate’ (1998) 445 *Drug & Alcohol Review* 447.

<sup>17</sup> *Ibid* 7.

<sup>18</sup> Bob Carr Premier of NSW, ‘Government to Consider Cannabis for Medicinal Purposes’ (News Release, 19 October 1999).

NSW Parliamentary Working Party on the Use of Cannabis for Medical Purposes, whose reports are examined in detail elsewhere in this thesis.<sup>19</sup>

Nearly three years elapsed before the government acted on the Working Party's recommendations when Premier Carr announced that a draft exposure bill would be introduced into the parliament providing for a four year trial of medicinal cannabis, 'at the earliest possible opportunity.'<sup>20</sup> He reported that cabinet had approved a proposal under which suitable patients could gain access to medicinal cannabis through an Office of Medicinal Cannabis to be set up within the Health Department and that the government would liaise with research, pharmaceutical and medical bodies to examine options for the supply of cannabis for the proposed trial.

Under the proposed trial, patients would have to register annually with the government Office of Medicinal Cannabis and would need a doctor's certificate and proof that they had a bona fide ongoing therapeutic relationship with that doctor. Contraventions of the proposed Act would constitute offences, punishable by penalties under the Act.

That same evening the Premier appeared on ABC TV's 'Lateline' program where he fleshed out the proposal. In response to a question as to whether the evidence for medicinal cannabis's efficacy was merely anecdotal, he replied, 'It's been proven in other jurisdictions ... The evidence is in ... there are enough cases for us to compassionately say this is an option for people and the law should no longer stand in the way.'<sup>21</sup>

Whereas the Working Party only found four therapeutic uses for medicinal cannabis – HIV wasting; nausea arising from cancer chemotherapy; neurological muscle spasm and pain unrelieved by analgesics, the Premier extended this list to include cancer wasting and muscle spasticity caused by multiple sclerosis or spinal cord injury.<sup>22</sup> He proposed to exclude from the trial people with convictions for illicit drug use, parolees, pregnant women, anyone under eighteen and, possibly, those prone to a psychotic condition.<sup>23</sup> He emphasised that, 'people are only eligible for this scheme if they face a terminal or a next to terminal condition ... with

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<sup>19</sup> See Section 7.1.

<sup>20</sup> NSW Parliamentary Debates, 'Cannabis Medical Use', Questions Without Notice, 20th May 2003, 697 (Premier of NSW Bob Carr).

<sup>21</sup> ABC Television, 'Cannabis trial won't lead to decriminalisation: Carr', *Lateline*, 20 May 2004.

<sup>22</sup> *Ibid* 2.

the qualification that there will be some people not terminal but in a really serious condition.’<sup>24</sup>

On the issue of supply he raised three alternatives: decriminalising the growing of small amounts for medicinal purposes; state supply of raw cannabis through the Office of Medical Cannabis or, in cooperation with the Commonwealth Government, the importation of GW Pharmaceutical’s sub-lingual spray – Sativex. Replying to a question as to NSW’s actions in the face of the Commonwealth’s refusal to cooperate, he claimed, ‘Our legal advice is that we’d win this. The Commonwealth wouldn’t have a strong legal position to stand on and the moral argument I think would overwhelm any strictly legalistic approach.’<sup>25</sup>

The Coalition leader, John Brogden, supported the proposal, adding that the cannabis used in the trial should be sourced from NSW.<sup>26</sup> Two days later Prime Minister Howard, in a radio interview, was quoted as saying that he was in favour of the trial in principle, providing it is prescribed, there is no legal alternative and ‘provided it does not take the form of being permitted to grow marijuana’.<sup>27</sup> This is the only known recorded statement of former Prime Minister Howard on medicinal cannabis and is notable in that, at face value, his wording appears to include a greater number of eligible patients as he, unlike Premier Carr, did not seek to restrict eligibility to the terminal or near terminally ill.

However, almost a year later, when there had been little or no publicly discernible movement on the matter, Greens MLC Lee Rhiannon asked the responsible Minister, John Della Bosca, in a Question Without Notice, to ‘explain why the Government has continually pushed back the deadline for announcing the trial of cannabis for medical use.’<sup>28</sup> Part of the Minister’s reply was that the Government’s earlier hopes that GW Pharmaceutical’s Sativex would soon be available were incorrect and it ‘will not be available for a few years.’<sup>29</sup> Perhaps influenced

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<sup>23</sup> Ibid.

<sup>24</sup> Ibid 3.

<sup>25</sup> Ibid 4.

<sup>26</sup> J Brogden, ABC News, ‘Grow medicinal cannabis locally’ 13 May 2003 <[http://www.abc.net.au/news/stories/2004/05/13/107701AAP\\_RTV\\_jh\sd\rgr\rp](http://www.abc.net.au/news/stories/2004/05/13/107701AAP_RTV_jh\sd\rgr\rp)> (accessed 13 May 2004).

<sup>27</sup> M Metherell and N O’Malley *Cannabis Trial Wins Howard’s Support* 22 May 2004 smh.com.au <<http://www.smh.com.au/articles/2003/05/21/1053196648522.html>> (accessed 13 May 2004).

<sup>28</sup> NSW Parliamentary Debates, ‘Cannabis Medical Use’, Questions Without Notice, 30 March 2004, 7648 (Greens MLC Lee Rhiannon).

<sup>29</sup> NSW Parliamentary Debates, ‘Cannabis Medical Use’, Questions Without Notice, 12 May 2004, 8888 (Minister John Della Bosca).

by Prime Minister Howard's refusal to countenance patients growing their own cannabis, he backed away from the Premier's earlier endorsement of this option, saying that:

NSW is opposed to any scheme that includes 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.<sup>30</sup>

Although the Minister claimed in his statement that he had 'today' written to the Prime Minister requesting the Commonwealth's cooperation and 'in particular asking him to nominate a ministerial representative to work with NSW on this matter',<sup>31</sup> nothing more emerged from either government until on 19 May 2008, NSW Minister for Health Reba Meagher announced a trial of Sativex, 'pending approval by the Commonwealth.'<sup>32</sup>

One of the most striking features of the history of cannabis, both medicinal and recreational, in Australia is the degree of ignorance which has characterised the debate on its uses and its dangers. Mention has already been made of Australia's complicity with the *Single Convention* in defining cannabis as a narcotic when it is not. Similarly, it was not until 1976 when the *Customs Act* was amended that the Federal government acknowledged that, 'cannabis plants [are] plants of the genus *cannabis* and not of the genus *cannabis sativa* as at present' the *Customs Amendment Act No. 2 1971* (Cth) defines a 'cannabis plant' as 'a plant of the genus *cannabis sativa*', even though this name refers to a species and not a genus.<sup>33</sup>

Arguably it is this ignorance which has enabled politicians to scapegoat and demonise cannabis, notwithstanding that, '[t]ime and again the extreme dangers attributed to it have been shown to be wrong and, in retrospect, bizarre.'<sup>34</sup> It is this ignorance and confusion that has enabled opponents of recreational cannabis to oppose medicinal cannabis by attributing the dangers of recreational use to cannabis medicine and by wrongly equating the dangers of opium, or later, of heroin, to cannabis.

As the above history demonstrates, it is difficult to chart the history of medicinal cannabis separately from that of recreational cannabis use. The role of cannabis as a scapegoat has led

<sup>30</sup> NSW Parliamentary Debates, above n 29.

<sup>31</sup> Ibid.

<sup>32</sup> K Sikora, 'Medical Use of Cannabis Re-opens Drug Debate', *Daily Telegraph* (Sydney), 19 May 2008, 5.

<sup>33</sup> Bills Digest no. 43 1976- *Customs Amendment Act (no.2) 1971* Parliament of Australia, Parliamentary Library <<http://www2.aph.gov.au/library/pubs/bd/1976/1976bd043.htm>> (accessed 4 March 2010).

<sup>34</sup> Manderson, above n 8, 146.

to a series of ebbs and flows of proposed reforms of the cannabis laws, often according to the whims of politicians and interest groups who use the issue as a whipping boy for their moral crusades against perceived social evils.

In his history, Manderson shows how early twentieth century drug policies were driven not by any groundswell of concern in Australia but by the politics of international diplomacy. He traces the movement for drug law reform to its apogee in the mid-1970s and its subsequent decline until, by the time his study was published in 1993, he could conclude that, '[p]olitical and social pressure for reform has faded away and the matter has been taken off the agenda ...',<sup>35</sup>

Previous chapters of this thesis may have substantiated a medical and scientific case for the legalisation and regulation of medicinal cannabis but it is submitted that the lesson to be learned from the history of this issue in this chapter, is that such legalisation will ultimately depend not on the weight of scientific evidence but on the political support that its proponents can garner, and on the vested interests opposed to law reform.

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<sup>35</sup> Ibid 189

## Chapter 5

# RELEVANT OVERSEAS MEDICINAL DRUG LEGISLATION AND CASE LAW

### *5.1 United States current medical marijuana legislation*

#### *Introduction*

By 2009 thirteen states in the United States had implemented effective laws which made the provision of medicinal cannabis legal to seriously ill patients with certain specified medical conditions. The first of these was California in 1996, followed in the same year by Washington state, by neighbouring Oregon in 1998, Alaska and Maine in 1999, Colorado, Nevada and Hawaii in 2000, Montana and Vermont in 2004, Rhode Island in 2006, New Mexico in 2007 and Michigan in 2008.

Some of these laws were the result of plebiscites voted upon by eligible state electors either as referenda in their own right or as propositions added to the ballot for the election of state parliamentary representatives. Others came about as the result of parliamentary bills passed by both houses of the states' bicameral legislatures. Where they were brought about by referenda, the majorities in favour of legalisation ranged between 54% in Colorado to 65% in Nevada.<sup>1</sup>

It is outside the scope of this thesis to explore the various campaigns which have been waged for and against the different states' medical marijuana propositions except to say that both the opponents and proponents of these laws were highly organised and well financed. Amongst the largest in the 'pro' camp were the grassroots lobby group NORML, (the National Organization for the Reform of the Marijuana Laws), while the federal government has been prominent for the 'con' case.

This section of the thesis is devoted to a detailed description and analysis of the US state and Canadian jurisdictions which have introduced medicinal cannabis legislation. The aim here is

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<sup>1</sup> Marijuana Policy Project [MPP], *State by State Medical Marijuana Laws* (2007) Marijuana Policy Project, <[http://www.mpp.org/assets/pdfs/download-materials/SBSR\\_NOV2008\\_1pdf](http://www.mpp.org/assets/pdfs/download-materials/SBSR_NOV2008_1pdf)> (accessed 17 July 2008).

to discover issues which would have to be addressed in my proposed New South Wales Medicinal Cannabis Act and to examine how these have been dealt with in existing legislation. This process should provide some insight into how such provisions should be drafted and into the implications of these provisions for the efficient regulation of a medicinal cannabis statutory regime in New South Wales.

This section of the thesis does not address aspects of the US states' legislation which are not relevant to the model proposed for NSW in this study, ie where the form of cannabis used by medicinal cannabis users is raw smokeable cannabis rather than in pharmaceutical form and where the procedure for obtaining cannabis is not through application by the applicant's treating doctor to the state health department but by a process of registration with a government agency.

### *Preambles*

It is customary both in the USA and Australia that a form of words is used to introduce the statute and to provide a rationale or explanation for its need.

Some states' preambles are minimalist, like that of New Mexico which reads:

The purpose of the ... act is to allow beneficial use of medicinal cannabis in a regulated system for alleviating the symptoms caused by debilitating medical conditions and their medical treatments.<sup>2</sup>

Similarly Oregon's *Medical Marijuana Act* reads:

**475.300 Findings.** The people of the state of Oregon hereby find that:

- (1) Patients and doctors have found marijuana to be an effective treatment for suffering caused by debilitating medical conditions, and therefore, marijuana should be treated like other medicines;
- (2) Oregonians suffering from debilitating medical conditions should be allowed to use small amounts of marijuana without fear of civil or criminal penalties when their doctor advises that such use may provide a medical benefit to them and when other reasonable restrictions are met regarding that use;
- (3) ORS [Sections] 475.300 to 475.346 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 have the benefit of their doctor's professional advice; and
- (4) ORS [Sections] 475.300 to 475.346 are intended to make only those changes to existing Oregon laws that are necessary to protect patients and their doctors from

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<sup>2</sup> (New Mexico) *Lynn & Erin Compassionate Use Act* (2007) NM STAT ANN § 30-31-5 (2007) Section 2.

criminal and civil penalties, and are not intended to change current civil and criminal laws governing the use of marijuana for non-medical purposes.<sup>3</sup>

This form of words covers most of the points that need to be made – the criminalising doctor's advice concerning medical marijuana and its use by eligible patients, whilst maintaining the prohibition on recreational use. However it is suggested that some element of justification of medicinal cannabis use be included in any New South Wales statutory preamble to make clear that the act is based on sound and adequate scientific evidence.

Such a suitable form of words may be found in the Hawaiian *Uniform Controlled Substances Act*, which states:

The legislature finds that modern medical research has discovered a beneficial use for marijuana in treating or alleviating the pain or other symptoms associated with certain debilitating illnesses such as [those qualifying under this Act. There is sufficient medical and anecdotal evidence to support the proposition that these diseases and conditions may respond favourably to a medically controlled use of marijuana.<sup>4</sup>

Since the Canadian medical marijuana regulatory system is based on regulations to an omnibus drugs statute, the *Controlled Substances Act 1996*, the *Canadian Medical Marijuana Act Regulations* do not include a preamble but the regulatory impact statement contains a background statement which canvasses the medical evidence, history and regulatory options which were taken into account in the drafting of the regulations.

### *Definitions*

#### *(a) 'Qualifying medical conditions'*

Under the various United States schemes the eligibility of patients to receive legal crude cannabis depends on their medical conditions or diseases. In this section I will review the qualifying conditions presently required in some of the thirteen US states with medical marijuana laws along with those in Canada and the proposed conditions listed in the NSW Working Party's report.

Some jurisdictions distinguish between 'diseases' and 'conditions' or 'symptoms'. For example Canada specifies one of the qualifying 'medical conditions' as 'cancer' and the

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<sup>3</sup> (Oregon) *Medical Marijuana Act*, ORS REV STAT 475.300– 475.346 (2003) (OMMA) p.1.

<sup>4</sup> (Hawaii) *Uniform Controlled Substances Act*, HAW REV STAT Chapter Part IX 329 § Preamble (2000).

corresponding symptom as ‘severe nausea’, so that both elements must be present to qualify<sup>5</sup> whereas other jurisdictions like Montana refer to qualifying ‘debilitating medical conditions’ such as ‘cancer’ but also separately list ‘severe nausea’ as a qualifying condition in itself, so that both it or ‘cancer’ qualify.<sup>6</sup>

Washington State places a restriction on the use of raw cannabis by requiring that other legally available medications must have been unsuccessfully tried before cannabis can be prescribed.<sup>7</sup> However if Sativex were to be legalised in NSW, such a provision would be needless and onerous as it would presumably require pharmacists and/or doctors to keep extensive files on what was used when and with what effect.

All the jurisdictions include cancer and HIV/AIDS and all but Vermont and the NSW Working Party’s proposals include glaucoma, whilst only Maine and Vermont exclude cachexia, anorexia or wasting syndrome and severe or chronic pain, whereas California and Vermont exclude severe or chronic nausea. All but two jurisdictions, (California and Vermont) allow epilepsy and muscle spasticity is excluded only by Maine and Vermont.<sup>8</sup>

There are also several conditions only permitted in one or two other jurisdictions such as spinal cord injury in NSW and New Mexico, arthritis and migraine in California; agitation of Alzheimers Disease in Oregon and hospice patients in New Mexico.<sup>9</sup>

All jurisdictions except Maine and Vermont make provision for their administering agency to add or remove conditions after some sort of expert review process.<sup>10</sup>

*(b) ‘Qualifying patient’*

In all US states a patient’s eligibility to receive legal medicinal cannabis is based on whether they have been diagnosed by a physician registered in the relevant state as suffering from one

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<sup>5</sup> *Marihuana Medical Access Regulations*, SOR/2001–227 Schedule to § 1 ‘Category 2 Symptoms’.

<sup>6</sup> *Montana Code Annotated* (2009) TITLE 50 Health and Safety, Ch 46 *Medical Majriuana Act*, 50–46–102 Definitions 2 (a) and 2 (b)(3).

<sup>7</sup> (Washington) *Medical Use of Marijuana Act* (1996) (Wash Rev Code Ann § 69.51A.005 to 69.51A 902 subsection2

<sup>8</sup> MPP, above n 1, Appendix T.

<sup>9</sup> *Ibid.*

<sup>10</sup> *Ibid.*

of the ‘debilitating medical conditions’ discussed above. In some but not all states, there is a further requirement that the patient be a resident of that state.<sup>11</sup>

*(c) ‘Attending physician/practitioner’*

Some jurisdictions simply require that ‘a physician’ diagnose a patient as having a debilitating medical condition and recommends medicinal cannabis for its treatment, eg Vermont, Colorado, Hawaii. Other states stipulate that the physician is the patient’s ‘attending physician’, meaning ‘a physician who has established a physician/ patient relationship with the patient...’<sup>12</sup> or has ‘primary responsibility for the care and treatment of a person diagnosed with a chronic or debilitating condition.’<sup>13</sup> A defeated bill in California was more specific, stating that a physician be an ‘attending’ physician if s/he:

has taken responsibility for an aspect of the medical care, treatment, diagnosis, counselling or referral of a patient and who has conducted a medical examination of that patient before recording ... the physician’s assessment of whether the patient has a serious medical condition and whether the medical use of marijuana is appropriate.<sup>14</sup>

It is suggested that this last definition would be inappropriate for NSW as on its face value, it requires only that the physician takes responsibility for ‘an aspect’ of the patient which could result in physicians with little knowledge of the patient recommending medical marijuana for a patient. Besides physicians, some states also allow osteopaths to perform the role of ‘attending physician’, eg Oregon.

*(d) ‘Bona fide physician/patient relationship’*

These phrases arise from the process which applicants have to undergo to acquire eligibility for medicinal cannabis use. It involves attending a physician for diagnosis and advice. However some jurisdictions insist that such diagnosis and advice only be given within the context of a prior and ongoing relationship of doctor and patient which some states term a ‘bona fide physician/patient relationship.’

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<sup>11</sup> Eg Oregon, *Medical Marijuana Act*, above n 3, § 475–300 (2xa).

<sup>12</sup> (Nevada) *Medical Marijuana Act* NRS 453A.030, NAC Chapter 453 A *Medical Use of Marijuana* (2000).

<sup>13</sup> (Oregon) *Medical Marijuana Act*, above n 3 OMMA OMNA 475–302 (2).

<sup>14</sup> (California) State Bill SB 848, 25 February 1999, Article 2–5,11362.7(a).

In Vermont a bona fide physician is defined as:

a treating or consulting relationship of not less than six month's duration, in the course of which the physician has completed a full assessment of the patient's medical history and current medical condition, including a personal physical examination.<sup>15</sup>

In Alaska the definition contains additional elements of 'documented, written findings, diagnosis, recommendations and prescriptions in written patient records maintained by the physician.'<sup>16</sup> The motivation for this criterion is clear and was expressed by general practitioners in my Northern Rivers survey as a fear that they may be overwhelmed by large numbers of new patients whom they knew little about, demanding that they be prescribed cannabis. Although under the proposed new NSW scheme the decision to grant prescription of medicinal cannabis would be made not by a general practitioner but by the state health department, there would seem to be merit in requiring that an applicant's practitioner perform a screening function in an effort to ensure frivolous or inappropriate applications are not made to the department.

(e) *'Written certification/documentation'*

In the United States regulatory systems a patient applicant must be medically assessed as suitable to obtain medicinal cannabis and the term 'written certification' or 'documentation' is used to specify the form of this assessment. The wording of these provisions is fairly standard, the Rhode Island definition reading:

the qualifying patient records or a statement signed by qualifying patient's physician, stating that in the physician's professional opinion, the qualifying patient has a debilitating medical condition and the potential benefits of the medical use of marijuana would likely outweigh the health risks for the qualifying patient'.<sup>17</sup>

The legislation adds that:

a written certification shall be made only in the course of a practitioner patient relationship after the practitioner has completed a full assessment of the qualifying patient's medical history. The written certification shall specify the qualifying patient's debilitating medical conditions.<sup>18</sup>

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<sup>15</sup> (Vermont) *Medical Marijuana Act*, 18 VSA 86 §4472(1) (2004).

<sup>16</sup> (Alaska) *Medical Uses of Marijuana Statute* (1999) AS 17.37.070 (2) (1999).

<sup>17</sup> *Edward O Hawkins & Thomas C Slater Medical Marijuana Act*, RI ALS 443, § 10 (2006).

<sup>18</sup> *Ibid.*

Other states simply refer to ‘written documentation’ by which they mean a statement signed by a patient's physician or copies of the patient's pertinent medical records<sup>19</sup> or a statement ‘signed by the attending physician of the person diagnosed with a debilitating medical condition ...’<sup>20</sup> Oregon’s *Medical Marijuana Act* is a little more specific, providing for a statement signed and dated by the attending physician of the person diagnosed with a debilitating medical condition or copies of the person’s relevant medical records, maintained in accordance with standard medical record practices.<sup>21</sup>

(f) ‘*Designated /primary/registered caregiver*’

This term refers to a person who acts for one or more qualifying patients in procuring, collecting and delivering medicinal cannabis to the patient. All jurisdictions include such a definition, the simplest of which is from Montana where she or he is defined as ‘an individual 18 years of age or older, who has agreed to undertake responsibility for managing the well-being of a person with respect to the medical use of marijuana.’<sup>22</sup> Some states go into more detail about the caregiver’s functions, for example California, which requires that the caregiver has an identity card and ‘has consistently assumed responsibility for the housing, health or safety of that person’.<sup>23</sup> Other states, for example Rhode Island, require that the caregiver has not been convicted of a felonious offence or that neither the qualifying patient nor the patient’s attending physician can be their caregiver.<sup>24</sup>

It is noted that while some states, for example California, require that at the time of application, the caregiver already ‘has consistently assumed responsibility’<sup>25</sup>, while others merely require that the caregiver ‘has agreed to undertake responsibility’, for example Montana.<sup>26</sup> I believe that the latter is preferable as it does not imply a pre-existing relationship between the caregiver and the qualifying patient which might be an unnecessary obstacle for medicinal cannabis applicants.

<sup>19</sup> *Constitution of the State of Colorado*, Article XVIII, § 14 (j) (2003).

<sup>20</sup> (Nevada) *Medical Marijuana Act*, above n 12, § 16 (1).

<sup>21</sup> *Medical Marijuana Act*, above n3 § (16).

<sup>22</sup> *Montana Code Annotated*, above n 6 § 50–46–102 Definitions 1 (a).

<sup>23</sup> (California) *Compassionate Use Act 1996*, H & S § 11362.7 (d).

<sup>24</sup> (Rhode Island) *M Edward O Hawkins & Thomas C Slater Medical Marijuana Act*, above n 18, § 6.

<sup>25</sup> (California) *Compassionate Use Act*, above n 23, § 11362.7 (d).

<sup>26</sup> *Montana Code Annotated*, above n 6,.

None of the jurisdictions specify who is to appoint the caregiver though in practice this would be the responsibility of the qualifying patient but it is recommended that a New South Wales caregiver definition should address this with words to the effect that the qualifying patient should notify their general practitioner as to whom they wish to act as caregiver, or failing that, that the general practitioner should appoint the caregiver and notify the qualifying patient and the health department to that effect.

Secondary ‘alternate’ caregivers are provided for under the Alaskan legislation<sup>27</sup> but it is submitted that this initiative is an unnecessary complication which could be better addressed by appointing a temporary caregiver if the need arose.

### *Exemptions from prosecution*

An effective law must provide legal protection of qualifying patients and for primary caregivers of patients who are too ill to provide for their own medical use of marijuana. In some jurisdictions this protection takes the form of an exemption from prosecution. Typically, the exemption covers possession and delivery of medical marijuana, aiding and or abetting another to do so, or any other criminal offence in which these acts are elements of the crime.<sup>28</sup>

Several jurisdictions, for example Nevada and Montana add a further exemption that:

A person may not be subject to arrest or prosecution for constructive possession, conspiracy ... or other provisions of the law or any other offence for simply being in the presence or vicinity of the medical use of marijuana as permitted under this chapter.

The presumption of this right ‘may be rebutted by evidence that the possession of marijuana was not for the purpose of alleviating the symptoms or effects of a qualifying patient's debilitating medical condition.’<sup>29</sup>

Similarly, the Californian act makes an exception to the general exemption where:

there is reasonable cause to believe that the information contained in the card is false or falsified, the card has been obtained by means of fraud or the person is otherwise in violation of the provisions of this article,

and a further exemption that:

a person may not be subject to arrest or prosecution for constructive possession, conspiracy or other provisions of the law or any other offence for simply being in the presence or vicinity of the medical use of marijuana as permitted under this chapter.<sup>30</sup>

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<sup>27</sup> *Medical Uses of Marijuana Statute*, above n 16, § 17.37.070 (1).

<sup>28</sup> *Medical Marijuana Act*, above n 12, § 25 (1).

<sup>29</sup> *Montana Code Annotated*, above n 6, § 4 50–46–201 (6).

<sup>30</sup> *Compassionate Use Act*, above n 23.

Other states add another exemption, such as in the Rhode Island legislation which reads

no school, employer or landlord may refuse to enrol, employ or lease to, or otherwise penalize a person solely for his or her status as a qualifying patient or registered caregiver.<sup>31</sup>

But the most comprehensive provision comes in the Montana statute which provides that:

the qualifying patient or caregiver who possesses a registry identification card may not be arrested, prosecuted or penalized in any manner or be denied any right or privilege for the medical use of marijuana or for assisting.<sup>32</sup>

In other jurisdictions these exceptions to the general exemptions are contained in a separate offences section which will be discussed below.

The references to ‘registry identification cards’ relate to voluntary or compulsory registration procedures to identify medicinal marijuana users so as to exempt such cardholders from arrest or prosecution. It will be argued below that this system would not be necessary in New South Wales which already has a process in place for the approval by the health department of restricted drugs, which could be amended to identify the qualifying patients or caregivers by their possession of a copy of the department's approval.

In Canada the Medical Marijuana Access Regulations adopt a different approach whereby, instead of ‘exempting’ people, from the provisions of the general drug laws, they are ‘authorized’ to use or assist in the use of medical marijuana.<sup>33</sup>

### *The medical necessity defence*

This form of legal protection for medical marijuana qualifying patients and caregivers is discussed at length elsewhere in this thesis. It is simply noted here that the state of Nevada, among others, specifically makes provision for this defence, stating that:

a person engaged or assisting in the medical use of marijuana who is charged with a crime pertaining to the medical use of marijuana is not precluded from (a) asserting a defence of medical necessity or (b) presenting evidence supporting the necessity of marijuana for treatment of a specific disease or medical condition if the amount of marijuana at issue is not greater than the amount described... in this act and the person has taken steps comply substantially with the provisions of this chapter.<sup>34</sup>

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<sup>31</sup> (Rhode Island) *M Edward O Hawkins & Thomas C Slater Medical Marijuana Act*, above n 18, § 21–28, 6–4 (B).

<sup>32</sup> *Montana Code Annotated*, above n 6, § 50–46–201 (1).

<sup>33</sup> *Medical Marijuana Access Regulations*, above n 5 Part 1 § 2 & Part 2, § 24.

<sup>34</sup> *Medical Marijuana Act*, above n 12, § 25 (3) (a) & (b).

Similarly, Oregon's statute states:

no person engaged in the medical use of marijuana who claims that marijuana provides medically necessary benefits and is charged with a crime pertaining to such use of marijuana shall be precluded from presenting a defence of choice of evils... or from presenting evidence supplying the necessity of marijuana for the treatment of a specific disease or medical condition, provided that the amount at issue is no greater than permitted under ORS 475.320 and the patient has taken a substantial step to comply with the provisions of ORS 475.300 to 475.346.<sup>35</sup>

However, unlike Nevada, which specifically allows the defence for, 'a person assisting in the medical use of marijuana...'engaged or,<sup>36</sup> the Oregon law only permits the defence to a 'person engaged in the medical use of marijuana'<sup>37</sup> and then goes on to refer to such a person as 'the patient'. Elsewhere in this thesis it is argued that the medical necessity defence should be available to both qualifying patients and caregivers as a matter of equal justice. The state of Hawaii also has a 'choice of evil' defence embodied in a separate act.<sup>38</sup>

Most US states permit an affirmative defence where the person charged is not registered under the state's medical marijuana scheme and/or they are charged with having more than the statutory amount of marijuana as long as they have substantially complied with the medical marijuana legislation.<sup>39</sup>

### *Legal protection for medical practitioners*

All US states with medical marijuana laws include provisions for the legal protection of attending physicians. They are rendered immune from prosecution and guaranteed that they will suffer no loss of rights or privileges if they advise patients about the risks and benefits of medical marijuana or provide written certification that the benefits outweigh the risks, on the proviso that the advice is based on the attending physician's professional opinion 'after having completed a full assessment of the patient's medical history and current medical condition made in the course of the finding physician-patient relationship.'<sup>40</sup>

It is submitted that it is important to the success of the operation of a legal medical marijuana regime in New South Wales that some sort of statutory protection be given to attending

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<sup>35</sup> *Medical Marijuana Act*, above n 3, 475.319 (3).

<sup>36</sup> *Medical Marijuana Act*, above n 12.

<sup>37</sup> *Medical Marijuana Act*, above n 3.

<sup>38</sup> MPP, above n 1, 12, Table 1.

<sup>39</sup> MPP, above n 1, 12–13, Table 1.

<sup>40</sup> *Lynn & Erin Compassionate Use Act*, above n 2, § 4 D.

physicians in this state and that this should be extended to pharmacists who, in Australia, unlike other US states, would play a part in the dispensing of medicinal cannabis.

*Provision of legal means for qualifying patients and caregivers to obtain medicinal cannabis*

Obtaining a reliable supply of medicinal cannabis continues to be an intractable problem for all medical marijuana jurisdictions due to its interface with criminality and represents one of the reasons why this thesis does not advocate the medical use of smokeable cannabis. Therefore only a brief consideration is given to this issue here.

Most of the US states' statutes address the issue of supply by allowing qualifying patients or their caregivers to grow a small number of cannabis plants (usually six) and to possess an ounce of dried marijuana at any one time. Allowable limits range from one pound and six plants in Montana<sup>41</sup> to 28 ounces and six mature or 12 immature plans in California.<sup>42</sup>

This has led to the inevitable problems where caregivers are growing multiple plants for several qualifying patients and it is difficult to determine which plants are for which patients. Then there are problems around the definition of mature and immature plans and between indoor and outdoor growing cannabis, the differing quantities needed for different medical conditions and differences between individual patients' needs. But a more serious problem arises for many qualifying patients who are unable to grow their own medical marijuana and unable to find a caregiver who will grow for them. Although a number of cannabis buyers' clubs have been established to meet this need, the United States state medical marijuana legislation makes no provision for their operation and they remain illegal and vulnerable to raids by local, state and federal law enforcement agencies and there are too few of them to meet the demand. Hence many qualifying patients and caregivers in all the jurisdictions are forced to buy their cannabis on the black market with the consequent risks of prosecution, contamination of the product, and variability in quality.

The Canadian legislation has gone further to address the supply problem than any other jurisdiction but there too the authorities continue to be plagued with problems.

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<sup>41</sup> *Montana Code Annotated*, above n 6, § 4(2).

<sup>42</sup> *Compassionate Use Act*, above n 23, 11362.77 a.

Canada has opted to contract a private company to grow medical marijuana on its behalf and then to sell it to medicinal cannabis users by mail order. The *Medical Marijuana Access Regulations* also make provision for medical practitioners to supply medical marijuana from licensed dealers to their patients, but it is unclear how many doctors are doing so as many Canadian doctors have been reluctant to participate in the statutory scheme. Health Canada, the governmental body with responsibility for the program is looking into the possibility of supply through pharmacies.

None of the medical marijuana jurisdictions include the supply of medical marijuana in other than smokeable form despite several US states' definitions of 'usable marijuana' as including 'any mixture or preparation thereof'<sup>43</sup> or in Hawaii, 'marijuana concentrate.'<sup>44</sup>

However, under separate legislation, the Canadian government has allowed pharmacists to dispense Sativex, a commercially marketed extract of THC and other cannabis constituents since late 2006. Similarly the UK government has legislated interim arrangements to permit the import of Sativex from Canada for use by multiple sclerosis patients.

#### *Offences and restrictions on use*

Many of these offences and restrictions would arguably not be necessary under the regulatory scheme proposed in New South Wales as they are concerned with smokeable medicinal cannabis. Thus, all US state jurisdictions banned smoking in or near schools and on public transport or in public places or places where tobacco smoking is banned unless the smoking is done in a building, while all states except California ban medicinal cannabis use in or near jails.

It is submitted that none of these restrictions are relevant to New South Wales. However all the US state legislation contains another range of offences which are potentially relevant to New South Wales in relation to fraud. Under the scheme proposed, the qualifying patient or caregiver would be required to keep a prescription for medicinal cannabis on their person at any time when they are also carrying medicinal cannabis on their person or when they give a prescription to a pharmacist to fill. These requirements are similar to those in the United States where a registration system exists for medicinal cannabis users and where qualifying patients and caregivers are required to carry registration identification cards to prove their

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<sup>43</sup> *Medical Marijuana Act*, above n 3, definitions 475.302 (11).

right to possession of medicinal cannabis. Consequently these jurisdictions have legislated against theft or fraudulent use of registration cards including counterfeiting or altering them and also against people fraudulently representing a medical condition or supplying false information for the purpose of obtaining medicinal cannabis or of preventing arrest. Penalties for all of these offences ranged from a fine of \$US250–\$1000 and/or one month to one year in jail.

A separate category of offences involves the sale of medicinal cannabis to anyone or its delivery to someone not entitled to use it, which is applicable to NSW.<sup>45</sup> Two other restrictions are potentially applicable in New South Wales: an offence for a breach of a qualifying patient's confidentiality<sup>46</sup> and the waiving of qualifying patients' rights to reimbursement by health insurance providers of any monies spent on medicinal cannabis.<sup>47</sup>

## 5.2 *United States medical marijuana case law*

This section seeks to explain the evolution of case law relating to medical marijuana in the United States by tracing a chain of selected legal cases. Some of the cases discussed also raise the 'medical necessity' defence and will be further scrutinised in the section dealing with that defence.

### *United States v Randall*

This was the first case to extend the medical necessity defence to the crimes of possession or cultivation of marijuana. The defendant suffered from almost total loss of vision which he had unsuccessfully treated with the then available proprietary drugs before discovering that marijuana gave him considerable relief. After he began growing several cannabis plants for his own medicinal use his property was raided by federal authorities and he was arrested and charged with cultivation and possession of an illegal substance. In his defence Randall raised the venerable doctrine of necessity, which holds that when faced with the sole choice of committing one of two illegal acts, it is not a crime to choose the lesser of the two.<sup>48</sup>

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<sup>44</sup> *Uniform Controlled Substances Act*, above n 4, definitions.

<sup>45</sup> *Ibid* § 453 A. 300.1 see 24 (e).

<sup>46</sup> See section 6(d) of my Draft Medicinal Cannabis Bill at Chapter 9.3.

<sup>47</sup> After consideration of the differences between the public health systems in the two countries, it was decided not to include such a provision in the Draft Bill.

<sup>48</sup> *United States v Randall*, 101 Daily Wash.L.Rep 2249 (DC Super.C1.1976).

The Court laid down a three-part test, specifying the necessary elements of the defence which still remains today as the authoritative statement of the medical necessity defence in the United States of America:

- (1) that the defendant did not intentionally bring about the circumstances that precipitated the unlawful acts;
- (2) that the defendant could not accomplish the same objective using a less offensive alternative; and
- (3) that the evil sought to be avoided was more heinous than the unlawful act perpetrated to avoid it.<sup>49</sup>

In weighing up the relative considerations, ‘the court concluded that the defendant's right to preserve his sight outweighed the state's interest in outlawing the drug.’<sup>50</sup> Consequently Randall was found not guilty of the possession of marijuana.

*State of Washington v Diana*<sup>51</sup>

In this early case the Court held that the defendant, who used medical marijuana to treat his multiple sclerosis, was entitled to present evidence that his use of marijuana was a medical necessity which justified his possession of the drug. Adapting the medical necessity three point test in *Randall* to the circumstances of Diana’s case, the court held that his conviction should be set aside if the preponderance of evidence showed:

- (1) he reasonably believed his use of marijuana was necessary to minimise the effects of multiple sclerosis;
- (2) the benefits derived from its use are greater than the harm sought to be prevented by the controlled substances law; and
- (3) no drug is as effective in minimising effects of the disease.<sup>52</sup>

The Court found that cannabis minimised the effects of multiple sclerosis and that these benefits outweighed society’s interest and no other effective drug was available. On this basis, the Court ruled that Mr Diana had established his defence and found him not guilty, setting aside his conviction.

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<sup>49</sup> A J LeVay, ‘Urgent Compassion, Prosecutorial Discretion and the Medical Necessity Defence’ (2000) 41 *Boston College Law Review* 699, 716.

<sup>50</sup> *Ibid.*

<sup>51</sup> *State of Washington v Diana*, 604 P 2d.1312 (Wash. App. 1979).

*New Jersey v Tate*<sup>53</sup>

This was one of the first of many subsequent cases in which the medical necessity defence was struck down or disallowed because it was seen to be in conflict with legislative provisions regarding marijuana. In this case the defendant, who suffered from quadriplegic spasticity, was denied that defence because he had not sought to obtain marijuana legally by taking part in the state's medical marijuana therapeutic research program, even though the program was not operating, had not approved any applications, had no funding and did not cover multiple sclerosis. The Court set out three criteria in relation to the status of the medical necessity defence where medical marijuana statutory provisions were in place:

- (1) the conduct is justifiable only to the extent permitted by law;
- (2) the defence is unavailable if either the Code or other statutory law defining the offence provides exceptions or defences dealing with the specific situation involved; and
- (3) the defence is unavailable if a legislative purpose to exclude the justification otherwise plainly appears.<sup>54</sup>

*Minnesota v Hanson*<sup>55</sup>

Hanson suffered from epilepsy for 35 years and although he had been prescribed many medications they all produced disturbing side-effects except marijuana. Despite hearing evidence of marijuana's efficacy in the treatment of epilepsy, the court followed *Tate* in holding that the existence of a *THC Therapeutic Research Act* in Minnesota was sufficient proof that the state legislature had considered the issue and determined that participation in the research program constituted the only exception to illegality that the law would countenance.

*United States v Burton*<sup>56</sup>

Here the Court acknowledged the applicability of the medical necessity defence but ruled that the defendant had failed to prove one element of the test. Although Burton had glaucoma and claimed that he grew and smoked marijuana for his illness, he was charged with manufacturing, cultivating and possessing marijuana. The Court ruled that he did not make out the second element of the test – that he had no other alternative – because he could have

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<sup>52</sup> S McGuire, 'Medical Marijuana State Law Undermines Federal Marijuana Policy: Is the Establishment Going to Pot?' (1997) 7 *San Joaquin Agricultural Law Review* 73, 86.

<sup>53</sup> *New Jersey v Tate*, 505A 2d 941, (NJ 1986).

<sup>54</sup> McGuire, above n 53, 85.

<sup>55</sup> *Minnesota v Hanson*, 468 N.W. 2d 77 (Minn. App. 1991).

involved the federal government's IND Investigation New Drug Program under which approved patients could obtain marijuana for their serious medical conditions.

*Jenks v State of Florida*<sup>57</sup>

The facts of this case are so tragic that they are worth quoting at length, as they clearly demonstrate the desperation of seriously ill patients, which impel them to use illegal marijuana:

Ken Jenks inherited haemophilia from his mother and contracted the acquired immune deficiency syndrome (AIDS) virus from a blood transfusion in 1980. He unknowingly passed it to his wife, Barbara Jenks. Mrs Jenks' health began to decline rapidly. Her weight dropped from 150 to 112 pounds during a three-week period as a result of constant vomiting and she was hospitalised at least six times for two to three weeks at a time. Although she had been prescribed over a half dozen oral medications for nausea, none of them worked. When given shots for nausea, she was left in a stupor and unable to function ... When the Jenks began participating in a support group ... a group member told them how marijuana had helped him. Although initially reluctant, Mr and Mrs Jenks tried marijuana and found that they were able to retain their AIDS medications, eat, gain weight, maintain their health and stay out of hospital. They asked their treating physician about prescribing the drug but were unable to obtain a legal prescription. The Jenks decided to grow two marijuana plants to ensure its availability, avoid the expense of buying it on the street, and decrease the possibility of arrest. On March 29, 1990 the Jenks were arrested and charged with manufacturing (cultivating) cannabis.<sup>58</sup>

Medical evidence given at the trial established that their treating doctor had been unable to find any effective treatment for their nausea which was so serious that, if uncontrolled, it could lead to their deaths. Marijuana was the only medication that controlled the nausea and their doctor had actively sought to obtain it from the federal government without success. This testimony and the court's value judgement considering their potential deaths outweighed the benefits of upholding the state's laws on marijuana and the Jenks were therefore found not guilty.<sup>59</sup>

*Idaho v Hastings*<sup>60</sup>

Here the defendant used marijuana to treat his rheumatoid arthritis and, when charged, sought to invoke the medical necessity defence. The Court in the first instance denied the defence,

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<sup>56</sup> *United States v Burton*, 894 F. 2d 188,191 (6<sup>th</sup> Cir. 1990).

<sup>57</sup> *Jenks v State of Florida*, 16F.L.W. D 1070 (Fla. 1<sup>st</sup> DCA, Ap. 16 (1991).

<sup>58</sup> *Ibid* 1–2.

<sup>59</sup> McGuire, above n 53, 7.

<sup>60</sup> *Idaho v Hastings*, 801 P. 2d. 563 (Idaho Sup. Ct 1990).

while on appeal the Idaho Supreme Court held that the defendant could present evidence under the common-law defence of necessity, similar to that given in *Jenks*.<sup>61</sup>

*Commonwealth v Hutchins*<sup>62</sup>

Hutchins unsuccessfully pleaded the medical necessity defence in respect of his sclerodoma and Reynaud's phenomenon. The Court held that evidence of necessity could not be considered until the trial court first considered 'whether the harm that would have resulted from compliance with the law significantly outweighs the harm that reasonably could result from the court's acceptance of necessity as an excuse in the circumstances presented....' The Court concluded that, while circumstances *can* overcome the 'competing harms' test, Hutchin's circumstances were insufficient.<sup>63</sup>

*Washington v Cole*<sup>64</sup>

Like the Court in *Hutchins*, the Court here held that Cole had not provided sufficient evidence to support the defence in relation to his chronic back pain.

*People v Trippet*<sup>65</sup>

This was the first case involving Proposition 215, of the *Californian Compassionate Use Act 1996* to be litigated. The defendant was apprehended by police in a car in which she was carrying two pounds of marijuana. In this case the defendant suffered from migraines which were specifically included in the Act as a medical condition which could allow a sufferer to apply for medical marijuana. However the defendant never produced any evidence of a physician's diagnosis of this condition and also stated that she sometimes used cannabis for spiritual purposes. The Court stated that a physician's approval was a critical factor in a successful medical necessity defence but found that this was absent in this case.<sup>66</sup>

Citing another case,<sup>67</sup> the court recast the elements of the medical necessity defence as it applied to the defendant in *Trippet* as:

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<sup>61</sup> McGuire, above n 53, 8.

<sup>62</sup> *Commonwealth v Hutchins*, 575 NE 2d 741 (Mass. 1991).

<sup>63</sup> McGuire, Above n 53, 8.

<sup>64</sup> *Washington v Cole*, 74 P. 2d 878 (Wash App. 1994).

<sup>65</sup> *People v Trippet*, 6 Cal Rptr 2d. 559 (Ct. App. 1994).

<sup>66</sup> Ibid 569.

<sup>67</sup> *People v Pena* 197 Cal. App. 3d. Supp 14, 25–6 (1983).

- (1) she transported and possessed marijuana to prevent a significant evil;
- (2) she had no adequate alternative to marijuana;
- (3) the harm from possessing and transporting marijuana was not greater than the harm avoided;
- (4) the defendant believed her actions were necessary to prevent a greater harm;
- (5) her belief was objectively reasonable; and
- (6) she did not contribute to the creation of the emergency situation.<sup>68</sup>

The Court held that her defence was excluded by the absence of the second element because she had access to Marinol, a cannabis-based pharmaceutical.

The case raised some important issues for the ongoing operation of the Californian Act, none more critical than that of the treating physician's opinion regarding the suitability of medical marijuana for a particular patient. It is also an issue that has relevance for the proposed New South Wales Medicinal Cannabis Act for here too the treating general practitioner has a role in approving medical cannabis. The Californian legislation requires the 'written or oral recommendation or approval of a physician'.<sup>69</sup> While the *Trippet* court observed that, 'approval' implied less involvement than a 'recommendation', it did not set a lowest level for what might constitute the approval. Again, the Act allows for a written recommendation of medical marijuana which may be seen by the courts as being in conflict with federal law which proscribes medical marijuana on a physician's prescription pad since the only difference may be the absence of a letterhead.

The other issue raised in commentary on the case is that of how serious is 'serious' in the context of the medical marijuana user's illness. Although the Californian Act defines migraine, headaches and arthritis as 'serious', there do not seem to be any guidelines set down by the courts as to the operational definition of 'serious'.

The Court in *People v Trippet* seemed to disregard any threshold level of illness that is a pre-requisite for protection under the Act

[b]ut there may be a point where a line will need to be drawn between those truly 'seriously ill' patients and those who are not sufficiently ill and maybe more able to use

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<sup>68</sup> Above n 66, 569.

<sup>69</sup> *Californian Health And Safety Code* 11362.5 (West 1997).

other forms of pain relief... if this line is not drawn... there is a possibility of a backlash against any medicinal use of marijuana...<sup>70</sup>

*Conant v Walters*<sup>71</sup>

Whilst this case is seminal to the evolution of United States laws on medical marijuana, it has limited relevance to New South Wales as it was largely fought on the US constitutional right to freedom of speech. The case concerned threats from the federal government to revoke the practising licences of physicians recommending medicinal cannabis and suspending their participation in publicly funded Medicaid and Medicare programs, following the passage of the Californian *Compassionate Use Act*. Several physicians and patients filed suit claiming they had the right under the First Amendment to the United States Constitution to recommend the use of medical marijuana for their patients. Following several hearings and appeals the Ninth Circuit Court issued a permanent injunction restraining the federal government from threatening or penalising physicians from recommending medical marijuana to eligible patients. The federal government sought to appeal to the Supreme Court but leave was refused, leading one advocacy group to claim this as an ‘historic victory’ which ‘appears to have put a stop to the Federal government’s efforts to punish physicians who recommended medical marijuana to patients.’<sup>72</sup>

*People ex rel Lundgren v Peron*<sup>73</sup>

This was California’s first attempt to shut down one of the cannabis buyers cooperatives that sprang up following the passage of the *Compassionate Use Act*. The defendant, Dennis Peron, was a high profile cannabis activist who had been openly defying the state government by going beyond the Act in operating his cannabis buyers club, which sold marijuana to qualifying patients. The state sought and was granted an injunction to close the club, on the basis that, by selling and possessing marijuana it had breached the Californian Health and Safety Code and that the designation of club workers as ‘primary caregivers’ was a ‘myth’ as it was held they did not consistently assume responsibility for the housing, health or safety of qualifying patients.<sup>74</sup> In the course of its judgment, the Court also held that a medical necessity defence was not available.

<sup>70</sup> A L Bergstrom, ‘Medical Use of Marijuana: A look at Federal and State Responses to California’s Compassionate Use Act’ (1997) 2 *De Paul Journal of Health Care Law* 181.

<sup>71</sup> *Conant v Walters*, 309 F.3d. 629, 936 (9<sup>th</sup> Cir 2002).

<sup>72</sup> MPP, above n 1, App. I, p 3.

<sup>73</sup> *People ex rel Lundgren v Peron*, 70 Cal. Rptr. 2d. 20 (1999).

<sup>74</sup> *Ibid* 30.

*United States v Cannabis Cultivators Club*<sup>75</sup>

In this case the federal government petitioned the court for an injunction to restrain six different cultivators and buyers clubs from operating but here, unlike the Court in *Peron*, this court did countenance a medical necessity defence, adopting the four-point test in *Aguilar*.<sup>76</sup>

*United States v Oakland Cannabis Buyers Cooperative*<sup>77</sup>

The Oakland Cannabis Buyers Cooperative (OCBC) was one of the defendants in the Cannabis Cultivators' case. Instead of appealing the decision in that case, the OCBC elected to file two motions in the United States Ninth Circuit Court of Appeals. One of these petitioned the court to modify its injunction preventing the Co-op from distributing medical marijuana to its seriously ill patient clients on the grounds of medical necessity. Although the Court granted the motion, the federal government appealed to the Supreme Court which ruled 8 to 0 that 'a medical necessity exception to marijuana is at odds with the terms of the *Controlled Substances Act*', because the Act's provisions, 'leave no doubt that the defence is unavailable' as 'the statute reflects a determination that marijuana has no medical benefits worthy of an exception.'<sup>78</sup>

Again OCBC appealed the case in the District Court, raising constitutional and other issues but in June 2003, Justice Breyer issued a permanent injunction prohibiting OCBC and two other organisations from distributing medical marijuana, ruling that the cooperative, 'has no constitutional right to distribute medical marijuana to sick patients.'<sup>79</sup>

On the issue of medical necessity,

the court found that the OCBC did not fit the paradigm of a defendant who may assert necessity' and that the Co-op was not forced to confront the choice but 'thrust that choice upon themselves by electing to become distributors for such patients.'<sup>80</sup>

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<sup>75</sup> *United States v Cannabis Cultivators Club*, F. Supp. 2d. 1086 (n.D. Cal.1998).

<sup>76</sup> *United States v Aguilar*, 583F 2d 667.693 (9<sup>th</sup> Circuit, 1989).

<sup>77</sup> *United States v Oakland Cannabis Buyers Cooperative*, 523 U.S. 483 (2001).

<sup>78</sup> *Ibid* 494.

<sup>79</sup> MPP, above n 1, 72 at App. I, p. 4.

<sup>80</sup> Oakland, above n 78, cited in Dennis S Newitt 'Notes and Comment: the Medical Use of Marijuana: State Legislation, Judicial Interpretation and Federal Drug Laws' (2002) 4 *Legal Advoc & Prac* 156, at 174.

*United States v Smith*<sup>81</sup>

The subject of this case was a Vietnam veteran suffering post traumatic stress disorder for which he grew and used marijuana. Federal officials raided his property and arrested Smith, charging him inter alia, with growing 87 cannabis plants. One academic commentator claims that:

the Ninth Circuit's Order in Smith is a historic decision, in so far as it represents the first time that a circuit court recognized the applicability of the medical necessity defence of medical marijuana in a federal criminal prosecution.<sup>82</sup>

However more recent cases have overtaken Smith's significance, leaving it with mainly historical significance.

*County of Santa Cruz et al. v Ashcroft et al.* and *Wo/mens Alliance for Medical Marijuana, Valerie Corral and Michael Corral v United States*<sup>83</sup> ('WAMM' case)

These two cases relate to the same set of facts which originated:

when heavily armed federal agents stormed the Wo/men's Alliance medical marijuana cooperative and destroyed 167 marijuana plants. During this raid, they handcuffed several medical marijuana patients while destroying the plants that Valerie and Michael Corral had been dispensing free of charge.<sup>84</sup>

As the *Santa Cruz* case involved mainly constitutional issues it is not considered further here. The *WAMM* case involves the Corral's attempts to have the marijuana plants seized in the Drug Enforcement Administration raid returned to them. At the time of writing the case is still before the courts.

*Raich v Ashcroft and Gonzales v Raich*<sup>85</sup>

Like *Santa Cruz*, these cases concerned a DEA raid on two medical marijuana users and the constitutional applicability of federal commerce powers over intra-state activities. Like most of the cases cited above, this case dragged on in different state and federal courts for years. Again, like many of the earlier medical marijuana cases, initial victories for the pro-medical marijuana parties were overturned on appeal, as the Supreme Court ruled 6 to 3 that,

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<sup>81</sup> *United States v Smith*, No. 99-10477 (9<sup>th</sup> Cir. 1999).

<sup>82</sup> LeVay, above n 50, 733.

<sup>83</sup> *County of Santa Cruz et al. v Ashcroft et al.* C-03-1802 JF Dis. Crt North California (2004) and *Wo/mens Alliance for Medical Marijuana, Valerie Corral and Michael Corral v United States*, No. 03-15062 Dis. Ct Northern California (2008).

<sup>84</sup> MPP, above n 1, App. I 5.

<sup>85</sup> *Raich v Ashcroft*, 352 F. 3d. 1222 (9<sup>th</sup> Cir. 2003) and *Gonzalez v Raich*, 125 (S. Ct. 2195 (2008)).

‘Congress’s power to regulate commerce extends to purely local activities that are ‘part of an economic class of activities that have a substantial effect on interstate commerce’.<sup>86</sup>

Nevertheless the Court did state:

we acknowledge that evidence proffered by the respondents in this case regarding the effective medical uses for marijuana, if found credible on trial, would cast serious doubt on the accuracy of the findings that require marijuana to be listed in schedule 1.<sup>87</sup>

*Abigail Alliance for Better Access to Developmental Drugs and Washington Legal Foundation v Eschenbach and Leavitt*<sup>88</sup>

The appellants in this matter took a different approach to seeking court permission for seriously ill patients to use medical marijuana. They employed human rights and constitutional principles to argue that such patients should have access to drugs which had undergone preliminary human trials but had not yet been approved by the federal regulatory body, the Food and Drug Administration. The Alliance argued that the Due Process Clause of the Fifth Amendment to the United States Constitution provides that ‘no person shall be deprived of life, liberty or property, without due process of law’. For parties to succeed in such a claim they must satisfy the tests laid down in *Washington v Glucksburg*<sup>89</sup> – that the fundamental right asserted is objectively, ‘deeply rooted in this nation’s history and tradition.’ The appellants argued that this fundamental right includes ‘the right of terminally ill patients, acting on a doctor’s advice, to obtain potentially life-saving medication when no alternative treatment approved by the government is available.’<sup>90</sup> In their submission, the decision to take the risks of a drug that has not yet been fully tested should be the prerogative of the terminally ill patient as she has a right to control what she puts in her body and that it is a crime for the FDA to interfere with this right to save or prolong one’s life.

These patients are only asking for the same rights accorded to human experimental subjects in new drug trials. The court accepted these arguments, ruling:

we conclude, upon applying the *Glucksburg* analysis and heeding the protected liberty interests articulated by the Supreme Court, that where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined

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<sup>86</sup> M Eddy, *Medical Marijuana: Review and Analysis of Federal and State Policies* Congressional Research Services, Library of Congress CRS Report for Congress, 29 December 2005, 11 citing *Gonzalez v Raich* 125 (S. Ct. 2195, 2008).

<sup>87</sup> *Gonzalez v Raich*, above n 86, 2211.

<sup>88</sup> *Abigail Alliance for Better Access to Developmental Drugs*, N (2006) and *Washington Legal Foundation v Eschenbach and Leavitt*, No. 04-5350 U.S. (2006) Dist of Columbia Circ Ct

<sup>89</sup> *Washington v Glucksburg*, 521 US 702 (1997).

<sup>90</sup> *Abigail*, above n 89, 14.

by the FDA after Phase 1 trials to be sufficiently safe for experimental human trials, warrants protection under the Due Process Clause. The prerogative asserted by the FDA to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access-this impinges upon an individual liberty deeply rooted in our nation's history and tradition of self-preservation.<sup>91</sup>

### 5.3 Canadian regulation of drugs<sup>92</sup>

The *Controlled Drugs and Substances Act 1996 (CDSA)* draws on the *United Nations Single Convention* in allocating different drugs into eight different categorised schedules and allocates cannabis to Schedule II which only contains cannabis-based substances.

With respect to drugs for medical and scientific purposes, sub-section 55(1) empowers the Governor in Council to make regulations. These regulations in particular apply to pharmacists, businesses and physicians and the sub-section covers a wide range of matters, including importation and exportation, control of production, delivery, possession, obtaining substances and the issuance of permits.

Under section 56:

the Minister for Health may, on such terms and conditions as s/he deems necessary, exempt any person or class of persons or any controlled substance or any precursor or any class thereof from the application of all or any of the provisions of the Act or the regulations, if in the Minister's opinion, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

For a time, medicinal cannabis users could apply for exemption from the other provisions of the *CDSA* under s. 56. This process required applicants to demonstrate that an exemption was necessary for medical purposes and also required the patient's physician to support the application with a written statement, along with details of the patient's drug and medical case history.

The s. 56 exemption process came under challenge in the case of *Wakeford v Canada*<sup>93</sup> in which the Court ruled that no real process had been established by s. 56 to handle exemptions

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<sup>91</sup> Ibid 29.

<sup>92</sup> This section draws on: G Irvine, 'Hitzig & Ors. v Canada: A Case Note' (2003) 7 *SCULR* 326–340.

<sup>93</sup> *Wakeford v Canada* [1998] O.J. No. 3522 (Ont Gen Div.).

and therefore the statutory exemption it provided was ‘illusory’ and not in accordance with the principles of fundamental justice in giving unfettered discretion to the Minister.

*Wakeford* was followed by *R v Parker*<sup>94</sup> which reached a similar conclusion. Although both cases were argued and decided on the basis of Canadian constitutional law under the provisions of the Charter of Rights which have no application in New South Wales, some of the *Parker* Court’s findings concerning the *Medical Marijuana Access Regulations (MMAR)* are relevant to a discussion of general principles and specific regulations concerning medicinal cannabis use regulatory regimes. The Court found that no pharmacist would fill a prescription for cannabis and that it was practically impossible to find a legal source of cannabis in Canada.<sup>95</sup>

### *The Medical Marijuana Access Regulations (MMAR)*

Consistent with the policy adopted throughout this thesis, the following discussion of the provisions of the *MMAR* excludes any which do not relate to the scheme propounded here for a medicinal cannabis regulatory regime in New South Wales. Consequently this discussion does not include consideration of patient registration, licensing and regulation of producers of cannabis for medicinal cannabis users, as these relate to the fact that the regulations only apply to raw cannabis and not, as here proposed for New South Wales, to pharmaceutical formulations of cannabis.

### *Eligibility*

Of all the jurisdictions studied in this research, Canada’s eligibility rules under the *MMAR* are the most complex and detailed. They provide for three categories – Category 1 for applicants suffering from a symptom associated with a medical condition for which the prognosis is death within twelve months; Category 2 for applicants suffering from specific symptoms associated with named medical conditions and Category 3 where applicants suffer from symptoms associated with a medical condition other than any described in Categories 1 and 2.

A requirement for the granting of medicinal cannabis use embodied in each of the categories is that the applicant patient must sign a written declaration that s/he is aware that no certificate

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<sup>94</sup> *R v Parker* [2000] 49 O.R. (3d) 481.

<sup>95</sup> *Ibid* 155.

of compliance under the *Food and Drug Act* has been issued concerning the safety and efficacy of cannabis as a drug and that s/he understands the significance of that. This was presumably inserted as an indemnity clause absolving the government and the patient's physician from liability in the event that the medicinal cannabis user suffered an untoward reaction which caused damage to their health.

It is submitted that this indemnity would also be necessary in any New South Wales medicinal cannabis use regulatory scheme because, as presently advised, the Therapeutic Goods Administration does not have sufficient valid research evidence of the efficacy of 'Sativex' to decide that it is safe and effective for particular conditions and symptoms.

Since their original introduction in 1999 the *MMAR* have twice been amended. The first group of amendments was gazetted on 3<sup>rd</sup> December 2003. Apart from very minor amendments and some amendments related to systemic features irrelevant to a NSW regime, (for example, licences to grow cannabis), section 4 removed the requirement that medical cannabis applicants are required to consult a specialist doctor specialising in the conditions in respect of which the application was made. This was prompted by difficulties experienced by rural applicants in finding an appropriate specialist within the range of where they lived.

Section 5 added general practitioners and section 70 added licensed dealers as sources of medical marijuana for medicinal cannabis users as many patients experienced problems in obtaining their medicine through the other legitimate channels. Section 34 was amended to require that packages of medical marijuana sent through the post could not be identified as such, that they had to have a seal on them and that records had to be kept to trace the packages in transit.

Further *MMAR* amendments were gazetted late in June 2005. Among these was the deletion of the requirement for doctors to make written declarations that they judged that the benefits outweighed the risks of prescribing medical marijuana for particular patients. Another amendment waived the stipulation that terminally ill patients were only assessed as such if their doctor believed. The amendments, primarily concerning doctors, were largely implemented to encourage more doctors to participate in the regulatory scheme, for the President of the Canadian Medical Association in June 2005 predicted that the majority of

Canadian doctors would continue to refuse to sign medical marijuana applications until there was more evidence of its efficacy.<sup>96</sup>

One of the ongoing problems for the Canadian scheme has been the allegedly poor quality of the cannabis grown for the federal government by its contractors for distribution to registered medicinal cannabis users. According to some patients, this has forced them to obtain their cannabis through the black market, thus exposing them to criminalisation.<sup>97</sup>

Another persistent systemic problem continues to be the price charged by the government for medical marijuana. Press reports, although denied by the government, claim that the government marks up the retail price by 1500% of its cost price, thereby putting it outside the financial reach of many seriously ill patients living on low incomes.<sup>98</sup>

Canada became the first nation to approve Sativex when they approved it for neuropathic pain in April 2005.<sup>99</sup> However this has not solved the financial problems of patients as press reports claim that patients are paying \$C 125 for a quantity which lasts for three and a half days' treatment.<sup>100</sup>

As of August 2007 Health Canada was working on a plan to make medical marijuana available through pharmacies<sup>101</sup> and has also made available a set of guidelines for the use of community groups known as 'compassion clubs' which want to distribute legal medicinal cannabis to patients.<sup>102</sup> However I have not found anything further on this issue.

<sup>96</sup> S Wharry, 'CMPA warns doctors ....' (2002) 166 (1) *Canadian Medical Association Journal*; N Greenway 'Medical Marijuana Rules to be Revamped', *medicalmarijuana* <<http://www.medicalmarijuana.ca/news-marijuana/news-archives/2005-news-archive/medical-marijuana-rules-to-get-revamped>> (accessed 5 May 2007).

<sup>97</sup> *Hitzig* n 93 par 20–21.

<sup>98</sup> Health Canada Marks Up Medical Marijuana 1500%, *Winnipeg Free Press* April 16 2007 <<http://ca.vlex.com/vid/canada-marks-medical-marijuana-1-63879519>> (accessed 2 April 2007).

<sup>99</sup> 'Health Canada *Fact Sheet 13* April 2005. <[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/sativex\\_fs\\_fd\\_091289-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/sativex_fs_fd_091289-eng.php)> (accessed 5 May 2007).

<sup>100</sup> Health Canada *Letter to health professionals* <[www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/sativex\\_dhcpl\\_lap](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/sativex_dhcpl_lap)> (accessed 2 April 2005).

<sup>101</sup> See S Martin S, *Sativex in Canada* (2005) <<http://newsgroups.derkeiler.com/Archive/Alt/alt.support.multiple sclerosis/2005-08/msg00100.html>> (accessed 12 January 2008).

<sup>102</sup> See *Canadian Drug Stores to Stock Cannabis* (2007) <[www.medicalmj.org/capharmacies.htm](http://www.medicalmj.org/capharmacies.htm)> <<http://www.MedicalMJ.org>> (accessed 12 January 2008) and 'Pharmacy Marijuana Pilot Program Planned for B.C.' (2004) 13 *The Tablet* 4, British Columbia Pharmacy Association, Vancouver, Canada.

## 5.4 *Canadian medical marijuana case law prior to Hitzig and Others v Canada*<sup>103</sup>

The aim of this section is to survey the body of Canadian case law which is concerned with the illegality of what Canadians term medical ‘marihuana’<sup>104</sup> with a view to its application in New South Wales courts. However it must be stressed at the outset that most of the leading Canadian cases have been fought on issues of constitutional law as Canada, unlike Australia, has a constitutional Charter of Rights and Freedoms which explicitly guarantees some basic human rights and provides a potential criminal defence to medical marijuana users. Consequently these cases are only examined insofar as they might apply in the context of New South Wales law.

The canon of Canadian medical marijuana law begins with such cases as *R v Richardson*<sup>105</sup> and *R v Smillie*.<sup>106</sup> These cases predate the promulgation of the *Medical Marihuana Access Regulations*, (the *MMAR*), on July 30, 2001 and are mainly concerned with pleading the defendant’s case for mitigation of penalties on the basis of their medical marijuana use. For instance, in *Smillie* the defendant was a 68-year-old epileptic who was charged with growing 323 cannabis plants for his own use and for sale and he received a one-year suspended sentence.

But the leading case prior to the enactment of the *Medical Marijuana Access Regulations* was *R v Parker*.<sup>107</sup> In July 1996 Terrance Parker, who had had severe epilepsy for 40 years, was charged with cultivating 71 cannabis plants contrary to section 61 of the *Narcotics Control Act* and on September 18, 1997 he was charged with possession of cannabis under section 4 of the *Controlled Drugs and Substances Act 1996* (the *CDSA*). He explained to the Court that the cannabis was used both by and for himself, to treat his condition and to give to other epilepsy sufferers. At first instance his case was stayed and the judge read into the legislation an exemption from its provisions for people using cannabis for their ‘personally medically approved use’. The Crown appealed, arguing that the judge had made a factual error in

<sup>103</sup> *Hitzig & Ors. v Canada* [2003] O.J. No. 3873 is discussed in the next section of this chapter.

<sup>104</sup> ‘Marihuana’ is spelt with an ‘h’ in the *Canadian Medicinal Marihuana Access Regulations 2001* and so this is the spelling in literature quoted in this section.

<sup>105</sup> *R v Richardson* (2000) Prov. Ct. BC North Vancouver Number 33558.

<sup>106</sup> *R v Smillie* (2000) BCPC 49.

<sup>107</sup> *R v Parker* (2000) CanLII 5762 (ON CA).

finding that Parker needed medical marijuana and that there were legal ways by which he could obtain it.

After hearing voluminous evidence as to the efficacy of cannabis and Parker's need for it, the Court found that 'Parker needs marihuana to control the symptoms of his epilepsy' and that 'the prohibition of the cultivation and possession of marihuana is unconstitutional'<sup>108</sup> because 'forcing Parker to choose between his health and imprisonment violates his right to liberty and security of the person'. The Court then made a declaration that, 'the prohibition on the possession of marihuana in the *Controlled Drugs and Substances Act* is of no force and effect' but suspended this declaration for a year to allow the parliament time to amend legislation.

In ruling that Parker needed medical marijuana, the Court noted that he had been hospitalised over 100 times, had brain surgery twice and had unsuccessfully tried all the other legal medications his specialist doctor had prescribed for him. Leaving aside points of Canadian constitutional law considered in the case, the *Parker* judgement contained some points of law potentially applicable to Australian law. The first of these is the medical necessity defence which the court asserted lent 'some common law support for access to drugs with a therapeutic value notwithstanding legal prohibition', citing the earlier case of *Parker v Queen*<sup>109</sup> and mentioning in passing that Parker himself had successfully defeated a marijuana possession charge in 1987 using this defence.<sup>110</sup>

Some of the reasoning of the Court reads somewhat like a codification of the necessity defence, for example 'a fair balance [should] be struck between the interest of the person who claims his liberty or security interest has been limited and the protection of society.'<sup>111</sup> Although this statement was based on the Canadian *Charter*, the Court also made reference to the *International Covenant on Economic, Social and Cultural Rights*, article 12, which states in part, 'The States Parties recognise the right of everyone to the enjoyment of the highest attainable standards of physical and mental health.'<sup>112</sup>

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<sup>108</sup> Ibid 10.

<sup>109</sup> *Parker v Queen* [1984] CanLII 23 (SCC), 93.

<sup>110</sup> Ibid 26.

<sup>111</sup> Above n 110, 145.

<sup>112</sup> *Parker v Queen*, above n 110, 148.

The Court held that, at least in Canada, ‘a broad criminal prohibition which prevents access to necessary medication is not consistent with fundamental justice’.<sup>113</sup> Citing Beetz J in *Morgenthaler, Smolley and Scott v The Queen*,<sup>114</sup> who held that the Charter right of security of the person ‘must include the right to access medical treatment for a condition representing a danger to life or health without criminal sanction’,<sup>115</sup> the *Parker* Court held that, ‘the right to make decisions that are of fundamental personal importance includes the choice of medication to alleviate the effects of an illness with life threatening consequences.’<sup>116</sup>

In the outcome the Crown’s appeal was dismissed and section 4(1) of the *Controlled Drugs and Substances Act* was held invalid and the defendant exempted from its prohibition of medical marijuana use during the 12 month period of the suspension of invalidity.

#### *Wakeford v Canada*<sup>117</sup>

As in most of the leading cases the medical marijuana user in *Wakeford* was seriously ill. He had been HIV positive for 13 years and had severe nausea, which he treated with marijuana because he had a violent reaction to Marinol and other prescribed medications. Thus he needed caregivers. Although he had previously attempted to legitimise his medical marijuana use under a section 56 exemption, the exemption which was granted did not give any exemption to his caregivers. The constitutional issue was over section 7 of the *Canadian Charter of Rights* which guarantees ‘everyone the right to life, liberty and security of the person and the right not to be deprived thereof ...’ and whether it had been breached. The court ruled that it had not.

Although there were weighty issues present in this case they were not addressed at any length since the case was technically disposed of ‘on the understanding that the appellant may make an application under the new *Regulation*.’<sup>118</sup> *Wakeford* was the first case to be heard after the 30th of July 2001 promulgation of the *MMAR* and revolved around whether the Canadian government’s failure to provide for a section 56 exemption for caregivers was a breach of the defendant’s section 7 rights.

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<sup>113</sup> Ibid 139.

<sup>114</sup> *Morgenthaler, Smolley and Scott v The Queen* [1988] CanLII 90 (SCC).

<sup>115</sup> Ibid 90.

<sup>116</sup> *R v Parker*, above n 126, 108, 188.

<sup>117</sup> *Wakeford v Canada* [2002] CanLII 23585 (ON C.A.).

It was arguably wrongly decided because it was based on the court's judgement as to whether the defendant was dependent on the government to supply him with medical marijuana. But what they arguably overlooked in this judgement was that the defendant had to commit a criminal act to obtain his necessary medication – he had to buy it on the black market which made him liable to prosecution and imprisonment. It is perhaps surprising that a superior court would turn a blind eye to such connivance of wrongdoing and illegality. Indeed the court had before it evidence that some of *Wakeford's* caregivers had already been charged with trafficking on his account.

*R v Patriquen*<sup>119</sup>

Here a medical marijuana user with severe epilepsy who grew cannabis for his condition was charged with cultivation of a prohibited drug. He claimed that the prohibition on cannabis cultivation and possession violated the *Charter's* article 7. However the court ruled lack of jurisdiction and again the opportunity to reform some of the manifest flaws of the *MMAR* was passed up.

*R v Stavert*<sup>120</sup>

Here again the issue was the constitutionality of section 4(1) of the Charter but this time in relation to recreational not medical use of marijuana. The judge in this small provincial court chose to follow *Parker*, which judgment was not restricted to cases of medical marijuana use. He held that it would be an abuse of process for citizens of Prince Edward Island to be subject to prosecution in relation to 4(1) when the citizens of nearby Ottawa were immune from such prosecution. He therefore stayed the matter, '[u]ntil such time as the law is changed by Parliament, or the higher courts provide a ruling ...'<sup>121</sup>

*R v J.P.*<sup>122</sup>

This case concerned a juvenile charged with possession of 30 grams of marijuana and breaching of his probation order. At first instance the judge found in JP's favour on the ground that the Parliament's failure to re-enact section 4(1) of the *CDSA* meant that the

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<sup>118</sup> Ibid 72, citing trial Court judge.

<sup>119</sup> *R v Patriquen* (2002) NSSC 235 (CanLII).

<sup>120</sup> *R v Stavert* [2003] P.E.I.J. No. 28 (P.E.I.P.C.).

<sup>121</sup> Ibid 51.

<sup>122</sup> *R v J.P.* [2003] CanLII 45115 (ON CA).

court's declaration of the invalidity of section 7 which had been suspended for a year, was now in force. The appeal court upheld the trial judge's decision, stating that:

Parliament had at no time re-enacted section four of the *CDSA* as it relates to marihuana. Accordingly, notwithstanding the enactment of the *MMAR*, in no place in those regulations is there a prohibition against simple possession of marijuana. It is to be noted that there are no penalties sections set out in these regulations.<sup>123</sup>

### 5.5 A Canadian case examined in detail: *Hitzig and Others v Canada*<sup>124</sup>

The next case is examined in more detail than the other cases in this chapter because it conveniently raises most of the factual, legal and constitutional issues that apply to other cases discussed here. Because I have had the opportunity to study this case in detail in writing a case note about it, I have taken this opportunity to examine this case in depth.

In keeping with its progressive tradition in dealing with social issues, the Canadian Federal Parliament passed into law the *Controlled Drugs and Substances Act 1996*.

Section 4 of the Act relevantly provides:

- (1) Except as authorized under the regulations, no person shall possess a substance included in Schedule ... II ... .
- (2) No person shall seek or obtain
  - (a) a substance included in Schedule ... II
  - (b) ...
- (3) ...
- (4) Subject to subsection (5), every person who contravenes subsection (1) where the subject-matter of the offence is a substance included in Schedule II
  - (a) is guilty of an indictable offence and liable to imprisonment for a term not exceeding five years less a day; or
  - (b) is guilty of an offence punishable on summary conviction ...

Section 56 provides:

The Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons ... from the application of all or any of the provisions of this Act or the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

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<sup>123</sup> Ibid.

<sup>124</sup> *Hitzig* n 93 This commentary draws on Irvine, above n 93.

Schedule II includes:

1. Cannabis, its preparations, derivatives and similar synthetic preparations, including:
  - (1) Cannabis resin
  - (2) Cannabis (marihuana) ...

In June 1999, pursuant to s 56 of the *Controlled Drugs and Substances Act 1996*, the Canadian Government commenced issuing ministerial permits allowing individuals to possess and/or cultivate marijuana for their own medicinal purposes. However in the matter of *R v Parker*<sup>125</sup> the Ontario Court of Appeal held that s 4, in providing for the criminal prohibition against possession of marijuana was unconstitutional. The Court held it did not provide for a constitutionally acceptable exemption from that provision for Canadians who use marijuana for medicinal purposes, since the statutory exemption scheme depended on the unfettered exercise of the Minister's discretion.<sup>126</sup> The declaration that s 4 was constitutionally of no force or effect, was suspended for a year to give the government time to remedy the deficiency.

The Canadian Government sought to do so by introducing the *Marihuana Medical Access Regulations* (the *Regulations*)<sup>127</sup> pursuant to s 55(1) of the Act. These *Regulations* allow exemptions from the provisions of the Act for three categories of seriously ill people by issuing an 'Authorization To Possess' (an Authority) allowing the possession of 'dried marijuana' for the treatment of various symptoms associated with serious illnesses.<sup>128</sup>

The *Regulations* also provide for licences to produce, store and transport marijuana in order to supply authorised medical users.<sup>129</sup> These renewable one-year licences may be issued to authorised users themselves or to their designates. The *Regulations* also prescribe formulae to govern how many plants may be grown, proscribe any consideration to these growers, to restrict them to growing for only one user and to limit production in common with more than two other licence holders.<sup>130</sup>

<sup>125</sup> *R v Parker* [2000] 146 C.C.C. (3d) 193.

<sup>126</sup> *Ibid* 37.

<sup>127</sup> *Marihuana Medical Access Regulations (Regulations)* S.O.R.2001-2, 27 June 4 2001.

<sup>128</sup> *Ibid* Part 1. These illnesses were cancer, HIV, AIDS, severe nausea, cachexia, anorexia, weight loss, multiple sclerosis, spinal cord injury or disease, persistent muscle spasms, epilepsy, severe pain, severe arthritis and seizures

<sup>129</sup> *Ibid* Part 2.

<sup>130</sup> *Ibid*.

Following promulgation of the *Regulations*, several medical marijuana users and the operator of the Toronto Compassion Club, an organisation set up to supply medical marijuana users, brought a joint application in the Superior Court of Justice challenging the constitutionality of the *Regulations*. The basis of their argument was that, because the *Regulations* did not make provision for medical marijuana users holding an Authority who were unable to grow their own medical marijuana or to engage a designate to do so for them, the government thus had a constitutional obligation to provide them with a legal supply. Constitutionally they claimed that this followed from a consideration of s 7 of the *Canadian Charter of Rights and Freedoms* which guarantees ‘the right to life, liberty and security of the person’. The argument was that the lack of a legal supply of medical marijuana had the effect of forcing those with an Authority to procure it on the black market, thereby rendering them liable to imprisonment and consequent deprivation of their liberty.

On 9 January 2003, Justice Lederman held that because the *Regulations* failed to provide a legal supply of medical marijuana for persons holding an Authority, the *Regulations* were unconstitutional and thus of no force or effect. As in the earlier case of *Parker*, the declaration of constitutional invalidity was suspended, this time for six months, to enable the government to amend the *Regulations*. In the meantime, on 29 July 2003 the government appealed Lederman J’s decision in the Ontario Court of Appeal before a panel of three judges.

### *The factual issues*

#### *(a) Eligibility for exemptions from s 56 of the Act*

The respondents argued that, under section 7 of the *Charter*, several of the *Regulations*’ eligibility requirements for those seeking an Authority deprived them of their constitutionally guaranteed right to liberty and security. They claimed that the *Regulations* did not accord with the principles of fundamental justice because they created so many impediments in the application process for exemption that they rendered such exemptions effectively unavailable to many applicants. Thus the issue of fact here was whether or not specific regulations had this effect.

#### *(b) The supply issue*

Originally the Government had envisaged supplying the medical marijuana required by authorised users itself and through licensed dealers. However, after complaints from medical

marijuana users that the dried marijuana supplied by the Government was not fit for their purposes, the only legal supply options left for medical marijuana users were to grow it themselves or designate someone to do so for them. Those unable to do either of these had, perforce, to procure their medical marijuana on the black market.

### *The arguments*

#### *(a) Eligibility*

The Appellants: The Government contended that all the eligibility requirements for obtaining an Authority or a licence to produce and distribute, a Personal Producer's Licence or a Designated Producer's Licence were necessary given the uncertainty of the evidence as to the medicinal value of marijuana and the real risks attendant upon its medicinal uses. In such a situation, the appellants argued, it behove the Government to carefully balance the rights of individuals to use medical marijuana with the Government's responsibility to protect public health and safety.

It was also the Government's position that the *Regulations* had to set variable eligibility requirements in order to maintain flexibility in the face of the different equations of risks and benefits applying to different medical marijuana users.

Government counsel further pointed to Lederman J's finding that there was insufficient evidence of the respondents experiencing practical difficulties in accessing appropriate specialists to endorse their applications.

The Respondents: The respondents referred to clauses in the Regulations relating to the requirement for the endorsement of a second specialist in the application for an Authority,<sup>131</sup> the role of doctors in the application process<sup>132</sup> and the dosage limits imposed in Authorities.<sup>133</sup> On the first matter, they submitted that the limited availability of specialists, especially in rural areas, their lack of specific knowledge of the medicinal qualities of marijuana and their professional associations' reluctance to cooperate with the medical

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<sup>131</sup> Ibid Part 2.

<sup>132</sup> Ibid sections 6, 7 and Hitzig, above n 99, 138.

<sup>133</sup> Ibid reg 9.

marijuana scheme combined to make the Authority requirements onerous if not impossible for medical marijuana users to meet.<sup>134</sup>

It was further argued that the *Regulations*' requirement for the endorsement of a second specialist in one of three categories of Authority was not justified by any information they were required to add to the application. As such, the requirement was an arbitrary intrusion of state control, which did not meaningfully advance any legitimate government interest.<sup>135</sup>

In reference to the role of doctors, the respondents contended that the need for a doctor's support for an Authority application placed unwarranted power in their hands, especially since several medical associations opposed the whole medical marijuana scheme and refused their members' cooperation with it.<sup>136</sup>

On the dosage issue, the Respondents claimed that the daily dosage limit set by the user's Authority was arbitrary and potentially harmful because the unpredictability of the potency of the marijuana might result in the deprivation of sufficient medication to properly treat the user's symptoms.

*(b) Supply*

The Appellants: Counsel for the Government contended that the judge at first instance had misinterpreted s 7 of the *Charter* because in their submission it does not seek to impose a positive obligation on the Government to ensure the security of medical marijuana users by provision of a safe and legal marijuana supply to them. Rather, the Government's obligation is a duty not to interfere by its policies and actions with individuals' liberty and security where such interference is consistent with the principles of fundamental justice.

Alternatively, counsel argued that there was no infringement of fundamental justice due to the lack of a legal supply of marijuana because medical marijuana users could access it by cultivating it personally or through a designate or through the same 'unlicensed suppliers' they had used prior to the *Regulations* coming into force.

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<sup>134</sup> Ibid reg 7.

<sup>135</sup> *Hitzig* ibid par 16.

<sup>136</sup> Ibid pars 16, 138.

The Respondents (and Appellants in the Cross Appeal): Hitzig and the medical marijuana users claimed that, with the withdrawal of Government supplies of medical marijuana, there were many who were either so ill that they were physically incapable of growing their own supply, did not have the facilities to do so or were unwilling to expose themselves and their families to the risks of criminality or the attentions of criminals who might rob them.<sup>137</sup> Similarly, many such medical marijuana users could not persuade a designate to produce medical marijuana for them because the *Regulations* prohibit the offer of any consideration for doing so, whilst at the same time proscribing any economies of scale by the prohibition against producing for more than one person or pooling resources with more than two other licence holders. Hitzig's personal testimony was that he had been bashed, robbed, raided and arrested in the course of acting as a designated distributor.<sup>138</sup>

The respondents' case was that such overwhelming difficulties left such would-be medical marijuana users with no effective choice other than to resort to the black market to procure their medication. In turn, this source caused its own problems for the price of illegal marijuana was artificially high and many of the medical marijuana users who are on low fixed incomes cannot afford to pay such inflated prices.<sup>139</sup>

In addition, such supplies are unreliable over time and in quality and may also be adulterated with substances inimical to the health of already very sick people.

The upshot of this reliance on the black market was that such medical marijuana users risked their constitutional right to liberty through running the risk of imprisonment for purchasing an illegal drug and/or their security by having to expose themselves to dealing with potentially dangerous criminals.

Even those medical marijuana users whose supply was legal were vulnerable to the failure or spoilage of their crops, so that they could not be assured of producing enough for their ongoing needs.<sup>140</sup>

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<sup>137</sup> Ibid par 21.

<sup>138</sup> Ibid par 20.

<sup>139</sup> Ibid par 22.

<sup>140</sup> Ibid par 22.

### *The constitutional issues and the Court's findings*

#### *(a) Section 7 of the Charter*

Even though the following discussion concerns Canadian Constitutional issues inapplicable to Australia, I have summarised the arguments because they do bear on human rights arguments which might be raised in future Australian medicinal cannabis litigation.

Section 7 of the Canadian Charter reads: 'Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.' The Canadian courts use a two-stage approach in determining whether these rights have been breached:

1. whether the (government) action complained of resulted in a threshold violation of one or more rights; and
2. whether, having found a threshold violation, this violation is inconsistent with the principles of fundamental justice.

The first stage involves consideration of whether the interests alleged to have been infringed come under the rubric of the section's operative words and whether such interests have been infringed by some form of state conduct.<sup>141</sup>

If a stage one violation is established, the court must then determine and enunciate which principle of fundamental justice is breached by the facts of a particular case and, having done so, must decide if the threshold infringement found in stage one is inconsistent with the relevant principle found in stage two.<sup>142</sup>

Determination of the questions in both stages must take into account the specific context of the claim made, including the factual matrix, the nature of the alleged rights and of the state's action, the nature of the alleged interference and the interests on which the state relies in support of its conduct. For these purposes, 'context' comprehends the purpose and effect of the state's actions and may include the language and history of relevant statutes.<sup>143</sup>

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<sup>141</sup> *Gosselin v Quebec (A.G.)* [2002] S.C.J. No. 85 pars 87, 91 (Q.I.).

<sup>142</sup> *Ibid* par 92.

<sup>143</sup> *R v Morgentaler* [1988] 1 S.C.R. 30, at 61.3, per Dickson C.JC.

The Court drew on the earlier related case of *R v Parker*<sup>144</sup> to find that the threshold liberty interest was engaged in two ways. In a narrow sense, medical marijuana users' rights to liberty were jeopardised by their risk of prosecution and imprisonment if they have no Authority because they cannot meet the eligibility requirements or because they exceed their production or dosage limits. More broadly the Court found that the right to liberty includes the right of individuals to make decisions of fundamental personal importance to them.<sup>145</sup> Therefore, if the state seeks to intervene in such decisions, it must justify such intervention on the basis of the operation of the principles of fundamental justice. On this ground the Court stated:

there is no doubt that the decision by those with the medical need to take marihuana to treat the symptoms of their serious medical conditions is one of fundamental personal importance. While this scheme of medical exemption accords them a medical exemption, it does so only if they undertake an onerous application process and can comply with stringent conditions. Thus, the scheme itself stands between those individuals and their right to make this fundamentally important personal decision unimpeded by state action.<sup>146</sup>

As to the right to security of the person, the Court found that this right encompasses the right to access medication reasonably required for the treatment of serious medical conditions when such access is interfered with by the state by means of criminal sanctions.<sup>147</sup> Moreover, the right to security is interfered with when the state applies criminal sanctions to one individual assisting another in making a decision of fundamental personal importance.<sup>148</sup>

Having determined that the operation of the *Medical Marijuana Access Regulations* engaged the constitutional rights of citizens to liberty and security, the Court went on to conclude that, because 'the *Medical Marijuana Access Regulations* do not remove the real risk of conviction and imprisonment ... [they] thus interfere with this aspect of their liberty'<sup>149</sup> and further found that, by 'placing ... significant hurdles in their way the state has interfered with this broader aspect of their right to liberty.'<sup>150</sup>

The Court also established that, since section 7 applies to an individual's right to make choices about their own body, their physical and psychological integrity and human

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<sup>144</sup> Above n 126

<sup>145</sup> *Rodriguez v British Columbia (A.G.)* [1993] 3 S.C.R. 579, 582. *Hitzig* n 93.

<sup>146</sup> *Ibid.*

<sup>147</sup> Note 142 87, 91 (QI).

<sup>148</sup> *Hitzig* n 93, 98.

<sup>149</sup> *Ibid* n 93, 99.

dignity,<sup>151</sup> the *Regulations* also raise criminal prohibitions which interfere with the constitutional right to security of the person, concluding that their operation constitute state actions ‘that stand between those in medical need and the marijuana they require.’<sup>152</sup>

This led the judges to conclude that:

... the *Medical Marijuana Access Regulations* constitute a scheme of medical exemption which deprives those who need to take marijuana for medical purposes of the rights to liberty and security of the person. This is a threshold violation of s. 7. We are therefore required to turn to the question of whether this deprivation is in accordance with the principles of fundamental justice.<sup>153</sup>

Applying the principles of fundamental justice to the supply issue, the Court ruled:

[i]t is undeniable that the effect of the *Medical Marijuana Access Regulations* is to force individuals entitled to possess and use marijuana for medical purposes to purchase that medicine from the black market.<sup>154</sup>

Even more strongly, they went on to agree with Lederman J that:

this aspect of the scheme offends the basic tenets of our legal system ... [for] it does not lie in the of the Government’s mouth to ask people to consort with criminals to access their constitutional rights.<sup>155</sup>

Such a scheme:

can only discourage respect for the law, ...bring the law into disrepute and devalue the worth and dignity of those individuals to whom the *Medical Marijuana Access Regulations* are applied.<sup>156</sup>

The Court concluded that ‘the absence of a legal source of supply renders the *Medical Marijuana Access Regulations* inconsistent with the principles of fundamental justice...’.<sup>157</sup>

Turning to the eligibility issue, the Court dismissed the Respondents’ arguments in relation to dosage limits and the role of doctors but accepted their contention that the requirement for the support of a second specialist in a Category 3 Authority application was unnecessary and thus an arbitrary restriction. In coming to this view the Court judged that:

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<sup>150</sup> Ibid n 93, 98.

<sup>151</sup> Ibid par 104.

<sup>152</sup> Ibid, above n 93, par 104.

<sup>153</sup> Ibid par 105.

<sup>154</sup> Ibid par 109.

<sup>155</sup> Ibid par 110.

<sup>156</sup> Ibid pars 116–117.

<sup>157</sup> Ibid pars 116–118.

the requirement for a second opinion adds so little if any value to the assessment of medical need that it is no more than an arbitrary barrier ... In this particular respect only, the eligibility conditions in the *Medical Marihuana Access Regulations* do not accord with the principles of fundamental justice.<sup>158</sup>

*(b) Section 1 of the Charter*

This section entitles the government to override the rights granted under s 7 if to do so constitutes the setting of reasonable limits on these rights ‘which are demonstrably justified in a free and democratic society.’<sup>159</sup> The Court answered this proposition in the negative for the same reasons they gave in reply to the s 7 arguments put before it, that is:

that the offending provisions of the *Medical Marihuana Access Regulations* do not advance the collective interest sufficiently to justify the limitation which they place on the individual’s rights...thus, neither aspect of the *Medical Marihuana Access Regulations* which we have found to contravene s. 7 can be saved by s. 1.<sup>160</sup>

*(c) The Section 52 Remedy*

This section of the Charter enables the Court to make a declaration to address unconstitutional conduct. The Court’s application of this section is covered below.

*The orders and reasons of the Court*

*(a) On the eligibility issue:*

The requirement for the endorsement of a second specialist to the application for a category 3 Authority in ss 4(2)(c) and 7 of the *Medical Marihuana Access Regulations* was declared to be of no constitutional force or effects<sup>161</sup>

*(b) On the supply issue:*

The Court held that the Designated Producer’s Licence/Personal Producer’s Licence provisions of the *Medical Marihuana Access Regulations* were ineffective to ensure a legal supply of marijuana to Authority holders<sup>162</sup> and that:

[t]hat ineffectiveness appears to stem very largely from two provisions in the *Medical Marihuana Access Regulations*. First, a Designated Producer’s Licence holder cannot be remunerated for growing marijuana and supplying it to the Authority holder (section 34(2)). Second, a Designated Producer’s Licence holder cannot grow marijuana for more than one Authority holder (section 41(b)) nor combine his or her growing with more than

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<sup>158</sup> Ibid par 145.

<sup>159</sup> Ibid par 146.

<sup>160</sup> Ibid pars 147 and 152.

<sup>161</sup> Note 133 at 8.

<sup>162</sup> Note 133 at par 159.

two other Designated Producer's Licence holders. (section 54). These barriers effectively prevent the emergence of lawfully sanctioned 'compassion clubs' or any other efficient form of supply to Authority holders.'<sup>163</sup> Taking these considerations together, we conclude that the remedy which most directly addresses the constitutional deficiency presented by the absence of a licit supply of marijuana is to declare invalid sections 34(2), 41(b) and 54 of the *Medical Marijuana Access Regulations*. This will allow all Designated Producer's Licence holders to be compensated, to grow for more than one Authority holder, and to combine their growing with more than two other Designated Producer's Licence holders.<sup>164</sup>

Whilst the Court felt that its judgement restored the constitutionality of the medical marijuana scheme it nevertheless adverted to the possibility that 'further serious barriers could emerge either to eligibility or to reasonable access to a licit source of supply.'<sup>165</sup>

The *Hitzig* judgement is timely for its implications for the proposed New South Wales Medical Marijuana trial. And it is submitted that there are two key lessons to be learnt from the Canadian experience – the inappropriateness of dispensing raw smokeable marijuana to medical marijuana users and the need for the government to directly control its distribution.

## 5.6 Canadian case law: Cases following *Hitzig* and *Others v Canada*

*R v Hadwen*<sup>166</sup>

Three men were charged under section 4(1) of the *CDSA* with possessing less than 30 grams of marijuana each and their counsel argued that, like *Parker, JP* and *Hitzig*, they should have been exculpated due to the invalidity of section 4(1) and to the unconstitutionality of the *MMAR* in not making provision for medical marijuana users to obtain legal supplies of marijuana and seed. But the single judge in the Saskatchewan provincial court held he was not obliged to follow the abovementioned cases, all of which were in other provinces and that he should not take judicial notice of the evidence adduced in *Hitzig* which would have weighed in the defendant's favour. Moreover, on reviewing the provisions of the *MMAR* he was, 'unable to agree with *JP* ... that the *MMAR* are insufficient to address the *Parker* concerns. Accordingly this argument for the invalidity of the marijuana possession law in Saskatchewan fails.'<sup>167</sup>

<sup>163</sup> *Hitzig*, above n 125, 161.

<sup>164</sup> *Ibid* par 165.

<sup>165</sup> *Ibid* par 166.

<sup>166</sup> *R v Hawden* [2003] SKPC 66 (CanLII).

<sup>167</sup> *Ibid* 82.

*R v Masse*<sup>168</sup>

Masse was another British Columbian case triggered by the defendant's arrest for possession of marijuana. His counsel argued that the court should apply *Parker* and find s. 4(1) of the CDSA of no force or effect; that the MMAR did not correct its invalidity or alternatively that *Hitzig* should be followed to find the MMAR unconstitutional and inadequate to cure the invalidity.<sup>169</sup>

In the course of his judgement, Chen J reviewed the provincial court decisions made after the *JP* case which revealed a good deal of judicial uncertainty and disagreement, with the Prince Edward Island Provincial Court holding in *Stavert* that because of the invalidity of s 4(1) CDSA, the prosecution was an abuse of process warranting a stay of proceedings. The judge in *R v Clarke*<sup>170</sup> in the Nova Scotia Provincial Court followed *Stavert* but then the next British Columbian case, *R v Nicholls*<sup>171</sup> declined to follow *Stavert* and *Clarke*, holding instead that *Malmo-Levine* had upheld the constitutionality of the prohibition against cannabis use except for its medicinal uses.

In the upshot Chen J chose to follow *JP* and *Hitzig* in holding that the *Parker* declaration was in force in respect of the failure of the *MMAR* to organise a legal marijuana supply to medical marijuana users, thereby infringing the defendant's section 7 rights. Hence, 'there is no offence known to law at this time for simple possession of marihuana. The appeal is allowed.'<sup>172</sup>

*R v Krieger*<sup>173</sup>

The defendant suffered from progressive multiple sclerosis which left him at times unable to see or to walk, with no control over his bladder or bowel. After discovering that his symptoms were greatly assisted by marijuana, he set up an organisation to supply other medical marijuana users which at the time of his arrest had some 425 clients.

As well as claiming that his section 7 rights (to life, liberty and security of the person) and his section 12 rights (to not be subjected to cruel or unusual punishment) were breached, which

<sup>168</sup> *R v Masse* [2003] BCPC 328 (CanLII).

<sup>169</sup> *Ibid* 45.

<sup>170</sup> *R v Clarke* [2003] N.S.J. No 124 (N.S.P.C.).

<sup>171</sup> *R v Nickols* [2003]B.C.J. No 881 (B.C.P.C.).

<sup>172</sup> *Ibid* 67.

the court dismissed, his counsel also led argument that where a criminal defence is provided for, ‘the defence should not be illusory or so difficult to obtain as to be practically illusory.’<sup>174</sup>

The main question at issue was then whether the process of obtaining legal medical marijuana user status under the *MMAR* was so difficult as to be ‘illusory’. To determine this matter the judge examined the procedure under the *MMAR* for obtaining doctors’ signatures and heard evidence as to the attitude of doctors towards signing applications. He took into account that there had been two sets of amendments to the Regulations, on December 3 2003 and on June 5 2005. The effect of the latter was, inter alia, that there is now no requirement for category 1 applicants to obtain a specialist’s signature and:

Physicians are no longer required in their declarations, to make definitive statements regarding benefits outweighing risks, or to make specific recommendations regarding the daily dosage of marijuana to be used by the applicant. In addition the information that the physician is required to provide in the medical declaration has been reduced to only those elements essential to confirm that the applicant suffers from a serious medical condition and that conventional treatments are inappropriate or ineffective.<sup>175</sup>

This led Pepler J to agree with *Hitzig* that enough physicians were signing applications that, ‘the medical exemption could not be said to be unavailable’ and therefore:

I am satisfied that there is insufficient particularity in the oral evidence to support a decision that it is practically impossible to obtain a doctor’s signature, thereby rendering the defence applied by the *Regulation* illusory.<sup>176</sup>

Nevertheless I would submit that there may well be applicants living in remote locations who could not reasonably comply with the *MMAR* because there is no doctor or no willing doctor to sign their application.

### *R v Malmo-Levine*<sup>177</sup>

Following a lengthy jurisprudential and historical analysis of the constitutional principles involved, especially in section 7 of the Charter, the majority concluded that the possibility that the defendants could be imprisoned under the charges of possession and trafficking of marijuana was enough to invoke section 7. However ‘Malmo-Levine’s desire to build a lifestyle around the recreational use of marihuana does not attract Constitutional

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<sup>173</sup> *R v Krieger* [2006] ABP.C. 259 CanLII).

<sup>174</sup> *Morgenthaler*, above n 115, 476.

<sup>175</sup> *Ibid* 65.

<sup>176</sup> *Ibid* Para 66.

protection.<sup>178</sup> But the appellants argued that unless the government could prove that their smoking marijuana constituted a harm to others, section 7 overrides the prohibition against possession.

This argument draws on J.S. Mill's utilitarian proposition that the individual is sovereign over his body and mind and that the only justification for interfering with this sovereignty is to prevent harm to others. The Court rejected this approach citing cannibalism, bestiality, incest and cruelty to animals as actions over which the Millian individual is not sovereign.

The appellants raised, and the Court accepted that avoidance of harm is a matter of 'state interest', the Court agreeing that:

Where the deprivation of the right in question does little or nothing to enhance the state's interest ... a breach of fundamental justice will be made out, as the individual's rights will have been deprived for no valid purpose.<sup>179</sup>

But the Court pointed to protection of 'vulnerable' groups, like children as being a valid purpose for anti marijuana legislation.

However, in my view, the court cannot justify prohibition of marijuana on the grounds that, 'criminalization seems to take marijuana out of the hands of users and potential users so as to prevent the associated harm and to eliminate the market for traffickers.'<sup>180</sup> but criminalization achieves quite the opposite, ie by putting the drug into the hands of traffickers with all of the adverse effects that this brings to the market and to its constituent users. To this extent, it is submitted that the prohibition is irrational and arbitrary.

The final appellant's argument rejected by the Court was that section 7 was triggered by the disproportionate balance of salutary and deleterious effects of prohibition. The Court confronted this by ruling that the alleged harms to society were relevant to section 1 but not to section 7. By a margin of six to three the Court denied that the prohibition of marijuana for use or possession infringes the constitutional rights of sections 7 and 15 of the Charter.

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<sup>177</sup> *R v Malmo-Levine* [2003] Can. Sup.Ct LEXIS 78 citing *Rodriguez v British Columbia (Attorney General)* [1983] 3 S.C.R. 519.

<sup>178</sup> *Ibid* 87.

<sup>179</sup> *Malmo-Levine*, above n 178, 131.

<sup>180</sup> *Ibid* 136.

It is submitted that this decision was and is out of touch with Canadian society which overwhelmingly dismisses prohibition as a justifiable and effective policy in regard to marijuana and that a subsequent case may revisit the evidence but come up with a different judgment.

*R v Long*<sup>181</sup>

This recent case involved the charging of the defendant under s. 4(1) of the *CDSA* with possession of 3 and a half grams of marijuana and his defence that that section was invalid because neither it nor the *MMAR* provided for a medical marijuana exemption. As in some of the earlier cases reported here, the judge ruled:

a criminal prohibition together with a regulatory exemption that unduly restricts access to a licit supply of medical marihuana is unconstitutional and cannot be saved by resort to a policy regardless of whether the policy is permitted by regulation.<sup>182</sup>

He pointed out that:

[t]here is nothing in the *CDSA* or the *MMAR* that requires the government to supply marihuana to eligible authorized persons ... [and] the exemption as re-enacted would only be constitutionally acceptable if the Government took on the obligation *by law* to supply to those in need. Without such an obligation, the exemption is constitutionally unacceptable. ... [The Government] must remove the barriers to access or impose on itself the obligation to supply marihuana to eligible authorized persons who do not obtain a licence, not simply as a matter of policy but as a matter of law.<sup>183</sup>

As of the time of writing, various medical marijuana users and support groups in Canada are contemplating legal challenges to the federal government based on the alleged failure of the government to supply an efficacious quality of marijuana for eligible patients.<sup>184</sup>

## 5.7 United Kingdom current drug legislation

In the United Kingdom the regulation of cannabis is controlled by the *Misuse of Drugs Act 1971* and the *Misuse of Drugs Regulations 1985*. Schedule 2 of the *Regulations* divides drugs into Class A or Class B according to the severity of the penalties their use attracts.

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<sup>181</sup> *R v Long* [2007] ONC.J. 340 (CanLII).

<sup>182</sup> *Ibid* 50.

<sup>183</sup> *Ibid* pars 63, 68, 70.

<sup>184</sup> See Section 5.3 in this thesis on Canadian medical marijuana laws.

There are five Schedules in the *Regulations*. Schedule 1 contains drugs to which no exemptions from the Act apply. Numbers 2 to 5 list drugs for which various exemptions from the Act may apply, eg Schedule 2 drugs may be administered by or on the instructions of a doctor or dentist (r 7); may be produced by a doctor or pharmacist (r 8); may be supplied (r 8) or possessed by various categories of people, including doctors and pharmacists and by patients (r 10).

As cannabis is a Schedule 1 drug it is not eligible to qualify for these exemptions although the *Regulations* do empower the Secretary of State to license anyone to produce, possess or supply any Schedule 1 drug (r 5). The Minister has now exercised his prerogative and issued a wholesaler's licence to GW Pharmaceuticals and a general licence to medical practitioners. The latter allows pharmacists to dispense and permits patients to use Sativex if it is dispensed in accordance with a bona fide prescription.<sup>185</sup> However these licences have so far only been granted for the treatment of multiple sclerosis and their extension to cover treatment of other serious conditions still awaits the completion of clinical trials by GW and their approval by the regulatory authority, the Medicines and Healthcare Products Regulatory Agency, (the MHRA).

The *Drugs Act 2005* introduced new police powers to test suspects for drugs; required courts to take aggravating factors into account; created a new intention to supply presumption; and created a presumption against arrest for cannabis possession absent of aggravating factors resulting instead in confiscation and a warning.<sup>186</sup>

In January 2004 cannabis was re-classified from a Class B to a Class C drug and the maximum penalty for supply, dealing and trafficking increased from five to fourteen years' gaol. This re-classification reflected the advice of the Advisory Council on the Misuse of Drugs that cannabis is not as harmful as other drugs in Class B.

The Home Office approved the import of Sativex on 14 November 2005 for the relief of individual patients with multiple sclerosis. It was to cost £4 to £5 a day and individual doctors

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<sup>185</sup> GW Pharmaceuticals website <<http://www.gwpharm.com>> (accessed 29 January 2008).

<sup>186</sup> J Pookkatt 'Is Drug Abuse a Crime?' (2006) *British Council India e-legalnews* <<http://www.indlaw.com/legalfocus/focusdetails.aspx?ID=73>> (10 February 2010).

would have to take responsibility for its prescription.<sup>187</sup> On 13 December 2007 the MHRA published a Public Information Report on Sativex because of the ‘huge public interest’ and the fact that 1400 patients in the UK had received Sativex. The Report contains an Experts’ Statement:

We conclude that Sativex meets a currently unmet medical need in patients where there is no other conservative treatment option. It is our view that Sativex should be licensed and become available on prescription for patients with spasticity due to multiple sclerosis and we urge the MHRA to do so.<sup>188</sup>

Since the relevant UK case law involves the necessity defence, these cases are examined elsewhere in this thesis under the heading; ‘The Medical Necessity Defence in the United Kingdom’ in Section 8.2.<sup>189</sup>

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<sup>187</sup> Multiple Sclerosis Society (UK) (12 Nov 2005) ‘Information about Sativex’ <[www.mssociety.org.uk](http://www.mssociety.org.uk)> (accessed 27 October 2009).

<sup>188</sup> Medicines and Healthcare Products Regulatory Agency, *Public Information Report on Sativex mucosal spray, UK/H/961/01Dc, 13.12.07*. 43–44.s.

<sup>189</sup> Chapter 8.2.

## Chapter 6

# CURRENT AUSTRALIAN COMMONWEALTH, NEW SOUTH WALES AND NEW ZEALAND DRUG LEGISLATION

This chapter describes the legislation relevant to the legalisation of medicinal cannabis as it is these laws which would need to be repealed or amended to allow for the import and distribution of medicinal cannabis.

### 6.1 *Australian obligations under international conventions*

The basis for current Australian and New South Wales regulation of medicinal cannabis use lies with Australia's ratification of international treaties on drugs. As the 'Report of the Working Party on the Use of Cannabis for Medical Purposes' notes:

Australian domestic drug laws are influenced, and to some extent determined by the obligations set out in international conventions to which Australia is a party. This is why the requirements of international conventions can limit the range and scope of legal strategies available for dealing with the medical use of cannabis.<sup>1</sup>

The three current conventions which Australia has ratified and which affect Commonwealth and New South Wales drug laws are: the United Nations *Single Convention on Narcotic Drugs 1961*, the *United Nations Convention on Psychotropic Substances 1972* and the *United Nations Convention Against Illicit Traffic in Narcotic Dangerous Psychotropic Substances 1988*.

#### *United Nations Single Convention on Narcotic Drugs 1961*

Although cannabis is not a 'narcotic' this Convention deems it to be so for the Convention's purposes which are primarily concerned with eliminating illicit recreational use of the drugs listed in its schedules. Cannabis is listed along with cocaine and the major opiates in Schedule

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<sup>1</sup> 'Report of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes', vol II, Main Report, Office of Drug Policy, New South Wales Government, August 2000, 63.

1 and also appears in Schedule IV, which contains drugs considered to have especially dangerous properties.

There are two references in the *Convention* to the medical and/or scientific use of drugs. The first is in Article 2(5) (b) which applies a general prohibition on any activities associated with Schedule IV drugs, ‘except for amounts which may be necessary for medical or scientific research only’. The Working Party was quick to point out that their proposals for medicinal cannabis use ‘should comply with the ‘special measures of control’ referred to in Article 2(5)(b).’<sup>2</sup>

The second reference to medical and scientific purposes appears in Article 4, which places a general obligation on ratifying states to:

take such legislative and administrative measures as may be necessary ... to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in and the use and possession of drugs.

Nowhere in the *Convention* does there appear a definition of the term ‘medical and scientific purposes’ but it seems to be generally accepted that it’s meaning ‘is sufficiently broad to encompass the prescription or certification of cannabis for the treatment of medical conditions.’<sup>3</sup>

#### *The United Nations Convention on Psychotropic Substances 1972*

This *Convention* was ratified by Australia and came into force on 17 August 1982. It supplements the international control system for the legal manufacture and distribution of such substances.

#### *The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1983*

Australia ratified this Convention on 16 November 1992. It requires states to prevent the illegal cultivation of plants containing narcotic or psychotropic substances of which it lists cannabis as one.

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<sup>2</sup> The Report is in error here for this quotation actually comes from Article 2(5)(a).

The New South Wales Parliamentary Working Party's Report claims that the *Single Convention* places an obligation on governments 'to ensure adequate availability of narcotic drugs for medical and scientific purposes and at the same time prevent their illicit production, trafficking and use.'<sup>4</sup> Although no such explicit statement appears in the document, Article 2(5) could be interpreted in this way as it specifies that:

(a) A Party shall adopt any special measures of control which in its opinion are necessary ... and ... shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical or scientific research ...

However my reading of the Article suggests that there is no such overriding obligation on Parties as the actions contemplated will only become mandatory if the two qualifications in the Article are fulfilled that is, the Party is of the opinion that special measures of control over the medical or scientific use of cannabis 'are necessary' and 'if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare ...'. So these two qualifications act as preconditions to the operation of the Article in relation to medical and scientific research. Only if these preconditions are fulfilled could the state be said to have an 'obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes.'<sup>5</sup>

Moreover, on my reading of the *Convention*, there is no obligation on Parties to conduct medical or scientific research and thus there can be no obligation on them to ensure adequate availability of narcotic drugs for these purposes.

## 6.2 Relevant Commonwealth legislation

### *Introduction*

Although New South Wales has jurisdiction over criminal matters concerning drugs, the federal character of the Australian political system means that the Commonwealth too has jurisdiction. Under the Commonwealth Constitution the relevant heads of power allocating

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<sup>3</sup> 'Report of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes', above n 1, 66.

<sup>4</sup> Ibid 68, citing H Woltring, 'Examining existing drugs policies: The UN Convention – Help or Hindrance?' (1990) *Criminology Australia* April/May 19–20.

<sup>5</sup> Ibid 68.

jurisdiction to the Commonwealth are section 51(i), the international trade and commerce power and section 51(xxix), the external affairs power.

The main Commonwealth legislation relevant to medicinal cannabis which derives jurisdiction from the trade and commerce power in section 51(i) includes the *Customs Act 1901* (Cth) and regulations made under that Act, such as the *Customs (Prohibited Imports) Regulations 1990* (Cth), the *Narcotic Drugs Act 1967*, the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances Act 1990* (Cth) and the *Therapeutic Goods Act 1989* (Cth). However, insofar as some provisions of the *Therapeutic Goods Act* were enacted to fulfil Australia's obligations under the international conventions discussed above, these provisions derive their jurisdictional authority from section 51(xxix), the external affairs power. Since the 'Tasmanian Dams' case<sup>6</sup> it is settled law that the Commonwealth can legislate to give effect to international conventions ratified by Australia.

#### *Customs Act 1901 (Cth)*

Until 1991, when the provisions of the *Therapeutic Goods Act* took effect, all drugs, both therapeutic and otherwise, were governed by the *Customs Act*. This Act provided for prohibitions and regulation of goods imported into Australia and put in place a system of permissions and licences for importers of goods, including therapeutic drugs.

Section 50 and 51 together designate certain goods as 'prohibited imports' and section 233B created a specific offence relating to the import of 'narcotic goods'. 'Narcotic goods' are defined in section 4(1) as, 'goods that consist of a narcotic substance, which in turn is defined by a drug's inclusion in Column 1 of Schedule VI to the Act'. Cannabis is listed in Column VI even though it is not, chemically speaking, a narcotic.

Section 233B created an offence of possessing without reasonable excuse a prohibited import classified under Schedule VI as a narcotic good. However through the exercise of the Minister's discretion medicinal cannabis can be legally imported (as my case shows) providing the application accompanies a permit and a license to do so, for this suffices as the 'reasonable excuse' contained in Section 233B. In this respect the granting of my doctor's

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<sup>6</sup> *Commonwealth v Tasmania* (1983) 158 CLR 1.

application to import Sativex has set a precedent for other patients to follow but as speculated earlier, the validity of my approval is perhaps questionable.

### *Customs (Prohibited Imports) Regulations*

These regulations include cannabis in Schedule IV and provide that all importation of drugs into Australia is prohibited but for certain specified circumstances. Any importation of drugs requires both a licence under r 5(1)(a)(i) and a permission under r 5(1)(a)(ii) from the Secretary of the Department of Health and Ageing. In order to obtain a licence, an applicant must supply any information required by the Department, including evidence that the applicant is a fit and proper person to hold a licence and that their premises are secure.

Under r 5(10) a licensee must apply for permission to import a specific shipment of drugs which permission will not be granted without satisfying the Secretary that proper procedures for the custody and transport of the drugs are in place. In addition, the importation of Schedule 1 drugs, which includes cannabis, under r 5 (10)(b) also requires applicants wishing to sell or supply such drugs to hold any relevant state or territory licences to do so. Where such importation is for medical or scientific purposes, no such licence or authorisation is required but,

[i]n practice, it is, however, unlikely that a permit would be issued unless the legislative requirements of a particular State or Territory had been met since once imported, possession of the substance by the applicant would be in breach of these requirements.<sup>7</sup>

Furthermore, an application for permission to import a shipment of a Schedule 1 or 2 drug must specify the quantity to be imported. This quantity, combined with all other authorised and anticipated imports for the year of application, must not exceed the amount that in accordance with the requirements of the *Single Convention*, has been determined to be the maximum amount of that drug that may be imported into Australia during the relevant year.<sup>8</sup>

Such an amount is determined annually by the Secretary in compliance with Australia's *Single Convention* obligations as a means of preventing any accumulation of stocks over and above what is required for medical or scientific purposes in a given year although the Convention does allow for intra-annual supplementary estimates.

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<sup>7</sup> 'Report of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes', above n 1, 71.

<sup>8</sup> Customs (Prohibited Imports) Regulation 5 (12).

As Australia has not notified the International Narcotics Control Board, the administrative arm of the *Convention*, that they wish to import cannabis, no Party States which export cannabis under the *Convention*'s provisions can legally supply to Australia without breaching their *Convention* obligations.

#### *Narcotic Drugs Act 1967 (Cth)*

This legislation enacted Australia's obligations as a signatory to the 1961 *Single Convention*. Besides introducing further controls over the importation and manufacture of drugs and their transit within Australia, it amended the *Customs Act* to ensure that therapeutic drugs manufactured legally do not leak onto the illicit drug black market.

#### *Therapeutic Goods Act 1989 (Cth)*

This Act is supplemented by complementary mirror legislation in the form of the *Poisons and Therapeutic Goods Act 1966* (NSW) so that this Commonwealth law applies in New South Wales. The *Therapeutic Goods Act* would be the single most important enactment to be complied with in any New South Wales governmental scheme for the legal supply and regulation of medicinal cannabis. The aim of the legislation is to create a national system of regulatory controls to ensure the quality, safety, efficacy and availability of therapeutic goods for human use and the Act establishes the Therapeutic Goods Administration [TGA] to administer this regulatory regime.

The Act set up the Register of Therapeutic Goods which lists all therapeutic goods which are approved for supply in Australia and, but for some limited exceptions, only those goods included in the Register can be legally marketed in Australia. Normally applications to include a therapeutic drug on the Register are made by pharmaceutical companies and, '[a]s this is an expensive process applications are not usually lodged unless the sponsor considers the product commercially viable.'<sup>9</sup> However there are four exception mechanisms under the Act whereby access to therapeutic drugs not on the Register may be sanctioned under sections 18 and 19 of the Act and under Regulation 12 and Schedules 5 and 5A of the Regulations. It is these exceptions which are relevant to the import of medicinal cannabis in pharmaceutical form, such as Sativex, and so these exceptions will now be discussed in some detail.

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<sup>9</sup> 'Report of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes', above n 1, 73.

*(a) Clinical trials*

These consist of an experiment conducted with human subjects to assess the efficacy, safety and effects of medicines and medical devices. They are usually classified according to their stage in the development of the drug, ranging from preliminary studies in Phase 1 to Phase 4 trials which are often conducted after the market release of the product. Such trials involve sponsors, generally pharmaceutical companies, the institution in which the research takes place, a human research ethics committee (HREC) either attached to the institution or set up for a specific trial, and the investigators themselves. HRECs play an important role in developing, monitoring and evaluating applications to use unapproved medicines. A HREC is:

[a]n independent body constituted of medical, scientific and non-scientific members whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving and providing continuing review of trial protocols and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.<sup>10</sup>

Their decisions are based on statutory regulations, which specify criteria for assessment of applications by balancing considerations of the patient, the product and the prescriber.

There are two procedures under the Act which provide for clinical trials – the Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) Schemes. They are distinguished mainly by the role which is played by the human research ethics committee in the conduct and evaluation of the trial. Under the CTN Scheme, all material concerning the proposed trial is submitted to the HREC which is responsible for assessing the scientific validity of the design and the safety and efficacy of the medicine. The institution where the trial is conducted, known as the ‘Approving Authority’, gives or withholds final approval for the trial to take place on their premises. The CTN is governed by sections 18(1), 31A(1) of the Act and Regulations 12 and Schedule 5A, Item 3.

Under the CTX Scheme, sponsors must submit applications to the Therapeutic Goods Administration for comment and evaluation. Trials cannot begin until the TGA provides written advice and the institution and the HREC grant approval. Specifically, the TGA must agree to the usage guidelines for the product being trialled. The HREC must consider the scientific and ethical issues involved in the proposed trial protocols. Extensive documentation

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<sup>10</sup> Ibid 74.

of administrative, chemical, pharmaceutical, biological, toxicological and clinical information is required by the TGA for assessment purposes which allows for either a thirty- or a fifty-day evaluation period, depending on the extent of required documentation. The CTX Scheme is governed by sections 19, 31B(1) and 31B(2) of the Act and Regulations 12AA to 12DD.

Regulation 12AB requires that all clinical trials be conducted in accordance with good clinical practice, as adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals (ICH) and the Committee for Proprietary Medicines (CPMP). Australia has adopted the CPMP/ICH Note for Guidance on Good Clinical Practice, (CPMP/ICH/135/95). This code is an international ethical and scientific quality standard for human trials which, inter alia, lays down the role of the investigator, sponsor, and HREC in trial preparation and conduct.

Before the parties grant approval they must be satisfied that the conduct of the proposed trial accords with:

- the National Health & Medical Research Council's 'National Statement on Ethical Conduct in Research Involving Humans', 1999;
- the current World Medical Association *Declaration of Helsinki*;
- the abovementioned ICH/CPMP Note;
- the requirements of the TGA;
- any other requirements of Commonwealth, State or Territory legislation.

*(b) The Special Access Scheme*

This Scheme constitutes the second exception to the general prohibition of therapeutic goods which are not listed in the ARTG and provides for the import and/or supply of unapproved therapeutic goods for single patients on a case by case basis.

The Scheme comprises two categories, Category A, where sections 18, 31A(2) and Regulation 12A apply to:

persons who are seriously ill with a condition for which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.<sup>11</sup>

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<sup>11</sup> Therapeutic Goods Administration, Regulation 12A, cited in Therapeutic Goods Administration, Department of Health and Ageing, Australian Government, *Access to Unapproved Therapeutic Goods via the Special Access Scheme*, Canberra, October 2004, 14.

All other patients come under Category B which is governed by sections 19 and 31B(1).

Because unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the TGA, the responsibility for the prescription of such products rests with the prescribers of these medicines, who are also responsible for classifying patients as Category A or B.

Category A patients' treating doctors do not need prior TGA approval to prescribe an unapproved drug but have to complete an 'Authority to Supply' form and send it to the TGA which then provides that sponsor with the legal authority to supply that drug and to the drug's sponsor which can opt either to supply the drug or not.

However because cannabis is in Schedule 9 of the Standard for the Uniform Scheduling of Drugs and Poisons under the *Drug Misuse and Trafficking Act 1985* (NSW), it cannot be supplied to Category A patients.<sup>12</sup>

Under Category B, a patient's treating doctor must apply to a 'delegate' authorised under the TGA. Applications must address criteria concerning the patient, product and prescriber. The delegate then arrives at a decision, having regard to factors such as the efficacy and safety of the product, the doctor's qualifications and the seriousness of the patient's condition.

In its explanation of how Category B application decisions are made, the TGA states:

For example, a product which has been approved in a country with a regulatory system comparable to our own is likely to be approved for supply under the SAS for a condition for which it has been approved in those countries.<sup>13</sup>

In a later chapter of this thesis, mention will be made of this statement in relation to the possibility of importing 'Sativex' under the SAS.

Usually any approval granted will contain conditions with which the applicant must comply, for example, maximum doses and duration of treatment for a medicine, the period of the approval's currency and the allocation of responsibility for any adverse results of the treatment.

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<sup>12</sup> TGA, above n 11 and email from Dr Jonathon Rankin, Head, Experimental Drugs Section, Therapeutic Goods Administration, to Graham Irvine, 1 February 2005.

<sup>13</sup> Ibid above n 10, 20.

*(c) Authorised Prescribers*

Under sections 19(5), 31B(3) and Regulation 12B, this is a third mechanism by which unapproved therapeutic goods can be supplied to patients. Regulation 12B provides that a medical practitioner endorsed by the Ethics committee of the hospital in which s/he engages in clinical practice or a doctor treating patients not in a hospital but who has been endorsed by an appropriate ethics committee may be eligible to become an Authorised Prescriber (AP).

The Authorised Prescriber system allows doctors to supply individual patients with unapproved therapeutic goods where medicines have been withdrawn from the Australian market, where medicines initially supplied as part of a clinical trial are still awaiting approval or where a medicine is available overseas but not in Australia. Such products can only be prescribed to patients suffering from a life threatening or otherwise serious illness or condition.<sup>14</sup>

An Authorised Prescriber's patient must give informed consent to the prescription of medicine by the AP. This consent must be freely given and based on an adequate appreciation of their condition and its consequences; sufficient knowledge of treatment options for that condition and their long term prognosis. The AP must specifically tell the patient that the medicine is not approved in Australia; that its benefits and side effects are not known and what, if any, approved alternative treatments are available to that patient.

If an application is approved by the TGA, it sends the AP a letter of authorisation which will include any conditions on which the authorisation is given. The authorisation only applies to the specific patient and the medicine can only be prescribed for patients under the AP's direct care.

*(d) Importation for personal use*

The final category of exemption from inclusion in the ARTG is that of 'personal Importation' under s 18(1), r 12(1), Schedule 5 Item 1.1. The operational definition of personal importation is the bringing into Australia by a person or the arranging by a person in Australia to have therapeutic goods sent to them by an overseas supplier where the goods are for the use of that

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<sup>14</sup> *Therapeutic Goods Act* section 19(6), 41HC and Regulation 12B(2).

person or for the use of that person's immediate family. These goods must not be supplied or sold to any other person.

However, notwithstanding the general exemption applying to importation for personal use, it is illegal to import cannabis or cannabis products because they are listed in Schedule 9 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), which prohibits any use of cannabis for any purpose whatsoever.

### ***6.3 Current New South Wales legislation impacting on medicinal cannabis use***

The two Acts directly relevant to medicinal cannabis use are the *Drug Misuse and Trafficking Act 1985* (NSW) and the *Poisons and Therapeutic Goods Act 1966* (NSW).

#### *Drug Misuse and Trafficking Act 1985* (NSW)

Schedule 1 of the 1985 Act lists the substances which are deemed to be prohibited unless their possession is authorised by the Director-General of the NSW Health Department or unless they are otherwise exempted under the second *Poisons and Therapeutic Goods Act*.

However possession of a Schedule 1 drug is not an offence if it is used for scientific research, instruction, analysis or study and authorised by the Director-General for that purpose.<sup>15</sup> Section 10(2)(d)(ii) also exempts possession of a Schedule 1 drug if it has been legally prescribed or supplied, providing that the possession is 'for the sole purpose of administering or assisting in the self-administration of the prohibited drug to the other person in accordance with the prescription or supply.'

Otherwise, section 12 creates an offence for self-administration and section 13 makes administering a drug to another person an offence, though section 13(2)(a) exempts drugs which have been licensed or authorised under the *Poisons and Therapeutic Goods Act 1966*. These offences are supplemented by section 19 which prohibits the aiding or abetting of such offences.

Section 25 defines drug offences involving distribution, including sending, offering, agreeing to offer or supply, having in possession for that purpose or authorising, causing, directing, permitting or attempting any of these actions. Section 40(A)(2) reverses the usual criminal onus of proof, placing this on the accused to prove that an alleged offence was not unlawful.

#### *Poisons and Therapeutic Goods Act 1966*

The second most relevant Act is the *Poisons and Therapeutic Goods Act 1966*, which generally complements the Commonwealth *Therapeutic Goods Act 1966* and seeks to regulate the supply and distribution of pharmaceutical drugs and poisons. Annexed to the Act is the ‘Poisons List’ divided into Schedules categorised by the level of control the Act exercises over particular drugs. If cannabinoids were to be prescribed in NSW, they would first have to be classified in the Poisons List. Then ‘they would be treated in much the same way as other ... drugs.’<sup>16</sup>

### 6.4 New Zealand drug legislation

The *Misuse of Drugs Act 1975* remains the primary legislative instrument for the enforcement of New Zealand’s drug policies. The basis of this policy is the principle of the risk of harm which is apparent in the classification of drugs into classes of ‘very high risk’, ‘high risk’ and ‘moderate risk.’ To determine the correct classification of a drug the *Act* provides a list of relevant factors, including its potential therapeutic advantages and its danger to public health. Under this scheme cannabis resin and oil and hashish are categorised as Second Schedule Part 1, Class B controlled drugs. To enable drug classification or re-categorisation the Government has set up the Expert Advisory Committee on Drugs which advises the Associate Minister of Health. If the Minister accepts the advice it may recommend to the Governor-General that s/he issue an Order in Council which is then voted upon in Parliament. If approved, the Order in Council will again be forwarded to the Governor General for signature and comes into force twenty eight days later.

However medicinal cannabis use is not only regulated by the 1975 Act, but also by its 1977 *Regulations* and by the *Medicines Act 1991*. Approval of drugs is the prerogative of the

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<sup>15</sup> *Poisons and Therapeutic Goods Act 1966* (NSW) s 10(2)(b).

<sup>16</sup> ‘Report of the New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes’, above n 1, vol. 2, 83.

therapeutic branch of the Health Ministry under delegation from the Minister. This has included the prescription of cannabis products such as Marinol on the basis of overseas approval or clinical trials.

Both of the Acts allow for exemptions for doctors to legally prescribe or administer a controlled drug such as medicinal cannabis to patients following Ministerial consent. According to the Health Committee into the public health strategies applicable to cannabis use and the most appropriate legal status for it,

Theoretically, a medical practitioner could procure a supply of cannabis under sections 25 & 28 of the *Medicines Act* and directly import the cannabis product ... for a particular patient ... but once this [Ministerial approval] has been obtained and the medicinal cannabis, there is nothing stopping that patient from lawfully consuming the prescribed drug.<sup>17</sup>

In its Report, the inquiry went on to recommend ‘to the government that it preserve the possibility of supporting the prescription of clinically tested cannabis products for medicinal purposes.’<sup>18</sup>

The Aotearoa Greens claimed that in the Inquiry ‘registered doctors had not been consulted regarding their views.’<sup>19</sup> They therefore resolved to conduct a survey of a representative sample of five hundred general practitioners and specialists. The questions asked what level of knowledge about medicinal cannabis was held by the doctors; what their position was regarding current use of medicinal cannabis and whether they would prescribe it if it were legalised and whether doctors felt they should be allowed to prescribe medicinal cannabis.

The methodology of the survey involved a random selection of names drawn from the doctors’ professional registries. The researchers then mailed the survey to the selected doctors for self-completion of the questions and received a response rate of 45%.<sup>20</sup>

Key results of the survey were that 32% of doctors would consider prescribing medicinal cannabis if it were legal; 30% thought that doctors should be allowed to prescribe cannabis

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<sup>17</sup> Report of the Health Committee, *Inquiry into the Public Health Strategies Applicable to Cannabis Use and the Most Appropriate Legal Status* (2003) House of Representatives, Wellington NZ 56–57.

<sup>18</sup> Ibid 57.

<sup>19</sup> Aotearoa Greens, *Medicinal Cannabis Survey of Registered Doctors* (October 2003) Green Party of Aotearoa New Zealand 4 <<http://www.greens.org.nz/sites/default/files/campaigns/cannabis/SurveyofDoctors.pdf>> (accessed 15 February 2010).

products for medicinal purposes and 37% felt they did not have enough knowledge of medicinal cannabis.<sup>21</sup>

Following on from the Parliamentary Inquiry, the Medicines Control branch of the Ministry of Health issued a paper directed towards doctors which specifies the requirements necessary for approval of Sativex as an unapproved medicine by the Ministry. The applicants must be doctors in good professional standing who ‘normally’ provide medical care to the patient for whom the application was made. The medical conditions which give rise to eligibility to use medicinal cannabis are:

Nausea, anorexia and wasting (cachexia) associated to [sic] cancer and AIDS or chronic pain including cancer pain for which other pain relief treatments are ineffective or have significant/ severe side-effects or neuropathic pain(associated with conditions including multiple sclerosis, stroke, cancer, spinal cord injury, severe physical trauma and peripheral neuropathy rising from diabetes) or muscle spasm and spasticity associated with multiple sclerosis or spinal cord injury.<sup>22</sup>

In addition, applicants must have treated the patient with standard treatments but either without success or with intolerable side effects over an appropriate period. A specialist in one or more of the specified medical conditions must assess and endorse the application and the patient must sign an informed consent form acknowledging that they understand that the treatment with Sativex is on a trial basis which may require changing the dose over time. There follows a detailed ‘Patient Management Criteria’ list, covering the stipulations mentioned above.<sup>23</sup>

By late 2008, three approvals had been granted with another pending and GW Pharmaceuticals had lodged an application with Medsafe [the New Zealand equivalent of the Therapeutic Goods Authority] to allow the marketing of Sativex in New Zealand. In 2008 the Ministry also issued a briefing paper which claimed there was ‘sufficient evidence of safety and efficacy of cannabis in some medical conditions’ to support consideration of

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<sup>20</sup> Report of the Health Committee , above n 17, 4.

<sup>21</sup> Aotearoa Greens, above n 19, 12–16.

<sup>22</sup> *Sativex (standardised cannabis pharmaceutical): Requirements for Physician Application-Approval*, Wellington NZ National Drug Policy, Ministry of Health, August 2007, 4.

<sup>23</sup> Ibid at 6–8.

compassionate controlled use.<sup>24</sup> Subsequently the Health Minister came out in support of medicinal cannabis legalisation.<sup>25</sup>

Meanwhile a medicinal cannabis users group presented a petition with 3,000 signatures to the Parliamentary Select Committee, urging them to legalise medicinal cannabis.<sup>26</sup> All of this activity around medicinal cannabis prompted newspaper speculation in New Zealand that ‘cannabis products could soon be used legally for medical purposes.’<sup>27</sup> But it was not to be. After attempts at legalisation of cannabis, stretching back to 2004, *The Misuse of Drugs (Medicinal Cannabis) Amendment Bill* was rejected by the Parliament on 2 July 2009 by 84 votes to 34.

The arguments against the proposition consisted of the same arguments used by anti-legalisation advocates all over the world – that medicinal cannabis was just a Trojan horse aimed at decriminalising recreational cannabis and that the scheme proposed would require additional administration by the government which would render the scheme too expensive.<sup>28</sup>

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<sup>24</sup> Ministry of Health, Briefing Paper to the Minister 2008.

<sup>25</sup> ‘Government to allow Sativex medicinal cannabis spray’ *NORML News* <<http://www.norml.org.nz/article653.html>> (accessed 5 October 2008).

<sup>26</sup> ‘Report of the Working Party on the Use of Cannabis for Medical Purposes’, above n 9.

<sup>27</sup> *Ibid.*

<sup>28</sup> No author listed *Dominion Post* (Wellington) 2 July 2009.

## Chapter 7

# MEDICINAL CANNABIS CASE STUDIES

### *7.1 A Critique of the New South Wales Parliamentary Working Party on the use of Cannabis for Medical Purposes*

Following calls on the State Government by the Australian Medical Association (NSW) ('AMA') and the NSW Law Society, in September 1999, for the controlled provision of medicinal cannabis to patients suffering from medical conditions which could benefit from its use, the then Premier, Bob Carr announced in October 1999 the establishment of an expert working party to inquire into the use of cannabis for medical purposes.

In his News Release of 19<sup>th</sup> October 1999, the Premier categorically rejected the legalisation of cannabis for recreational use but referred to the 27,000 NSW cancer patients whose suffering could potentially be eased by medicinal cannabis use.

Choosing his words carefully, he cited the 1998 House of Lords Select Committee (the Runciman Committee) and the AMA as stating that cannabis could serve a therapeutic function but that he wanted 'a full investigation of the drug to ensure that any benefit ... is not outweighed by negative health and social effects.'<sup>1</sup>

He went on to enumerate the stakeholder groups to be included in the membership of the working party and to stress that 'there would be widespread community consultation following the delivery of the Working Party's Report'<sup>2</sup> in July 2000.

When finally constituted, the Working Party was chaired by Professor Wayne Hall, then Executive Director of the National Drug & Alcohol Research Centre at the University of New South Wales and its members included academics, pharmacologists and representatives of the AMA, Law Council, AIDS Council, Cancer Council, Royal College of General Practitioners, Police, Attorney-General's Cabinet and Health Departments.

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<sup>1</sup> B Carr, 'Government to Consider Cannabis for Medicinal Purposes', (News Release, Premier's Office, NSW Government, 19 October 1999).

<sup>2</sup> Ibid.

Its Terms of Reference were:

- to assess the efficacy 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 identify legal, ethical, pharmacological, 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.

In the course of their deliberations the Working Party invited submissions from fifteen organisations including the Australian Pharmaceutical Manufacturers Association, GW Pharmaceuticals Limited, New South Wales Nurses Association, Royal Australian and New Zealand College of Psychiatrists (NSW), Royal Australian College of Physicians, Catholic Health and the Salvation Army. In addition, submissions were volunteered by one individual and five advocacy groups.

The Working Party's Main Report<sup>3</sup> states that the medical, therapeutic, legal and regulatory issues surrounding the subject raised five questions. These were:

- Whether cannabis and cannabinoids can safely and effectively treat a number of medical conditions for which cannabis has been recommended.
- Whether smoking cannabis is a safe and effective method of drug delivery for the stated conditions.
- How cannabis compares with other treatments as to safety and efficacy.
- Whether cannabis or cannabinoids would be likely to satisfy the criteria for registration in New South Wales as pharmaceutical drugs.
- What further research is needed to clarify the medical uses of cannabis and cannabinoids.

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<sup>3</sup> New South Wales Parliamentary Working Party on the Use of Cannabis for Medical Purposes, *Report of the Working Party on the Use of Cannabis for Medical Purposes*, Volume II, Main Report, August 2000, 10 ('Working Party Report').

However the Working Party's Main Report is not specifically structured around answers to these questions and the reader must perforce sometimes 'read between the lines' to divine their answers to these crucial questions.

The structure of the Report is in four parts: Part 1, an Introduction; Part 2, 'Medical and Therapeutic Uses'; Part 3, 'Legal and Regulatory Options' and Part 4, Appendices and References. This summary and critique will follow those divisions of the Report and evaluate its conclusions.

Following an introduction in Chapter 1, Chapter 2 of Part 1 gives a brief botanical and pharmacological description of cannabis and then goes on to briefly review the history of its medical uses before turning attention to the level of contemporary medicinal cannabis use, concluding that '[i]t is not possible to estimate how many people currently use cannabis for medical purposes, or how many would do so if it were legally available.'<sup>4</sup>

However, since that was written, some overseas and Australian data has become available which enables some estimates to be made about the size of the medicinal cannabis user population<sup>5</sup>, both to provide a justification and motivation for the Government to implement medicinal cannabis legislation and to ensure that the regulatory framework established for its introduction is adequate to the needs of the using population.

Chapter 3 examines several relatively recent authoritative reports on medicinal cannabis, in particular the United Kingdom House of Lords Report (the Runciman Report) and the United States' Institute of Medicine Report. It is noteworthy that all of these reports recommended further research should be undertaken, especially into non-smoked medicinal cannabis.

Although a more detailed examination of the United Kingdom's policies and legislation is included elsewhere in this thesis<sup>6</sup> one of the Working Party's findings bears noting here – that the United Kingdom felt hamstrung in adopting a less restrictive policy on medicinal cannabis use by its adherence to the United Nations Single Convention on Narcotic Drugs, which was formerly thought to constrain Australia. However the action of the UK government since the

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<sup>4</sup> Ibid 13.

<sup>5</sup> See Chapter 2.2 1(d).

<sup>6</sup> See Chapter 5.4.

Runciman Report in re-allocating cannabis from Schedule 1 of the treaty to Schedule 2, demonstrates that the Convention need not operate as a barrier to reform.

Chapter 4 summarises submissions on medicinal cannabis use made to the Working Party. Most of the submissions advocated the development of non-smoked cannabis because it is pure and standardised and because of health risks associated with smoking. However several submissions made the point that smoking cannabis allows for patients to titrate their dose and delivers faster onset relief.<sup>7</sup> ‘Virtually all the submissions referred to the need for further research and clinical trials of cannabis.’<sup>8</sup>

Under the sub-heading of ‘Supply of Medical Cannabis’, several submissions made the point that any legalisation of medicinal cannabis use would have to clearly separate its medical uses from its recreational uses, though none suggested how this could be done, though that issue is further addressed in the next sub-section, ‘Prescription and Dispensing’, where most submissions note that the NSW and Commonwealth Therapeutic Goods Act would need to be amended to permit dispensing of medicinal cannabis in a pharmaceutical form. The Royal Australian College of Physicians and the Australian Professional Society on Alcohol and Other Drugs suggested a system providing for exemptions from prosecution for patients with certain prescribed conditions which would be identified and selected by an expert committee. The NSW branch of the Pharmaceutical Society of Australia commented that pharmacists already have the facility to store and dispense Schedule 8 products ‘with minimal diversion to illicit uses’<sup>9</sup> and thus advocates that cannabis be re-scheduled in Schedule 8. The People Living with AIDS group felt that medicinal cannabis ‘should be accessible via a script from a GP or specialist as long as that person is a registered ... prescriber.’<sup>10</sup>

Chapter 5 in Part 2 is devoted to ‘Cannabinoids and Animal Physiology’ which raises no issues for the present study except for the conclusion that ‘Research has also revealed that ... tolerance to and dependence on cannabinoids is developed as with other drugs.’<sup>11</sup> Since these

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<sup>7</sup> See Working Party Report, above n 3, p. 25 and also New South Wales Parliamentary Report of the Working Party on the Use of Cannabis for Medical Purposes, Volume III, Submissions Received, August 2000, at Submission 2, 8.

<sup>8</sup> Working Party Report, above n 3, 28.

<sup>9</sup> Ibid 30.

<sup>10</sup> Ibid .

<sup>11</sup> Ibid 36.

issues are currently highly controversial it is surprising that they should only occupy three paragraphs of the Report's 145 pages.

Their statements on tolerance are equivocal. They claim that it 'may result ... [and] there is some uncertainty about the relevance of animal findings to human use ...'<sup>12</sup>.

As to dependence, physical dependence on cannabinoids has been observed only under experimental conditions of 'precipitated withdrawal' in ... animals. ... Physical dependence can be demonstrated in animals, but in humans the long half life and slow elimination of THC from the body prevent most users from experiencing abstinence symptoms.<sup>13</sup>

However, insofar as the data considered by the Group relate to recreational use of smoked cannabis, they provide no clear evidence of tolerance and dependence in relation to pharmaceutical cannabis in medicinal cannabis users. On the other hand the product monograph produced for Sativex does not indicate any evidence that Sativex develops tolerance or dependency,<sup>14</sup> and the issues of tolerance and dependence have already been addressed in Chapter 2.<sup>15</sup>

Chapter 7, 'The Risks of Cannabis Use' briefly returns to the dependence issue but again, apart from noting an age difference between recreational and medicinal users, fails to establish the existence of dependence among medicinal cannabis users. Despite concluding that dependence 'is an important consideration when considering approval of the therapeutic use of cannabis. [They claim] on the other hand, some controlled substances which are currently approved medications also produce dependence on long term use. This issue is a normal part of patient management and does not present undue risk to them.'<sup>16</sup>

The chapter then discusses whether or not there is a link between medical drug use and drug abuse. Relying on the findings of the Institute of Medicine study, it concludes that fears of iatrogenic addiction 'have proved unfounded'<sup>17</sup>; that 'decriminalising cannabis use does not appear to have resulted in observable changes in the prevalence of cannabis use; [and] the

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<sup>12</sup> Ibid 35.

<sup>13</sup> Ibid.

<sup>14</sup> *Sativex Product Monograph* GW Pharma Ltd, Salisbury, Wiltshire, UK, Submission No. 091289, 13 April 2005, 32.

<sup>15</sup> Chapter 2.

<sup>16</sup> Working Party Report, above n 3, 45.

<sup>17</sup> J Joy et al (eds), *Marijuana and Medicine: Assessing the Science Base* (1999), cited in ibid Working Party n 3, 20.

1996 Californian medical cannabis campaign was not associated with a change in voters' perceptions of the risks of cannabis that differed from US states where no such campaigns were held.'<sup>18</sup>

The remainder of Chapter 7 deals with psychological and physiological harms associated with cannabis but an examination of their data indicates that it only relates to recreational rather than medicinal use and, in particular, focuses on smoking. For example, in introducing the psychological harms of cannabis, they are careful to explain that 'There are a number of reasons to be wary of assuming that the health and psychological effects of non-medical uses of cannabis will predict the health hazards of its medical uses'<sup>19</sup> but then go on to review psychiatric disorders with 'heavy use'<sup>20</sup> of smoked cannabis and cognitive effects of 'heavy uses' [sic].<sup>21</sup> They conclude that while cannabis adversely affects psychomotor performance, 'There is little convincing evidence that cannabis causes the amotivational syndrome.'<sup>22</sup> Yet the relevance of these findings on smoked cannabis to an evaluation of medicinal cannabis is, by their own admission, questionable. The rest of Chapter 7 is devoted to an examination of the harms of smoked cannabis, which need not concern us here.

Chapter 8, 'The Development of Cannabinoid Drugs', is introduced with the categorical statement that '[t]he future uses of cannabinoids lie in pharmaceutical drug development in which the chemical structures of cannabinoids are manipulated to design better drugs.'<sup>23</sup> They follow this with a review of the United States' drug regulatory system<sup>24</sup> and a case study on the development and marketing of 'Marinol' on the United States' market, before surveying the US market outlook for cannabinoids and concluding that it 'is not favourable ... [because] commercial interest ... appears non-existent.'<sup>25</sup>

However, whilst it remains true that there are significant impediments to the development and marketing of cannabinoid drugs, the development of the whole plant extract of cannabis marketed as 'Sativex' has rendered the Working Party's conclusion somewhat obsolete. This pharmaceutical product is now legally available by prescription in the United Kingdom and in

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<sup>18</sup> Working Party Report, above n 3, 47.

<sup>19</sup> Ibid.

<sup>20</sup> Ibid 48.

<sup>21</sup> Ibid.

<sup>22</sup> Ibid 49.

<sup>23</sup> Working Party Report, above n 3, 59.

<sup>24</sup> Working Party (covered here in Chapter 5.1)

Canada. As well, its distributors have applied to the United States' authorities for permission to market it there. Given that its distributors, the multinational pharmaceutical corporation Bayer, have already made a commercial judgment that it is economically worthwhile to market Sativex there and given that the Australian market is comparable in many respects to that of Canada and that Bayer also hold distribution rights in Australia, it is arguable that these developments undermine the Working Party's key recommendations on the need for legalisation of smoked cannabis, at least for multiple sclerosis sufferers. Specifically, the emergence of Sativex contradicts their finding that:

[i]t does not currently appear feasible that there exist alternative routes of administration of cannabinoids that would be reliable and inexpensive, which would eliminate the use of smoked cannabis while making dose titration easier.<sup>26</sup>

Much of the ground covered in Part 3, 'Legal and Regulatory Options', has been addressed elsewhere in this thesis, so the following analysis of this section of the Report is limited to a discussion of matters not otherwise examined.

Chapter 9 looks at international, national and NSW legislation and regulations,

for facilitating both the therapeutic use of cannabis and the performance of therapeutic trials for selected medical conditions. The objective was to explore and develop models which would permit the use of cannabis and cannabinoids for therapeutic purposes and scientific trials in NSW ...<sup>27</sup>

The Report first analyses the applicable international law and concludes that 'The controlled availability of cannabis and cannabinoids for medical or scientific purposes would not place Australia in breach of any international treaty obligations.'<sup>28</sup> This judgment supports my (and others') conclusions on this matter.<sup>29</sup>

Chapter 9 then examines applicable Commonwealth legislation. From the outset it is made clear that 'Owing to the health risks associated with smoking, cannabis, *in smoked form*, will never comply with Therapeutic Goods Administration (TGA) requirements.'<sup>30</sup> It then proceeds to argue that 'it would not be possible to manufacture of cannabis [sic] for use as a

<sup>25</sup> Working Party Report, above n 3, 62.

<sup>26</sup> Ibid.

<sup>27</sup> Ibid 63.

<sup>28</sup> Ibid 68.

<sup>29</sup> See, eg K Dawkins, 'International Law and Legalising Cannabis' (1997) *New Zealand Law Journal* 281, 282.

<sup>30</sup> Working Party Report, above n 3, 73.

therapeutic good’<sup>31</sup> in the context of registration on the Australian Register of Therapeutic Goods (ARTG). The Report is unclear at this point as to whether it is referring only to raw cannabis or to pharmaceutical cannabis products like Sativex. If it is meant to apply to pharmaceuticals I would disagree with their conclusion on the basis of the discussion above in relation to the possibility of Sativex being manufactured or distributed by Bayer in Australia.<sup>32</sup>

As the Report’s next sub-section explains, the lengthy ARTG procedure could be considerably truncated by Bayer invoking the provisions of the Orphan Drug Program under the ‘Special Access Scheme’ of the TGA. This was set up to encourage the registration of non-commercially viable drugs by waiving some evaluation procedures and some fees and charges with the result that approval can be given sooner than would otherwise occur. However the TGA’s definition of an orphan drug includes the stipulation that it only applies to drugs which could potentially benefit at least 2000 patients.

Moreover orphan drugs can qualify for listing with the Pharmaceutical Benefits Scheme which would enable medicinal cannabis users to purchase their cannabis medication at a subsidised price. The Report claims that ‘overseas manufacturers of cannabis derivatives are likely to give more thought to this option but it is still doubtful whether they would lodge an application.’<sup>33</sup> However it is submitted that the introduction of Sativex to world markets changes this judgment, for, whilst Bayer has not yet made a decision to apply to make the product available in Australia,<sup>34</sup> the economics of the market may be favourable to its introduction as there are 15,000 MS patients in Australia<sup>35</sup> compared with 50,000 in Canada, where the drug has already been released.<sup>36</sup> In addition there are grounds for belief that the UK and Canadian authorities may soon authorise its use for other conditions, thereby expanding the potential Australian market substantially.

The section on Commonwealth legislation also makes two other points, which should be noted here. Because cannabis in any form is defined as a narcotic under the *Customs*

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<sup>31</sup> Ibid 73.

<sup>32</sup> See below discussion in par 3.

<sup>33</sup> Working Party Report, above n 3, 73.

<sup>34</sup> Letter from Jane Worrallo, Manager, Pharmacovigilance and Medical Information, ANZ Bayer to Graham Irvine, 7 May 2009.

<sup>35</sup> MS Society website, <<http://www.msaustralia.org.au>> (accessed 3 August 2006).

<sup>36</sup> Bayer website, <<http://www.Bayer.com.au>> (accessed 3 August 2006).

*(Prohibited Imports) Regulation* it is not eligible for import under the TGA Personal Import Scheme. Although the synthetic cannabinoid drug Dronabinol was made available under the TGA's Special Access Scheme, patients using it had to bear the full cost, which was substantial. On these bases, the Working Party considered both these options for the provision of cannabis medicine as unviable.<sup>37</sup> Whilst I agree with these judgments, there is no inherent reason why the *Therapeutic Goods Act* could not be amended to allow the import of cannabis medicine, at least until it is manufactured in Australia.

The NSW legislation section of the Report examines the *Drug Misuse and Trafficking Act* and points out that medical use of cannabis, without committing an offence, is potentially provided for under section 10(2)(b) which empowers the Director-General of Health to authorise such use and, under section 10(2)(d) to authorise exemption from criminal liability for the possession of the drug in the context of a caregiver assisting a person with a valid prescription for that drug. Although this mechanism would not be suitable for application to all medicinal cannabis users, it might serve an initial purpose as a stopgap measure enabling its application in cases of compassionate emergency.

Under the *Poisons and Therapeutic Goods Act 1966* (NSW) cannabis is classified in Schedule 8 which means it is only available with a doctor's prescription and with the Health Department's approval where the prescription is for more than two months.<sup>38</sup> Other mandatory safeguards are also imposed, including storage of the drug in a safe, the keeping of a drug register containing purchase and supply details and retention of all prescriptions by the dispensing pharmacist.<sup>39</sup> Such a system is already in place under this Act whereby, if a legal supply of Sativex or similar were available, it could be provided to qualifying patients just as, for example, heroin is currently in NSW.

Chapter 10 looks at 'Prescribing Issues and Options' and considers four options. Under the first, doctors would apply in writing to the Health Department each time they wanted to prescribe cannabis to one of their patients. The Working Party felt that 'this model applies the greatest controls and would require considerable resources.'<sup>40</sup> This is disputed inasmuch as the appropriate system is already in place in respect of opiates prescriptions, of which there

<sup>37</sup> Working Party Report, above n 3, 76.

<sup>38</sup> *Poisons and Therapeutic Goods Act 1966* (NSW) s 28.

<sup>39</sup> Regulations 24, 42, 49 *Poisons and Therapeutic Goods Act 1966* (NSW).

are many more applications than would likely be the case with Sativex. If, as the Report suggests, prescribing doctors were issued with clear guidelines which specified, inter alia, which medical conditions were approvable, no further training would be needed by prescribing doctors as it would be the Department of Health which would make the decision to prescribe or not. Under my proposed scheme it would be the NSW Government which would have ultimate responsibility and liability for such decisions. This is an important consideration for we have seen that in other jurisdictions, where it is the patient's doctor who makes this decision, many practitioners are unwilling to risk legal sanctions, resulting in their refusal to prescribe cannabis.

The Working Party's second option would see only medical specialists or general practitioners with additional training and accreditation as eligible to prescribe. The problem with this option may well be that it gives little incentive for doctors to undergo the required training, with the result that patients may not have feasible geographical access to any authorised doctor and/or, especially in rural and remote areas, there would probably not be enough specialists to service the demand. Unless a large number of doctors were authorised, those who were authorised might incur excessive patient caseloads.

The third model would see the Department of Health approving not the patients but the prescribing doctors who would have the responsibility of approving prescriptions and would be required to keep records and clinical notes. This model would leave prescribing doctors to carry moral and legal responsibility for their clinical decisions. The fourth option would require legislation which specified the criteria patients would need to be eligible for prescription of cannabis and also the criteria necessary for prescribing doctors.

Options 3 and 4 are subject to the same objections as number 2 and thus I consider only model 1 is a desirable option. Unlike other sections of the Report, the Working Party does not express an opinion on which model they favour, though in their Report on Consultation, Recommendation 20 refers to the training of 'accredited medical practitioners' which would seem like an endorsement of Option 2.<sup>41</sup>

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<sup>40</sup> Working Party Report, above n 3, 81.

<sup>41</sup> *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 v 2 New South Wales Government July 2001 at 27.

In Chapter 11 the Working Party considers three options for regulating legalised medicinal cannabis – a non-enforcement agreement; amendments to existing NSW legislation and new legislation. They effectively rule out number 1, citing the inherent uncertainties of such instruments which would perforce include as parties large numbers of NSW and Commonwealth agencies and the ever-present possibility that a party might revoke the agreement at any time.

Of Option 2, they claim ‘If cannabinoids can be lawfully prescribed under the *Poisons and Therapeutic Goods Act 1966*, very little amendment would be necessary.’<sup>42</sup> If Option 3 were adopted, the new Act would have to override other statutes and would possibly need a ‘sunset clause’. Again no option is recommended but, in the next Chapter, ‘General Regulatory Models at the State Level’, it is stated that ‘[t]he conclusion favoured thus far is to use existing regulatory mechanisms.’<sup>43</sup> The chapter then considers options for legislation of recreational cannabis use and is thus not relevant here.

Again, Chapter 13 is largely irrelevant to this study’s concerns as it focuses on possible sources of raw cannabis. Nevertheless while this study advocates the initial sourcing of medicinal cannabis by the importation of ‘Sativex’ in the short term, in the longer term there may be scope for the growing of cannabis and its manufacture for medicinal purposes to take place in NSW.

If or when this becomes feasible then some of the Report’s findings may be apposite. For example, it canvasses a system of licences whereby companies or authorities could cultivate cannabis for medicinal and scientific purposes though they claim that the cost of a body set up to regulate such a scheme ‘would be considerable’.<sup>44</sup> However such a body already exists in respect of opium poppy cultivation, the Opium Poppy Advisory and Control Board in Tasmania, which functions on a quite small budget.<sup>45</sup>

Chapter 14 examines issues and methods of distribution and dispensing medicinal cannabis. It claims that, ‘[i]f and when cannabis can be delivered safely and in compliance with TGA

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<sup>42</sup> Working Party Report, above n 3, 83.

<sup>43</sup> Working Party Report, above n 3, 85.

<sup>44</sup> Working Party Report, above n 3, 87.

<sup>45</sup> According to a telephone interview on 4<sup>th</sup> November 2009, with the Board’s Manager, Mr Terry Stewart, the annual budget is around \$900,000.

requirements, a prescription model based on existing schedule 4 or schedule 8 drugs could be established.<sup>46</sup>

The chapter also explores three options for the certification of medicinal cannabis patients and/or doctors wishing to use or prescribe medicinal cannabis. The first model envisages doctors applying to the NSW Department of Health (DOH) for approval to make medicinal cannabis available to individual patients but the Report states that this would be ‘costly and time consuming.’<sup>47</sup> Yet this system is already operating in NSW in respect of addictive drugs like heroin and drugs such as amphetamines and could be readily and cheaply extended to medicinal cannabis use.<sup>48</sup>

The second model would see doctors applying to the Department of Health for permission to prescribe or the amendment of the *Drug Misuse & Trafficking Act 1985* to define a class of doctors who would be authorised to certify patients as suitable for prescription of medicinal cannabis, whilst the third option canvasses legislative amendments under the Act which would detail the criteria both for patient certification and doctors’ approval to prescribe. However, both options 2 and 3 seem problematic as to the authorisation of ‘a class of doctors’ authorised to certify patients. What would be the basis for designating such a class and what incentives would operate to motivate doctors to agree to become involved? Indeed, the author’s study of NSW North Coast general practitioners elicited some concern that doctors may be swamped with patients wanting medicinal cannabis so as to render their heavy case loads unsupportable.<sup>49</sup>

Perhaps if option 3 were modified so that any doctor was authorised to apply the certification criteria laid down in the Regulations this would avoid a situation where there were too few doctors prescribing for too many patients. But this would still not address possible practitioners’ concerns that such a scheme would place on individual doctors all the responsibility and its potentially associated liability for their clinical decisions.

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<sup>46</sup> Working Party Report, above n 3, 93.

<sup>47</sup> Ibid.

<sup>48</sup> Interview with Dr David Helliwell, Director Riverlands Drug & Alcohol Rehabilitation Centre, Lismore at Nimbin NSW (6<sup>th</sup> December, 2007).

<sup>49</sup> See Chapter 2.4, 83.

Hence, of the three options posited it would appear that option 1 would be preferable for the type of model advocated here as it has the advantages of being relatively easily and cheaply incorporated into the existing scheme for addictive drugs and leaves liability to be borne by Department of Health instead of individual doctors.

Chapter 15 comprises a brief and general examination of civil liability issues and how these could be minimised. It recommends ensuring that patients and trial subjects be required to give informed consent and waivers to treatment with medicinal cannabis. Such measures are adopted in the United States and Canadian medicinal cannabis use laws and will be further considered in more detail in another section below. This also applies to the Report's recommendation of statutory exemption clauses to exclude persons acting under medicinal cannabis legislation from civil and/or criminal liability for their legitimate actions.

The other Chapter 15 recommendation is that the confidentiality of patients and trial subjects be ensured. Once again there are ample precedents in the United States and Canadian statutes which can be readily adapted to NSW legislation and which will be considered later, along with the civil liability issues. Despite its focus on raw cannabis, Chapter 16 raises some questions of criminal liability which may be pertinent to pharmaceutical medicinal cannabis use as they are to the plant itself and so it is relevant to discuss these here.

The first relevant issue raised concerns NSW medicinal cannabis patients travelling to other states and being prosecuted for taking their legally prescribed medicinal cannabis with them. These potential problems may be addressed by amendment of the ARTG to re-schedule cannabis for medicinal purposes. Since the states and territories have 'mirror' provisions in their legislation which is complementary with the Commonwealth's, the TGA's re-scheduling would make it sensible for the states and territories to similarly amend their statutes. In any event it is arguable that the Commonwealth legislation would override the states and territories in respect of the lawfulness of medicinal cannabis use and possession in a criminal trial in any state or territory.<sup>50</sup> Otherwise, the Report suggests that NSW could enter into an arrangement with other state governments not to prosecute patients.<sup>51</sup>

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<sup>50</sup> S Bronitt and B McSherry, *Principles of Criminal Law* (2<sup>nd</sup> ed, 2005) 1140.

<sup>51</sup> Working Party Report, above n 3, 101.

Chapter 16 then goes on to address several police concerns, two of which are relevant here – the others being concerned principally with raw cannabis. The first is the danger that a medicinal cannabis patient could sell their medication on the black market. Again, this is more of a problem with plant cannabis as trials to date indicate that only a relatively small percentage of medicinal cannabis patients experience any psychoactive effects from medicinal cannabis pharmaceuticals, so that there is unlikely to be a black market for them. What is more, with adequate documentation by the Department of Health and/or treating doctors, this should be readily detectable by examining patient records as to the amount prescribed and the period for which the medication could be expected to last given the doctor's frequency and dosage directions. Moreover there would be little likelihood that a patient relying on medicinal cannabis for symptom relief would want to part with their medication if they were to compare the extent of that relief with the relatively small price they could obtain for it on the black market, especially as they would also be risking being caught out, prosecuted and facing having their medication withdrawn from them by their doctor.

The other relevant policing issue raised in Chapter 16 is the potential conflict between a patient's right to privacy and confidentiality and the right of police to be able to identify those illegally using or in possession of medicinal cannabis. Here I endorse the Report's suggestion that the solution to this dilemma is by the NSW Department of Health maintaining a confidential register of patients authorised to use and possess medicinal cannabis. Police could apply for access to information on the register by a request to an independent person empowered by legislation to decide whether the officer has a need to know this information.

The medicinal cannabis legislation proposed below addresses this issue by stipulating that sufficient evidence of a person's right to use and possess medicinal cannabis could be the production to a requesting police officer of the patient's current prescription which the patient must keep with them at all times. If a patient was unable to produce a current prescription, the officer would have the right to be told by an appropriate Department of Health officer whether the particular person was on the register or not.

### *The Working Party's recommendations*

The Working Party's six month inquiry resulted in the August 2000 publication of three volumes of their report – volume 1, an Executive Summary; volume 2, the Main Report and volume 3, Submissions Received. These documents were then released for public comment on 1<sup>st</sup> November 2000 for a period of three months and advertisements were placed in 23 metropolitan, regional and ethnic newspapers, inviting submissions.<sup>52</sup> One hundred and seventeen submissions were received, two-thirds from private individuals and the rest from government agencies, medical, legal, religious and community organisations. Of the 97 which outlined their stand on whether or not medicinal cannabis should be legal, 72% thought that it should and 11% were opposed.<sup>53</sup>

The submissions from private individuals covered all regions of New South Wales and several other states as well as one from Italy and their occupational backgrounds ranged from doctors, academics and media workers to business people, retirees and pensioners.<sup>54</sup> Of the 46 individuals who reported their medical conditions in their submission, the largest groups by far were multiple sclerosis and cancer patients. However, much in common with other populations of medicinal cannabis users, 36% used medicinal cannabis to relieve pain; 18% for depression and/or anxiety; 15% for appetite loss; 13% for muscle spasms and 12% for nausea.<sup>55</sup> The organisations' submissions revealed that 45% supported medicinal cannabis use and 16% were against it, though 39% did not express an opinion. The working party's report was tabled in the Parliament but none of its recommendations have been adopted.

### *7.2 The co-optation of scientific research: The case of the National Drug And Alcohol Research Centre*

Perhaps the best exposition of how cannabis has been demonised to suit policy ends is found in Jack Herer's book, *The Emperor Wears No Clothes*,<sup>56</sup> which demonstrates how selective and partial evidence has been used throughout world history to condemn cannabis. This process continues today and an extraordinary example is the announcement by the United

<sup>52</sup> 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*, Appendix E, p 42.

<sup>53</sup> Ibid 5.

<sup>54</sup> Ibid Appendix H.

<sup>55</sup> Ibid 7.

States Federal Drug Administration that cannabis has no medical uses at all, which is discussed elsewhere in this thesis.<sup>57</sup>

I personally witnessed the way in which data can be manipulated to yield a pre-determined result when I worked as principal interviewer on a large-scale study of long-term recreational and medicinal cannabis users on the New South Wales North Coast in 1994–1995.<sup>58</sup>

The study interviewed 268 cannabis users who had used cannabis at least three times a week for a minimum of ten years. Its stated objectives were:

to describe the characteristics of long term current and ex-cannabis users in a rural area ... to describe their patterns of cannabis and other drug use and the contexts of use ... to determine the extent of cannabis dependence, and, to the limited extent possible, the prevalence and correlates of some of the harmful health and psychological effects that have been attributed to long-term cannabis use ... to investigate the attitudes and beliefs of cannabis users, their families and significant others, about their reasons for the use of cannabis, the health and psychological effects of the drug, whether there was a need for treatment and the effects of law enforcement on their cannabis use.<sup>59</sup>

Several points are apparent from a perusal of the study's aims. Firstly, there was no attempt to study medicinal and recreational cohorts separately despite the finding that 64% of the sample had used or continued to use cannabis to treat their medical conditions. Secondly, the study assumed that dependence among the sample existed without citing any evidence. Thirdly, although the authors claimed that they would investigate 'whether there was a need for treatment', not one of the 563 questions asked respondents if they thought they needed treatment for their cannabis use.

The issue of 'treatment' must be seen in the context of the concurrent policy position of the National Drug and Alcohol Research Centre (NDARC) and its spinoff organisation the National Cannabis Prevention and Information Centre, that some cannabis users become 'addicted' to the drug and therefore need 'treatment' to overcome this addiction. To achieve this NDARC researchers proposed that significant government funding should be provided to establish treatment centres for these 'addicts' just as they had been involved in setting up methadone clinics for heroin users. Such large-scale funding would clearly bring major

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<sup>56</sup> J Herer, *The Emperor Wears No Clothes* (1985) 51.

<sup>57</sup> See discussion in Section 7.3.

<sup>58</sup> P Didcott et al, *Long Term Cannabis Users on the New South Wales North Coast* (1996) Monograph No. 30, National Drug & Alcohol Research Centre, Sydney.

<sup>59</sup> *Ibid* vii.

research moneys to NDARC if they could demonstrate to governments that there existed a demographically significant group of cannabis ‘addicts’. This wholesale shift in the authorities’ view of cannabis is an example of what Thomas Szasz termed the ‘medicalisation’ of drug users in a society.

This bias in NDARC’s corporate view of cannabis should have been apparent but as the Centre is titled a ‘Research Centre’ and is part of the University of New South Wales, I assumed its academic integrity as a given. Had I looked a little closer, I might have discovered that this bias is inherent in the very foundation of the Centre, as expressed in its mission statement, which is, ‘to conduct high quality research and related activities that increase the effectiveness of the Australian and international treatment or intervention responses to alcohol and other drug related harm’.<sup>60</sup> Thus their assumptions colour their research and their emphasis is not on research per se but research which, ‘increases the effectiveness of ... treatment.’ They *assume* that drug takers need ‘treatment’ before they have established through research that this is the case. Their policy-driven approach to research is even more exposed by the name they initially chose for the cannabis research body which they fatuously called the ‘National Cannabis Control and Prevention Centre’<sup>61</sup> when they were in no position either to ‘control’ or ‘prevent’ cannabis use. This name and the conflict of interest it bespeaks accords well with the so-called ‘War on Drugs’ but such an approach to research cannot be and is not consistent with disinterested scientific research or with any professional credibility this body may have had.

The self-interested nature of the study’s discussion of its implications for future research is indicated in the following quotation:

A second set of questions concerns the potential seriousness of cannabis dependence as a personal and public health issue. Among these are the following questions: How prevalent is cannabis dependence among long term users? ... What is the best way to assist those who experience difficulty in stopping using cannabis? Answers to these questions require more detailed and rigorous studies of the prevalence of dependence symptoms and their correlates among long term users. They also require intervention studies to evaluate the best ways of helping dependent cannabis users to stop their cannabis use.<sup>62</sup>

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<sup>60</sup> National Drug & Alcohol Research Centre website <[www.ndarc.unsw.edu.au](http://www.ndarc.unsw.edu.au)> (accessed 21 September 2008).

<sup>61</sup> UNSW classified job advertisement for Director of the National Cannabis Control & Prevention Centre, *Sydney Morning Herald*, 28 July 2007.

<sup>62</sup> Didcott, above n 58, 93.

How then did the survey establish the level of dependence? The researchers used three United States' scales, which had originally been devised to test for heroin, opiate and amphetamine addiction.<sup>63</sup> The three scales were based on lists of criteria for dependence, (the DSM III and ISD – 10) or for severity of dependence (the SDS). Results using the first two scales purported to show that '57% of the current cannabis users were dependent on cannabis in the last year.'<sup>64</sup>, whilst, measured by the third, 'only 15% of current cannabis users<sup>65</sup> were defined as dependent on cannabis in the past year.' Notwithstanding this discrepancy in the study's results section, in the discussion section they claim, 'The prevalence of cannabis dependence among study participants was 57% according to both sets of diagnostic criteria,'<sup>66</sup> but not including the SDS!

The authors claim that:

in the modern concept of the drug dependence syndrome embedded in the ICD-10 and DSM III-R [n]either system of diagnosis requires withdrawal symptoms or the use of a drug to avert withdrawal symptoms to diagnose dependence.<sup>67</sup>

Nevertheless withdrawal is listed as a criterion for judging a user as having a 'dependence' in both these scales.<sup>68</sup>

But the most telling way in which the respondents' answers were interpreted to conclude that they were dependent was in the mismatch between the scales' stated criteria for dependence and the questions asked to test for the presence or absence of these criteria. Whether deliberate or not the non-correspondence of the two arguably invalidates this whole section of their study. The conclusion that 57% of cannabis users are dependent on the drug is clearly a serious allegation. In order to assess its validity, what follows is a detailed examination of the criteria on which this judgement was made and of the questions used to assess participants according to those criteria.

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<sup>63</sup> Note 20 at 43. It is noteworthy that the DSMIII has more recently been significantly discredited as a diagnostic tool, e.g. see Chung et al 'Usefulness of DSM questioned' (2004) 12(2) *Experimental Clinical Psychopharmacology* 136–146.

<sup>64</sup> Didcott, above n 58, 45.

<sup>65</sup> Ibid.

<sup>66</sup> Ibid 89.

<sup>67</sup> Ibid 89.

<sup>68</sup> Ibid 44.

The DSM-III-R scale adapted by the study to measure ‘cannabis dependence’<sup>69</sup> requires respondents to meet three of the nine criteria in order to qualify as dependent. The first criterion is, ‘Substance often taken in larger amounts or over a longer period than the person intended.’ The North Coast survey’s take on this was that, ‘Criterion 1 was assumed to have been met if the respondent answered ‘yes’ to question 156.’<sup>70</sup> The wording of this question was, ‘Have you used cannabis for much longer than you intended to?’ Apart from the ambiguity in the question as to whether it refers to ‘much longer’ on a particular occasion or whether during the respondent’s cannabis-using lifetime, the wording does not match the meaning of criterion 1, that the ‘Substance [is] *often taken in larger amounts* or over a longer period than the person intended.’<sup>71</sup> [italics added]. This sort of interpretation could and did easily lead to interviewees meeting one out of the three criteria which would deem them dependent simply because, on one occasion in their life, they had ‘used cannabis for much longer than [they] intended to – for example, if they meant to smoke one joint but ended up smoking three. Indeed the authors themselves admit that:

the question used to assess criterion 1 only inquired about use for longer than intended, not larger amounts than intended; it did not specify how ‘often’; and it only asked about the last twelve months.<sup>72</sup>

My colleague, Sandra Heilpern, a very experienced social researcher and interviewer, who also conducted many of the survey interviews, was similarly dismayed by the way the authors of the study misinterpreted the DSM criteria in their qualifying questions. In relation to the second criterion, (‘Persistent desire or one or more unsuccessful efforts to cut down or control substance use’), she wrote:

The study reports that 53% of the long term users showed another criterion from the standard tests for dependence relating to ‘persistent unsuccessful attempts to give up or stop.’ But they weren’t asked about ‘persistent unsuccessful attempts’. They were asked (Q 165) if they had ‘ever tried to stop or cut down on your use of marijuana but found you couldn’t?’ Many of the people I interviewed said they had tried – once or twice.<sup>73</sup>

Again the authors acknowledge that ‘criterion 2 only asked about persistent desire to use in the last 12 months.’<sup>74</sup>

<sup>69</sup> Ibid 39.

<sup>70</sup> Ibid Appendix F, 135

<sup>71</sup> Ibid 136.

<sup>72</sup> Ibid.

<sup>73</sup> Letter from S Heilpern to the Editor, *Connexions* (June–July 1998) 2.

<sup>74</sup> Didcott, above n 58, 136.

Heilpern continues:

A third criterion for dependence was whether the user ‘had spent a lot of time using cannabis, getting over its effects or doing things to get it?’ It is true that many said ‘yes’ to this question, but many of the users I interviewed grew their own plants from seed, harvested, dried and stored it. They certainly had spent a lot of time getting it, thus giving them the third criterion they needed for inclusion in that 57% who were reported as being dependent.<sup>75</sup>

Regarding criterion 4, Heilpern states,

The study says that 73% of the long-term users met the following criterion:

‘Frequent intoxication or withdrawal symptoms when expected to fulfil major role obligations at work, school or home, (e.g. does not go to work because hung over, goes to work or school ‘high’, intoxicated while taking care of children) or when substance use is physically hazardous (e.g. drives when intoxicated.)’ But the subjects were not asked about ‘major role obligations’ or about being too hung over to work. They were asked about ‘day to day tasks’ (Q 48).

They were not asked if they were ‘intoxicated when use is physically hazardous.’ They were asked about ‘doing physical activities like swimming, sport or manual labour’ (Q 49). Lots of subjects reported that they went swimming or did the weeding.<sup>76</sup>

Heilpern explained in her letter that:

These are not the only examples I have. These are the only examples I have space for. I do not know whether or to what degree long-term users are dependent on cannabis. I am not even sure it matters more than being dependent on coffee or chocolate. But I do know that this study is drawing a very long bow by claiming that 57% of the sample are dependent. My major concern is that because it is the prestigious NDARC which is making this claim, people will believe it, and like your journal, quote the figures in good faith. The figures are then there, in the public arena as the basis for decision and policy making. What if they are just not true?<sup>77</sup>

Dependence criterion 5 reads, ‘Important social, occupational or recreational activities given up or reduced because of substance use’. This criterion was met if the subject answered ‘yes’ to question 324. But this question read, ‘Would you say you have given up or neglected pleasures or interests in favour of using marijuana?’ There are clear differences of significance and emphasis here – the question does not ask about important activities or occupational activities. The internal logic of the question predisposes a ‘yes’ answer as it is obvious that the time now spent on using marijuana has perforce displaced ‘other pleasures or interest’ such as alcohol consumption. Again, the question’s authors admit that ‘the questions

<sup>75</sup> Heilpern, above 73, 2.

<sup>76</sup> Ibid.

<sup>77</sup> Ibid 2.

[sic] used to assess criterion 5 was more generally worded than the criterion and made no specific mention of work.’<sup>78</sup>

Criterion 6 refers to ‘a persistent or recurrent social, psychological or physical problem that is caused or exacerbated by the use of the substance’. However, none of the corresponding questions specify ‘persistence’ or ‘recurrence’ and the wording of these questions makes them susceptible to being answered in relation to ‘one-off’ occasions rather than continuing incidents. Indeed, question 320, on which question 324 is predicated, asks, (‘Does your use of cannabis *ever* [emphasis added] lead to problems with your family/friends/at work/school?’). Thus any respondent who had once had a problem with any of these groups or who had once experienced the well-documented phenomenon of temporary paranoia while stoned, would artificially satisfy this criterion. As for question 152, (‘Did you keep on using cannabis although you had a health problem that was caused or made worse by it?’), a typical response was to answer ‘yes’ because the interviewee had once had a cough which cannabis seemed to make worse, so s/he suspended cannabis use for the duration of the coughing period but subsequently ‘[kept] on using’.

Criterion 7 specifies ‘at least a 50% increase’ in the amount of cannabis used ‘in order to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount.’<sup>79</sup> However the corresponding question, 97, simply asks, ‘Have you found that your usual amount of cannabis has much less effect on you than it once did?’ So there is no data here on whether subjects have increased the amount of cannabis used ‘by at least 50%’ over their cannabis-using careers and the data concerning any differences in effect of using the same amount of cannabis over the period of time is ambiguous. Does ‘much less’ equate to ‘at least 50%’? Moreover, the wording, ‘than it once did’ in question 97 frequently elicited a ‘yes’ answer because the respondent was comparing the effect of their first-ever occasion of use with the effects of their current amount used as an experienced user.

Criterion 8 refers to ‘characteristic withdrawal symptoms’ but the corresponding question 167 asks, ‘Have you felt sick or found yourself shaking when you cut down or stopped using cannabis?’ though the medical literature does not characterise sickness or shaking as being characteristic of cannabis withdrawal.

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<sup>78</sup> Didcott, above n 58, 136.

<sup>79</sup> Ibid.

Whereas criterion 9 reads ‘Substance often taken to relieve or avoid withdrawal symptoms’, the corresponding question 168 asks, ‘Have you ever [not ‘often’] taken cannabis to get over the bad after-effects of using cannabis?’

Hence the methodology of the construction of the questions on dependence and their application to the DSM scale was so flawed that their conclusions may be completely discounted and discredited. This too is largely Ricketts’ conclusion.<sup>80</sup> After examining the scale criteria and the corresponding questions, he writes:

You will note immediately that the questions and the criteria do not match. ... The DSM-III-R test is the highest [in terms of the percentages of respondents deemed to be ‘dependent’] and on different tests [the ICD\_10 and SDS scales] the result was far lower. Given that many people mixed their cannabis with tobacco it is questionable how many of these were in fact dependent on their tobacco rather than their cannabis.<sup>81</sup>

In a paper given at a Harm Reduction and Drug Awareness Seminar<sup>82</sup>, I detailed some further criticisms of the North Coast survey. In contrast to the largely negatively framed conclusions of the Didcott et al. monograph, I claimed that ‘the real conclusions are that long term cannabis users appear to be healthier and happier for their age, than the so-called ‘normal’ Australian and NSW North Coast populations.’

Almost all respondents reported beneficial or therapeutic effects of cannabis use; two-thirds of them reported no adverse physical or mental health effects; they were less likely to suffer long term respiratory problems or to experience psychological problems than non cannabis users; they had higher self esteem and higher standards of parenting than the normal population; nearly half were politically active in the community, whilst more than half reported a new interest in the last three months. They are just as, or more, supportive of cannabis education and counselling as the norm – and 98% think the cannabis laws are unjust and should be changed.

### *Negative bias*

Despite this good news, the Report consistently portrays cannabis negatively. Appendix H has a subheading entitled ‘Negative effects of cannabis’ but no Appendix is devoted to

<sup>80</sup> A Ricketts, *Drugs, Crime and the Law* (2003) Study Guide, School of Law & Justice, Southern Cross University, Lismore.

<sup>81</sup> *Ibid* 3–12.

‘Positive effects of cannabis’, even though there are more positives than negatives in the Report’s findings.

Whereas only two out of the 268 respondents reported not liking anything about cannabis, 137 people, or over 50% of the sample, could not think of anything except cost and illegality that they disliked about it. Nevertheless, page 41 devotes two paragraphs to the negative effects reported by a minority of the sample and one small paragraph to the 99.6% of the sample who reported things they liked about cannabis.<sup>83</sup>

Given the finding that:

there was a small negative correlation between the reported quantity of cannabis used and psychological distress, i.e. the more cannabis that was typically used, the fewer the symptoms of psychological distress that were reported,<sup>84</sup>

it was mischievous and misleading of the authors to claim, ‘our sample of long term cannabis users did not display a markedly elevated rate of psychological distress...’<sup>85</sup> when in fact it displayed a decreased rate.

This same negative bias in interpreting and reporting results permeates the report, especially, as I will demonstrate, regarding psychological health, and the rates of respiratory problems and accidents.

Much of the report’s negativity is programmed into the study because so much of it is based on questions which seek to elicit negative responses. An example is the way in which the report deals with respiratory problems. The questionnaire asks about ‘perceived health risks’; then about what negative health effects had been experienced; then about why cannabis use is a problem; about what cannabis users would do if it *were* a problem to them; what medical or psychological or medical conditions they had had in the last two weeks; then their long term health problems; then about treatment for those problems and *finally*, in case the respondent had not yet mentioned respiratory problems – there are two specific questions about wheezy

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<sup>82</sup> G Irvine, *The North Coast NSW Long Term Cannabis Users Survey*, Conference paper, Nimbin Mardi Grass Organising Committee, Nimbin Town Hall, 2 May 1997.

<sup>83</sup> Didcott, above n 58; Results booklet group 8 M 38 # SET p 6.

<sup>84</sup> Didcott, above n 58, 82.

<sup>85</sup> *Ibid* 91.

chests and persistent coughs. In this way the sheer weight of negative questions in the report exaggerates the extent of the negative aspects of long term cannabis use.

### *Respiratory problems*

Let us take this issue of respiratory problems – remember that Hall found in his 1994 study, ‘an increased risk of respiratory diseases... such as chronic bronchitis’<sup>86</sup> But our study’s findings are not at all consistent with this. We found that only 26% of those who reported any long-term medical conditions had personally had a respiratory problem, this figure being significantly less than for the normal population).<sup>87</sup> So our study did *not* find respiratory problems to be a major consequence of long term cannabis users and does *not* support Hall’s opinion that it is.

### *Psychological functioning*

Despite reporting that, ‘heavier cannabis users are less likely to experience psychological symptoms of distress’,<sup>88</sup> the Report still tries to convince us of , ‘[t]he probable adverse effects’ claimed by Hall<sup>89</sup> which were *not* found by us and are in no way supported by our data.

### *Other misstatements*

I strongly object to the statement on page 72 that:

there is no reason to believe it [the survey] is biased in favour of users who are either unusually healthy or ill, although this may have introduced sampling biases in the direction of recruiting less troubled users.<sup>90</sup>

There is absolutely no evidence of this occurring and since it was the fieldworkers who were responsible for recruitment this casts an unwarranted slur on the integrity and professionalism of the interviewers.

The report claims that respondents ‘underestimated their cannabis use and minimised personal and health problems that *may* [italics added] be related to their cannabis use.’<sup>91</sup> This too is not

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<sup>86</sup> W Hall et al, *The Health and Psychological Consequences of Cannabis Use* (1994) Canberra National Drug Strategy Committee monograph no. 25 Canberra, Australian Government Publishing Service 110 at 1–2.

<sup>87</sup> Didcott, above n 58, 54.

<sup>88</sup> Ibid 49.

<sup>89</sup> Hall, above n 86, 1.

<sup>90</sup> Didcott, above n 58, 85.

supported by the data. On the contrary, *over-estimation* [italics added] is just as likely to have occurred because the data is not reliable as to just how much of a given joint reported has to have been smoked by several people was consumed by each of them. Hence the whole of that joint may have been attributed to one subject rather than several. In addition, there may have been a tendency, especially among younger subjects, to exaggerate their use, in the same way they do with alcohol.

Despite the objections of the two main interviewers in the survey, both authors, Hall and Swift, have continued to cite the survey's DSM results as evidence of a cannabis dependence syndrome. For example:

An examination of 243 rural long term cannabis users, who had been consuming cannabis several times weekly for an average of 19 years, 57% qualified for both a lifetime DSM-III-R and a last year ICD-10 cannabis dependence diagnoses.<sup>92</sup>

But how could it be claimed that 57% qualified for 'life time' dependent status when it had been made quite clear in the questionnaire that several of the questions only referred to 'the last twelve months'? Moreover the layout of the questionnaire itself quite probably inflated the number of 'yes' answers because the time period of twelve months was only specified in the introduction to the whole suite of sixteen questions to which it was meant to apply, which included seven used in the DSM test and without further interviewer prompting, which did not always occur, it is quite possible, if not likely, that an unknown number of subjects answered in relation to their lifetime use, not their use in the last twelve months. This tendency would have been further reinforced by the wording of two of the questions, numbers 165 and 168, which took the form of 'Have you ever ...?'

What this case study demonstrates is that the issue of legalising medicinal cannabis, whilst being a discrete issue in its own right, is also inextricably enmeshed with the wider ideological battleground of drug policies and politics. The above analysis of cannabis research should serve as a timely reminder that an unknown and perhaps unknowable proportion of it is contaminated by policy and/or financial considerations.<sup>93</sup>

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<sup>91</sup> Ibid 86.

<sup>92</sup> W Hall and R Pacula, *Cannabis Use and Dependence* (2003) 74.

<sup>93</sup> eg see L Iversen, 'The Science of Marijuana' (2<sup>nd</sup> ed, 2008), ix.

### 7.3 *The United States Drug Enforcement Agency and academic referencing*

In 2002 three major scientific works on medicinal cannabis were published – one in Australia, one in Europe and one in the United States.<sup>94</sup> The recent leading Australian work on cannabis by Hall and Pacula, devotes most of a chapter to examining the evidence of the efficacy of cannabis and cannabinoids for the treatment of various medical conditions.<sup>95</sup> For the most part their conclusions are lukewarm or negative. Such pessimistic conclusions may seem odd in the light of very different conclusions arrived at by the other two contemporaneous studies which are uniformly more positive. However, when the authorities cited by Hall and Pacula are compared with those employed by the other studies it becomes apparent that they largely relied on different studies to come to their discrepant conclusions.

For instance, most of Hall and Pacula's references relating to cannabis medicinal use for anti-emesis are old, (1975–1986) and only three of nine references listed in support of their conclusion that medicinal cannabis has limited efficacy in the treatment of emesis are listed in a corresponding paper by Darmani,<sup>96</sup> who cites 15 clinical studies of delta nine THC from 1975 to 1990, eight of which report the superior efficacy of that substance over prochlorperazine.<sup>97</sup> Darmani also cites 14 clinical studies of the synthetic cannabinoid Nabilone from 1975–1988 of which nine indicate superior efficacy compared with other anti-emetic drugs and/or placebo and none indicating inferior efficacy.<sup>98</sup> Darmani cites 10 clinical studies of levonantradol of which nine demonstrated significant efficacy.<sup>99</sup>

These findings contrast with Hall and Pacula's conclusions on anti-emetic efficacy which quoted Ungerleider that:

Comparisons of oral THC with existing anti-emetic agents have been less consistent than the results of comparisons with placebo. The results generally indicated that THC was as

<sup>94</sup> Respectively: W Hall and R Pacula, *Cannabis Use and Dependence* (2003); E Onaivi et al (eds), *The Biology of Marijuana: From Gene to Behaviour* (2002) and F Grotenhermen and E Russo (eds), *Cannabis and Cannabinoids: Pharmacology, Toxicology and Therapeutic Potential* (2002).

<sup>95</sup> Hall and Pacula, above n 92, 146–152.

<sup>96</sup> N Darmani, 'Anti-emetic Action of Delta Tetrahydrocannabinoid and Synthetic Cannabinoids in Chemotherapy Induced Nausea and Vomiting', in Onaivi, above n 94, 356–389.

<sup>97</sup> Ibid 362–363, table 13.1.

<sup>98</sup> Ibid 367–368, table 13.2

<sup>99</sup> Ibid 370–371, table 13.3.

effective as the anti-emetic drug PCP. Their equivalence was demonstrated in one of the largest and best conducted studies.<sup>100</sup>

‘Nonetheless the anti-emetic efficacy of cannabinoids was modest, with THC failing to stop nausea in two thirds of patients.’<sup>101</sup> Yet Darmani cites three studies which, ‘clearly demonstrated the anti-emetic superiority of delta nine THC over PCP’.

In contrast to Hall and Pacula’s largely negative conclusions as to the anti-emetic efficacy of cannabinoids, Darmani is much more positive – ‘In the main, it is clear that these cannabinoids possess significant anti-emetic properties in patients receiving chemotherapy’<sup>102</sup> and:

A recent MEDLINE search yielded 194 titles on the anti-emetic properties of marijuana and cannabinoids. This list suggests that delta9 THC is a useful anti-emetic for nausea and vomiting associated with cancer chemotherapy.<sup>103</sup>

And also, that:

Cannabinoids, with their recently discovered potent analogs and ligands provide a unique potential for the further development of new anti-emetic agents in our present armamentarium to combat chemotherapy-induced emesis.<sup>104</sup>

Further, Musty<sup>105</sup> shows that, in cancer chemotherapy, of 10 studies, one reported THC as better than PCP; two reported PCP better than THC and two reported no difference. However all 13 studies of Nabilone were positive, with Nabilone superior to PCP in seven out of seven studies.

A contemporaneous article on the efficacy of cannabinoids as anti-emetics<sup>106</sup> again shows up a stark discrepancy in the numbers and identities of authors cited, with Bayer citing 33 references of which only two were cited in the ten references listed in Hall and Pacula<sup>107</sup>

<sup>100</sup> J Ungerleider et al, ‘Cannabis and Chemotherapy: A Comparison of Delta nine TCH and Prochlorperazine’ (1982) 50 *Cancer* 636–645.

<sup>101</sup> Hall and Pacula, above n 92, 148.

<sup>102</sup> Darmani, above n 96, 356.

<sup>103</sup> Ibid 360.

<sup>104</sup> Ibid 361.

<sup>105</sup> R Musty, ‘Cannabinoid Therapeutic Potential in Motivational Processes, Psychological Disorders and Central Nervous System Disorders’, in Onaivi, above n 94, 55–56.

<sup>106</sup> R Bayer, ‘Therapeutic marijuana as an Anti-emetic and Appetite Stimulant in Persons with Acquired Immunity Deficiency Syndrome AIDS’ in Russo and Grotenhermen, above n 94, 5–16, 14–16.

<sup>107</sup> Hall and Pacula, above n 92, 147–148.

while another paper lists 31 references compared with Hall and Pacula's ten, of which two are common.<sup>108</sup>

In other purported uses for medicinal cannabis we see the same pattern emerging – relatively few of the authors cited by Hall and Pacula are to be found in the reference lists of other contemporaneous studies.

On analgesia, Hall and Pacula cite fourteen references of which only three are listed in a contemporaneous study on cannabis and analgesia<sup>109</sup> which contained 68 references. Whereas Hall and Pacula claim that 'the few controlled studies of the analgesic efficacy in humans have been inconclusive',<sup>110</sup> Walker et al., who have conducted recent trials themselves concluded that, '... synthetic cannabinoids are equal to morphine in potency and efficacy ... [and have] high efficacy ... in models of chronic pain.'<sup>111</sup> They go on to state:

[a]lthough the literature on the antinociceptive effects of cannabinoids in man is replete with contradictions, several elements of cannabinoid pharmacology suggest significant clinical potential: (1) Cannabinoids have shown efficacy in the treatment of chronic pain in humans ... (2) Progress has been made in the synthesis of better, less lipophilic synthetic cannabinoids ... (3) Endogenous cannabinoids are a logical target for novel pain pharmacotherapies ... (4) Cannabinoids possess very low toxicity.<sup>112</sup>

Thus Walker et al's more thorough study led them to more optimistic conclusions than the limited and selective review of the literature by Hall and Pacula.

The same divergence is reflected in another contemporaneous review of analgesia studies, which concludes, 'The cellular basis for their synergistic analgesic actions suggest [that] ... cannabinoids warrant urgent study as therapeutic agents ...'.<sup>113</sup> This work on analgesia lists 55 references<sup>114</sup> as against Hall and Pacula's fifteen<sup>115</sup> and the two lists have no reference in

<sup>108</sup> T Plasse, 'Anti-emetic Effects of Cannabinoids' in Grotenhermen and Russo, above n 94, 178–180.

<sup>109</sup> J Walker, M Strangman and S Huang, 'Cannabinoids as Analgesics', in Onaivi, above n 94.

<sup>110</sup> Hall and Pacula, above n 92.

<sup>111</sup> Also J Walker, S Huang, N Strangman, K Tsou and M Sanudo-Pena 'Pain Modulation by Release of the Endogenous Cannabinoid Anandamide' (1999) 96 *Proceedings of the National Academy of Sciences (USA)* 12198–12203 and J Walker and S Huang, 'Cannabinoid Analgesia' (2000) *Pharmacology and Therapeutics*.

<sup>112</sup> Walker et al, above n 109, 585.

<sup>113</sup> Walker et al, above n 109, 587; C Vaughan and J MacDonald, 'Mechanisms of Cannabinoid Analgesia' in Grotenhermen and Russo, above n 94, Ch 8, 95.

<sup>114</sup> Vaughan and MacDonald, above n 113, 96–99.

<sup>115</sup> Hall and Pacula, above n 92, 151–152.

common. A further chapter on analgesia in the same book shows six references out of 24 common, compared with Hall and Pacula's fifteen references.<sup>116</sup>

In the chapter by Grotenhermen on the therapeutic effects of cannabinoids on glaucoma only one of Hall and Pacula's references appears on intraocular pressure<sup>117</sup> (another study in the same work cites 59 references for glaucoma compared to Hall and Pacula's seven, of which two were common<sup>118</sup>); three out of ten<sup>119</sup> and twelve<sup>120</sup> respectively regarding multiple sclerosis and spinal cord injury; regarding movement disorders, one of Hall & Pacula's ten compared to Grotenhermen's twelve. (In another chapter in the same work on movement disorders 35 references are given compared to Hall and Pacula's 11 of which six are common<sup>121</sup>; regarding asthma, two in common of four and five respectively).

In Onaivi's 2002 compendium of scientific studies on medicinal cannabis<sup>122</sup> only one of the dozens of authors was not attached to a scientific institution – a Mr. Hubbard whose chapter contrasts markedly with all the other authors published in Onaivi's work. Hubbard's chapter, entitled 'Adverse effects of marijuana', reports on the whole range of human effects, whereas most of the other contributors focus on one specific modality or effect.

While it is beyond my competence to evaluate the comparative standing of the different authors and their studies, it is noteworthy that the references cited by Hubbard do not often appear in any of the other chapters which were written by acknowledged experts in these fields. For example Hubbard cites three studies in his section on 'immune system' though none of these are cited in Cabral's chapter on 'Marijuana and cannabinoid effects on immunity and AIDS' which lists 104 references.<sup>123</sup> Hubbard's section on the 'Reproductive system, hormone system and foetus' cites seven authorities, of whom none are cited in the

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<sup>116</sup> A Holdcroft, 'Pain Therapy' in Grotenhermen and Russo, above n 94, Ch 15, 185–186.

<sup>117</sup> F Grotenhermen, 'Review of Therapeutic Effects' in Grotenhermen and Russo, above n 94, Ch 11, 139.

<sup>118</sup> D Pate, 'Glaucoma and Cannabinoids' in Grotenhermen and Russo, above n 94, Ch 19, 220–224.

<sup>119</sup> Hall and Pacula, n 92.

<sup>120</sup> Grotenhermen and Russo, above n 94, 135–136.

<sup>121</sup> K Muller-Vohl, R Hans Kolbe, U Schreider and H Emrich, 'Movement Disorders' in Grotenhermen and Russo, above n 94, Ch 18, 211–214.

<sup>122</sup> E Onaivi et al, *Endocannabinoids: the Brain and Body's Marijuana and Beyond* (2002).

<sup>123</sup> G Cabral, 'Marijuana and Cannabinoid Effects on Immunity and AIDS' in Onaivi, above n 94, Ch 9, 282–307.

references in Paria and Dey’s chapter on ‘Embryonic cannabinoid receptors are targets for natural and endocannabinoids during early pregnancy.’<sup>124</sup>

It is also noteworthy that quite a few authorities cited by Hubbard in respect of one modality are also cited for others. For example, ‘Ashton’ is cited as an authority on task performance, cardiovascular, neuropsychiatric, reproductive, immune and respiratory systems and chemical dependence. Throughout his chapter, the same narrow band of experts is invoked time after time, including some notorious anti-cannabis researchers such as Gabriel Nahas.

As a check on the above comparative content analysis I repeated the same exercise, this time comparing a 2006 paper written by the director of the Australian National Cannabis Prevention and Information Centre.<sup>125</sup>

Comparing the references cited in each study, none of Copeland’s six references as to the efficacy of medicinal cannabis in the treatment of nausea<sup>126</sup> appear in Darmani’s study of the gastrointestinal functions of cannabis which lists 146 references.<sup>127</sup> As was the case for Hall and Pacula in my earlier analysis, the selection of her references leaves Copeland lukewarm regarding the efficacy of medicinal cannabis in the treatment of nausea, whereas Darmani is more enthusiastic.

As to analgesia, Copeland cites five references,<sup>128</sup> none of which matched any names in Darmani’s six pages of references.<sup>129</sup> Only one out of five references on neurological conditions in Copeland matches any references in Glass’s chapter in Onaivi which cites six pages of un-numbered references. None of Copeland’s six references on appetite stimulation<sup>130</sup> are to be found in Thiebot’s chapter in Onaivi.<sup>131</sup>

<sup>124</sup> Paria and Dey, ‘Embryonic Cannabinoid Receptors are Targets for Natural and Endocannabinoids During Early Pregnancy’ in Onaivi, above n 94, 355.

<sup>125</sup> J Copeland et al, *Evidence-based Answers to Cannabis Questions: a Review of the Literature* (2006) Canberra, Australian National Council on Drugs.

<sup>126</sup> Ibid 20.

<sup>127</sup> N Darmani, above n3, 410.

<sup>128</sup> Copeland, above n 125, 21.

<sup>129</sup> Darmani, above n 96, 414–420.

<sup>130</sup> Copeland, above n 125, 21.

<sup>131</sup> M Thiebot et al, ‘Behavioural Effects of Endocannabinoids’ in Onaivi, above n 94, Ch 13, 303–349.

From these results it appears that Copeland is out of step with the world-wide consensus of scholars as to the efficacy of cannabis. The two studies yielded comparable results which suggest that both the research of Hall and Pacula and that of Copeland pick and choose selected references which shore up their policy positions on medicinal cannabis.

This excursion into the medical and scientific literature on medicinal cannabis demonstrates how the selective use of sources can be used to arrive at consciously or unconsciously desired policy positions.

### *The case of The United States Drug Enforcement Agency*

However the most blatant manipulation and co-optation of scientific research in the service of a political position in the medicinal cannabis debate was recently perpetrated by the United States' Drug Enforcement Agency [DEA] in the Department of Justice in their three-page 2006 publication entitled 'Exposing the Myth of Medical Marijuana: Marijuana: The Facts'.<sup>132</sup>

The three-page DEA Fact Sheet proceeds by way of four questions, each with a number of dot point 'answers'. These will be examined and rebutted in order where they may relate to Sativex but where they relate solely to smoked cannabis or to recreational use the answers are outside the purview of this thesis and are not considered here.

#### *1. 'Does marijuana pose health risks to users?'*

Marijuana is an addictive drug with significant health consequences for its users and others. Many short-term and long-term problems have been documented with its use: ...

Rebuttal 1(1): All drugs have some potential to be addictive, so the real question here is whether marijuana is significantly more or less addictive than other medications used to treat the same symptoms as cannabis. The US Institute of Medicine (IOM) Report concluded, 'Risk factors for marijuana dependence are similar to those of other forms of medication. ... A distinctive marijuana withdrawal syndrome has been identified but it is mild in comparison.'<sup>133</sup> A more recent study found that 'animal research does not provide a clear

<sup>132</sup> United States Department of Justice, Drug Enforcement Agency ('DEA'), *Exposing the Myth of Medical Marijuana: Marijuana: The Facts* (2006) Drug Enforcement Agency, Washington DC.

<sup>133</sup> J Joy, *Marijuana and Medicine: Assessing the science base* (1999) Institute of Medicine Report, National Academies Press, Washington DC, 6.

picture of a consistent withdrawal effect.’<sup>134</sup> The DEA’s cited authorities for its claim of marijuana’s addictiveness carry little weight in comparison with the abovementioned scientists. Their first reference is not to a scientific or medical journal but to a Foreign Affairs journal article which only briefly mentions marijuana addiction and gives no source for its statements. The other two references are incorrectly cited, and the second is only a newspaper article that misquotes its source for its headline that marijuana is addictive while the source claims only that, ‘Smoking marijuana can be addictive.’<sup>135</sup>

The short-term effects of marijuana use include: memory loss, distorted perception, trouble with thinking and problem solving, loss of motor skills, decrease in muscle strength, increased heart rate and anxiety.

Rebuttal 1(2): These reported side effects are the same as for the synthetic cannabis formulation marketed as ‘Marinol’ which is described on page 2 as ‘safe, effective and has therapeutic benefits ...’ Again, the Fact Sheet inadequately cites references, naming journals without providing any citation details.<sup>136</sup>

In recent years there has been a drastic increase in the number of emergency room mentions of marijuana use. From 1993–2000 the number of emergency room marijuana mentions more than tripled.

Rebuttal 1(3): Because a patient ‘mentions’ marijuana may, and often does, have little to do with why they presented to the emergency room. Moreover the statistics themselves are dubious as they mask the fact that ‘mentions’ of many other drugs increased by more than triple in the same time period.<sup>137</sup>

... Users can become dependent on marijuana to the point they must seek treatment to stop abusing it. In 1999, more than 200,000 Americans entered substance abuse treatment primarily for marijuana abuse and dependence.<sup>138</sup>

Rebuttal 1(4): The reason for the large number of people entering into treatment is that changed laws now give convicted cannabis users a choice of jail or treatment and many opt for treatment whether they think they need it or not.

<sup>134</sup> N Smith, ‘A Review of the Published Literature into Cannabis Withdrawal Symptoms in Human Users’ (2002) (6) *Addiction* 621–632.

<sup>135</sup> D Campbell, *A Rebuttal to the Anti Medical Marijuana Arguments Posed by the USDEA* (2002) Drug Policy Education Group Inc.

<sup>136</sup> DEA, above n 132, 3 footnote 2.

<sup>137</sup> Campbell, above n 135, 5 and Patients Out of Time, *Rebuttal to DEA’s ‘Exposing the Myth of Medical Marijuana’* <[www.MedicalCannabis.com](http://www.MedicalCannabis.com)> (accessed 20 May 2008).

<sup>138</sup> DEA, above n 132, 2.

## 2. 'Does marijuana have any medical value?'

Advocates have promoted the use of marijuana to treat medical conditions such as glaucoma. However this is a good example of more effective medications already available. According to the Institute of Medicine, there are six classes of drugs and multiple surgical techniques that are available to treat glaucoma. ...<sup>139</sup>

Rebuttal 2(2): It is noteworthy that glaucoma is not included in the list of conditions approved for use by US states which have recently enacted medical marijuana legislation. However the Drug Policy Education Group still claims that:

a significant population of patients suffering glaucoma do not enjoy success from the use of any of those six classes of drugs nor from the multiple surgical techniques available. Within the population, however, a significant number report success with marijuana in controlling the progress of glaucoma.<sup>140</sup>

In other studies, smoked marijuana has been shown to cause a variety of health problems, including cancer, respiratory problems, increased heart rate, loss of motor skills, and increased heart rate [sic]. Furthermore, marijuana can affect the immune system by impairing the ability of T-cells to fight off infection, demonstrating that marijuana can do more harm than good in people with already compromised immune systems.

Rebuttal 2(3): Cannabis has never been known to cause cancer and the DEA provides no references for this claim. Although this paragraph of the fact sheet refers to smoked cannabis, their claims are so serious and misleading that I have addressed them here as if they were referring to Sativex. Their claim regarding T-cells and the immune system has in effect refuted by Zimmer and Morgan who, after surveying more than forty studies, concluded that, 'scientists have consistently found no difference in the transformation of in T-cells from marijuana users and non-users.'<sup>141</sup> Another 1997 article reported that, 'findings in the present study do not support an association between even heavy, regular marijuana smoking and the development of chronic obstructive lung disease.'<sup>142</sup> Increased heart rate and loss of motor skills under the influence of marijuana are comparable or less severe than with Marinol, of which the DEA approves.

... in a recent study by the Mayo Clinic, THC was shown to be less effective than standard treatments in helping cancer patients regain lost appetites.<sup>143</sup>

<sup>139</sup> Ibid.

<sup>140</sup> Campbell, above n 135, 12.

<sup>141</sup> L Zimmer and J Morgan, *Marijuana Myths: Marijuana Facts* (1997) 127.

<sup>142</sup> D Tashkin, 'Heavy Habitual Marijuana Smoking does not Cause an Accelerated Decline in FEV1 with Age' (1997) *American Review of Respiratory Diseases* 112, 377–386.

<sup>143</sup> DEA, above n 132, 3.

Rebuttal 2(4): Campbell claims that there is ‘a much greater number of studies showing just the opposite. In fact, a significant majority of studies show that marijuana is more effective than other treatments.’<sup>144</sup>

The American Medical Association recommends that marijuana remain a Schedule 1 controlled substance.<sup>145</sup>

Rebuttal 2(5): This statement is directed towards smoked cannabis and not to, for example, Marinol which has been prescribed by AMA member doctors for over two decades, or to Sativex which could, at the present rate of progress in their US clinical trials, be prescribable by AMA members within a few years.<sup>146</sup>

3. *‘Marijuana affects many skills required for safe driving ...’*<sup>147</sup>

Rebuttal 3(1): The scientific data on these alleged effects is equivocal<sup>148</sup> but, insofar as medicinal use of Sativex may affect driving, this is clearly listed in the patient information leaflet as a contraindication,<sup>149</sup> and all jurisdictions which have legalised medicinal cannabis prohibit its use when driving.

In a 1990 report, the National Transportation Safety Board studied 182 fatal truck accidents. It found that just as many of the accidents were caused by drivers using marijuana as were caused by alcohol. ...

Rebuttal 3(2): No reference to this study is given and the relationship it posits is spurious according to the Patients Out of Time report, in that the study apparently relied on tests which found that the studied drivers had used cannabis within a month of their accident. No data was present to indicate that cannabis intoxication was present or was a causal factor in the accidents.<sup>150</sup>

Consider that drug use, including marijuana, contributes to crime. A large percentage of those arrested for crimes test positive for marijuana. Nationwide, nearly 40% of adult males tested positive for marijuana at the time of arrest.<sup>151</sup>

<sup>144</sup> GW Pharmaceuticals Fact Sheet 2007, ‘A US marketing application could reasonably be expected to occur 24–35 months after clinical studies begin’ 2.

<sup>145</sup> American Medical Association. Report 6 of the Council on Scientific Affairs <<http://www.ama-assn.org/ama/no-index/about-ama/13625.shtml>> (accessed 4 march 2010).

<sup>146</sup> GW Pharmaceuticals Patient Information Sheet.

<sup>147</sup> Patients Out Of Time, above n 137, 7.

<sup>148</sup> DEA, above n 132, 3.

<sup>149</sup> Drummer, above n 145.

<sup>150</sup> GW Pharmaceuticals Patient Information Sheet (2009) Patients Out Of Time, above n 137, 7.

<sup>151</sup> DEA, above n 132, 3.

Rebuttal 3(3): As noted above, the persistence of cannabis residues in urine for weeks after ingestion means that a positive test bears no relationship to whether that person was involved in crime as a result of being intoxicated by cannabis at the time when the offence was committed. Campbell cites a reference to a study which found that, ‘marijuana abuse plays no statistically significant role in influencing one to commit a violent crime.’<sup>152</sup>

4. ‘Q. *Is marijuana a gateway drug?*’<sup>153</sup>

Yes. Among marijuana’s most harmful consequences is its role in leading to the use of other illegal drugs like heroin and cocaine. Long-term studies of students who use drugs show that very few young people use other illegal drugs without first trying marijuana. While not all people who use marijuana go on to use other drugs, using marijuana sometimes lowers inhibitions about drug use and exposes users to a culture that encourages use of other drugs.

Rebuttal 4(1): The DEA provides no references for this allegation, which has been extensively studied and thoroughly refuted, both in the IOM study and in a more recent study the London Center for Economic Policy which found that, ‘There is no conclusive evidence that the drug marijuana [is] causally linked to the subsequent abuse of other illicit drugs.’<sup>154</sup>

The risk of using cocaine has been estimated to be more than 104 times greater for those who have tried marijuana than for those who have never tried it.<sup>155</sup>

Rebuttal 4(2):

Over 72 million people have used marijuana. Yet for every 120 marijuana users, there is only one active, regular user of cocaine. Obviously marijuana does not lead to the use of harder drugs or there would be a one to one correlation.<sup>156</sup>

On the face of it, it seems outrageous that a governmental body like the DEA, with a budget of millions and a staff of hundreds would write such a shoddy paper, full of mistakes and half-truths and with so little authoritative evidence to support their position.

Nevertheless, as the chapters on the historical dimensions of medicinal cannabis policy demonstrate, such co-optation is nothing new. For example Iversen believes that the findings of the British House of Lords Commission and the U.S. Institute of Medicine report on

<sup>152</sup> J Merrill and K Fox, *Cigarettes, Alcohol, Marijuana: Gateways to Illicit Drug Use* (1994) cited in Campbell, above n 135, 17.

<sup>153</sup> DEA, above n 132, 3.

<sup>154</sup> Merrill and Fox, above n 152, 17.

<sup>155</sup> DEA, above n 132, 3.

<sup>156</sup> Campbell, above n 135, 19.

marijuana's efficacy, 'bear remarkable similarities to analogous efforts going back at least a hundred years.'<sup>157</sup> He continues,

[a]s a scientist ... I am exasperated by the way in which proponents and opponents of cannabis use and abuse science in defending their positions. ... Cannabis has been demonised ... and the available scientific information is largely ignored or distorted by various groups who use science as a propaganda weapon.<sup>158</sup>

Iversen describes a typical process which often characterises the debate over the efficacy of medicinal cannabis:

This history of research on [the effects of cannabis on hormones and reproduction] followed a similar pattern that described the immunosuppressive effects of cannabinoids. An initial apparently damning report was followed by a great deal of research that largely failed to support the initial claims.<sup>159</sup>

However, such negative claims are often are picked up by the media and passed on to the general public who never get to hear that the original negative research has since been debunked.

It is hoped that the cautionary tale spelt out here in Chapter 7.3 will serve as a salutary warning to lay people interested in this topic not to take research for granted.

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<sup>157</sup> Iversen, above n 93, vi.

<sup>158</sup> *Ibid* ix.

<sup>159</sup> *Ibid* 68.

## Chapter 8

# AN INTERIM LEGAL DEFENCE FOR MEDICINAL CANNABIS USERS AND AN ETHICAL SUPPLIER OF MEDICINAL CANNABIS

Most of this chapter is concerned with the ‘medical necessity defence’ which has been successfully argued in the United States and raised in Britain and Canada.

In some detail this and the succeeding sections analyse different versions of the elements of the necessity defence and evaluates them with a view to running such a defence in New South Wales. As part of this exercise I have developed a critique of the current tests for necessity and made suggestions for a re-definition of the concept.

However the legal system is ponderous and expensive and many patients cannot wait for the outcome of a future court case before they need to take medicinal cannabis. In such circumstances the Chapter begins with an interview conducted with the two principals of a northern New South Wales welfare group which supplies cannabis in different processed forms through the postal service. This service may be an option, albeit still an illegal one, for medicinal cannabis users currently having to resort to the black market for their medicine.

### *8.1 The Medical Cannabis Information Service*

The Medical Cannabis Information Service (MCIS) is a last resort for many seriously ill patients throughout Australia because it is the only supplier of medical tinctures and cookies, despite the illegality of their position. Because the possession, use of or dealing in non-synthetic cannabis in any form is illegal their clients tend to be either desperate, politically committed or both to choose this option.

Its predecessor, the Compassion Club was established in 1997 in New South Wales by two prominent cannabis activists, both of whom are strong advocates of changes to the current state and federal drug laws. The Club’s two themes were, firstly, to encourage public debate

over the erosion of civil rights brought about by the drug laws and, secondly, to raise awareness of the medicinal uses of cannabis.

However within months of the Club's grand opening which attracted a large crowd on the day, internal bickering within the group culminated in the two founders withdrawing and the present organisers taking over. They changed the emphasis from 'in your face' public protest to a position 'under the radar' which has so far enabled them to operate without intervention by government or police. Initially they recruited members by placing advertisements in the Weekend Australian newspaper for a few months and attracted enough interest to maintain the organisation's membership by word of mouth and without further advertising until now.

As well as providing advice and support for their clients the principal organisers manufacture, pack and post between four and fourteen packs of cookies and an average of ten vials of cannabis tincture each fortnight. To obtain these medications, patients must first become members (\$15) and can then buy tinctures (\$15) and cookies (\$25). Thus the Service operates entirely through the unpaid volunteer efforts of its two principal members and is barely self-sustaining.

As for the police and the government, they turn a blind eye to the Service. It is not that they don't know what MCIS is doing but maybe it is the threat of public outrage and opposition from a range of stakeholders that they have so far not tried to enforce the law. And perhaps, just perhaps in their heart of hearts they recognise the moral correctness of the Service's work.

MCIS's trouble-free operation demonstrates that it should be considered as a possible model for distribution of medicinal cannabis throughout New South Wales. By utilising volunteers in a not-for-profit business structure the pitfalls of the United State's medicinal cannabis schemes, some of which operate on a profit basis, may be avoided. Unlike these overseas profit-making models the MCIOS is able to keep overheads and hence prices low as many of their clients are living on or beneath the poverty line.

Until medicinal cannabis is legalised the MCIS may be a better and cheaper option for clients to obtain their medicinal supplies as they would not be buying their medicine on the black market.

On Friday 23<sup>rd</sup> October 2009 I interviewed the two organisers in a discussion lasting the best part of an hour. The interview transcript follows.

Clearance for this interview was obtained from the SCU Ethics Committee (ECN: 09127).

*Interview with X and Y, members of the Medical Cannabis Information Service, by Graham Irvine held in Nimbin NSW on Friday 23 October 2009*

**Graham:** X, why was the MCIS set up in the first place?

**X:** That question should go to Y first.

**Y:** It came about, the first thing that was established was the NSW Compassion Club. And then it changed name to the Ethical Medicinal Cannabis Suppliers. And then the latest name change probably about five, six years ago was to the Medical Cannabis Information Service so it could reach a broader patient group and be able to offer more information without falling in too much trouble about the supply side.

**Graham:** So why was it necessary to change the name earlier than that?

**Y:** I suppose even the Compassion Club was kind of, wasn't so much a club, a physical club you could come to. We didn't need to be hanging on to like the American sort of model of compassion clubs and that. We weren't operating like that at all. And so that's where the first name came in. And the second name change from Ethical Medicinal Cannabis Suppliers to Medical Cannabis Information Service was purely just again to not raise suspicion and issues about the supply of cannabis.

**Graham:** Whose ...

**X:** To protect not only us, the workers, but the clients as well and not to draw attention, too much.

**Graham:** Whose idea was it X? Who started the service off?

**Y:** In 1998 we brought Dennis Peron [an American cannabis activist], over from California. He was the instigator of Proposition 215 which got the first medical cannabis referendum up

in the US. And so, yeah from that was born a lot of activism, a lot of questions and it was decided that the Medical, the Compassion Club would be started right away.

**Graham:** So, *Peron's case* was an inspiration for you and part of the reason for ...

**Y:** Absolutely, yeah, yeah. They were doing it, yeah.

**X:** And then I came into it about 2000 because there was no one that was maintaining the service, not in being able to service the clients so I took it on then and I've been doing ever it since, so.

**Graham:** How did you get involved?

**Y:** I took over and did it from my office and um, just went from there. And, it became a professional thing. And, the enquiries and the questions that were coming up were pretty awesome, and of the amount of them and um, and the NSW Government right at that time had decided to look at the question of medical cannabis so we put it sort of more of a professional level and tried to be involved with whatever the Government was trying to do to get medical cannabis to patients.

**X:** That was in the era of Carr. And, we had a few supporters in the State Government and [Greens Member of the New South Wales Legislative Council] Lee Rhiannon. We would go down and lobby and in those days I felt quite safe to do lobbying and to put yourself out there. Times have changed so drastically. I wouldn't feel as comfortable doing that lobbying any more. Mainly because I think that we live now in a police state that is totally and utterly going mad with power and control and I really feel at the moment that the Compassion Club is best to stay as under a rock as it possible can so it can maintain and help the people it already has in its books without the threat of us all ending up in a court case. It could go on forever, or for many years.

**Graham:** How was this service set up in the first place? How does it work?

**Y:** People would write or ring and we would send them out an application form, an information sheet, an order form, um.

**Graham:** How did they get to know you then?

**Y:** We advertised in, um, there was media surrounding the opening and then we advertised in um a leading weekend paper for about a year, every fortnight for about a year offering ethical medicinal cannabis supplies, offering cannabis basically in edible food form.

**Graham:** And that was your limit of your publisher, publicisation of the service.

**Y:** Yep, yeah. We got, oh yeah, in terms of publicising ourselves we got covered by a lot of you know public media yeah.

**X:** We picked it up at that time and it became quite topical. But as I said again, times have changed so drastically and none of us now are out there so much um admitting, or, or broadcasting because there are so many people in need of this type of medicine that we could become swamped, overwhelmed. We get a lot of enquiries come via the Nimbin Hemp Embassy, people either ringing there or just walking in off the street and saying please, please help me, where are these people. That's how we, we don't need, we don't advertise, we don't need other than word of mouth nowadays.

**Graham:** So how many clients have you serviced over the years and how many have you got now?

**X:** We could range into about into the hundreds over the years. Some have died, some have passed on, some have got well enough to not need the medicine. Some people just order just when they're about to have chemotherapy sessions or when they're just having a hard time and they'll go back and maintain their own health standards, Other people rely on it as their main medicine now and I would say actively we probably have 56 to 70 active members at the moment.

**Graham:** What do you class as an active member?

**X:** Someone that is using the service quite regularly, on a fortnightly basis. As you have read in the book, in the letters, most of the people that do access this service are on a pension because they can't work of course, they are sick people. So again, maintaining price, we haven't had a price change for ever, ever and we even at times we cover postage costs for people.

**Graham:** And I was going to ask you what sort of people are your clients in terms of demographics, age, gender, location ?

**X:** That's so broad. We've from 86 year olds with terminal cancers and they don't expect a cure. What they hope for, what they hope for is a better quality of life which is oftentimes what they achieve by using medicinal cannabis. It's never going to be a cure, I don't believe, but it relieves so many of the symptoms and anxiety that goes with being ill.

**Graham:** OK, the oldest client is 86 what's the youngest.

**X:** Ah, the youngest would be in their 20s and that's probably MS usually or AIDs related diseases.

**Graham:** Is there any noticeable trend in terms of gender or?

**X:** Not at all, not at all.

**Graham:** 50–50 male and female?

**X:** Well, yep, it, I've, I've, disease touches many people as we all know and oftentimes like today I'm answering the phone there was a message from a husband thanking the Club so much for just sending a sample for his wife who has got great relief. And as I said, her anxiety levels have been brought down to, to manageable state that she can now make decisions for her next treatment. She has been diagnosed with lung cancer, denied treatment, she doesn't want treatment. But now that she can settle all of her anxieties as well, I think now she can go on to make better decisions in respect to treatments and that's what her husband was thinking as well, that she had a decent night's sleep, that her anxiety levels had levelled out and she could now start to think clearer to make decisions.

**Graham:** What sort of um location spread have you got amongst your members, are they all from NSW or?

**Y:** Majority are from NSW but you know Queensland, Victoria, South Australia we've had in the past. Northern Territory but you know yeah kinda everywhere, Tasmania but mostly NSW.

**Graham:** And as far as you know it's the only club of its kind in Australia?

**Y:** Yeah, often hear rumours and we go looking and no, there is no one really you know, doing it. Especially no one has gone as long as we have or as long...

**X:** Or consistently.

**Y:** And consistently non stop. We're the voice, yeah.

**Graham:** What sorts of things do your clients tell you about themselves, their lives, their treatment and their need for your service.

**X:** Well, as you said, looking through some of these letters, a lot of the people are, by the time they get to us they're in a pretty chronic stage with their illness. Arthritis is a really interesting one. We get a lot of enquiries from people with chronic arthritis. This is their last call and it is a very, very good medicine for helping with arthritis to also help cut back use of their other medications which, as you know, any sick person sometimes has up to 15–20 tablets a day they need to be consuming, it could become confusing. Whereas a lot of people can find that they can cut down on that medication and slowly rely on the cookies. Again, it's trial and error and it doesn't work for everyone but for most people it at least alleviates the anxiety, it allows people to rest their bodies and um it's a pain reliever. So, the letters come from a vast, vast array of people.

**Graham:** Would you like to read one for us?

**X:** Well, I've got this one from um, he was watching TV recently and this is a wife writing on behalf of husband. He suffers from chronic back pain. He's reluctant to take any medications prescribed by a doctor due to the unpleasant side effects and possible accumulative effects of the medication in the long term. We both feel he may benefit with marijuana and would like to try growing it. So these people are just asking us if we could possibly source them some seeds to send so then that they can grow them which would be great. If people were well enough they could do maybe 5, 6 plants in their own backyard and create and make their own medicine. It's not a big deal. It's not a hard thing to do. But unfortunately, as it says here, 'We are aware at present and hopefully for not much longer the use of this is not legal and we don't want to get into any trouble.' So, they are now asking for our help. They don't want to go into the street, to the black market which a lot of people have tried before they find us. They've been out there trying to source their own, um, stock or, or base product to make cookies and, um, that's how they end up with us because, as I say, being out there in the black market it's a bit spooky and especially if like a grandma out there, 'um, where can I score?' Where do they even go? Where do they even begin? It's oftentimes what the letters are filled with too.

**Graham:** And were you able to help people out with seeds, or?

**X:** Yep. Oh, I shouldn't say that, it's totally illegal. That's like a hanging offence (laughter).

**Y:** ... some kind of. Yep, You know what got me um pretty early on was the amount of doctors who not only fill in the application form that we send the patients, um, yep the patient who applied to take that form to their doctor who had to sign it. This patient has a particular chronic illness and their um, in that doctor's opinion that patient would find benefit from using cannabis for medical purposes. So yeah, you um, you've got a letter, you know doctor's letterhead everything um, about a 40 year old lady um, who um, She has a chronic degenerative disease and um, you know, agonising muscle spasms, increased pain from crumbling bones in her hips, etc, etc, um. She tells me that a friend offered her some cannabis to see if it helped and she has found that it is very beneficial, relieving the intensity of the pain, dissipating nausea, totally relaxed and to her surprise alleviating her emotional misery. And then there you've got a doctor asking if it is possible to put her on your scheme and convinced that much of her misery will be alleviated. Um, another doctor, psychiatrist who referred a patient on, on his letterhead paper. 'The patient suffers from arthritis, anxiety, depression. Um as there are no medicines that I am able prescribe that has the range of effects

that marijuana offers I will support the use of this substance for medical purposes.’ And, it just goes on and on.

**X:** And if the, um, the patient when I suggest that they need to take this form to their doctor in the hope that they get it signed. If the doctor is unwilling to sign it, ah, we don’t totally dismiss them. But it is important that their doctor knows that they are using this medication. Because, of course, as I said earlier there are so many medications sometimes you must, you could get quite confused. So it is important that the doctor knows that you are actually trialling or using this medication.

**Y:** Yeah, we always knew, yeah that was a always a bit of an emphasis on that even if a doctor didn’t agree, um, that’s was one thing. But if the patients could still, we put certain criteria on that, like if a patient could supply a photocopy of a recent, opiate um, um ..

**X:** Prescription

**Y:** Prescription, you know that’s good enough for us. If they reckon it’s OK to have opium or opiates I’m sure cannabis is going to be alright.

(laughter)

**Graham:** How do you ensure the quality and consistency of the ingredients that you use in your cookies and keep tinctures fresh?

**X:** Well that’s taken a number of years to perfect. But now I feel very confident and have had feedback from clients in respects to that. It is ..um

**Y:** We’ve already had years of experience before. So, you know, we’re pretty easy.

**Graham:** Trial and error was it?

**X:** No

**Y:** It was done in the year probably before.

**X:** Many, many years ago my mother was a chronic arthritis sufferer and that’s how I started trialling it at home, started working out batches and consistency on my own, just for my mother, just for my mum. And that’s how I really basically got interested in it because I saw how much relief it did give her. So then it was experimentation. Then we have good people that do support us in supplying the base product that we do need. That’s becoming a harder, harder, ah, product to source unfortunately but, we do have some good friends that help us out and it’s a different grade we use. The grade, the um base product, and then it’s mixed and it’s as I said, it’s been a trial and error but now it’s most just like ...

**Y:** Easy

**X:** Easy.

**Graham:** How much marijuana would you put in a cookie?

**X:** Well, in per cookie I couldn't do. I was really hoping a few years ago when we were working with the University that we would be able to get some trial and test it like that willing to take in different batches, different batches so that they could test the consistency of it and what was in each. I can't do that. I've got no idea. I can't say there's a fifth of a gram in each cookie because I don't know.

**Graham:** Yep. So how do you judge it when you are cooking it.

**X:** I know from the ingredients I use and the pot size I use and the quality of the base product that I have.

**Graham:** So ...

**X:** That is a trial and error over so many years but now it's perfected.

**Graham:** So what do you use to put the marijuana in the mixture, a spoon or ...

**X:** No, no it's a huge pot.

**Graham:** Ah, right

**Y:** Do pounds

**X:** Pounds

**Y:** At a time

**X:** At a time, because I mean ...

**Y:** Simmered in water and butter and then, then

**X:** For hours cooked and so forth. But I don't do like home little batches. This is enough to, to supply for maybe two weeks. It depends. Some weeks there's orders for up to twelve dozen. Other weeks there's four dozen. Other weeks I'm doing double batches. So ah, I just keep butter, in the freezer, ready to make up.

**Graham:** So is it a secret recipe or is it something can you share with other people?

**X:** No, I mean, there's a book available at the Nimbin Hemp Embassy that has a basic recipe that is pretty well what I use.

**Y:** We use a basic shortbread.

**X:** Yeah

**Y:** With lots of butter.

**X:** Yeah, and um, very, you do not detect the flavour, the way we make it.

**Graham:** Ah, really

**X:** It's not green and tasting foul. They're just like Y just said, they're, they're shortbreads.

**Graham:** Hm, mm. And, have you had independent audits or inspections, have you?

**X:** Never

**Graham:** Manufacturing or ...

**X:** Never

**Graham:** or processing?

**X:** Never, never, Who would ever find us? We do, what we do is so, so illegal that we had once, we had the police looking for us via the post office. I am very thankful to a few people within the community that support what we do by keeping their mouths shut and, that's an important thing.

**Y:** Including the police.

**X:** It keeps us all safe.

**Y:** Including the police.

**X:** Including the police.

**Graham:** Sure

**Y:** At the time, yeah.

**X:** We were dobbed in or something.

**Graham:** When was this?

**X:** That was a number of, four years, five years ago.

**Y:** Yeah, it was a number of years ago, yeah. There was ...

**X:** Hauled down to the police station.

**Y:** It was a package that went to the wrong post office box and anyway there was a police complaint to NSW Police and, um, um, an officer, a local officer had to come and speak to

**X:** Certain people

**Y:** Yeah. But no, he came and saw me and asked if I wanted to be interviewed about the, the matter and I, said no and so we didn't talk about it any more. It, it was gone.

Unless and until medicinal cannabis use is legalised, the only legal avenues for the medicinal cannabis user to avoid or limit penalty for his/her use is the common law defence of necessity.

This section will review the case law and commentary from the common law jurisdictions of the United States, United Kingdom, Canada and Australia to assay the chances of a successful medical necessity defence in NSW. Whilst there has never been a successful use of this defence in Australia, the chapter will argue that, given the right situation, there may be some justification for optimism regarding a possible case in future.

## 8.2 *United States' medical cannabis necessity cases*

*United States v Randall*<sup>1</sup> was the first US case in which the Medicinal Cannabis Medical Necessity Defence (MCMND) was successfully pleaded. The facts of this case are reported elsewhere in this thesis<sup>2</sup> but the test laid down has formed the basis of more recent explications of the defence:

- (1) that the defendant did not intentionally bring about the circumstances that precipitated the unlawful acts;
- (2) that the defendant could not accomplish the same objective using a less offensive alternative; and
- (3) that the evil sought to be avoided was more heinous than the unlawful act perpetrated to avoid it.<sup>3</sup>

There are several points arising from the *Randall* test. Firstly there is no reference to patients who recklessly (but not intentionally) bring about the circumstances precipitating the necessity. An example might be of a person having unprotected coitus with an AIDS victim knowing that person had the disease but not at the time considering this. Public policy would likely intrude to bar the defence in such cases but, in any event, 'recklessness' as an issue needs to be adjudicated.

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<sup>1</sup> *United States v Randall* 1104 Daily Wash. L.Rep. 2249 (D.C. Super. Ct. 1976).

<sup>2</sup> See section 5.2.

<sup>3</sup> Andrew J Levay, 'Urgent compassion, prosecutorial, discretion & the medical necessity defence' (2000) 41 *Boston College L R* 699, 715.

The second element of the test is potentially problematic because it admits of some difficult definitional areas. For example, what if the patient had legal access to a drug which was one-third as effective as cannabis but brought with it side-effects 90% greater than medicinal cannabis? Would that fulfil the requirements for a ‘less offensive alternative’? I would argue that this would depend on how ill the patient was and what effect the legal drug has on the remaining quality of life experienced by the patient. In practical terms it could be argued that there would have been little point in Mr Randall using a less effective legal drug to improve his eyesight if that drug made him so nauseous that he could not read a newspaper.

Thirdly, the *Randall* court arguably unnecessarily raised the evidentiary bar too high by demonising the choice of acts as ‘evil’ and ‘heinous’ where other jurisdictions have allowed the defence where the ‘heinous’ act was exceeding the vehicular speed limit in a deserted street to transport a birthing mother to hospital.<sup>4</sup> This example points up two other possible elements of the defence – firstly, that what matters is not the morality of the two evils but their disproportionality and secondly, that there may be a good argument that the defence is always specific to the objective’s seriousness, in terms of life or its experienced quality. Taking the same basic set of facts as in *White* but ‘upping the ante’ of the gravity of the surrounding circumstances might well have resulted in a different judgment. For instance if the vehicle had been speeding down a street full of marchers in an Anzac Day procession and had there been no objective likelihood of injury to mother or baby if there were a delay in reaching the hospital.

In the second successful use of the defence in the USA, the test was stated as:

- (1) he reasonably believed his use of marijuana was necessary to minimise the effects of multiple sclerosis;
- (2) the benefits derived from its use are greater than the harm sought to be prevented by the controlled substances law; and
- (3) no drug is as effective in minimising effects of the disease.<sup>5</sup>

This test is arguably too wide because, by using the term ‘minimise’ it leaves open the opportunity for the same defence to be allowed where there is only an incremental

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<sup>4</sup> *re Appeal of White* (1991) 10 MVR 474.

amelioration of the patient's condition, such that s/he would be justified in using medicinal cannabis if 'the benefits derived from its use are (say 10%) greater than the harm sought to be avoided by the controlled substances' and (3) 'no drug is as effective (by less than 10%) in minimising the effects of the disease.'

The third successful case involved another glaucoma sufferer, Elvy Musikka.<sup>6</sup> Here the court's summation of the elements of the defence was somewhat more detailed.

The court found that the defence of medical necessity would apply in Ms. Musikka's case if the trier of fact found by a preponderance of the evidence that:

- a. a genuine medical disorder does in fact exist;
- b. the defendant did not bring about the circumstances causing her to break the law, that is Ms. Musikka was not responsible for causing her disorder, glaucoma;
- c. weighed under the totality of the circumstances, Ms. Musikka's decision to do the illegal act, that is, to grow and use marijuana was genuine and reasonable, tailored to minimize the effects of the medical disorder; and
- d. the benefits derived from the use of the illegal substance are greater than the harm sought to be prevented by the controlled substances law, that is, whether Ms. Musikka's alleged 'right to sight' outweighs the social harm that her use of marijuana might cause.

Again I would argue that the description of the test is vulnerable to abuse because it omits any reference to disproportionality. For example, on its face, it would accept the application of the test to a fact situation where the 'genuine medical disorder' was a common cold and, as in *State v Diana*, the use of medicinal cannabis 'minimised' its effects by a margin of, say, 10% over the next best legal cough medication. However the Musikka court's stipulation that the defendant's decision to use and grow medicinal cannabis was 'reasonable' goes some way towards restricting the frivolous uses of the defence.

Another successful use of the defence came in the case of *Jenks v State*.<sup>7</sup> The Jenks court outlined the defence in these terms:

The pressure of natural physical forces sometimes confronts a person in an emergency with a choice of two evils: either he may violate the criminal law and thus produce a harmful result, or he may comply with those terms and thus produce a greater or equal or

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<sup>5</sup> *State v Diana* as cited in S McGuire, 'Medical marijuana state law undermines Federal marijuana policy: Is the establishment going to pot?' (1997) 7(73) *San Joaquin Agricultural Law Review* 86.

<sup>6</sup> *State v Musikka* 34 SE 202 (Ga) as cited in M L Mathre, 'Cannabis in Medical Practice' (1997) McFarlane & Co, Jefferson ILL 25.

<sup>7</sup> *Jenks v State* 82 Sop2d 676 (Fla Dist Ct App 1991) 4-5.

lesser amount of harm. For reasons of social policy, if the harm which will result from the compliance with the law is greater than that which will result from violation of it, he is by virtue of the defence of necessity justified in violating it.

Jenks was perhaps the first US case to interpolate the element of ‘emergency’ into the medical necessity defence. As I will submit later in this chapter I do not believe that ‘emergency’ is apt in finding the defence relevant.

A 1990 Idaho case where the defence was upheld was *State v Hastings*<sup>8</sup> which stated the common law defence as having four elements, ‘(1) a specific threat of immediate harm; (2) the circumstances were not brought about by the defendant; (3) the same objective could not have been accomplished by a less offensive alternative; and (4) the harm caused was not disproportionate to the harm avoided.’

Once more I would contend that the ‘immediacy’ element is not useful. The other problem raised by the definition of the defence here is the court’s insistence in restricting the defence ‘where the same objectives could not have been accomplished by a less offensive alternative.’ This would appear to confuse medicine and the law because the alternative is only less offensive because of its legality but may be more offensive medically because of its much worse side-effects and/or its efficacy when compared with medicinal cannabis. To merge two metaphors, this is like opening the door to the slippery slope of relativity. For example, what would the court decide in a situation where the efficacy of a legal drug was 50% and that of cannabis 80%? Would the legal drug then ‘accomplish the same objectives?’

Mathre usefully includes some generic explanations for the failure of other US MCMND cases. Some defences were struck out because the patient and doctor had not tried all legal avenues to obtain medicinal cannabis.<sup>9</sup> Defending the growing or possession of large amounts of medicinal cannabis is likely to be difficult even if the defendant objectively needed to use such a quantity.<sup>10</sup>

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<sup>8</sup> *State v Hastings* No. 18444 (Sup Ct Idaho, November 27, 1990) 2–3.

<sup>9</sup> *United States v Burton* 894 F 2d 188 (6<sup>th</sup> Cir 1990); *State v Tate* 102 NJ 64, 508 A 2d 1000 (1983); *People v Trippet* 66 Cal Rptr 2d 559, (Ct App 1994).

<sup>10</sup> See, eg, *United States v Burton* at n 9.

Practical issues cited by Mathre in arguing the defence include the importance of focusing on the mitigation of sentencing should the defence not otherwise succeed, since relatively few do succeed. Good medical, scientific and medicinal cannabis user witnesses are important, as is the court's perception of the defendant as an honest law-abiding citizen who has been forced to make this difficult decision based on circumstances beyond their control.<sup>11</sup> The other issue raised in commentary on the case is that of how serious is 'serious' in the context of the medical marijuana user's illness. The Code's definition section (S11362.7) does not define 'serious' but instead, includes it with the other conditions for which medical marijuana is approved.

Mathres's view is that:

The court in *People v Trippet* seemed to disregard any threshold level of illness that is a pre-requisite for protection under the Act,... [b]ut there may be a point where a line will need to be drawn between those truly 'seriously ill' patients and those who are not sufficiently ill and maybe more able to use other forms of pain relief... if this line is not drawn... there is a possibility of a backlash against any medicinal use of marijuana....

What appears to be the current explication of the defence in *United States v Oakland Cannabis Buyers Co-operative*<sup>12</sup> was adopted from the earlier case of *United States v Aguilar*<sup>13</sup> where it was stated that the defendant must prove '(1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a direct causal relationship between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law.'

For the reasons given above I do not regard this summation as satisfactory. Moreover its stipulation that there must be 'no other legal alternatives to violating the law' is simplistic and unjust. The defendant in *Trippet* was denied the defence because she had not tried Marinol, when there was available to the court a plethora of evidence that Marinol was, by a wide margin, less efficacious than medicinal cannabis. The danger here is that courts can deny medicinal cannabis whenever they find a legal drug that is barely, if at all, efficacious – like Marinol.

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<sup>11</sup> Mathre, n 6, 29.

<sup>12</sup> *US v Oakland Cannabis Buyers Co-operative* 190 F. 3d. 1109.

<sup>13</sup> *United States v Aguilar* 583 F. 2d 667.693 (9<sup>th</sup> Cir, 1989).

Before leaving this consideration of United States’ Medical Necessity Defence case law, mention should be made of another medicinal cannabis user’s defence grounded in human rights law, which, by an admittedly long stretch of the imagination, may be in future available in Australia. It might particularly apply to Sativex. The case is *Abigail Alliance for Better Access to Developmental Drugs and Washington Legal Foundation v Eschenbach and Leavitt*.<sup>14</sup>

The appellants in this matter took a different approach to seeking court permission for seriously ill patients to use medical marijuana. They employed human rights and constitutional principles to argue that such patients should have access to drugs which had undergone preliminary human trials but had not yet been approved by the federal regulatory body, the Food and Drug Administration (FDA). The Alliance argued that the Due Process Clause of the Fifth Amendment to the United States Constitution provides that ‘no person shall be deprived of life, liberty or property, without due process of law’. For parties to succeed in such a claim they must satisfy the tests laid down in *Washington v Glucksberg*<sup>15</sup> – that the fundamental right asserted is ‘objectively, “deeply rooted in this nation’s history and tradition.”’<sup>16</sup> The appellants argued that this fundamental right includes the right of a terminally ill patient, acting on a doctor’s advice, to obtain potentially life-saving medication when no alternative treatment approved by the government is available.<sup>17</sup>

In their submission, the defendants argued that the decision to take the risk of using a drug that has not yet been fully tested should be the prerogative of the terminally ill patient as she has a right to control what she puts in her body and that it is a crime for the FDA to interfere with this right to save or prolong one’s life. These patients are only asking for the same rights accorded to human experimental subjects in new drug trials. The court accepted these arguments, ruling:

we conclude, upon applying the *Glucksberg* analysis and heeding the protected liberty interests articulated by the Supreme Court, that where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined by the FDA after Phase 1 trials to be sufficiently safe for experimental human trials, warrants protection under the Due Process Clause. The prerogative asserted by the FDA –

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<sup>14</sup> *Abigail v Eschenbach and Leavitt* No. 04-5350, (2006).

<sup>15</sup> *Washington v Glucksberg* 521 US 702, (1997).

<sup>16</sup> *Ibid* 720.

<sup>17</sup> *Abigail*, above n 14, 14.

to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access – this impinges upon an individual liberty deeply rooted in our nation’s history and tradition of self-preservation.<sup>18</sup>

The Abigail judgment relied heavily on *Washington v Glucksberg*<sup>19</sup> in asserting the rights of patients in palliative care – ‘a patient who is suffering from a terminal illness and who is experiencing great pain [should face] no legal barriers to obtaining medication from qualified physicians to alleviate that suffering.’<sup>20</sup> This and other passages led Hyatt to conclude, ‘In totality then, the *Glucksberg* concurrences represent the notion that there is a fundamental right to palliative care. Furthermore they suggest that this liberty interest may outweigh states’ interests.’<sup>21</sup>

The Abigail court decided that:

where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient’s informed access to potentially life-saving investigational new drugs determined by the FDA after Phase 1 trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Code 30.<sup>22</sup>

However the majority judgment was adamant that, ‘Nothing in the court’s holding supports the dissent’s inference that marijuana or any other Schedule 1 substance, if tested, would qualify for Phase 1 clearance and be potentially life-saving.’<sup>23</sup>

### 8.3 United Kingdom medical necessity case law

There is considerable discussion among the authorities as to the elements of the necessity defence – whether the basis of the defence is justification or excuse and its relationship to duress.<sup>24</sup> Several English cases in the last twenty years have sought to lay down criteria for the invocation of the necessity doctrine. Part of the difficulty in establishing a consistent

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<sup>18</sup> *Abigail*, above n 14, 29.

<sup>19</sup> *Washington*, above n 15.

<sup>20</sup> *Ibid* 736–737.

<sup>21</sup> A Hyatt, ‘Medical Marijuana and Palliative Care: carving a liberty interest out of the *Glucksberg* framework’ (1996) 33 *Fordham Urban LJ*, November quoting no author, ‘Note: Last Resorts and Fundamental Rights: The substantive due process implications of prohibitions of medical marijuana’ (2005) 118 *Harvard LR* 1985.

<sup>22</sup> *Abigail*, above n 14, 21.

<sup>23</sup> *Abigail*, above n 14, 12.

<sup>24</sup> C Clarkson, ‘Necessary Action: A New Defence’ (2004) *Crim LR* 81; W Chan and A Simester, ‘Duress, Necessity: How Many Defences?’ [2005] 16 *Kings College LJ* 121.

doctrine of necessity is the wide variety of fact situations in which it has been raised. These range from threats of suicide<sup>25</sup>, through to a case where the defendant was found in possession of an unlicensed gun after taking it from someone who threatened to kill someone with it<sup>26</sup>, to divulging state secrets.<sup>27</sup>

Furthermore, there is a related but separate body of cases generally subsumed under the rubric of cases of ‘medical necessity’, both in Australia<sup>28</sup> and England.<sup>29</sup> Many of these cases raise the defence in the context of doctors performing abortions or sterilisations to save patients’ lives. It is in this class of cases of ‘medical necessity’ that defendants in the UK<sup>30</sup>, the United States<sup>31</sup> and Australia<sup>32</sup> have sought to base their defence. In these cases, the courts were not required, for various reasons, to squarely address whether the doctrine applies to a case where a defendant pleads that s/he should not be convicted for possessing, cultivating or administering a prohibited drug where s/he does so to avoid severe pain and/or death.

These and other issues relating to medicinal cannabis use were addressed by the Criminal Division of the English Court of Appeal before Mance LJ and Newman and Fulford JJ in *Quayle & Others v R*.<sup>33</sup> The case consisted of appeals by five defendants against their sentences under the *Misuse of Drugs Act 1971*, (UK) or the *Customs and Excise Management Act 1979* (UK), together with an Attorney-General’s Reference to the Court in respect of the acquittal of another person charged under the Act.

### *The facts of the cases*

Quayle, Wales and Kenny were charged and convicted of cultivating cannabis under several sections of the *Misuse of Drugs Act 1971*. They all admitted self-medicating with cannabis

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<sup>25</sup> *Martin* [1988] 88 CAR 343, *Rodger & Rose* [1988] 1 CAR 143.

<sup>26</sup> *Pommell* [1995] 2 CAR 607.

<sup>27</sup> *Shayler* [2001] EWCA 1977, on appeal [2003] 1 AC 247 (HL).

<sup>28</sup> *Davidson* [1969] VR 667, *R v Wald* (1991) 3 NSWDCR 25 and *K v Minister for YACS* [1982] 1 NSWLR 311.

<sup>29</sup> *Bourne* [1939] 1 KB 687, *Gillick v West Norfolk and Wisbech Area H.A.* [1986] 1 AC 142, *In re F (Mental Patient: Sterilisation)* [1990] 2 AC 1.

<sup>30</sup> *R v Phillip David Lockwood* [2002] EWCA Crim 60; *Brown v R* [2003] EWCA Crim 2637.

<sup>31</sup> *United States v Randall* 1104 Daily Wash. L.Rep. 2249 (D.C. Super. Ct. 1976), *United States v Aguilar* 583 F. 2d 667.693 (9<sup>th</sup> Cir, 1989), *State v Diana* 604 P. 2d 1312 (Wash. Ct. App. 1979), *Jenks v State* 582 So. 2d 676 (Fla. Dist. Ct. App. 1991), *United States v Bailey* 444 U.S. 394. 410 (1980), *United States v Oakland Cannabis Buyers Co-operative* 532 U.S. 483 (2001).

<sup>32</sup> *Davidson* [1969] VR 667, *R v Wald* (1971) 3 NSWDCR 25, *K v Minister for YACS* [1982] 1 NSWLR 311.

<sup>33</sup> *Quayle & Others v R* [2005] EWCA Crim 14145.

which they grew to treat severe and chronic pain from which they suffered as a result of accidents. But they claimed they only did so from necessity because no other legally available drug could be used successfully to treat their pain without serious adverse side-effects. At their trials all three produced evidence from medical and other expert witnesses that cannabis was efficacious in treating such pain.

In Wales's case his doctor added that he, 'was unable to tolerate anti-inflammatory drugs because of their gastric effect and the risk of them causing pancreatitis.'<sup>34</sup> and another expert witness testified that such drugs could cause peritonitis, which can be fatal.<sup>35</sup>

Taylor and Lee were convicted of knowingly being concerned in the fraudulent evasion on the prohibition on the importation of a Class B controlled drug, cannabis, under section 170(2) of the *Customs and Excise Management Act 1979*. They had been arrested at an airport trying to smuggle cannabis into England from Switzerland. They intended to sell the cannabis to some of the 700 patients on the books of Taylor's 'Tony's Holistic Clinic' in London, many of whom suffered from multiple sclerosis or HIV/AIDS.

Ditchfield, the subject of the Attorney-General's Reference was a medicinal cannabis campaigner who provided cannabis free of charge to those he considered in need of it. Police found cannabis and cannabis resin in his car and he was subsequently charged with possession and intent to supply under section 5(3) and 5(2) of the *Misuse of Drugs Act 1971*. Unlike the other appellants, Ditchfield successfully pleaded necessity, leading the Attorney-General to seek the court's opinion on whether:

the defence of necessity be available to a defendant in respect of an offence of possession of cannabis or cannabis resin with intent to supply, contrary to section 5(3) of the *Misuse of Drugs Act 1971*, if his case is that he was in possession of the controlled drug intending to supply it to another for the purpose of alleviating pain arising from a pre-existing illness such as multiple sclerosis?<sup>36</sup>

### *The Court's judgement*

After summarising the defendants' cases, the judgement spelt out the legislative framework of the *Misuse of Drugs Act 1971* and the several parliamentary reports on medicinal cannabis. It

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<sup>34</sup> Ibid para 3(iii).

<sup>35</sup> Ibid para 6(vi).

<sup>36</sup> Ibid para 6(vi).

then recited the parties' cases before considering '[t]he legislative scheme' and the *European Convention on Human Rights*. Finally, the court set out '[t]he detailed requirements of any defence of necessity' and employed them to dismiss all the appeals and answer the Attorney-General's Reference question in the negative.<sup>37</sup> These 'requirements' for a defence of necessity – the need for extraneous circumstances; the danger of physical injury and the imminence of the danger – form the focus of this commentary.

### *The need for extraneous circumstances*

The *Quayle* court relied on the authority of a handful of earlier cases to establish that the danger against which the defendant acts must be in the form of 'extraneous circumstances'.

They held, at paragraph 33 that:

the cases of *Quayle*, *Wales* and *Kenny* lack at least one fundamental and essential ingredient, namely, that the allegedly causative feature of the commission of the offence must be extraneous to the defendant.

The court referred with approval to the judgment of Leveson J in *Brown*<sup>38</sup> which stated that:

the causative feature of the applicant's commission of the offence was, or may have been, extraneous to the applicant on the basis that the defence does not extend to include the subjective thought processes and emotions of the defendant.<sup>39</sup>

The court went on to approve the following ruling in *R v Roger*:<sup>40</sup>

where the suicidal thoughts of a prisoner were judged to be no defence to the offence of breaking prison. Suicide or depression is an innate affliction, as are the side effects of pain relief using lawful medication.<sup>41</sup>

It is submitted that this ruling is clearly wrong in fact. The word 'innate' is defined as 'existing in a person ... since birth, ... inherent'<sup>42</sup>, whereas the side effects of 'lawful medication' are not inherent to the patient taking it but to the medication itself. Moreover the court's comments on 'side effects' trivialise the seriousness of these effects when applied to the constant and debilitating wasting, nausea and other effects caused by 'lawful medication'.

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<sup>37</sup> Ibid para 82.

<sup>38</sup> *Brown* [2003] EWCA Crim 2637.

<sup>39</sup> Cited n 38, para 50.

<sup>40</sup> *R v Roger* [1988] 1 Cr App R 1423.

<sup>41</sup> *R v Roger*, n 40, 50.

<sup>42</sup> J Simpson and E Weiner (preparers), *The Oxford English Dictionary* (2<sup>nd</sup> ed, 1989) Clarendon Press, Oxford, U.K., vol. VII, 991.

So much is this so that such patients can either die of these side effects or are obliged to discontinue these drugs, with consequent ill effects on their medical condition/s. In any case the serious illnesses which oblige medicinal cannabis users to break the law are clearly, with the possible exception of inherited conditions, ‘extraneous’ to the defendant and not subject to ‘the subjective thought processes and emotions of the defendant.’<sup>43</sup>

### *Pain is not enough*

This discussion relates back to the previous heading of ‘extraneous circumstances’, where the court in *Quayle* seems to conflate ‘extraneous’ with ‘objective’. In order to understand their argument, it is necessary to quote at some length from the judgement. In concluding their discussion of extraneous circumstances, they state, as follows:

[T]hat for the defence of necessity of circumstances to be available, there must be extraneous circumstances capable of objective scrutiny by judge and jury ... [76] It is however, submitted on behalf of Messrs. Quayle, Wales and Kenny that any such test is satisfied ... because of the objectively ascertained facts giving rise to the pain that they suffer ... and because pain is capable of some degree of objective scrutiny and is not wholly subjective. ... [W]e do not gain any real assistance from cases ... where distinctions may or may not have been drawn between injury and harm or pain. [77] The reason why we would not accept the submission is that the law has to draw a line at some point in the criteria which it accepts as sufficient to satisfy any defence of duress or necessity. If such defences were to be expanded in theory to cover every possible case in which it might be felt that it would be hard if the law treated the conduct in question as criminal, there would be likely to be arguments in considerable numbers of cases where there was no clear objective basis by reference to which to test or determine such arguments. There is, on any view, a large element of subjectivity in the assessment of pain not directly associated with some current physical injury. ... The legal defences of duress by threats and necessity by circumstances should in our view be confined to cases where there is an imminent danger of physical injury.<sup>44</sup>

In summary, the court regarded pain as ‘innate’ and ‘subjective’, not ‘extraneous’ and ‘objective’. On that basis the appellants failed.

It is submitted that in the cases of Quayle, Wales and Kenny, each of them *did* suffer pain ‘directly associated with some current physical injury’. Moreover, even if the defence of necessity were restricted to ‘imminent danger of physical injury’, other categories of

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<sup>43</sup> *Roger*, n 40, para 50.

<sup>44</sup> *R v Roger*, n 40, paras 75–77.

medicinal cannabis-using patients would qualify on account of, for example, blindness from glaucoma or chronic nausea or wasting from HIV/AIDS, not to mention suicide.<sup>45</sup>

### *The need for imminence and immediacy*

Although Their Honours' third detailed requirement for a necessity defence is headed, 'Imminence and immediacy', they themselves cite, with seeming approval, Lord Woolf's assessment of *Abdul-Hussein*<sup>46</sup> in *Shayler*<sup>47</sup> – that that case had the effect of 'making it clear that the harm threatened need not be immediate but should be imminent.'<sup>48</sup> In *Abdul-Hussein* the threat was explained as 'hanging over one's head'. This Damoclean analogy is apt to describe the position of seriously ill people who will suffer or die if they do not illegally use medicinal cannabis. Again, in *In re A*<sup>49</sup> the requirement was stated as, 'one of necessity, not emergency.'

Contrary then to the emphasis on immediacy in *Quayle*, it may be sufficient for the defence of necessity that the danger prompting the illegal action is 'imminent', meaning 'impending' which imports meanings of 'inescapable', 'threatening', 'anticipated' or 'forthcoming'.<sup>50</sup> It is submitted that there is no logical reason why a necessity defence should require urgency. This view gains some support from two Australian commentators who claim that, '[a]n extraordinary emergency may not entail this notion of suddenness or unexpectedness. It may occur over a period of time such as living in a war zone.'<sup>51</sup> It is perhaps also noteworthy that s 10.3 of the *Commonwealth Criminal Code 1995* (Cth) defines this element of the defence as 'sudden or extraordinary'.<sup>52</sup> In this sense 'extraordinary' can connote 'exceptional' or 'unusual' rather than 'impending'.

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<sup>45</sup> See also D Ormerod, 'Necessity of Circumstance, Case Comment, *R v Quayle*' [2005] *Crim LR* 148–153, at 152.

<sup>46</sup> *Abdul-Hussein* [1999] *Crim LR* 570.

<sup>47</sup> *Shayler* [2001] EWCA 1977, [2003] 1 AC 247.

<sup>48</sup> *Ibid* para 46.

<sup>49</sup> *In re A: Conjoined Twins: Surgical separation* [2001] 2 WLR 480.

<sup>50</sup> J Bernard (General Editor), *Macquarie Encyclopedic Thesaurus* (1990) Macquarie Library, Sydney, para 245 and R Dutch (ed), *Roget's Thesaurus*, Penguin, Ringwood, Vic, para 155.

<sup>51</sup> S Bronitt and B McSherry, *Principles of Criminal Law* (2<sup>nd</sup> ed, 2005) LawBook Co, Pyrmont NSW, 335, citing *Pagawa v Mathew* [1986] PNGLR 154.

<sup>52</sup> Emphasis added.

All told, the court's three requirements still leave the 85,000 multiple sclerosis patients in the UK<sup>53</sup>, as well as the many other thousands of medicinal cannabis users, without a legal defence. A differently constituted defence of necessity or a different approach to the regulation of pharmaceutical substances could deliver a just outcome to these unfortunate people.

### *The distinction between necessity and duress*

Besides its failure to adequately define the essential elements of a necessity defence, the *Quayle* court fails to make a clear distinction between 'duress' and 'necessity'. Throughout much of the judgment the court speaks of duress in relation to the facts in *Quayle*, though none of these defendants raised duress as a defence. For example, at paragraph 81, in its conclusions, the Court refers to 'over-rid[ing] the defendant's will' which is an element of duress but not of necessity. Indeed they quote with approval the dicta of Lord Woolf in *Shayler*, that, 'the distinction between duress of circumstances and necessity has, correctly, been by and large ignored or blurred by the courts.'<sup>54</sup>

The distinction between necessity and duress needs to be made, because in cases of duress the mind of the defendant is overborne so that s/he is rendered incapable of making an independent and voluntary decision, whereas in necessity cases, the defendant perceives that s/he can choose between two options – 'evils' – and does so on the basis of weighing up the consequences of those options. This distinction is borne out in Brooke LJ's judgment in *In re A* where he distinguished between what he called 'necessity caused by wrongful threats' and 'cases of pure necessity' where the actor's mind is not irresistibly overborne by external pressures<sup>55</sup>. Fairall and Yeo make the same point in stating that,

[n]ecessity does not of itself displace the element of voluntary action. ... A person acting under necessity does not disown the physical act but seeks to explain the behaviour as a rational, moral and in any case forgivable response to extreme circumstances.<sup>56</sup>

In a recent case commentary on *Quayle*, Professor David Ormerod is also of the opinion that '[t]he courts have recently begun to treat the defences of duress of circumstances and

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<sup>53</sup> Report of the Independent Inquiry into the *Misuse of Drugs Act 1971* (1999) Police Foundation, London, ('The Runciman Report'), para 85, cited at para 19.

<sup>54</sup> *Shayler*, n 47, para 45.

<sup>55</sup> *In re A: Conjoined Twins: Surgical separation* [2001] 2 WLR 480, at 569.

necessity as synonymous.’<sup>57</sup> He goes on to argue that there are good grounds for treating the two defences separately and that these reasons have been accepted by the courts.<sup>58</sup> Ormerod concludes that, ‘[c]larification from the House of Lords as to the elements of the defence of necessity, its rationale, and its relationship to duress of circumstances is urgently needed.’<sup>59</sup> Whereas the court in *Quayle* eschewed the existence of any general principles of the necessity defence, Brooke LJ in *In re A* clearly identifies three such principles, namely (1) that the unlawful act giving rise to the defence must have been carried out to avoid inevitable and irreparable harm, (2) that this act constituted action that was no more than necessary to achieve its purpose, and (3) that the evil committed must not outweigh the evil avoided.<sup>60</sup>

In his discussion of *Quayle & Ors*. Professor Ormerod claims that:

[a]pplying those criteria it would not come as a surprise if a jury, having heard expert evidence of the genuine nature of pain being avoided, regarded the action of breaking the law as justified.<sup>61</sup>

### *Conclusion*

It is submitted that Brooke LJ in *In re A* accurately described the first of the three principles of the defence as avoidance of ‘inevitable and irreversible harm’. This wording makes it clear that the harm to be avoided has to be serious and irreversible though not necessarily imminent.

I believe that much of the confusion surrounding the distinctions between necessity, duress and self defence could be alleviated by confining necessity to fact situations in which there is no direct involvement of a second person. Such a definitional distinction would avoid the growing miscegenation of the three defences and their conceptual bases.

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<sup>56</sup> P Fairall and S Yeo, *Criminal Defences in Australia*, (4<sup>th</sup> ed, 2005) LexisNexis, Chatswood, NSW, 102, at 6.10.

<sup>57</sup> Note 23, 152, citing *Shayler*, n 6, *Jones et al* [2004] EWCA Crim 1981 and *Hasan* [2005] UKHL 22. See also W Wilson, ‘The Structure of Criminal Defences’ (2005) *Crim LR* 122.

<sup>58</sup> Citing *Re F* [1990] 2 AC 1, *R v Bournewood Community Mental Health Trust NHS Ex p*, [1999] 1 AC 458, *Safi*, [2004] 1 Cr.App.R.12 and *In re A: Conjoined Twins: Surgical separation* [2001] 2 WLR 480.

<sup>59</sup> Note 45, 153.

<sup>60</sup> Note 49, at 1051.

<sup>61</sup> Note 45 at 152.

It may be useful to re-work two of the essential elements of the necessity defence as follows:

1. the action invoked by the necessity must be performed to avoid loss of life or loss of the opportunity to lead a pain-free life or a life with significant pain reduction;
2. the lesser of the two unlawful acts must be chosen by the defendant.

#### 8.4 *The medical necessity defence in Canada*

Two Canadian cases have substantially contributed to the jurisprudence regarding the necessity defence and have been widely cited in other common law jurisdictions.

*R v Perka* laid down a tripartite test for the application of the defence:

At a minimum the situation must be so emergent and the peril must be so pressing that normal human instincts cry out for action and make a counsel of patience unreasonable. Secondly, a defendant must have had no reasonable legal alternative to disobeying the law. Thirdly the harm inflicted must be less than the harm sought to be avoided.<sup>62</sup>

The court was clearly concerned that the defence, ‘could well become the last refuge of scoundrels’<sup>63</sup> and so stipulated that it be restricted to rare cases in which ‘true involuntariness is present.’<sup>64</sup> However, as noted above in my analysis of *Quayle*, there is good authority for the proposition that involuntariness may be a requirement for duress but not for necessity.<sup>65</sup>

The second relevant case, *R v Latimer*<sup>66</sup> attempted to clarify the *Perka* test in relation to whether the required standard for determining reasonableness was subjective, objective or modified objective, resolving that the first two elements required a modified objective standard<sup>67</sup> while proportionality should be judged by an objective standard.<sup>68</sup> But the judgement has been criticised by commentators for adding that:

while an accused’s perception of the surrounding facts may be highly relevant in determining whether his conduct should be excused, those perceptions remain relevant only so long as they are reasonable.<sup>69</sup>

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<sup>62</sup> *R v Perka* [1984] 2 SCR 232, cited in *Bayley v Police* [2007] SASC 411, at [42].

<sup>63</sup> *Ibid* 32.

<sup>64</sup> Note 62, 38.

<sup>65</sup> The medical necessity defence in the United Kingdom, Ch 8.3.

<sup>66</sup> *R v Latimer* [2001] 1 SCR 3.

<sup>67</sup> Note 66, 32.

<sup>68</sup> Note 66, 33.

<sup>69</sup> Note 66, 33

This they feel simply further complicates the test.<sup>70</sup>

Thus it is apparent that Canadian law is, like law in the United Kingdom, in a state of confusion over the necessity defence and its application.

### 8.5 *The medical necessity defence in Australia and New Zealand*

The classic statement of the elements of the defence was enunciated in the Australian case *R v Loughnan* as:

(a) the criminal act must have been done only in order to avoid certain consequences which would have inflicted irreparable harm upon the accused or upon others whom he was bound to protect; (b) the accused must honestly believe on reasonable grounds that he was placed in a situation of imminent peril; (c) the acts done to avoid the imminent peril must not be out of proportion to the peril to be avoided.<sup>71</sup>

Although this remains the test in Australia, the elements have been modified in medical necessity cases like *K v Minister for YACS*<sup>72</sup>, where, in relating the defence to a fact situation of abortion, the court held that:

there is no legal wrongdoing of a miscarriage as procured by a person who has an honest belief on reasonable grounds that the termination of pregnancy was necessary to preserve the woman involved from serious danger to her life or physical or mental health and that in the circumstances the danger of the operation was not out of proportion to the danger intended to be averted. Reasonable grounds can stem from social, economic or medical bases.

The latest attempt to define the elements of the defence in Australia came in *Bayley v Police*<sup>73</sup> where the Full Court of the South Australian Supreme Court held that:

- The issues raised by the defence of necessity are whether an accused believed on reasonable grounds that commission of the crime charged was necessary in all the circumstances in order to remove a threat of death or serious injury to himself or another. Accordingly, there are subjective and objective considerations.

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<sup>70</sup> P Guy, 'R v Latimer and the Defence of Necessity: One Step Forward, Two Steps Back' (2003) 66 *Saskatchewan Law Review* 485; B Berger, 'A Choice Among Values: Theoretical and Historical Perspectives on the Defence of Necessity' (2002) 39 *Alberta Law Review* 848; B Sneiderman, 'Latimer in the Supreme Court: Necessity, Compassionate Homicide and Mandatory Sentencing' (2001) 64 *Saskatchewan Law Review* 511.

<sup>71</sup> *R v Loughnan* [1981] VR 443.

<sup>72</sup> *K v Minister for YACS* [1982] 1 NSWLR 311.

<sup>73</sup> *Bayley v Police* [2007] SASC 411, at [53] (23 November 2007).

- A defence of necessity can only succeed if it is reasonably possible that an accused believed on reasonable grounds that there was a threat of death or serious injury to himself or another, and that the commission of the offence with which he was charged was necessary in order to remove the threat. Further, objectively viewed, there must have been no reasonable alternative course of action open to the accused.
- Assuming there was an imminent peril, a defendant must have honestly believed on reasonable grounds that it was necessary for him to do the acts which are alleged to constitute the offence in order to avoid the threatened peril. That test will, as a matter of fact, not be met if it is proved that the conduct was disproportionate to the threat. A response is not proportionate to the threat if there are reasonable grounds for believing there were alternative courses of action available.
- The prison escape cases make clear that each aspect of the criminal conduct must be addressed. That is, even if certain criminal conduct were necessary, the remainder may not be. That is so because such actions may not be either proportionate or reasonable.
- The response must be proportionate to the danger and cannot go further. If alternatives are reasonably available, the offending is not proportionate and therefore not reasonably necessary. The threat must be imminent and operative. An accused must be afforded no reasonable opportunity for an alternative course of action which did not involve a breach of the law, or involved some lesser breach of the law. Reasonableness and proportionality has to be assessed objectively. The existence of any possible alternative courses of action is of central factual importance.
- The event justifying the conduct must be imminent and operational. If the threat abates there can be no emergency, nor can an action in response be said to be reasonable or proportionate. This is an obvious limiting factual consideration on the ‘reasonable necessity’ element.
- The defence may only be expected to arise on rare occasions.
- ... a case when the accused claimed that necessity caused him to drive dangerously because just prior to his arrest, another driver had got out of his vehicle and came to the accused’s drivers window, threatening to damage him.

An enquiry by the New Zealand Law Commission concluded that a necessity defence still exists in New Zealand. It spelled out the defence’s elements as being that the accused had to have a genuine belief on reasonable grounds of imminent peril of death or serious injury; that

there was no other realistic choice than to commit the offence; that the crime committed was proportional to the harm avoided and that the necessitous situation was not reasonably foreseeable.<sup>74</sup>

## 8.6 *The medical necessity defence – conclusion*

It is submitted that there are reforms which would greatly reduce the confusion surrounding the definition and use of the necessity defence. These reforms, which take the form of legislation or re-interpretation of case law, have the potential to make the necessity defence more successful in medicinal cannabis cases.

Considering the venerable lineage of the necessity defence, it is perhaps at first glance surprising that there is so little case law relevant to it and so much definitional confusion over its proper use. But the dearth of cases may be a clue as to the true nature of the defence which is demonstrated by the Australian Criminal Code's stipulation that the necessitous situation or condition must be 'extraordinary'.<sup>75</sup>

The reason for the invocation of a 'floodgates' argument is encapsulated in Lord Justice Edmund Davies' dictum that, unless the defence is closely circumscribed in its use, it would 'very easily become simply a mask for anarchy',<sup>76</sup> and Dickson J's remarks in *Perka* that, 'To hold ... that ostensibly illegal acts can be validated on the basis of their expediency ... would invite the courts to second guess the legislature.'<sup>77</sup>

Hence the dearth of cases may be due to public policy 'floodgates' considerations<sup>78</sup> and to judicial resolve, as demonstrated by *Quayle*, that the defence must be confined to highly unusual fact situations. Arguably, necessity should only be invoked where it is used in the service of a fundamental human right such as the right to life or to bodily freedom or health.

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<sup>74</sup> New Zealand Law Commission, *Is there a defence of necessity in New Zealand?* 178.

<sup>75</sup> *Commonwealth Criminal Code Act 1995*.

<sup>76</sup> *Southwark London Borough Council v Williams* [1976] Ch 734 (Eng CA) at 746.

<sup>77</sup> *Perka*, n 62, [32]s.

<sup>78</sup> Ormerod, n 45, 153,

The Australian, and indeed the international, case law relating to necessity falls into two distinct categories – medically-related and non-medical cases. In Australian case law the former is typified by fact situations of gaol escapes<sup>79</sup> and the latter by abortions.<sup>80</sup>

The distinction between the two lines of cases is important in that if the element of ‘imminence’ or ‘immediacy’ is not to be required in cases of medical necessity then defendants in medical cannabis cases would not be defeated because, as in *Quayle* for example, ‘... they deliberately chose to act contrary to law on a continuous basis.’<sup>81</sup>

As I argue above in my analysis of *Quayle*, there is no logical or doctrinal reason for any such requirement of immediacy in medical necessity cases. Given the unsatisfactory nature of the use of the defence in current common law jurisdictions, we await the arrival of a test case containing a suitable fact situation in order that medical necessity may be successfully raised in cases of the medical use of cannabis.

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<sup>79</sup> See, eg, *R v Loughnan* [1991] VR 443; *R v Rogers* (1996) A Crim R 542.

<sup>80</sup> See, eg, *R v Davidson* [1969] VR 667; *R v Wald* 919710 # NSWDCR 25; *K v Minister for YACS* [1982] 1 NSWLR 311 and see *R v Bourne* [1939] 1 KB 687.

<sup>81</sup> Ormerod, n 45, 79.

## Chapter 9

# THE ROAD TO REFORM

### *9.1 Implications drawn from international medicinal cannabis legislation and case law for the drafting of New South Wales legislation*

This section draws upon the findings of earlier chapters and especially Chapters 4 and 5 to throw light on specific aspects of medicinal cannabis legislation in the United States and Canada, which need to be considered in the drafting of any legislation regulating the provision of medicinal cannabis in New South Wales. It will then discuss the findings of three official United States reviews and one unofficial review of United States medicinal marijuana legislation. The section ends with a review of the Australian Capital Territory (ACT) *Drugs of Dependence (Cannabis for Medical Conditions) Amendment Bill 2004*, the first such bill in Australia presented to, but not passed by, the ACT Legislative Assembly.

By far the greatest problem identified in the overseas legislation and subsequent legislative reviews is that concerning the supply of cannabis in raw, smokeable form. Many doctors do not endorse or recommend the smoking of cannabis for medicinal purposes because of the associated health problems. There are also problems of contamination of the raw plant with pathogens and problems with variations in the levels of the different active constituents of the plant. Added to this are the psychoactive effects of the plant, which often result in unwanted side effects for patients.

Besides the above, potentially serious health issues attaching to the medicinal use of raw cannabis, there are also substantial law enforcement issues. Where cannabis in smokeable form is prescribed for patients, the raw form in which it is used is the same form in which the plant is used recreationally. This presents problems for law enforcement authorities in distinguishing legal medicinal use from illegal recreational use.

Where legislative provision for ensuring a regular, adequate and licit supply of medicinal cannabis is not made, patients are obliged to break the law to maintain a supply by purchasing the recreational product on the black market.

The Canadian case of *Hitzig & Ors. v Canada*<sup>1</sup> demonstrates that this may in turn lead to constitutional issues for governments legislating for medicinal cannabis.

Unlike pharmaceutical forms of medicinal cannabis, illicit suppliers place patients at risk of impurities and adulterations of the raw cannabis they purchase, besides the legal and safety risks they run in associating with criminals.

Where the legislating government does provide for a legal supply of medicinal cannabis for approved patients, this may lead to other law enforcement problems. Again, the *Hitzig* case illustrates one of these problems which can arise where the government assumes the role of cannabis supplier. In Canada, the federal government franchised a private company to supply it with cannabis but the quality of the raw plant was so poor that the patients complained it did not alleviate their symptoms. This relates back to the health issue that, because of the plant's complex chemistry, no one plant has the same levels of the more than 460<sup>2</sup> compounds as another.

Where a legislating government provides for patients or their surrogates to grow their own cannabis, this presents problems of enforcing limits to the number of plants which can be legally grown and the possible diversion of surplus medicinal cannabis to the recreational black market. This problem is evident in the legislative review of the Hawaiian legislation in 2004.<sup>3</sup>

Some overseas legislative provisions go into great detail to attempt to specify a realistic limit to the number and type of plants which registered medicinal cannabis patients can legally grow. For example Hawaii allows, 'three mature marijuana plants, four immature marijuana plants and one ounce of usable marijuana per each mature plant.'<sup>4</sup> However this raises more problems. For example, what is meant by 'usable marijuana'? Whilst both leaves and flower heads have medicinal effects, their potency and thus their medicinal efficacies are so different that it might be argued that the leaves are not 'usable' as medicine in the treatment of many conditions. Also, this provision is unclear as to whether the 'one ounce' is in addition to

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<sup>1</sup> *Hitzig & Ors. v Canada* [2003] O.J. No. 3873; Con L11 30796 (ON.C.A.);177C.C.C.(3d) 449 (2003) 231 DLR (4th) 104.

<sup>2</sup> L Grinspoon and J Bakalar, *Marihuana, the Forgotten Medicine* (1993) 2.

<sup>3</sup> P G Pan, *In Search of a Viable Distribution System for Hawaii's Medical Marijuana Program*, Report no. 4, Legislative Reference Bureau, December 2004.

whatever ‘usable marijuana’ is left on the three mature plants. The provision is also silent on what the grower is supposed to do with any ‘usable marijuana’ left on the mature and immature plants.

Another problem concerns where a grower is growing for more than one registered patient and it is unclear to law enforcers just which plants are ‘owned’ by which patients in enforcing quantity limits, or where a grower is growing more than the legal maximum in anticipation of some of the plants dying or being consumed and therefore is obliged to grow more than is legally allowable to maintain the patients’ ‘adequate supply’. Given the nature and limits of plant growth it is either unrealistic or impossible to confine a patient’s supply to any separately designated plants because these plants would not produce enough to ensure the patient’s consistent ‘adequate supply’.

It is submitted that the multifarious problems discussed above, which are associated with supplying medicinal cannabis to patients their medication in raw form, lead to the clear implication that NSW should not go down this path in legislating for medicinal cannabis in plant form. Instead, it is recommended that the NSW government should legislate a medicinal cannabis law in which medicinal cannabis is prescribed for patients in a pharmaceutically manufactured pure and consistent dose in synthetic form. This, at one stroke, would eliminate problems of smoking cannabis, distribution, criminality, growing and law enforcement and provide a virtually failsafe system of supply.

As the synthetic form of cannabis contains appreciably lower psychoactive properties, there would be no motivation to divert such supplies of medicinal cannabis to the black market recreational use because such users would not get a strong enough ‘high’ from it.

The earliest official evaluation of medicinal cannabis legislation was the Report to the Chairman of the Subcommittee on Criminal Justice Drug Policy and Human Resources Committee on Government Reform of the United States House Of Representatives of November 1992, entitled ‘Marijuana: Early Experiences for State Laws That Allow Use for Medicinal Purposes’, written by the United States General Accounting Office (‘GAO’).<sup>5</sup> This

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<sup>4</sup> *Hawaii Revised Statutes* (2000) Ch 329, § 329–121 to § 329–128 Definitions.

<sup>5</sup> United States General Accounting Office, *Marijuana: Early Experiences for State Laws That Allow Use for Medicinal Purposes*, Report to the Chairman of the Subcommittee on Criminal Justice, Drug Policy, Human

report analysed medicinal cannabis legislation in the states of Oregon, Alaska, Hawaii and selected Californian counties. It generated data on how these states implemented the law; the number, age, gender and medical conditions of medicinal marijuana patients; the numbers and roles of doctors participating; and the legislation's effects on the enforcement of drug laws in each of the four states. In doing so, it analysed data provided by the administrators of the schemes and spoke with officials at all levels.

The report emphasises the preliminary nature of the findings, because at the time their statistics were collected the laws in the four states had only recently been promulgated. Hence the findings showed low participation rates for medicinal cannabis users and their doctors. Registrants, as a percentage of the state population ranged from 0.03% in Alaska to 0.49% in California's Mendocino County, while most registrants were male and over 40. Such results accord with other sources.<sup>6</sup> Participating doctors as a percentage of all doctors in the State were recorded as being less than 1% in Hawaii and 3% in Oregon.

Data were not readily available to measure how marijuana-related law enforcement has been affected by the introduction of medical marijuana laws. ... Officials from over half of the... law enforcement organisations we interviewed ... said [they] had not greatly affected their law-enforcement activities.<sup>7</sup>

The GAO Report is almost entirely descriptive, with no conclusions as to any shortcomings of the regulatory regimes or recommendations as to their reform. Moreover, it drew criticism from the Department of Justice which castigated the Office for not adequately addressing the conflict between state and federal laws; the potential of medical marijuana to facilitate illegal trafficking; the impact of the laws on the cooperation between law enforcement agencies at different levels and the lack of data on marijuana's medical value.<sup>8</sup> Although the Office disagreed with these criticisms, my reading of the Report suggests that it is superficial and so any implications drawn from it are very general in nature.

Three implications can be drawn from the Report. Firstly, it confirms that a registry system for medicinal cannabis users would not be sufficiently comprehensive in New South Wales, as the majority of medicinal cannabis users would be unlikely to register, given the

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Resources Committee on Government Reform, United States House Of Representatives, Washington DC, November 1992 ('GAO Report').

<sup>6</sup> See, eg, Section 2.2 of this thesis.

<sup>7</sup> GAO Report, above n 5, 4.

<sup>8</sup> Grinspoon and Bakalar, above n 2, Appendix A1.

experience of the United States states' systems where only a minority of medicinal cannabis users register.

Secondly, although relatively few doctors are likely to be involved in the prescription of medicinal cannabis, the Report's statistics, but more so the results of my survey of Northern Rivers' general practitioners in Section 5 of Chapter 1, indicate that there would be enough participating doctors to operate a regulatory medicinal cannabis regime.

Thirdly, the Report's extensive enquiries of law enforcement officials did not raise many concerns that a medicinal cannabis regime would substantially affect enforcement of the drug laws.

The second review of the operation of medicinal matter marijuana legislation is confined to Hawaii.<sup>9</sup> The study gives consideration to several models of marijuana distribution and some of the inherent difficulties of compliance with medical marijuana laws, including acquisition, possession, transport and adequate supply.

Pan observes that the *Hawaiian Medical Use of Marijuana* statute does not provide for the acquisition of medical marijuana apart from do-it-yourself growing or supply by a carer. This potentially exposes medicinal cannabis users to the danger of buying cannabis on the black market. He goes on to point out some definitional problems with the concepts of acquisition, adequate supply, distribution, possession and transport, none of which are applicable in New South Wales as these problems are all in relation to raw cannabis.

Focusing on the issue of distribution, the study concludes that neither the Netherlands nor the Californian model is satisfactory – the former because of quality and financial concerns and the latter owing to the uncertainty of knowing what the federal reaction to such a scheme might be.

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<sup>9</sup> P G Pan, *In Search of a Viable Distribution System for Hawaii's Medical Marijuana Program*, December 2004.

The third evaluation study<sup>10</sup> reviews the history of drug and cannabis policy and law in the USA before outlining the main arguments for and against legalising medical marijuana. However, the paper comes to no conclusions as to preferred policy options.

The final, unofficial review is by far the most comprehensive as it examines just how each state's medical marijuana law is working, state-by-state. It should be noted that this study was conducted by the Marijuana Policy Project,<sup>11</sup> a pro-legalisation lobby group which therefore might be expected to make an optimistic judgment as to the success of the states' medical marijuana laws. Nevertheless the conclusions reached accord with the above official reviews in concluding that the different states' medical marijuana programs are working well. The principal problems they report concern sources of supply for those unable to grow their own or do not have a carer to grow it for them; the amount of medical marijuana allowed to each patient and/or carer; and teething problems with the registration process, none of which are relevant to the regime proposed for New South Wales.

Drawing on the earlier detailed analysis of the provisions of United States state medicinal cannabis statutes, this section of the chapter derives some principles and forms of words which it is considered need to be addressed in any NSW Medicinal Cannabis Act.

### *Preamble*

Having reviewed United States preambles, it is recommended that a succinct statement explaining the need for the legislation be included in the New South Wales Bill as a preamble. One suggested form of words would be based on the preamble to the Hawaiian medical marijuana law, which reads:

The legislature finds that modern medical research has discovered a beneficial use of marijuana in the treating or alleviating pain or other symptoms associated with certain debilitating illnesses such as ...<sup>12</sup>

### *Qualifying medical conditions*

Some United States states have provisions in their medicinal cannabis legislation which require that the applicant patient must have unsuccessfully tried all other legal medications

<sup>10</sup> M Eddy, *Medical Marijuana: Review and Analysis of Federal and State Policies*, Domestic Social Policy Division, Congress, Washington, DC, 27th July 2007.

<sup>11</sup> Marijuana Policy Project ('MPP') State Policies Dept, *State by State Marijuana Laws*, Washington DC, July 2007.

before being eligible to use medicinal cannabis.<sup>13</sup> Although it may seem prudent to include such an injunction in New South Wales, the anecdotal evidence from my study of New South Wales Northern Rivers General Practitioners in Chapter 2.4, indicates that that would be their *modus operandi* anyhow as they regard cannabis-based medications as medicines of last resort. However, the principle of making medical decisions in the best interests of the patient may dictate that it would be pointlessly cruel to deny that patient prompt access to medical cannabis when there is good evidence that other medicines are unlikely to be efficacious where medicinal cannabis would.

The list of qualifying medical conditions accepted by the United States states is considerably more comprehensive than those referred to in my New South Wales Northern Rivers General Practitioners study or in the Recommendations of the New South Wales Working Party on the use of cannabis for medicinal purposes Report.<sup>14</sup> However, I submit that in any New South Wales legislation, it is more useful to focus on the symptoms which medicinal cannabis can relieve rather than on underlying causes of those symptoms. Thus use of medicinal cannabis should be legalised to treat any form of severe and/or chronic pain however it is caused – whether by cancer, HIV/AIDS, Multiple Sclerosis or whatever. I would apply the same approach to severe and/or chronic nausea and wasting.

Given the current unfinished state of research on the ability of medicinal cannabis to treat migraines and arthritis, and given the large number of patients with these conditions, it would be unwise to include them on a list of medicinal cannabis medical conditions until there is more evidence of efficacy, notwithstanding that California allows both conditions to be treated with medicinal cannabis<sup>15</sup>.

However, earlier research in this thesis has commented on the quickening rate of medicinal cannabis research, such that there may, in coming years, be enough scientific evidence to justify the inclusion of other medical conditions on any medicinal cannabis-treatable list. To cover this contingency my suggestion would be that the Medicinal Cannabis Bill should include a clause which sets out a straightforward process in which responsibility for

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<sup>12</sup> (Hawaii) *Medical Marijuana Act*, Haw Rev Stat 475.300–346 § Preamble [2003].

<sup>13</sup> (Washington) *Medicinal Use of Marijuana Act* (Wash Rev Code ANN 69.51A.005-69.51 902 subsection 2.

<sup>14</sup> Report of the *Working Party on the Use of Cannabis for Medical Purposes*, NSW Parliament, v 2, Main Rept, August 2000.

<sup>15</sup> (California) *Compassionate Use Act*, (1996) Health & Safety Code, U362.5.

considering recommendations for new uses is vested in the Pharmaceutical Services Board (PSB) of the New South Wales Health Department, whose duty it would be to put any such recommendations to the Scheduling Committee of the Therapeutic Goods Administration which is authorised to make such determinations. Such a system should be flexible enough to enable an interested party to suggest additions to the list while still allowing the PSB to exercise its discretion in determining whether they need to investigate further.

All the United States states with medicinal cannabis legislation except for Vermont and Maine make provision for the acceptance of new treatable conditions. Most of them give responsibility to the health department or whichever government agency operates the medicinal cannabis registration system. Although it is argued here that a registry system is unnecessary in New South Wales, it would clearly be appropriate for the authority with the knowledge to accept or reject applications for medicinal cannabis use to be the initiator of suggestions for new uses of medicinal cannabis.

### *Qualifying patients*

In all jurisdictions having medical cannabis legislation, the basis of patient eligibility to use medicinal cannabis is the certification of a qualified doctor that the patient has one or more of the qualifying conditions. This raises three issues:

- (1) who is qualified to give the required certification?
- (2) does the certifying practitioner have an obligation to screen applicants?
- (3) should interstate patients in Australia have the right to obtain medicinal cannabis through the New South Wales system?

Although Oregon allows osteopaths to give certifications, I believe that they should not be considered in New South Wales for osteopaths do not primarily treat their patients with medications.

Some United States states stipulate that only doctors with a bona fide professional relationship with their applicant patients should be permitted to make decisions concerning the patients' access to medicinal cannabis. The reason for this is to protect both the treating physician and the registering authority from baseless applications. For example, whilst it may be unfair to require that the treating doctor must know the patient for a mandated time period

before being allowed to forward an application to the relevant authority, the treating physician should be permitted some discretion in deciding whether or not to forward an application. In this regard a provision like that in the Vermont *Medical Marijuana Act* should be considered for inclusion in the New South Wales legislation. This provision requires the treating physician to make a preliminary judgment as to the patient's suitability for medicinal cannabis treatment on the basis of a 'full assessment of the patient's history and current medical condition including a personal physical examination'.<sup>16</sup>

Until other states adopt their own medicinal cannabis legislation it would seem prudent to restrict participation in the medicinal cannabis regulatory scheme to New South Wales residents. This would avoid cross-border patients using the scheme at the expense of New South Wales taxpayers and could stimulate patients in other states to agitate for their own medicinal cannabis regulatory system.

### *Carers*

Since pharmaceutical cannabis is not suitable for recreational use, the complex issues involving people who procure, transport, collect and deliver medicinal cannabis for patients need not occur under the regime here suggested for New South Wales. For example in Canada and the US it is carers who may grow and deliver cannabis to supply medicinal cannabis to patients, whereas in New South Wales medicinal cannabis would already be in pharmaceutical form and would only be available through a process which involved the PSB – the Pharmaceutical Services Branch, NSW Health Department.

The overseas provisions regarding carers are often quite detailed, for example in California which requires that carers have 'consistently assumed responsibility for the housing, health or safety' of the patient.<sup>17</sup> The proposed New South Wales system would obviate these requirements because the carer's only role would be to collect medicinal cannabis and deliver it to the qualifying patient in circumstances where that patient is unable to do this for themselves. Therefore the main function of the carer's provisions is to ensure that the carer accepts responsibility for transporting the medication to the intended patient and that it not be either diverted to other people or uses. For this reason it is submitted that it isn't important

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<sup>16</sup> *Medical Marijuana Act*, 18 VSA 86 §§ 4472–4474d (2004).

<sup>17</sup> *California Health & Safety Code Ann.* § 113622.5–7(d).

that there be a strong, pre-existing relationship between patient and carer like that required by the overseas jurisdictions where the carer's duties are much more substantial.

In view of the importance of the carer to the operation of the overseas medicinal cannabis regulatory systems, it is curious that none of them specify how carers are to be appointed. My suggestion is that it should be the responsibility of the patient to designate their carer because they need to feel that they can trust and rely on that person. However, in situations where the patient can't or won't appoint a carer, it would be up to the patient's guardian or treating physician to appoint someone to fulfil this role. To maintain the security of the medicinal cannabis medication, the carer's name and contact details would need to be kept on records held by the New South Wales Pharmaceutical Services Board, the treating doctor and patient and/or any chemist dispensing the medication. It is envisaged that a typical transaction would work in this way: the qualifying patient might request the treating doctor to prescribe them medicinal cannabis or the doctor may suggest the patient try it. After physically examining the patient and referring to their history the treating doctor may decide to apply to the PSB to obtain medicinal cannabis for the patient. In doing so, the treating physician would inform the PSB of the name of any carer who might be required. If the PSB accedes to the application, it would issue a prescription to the carer which would contain their name and address. The carer would then take it to the chemist or other supplier. The supplier would ask the person who comes to collect the medicine for the prescription and for adequate sources of personal identification and would check these against the details on the prescription before handing over the medication to the collector.

Some overseas jurisdictions provide for secondary carers but this would seem an unnecessary complication in the context of the proposed New South Wales system.

In the event that the qualifying patient's carer wasn't able to fulfil their function, either the qualifying patient or the treating physician could notify each other and the treating physician could notify the PSB of the name of an alternative carer who would continue to act as that patient's carer until such time as the regular key carer could resume their duties.

### *Exemption from prosecution*

Such a provision is at the heart of United States state medical marijuana laws because, since there is no difference in the form of raw cannabis smoked by recreational users and medical users, there may be nothing to distinguish recreational and medical users except the latter's documentation of their right to use the drug.

This should not be an issue in New South Wales for the regulatory scheme proposed presupposes that pharmaceutical cannabis has been rescheduled under both Commonwealth and state legislation into a category of pharmaceuticals which makes it legal to prescribe. Nevertheless it is submitted that any medicinal cannabis legislation in New South Wales should contain a general exemption from prosecution in a clause to protect doctors, patients and carers and prevent any form of discrimination against them. The wording of such a clause could be along the lines of the Montana *Medical Marijuana Act*, which provides that

the qualifying patient or caregiver... may not be arrested, prosecuted or penalized in any manner or be denied any right or privilege for the medical use of marijuana or for assisting.<sup>18</sup>

### *Statutory medical necessity defence*

As discussed earlier in this thesis, the common-law doctrine of necessity has not met with much success when applied to medicinal cannabis users. Never in an Australian or English superior court, and infrequently in a United States court, has this defence been successful in exonerating medicinal cannabis users.

For this reason I have added a clause to the proposed Act to make it clear that the defence may lie with a medicinal cannabis user or a carer using or transporting medicinal cannabis without a prescription. The elements of this defence would be that the patient or carer has a legally valid reason for not obtaining medicinal cannabis according to the procedure set down in the *Medicinal Cannabis Bill*. This defence would also require that the amount of medicinal cannabis possessed and/or used or transported was not disproportionate to the patient's medical needs and that the patient concerned would have been eligible to obtain medicinal cannabis under the provisions of the Act.

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<sup>18</sup> *Montana Code Annotated* 2009 .§§ 50-46-101 to §§ 50-46-210.

*Legal protection for medical practitioners and pharmacists*

As with exemptions from prosecution of qualified patients and carers, a clause like this should not be required in the context of a scheme like that proposed for New South Wales. This is because the form of the cannabis about which they would advise or prescribe would have previously been legalised under Commonwealth and state legislation. However there would appear to be some utility in retaining some sort of protection against any forms of informal discrimination which might be visited on patients using medicinal cannabis by the authorities or the public. It would also serve as a reassurance to general practitioners and pharmacists who may worry that they may incur some inconvenience or notoriety.

*Offences and restrictions on use*

Again, many of the United States' states restrictions are inapplicable to New South Wales because they involve smoked cannabis – for example, prohibitions on smoking cannabis near schools, in gaols or on public transport. However the overseas experience of the operation of these medical marijuana schemes suggests that there must be some penalties in place to deter illegal dealings with the drug. So it is considered essential that the New South Wales Act prohibit the sale, possession, use or transport of medicinal cannabis without a valid prescription.

There need to be criminal sanctions against people falsely claiming qualifying conditions. Similarly, stealing a qualifying patient's prescription must be an offence, as should be the unauthorised manufacture or tampering with pharmaceutical cannabis.

Other necessary sanctions would include prohibiting medical practitioners from prescribing medicinal cannabis without PSB approval and any inappropriate divulging of patients' records by doctors, the PSB or their staff needs to be subject to appropriate penalties.

*The Drugs of Dependence (Cannabis for Medical Conditions) Amendment Bill 2004 (ACT)*

This Bill marks the first and only time that an Australian legislature has substantively considered the medicinal cannabis issue. Although it was defeated, some of the points it raises need to be accommodated in any NSW legislation, so it is appropriate to comment on some of its provisions here.

For a start it has an unfortunate title – ‘Drugs of Dependence’ – when this thesis and many scientific authorities dispute that cannabis is a drug of dependence.<sup>19</sup> However it is appreciated that the Bill seeks amendments to the principal Act and therefore carries the original title. Similarly any NSW statute could be titled *Drug Misuse and Trafficking (Medicinal Cannabis) Amendment Act 2009*.

The scheme envisaged in the Bill would have operated by patients making written applications to the Territory’s Chief Health Officer for approval to possess and use cannabis for the treatment of medical conditions or symptoms specified in the Bill. As discussed above such registration systems have proved unsuccessful overseas. It would also inevitably entail the establishment of a new bureaucracy to process the applications. Conversely, my Bill requires that the application be made by the requesting patient’s doctor and not the patient. This seems preferable as patients may be illiterate or too ill to write.

In the Bill the medical conditions for which eligibility to use cannabis may be granted are divided into three categories. ‘A category 1 is an application for approval to possess and use cannabis for the mitigation of a symptom of a terminal illness [“a medical condition for which the prognosis is death within one year.”]<sup>20</sup> or its treatment’.<sup>21</sup> This category includes applicants with HIV for the treatment of severe cachexia, anorexia, weight loss and severe pain.

Category 2 applies to patients with persistent muscle spasms from multiple sclerosis as a result of spinal cord injury or disease.

Category 3 is described as, ‘an application for approval to possess and use cannabis for the mitigation of any other medical condition or its treatment.’<sup>22</sup> However the accompanying Table 159B only lists ‘seizures’ and ‘epilepsy’ under category 3.

I submit that this categorisation process is confusing and unnecessary. Why make distinctions between terminal and chronic conditions when medicinal cannabis could assist both groups? Why is ‘epilepsy’ placed in category 3 which is supposed to be for ‘the mitigation of a

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<sup>19</sup> See Chapter 2.1 and 7.2

<sup>20</sup> *Drugs of Dependence (Cannabis for Medical Conditions) Amendment Bill 2004* (ACT), §159A, Definitions.

<sup>21</sup> *Ibid* §159B (3).

symptom of *any other* [emphasis added] medical condition or its treatment’? There is no rationale given for this system of categories in the Bill and no accompanying documents explaining the need for it and, to my mind, there is no good reason for it.

Any application for category 2 or 3 approval must include a medical declaration by a doctor specialising in an area of medicine relevant to the treatment of the patient’s medical condition, though for category 1 patients only a ‘doctor’ not a specialist need make the declaration. For all three categories the declaration must affirm that, ‘all conventional [defined as “a medical or surgical treatment that is generally accepted by the Australian medical community as a treatment for the symptom”]<sup>23</sup> for the symptoms of the illness or its treatment have been tried or considered’.<sup>24</sup> Whilst this is sufficient for a category 1 application, categories 2 and 3 require more details as to why conventional treatments are inappropriate.<sup>25</sup> To complicate matters further, s 159D requires that category 3 applicants submit a second medical declaration from a specialist who has reviewed the applicant’s medical file, discussed the case with the first doctor and agrees with their declaration. If category 3 were restricted to medical conditions or symptoms not included in Table 159B, it is understandable that that a second opinion may be called for, but why this should be a requirement for epileptics only but for no other conditions in the Table is baffling.

As proposed under this Bill, after an application is made the Chief Health Officer must decide to approve, with or without conditions, or refuse the application<sup>26</sup> and give written notice of the decision to the patient and doctor/s supplying the medical declaration.<sup>27</sup> An approval is current for up to one year<sup>28</sup> and can be cancelled if the Chief Health Officer believes, on reasonable grounds, that the approval holder has breached a condition of the approval.<sup>29</sup> When an application is refused, the Chief Health Officer must so inform the applicant and give them ‘a reasonable time’ to make representations to the Chief Health Officer about their case, which s/he must consider.<sup>30</sup> However there is no requirement for the Chief Health

<sup>22</sup> Ibid §159B(5).

<sup>23</sup> Ibid § 159A, Definitions.

<sup>24</sup> Ibid § 159B(2).

<sup>25</sup> Ibid §159B(3) (i)–(vi).

<sup>26</sup> Ibid §159E.

<sup>27</sup> Ibid §159G.

<sup>28</sup> Ibid §159H.

<sup>29</sup> Ibid §159I.

<sup>30</sup> Ibid §159E(5).

Officer to give refused applicants written reasons for their decision or to define ‘a reasonable time’ and no appeal mechanism from the Chief Health Officer’s decision.

The Bill’s second group of provisions concerns the cultivation of cannabis for medical purposes and does not concern us here. The remainder of the Bill comprises a provision requiring the Chief Health Officer to keep a registry of applications and growers’ licences and for a review of the putative Act after two years of operation and some amending sections.

Since the Bill was never enacted, it does not carry the same implications for NSW legislation as it would have had if it had been enacted. Nevertheless, it illustrates the difficulties of enacting any legislation concerning the raw herb cannabis. In a more general sense it points up the need to keep straightforward whatever system is adopted and the need for careful amendment of existing statutes.

## 9.2 Draft Medicinal Cannabis Act

### *Section 1: Aims and Purposes of this Act*

- (a) To ensure that seriously ill residents of New South Wales have the right to obtain and use cannabis for medicinal purposes where that medicinal use is recommended by a physician who has determined that a person’s health would benefit from the use of cannabis in the treatment of cancer, AIDS-related severe wasting, chronic pain or chronic nausea and/or vertigo, glaucoma, seizures, multiple sclerosis/muscle spasticity or any other illness for which the Pharmaceutical Services Branch [PSB] of the New South Wales Health Department determines can be relieved by cannabis.
- (b) To ensure that patients, designated carers and pharmacists who obtain medicinal cannabis for medicinal purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction on that account.
- (c) To enable treating physicians to prescribe and/or advise patients concerning the suitability or otherwise of medicinal cannabis for their medical condition and to ensure that in so doing these treating physicians shall not be subject to penalties of any kind.
- (d) To establish a legal regulatory scheme in New South Wales to enable and facilitate the aims and goals set out in (a), (b) and (c) above.

### *Section 2: Definitions*

As used in this section:

‘Adequate supply’ means an amount of medicinal cannabis prescribed for a qualifying patient that is not more than is reasonably necessary to assure the uninterrupted availability of medicinal cannabis for the purpose of alleviating the symptoms or effects

of that qualifying patient's qualifying condition for a period deemed appropriate by the qualifying patient's treating physician.

'Designated carers' means a person over the age of 21 nominated by the qualifying patient, notified by them to the qualifying patient's physician and registered as that patient's designated carers by that physician who is authorised under this Act to possess for, and distribute and administer medicinal cannabis to a qualifying patient.

'Medicinal cannabis' means any pharmaceutical form or formulation containing any of the pharmacologically active ingredients of *cannabis sativa*.

'Medicinal use' means the acquisition, possession, use, distribution, or transportation of cannabis to alleviate the symptoms or effects of a qualifying patient's qualifying condition

'Qualifying condition' means cancer, AIDS-related severe wasting, chronic pain or chronic nausea and/or vertigo, glaucoma, seizures, multiple sclerosis/muscle spasticity or any other illness for which the Pharmaceutical Services Branch of the New South Wales Health Department determines that cannabis provides relief.

'Qualifying patient' means a person who has been diagnosed by a physician as having one or more qualifying condition.

'Treating physician' means a person licensed to practise medicine in the state of New South Wales who has prescribed or been asked to prescribe medicinal cannabis by a qualifying patient.

'Valid prescription' means an order, written, signed and dated by a treating physician or other approved person under this Act to a pharmacist or other approved person under this Act to provide a qualifying patient with an adequate supply of medicinal cannabis for their exclusive personal use for a period deemed by that treating physician to be appropriate in all the circumstances of the case.

### *Section 3: The Prescription of Cannabis for Medicinal Purposes*

- (a) To enable and facilitate the aims and purposes of this Act, the *Drug Misuse and Trafficking Regulation 2006* is hereby amended by the removal of medicinal cannabis from Schedule 8 to Schedule 4 of the Regulations made under the Act.
- (b) If a treating physician determines that it is appropriate in all the circumstances of the case to prescribe medicinal cannabis to a qualifying patient, that treating physician shall make application on the prescribed form under Section 28(1) of the *Poisons and Therapeutic Goods Act 1999* to the Pharmaceutical Services Branch of the New South Wales Health Department.
- (c) Following receipt of an application to prescribe medicinal cannabis the Pharmaceutical Services Branch shall, within 14 days, determine that application and notify the treating physician in writing of that determination.
- (d) If the Pharmaceutical Services Branch approves an application under (b) above, the treating physician may prescribe medicinal cannabis to a qualifying patient under any conditions specified by the Pharmaceutical Services Branch or any conditions which that treating physician sees fit.
- (e) If the Pharmaceutical Services Board approves an application it shall issue a prescription in quadruplicate – one copy being retained by the Board; one by the treating physician; one by the supplying pharmacist or other designated supplier and one by the qualifying patient or their carer.
- (f) If the Pharmaceutical Services Branch does not approve the treating physician's application, the treating physician shall not prescribe medicinal cannabis to that

patient for whom application was made providing that the physician can make a new application six months after a previous application was rejected.

#### *Section 4: Conditions for the Use of Medicinal Cannabis*

- (a) Presentation of a valid prescription shall be adequate to prevent arrest and prosecution for possession, supply, distribution or use of validly obtained and validly prescribed medicinal cannabis.
- (b) At all times when a qualifying patient or their designated primary carer is administering, distributing or possessing medicinal cannabis, that person shall carry and make available the qualifying patient's valid prescription to a requesting officer of the state police.
- (c) Upon their appointment carers must sign a declaration which is to be forwarded and retained by the PSB. This declaration enjoins them from delay in delivering the medicine to the qualifying patient and from opening the medicines packaging.

#### *Section 5: Prescription of Medicinal Cannabis for Minors and the Mentally Incapacitated*

- (a) In addition to the procedures mandated in Section 3 above, a treating physician may prescribe medicinal cannabis to a person who is under 18 years of age or who suffers from mental incapacity as diagnosed by a practitioner qualified to diagnose such mental incapacity if:
- (b) The custodial parent or legal guardian with responsibility for health care decisions for the mentally incapacitated person or the person under 18 years of age signs a written statement, the original of which shall be held by the Pharmaceutical Services Branch setting forth that:
- (c) The treating physician of the mentally incapacitated person or the person under eighteen years of age has explained to the custodial parent or legal guardian with responsibility for health care decisions for the mentally incapacitated person or the person under 18 years of age the possible risks and benefits of the medicinal use of cannabis;
- (d) The custodial parent or legal guardian with responsibility for health care decisions for the mentally incapacitated person or the person under 18 years of age consents to the use of cannabis by the mentally incapacitated person or the person under 18 years of age for medicinal purposes;
- (e) The custodial parent or legal guardian with responsibility for health care decisions for the mentally incapacitated person or the person under 18 years of age agrees to serve as the designated primary carer for the mentally incapacitated person or the person under 18 years of age; and
- (f) The custodial parent or legal guardian with responsibility for health care decisions for the mentally incapacitated person or the person under 18 years of age agrees to control the acquisition of cannabis and the dosage and frequency of use by the mentally incapacitated person or the person under 18 years of age as advised by the patient's treating physician.

#### *Section 6: Offences under this Act*

- (a) Any person in possession of medicinal cannabis without a valid prescription is guilty of an offence punishable by a maximum fine of ten penalty units and/or a maximum sentence of one month's gaol.

- (b) Any person who fraudulently represents a medical condition to a treating physician, a state government agency or a state law enforcement official for the purpose of falsely obtaining a medicinal cannabis prescription or for the purpose of avoiding arrest and prosecution for a cannabis-related offence, commits an offence punishable by a maximum fine of one hundred penalty units and/or a maximum sentence of two years' gaol.
- (d) The fraudulent alteration, use or theft of cannabis prescription is an offence punishable by a maximum fine of one hundred penalty units and/or a maximum sentence of two years' gaol.
- (e) The fraudulent production or counterfeiting of, or tampering with, one or more cannabis prescriptions is an offence punishable by a maximum fine of one hundred penalty units and/or a maximum sentence of two years' gaol.
- (f) Any treating physician prescribing medicinal cannabis without the prior approval of the Pharmaceutical Services Branch of the New South Wales Health Department is guilty of an offence punishable by a maximum fine of one hundred penalty units and/or a maximum sentence of two years' gaol.
- (g) Any person including, but not limited to, any officer, employee, or agent of the state, or any officer, employee, or agent of any state law enforcement agency who makes public any qualifying patient's confidential record relating to their use of medicinal cannabis or any confidential information contained in any such record that is provided by the treating physician to any state government agency without the written authorisation of the qualifying patient commits an offence punishable by a maximum fine of ten penalty units and/or a maximum sentence of two years' gaol.
- (h) Nothing in this Act shall protect a person from a criminal cause of action founded on administration, possession, production, or delivery of cannabis that is not authorised by this Act.

#### *Section 7: Immunity from sanctions*

A treating physician shall not be subject to any penalty whatsoever, including but not limited to arrest, prosecution, or disciplinary proceeding, or denial of any right or privilege, for advising a patient whom the treating physician has diagnosed as having a qualifying medicinal condition about the risks and benefits of medicinal use of cannabis or that the patient might benefit from the medicinal use of cannabis, provided that the advice is based upon the treating physician's contemporaneous assessment of the qualifying patient's qualifying condition in the context of a bona fide physician-patient relationship and having regard to the patient's medical history and current medical condition and to other approved medications and treatments that might provide relief and that are reasonably available to and can be tolerated by the qualifying patient.

#### *Section 8: Patients' records*

Treating physicians shall provide to the Department of Health or other agency authorised under this Act shall, within seven days of their consultation with a patient requesting medicinal cannabis, forward information concerning that patient's age, sex, residential area and purported qualifying condition.

## Chapter 10

# CONCLUSION

This thesis research began with an investigation into a contemporary social, political, cultural and legal issue – whether or not the people of New South Wales should have the right to self-medicate. As the research evolved it took on a personal dimension when I was diagnosed with Parkinsons disease. At that point the research question was narrowed to read; ‘Should New South Wales citizens have the right to self medicate with pharmaceutical cannabis?’

I was in a unique position to examine the research question for myself and for others struck by chronic debilitating medical conditions, because I was the end user of the products of the pharmaceutical industry and its regulators.

Even though my doctor was successful in changing policy by convincing the TGA to allow me to be the only person in Australia with the right to import medicinal cannabis for my condition, I believe that this individual application process is not a reasonable option for other seriously ill patients, due to the lengthy and exhausting bureaucratic process involved. And so I began researching the need and opportunity for legal reform of New South Wales and Commonwealth legislation impacting on medicinal cannabis.

Throughout this thesis I have adduced evidence which I believe is indicative if not definitively in support of the practicalities of medicinal cannabis reform at both federal and state levels. Moreover such an initiative is well-rooted in ethical and jurisprudential doctrine as discussed in Chapter 1.1.

Now, it is appropriate to draw together the different strings of argument to enable us to make conclusions and to answer the primary question which precipitated this research – ‘Is there a case for legalising medicinal cannabis in New South Wales?’ In doing so I shall revisit the different chapters in order to extract their implications for the overall conclusion.

### *Chapter 1.1 Ethical and jurisprudential considerations*

In Chapter 1.1 I characterised the ethical argument for medicinal cannabis in Millian terms – that the only purpose for which power can rightfully be exercised by a State over its citizens against their will is to prevent harm to others. I conclude that this is the case for medicinal cannabis users and that the ‘Big Brother’ approach of modern states, detailed here in the works of Szasz and others is not ethically justifiable.

In other jurisdictions such as the United States and Canada the Millian ethic is embodied respectively, in the Bill of Rights and the Charter of Rights and Freedom, which impliedly recognise the right of the individual to her/his choice of medicine.

I conclude that, while these ethical arguments would have little prospect of success in an Australian court, such an exercise would be useful in gauging the court’s attitudes to the medicinal cannabis issue.

### *Chapter 1.2 Personal dossier and 1.3 Battling the bureaucrats*

My experience with Commonwealth and New South Wales bureaucracies has been a source of frustration and sometimes wry amusement. The conclusion I draw from this communication are that it is unjust and unviable to subject other patients with serious conditions to the lengthy process for determination of applications to import Sativex. This is too slow for patients living or dying with pain and discomfort. In my case it took most of a year for my doctor to obtain approval from the TGA to import Sativex for the treatment of my condition.

Sloth and evasion also characterised the response to my questions to politicians I asked the New South Wales Government when they would conduct a medicinal cannabis trial that they had been promising since 1999 and asked the Federal Labour Government what is its policy on medicinal cannabis. The former correspondence with NSW politicians was not only slow, as my last letter was dated 21<sup>st</sup> August 2009 and the Health Department’s reply was received on 26<sup>th</sup> January 2010, but it also neglected to answer the question in my letter as to the fate of the medicinal cannabis trial. The same department had altogether failed to reply at all to earlier letters.

In the latter correspondence with Commonwealth politicians and bureaucrats I have been unsuccessful in obtaining details of their medicinal cannabis policy, if they have one at all. This Government has stone walled on the issue, not only in relation to my enquiries but to those of the New South Wales Government as well.

Similarly the TGA's Doctor Rankin in his 2005 letter to me, stated that an application, 'typically takes a few days to consider and provide a written decision...'<sup>1</sup> In contrast our application was lodged on 31<sup>st</sup> July 2008 but we only received their decision on the 29<sup>th</sup> October 2008. In this letter he also stated that 'Sativex would be considered cannabis and in Schedule 9.'<sup>2</sup> Given that cannabis has not been rescheduled and is still in Schedule 9, does this make their eventual approval of our application invalid?

The general conclusion arising from the discussion of politics and the bureaucracy is clearly that they cannot be relied upon.

### *Chapter 2.1 Efficacy*

This Chapter demonstrates that the efficacy of Sativex is now well-established. However, importing it into Australia is not a viable option for most patients as it would be well above their capacity to pay since a three month supply cost me \$A800.

### *Chapter 2.2 The medicinal cannabis constituency*

The evidence brought to bear in this section indicates that most attempts at estimating the numbers of medicinal cannabis users in a general population have resulted in under-estimates of the actual population of medicinal cannabis users. The real figure lies somewhere between seven thousand and fifty thousand but whatever the correct number, it is clear that a significant cohort exists in this state. I concluded that these population numbers are sufficient to constitute a constituency in political terms.

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<sup>1</sup> Rankin, Doctor Jonathan letter to GI 8<sup>th</sup> February 2005.

<sup>2</sup> Ibid.

Chapter 2.3 A preliminary comparative analysis of three surveys of medicinal cannabis use

In terms of which medical conditions might be recognised as qualifying patients with medicinal cannabis, the Australian surveys discussed here rated chronic pain, depression and arthritis as the most common conditions of medicinal cannabis users. The United Kingdom figures in that study were discrepant because the questionnaire provided a much longer list of symptoms than the Australian samples. As to efficacy, respondents in the three surveys overwhelmingly reported that medicinal cannabis gave them great relief or made them feel much better. In comparison with other drugs, medicinal cannabis was rated as ‘a bit better’, ‘much better’ or ‘only cannabis is effective’ by at least three quarters of respondents in all the surveys. When asked to compare the side effects of medicinal cannabis with those of other drugs they had taken for their conditions, the great majority averred that other drugs were ‘much or somewhat worse’. It is speculated that these United Kingdom statistics vary from the Australian studies because their questionnaire did not include an answer category of ‘no bad effects from cannabis’. The majority of Australian respondents were concerned about medicinal cannabis being illegal. There was also strong support from health workers and family for a patient’s right to use medicinal cannabis.

All in all we learn from these comparative studies that their data provide guidelines to the symptoms needed for inclusion in any New South Wales list of qualifying patients – chronic pain, depression, arthritis, migraine, and multiple sclerosis. The objective efficacy of medicinal cannabis reported in Chapter 2.1 largely matches the subjective experience of the respondents in these surveys.

#### *Chapter 2.4 Rural doctors’ attitudes to and knowledge of medicinal cannabis*

Whereas the study found initial significant opposition among general practitioners to medicinal cannabis use in the United States and Canada, the present research indicates that this is unlikely in New South Wales. On the contrary this research suggests that this significant stakeholder group would cooperate with a legalised cannabis regulatory framework. This conclusion stems from the very high percentage of this sample prepared to prescribe medicinal cannabis if legal; the high proportion of respondents in the surveys reported in Chapter 2.3 reporting the favourable attitude of their general practitioners and the long standing approving stance of the Australian Medical Association towards the New South Wales governments’ proposed medicinal cannabis trial.

### *Chapter 3.1 The early history of medicinal cannabis*

From this brief history the following lessons may be learned; – that, internationally, cannabis was not a big problem until the international drugs conferences included it in their regulation of opium and cocaine; that, like their domestic policies, governmental interest in regulating cannabis fluctuates according to political pressure at the time and that the many different official enquiries into cannabis found it to be efficacious for a number of diseases. Hence this Chapter reinforces the evidence of medicinal cannabis efficacy by referring to the length of time during which the same conditions have been treated with medicinal cannabis and the large number of Enquiries which have exhaustively investigated cannabis and come up with the conclusion that it is efficacious and safe.

### *Chapter 3.2 to 3.5*

The points to be garnered from this excursion into overseas drug law history are these; – medicinal cannabis has been used all over the world for longer than any other drug; – the notion of the cyclical nature of the cannabis issue is further strengthened and it demonstrates that there is no country which has successfully regulated medicinal cannabis, whether approaching the issue positively ( the Netherlands, Canada) or negatively (United States). I have documented that, even in jurisdictions with progressive attitudes to medicinal cannabis, their legislation is still causing problems. The Canadian *Medical Marihuana Access Regulations* governing the conduct of the medicinal cannabis regulatory regime allow for doctors to supply medicinal cannabis to participants. This is a practice not to be recommended in New South Wales as it is unnecessary for the proposed New South Wales scheme. In relation to Holland’s approach to medicinal cannabis it can be seen that even progressive policies such as theirs are fraught with problems and thus the Dutch model is not to be recommended for New South Wales.

### *Chapter 4.1 to 4.2*

These studies show that medicinal cannabis was widely used as a cure-all throughout the nineteenth century and was only removed from the Australian Pharmacopeia in the later twentieth century, which roughly paralleled the situation in Canada and the United Kingdom. It was Australia’s involvement in international affairs through firstly the League of Nations and then the United Nations which precipitated ever harsher laws. These often draconian

laws, ‘... became a special case in which the normal principles of proof and normal levels of punishment did not apply.’<sup>3</sup>

As we have seen elsewhere in the thesis, the impetus for medicinal cannabis reform tends to run in cycles, waxing & waning in the consciousness of politicians and the public. This insight should instruct would-be activists to focus their agitation during the periods of heightened public and/or political interest.

The Carr Government’s unfulfilled initiative to legalise medicinal cannabis use and the expressions of support by the then Opposition Leader, John Brogden, indicate that the issue is not beyond the pale for either major party in New South Wales. However the rise and fall of the Carr Government proposal demonstrates that the medicinal cannabis issue is subject to political peaks and troughs such that it is brought up when the Government feels electorally secure and dropped at less propitious times.

#### *Chapter 5.1 to 5.7*

I do not propose to summarise my conclusions from this Chapter because this has already been done in Chapter 9.1 where the implications of overseas cases and statutes were examined in some detail.

#### *Chapter 6.1 to 6.4*

A close examination of international treaties to which Australia is a signatory shows that, contrary to what the current Federal Government claims, these instruments do not debar Australia from setting up a regulated legal medicinal cannabis regime. Legislation in New South Wales and New Zealand allows for the Health Minister’s discretion in approving medicinal cannabis for medical purposes.

#### *Chapter 7.1 A critique of the New South Wales Government Working Party on the use of cannabis for medical purposes*

While many of the Working Party’s recommendations are rejected here, some have been adopted and incorporated into the Draft Bill in Chapter 9. Among these are the conclusion

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<sup>3</sup> D Manderson, *From Mr Sin to Mr Big* (1993) 160.

that, contrary to the Rudd Government’s expressed view<sup>4</sup> the United Nations conventions to which Australia is a party do not forbid the use of medicinal cannabis for medical purposes<sup>5</sup>. This is an important assumption in my legislative model, for pharmacists as well as GP’s are vital stakeholders in this scheme. It is noteworthy that the Pharmaceutical Society of Australia, in their submission to the New South Wales Parliamentary Working Party’s Enquiry made the point that pharmacists already have the facility to store and dispense Schedule 9 products, ‘... with minimal diversion to illicit uses’<sup>6</sup> and suggested that cannabis be moved to Schedule 8 to enable this.

There is support for my model in the submission of the People Living With AIDS group which advocated that medicinal cannabis, ‘... be accessible via a script from a GP or specialist so long as the person is a registered subscriber.’<sup>7</sup>

I also agree with the Report that the New South Wales Health Department should be required to keep a confidential register of patients supplied with medicinal cannabis and that anyone wishing access to these records should be screened.

### *Chapter 7.2 and 7.3*

The Chapter analysing the corporate world view of the National Drug and Alcohol Centre, focusing particularly on one of its major research projects provides a cautionary tale in not taking cannabis research at face value. The same could be said of Chapter 7.3 which rebuts many of the statements in a ‘Fact Sheet’ put out by the United States Drug Enforcement Agency. This shoddy work reveals the continuing demonisation of cannabis by the United States and other western governments over a long period and their unashamed use and manipulation of research to justify their cannabis policies.

### *Chapter 8.1 The Medical Cannabis Information Service*

Most of this thesis has focused on the future but there are seriously ill people who need medicinal cannabis right now. In the reviews of other jurisdictions I have examined the

<sup>4</sup> Letter to G Irvine from V Hart, Assistant to Secretary, Drug Strategy Branch, Commonwealth Department of Health and Aging, 24<sup>th</sup> April 2008.

<sup>5</sup> H Woltring, ‘The 1988 UN Convention – help or hindrance?’ (1990) *Criminology Australia*, April–May 19, 19.

<sup>6</sup> Working Party Main Report, Volume II, 30.

<sup>7</sup> Ibid.

various supply options and found none of them suitable, being either profit-oriented or too bureaucratised. Until medicinal cannabis is legalised the Medical Cannabis Information Service model of postal distribution may be the best, if not the only present option for those needing to obtain medicinal cannabis.

Since the whole business is run through the postal service the organisation has no need of a shop front location and does not have problems with people hanging around. The MCIS is really just another community-based welfare service organisation, like those groups supporting sufferers of particular diseases, like the Multiple Sclerosis Society or the different HIV/AIDS support groups. Thus they are motivated to serve the community rather than to profit from it. Because the organisers work without payment they are able to keep costs down to a level their clients can afford, many of them being pensioners.

#### *Chapter 8.2 United States' medical cannabis necessity cases*

The survey of United States medical necessity defence cases shows that there is now a considerable canon of these cases but since many of them were decided by invoking constitutional principles or statutory necessity provisions which do not exist in Australia, they are of limited precedential value for New South Wales. Nevertheless some of the elements of the common law defence of necessity have been usefully re-defined by various United States' courts such that they may be of assistance in future Australian medical necessity defence cases.

#### *Chapter 8.3 United Kingdom medical necessity case law*

The state of the law in the United Kingdom is one of confusion. From my detailed analysis of *Quayle* I believe that the court's judgement was a policy decision driven by the fear of 'opening the flood gates' to a torrent of spurious claims. The further development of the common law necessity defence awaits a case sufficiently on point to enable a more vigorous definition of the elements of the defence.

#### *Chapter 8.4 The medical necessity defence in Canada*

The upshot of the two leading Canadian medicinal cannabis cases is that the necessity defence is still in flux and hence is not presently of much assistance to Australian litigants.

### *Chapter 8.5 The medical necessity defence in Australia and New Zealand*

The only recent necessity case in Australia was heard by the Full Court of the South Australian Supreme Court in 2007. Yet like *Perka*, which the Court cites with approval, I believe that they are similarly in error in equating ‘imminence’ with ‘emergency’. Unless or until the High Court of the British House of Lords definitively pronounces on the defence it will not assist medicinal cannabis users in Australia.

For the reasons given above I concur that ‘proportionality’ is a necessary element in any test of necessity but I do not agree with the Court, ‘...[a]ssuming there was an imminent peril...’<sup>8</sup> A useful discussion of necessity in the context of medicinal cannabis is the article by Heilpern and Rayner, which suggests that, ‘an easier road for the defence would be encountered if the courts accept that the use of cannabis products falls within the realm of necessity/abortion cases. The defendant would have to show that she acted with an honestly held belief and on reasonable grounds that the use of cannabis was necessary to preserve her from serious danger to her life or physical and mental health and that in the circumstances the use of cannabis was not out of proportion to the danger intended to be averted.’<sup>9</sup>

### *Chapter 8.6 The medical necessity defence – conclusion*

By now there may be sufficient cases and commentary to attempt a necessity defence in Australia. The outcome would likely hinge on whether the court accepted the arguments above that immediacy or emergency is not required in a statement of the elements of this defence.

### *Chapter 9.1 Implications drawn from international medicinal cannabis legislation and case law for the drafting of New South Wales legislation*

This section draws on the findings of the earlier chapters and especially on Chapter 5 to point the way towards workable provisions in my Medicinal Cannabis Bill.

The strongest recommendation to emerge from this study accords with the New South Wales Parliamentary Working Party Report which found that smokeable medicinal cannabis, as used

<sup>8</sup> *Bayley vs Police*, [2007] SASC 411, [53].

<sup>9</sup> D Heilpern and G Rayner, ‘Drug Law and Necessity’ (1997) 22 *Alternative Law Journal* August 4, 191.

in all the overseas statutes, is not a viable option for New South Wales because the state government would never accept it.

After exhaustively examining the clinical literature I conclude that there is good and abundant evidence for patients to qualify for medicinal cannabis if they have severe chronic pain or nausea/wasting however it is caused. I do not feel that there is yet enough evidence to include depression, arthritis and migraine among the qualifying modalities.

To minimise the incidence of frivolous applications for medicinal cannabis to the New South Wales Pharmaceutical Services Branch, it is recommended that the treating physician conduct a thorough examination and history of the applying patient.

As the duties of carers under the proposed legislation are much less onerous than those of their counterparts in overseas jurisdictions it is felt that the requirement in several overseas jurisdictions that carers must have, ‘...consistently assumed responsibility for the housing, health or safety’ of patients is not necessary for the New South Wales legislation.

Finally, any New South Wales medicinal cannabis legislation should avoid creating a category system for qualifying patients or qualifying carers as these perform no useful function.

These recommendations have been adopted and included in my medicinal cannabis bill in Chapter 9.2.

In detailing my experience of the harm that is caused by the government’s refusal to allow the medicinal use of cannabis I have used various methods to gather and present evidence. I do not want other people having to individually seek permission to use this drug on a case by case basis as I had to do with all the bureaucratic hurdles that entails.

There is a demonstrated need in New South Wales for medicinal cannabis, and as it is currently illegal I argue that the law must be changed or a vulnerable group of people will be denied their ‘rights’ to health. In coming to a conclusion to this research I am mindful that the issue of people’s rights to medicinal cannabis will not go away.

I conclude that there's a strong case for the legalisation of medicinal cannabis, not only in New South Wales but in other Australian states.

The answer then, to my research question, is that I believe the evidence I have adduced in this thesis indicates that there is indeed a case for reform of the law in NSW to allow the use of cannabis for medicinal purposes.

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# APPENDIX 1

## NSW NORTHERN RIVERS DOCTORS' SURVEY

### **Introduction –**

Thank you for agreeing to be interviewed. All your answers will be kept confidential and you will not be identified personally in any way. You may choose to discontinue your participation at any time, in which case your answers will not be used.

Have you read, understood and signed the Informed Consent letter already posted to you?

[If YES: Please fax the signed letter to me on 66 224 167].

[If NO: Then I will read out to you now the Informed Consent portion of the letter and you can then verbally agree to the interview or not].

[RESEARCHER'S DECLARATION: *I certify that the applicable terms of the Informed Consent letter have been verbally explained to the subject and that the subject appears to have understood the terms prior to signing the form.*

Researcher's signature: \_\_\_\_\_ Date: \_\_\_\_\_ ]

I would like to ask you five questions about your knowledge of and attitude to the prescription of medicinal cannabis for serious medical conditions. To start, I would like you to listen to some information and I will then ask you some questions about that information.

[READ SHOW CARD 1]

Showcard 1: Nature, Use & Endorsement of Medicinal Cannabis

Medicinal cannabis is a pharmaceutically synthesised liquid preparation of some of the active constituents of the *cannabis sativa* plant, produced for the treatment of a range of medical conditions.

In recent years the Australian Medical Association, (*'Report on Consultation on the Use of Cannabis for Medical Purposes'*, Office of Drug Policy, NSW Government, July 2001, at page 2), the British Medical Association, (*'Therapeutic Uses of Cannabis'*, Academic Publishers, Amsterdam, Netherlands, 1997, at page 78–9), and the US National Institute of Medicine (*'Marijuana and Medicine'*, National Academy Press, Washington. D.C., U.S.A., 1999, Executive Summary, page 10) have reviewed the clinical literature on the use of medicinal cannabis in the treatment of a range of serious medical conditions and have endorsed its use with some or all of the following conditions:- palliative care, severe AIDS-related wasting, multiple sclerosis / muscle spasticity, Crohn's Disease, chronic pain, chronic nausea / vertigo, seizures.

**Question 1:** Before hearing that information, which of those conditions were you aware could be treated with medicinal cannabis?

[TICK BOXES FOR Q1]

Comments: .....  
 .....

**Question 2:** Regarding the conditions just mentioned, can you estimate approximately how many patients you saw with each of those conditions in your practice in 2004?

[WRITE IN NUMBER IN Q2 BOXES]

Comments: .....  
 .....

(YNM)	Q1 (tick)	Q2 (Nos.)	Q3
Palliative care-----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severe AIDS-related wasting -----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Multiple Sclerosis/ muscle spasticity -----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crohn's Disease -----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chronic pain -----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chronic nausea/vertigo -----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Seizures-----	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Question 3:** If the use of medicinal cannabis for the treatment of each of those conditions was legal, professionally supported and backed by research, might you consider prescribing it?

Yes                  No                  Maybe                  Don't know

Comments: .....  
 .....

**Question 4:** Would you approve or disapprove of clinical trials of medicinal cannabis for treating any of the conditions listed above being conducted in government sponsored research?

I would approve          I would disapprove          I am undecided

Other (please write in) .....

Comments: .....  
 .....

[READ SHOWCARD 2]

### Hypothetical Medicinal Cannabis Regulatory Scheme

A possible trial scheme for the regulation of medicinal cannabis prescription could operate by the NSW Government legislating to place medicinal cannabis into Schedule 8 of the *Poisons and Therapeutic Goods Act*. This would enable GP's wishing to prescribe medicinal cannabis to apply to the Pharmaceutical Services Branch of the Department of Health for approval to prescribe medicinal cannabis on a case by case basis, as they already do for opioids. Whilst this decision would be made by the PSB, the Branch would provide GP's with appropriate clinical support to guide them in deciding whether an application to the PSB would be appropriate in a given case. If the PSB gave approval, the GP would write a script for medicinal cannabis which the patient would have filled by a pharmacist.

**Question 5:** If clinical trials of medicinal cannabis were successful, would you participate in a trial scheme like that described on the card, by applying to prescribe medicinal cannabis to suitable patients?

Yes                      No                      Don't know

Depends (please write in dependent conditions) .....

.....

Comments: .....

.....

## APPENDIX 2

# SCHEDULING SATIVEX

As discussed in Chapter 1.1, on 12<sup>th</sup> March 2009 I became the only person in Australia to be granted the legal right to import Sativex from Britain for my medical conditions.

However this decision was only an exception to the rule that all goods imported to Australia must first be listed in the Australian Register of Therapeutic Goods (ARTG). This exemption comes under the provisions of the Special Access Scheme pursuant to s. 18 of the *Therapeutic Goods Act 1989 (Cth) (TGA)* to the TGA for registration in the ARTG.

This permission to import a cannabis-based medicine appears to contradict advice given by the regulatory authority four years ago when they advised me, ‘unless the amendment is made to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDPP), Sativex would be cannabis.’<sup>1</sup>

If this is correct then it is arguable that if I can be granted access to one drug in a particular Schedule, then I should be granted access to another drug in that Schedule – raw cannabis. However such an application would probably be denied on the ground that cannabis is more likely to be abused than Sativex.

Putting aside these exceptions, in order to import Sativex from Britain it will be necessary to make an application under s 23 *TGA*. So, drawing upon the findings in Chapter 2(a) on efficacy and the data on the overseas experience of Sativex, the remainder of this sub-chapter is devoted to making a draft application on the appropriate form to the National Drug and Poison Schedule Committee (NDPSC) for Sativex to be classified as a Schedule 4 drug. Although most applicants are pharmaceutical companies the *TGA* does not state who has standing to apply.

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<sup>1</sup> Dr Jonathon Rankin TGA Head, Experimental Drugs Section, email 7 February 2005 to Graham Irvine.

I believe that, in the same way that I had standing to appeal the agency's initial decision on the ground that I was the person directly affected by that decision, so I should be eligible to apply on the basis that I will be the end user if the application is successful.

The *Therapeutic Goods Act 1989* (Cth) at section 52(e) specifies the nine criteria used by the Committee to determine the most appropriate Schedule for an application for scheduling as:

- (a) the toxicity and safety of a substance;
- (b) the risks and benefits associated with the use of a substance;
- (c) the potential hazards associated with the use of a substance;
- (d) the extent and patterns of use of a substance;
- (e) the dosage and formulation of the substance;
- (f) the need for access to a substance, taking in to account its toxicity compared with other substances available for a similar purpose;
- (g) the potential for abuse of a substance;
- (h) the purposes for which a substance is to be used;
- (i) any other matters that the Committee considers necessary to protect public health, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use and may take into account the labelling, packaging and presentation of a substance.

What follows here is a formal proposal to schedule Sativex as a Class 4 substance under the provisions of the Committee's Guidelines and the presentation of evidence drawn largely from the Sativex Product Monograph which addresses each of the criteria above in relation to Sativex, using the headings and format of the Application for Scheduling Form.<sup>2</sup>

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<sup>2</sup> *Sativex Product Monograph* GW Pharma Ltd, Salisbury, Wiltshire, UK, Submission No. 091289, 13 April 2005, at 32.

SATIVEX  
Scheduling Application

21 October 2009

Graham Oliver Irvine 199 Falls Road, Nimbin NSW 2480

**Applicants Details**

1	<b>Applicant's name</b>	Graham Oliver Irvine
2	<b>Business name (if applicable)</b>	
3	<b>Date of submission</b>	21 October 2009
4	<b>Contact person for this application</b>	Graham Oliver Irvine
5	<b>E-mail Address</b>	girvine@scu.edu.au
6	<b>Phone Number</b>	0266 891 666
7	<b>Fax Number</b>	–
8	<b>Suggested pre-meeting gazette notice wording</b>	
9	<b>Is commercial-in-confidence data identified?</b>	NO
10	<b>Is a justification of information to be considered commercial-in-confidence included?</b>	NO

**Declaration**

I, Graham Oliver Irvine declare that

the information provided in this application is true and current;  
and should I receive notice of the outcome or decision from the NDPSC's consideration of this issue, prior to the release of the NDPSC's Record of Reasons, such information is confidential and **not for public disclosure until the Record of Reasons has been released.**

{Electronic signature or scanned copy of signed page}

Name: Graham Oliver Irvine

Date: 23 October 2009

**PART A – SUMMARY OF THE APPLICATION****PROPOSED SCHEDULING / RESCHEDULING CHANGE**

I, Graham Oliver Irvine, as an interested party, being a potential end user of Sativex hereby request its scheduling.

Suggested Scheduling Wording

**SCHEDULE 4 – PROPOSED NEW ENTRY**

Sativex is indicated as an adjunctive treatment for the symptomatic relief of neuropathic pain in preparations for sub-lingual and buccal use of 27 mg/ml (from Tetrabinex – cannabis sativa. extract) and cannabidiol 25mg/ml (from Nabidiole – cannabis sativa L) extract

**OVERVIEW****(a) Purpose**

The purpose of this application is to obtain the listing of Sativex in Schedule 4 of the Classification of Medicines and Poisons so that it is available by prescription for use by a significant group of patients subject to severe and /or chronic pain..

**(b) Major Points**

- Approved in United Kingdom, Canada, New Zealand
- is a drug of last resort for a significant cohort of patients
- is unlikely to be abused
- no clear evidence of dependence or tolerance
- very low acute toxicity suggests a likely good margin of safety
- extremely high lethal dose

**(c) Proposals arising from major points**

It is proposed that Sativex be categorised under Schedule 4 and made available on prescription for pain relief in patients with severe illnesses.

**(d) Summary of Data**

In general the scientific evidence indicates a very low acute toxicity and a very high lethal dose which suggest a likely good margin of safety in humans. The clinical data demonstrate the efficacy of Sativex in relieving pain across a range of conditions.

## **PART B – BODY OF THE APPLICATION**

### **BACKGROUND**

1. Sativex has been approved by the appropriate regulatory bodies in the United Kingdom and Canada in 2005. Since this approval, further scientific studies have confirmed not only its efficacy as an analgesic and as a treatment for insomnia for multiple sclerosis and cancer patients but also for appetite stimulation in patients with HIV/AIDS.
2. Raw cannabis has been used for thousands of years for the same or similar conditions to those listed above. However the medical risks of smoking raw cannabis; the variability of potency and of its constituents and the possibility of its leakage onto the recreational market render the raw herb unsuitable for listing as a scheduled drug.
3. However Sativex is a pure standardised pharmaceutical product which successfully overcomes these problems. While Sativex is not currently scheduled, another cannabis-based pharmaceutical is already scheduled 4 – Dronabinol, marketed as Marinol.
4. Quantitative survey research, both in Australia and overseas indicates a potentially significant cohort of seriously ill patients, (who have unsuccessfully tried a range of presently available medications), would greatly benefit from Sativex.

### **CHEMICAL PROPERTIES OF THE SUBSTANCE**

#### **PHYSIOCHEMICAL PROPERTIES**

Tetranabinex®, (THC BDS) is brown, viscous and semi-solid with an absence of immiscible liquid. It has a characteristic smell of decarboxylated cannabis. It typically contains not less than 64% THC while the remainder consists of co-extracted plant extract.

It is soluble in Methanol, Ethanol, Acetone, Dichloromethane and is insoluble in water.

The CBD BDS (Nabidiolex®) is also brown, viscous and semi-solid with an absence of immiscible liquid. It has a characteristic odour of decarboxylated cannabis. Typically it contains not less than 60% CBD with the remainder comprising co-extracted plant extract.

It is soluble in Methanol, Ethanol, Acetone and Dichloromethane and is insoluble in water.

## PHARMACOLOGY

- (1) *Pharmacokinetics*: see Sativex Product Monograph (SPM) p 33.
- (2) *Pharmacodynamics*: see SPM p 34–35

### **Onset of Action (PK/PD Relationships)**

The pharmacokinetic studies have shown that following buccal administration of SATIVEX®, THC, CBD and 11-OH-THC appear in the plasma almost simultaneously from about 30 minutes post-dose although there is wide inter-subject variability.

- (3) *Indications and dosing*: Sativex® indications include:
  - nausea, anorexia and wasting (cachexia) associated with cancer and AIDS;
  - chronic pain (including cancer pain) for which other analgesics are ineffective, or have significant/severe adverse side-effects;
  - neuropathic pain ( when associated with conditions including multiple-sclerosis, stroke, cancer, spinal cord injury, severe physical trauma and peripheral neuropathy resulting from diabetes);
  - muscle spasm and spasticity associated with MS or spinal cord injury

*Individualisation of dose*: The pharmacologic effects of Sativex® are dose-related and subject to considerable variability among patients. Absorption from a buccal spray is similar to inhalation of smoked cannabis and the intensity of the effect using this route of administration is greater than an equal dose taken orally.

The Sativex® Product monograph recommends that dosing for MS should begin at a maximum rate of one spray every four hours on the first day, up to a maximum of four sprays on the first day. On subsequent days, the patient may need to gradually increase the total number of sprays. As such dosing is self-limiting, individual response and side effects will determine an upper-limit. During initial titration, doses should be evenly spread out over the day. If unacceptable adverse reactions such as dizziness or other intoxication type reactions occur then dosage should be reduced and potentially tapered off or stopped.

Dose selection for an elderly patient should be cautiously conducted starting at the low end of the dosing range. This low dose should reflect the greater frequency of decreased hepatic, renal and cardiac function and the incidence of concomitant disease, an increased body fat content, and the probability of poly-pharmacy in this population.

Some of the psychological effects experienced by patients include dysphoria and anxiety and a dependence potential. These can be minimised through preparation, explanation and reassurance given before the start of the treatment and should particularly be considered when administered in a palliative setting.

**See also SPM pp 21–23.**

(4) *Contraindications:*

SATIVEX® is contraindicated in:

- patients known or suspected to be allergic to cannabinoids, propylene glycol, ethanol or peppermint oil;
- patients with significant hepatic or renal impairment;
- patients with serious cardiovascular disease, such as ischaemic heart disease, arrhythmias, poorly controlled hypertension or severe heart failure;
- patients who have a history of schizophrenia or other psychotic disorder;
- children under 18 years of age;
- women of child-bearing potential who are not on a reliable contraceptive or men intending to start a family (see ‘Use in Women of Child-Bearing Potential’);
- pregnant or nursing women (see ‘Use in Women of Child-Bearing Potential’).

(5) *Precautions and serious warnings:* **See SPM pp 7–10**

(6) *Adverse reactions:*

The following data summarise the adverse events reported in clinical trials conducted by the manufacturers of Sativex, GW Pharma. In all placebo-controlled trials the level of severity of the events reported was usually mild to moderate. The discontinuation rate of patients taking Sativex was 10.7% compared with 3.2% for those on placebo. Due to patients’ self-titration they are likely to experience adverse effects until they reach the

optimal dose. The great majority of adverse events were resolved without treatment or by reducing the dose.

Adverse events at the application site which affect 20% of patients include ulceration, glossodynia, pain and dysgeusia. Most application site effects were confined to mild to moderate stinging at application times. Mouth ulcers were reported in 1.8% of patients on Sativex and 1.4% on placebo. Patients experiencing application adverse site events are advised to vary the application site and should not continue to spray on the affected site.

The principal active components in SATIVEX® are THC and CBD. THC has complex effects on the central nervous system, some of which are called ‘intoxication type reactions’. These may result in changes of mood, decrease in cognitive performance, memory, decrease in ability to control drives and impulses, and alteration of the perception of reality, particularly altered time sense. Fainting episodes have been observed with the use of SATIVEX®. ‘Intoxication type reactions’ appear to be dose-related, increasing in frequency with higher dosages, and subject to great inter-patient variability. They usually remit on reduction of doses, increasing the interval between doses or interruption of SATIVEX®.

Because of the potential of THC to alter the mental state, SATIVEX® should be used only as indicated and prescriptions should be limited to the amount necessary for the period between clinic visits.

Drug administration should be discontinued in patients experiencing a psychotic reaction and the patient should be closely observed in an appropriate setting until his/her mental state returns to normal. Patients should be warned not to drive or engage in activities requiring unimpaired judgment and coordination.

Cannabinoids have cardiovascular effects that include tachycardia, and transient changes in blood pressure, including episodes of postural hypotension. Use of SATIVEX® is not recommended in patients with pre-existing cardiovascular disease, such as ischemic heart disease, arrhythmias, poorly controlled hypertension or severe heart failure. **See also SPM pp 12–20.**

## DETAILED CLAIMS AGAINST SCHEDULING CRITERIA

### (a) Toxicity and safety of the substance

Overall, the toxicological data suggest that both THC and CBD have very low acute toxicity after single doses, suggesting a likely good margin of safety for SATIVEX® in humans. There is some evidence, from repeat dose studies, for cumulative toxicity for THC in rodents which may be due to metabolic overload. Both THC and CBD appear to have similar pharmacotoxicological profiles in laboratory species, although at dose levels up to 300 mg/kg/day in repeat-dosing studies, in rats and monkeys, CBD produced no evidence to suggest significant effects on behaviour or on CNS function generally. Both THC and CBD reduced the weight of sex organs, an effect that is more pronounced for THC and which appears to be due to change in the functional status of the organs probably mediated via inhibitory effects on the release of sex hormones. These effects are reversible for both compounds. Both compounds caused increases in weight of the liver and adrenal glands but these effects are not associated with any histopathological changes. At the maximum dosage levels used in humans of about 2 mg/kg/day for each, it is considered that SATIVEX® is unlikely to produce any significant target organ toxicity in humans. However, detrimental effects on reproductive function cannot be ruled out at this dosage level.

Acute studies – Administration site skin irritation occurred in almost one quarter of patients in a short term use trial but this incidence reduced to 6.6%, compared with placebo 6.8 for ‘oral pain’ and 3% compared with 0.6 % for mouth ulceration. Reproductive studies – Both THC and CBD have been demonstrated to reduce the weights of reproductive organs, including uterus and testes in repeat dosing studies and functional effects such as increased oestrus cycle lengths and inhibitory effects on spermatogenesis have also been reported. Moreover the use of cannabinoids or cannabis extracts during pregnancy has been reported in a few animal studies to produce adverse effects on the number and weight of offspring and of their survival. However as full dose response curves for individual cannabinoids have not yet been published, it is impossible to predict the likely safe dosage levels in pregnant women.

*Genotoxicity and carcinogenicity*

A number of tests to evaluate genotoxic potential have been performed using THC and CBD individually and administered together. Although data on the genotoxic potential of THC and CBD have shown ambiguity in some studies, the risk of THC and CBD in causing genotoxicity in humans in vivo is estimated to be low.

THC has been fully evaluated for carcinogenic potential by well-documented and reported 2-year studies in mice and rats (NTP, 1996).

The results obtained in both species were generally consistent in terms of clinical signs, body weight changes and incidences of non-neoplastic and neoplastic lesions. The results obtained in rats were clearly negative whilst in mice a non-dosage related increase in thyroid follicular cell tumours was seen at a single dosage level (125 mg/kg/day, which is 100 times the highest tested dose in humans, on a mg/kg basis). This effect is considered to be of doubtful toxicological significance in view of the lack of a dose-response relationship and the lack of evidence to suggest that hyperplasia of thyroid follicular cells progressed to adenomas or carcinomas. This evidence, taken together with the lack of structural relationship of THC to any known carcinogen and to its negative responses in most genotoxicity tests, suggests that it is likely to have a very low carcinogenic potential in humans. Positive carcinogenic effects reported for THC after subcutaneous administration in mice are considered of doubtful scientific validity since the results have not been published in full or confirmed by other workers.

CBD, like THC, is not structurally related to known carcinogens, has produced predominantly negative results in genotoxicity tests and has a spectrum of pharmaco-toxicological activity similar to, but generally weaker than, THC. Although data on THC's and CBD's genotoxic potential have shown some ambiguity, the risk that they cause genotoxicity in humans in vivo is considered quite low. Together with the lack of structural relationship of THC to any known carcinogen and to its negative response to most genotoxicity tests and thus it is considered likely to have a low carcinogenic potential in humans.

*Reproductive and developmental toxicity*

Although formal animal reproduction tests with SATIVEX® have not been performed, there exists sufficient published information on the effects of THC, CBD and cannabis extracts on

reproductive function to allow an assessment of the potential effects of SATIVEX® on human reproductive function. Both THC and CBD have been demonstrated to reduce the weights of reproductive organs, including uterus and testes, in repeat-dosing studies. Functional effects such as increased oestrous cycle lengths and inhibitory effects on spermatogenesis have also been reported for both compounds and for cannabis extracts. These effects of cannabinoids appear to be mediated predominantly via effects on the hypothalamus and/or pituitary which result in reduced circulating levels of sex-related hormones including testosterone, progesterone, LH, FSH and prolactin.

Administration of cannabinoids or cannabis extracts during pregnancy has been reported, in several studies, to produce adverse effects in terms of number and weight of offspring and of their survival. Although these effects appear to be dosage-related, full dose-response curves for individual cannabinoids or for cannabis extracts have not been reported and it is therefore impossible to predict likely safe dosage levels in humans.

There is some evidence which suggests that cannabinoids, particularly THC, may exert adverse effects on reproductive function at relatively low dosage levels. For example, Park et al. (1983)<sup>1</sup> reported that 1.25 mg subcutaneous of THC, administered three times weekly, disrupted the menstrual cycles of monkeys and in the study of Ayalon et al.<sup>2</sup> (1977), 2 mg/kg IP delayed ovulation and suppressed the rise in sex hormone levels in pre-oestrous rats.

Although treatment with THC has been associated with increased embryo-foetal mortality in several species, only in some mouse studies at relatively high dosage levels, have teratogenic effects been reported. THC is non-teratogenic in rats and rabbits and probably also in Rhesus monkeys.

Possibly the most significant adverse reproductive effects of THC reported are alterations in foetal sexual and behavioural development induced by administration of dosage levels as low as 1 µg/kg to either pregnant rats or sexually immature offspring. These effects suggest that long-term adverse effects may occur in offspring of mothers exposed during pregnancy or during the nursing period to low doses of cannabinoids. Although fewer data are available for CBD, the results suggest that it is likely to produce similar effects to THC on embryo-foetal

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<sup>1</sup> B Park et al, 'Identification of the CB1 Cannabinoid Receptor and Fatty Acid Amide Hydrolase (FAAH) in the Human Placenta' *Placenta*, 24, 10 189.

development but to be somewhat less potent. Based on these data, and in the absence of completed animal tests with SATIVEX®, it would clearly be inadvisable to use the preparation in human females either during pregnancy or nursing. Adequate contraceptive precautions should also be taken in all females of child-bearing potential treated with SATIVEX® and the preparation is unsuitable for use in pre-pubertal children.

## **(b) Risks and benefits**

### **Complicating factors**

Several factors make it difficult to assess the many scientific studies of medicinal cannabis and thus to assess its efficacy in treating different medical conditions.

Firstly, the results of tests of efficacy vary widely according to whether smoked or other delivery systems of cannabis ingestion are used. There is already a scientific consensus that the many substances in smoked cannabis produce a synergistic effect that does not occur when synthetic cannabis formulations are employed.<sup>3</sup> This sometimes results in findings where smoked cannabis is efficacious for certain conditions while the synthetics are not or are less so. Furthermore, different results have been reported due to the use of different synthetics, eg nabilone and dronabinol (Marinol).

Secondly, placebo studies with smoked cannabis are problematic especially with experienced cannabis smokers who can readily detect placebo ‘joints’ due to the lack of the characteristic smell and taste of combusted cannabis.<sup>4</sup>

Thirdly, dosage rates, especially with test animals, are extremely variable and can be associated with aberrant results especially since several studies have found that the therapeutic dose of medicinal cannabis is quite specific within a narrow range – that is too much or too little can eliminate its effects, as can including or excluding ingredients. For example Table 4 in the recent review of ben Amar<sup>5</sup> lists one study of the efficacy of oral THC

<sup>2</sup> D Ayalon et al ‘Effect of delta THC...’ (1977) 23 (1) *Neuroendocrinology* 31.

<sup>3</sup> M Eddy, ‘Medical Marijuana: Review and Analysis of Federal and State Policies’, Congressional Research Service, Library of Congress, CRS Report for Congress, 29 December 2005, 22 and see L Grinspoon, Opinion: Marijuana as Wonder Drug *Boston Globe*, 1<sup>st</sup> March 2007  
<<http://www.mpp.org/site/apps/nl/content2.ap?c=g1KZLeMOIsG&I=1847069&ct=361>> (20 June 2007).

<sup>4</sup> M ben Amar, ‘Cannabinoids in medicine: A review of their therapeutic potential’ (2006) 105 *Journal of Ethnopharmacology* 1\_25 and L Iversen, ‘The Science of Marijuana’ (2000) OUP NY Table 4, 14–18.

<sup>5</sup> M ben Amar, ‘Cannabinoids in medicine: A review of their therapeutic potential’ (2006) 105 *Journal of Ethnopharmacology* 1–25 and L Iversen, *The Science of Marijuana* (2000) OUP NY 144.

with 20% CBD which found ‘no benefits on spasticity’<sup>6</sup> whereas another study in Table 4, using THC with 50% CBD reported, ‘Statistically significant reductions in spasticity.’<sup>7</sup> Similarly, a study by Vaney et al,<sup>8</sup> using 2.5 mg THC and 0.0 mg CBD found, ‘no beneficial effects of cannabinoid extracts on spasticity while Wade et al<sup>9</sup> in a 2004 study using 2.7mg THC and 22.5 CBD reported a, ‘statistically significant reduction in spasticity.’<sup>10</sup> This is backed up by a more recent study which claimed that, ‘the combination of cannabinoid and non-cannabinoid compounds, as present in [plant-derived] extracts provide significant advantages in the relief of neuropathic pain compared with pure cannabinoids alone.’<sup>11</sup> Lately, in studying the effects of medicinal cannabis on insomnia, the researchers found that a dose of 15mg THC was sedative whereas 15mg CBD increased waking activity.<sup>12</sup>

Fourthly, ‘Cannabinoids can exert opposite actions at the cellular level and at the level of the circuitry within a nucleus or in between nuclei. They inhibit or excite neurons and oppose excitatory and inhibitory input transmission within the same nucleus ... Similar complexity in actions is observed after systemic administration of cannabinoids where relatively low doses enhance motor output while relatively high doses inhibit movement and furthermore induce catalepsy.’<sup>13</sup>

Fifthly, a significant factor impeding large-scale clinical studies in the United States is the obstructionism of Federal Government agencies which still threaten, raid, arrest and prosecute medicinal cannabis users. The result is that it is extremely difficult for researchers there to obtain large enough sample populations of medicinal cannabis users for effective testing of medicinal cannabis’ efficacy. The American Federal Government’s hypocrisy is demonstrated by its claims that there are not sufficient epidemiological studies to justify legalising

<sup>6</sup> Killestein et al, ‘Safety, tolerability and efficacy of naturally administered cannabuinoids in multiple sclerosis’ (2002) 58 *Neurology* 1404–1407.

<sup>7</sup> D R Wade et al, ‘A preliminary controlled study to determine whether whole -plant cannabis exrtracts can improve intractable neurogenic pain’ (2003) 17 *Clinical Rehabilitation* 21–29.

<sup>8</sup> C Vaney et al, ‘Efficacy, safety and tolerability of an orally administered cannabis extract in the treatment of spasticity in patients with multiple sclerosis’ (2004) 10 *Multiple Sclerosis* 417–424.

<sup>9</sup> D R Wade et al, ‘Do cannabis-based medicinal extracts have general or specific effects on symptoms of spasticity in multiple sclerosis?’ (2004) 10 *Multiple Sclerosis* 424–441.

<sup>10</sup> Wade et al, n 6, 440.

<sup>11</sup> P Comelli et al, ‘Anti hyperanalgesic effect of a cannabis sativa extract in a rat model of neuropathic pain’ (2007) 22 *Phytotherapy Research* 1017–1924 at 1022.

<sup>12</sup> P Nicholson et al, ‘Delta9 Tetrahydrocannabinoid and cannabidiol on nocturnal sleep and early morning behaviour in young adults’ (2007) 24 *Journal of Clinical Psychopharmacology* 305–314 at 313.

<sup>13</sup> M C Sanudo-Pena and E Fride, ‘Marijuana and Movement Disorders’ in E S Onaivi (ed), *The biology of marijuana New York* (2002) Taylor & Francis, 205.

medicinal cannabis.<sup>14</sup> For many years this government refused all applications to conduct the very research which could provide evidence of the efficacy of cannabis which they claimed was lacking.

Although the United States' Drug War czar General Barry McCaffery stated in August 1996 that, 'There is not a shred of scientific evidence that shows that smoked marijuana is either useful or needed.'<sup>15</sup> and while the Drug Enforcement Administration (DEA) continues to claim that, 'Marijuana has no medical value that cannot be met more effectively by legal drugs',<sup>16</sup> its own Independent New Drug (IND) Compassionate Access Program, which has provided low-grade government-supplied medical marijuana to a select group of patients since 1978, 'would seem to affirm that marijuana has medical value and can be used safely.'<sup>17</sup> A thorough going and rigorous health study of four of the seven remaining 1978 IND patients concluded, inter alia, '1. Smoking, even of a crude, low-grade product, provides effective symptomatic relief of pain, muscular spasms and intraocular pressure elevations in selected patients failing other modes of treatment; 2. These clinical cannabis patients are able to reduce or eliminate other prescription medicines and their accompanying side effects. 3. Clinical cannabis provides an improved quality of life in these patients. ...'.<sup>18</sup>

Sixthly, and related to the fifth point is the oscillating presentation of evidence in the scientific literature, such that, 'An initial apparently damning report was followed by a great deal of research that largely failed to support the initial claims.'<sup>19</sup> This can be demonstrated in relation to the issue of the role of cannabis, (in this case smoked cannabis), in the pathology of adolescent schizophrenia. Initial reports drew mixed conclusions, such as, 'cannabis use is associated with an increased risk of developing schizophrenia, consistent with a causal relation'<sup>20</sup> compared with another study which found that, 'There is no evidence that cannabis is a causal factor in schizophrenia.'<sup>21</sup> By 2005 the journal *Psychiatric Research* reported that,

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<sup>14</sup> US Department of Justice, Drug Enforcement Administration, 'Marijuana Scheduling Petition', 57 Federal Register 10499, n 26 March 1992, 10506.

<sup>15</sup> Cited in Iversen, n 6, ix.

<sup>16</sup> Drug Enforcement Administration *Exposing the myth of medical marijuana: the facts* <<http://www.us.doj.gov/dea/ongoing/marijuanap.html>> (accessed 2<sup>nd</sup> June 2006).

<sup>17</sup> E Russo et al, 'Chronic Cannabis Usage in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis' (2005) 2(1) *Journal of Cannabis Therapeutics* 51.

<sup>18</sup> Ibid.

<sup>19</sup> Iversen, n 2, 68.

<sup>20</sup> S Zammit and P Allebek (2002) 325 *British Medical Journal* 23<sup>rd</sup> November 1199.

<sup>21</sup> A Johns, 'Psychiatric Effects of Cannabis' (2001) *British Journal of Psychiatry* February 119.

‘the onset of schizotypal symptoms generally precedes the onset of cannabis use. The findings do not support a link between cannabis use and schizotypal traits.’<sup>22</sup>

**(c) The current state of evidence of the efficacy of medicinal cannabis**

Until recently it could fairly be claimed that there was not sufficient hard evidence to justify policy-makers to responsibly legalise medicinal cannabis.

However in the last twenty years there has been what one scientist has called an ‘explosion of scientific information on cannabis.’<sup>23</sup> He speaks of ‘thousands of researchers moving into the cannabinoid field ... and hundreds of presentations on cannabis every year’ and claims ‘There is no reason to believe that the increase in scientific interest in cannabis will level off in the coming decade.’<sup>24</sup>

Nevertheless the value of cannabis as a medicine is still disputed. Whilst a major review by Zimmer and Morgan concluded that, ‘marijuana’s therapeutic uses are well-documented in the modern scientific literature’<sup>25</sup> another contemporaneous study claimed that, ‘The medicinal properties of cannabis are still mainly delineated by the anecdotal reports of those who believe their symptoms are relieved by its use and these accounts are often dismissed as wishful thinking or even mischievous.’<sup>26</sup>

However it is submitted that no longer are the medicinal properties of cannabis ‘still only delineated by.... anecdotal reports...’ But in an expansive survey the United States lobby group Medical Marijuana ProCon’s publication<sup>27</sup> examined 29 studies divided into double blind human studies, other human studies and animal studies, assessing these as either pro cannabis or anti cannabis. Among the double blind papers 46.7% were pro cannabis: 40% were neutral and 13.3% con. In the other human studies, the respective percentages were 42.9% pro: 35.7% neutral and 21.4% con. The animal studies showed 100% pro. The overall percentages across all the studies were 47.6% pro: 34.4% neutral and 18% con. While

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<sup>22</sup> J Schiffman et al, ‘Symptoms of schizotypy precede cannabis use’ (2005) 134 (1) *Psychiatric Research* 37, 42.

<sup>23</sup> P Smith, *Cannabis on the Brain* (2002) Dunmore Press, Palmerston North, New Zealand, 9.

<sup>24</sup> Smith, n 28, 23.

<sup>25</sup> L Zimmer and J P Morgan, *Marijuana Myths, Marijuana Facts* (2002) Lindesmith Center, New York, 127.

<sup>26</sup> Smith, n 25.

<sup>27</sup> Medical Marijuana ProCon.org *Peer-Reviewed Scientific Studies involving cannabis and cannabis extracts 1990 –2008* <<http://medicalmarijuana.procon.org/viewresource.asp?resourceID=884>> (accessed 19 January 2010).

their assessments may be questioned as to the rating criteria used, the general trend of the studies was clearly substantially more favourable to a pro cannabis position than to a neutral or negative stance.<sup>28</sup> Since that study there have been several large collections of articles in books edited by Onaivi,<sup>29</sup> Grotenhermen<sup>30</sup> and Guy et al<sup>31</sup> and a comprehensive review by Walker et al<sup>32</sup> all of which are favourable to cannabinoid treatment.

Adopting, for the sake of this exercise, the medical conditions and symptoms recommended by the NSW Working Party on the Use of Cannabis for Medical Purposes as being effectively treated with medicinal cannabis, the scientific evidence for its efficacy can be noted here.

### Chronic pain

As reported in Chapter 7(c) regarding the co-optation of scientific research, the conclusions drawn from the two exhaustive reviews of the literature on the analgesic properties of medicinal cannabis were highly favourable as to its efficacy. Walker et al found that ‘...synthetic cannabinoids are equal to morphine in potency and efficacy....[and have] high efficacy....in models of chronic pain’.<sup>33</sup> Similarly Vaughan and Christie concluded that, ‘cannabinoids warrant urgent study as therapeutic agents.’<sup>34</sup> Two comprehensive review articles in 2006 both endorsed the value of medicinal cannabis as an analgesic,<sup>35</sup> the former quoting Blake et al<sup>36</sup> that, ‘Sativex produced statistically significant improvements in pain on movement, pain at rest, quality of sleep and disease activities.’ The latter concluded, ‘to the extent that pain and inflammation accompany many of the disorders discussed in the rest of

<sup>28</sup> Medical Marijuana ProCon ibid at 1.

<sup>29</sup> E S Onaivi et al (eds), *Endocannabinoids: the brain and body's marijuana* (2005) CRC Press, London, United Kingdom and E S Onaivi (ed), *Marijuana and Cannabinoid Research: Methods and Protocols* (2006) Inc Net Library, Boulder, Colorado USA.

<sup>30</sup> F Grotenhermen and E Russo (eds), *Cannabis and Cannabinoids: Pharmacology, Toxicology and Therapeutic Potential* (2005) Haworth Press, Philadelphia USA.

<sup>31</sup> G F Guy et al, *The medical uses of cannabis and cannabinoids* (2004) Pharmaceutical Press, London UK.

<sup>32</sup> J M Walker et al, *Pain modulation by the release of the endogenous cannabinoid anandamide* (1999) 96 *Proceedings of the National Academy of Sciences (USA)* 12198–12203.

<sup>33</sup> J M Walker et al, ‘Pain modulation by the release of the endogenous cannabinoid anandamide’ (1999) 96 *Proceedings of the National Academy of Sciences (USA)* 12198–12203 and see J M Walker and S M Huang ‘Cannabinoid analgesia’ (2000) 95(2) *Pharmacology and Therapeutics* 127–135.

<sup>34</sup> C W Vaughan and J C Macdonald, ‘Mechanisms of cannabinoid analgesia’, Ch 5 in Grotenhermen and Russo, n 20.

<sup>35</sup> P Pacher et al, ‘The endocannabinoid system as an emerging target of pharmacotherapy’ 58 *Pharmacology Review* 389–462 at 405–407 and M Ben Amar ‘Cannabinoids in medicine: a review of their therapeutic potential’ (2006) 105 *Journal of Ethnopharmacology* 1–25 at 9–11.

<sup>36</sup> D R Blake et al, ‘Preliminary assessment of the efficacy, tolerability and safety of a cannabis-based medicine (Sativex) in the treatment of pain caused by rheumatoid arthritis’ (2006) 45(1) *Rheumatology* 50–52 at 51.

this review cannabinoids would be expected to provide significant benefits due to their analgesic and anti-inflammatory properties.’<sup>37</sup>

A series of clinical trials run by GW Pharma and others demonstrated the superior efficacy of Sativex in treating neuropathic pain, concluding that, ‘these early studies have involved significant numbers of patients and their results have been positive with regard to relief of spasticity and pain.’<sup>38</sup> This was backed up by another specialist’s conclusion that, ‘these early studies have involved significant numbers of patients and the results have been positive with regard to relief from spasticity and relief of pain.’<sup>39</sup>

Finally a review of 134 studies in late 2006 led its author to conclude. ‘there is an overwhelming body of research... supported by a vast number of recent laboratory studies on animal and human models to demonstrate the increased tolerance of pain from administration of cannabis or individual cannabinoids including THC’.<sup>40</sup>

## Nausea

Nissar Darmani, a researcher who has contributed significantly to research into the use of cannabinoids in treating nausea sums up the dominant current scientific view that ‘significant evidence supports the selective use of ... cannabinoids for the treatment of nausea and vomiting in some patients treated with chemotherapy.’<sup>41</sup> He goes on to report, ‘a recent MEDLINE search yielded 194 titles on the anti-emetic properties of marijuana and cannabinoids. This list suggests that delta 9 THC is a useful anti-emetic for nausea and vomiting associated with cancer chemotherapy.’<sup>42</sup> Similarly, Robson states that ‘Cannabis and THC are very effective appetite stimulants.’<sup>43</sup>

<sup>37</sup> Pacher et al, n 37, 407.

<sup>38</sup> J Perez, ‘Combined cannabinoid therapy via an oromucosal spray’ (2006) 42(8) *Drugs of Today* 495–503, D T Wade et al, ‘Long term use of a cannabis based medicine in the treatment of spasticity and other symptoms in multiple sclerosis’ (2006) 12 *Multiple Sclerosis* 639–645, at 644.

<sup>39</sup> M P Barnes, ‘Sativex clinical efficacy and tolerability in the treatment of MS and neuropathic (2006) 7(5) *Expert Opinion on Pharmacotherapy* 607–615 at 614.

<sup>40</sup> M J Atha, *Cannabis and pain relief: a literature review* (2006) Independent Drug Monitoring Unit, London UK, Sept. <<http://www.idmu.co.uk/>> (accessed 19 January 2010).

<sup>41</sup> N A Darmani, *Anti-emetic action of deltahydrocannabinoid and synthetic cannabinoids in chemo-therapy induced nausea and vomiting*, Ch 5 in Onaivi, n 19 *Endocannabinoids*.

<sup>42</sup> Darmani *ibid* 3.

<sup>43</sup> P Robson, *Cannabis and RHC are effective appetite stimulants. Therapeutic aspects of cannabis and cannabinoids* (2001) 178 *British Journal of Psychiatry* 107–115 at 110.

In Ben Amar's compendious review of the therapeutic potential of medicinal cannabis and its synthetic analogues, he lists 31 studies of its use as an anti-emetic of which 29 were assessed as significantly superior to placebo or other drugs.<sup>44</sup> The other literature review in 2006 concluded that, 'THC has gained acceptance as a highly efficacious therapeutic agent, often effective in cases resistant to other more conventional medications.'<sup>45</sup>

### **Spasticity**

While there have been fewer studies of multiple sclerosis focussing on spasticity rather than neuropathic pain, by 2006 three teams of researchers were advocating cannabinoids for the treatment of spasticity. One stated, 'In conclusion, controlled clinical trials with cannabinoids have demonstrated their efficacy in eliciting symptomatic improvements in MS patients. These results suggest that there is place for the use of cannabis in the treatment of MS, which should be confirmed in further larger-scale clinical trials.'<sup>46</sup> The second study found '[t]here is a compelling neuropharmacological rationale to support the use of CBM [cannabis based medicines] in the relief of spasticity in multiple sclerosis with evidence from both human and animal studies.'<sup>47</sup>

The third study concluded that earlier trials had 'involved significant numbers of patients and the results have been positive with regard to the relief of spasticity and relief of pain.'<sup>48</sup>

### **Appetite and wasting**

Cancer and HIV/AIDS patients are prone to cachexia, wasting and loss of appetite. It is notorious among herbal recreational cannabis users that the herb stimulate appetite and hence it was to be expected that a 1986 study found that, '[s]moked marijuana can produce significant increases in food intake...'<sup>49</sup> Two more studies using THC, found that it stimulates appetite associated with cancer and HIV/AIDS.<sup>50</sup> More recent studies with THC have confirmed the earlier conclusions.<sup>51</sup> In a more recent literature review of seventy-two

<sup>44</sup> ben Amar, n 6.

<sup>45</sup> Pacher et al, n 37, 420.

<sup>46</sup> Pacher, n 37.

<sup>47</sup> C Collin et al, 'Randomised control trial of cannabis based medicines in spasticity caused by multiple sclerosis' (2007) 14 (3) *European Journal of Neurology* 290–296, at 296.

<sup>48</sup> Barnes, n 41.

<sup>49</sup> R W Foltin et al, 'Behavioural analysis of marijuana' (1986) 25 (3) 577, 585.

<sup>50</sup> L E Hollister, 'Hunger and appetite after single doses of marijuana, alcohol and dextroamphetamine' (1971) 12(1) *Clin Pharmacol Ther* Jan–Feb 44–49 and E Regelson et al, *The Pharmacology of Marihuana* (1976).

<sup>51</sup> See J E Beal et al, 'Dronabinol as a treatment for anorexia associated with weight loss in patients with AIDS (1995) 10(2) *J of Pain and Symptom Management* Feb 89–97.

controlled studies, the conclusion reached was that, ‘cannabinoids exhibit an interesting therapeutic potential as anti-emetics and appetite stimulants in debilitating diseases (cancer and AIDS), analgesia, as well as in the treatment of multiple sclerosis, spinal cord injuries, Tourette’s syndrome, epilepsy and glaucoma.’<sup>52</sup>

### Neurological disorders

This category of serious medical conditions includes Multiple Sclerosis, Motor Neuron Disease, Parkinson’s Disease and Tourette’s Syndrome and has been researched using Sativex and several of the synthetic cannabinoids. Recently Pacher et al,<sup>53</sup> in an extensive review of multiple sclerosis cited 24 studies of multiple sclerosis patients, 19 of which produced positive results. Two of these studies<sup>54</sup> employed Sativex and one used Cannador.<sup>55</sup> Two of those three, reported improvement in spasticity and pain. Plant-derived cannabinoids, in a series of clinical trials conducted by Muller – Vahl on Tourettes patients, were found to be effective in treating tics and behavioural problems.<sup>56</sup>

Another extensive review of 135 research studies concluded that ‘[S]ince 1998 scientific investigation of the effects and causes of cannabinoid action of multiple sclerosis has exploded with the vast majority of studies and reviews showing a potential therapeutic effect.’<sup>57</sup> It should be noted that multiple sclerosis is accepted by the United Kingdom, Canada and several United States states as a medical condition warranting the prescription of medicinal cannabis. The evidence of cannabinoid efficacy in the treatment of Parkinson’s Disease is as yet equivocal and is examined more fully in Chapter 1(a).

<sup>52</sup> P Smith, n 25, 12.

<sup>53</sup> Pacher, n 37.

<sup>54</sup> Killestein et al, ‘Cannabinoids in multiple sclerosis: urgent need for long term trials’ (2002) *Neurology* 58, 1404–1407 and D Wade et al (2003) 17(2) *Clin Rehabil* 21–29.

<sup>55</sup> J Zajicek et al, ‘Cannabinoids for treatment of spasticity and other symptoms relating to multiple sclerosis’ (2003) 362(9395) *The Lancet* 1517–1526.

<sup>56</sup> KR Muller-Vahl et al, ‘Gilles de la Tourette syndrome: Effect of nicotine, alcohol and marihuana on clinical symptoms’ (1997) 68(12) *Nervenarzt* Dec 985–989; Muller-Vahl et al, ‘Cannabinoids possible role in pathophysiology and therapy of Gilles de la Tourette syndrome’ (1998) 98(6) *Acta Psychiatrica Scandinavica* 502–506; K R Muller-Vahl et al, ‘Treatment of Tourettes syndrome with delta9tetrahydrocannabinol’ 35(2) *Pharmacopsychiatry* Mar, 57–61; K R Muller-Vahl et al, ‘Delta9tetrahydrocannabinol (THC) is effective in the treatment of tics in Tourette syndrome’ (2003) 64(4) *J of Clinl Psychiatry* 459–465; K R Muller-Vahl et al, ‘Treatment of Tourette’s syndrome with delta9tetrahydrocannabinol (delta9 THC): no influence on neuropsychological performance’ (2003) 28(2) *Neuropsychopharmacology* Feb 384–388.

<sup>57</sup> Atha, n 42 (unpaginated).

### The issues of tolerance and dependence

The mechanics of ascertaining tolerance and dependence are explored in some detail in Chapter 7(d). The concepts are raised here as they obviously relate to the efficacy of medicinal cannabis. In Chapter 6(b) I raise concerns that the interpretation of test results of tolerance and dependence may be distorted by the researchers' policy objective of persuading government to set up cannabis clinics to treat such 'dependent' cannabis users.

However even the most enthusiastic acolytes of the dependence hypothesis acknowledge that, 'it is uncertain whether the risk of dependence in regular recreational users can be applied to patients using cannabinoids for therapeutic reasons'.<sup>58</sup> As to tolerance they concede that 'some reports indicate that patients achieve stabilization of dose and persistence of therapeutic benefit.'<sup>59</sup>

Former concerns regarding the long term effects of the use of Sativex were allayed by the findings of Wade et al that, '[S]ativex can be used in the long term without tolerance or intoxication and with maintenance of subjective symptomatic relief.'<sup>60</sup>

More recently, several studies of the use in treatment of Sativex have failed to find significant tolerance or dependence among patient groups. In a long term study of 404 multiple sclerosis or chronic pain patients, '[p]atients treated for one year had sustained improvements in symptom scores,.....with no evidence of treatment tolerance.'<sup>61</sup> Although 46% of these patients exhibited some symptoms of withdrawal they did not meet the criteria which would warrant their characterization as withdrawing from cannabinoids.<sup>62</sup>

There is now available data on the long term effects of Sativex as recently several studies into the uses of Sativex have failed to find significant tolerance or dependence among patient groups.<sup>63</sup> 'The existence of a clear-cut physical dependence syndrome is much less

<sup>58</sup> W Swift and W Hall, 'Cannabis and dependence', Ch 23 in Grotenhermen and Russo n 20, 263.

<sup>59</sup> Ibid.

<sup>60</sup> D T Wade et al, 'Long term use of a cannabis based medicine in the treatment of spasticity and other symptoms in multiple sclerosis' (2006) 12 *Multiple Sclerosis* 639–645, at 644.

<sup>61</sup> Perez, n 24, 500.

<sup>62</sup> M Serpell et al, 'Sativex in the treatment of pain of neurological origins or symptoms of multiple sclerosis' (2005) 24<sup>th</sup> *Annual Sci Society Meeting*, Boston USA Abstract 722 and Serpell et al, 'Sativex for the treatment of pain of neurological origin or symptoms of multiple sclerosis', 8<sup>th</sup> *Congress of the European Federation of Neurological Science*, Paris, France Abstract 1431.

<sup>63</sup> A J Budney et al, 'Review of the validity and significance of cannabis withdrawal syndrome' (2004) 161 *American Journal of Psychiatry* 1967–1977; E Russo and P Robson, 'Abrupt interruption of long-term

convincing on the basis of the published literature. If it exists at all it is probably mild and fleeting ...’ (Guy, GW et al (eds)(2004) *The medical uses of cannabis and cannabinoids*, Pharmaceutical Press, Salisbury, UK, at 252).

In a long term study of 404 MS and chronic pain patients, ‘Patients treated for one year had sustained improvements in symptoms ... with no evidence of treatment tolerance.’ (Perez, J ‘Combined cannabinoid therapy via an oromucosal spray’, (2008) *Drugs of Today*, v 42(8), pp 495–503, at 500).

As to safety, ‘[c]annabis has an exceptional record of safety (Grinspoon, L and JB Bakalar, *Marihuana the forbidden medicine*,(1997) New Haven, Yale UP). It is virtually impossible to kill animals with acute doses and there are no substantiated deaths from ingestion of cannabis.’ (Guy et al, above at 450).

### **The different cannabis-based pharmaceuticals**

By one count, there are 27 different cannabis based different pharmaceuticals available around the world.<sup>64</sup> However in this thesis I have only advocated one – Sativex. This preference is based on an evidence based judgement that Sativex has proved superior in efficacy over the other brands.

The two earliest cannabis based medicines are Dronabinol marketed by Solvay Pharmaceuticals in the USA under the name Marinol and Nabilone produced by the United States’ Valeant Pharmaceuticals and marketed as Cesamet. While the medicines have had some success in the treatment of weight loss and anti emetics, and Marinol has shown some promise in some neurological conditions, in general their efficacy is low and their price high. The Los Angeles Cannabis Resource Center has estimated that the cost of one year’s treatment using Marinol would amount to \$US8,260.<sup>65</sup> Excessive cost is also the reason it is not widely prescribed in Australia.<sup>66</sup>

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treatment with Sativex was not associated with a withdrawal syndrome’, *XV Symposium on the Cannabinoids*, Clearwater 2005, Abst 45: E Russo, ‘Sativex and tolerance: Sativex cannabis-based medicine provides long-term clinical efficacy without dosage increases or withdrawal’, *American Public Health Association 133<sup>rd</sup> Annual Meeting and Exposition*, Philadelphia 2005 , Abst. 106317

<sup>64</sup> Pacher et al, n 37, 441.

<sup>65</sup> K Zwier and J Ahrens, (2005) 100(7) *Calvin College, Chimes*, Michigan  
<<http://www.cannabisnews.com/thread21214.shtml>> (accessed 6th October 2008).

Another North American synthetic cannabinoid – Cannador – which contains other cannabinoids has been trialled for the treatment of neurological disorders but without much success.<sup>67</sup>

Rimonabant is a cannabinoid receptor agonist used to treat obesity but its manufacturers were denied approval by the Food and Drug Administration to market in the United States due to neurological side effects.<sup>68</sup>

The results of comparative tests of other cannabinoid medicines show the consistent efficacy of Sativex over other cannabis-based pharmaceuticals,<sup>69</sup> in the treatment of a range of conditions. Both Russo et al<sup>70</sup> and McCarberg and Barkin<sup>71</sup> maintain that this is due to its different formulation in containing almost equal parts of THC and cannabidiol, the latter concluding that, ‘the interaction of THC with CBD appears to improve the risk/benefit profile of a THC-containing cannabinoid product.’<sup>72</sup>

But what distinguishes Sativex from these other products is its success in ongoing clinical trials and its unique formulation which balances the psychoactivity of delta 9 THC with the non-psychoactive cannabidiol. However it is to be hoped that eventually an Australian cannabis-based pharmaceutical will be available to Australian patients.

The efficacy of medicinal cannabis in the treatment of the medical conditions examined in this chapter are only those for which there is a substantial and/or growing body of evidence in support of efficacy. However there are many more conditions for which medicinal cannabis has been successfully used in their treatment, but there is as yet insufficient evidence to satisfactorily claim efficacy, these include (in no particular order) cachexia, anorexia, neurotoxicity, stroke, neurotrauma, Parkinson’s Disease, Tourettes syndrome, Huntington’s disease, amyotrophic lateral sclerosis, epilepsy, schizophrenia, anxiety, depression, insomnia, nausea, emesis, opiate, nicotine, cocaine and alcohol addiction, hypertension, circulatory

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<sup>66</sup> M Kyriagis, ‘Just what the doctor ordered?’ (1997) 20 *University of New South Wales Law Journal* 594.

<sup>67</sup> E Russo and G W Guy, ‘A tale of two Cannabinoids’ (2006) 66 *Medical Hypotheses* 234–246 at 239.

<sup>68</sup> United States Federal Drugs Administration 2007  
<[http://en.sanofi-aventis.com/Images/20070613\\_Rimonabant\\_AD\\_Comm\\_EN\\_tcm24-16868.pdf](http://en.sanofi-aventis.com/Images/20070613_Rimonabant_AD_Comm_EN_tcm24-16868.pdf)> (accessed 6 October 2008).

<sup>69</sup> See eg Russo et al, above at 1734–1735 and 1738–1739.

<sup>70</sup> Ibid 1739.

<sup>71</sup> C McCarberg and E Barkin ((2007) 14(5) *American Journal of Therapeutics* 475–483, at 480.

<sup>72</sup> Ibid, n 73.

shock, myocardial reperfusion injury, atherosclerosis, asthma, glaucoma, retinopathy, cancer, inflammatory bowel disease, hepatitis, liver cirrhosis, arthritis, and osteoporosis.<sup>73</sup>

Many of the United States states with medical marijuana laws include a provision to include new qualifying conditions as the evidence to support their inclusion grows. The New South Wales Parliamentary Report on Consultation on the findings and recommendations of the Working Party on the use of Cannabinoids for medical purposes recommended that, ‘as this list [of approved conditions] may need to be amended in the light of further medical research, it should be specified by regulation rather than by primary legislation.’<sup>74</sup>

### **Adverse effects**

A recent Canadian study which reviewed the medicinal cannabis literature found 31 relevant studies which collectively reported 4779 adverse effects of which 4615 (96.6%) were not serious. Of the 164 serious adverse events, the most common were relapse of multiple sclerosis, (12.8%) and vomiting (9.8%). The authors concluded that short-term medicinal cannabis use increased the risk of non-serious adverse events. Long-term medicinal cannabis use risks were ‘poorly characterized’ and they urged more research trials to address safety concerns.<sup>75</sup>

The rates of non-serious adverse events were higher in the group taking medicinal cannabis than in the control group but there was no significant difference between the two groups as to the rate of serious adverse events.<sup>76</sup> In a response to this review, Degenhardt and Hall raise the issue of a possible association between cannabis use and psychosis. However they point out that the evidence for this association comes from recreational users and, ‘there are currently no data on the extent of risk for psychotic symptoms among medical users ...’.<sup>77</sup> They conclude that, ‘the findings of Wang and colleagues’ review, suggest that, based on the current data, the risk of adverse events associated with short term medical use of cannabinoids and cannabis extracts are minor.’<sup>78</sup>

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<sup>73</sup> Pacher et al, n 37, 389–390.

<sup>74</sup> Recommendation 13 at 39.

<sup>75</sup> T Wang et al, ‘Adverse effects of medicinal cannabinoids: a systematic review’ (2008) 178(3) *Canadian Medical Association Journal* 1669–1678, 1669.

<sup>76</sup> Wang et al, n 77, 1669.

<sup>77</sup> L Degenhardt and W Hall, ‘The adverse effects of cannabinoids: implications for use of medical marijuana’ (2008) 178 *Canadian Medical Association Journal* June.

There are two types of risk potentially applicable to Sativex:-1). That it has the potential to be abused as a recreational drug, and 2) that it has significant side-effects. Addressing 1), the Australian experience with dronabinol, (Marinol) is that such abuse has not been problematic. After some years of availability in the United Kingdom and Canada, there is no evidence of abuse intuitively it is obvious that Sativex would not be subject to abuse because it is many times dearer than raw cannabis and has much less potency than smoked cannabis.

A risk-benefit analysis should be conducted to assess the patient's suitability to the prescription of this drug.

In AIDS or immuno-compromised patients, long-term administration should be carefully monitored as cannabinoids interact with aspects of the immune system. Such patients are therefore at risk of aggravating certain aspects of this disease, which includes ulceration of the mucosa at the site of administration.

Elderly patients are more sensitive to the neurological, psychoactive and postural-hypotensive effects of cannabinoids. This is especially applicable to elderly patients who are prone to falls and those with dementia.

**(d) Potential hazards**

Sativex is contra-indicated for patients with significant hepatic or renal impairment; patients with serious cardio-vascular disease; patients with a history of schizophrenia or any other psychotic disorder; patients with known or suspected allergy, women who are pregnant or nursing or who are not using effective contraception and men wanting to have children. In addition, caution is advised in the use of Sativex by elderly patients as the current data on their use of Sativex is limited. There are also risks related to mood changes, a decrease in cognitive performance and memory, altered time sense, fainting, intoxication reactions, though most of these remit when doses are decreased or the interval between doses is increased.

No culturally significant abnormalities of immune function have been observed in clinical trials with Sativex and nor did clinical laboratory investigations reveal any clinically

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<sup>78</sup> Degenhardt and Hall, n 79.

significant trends in haematological parameters while the only hazard revealed in clinical studies on neurological function with Sativex was an increase in the number of falls in patient trials and 5% of patients have reported depressive conditions when using Sativex.

**(e) Extent of use**

Since any cannabis product is illegal in Australia it is difficult to assess the potential demand for sativex. Survey estimates in New South Wales suggest that there are currently 20,000 to 40,000 users of raw cannabis for medical purposes. In Canada and the United States legal medicinal cannabis users make up 1–2% of the general population.

**(f) Dosage and formulation**

In a trial of multiple sclerosis patients, the mean daily dosage of Sativex was five sprays but the manufacturers advise an initial rate of four sprays per day, spread equally across the day and titrated by the individual patient after that, which may take a week or more.

Mild symptoms of overdose include drowsiness, euphoria, heightened sensory awareness, altered time perception, reddened conjunctiva, dry mouth and tachycardia. Moderate THC overdose symptoms include memory impairment, lowered bowel motility, urinary retention and mood changes. Severe THC overdose symptoms include decreased motor coordination, lethargy, slurred speech and postural hypotension. The estimated lethal dose of intravenous THC is 30mg/kg (2100 mg/ 70 kg).

The formulation of Sativex is delta-9-tetrahydrocannabinol 27 mg/ml (from Tetrabinex – Cannabis sativa L. extract and cannabidiol 25 mg/ml ( from Nabidiolex – Cannabis sativa L extract. The route of administration is buccal and the clinically relevant non-medicinal constituents are ethanol anhydrous, propylene glycol and peppermint oil.

**(g) Need for access**

The need is based on its superior efficacy and/or significantly fewer and less severe side effects when compared with other cannabis medications.

**(h) Potential for abuse**

Unlike smoked cannabis it is considered that the potential for abuse of Sativex is low for three reasons:

1. its cost renders recreational use unlikely;
2. the strict protocols for its availability will largely prevent it reaching the black market;
3. Sativex does not produce the same reliable or adequate effects as smoked cannabis and therefore would not be attractive to recreational users.

**(i) Purpose of use**

Sativex is approved in the United Kingdom and Canada ‘as adjunctive treatment for the symptomatic relief of neuropathic pain in multiple sclerosis in adults.’ However the growing body of medical research indicates its use as an analgesic for other conditions such as cancer, HIV/AIDS, muscle spasms and as an anti-emetic in these and other conditions.

**(j) Risk of death**

There has never been a death recorded attributed solely to Sativex or to cannabis generally.<sup>79</sup>

**ADDITIONAL MATTERS**

On 13<sup>th</sup> December 2007 the British drug regulatory agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), published a Public Information Report on Sativex which contains an Experts Report stating,

More than 1200 patients have been prescribed Sativex in the UK. In a recent postal survey of UK physicians who have prescribed Sativex to at least 2 of their patients, 80% of physicians indicated that Sativex provided useful clinical benefits to their patients and 88% regarded Sativex as a useful addition to their therapeutic options.

A carefully constructed questionnaire was also sent to patients who have been receiving Sativex over a period of at least 1 year. The results of this questionnaire confirm that relevant functional improvements are being achieved, and these improvements are independently confirmed by their carers. A remarkable 19% of patients report a reduced need for either supportive equipment or specific assistance to improve their mobility. Ninety-four of respondents report an improvement in general life benefits from the improvement they have experienced on Sativex. These reports are exactly what doctors rely on when assessing the clinical relevance of treatments for spasticity, and indicate that Sativex does produce relevant

benefits and functional improvements. A notable 71% of carers report that night-time care of the patient is less burdensome.

In summary, we note that all the elements which are required to conclude that Sativex is providing worthwhile clinical benefit at low risk are present in the data we have seen. Controlled clinical trials show statistical significance, and analyses of the improvement seen, especially in responders, show clear evidence of clinical relevance. Long-term use confirms maintenance of the treatment effect without the emergence of new adverse events, and with no evidence of tolerance. Questionnaire responses confirm that independence is improved in long term use, a view expressed by patients and confirmed by carers. Prescribers overwhelmingly agree that Sativex provides them with a valuable treatment option. We conclude that Sativex meets a currently unmet medical need in patients where there is no other conservative treatment option. It is our view that Sativex should be licensed and become available on prescription for patients with spasticity due to multiple sclerosis, and we urge the Medicines and Healthcare Products Regulatory Agency (MHRA) to do so.’

Given that this favourable evidence comes in addition to the support for medicinal cannabis’ efficacy by the United States National Institute of Medicine<sup>80</sup>, the British Medical Association<sup>81</sup> and the Australian Medical Association<sup>82</sup> it is submitted that, the case for relaxing current regulations to make cannabis and cannabis-based medicines more widely available to patients who want them seems overwhelming.’<sup>83</sup>

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<sup>79</sup> National Commission on marijuana and drug abuse 1<sup>st</sup> Report, Washington, US Government Printing Office, cited in M Booth, ‘Cannabis’ (2003) London Transworld at 340.

<sup>80</sup> J E Joy, *Marijuana and Medicine: Assessing the science base* (1999) United States National Institute of Medicine National Academy Press, Washington. D.C., U.S.A., Executive Summary, 10.

<sup>81</sup> British Medical Association, *Therapeutic Uses of Cannabis* (1997) Academic Publishers, Amsterdam, Netherlands, 78–9.

<sup>82</sup> Australian Medical Association Medicine, *Report on Consultation on the Use of Cannabis for Medical Purposes* (2001) Office of Drug Policy, NSW Government, July, 2.

<sup>83</sup> Iversen, n 2, 264.