

General Purpose Standing Committee No. 4

The use of cannabis for medical purposes

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How to contact the Committee

Members of the General Purpose Standing Committee No. 4 can be contacted through the Committee Secretariat. Written correspondence and enquiries should be directed to:

The Director

General Purpose Standing Committee No. 4

Legislative Council

Parliament House, Macquarie Street

Sydney New South Wales 2000

Internet www.parliament.nsw.gov.au/gpsc4

Email gpscno4@parliament.nsw.gov.au

Telephone 9230 3504

Facsimile 9230 2981

Terms of reference

1. That General Purpose Standing Committee No. 4 inquire into and report on the use of cannabis for medical purposes, and in particular:
 - (a) the efficacy and safety of cannabis for medical purposes
 - (b) if and how cannabis should be supplied for medical use
 - (c) legal implications and issues concerning the use of cannabis for medical purposes, and
 - (d) any other related matters.

2. That the Committee report by 17 May 2013.

These terms of reference were referred to the Committee by the Legislative Council on Thursday, 22 November 2012.

Committee membership

Hon Sarah Mitchell MLC	The Nationals	<i>Chair</i>
Hon Robert Borsak MLC	The Shooters and Fishers Party	<i>Deputy Chair</i>
Hon Amanda Fazio MLC*	Australian Labor Party	
Dr John Kaye MLC**	The Greens	
Hon Trevor Khan MLC	The Nationals	
Hon Charlie Lynn MLC	Liberal Party	
Hon Adam Searle MLC	Australian Labor Party	

* Substituting for Hon Lynda Voltz MLC for the duration of the inquiry.

** Substituting for Mr David Shoebridge MLC for the duration of the inquiry.

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Chair's foreword

I wish to begin by noting that I am delighted that this report was unanimously adopted by the Committee.

The inquiry was referred to the Committee by the Legislative Council, and is the first time in fifteen years that the use of cannabis for medical purposes has been formally considered in New South Wales. While allowing the use of pharmaceutical cannabis products for medical purposes is a promising and workable area of reform, understandably the use of crude cannabis products such as plant material, resin or liquids is more complex. The latter has significant implications for both health and legal policy, not least because it concerns whether the use of a drug should be decriminalised. It is also an issue with substantial implications for individual patients who stand to gain from the relief of their severe and distressing symptoms. The duality of these implications means that a careful, considered approach will be essential to developing a way forward in this area.

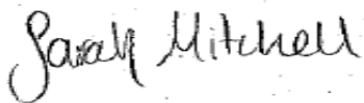
The Committee has found that in general terms medical cannabis has potential as an effective treatment for some medical conditions with appropriate safeguards in place. Our reading of the evidence – including rigorous scientific evidence – is that cannabis products are emerging as a promising area of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

While the Committee has set out a possible way forward in a number of areas, we recognise that further consideration needs to be given to certain issues, most particularly that of the supply of crude cannabis products. However, given the short inquiry timeframe handed down by the House we were not able to examine this issue in sufficient detail, because of its complex implications for state, national and international law.

On behalf of the Committee, I express our gratitude to all who participated in the inquiry, particularly the individuals and organisations who made submissions and those who gave evidence at the public hearings. The inquiry was noteworthy for the number of patients affected by significant illness or pain, and their carers, who made their views known to the Committee in submissions. Their experience is reflected in the several case studies included in the report.

I thank my Committee colleagues for their engagement throughout the inquiry and for working so constructively to produce this unanimous report. The issues discussed were complex and weighty and each member brought a valuable perspective.

I also thank the Committee Secretariat for their guidance, hard work and professionalism.



Hon Sarah Mitchell MLC
Committee Chair

Executive summary

This unanimously adopted report makes five important recommendations to address the issue of the use of cannabis for medical purposes.

Chapter 1 - Introduction

The inquiry into the use of cannabis for medical purposes was referred by the Legislative Council to General Purpose Standing Committee No. 4 on 22 November 2012. Its terms of reference are set out on page iv. The Committee received a total of 123 submissions and seven supplementary submissions, and held two public hearings on 11 and 18 March 2013. The Committee thanks all who participated in the inquiry, whether by making a submission, giving evidence, or attending the hearings.

Chapter 2 – Cannabis

This chapter provides the foundation for the report by setting out factual information in relation to cannabis and cannabis products. It provides a brief description of cannabis and its chemical substances, discusses the efficacy and safety issues related to the use of cannabis for medical purposes, then documents key policy developments in New South Wales, along with regulatory frameworks in Australia and other jurisdictions.

In this report the Committee use the term ‘cannabis’ in general terms, to refer to processed, unprocessed and synthetic materials containing cannabinoids. We draw a key distinction between pharmaceutical cannabis products, that is, products containing synthetic or natural cannabinoids in pharmaceutical form, and crude cannabis products in plant, resin or liquid form.

Chapter 3 – Pharmaceutical cannabis products

This chapter focuses principally on pharmaceutical cannabis products, but commences by examining participants’ broad views about the potential use of cannabis - in its general sense - for medical purposes. Here it documents participants’ views on the priority to be afforded to the issue, ideological considerations and the risks and harms that might arise from the use of cannabis for medical purposes. It then examines views on pharmaceutical cannabis products, noting a number of important advantages of cannabis in this form, before turning to the critical issue of whether there is now sufficient scientific evidence to justify the expanded use of pharmaceutical cannabinoids and for which medical conditions.

The Committee considers that in general terms medical cannabis has potential as an effective treatment for some medical conditions with appropriate safeguards in place. Our reading of the evidence gathered during the inquiry – including rigorous scientific evidence – is that cannabis products are emerging as a promising area of medicine, most notably in respect of a number of painful conditions that do not respond to existing treatments. Given this evidence, a compassionate approach is appropriate here.

While we recognise the risks and negative effects of crude cannabis use particularly via smoking, and by no means do we endorse the recreational use of cannabis, we agree that there is sufficiently robust scientific evidence to indicate that cannabis products can be an effective treatment for certain conditions in very specific circumstances.

We recognise that particular attitudes have perhaps prevented us from recognising and harnessing the therapeutic potential of cannabinoids in Australia to date. Such attitudes include those about the harms

of illicit drugs, along with concerns about how progress in regard to medical cannabis might be perceived by the public and media.

The Committee notes public opinion in relation to medical cannabis, with 69 per cent of people in a recent Australian Institute of Health and Welfare survey indicating that they support legislation to allow medical use of cannabis, matched with 74 per cent of participants showing support for clinical trials investigating the benefits of cannabis for medical conditions.

We consider that on the present medical evidence, cannabis based treatments will only be appropriate for a small number of people in specific circumstances, and under the supervision of medical practitioners with suitable expertise. Those patients would necessarily be people with severe and distressing symptoms that are not able to be addressed by existing medications.

While we are not convinced that allowing medical use of cannabis will lead to greater non-medical use, we do recognise that government needs to be cautious about the messages it sends to the broader community in such a sensitive area of policy, but we are confident that appropriate communication strategies can be developed in this respect.

While we take seriously the harms associated with cannabis, we note the point made in evidence that all medicines have harms that must be balanced against benefits in order to determine their therapeutic potential. We have a robust system in place to make these judgments – the Therapeutic Goods Administration (TGA) regime – and consider any such harms are more able to be controlled in a therapeutic context.

Turning specifically to pharmaceutical cannabis products, we see this as a promising and workable area of reform, not least because such products are by definition subject to a robust regulatory system. Their active ingredients and doses are standardised and their unwanted effects are able to be controlled. In addition, pharmaceutical cannabis products are more acceptable to many individual patients, to the broader community and of course from a law enforcement perspective. Significantly, the product nabiximols (under the trade name Sativex) has demonstrated effectiveness is now available for prescription in Australia for the treatment of a highly specific condition, muscle spasticity arising from multiple sclerosis. While the Committee explicitly does not endorse any particular pharmaceutical product, we recognise that this is presently the only pharmaceutical cannabis product on the horizon for which there is an evidence base that can be recognised by the TGA.

In relation to side effects, we are sufficiently reassured by the available evidence that short term use of pharmaceutical cannabinoids is reasonably safe. It will be very important to build up the evidence base in respect of risks arising from long term use.

While there is clear support for a compassionate approach to the use of pharmaceutical cannabis medications by people in the terminal stages of illness, we recognise the dilemma in providing them to people over a long period in the absence of studies on the effects of long term use. This needs to be balanced with the desirability of relieving serious and distressing symptoms. We feel comfortable with the provision of pharmaceutical cannabis products to such patients over a longer period within the context of careful and ongoing biopsychosocial assessment of the patient by a medical practitioner with recognised expertise in pain management, as is good medical practice and occurs with other medications.

The Committee also notes certain participants' views regarding the urgent need for more options to treat pain, and that there is ample scientific evidence to justify the introduction of cannabis

pharmacotherapies. At the same time, we appreciate the need for such products to be subject to standard regulatory processes. As a committee of the NSW Parliament we urge in the strongest possible terms that action proceed as quickly as possible to enable access by various groups of patients to medicine which could have a profoundly relieving effect.

The Committee respects that other target groups will be appropriately determined over time, according to the proper evidence based processes of the TGA. At the same time, we underscore that there is strong evidence on efficacy in relation to a range of conditions, and consider that access by patients should not be determined by the commercial decisions of pharmaceutical companies alone.

We thus strongly encourage the expansion of the evidence base across a range of treatment groups, as well as the development of products by other companies. We are especially mindful here of people suffering from chronic pain for whom existing pain management is not effective.

Finally, the Committee underscores that the affordability of pharmaceutical cannabis products will be a critical determinant of patient access, and like numerous inquiry participants, we observe that many patients who would benefit from these products are of very limited means at a most vulnerable time of their lives. We agree that the affordability of such products would appropriately be addressed via the Pharmaceutical Benefits Scheme.

The Committee notes that the NSW Government's role in this regulatory area is extremely limited, and that we are unable to make recommendations to the Commonwealth Government. We consider it appropriate, however, for the NSW Minister for Health to write to the Commonwealth Minister for Health and Ageing, expressing in principal support for the timely, evidence based expansion of access to approved pharmaceutical cannabis products by additional patient groups including those suffering from chronic pain for whom existing pain management is not effective, for further clinical trials of pharmaceutical cannabis products to continue to build this evidence base, and for approved pharmaceutical cannabis products to be affordable to patients.

Chapter 4 – Crude cannabis products

Chapter 4 explores participants' views on whether and how the use of crude cannabis products for medical purposes might be decriminalised. First, it presents the arguments put forward by a number of inquiry participants that a pharmaceutical approach, as proposed in the previous chapter, will not be sufficient to address this policy issue at this time. It then paints a picture of current use of crude cannabis for medical purposes, and notes participants' comments on the present legal consequences of such use. The Committee then charts participants' arguments for and against reform, before setting out the alternative models for reform presented to us which would provide for the legal use of crude cannabis for medical purposes.

While there was general agreement among inquiry participants about allowing use of pharmaceutical cannabis products for medical purposes in certain circumstances, the use of crude cannabis products such as plant material, resin or liquids was understandably more controversial.

The Committee agrees with the argument put forward by the majority of inquiry participants that provision be made for a very small and specific group of patients to use crude cannabis products for medical purposes legally.

Ideally, pharmaceutical cannabis products would be of sufficient efficacy and safety as to provide relief to patients who experience severe and distressing symptoms that do not respond to existing

medications, most especially people in the end stage of terminal illness. However, the only pharmaceutical cannabis product currently approved for use is allowed for a single specific indication, namely muscle spasticity arising from multiple sclerosis. As the TGA approval process is lengthy, it is likely to take years before the use of Sativex for other conditions might be approved. In addition, we are very mindful that unless subsidised by the taxpayer under the Pharmaceutical Benefits Scheme, this product would be unaffordable to many, who as we noted in the previous chapter, will be of very limited means at a most vulnerable time in their lives. We further recognise that the effectiveness of pharmaceutical cannabinoids will vary from individual to individual. In these and other understandable circumstances, some patients will use crude cannabis products.

Indeed, it is a given that some patients are already using crude cannabis for medical purposes, and we received evidence that this is often occurring with the knowledge of their doctor, and sometimes at his or her recommendation.

The Committee agrees with the argument put forward by inquiry participants that a compassionate approach that recognises individual needs and choices is highly desirable and morally justified. We have some sympathy for the argument that patients can be trusted to make the best decisions for themselves, and that it is preferable that they do so under the guidance of their doctor.

The Committee considers that provision should be made to allow medical use of cannabis by patients who have been advised by their treating specialist that they have end stage terminal illness, and those who have moved from HIV infection to AIDS.

We believe, like almost all inquiry participants, that people with terminal illness who take measures to relieve their severe pain should not be criminalised. While presently the Cannabis Cautioning Scheme provides a 'safety net' in these circumstances, it is a very limited and discretionary one. The Committee considers it important to protect this small and highly vulnerable group from any criminal justice consequences for their end stage health condition. Such individuals should not be subject to the humiliation and stress of arrest and appearing in court, and indeed, should be able to rest in the knowledge that they are actively protected from such consequences.

Thus we consider that a system which qualifies this group for the use of cannabis for medical purposes should be established by providing a complete defence from arrest and prosecution. We believe that this could be achieved via amendment to the *Drug Misuse and Trafficking Act*, by adding a complete defence to the list of present defences for use and possession, so as to cover the authorised medical use of cannabis.

We recommend that in order to qualify for the exemption that we are envisaging, a patient would need to be certified by their treating specialist medical practitioner as having been diagnosed with a specific incurable condition. Such a certificate would make the person and their carer eligible for inclusion on a register of 'authorised patients and carers' held by the NSW Ministry of Health. Registration would make the patient eligible to possess up to 15 grams of dry cannabis or equivalent amounts of other cannabis products, and to use but not supply cannabis. Upon registration, the patient and their carer would be issued with a photo identification card, linked to the register, which he or she would produce for inspection in the event that they are found by police to be in possession of cannabis. It is the Committee's intention that police take no action in respect of such possession or use, but that if arrest and charge do occur, the defence would protect the individual from criminal sanction. It will be important for Police to receive training which makes clear this intention.

The Committee is satisfied that providing an exemption from arrest and prosecution for personal possession and use would not in itself conflict with Commonwealth law. However, the supply of seeds, plants and equipment to a patient, whether by a carer or another third party, may contravene the *Therapeutic Goods Act*. We believe that provision should be made to exempt carers from arrest and prosecution for possession and supply (in order to provide a product to the patient) under New South Wales law, but note that they would remain vulnerable under Commonwealth law. We trust that Commonwealth law enforcers will adopt a compassionate approach to such persons, who are categorically different to other ‘suppliers’ as are captured by Commonwealth law.

At the same time, the Committee recognises that the issue of supply needs further careful and detailed consideration, as it was not possible for the Committee to examine it in sufficient detail within the timeframe for this inquiry. We believe that it would be preferable for patients and carers to purchase crude cannabis products, seeds and equipment legally. We recognise that this may not be realistic in the present environment.

The Committee acknowledges the many powerfully argued submissions made to us by people with chronic debilitating pain who wish to use cannabis legally to treat their medical conditions. We empathise strongly with them and take at face value that cannabis is an effective treatment for them. However, owing to the present absence of evidence on the long term effects of cannabis use, and the risks associated with smoking it, the Committee considers that at this stage, the target group for this provision should not include people with chronic conditions. This exclusion would apply to people with multiple sclerosis, although we note that in certain circumstances they can now access the pharmaceutical cannabinoid Sativex.

We further consider that the legislative amendments would appropriately exclude the use and supply of cannabis in a public place, and that a three year review of the amendment be written into the legislation. It would be valuable for the Ministry of Health to proactively prepare for this review by collecting qualitative and quantitative data, including from medical practitioners, patients and carers, from the commencement of the register.

We believe that provision for the legal use of cannabis for medical purposes within the context of an ongoing therapeutic relationship with a specialist medical practitioner will ensure two things: first, that eligibility is well guarded; and second, that the appropriate level of clinical oversight is afforded to this cannabis use. As with certain pharmaceutical products, we envisage that such specialist medical practitioners would necessarily provide ongoing ‘biopsychosocial’ assessment of the patient, noting the impact of this particular treatment on patients’ pain and holistic functioning.

The Committee considers the risk of diversion arising from our recommendations to be minimal, given the very tight restrictions that we envisage on eligibility and on the amount of cannabis that might be possessed, as well as the present availability of cannabis within the community. We believe that the community will be prepared to tolerate this small risk on compassionate grounds, in light of the potential benefits to a very restricted group of eligible patients, not all of whom would pursue this option anyway.

We believe that the cost of regulating this system would not be significant, and would be offset to some extent by the police not taking action with respect to this group, as well as the court system not having to adjudicate such matters. We also consider that such a move is unlikely to normalise or legitimise broader cannabis use within the community. Nor is it intended to glamourise cannabis to potential recreational users.

Finally, we recommend that the Government accompany these reforms with an education strategy informing the medical profession, community and relevant patient groups about the changes to be brought about. This should include information for patients on the possible harms of smoking cannabis and on other methods of cannabis consumption than smoking

Summary of recommendations

Recommendation 1

41

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

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

Recommendation 2

71

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

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

Recommendation 3

72

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

Recommendation 4

72

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

Recommendation 5

72

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

Acronomyns

ACI	Agency for Clinical Innovation
ADLRF	Australian Drug Law Reform Foundation
ADLRI UNSW	Australian Drug Law Reform Initiative at the University of NSW
AMA	Australian Medical Association
ARTG	Australian Register of Therapeutic Goods
BMC	Bureau voor Medicinale Cannabis
CBD	Cannabidiol
CBT	Cognitive Behavioural Therapy
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DMTA	<i>Drug Misuse and Trafficking Act 1985</i>
EDMD	Emery Dreofiss muscular dystrophy
HIV	Human Immunodeficiency virus
IQ	Intelligence quotient
MS	Multiple Sclerosis
NCPIC	National Cannabis Prevention and Information Centre
NDARC	National Drug and Alcohol Research Centre
SAS-MC Card	Special Access Scheme Card(s), for medical Cannabis
TGA	Therapeutic Goods Administration
THC	Delta-9-Tetrahydrocannabinol
THCV	Cannabivarin

Chapter 1 Introduction

This chapter provides an overview of the inquiry process, including the methods the Committee used to facilitate participation by members of the public, government agencies and relevant organisations. It also includes a brief outline of the report structure.

Conduct of the inquiry

Terms of reference

- 1.1 The inquiry terms of reference were referred by the House on 22 November 2012 and required the Committee to inquire into and report on the use of cannabis for medical purposes.¹ The House later agreed to amend the referral to extend the reporting date to 17 May 2013.²
- 1.2 The terms of reference can be found on page iv.

Submissions

- 1.3 The Committee invited submissions by advertising in *The Sydney Morning Herald* and *The Daily Telegraph* on 28 November 2012. A media release announcing the Inquiry was sent to all media outlets around the State. The Committee also sought submissions by writing directly to individuals or organisations with a likely interest in the inquiry, including government agencies, community organisations and experts in the field. The closing date for submissions was 15 February 2013.
- 1.4 The Committee received a total of 123 submissions and seven supplementary submissions from a range of stakeholders, including individuals with concerns as to their own or their loved ones' health and well-being.
- 1.5 A list of submissions is available at **Appendix 1**.

Hearings

- 1.6 The Committee held two public hearings at Parliament House on 11 and 18 March 2013.
- 1.7 A list of witnesses who appeared at hearings is reproduced in Appendix 2. The list of documents tabled during the hearing is available in Appendix 3, and the list of witnesses who provided answers to questions taken on notice during hearings is available in **Appendix 4**.
- 1.8 Transcripts of the hearings are available on the Committee's website www.parliament.nsw.gov.au/gpsc4 and the minutes of the proceedings of all Committee meetings relating to the inquiry are included in **Appendix 5**.

¹ *LC Minutes* (22/11/2012) 1425.

² *LC Minutes* (19/03/2013) 1544.

- 1.9** The Committee would like to thank all those who participated in the inquiry, whether by making a submission, giving evidence or attending the public hearings.

Report structure

- 1.10** Chapter 2 of this report provides basic factual information about cannabis and cannabis products. It outlines the efficacy of cannabis for key medical conditions and summarises safety issues surrounding the use of cannabis for medical purposes. It documents key developments in this area in New South Wales and provides an overview of the current regulatory frameworks in Australia and overseas.
- 1.11** Chapter 3 examines participants' broad views on the potential use of cannabis for medical purposes, with a focus on cannabis in pharmaceutical form.
- 1.12** Chapter 4 explores participants' views on whether and how the use of crude cannabis products for medical purposes might be decriminalised.

Chapter 2 Cannabis

This chapter provides the foundation for this report by setting out factual information in relation to cannabis and cannabis products. It starts by providing a brief description of cannabis and its chemical substances. Next, it discusses the efficacy and safety issues related to the use of cannabis for medical purposes. The chapter concludes by documenting key policy developments in New South Wales, as well as regulatory frameworks in Australia and other jurisdictions.

In this inquiry we use the term ‘cannabis’ in general terms, to refer to processed, unprocessed and synthetic materials containing cannabinoids. We draw a key distinction between pharmaceutical cannabis products, that is, products containing synthetic or natural cannabinoids in pharmaceutical form, and crude cannabis products in plant, resin or liquid form.

Cannabis

- 2.1** Cannabis is a generic term used for drugs that are made from any of the genus cannabis plants, including *Cannabis Sativa* and *Cannabis Indica*.³ Cannabis-derived drugs are usually produced in three main forms: marijuana (dried leaves and flowering top of the plants), hashish (cannabis resin) and cannabis oil.
- 2.2** When consumed, cannabis can result in users experiencing an alteration in mood and ‘a feeling of “high”’.⁴ The psychotropic or psychoactive effect of cannabis gave rise to the inclusion of cannabis as a controlled drug in the United Nations *Single Convention on Narcotic Drugs in 1961*.⁵
- 2.3** In Australia, cannabis is an illicit drug under both Commonwealth and state laws.⁶ Despite cannabis being illegal, the *2010 National Drug Strategy Household Survey Report* found that 1.9 million Australians aged 14 or above had used cannabis in the previous 12 months, including 9.1 per cent of the NSW adult population.⁷ Cannabis is the most widely used illicit drug in Australia.

³ World Health Organisation, Cannabis, accessed 11 February 2013, <http://www.who.int/substance_abuse/facts/cannabis/en/>; Submission 46, Professor Wayne Hall, Deputy Director (Policy), University of Queensland Centre for Clinical Research and Professor Michael Farrell, Director, National Drug and Alcohol Research Centre, University of New South Wales, p 4.

⁴ Submission 21, Australian Medical Association NSW, p 4.

⁵ United Nations, Single Convention on Narcotic Drugs 1961, 3 April 2013, http://www.unodc.org/pdf/convention_1961_en.pdf.

⁶ Ms Penny Musgrave, Director, Criminal Law Review, Department of Attorney General and Justice, Evidence, 11 March 2013, p 13.

⁷ Australian Institute of Health and Welfare, 2010 National Drug Strategy Household Survey report, July 2011, p 102 and p 108, accessed 10 April 2013, < <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737421314&libID=10737421314>>.

Cannabinoids

- 2.4** Cannabis is ‘not a single drug’⁸ that induces one single effect. Rather, it consists of over 400 chemical substances. Over 60 of these are cannabinoids⁹ which, when ingested, activate the cannabinoid receptors in the body¹⁰ and produce a variety of effects on movement, appetite, emotion, memory and cognitive functions.¹¹
- 2.5** The most commonly recognised cannabinoids found in the cannabis plant are Delta-9-Tetrahydrocannabinol (THC) and Cannabidiol (CBD).¹² THC is responsible for producing the psychoactive effects of cannabis. It can also be used to produce therapeutic effects that help to reduce pain, nausea and vomiting, and to stimulate appetite.¹³ CBD is non-psychoactive and may reduce the unwanted psychoactive effects of THC.¹⁴
- 2.6** The combination and strength of cannabinoids in a cannabis plant can vary depending on plant strain and gender, conditions of growth (climate, soil etc), conditions of storage and chemical contamination (such as from pesticide, heavy metals, fungus and mould).¹⁵
- 2.7** As well as being found in cannabis plants, cannabinoids can be produced naturally in the human body (known as endocannabinoids) or manufactured in pharmaceutical laboratories as pharmaceutical drugs.¹⁶ Three pharmaceutical cannabinoids are:
- dronabinol, a synthetic form of THC, has been approved for treating chemotherapy-induced nausea and vomiting and AIDS related weight loss. It is also marketed with a trade name of Marinol.¹⁷
 - nabilone, another synthetic form of THC, is a licensed medicine used to treat chemotherapy related nausea and vomiting.¹⁸
 - nabiximols, containing a 1:1 ratio of THC and CBD extracted from cannabis plants, has been approved to treat multiple sclerosis related spasticity and is known under the trade name of Sativex.¹⁹
- 2.8** Dronabinol and nabilone have been approved for use in Canada, the United States of America and the United Kingdom, but not in Australia.²⁰ Nabiximols (Sativex) has been approved for

⁸ Supplementary Submission 14a, Emeritus Professor Lawrence Mather, p 2.

⁹ Submission 14, Emeritus Professor Laurence Mather, p 8; Submission 10, Mullaways Medical Cannabis, p 5.

¹⁰ Submission 14, p 8; Submission 4, Cancer Council NSW, p 2.

¹¹ Submission 56, National Cannabis Prevention & Information Centre, p 5.

¹² Submission 4, p 2.

¹³ Hall & Degenhardt, 2003; in submission 29, Australian Drug Foundation, p 6.

¹⁴ Submission 10, pp 5-6; Submission 14, p 8.

¹⁵ Submission 14, p 8; Submission 14a, p 1.

¹⁶ College of Judea and Samaria, Israel, ‘Endocannabinoids in the central nervous system – an overview’, in Submission 10, pp 4-5; Submission 4, p 2.

¹⁷ NSW Parliamentary Library Research Service, *The Medical Use of Cannabis: Recent Developments*, Sydney, NSW Parliament, Briefing Paper No 11/99, May 1999, p 16.

¹⁸ NSW Parliamentary Library Research Service, Briefing Paper No 11/99, p 6.

¹⁹ Submission 4, p 2; Submission 46, p 5.

use to treat multiple sclerosis related spasticity in the United Kingdom, Spain, Canada, New Zealand²¹ and most recently in Australia as a controlled drug, available on prescription, for this same indicator.²²

Forms of administration

- 2.9** Plant-based cannabinoid preparations can be ingested by smoking, inhaled through a vaporiser, consumed in food or drinks,²³ applied to skin as a cream²⁴ or administered under the tongue as a tincture.²⁵ Pharmaceutical cannabinoids are available in capsule form (dronabinol and nabilone) or as an oral spray (nabiximols).²⁶
- 2.10** Smoking is the most common way to ingest cannabis.²⁷ When smoked, cannabis is inhaled via hand-rolled cigarettes (joints), often mixed with tobacco, or via water pipes (bongs). The medical evidence indicates that while smoking cannabis produces immediate effects which make it easy for the users to titrate (or measure) doses, smoking is not safe and is not recommended for administration of any drugs.²⁸ (The risks associated with smoking cannabis are explained in paragraph 2.34).
- 2.11** Vaporisation of cannabis for medical use is a more recent development. Vaporisation produces the same rapid absorption of cannabinoids as smoking without many of the risks normally associated with smoking cannabis.²⁹
- 2.12** Edible forms of cannabis (such as in food or drink), or cannabinoids such as dronabinol and nabilone ingested via capsules, are not absorbed as quickly as cannabis ingested via smoking or vaporizing, which makes it harder for users to titrate doses of both these forms. The edible products are unsuitable for patients with nausea or vomiting conditions.³⁰

²⁰ NSW Parliamentary Library Research Service, *Medical Cannabis*, Sydney, NSW Parliament, Issues backgrounder, No 1, February 2013, p 7.

²¹ GW Pharmaceuticals, Sativex FAQs: Where is Sativex available?, accessed 10 April 2013, < <http://www.gwpharm.com/sativex-faqs.aspx>>.

²² Therapeutic Goods Administration, Department of Health and Ageing (Cth), Public Summary [of nabiximol], accessed 17 April 2013, < [https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=80AE3C9BF0BDD408CA257AC2003CB6EF&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=80AE3C9BF0BDD408CA257AC2003CB6EF&agid=(PrintDetailsPublic)&actionid=1)>.

²³ NSW Government Health, 'Cannabis factsheet', in Submission 4, pp 3-4 and p 7.

²⁴ Submission 10, p 9.

²⁵ Mr Tony Bower, Director, Mullaways Medical Cannabis, Evidence, 11 March 2013, p 32.

²⁶ Medline Plus, 'Dronabinol' and 'Nabilone', and GW Pharmaceuticals, 'What is Sativex?', in Submission 4, p 4.

²⁷ Submission 56, p 5.

²⁸ Submission 4, pp 3-4.

²⁹ Submission 14, p 17.

³⁰ NSW Parliamentary Library Research Service, *Medical Cannabis Programs: A Review of Selected Jurisdictions*, Sydney, NSW Parliament, Briefing Paper No 10/04, August 2004, pp 4-5.

- 2.13** The tincture form of cannabis was prescribed for various medical conditions throughout the nineteenth century.³¹ An inability to standardise cannabinoid content using this method may have led to its discontinued use by pharmacologists,³² although in recent years tinctures have been manufactured in Australia.³³
- 2.14** Medical experts have suggested that the oral spray form of pharmaceutical cannabinoids, nabiximols (Sativex), is the best controlled dosage form for plant-based cannabinoids.³⁴ Sativex is produced using standardised cultivars grown in controlled conditions. It does not provide fast absorption of cannabinoids,³⁵ but it helps patients to relieve their symptoms without having to experience an unwanted ‘high’.³⁶ It is a suitable method of administration for patients with nausea and vomiting issues.³⁷

Efficacy

- 2.15** In recent years, studies and clinical trials have examined the efficacy of both crude and pharmaceutical cannabis in treating various medical conditions. The efficacy of cannabis in treating key medical conditions is summarised below.

Chemotherapy-induced nausea and vomiting

- 2.16** Studies have shown that cannabinoids produce anti-emetic effects that reduce nausea and vomiting experienced by cancer patients undergoing chemotherapy.³⁸ However, the studies also suggest that cannabinoids are not needed as the first line treatment for these conditions as anti-emetic drugs more potent than cannabinoids are now available to treat these conditions.³⁹
- 2.17** It is important to note that cannabinoids have been shown to produce anti-emetic effects through mechanisms different from other drugs. This finding suggests cannabinoids might be of potential use for patients whose conditions either fail to respond to, or cannot tolerate the side effects of standard treatments.⁴⁰

³¹ Kalant (2001); in Submission 46, p 4.

³² Submission 14, p 20.

³³ Submission 10, pp 11-15.

³⁴ Submission 14, p 2.

³⁵ Submission 14, p 2 and p 18.

³⁶ GW Pharmaceuticals, Sativex FAQs: Will patients experience a ‘high’ with Sativex, accessed 10 April 2013, < <http://www.gwpharm.com/sativex-faqs.aspx>>.

³⁷ Submission 4, p 8.

³⁸ Christie (2006); Kalant (2001); US Institute of Medicine (1999); Tramèr et al (2001); Rocha, (2008); Berry & Mechoulam (2002); Navari (2009); Guindon (2008); Ungerleider (1982); in Submission 46, pp 6-8.

³⁹ Christie (2006); Kalant (2001); US Institute of Medicine (1999); Tramèr et al (2001); Rocha, (2008); Berry & Mechoulam (2002); Navari (2009); Guindon (2008); Ungerleider (1982); in Submission 46, pp 6-8.

⁴⁰ B Amar, *Cannabinoids in medicine: A review of their therapeutic potential*, Journal of ethnopharmacology, 2006; RM Navari, *Pharmacological management of chemotherapy-induced nausea and vomiting*, Drugs, 2009, in Submission 46, p 7.

Appetite stimulant for AIDS and cancer patients

- 2.18** Cannabinoids have been used to stimulate appetite in patients with AIDS or cancer related wasting and weight loss.⁴¹ For example, in the early 1970s, dronabinol was registered in the United States and used as an appetite stimulant for AIDS patients.
- 2.19** Today, AIDS related wasting can be prevented by using antiretroviral drugs.⁴² It has been suggested that this new medical development precludes the use of cannabinoid drugs in most AIDS related treatments, except for those AIDS patients whose conditions do not respond to the antiretroviral drugs.
- 2.20** Cannabinoids may still be a useful appetite stimulant for cancer patients.⁴³

Pain and neurological disorders

- 2.21** The results of research and clinical trials generally accept that cannabinoids have some beneficial effects in reducing pain, especially neuropathic pain (the pain that is caused by abnormalities or diseases of the nervous system). Cannabinoids control pain by influencing similar but distinct pathways targeted by opioids. The evidence suggests that, when used in conjunction, cannabinoids and opioids could potentially produce a total analgesic effect that is greater than the sum of the individual drug effects.⁴⁴

Pain and spasticity in multiple sclerosis

- 2.22** Clinical trials have shown that cannabinoids have some modest effect in addressing pain and spasticity experienced by patients with multiple sclerosis.⁴⁵
- 2.23** A 2012 review of studies concluded that the cannabinoid Sativex reduced the severity of symptoms of spasticity in patients with multiple sclerosis greater than placebo used in trials. It also reported that the adverse effects such as dizziness, diarrhoea, fatigue, nausea, headache and somnolence (drowsiness) in patients using Sativex were found to be mild to moderate.⁴⁶
- 2.24** However, Sativex is used as an adjunctive drug to increase the efficacy of standard anti-spasticity drugs. No study has suggested that Sativex is effective as a monotherapy or stand-alone treatment for these symptoms.⁴⁷

Safety

- 2.25** This section considers the safety of cannabis for medical purposes including the side effects, impacts of long-term use and toxicity.

⁴¹ Submission 46, pp 7-8.

⁴² Submission 46, pp 7-8.

⁴³ Submission 46, pp 7-8.

⁴⁴ Christie, 2003; IOM, 1999; Russo, 2008; in submission 46, p 8.

⁴⁵ Consroe, 1997; Zajicek et al, 2003; Iskedjian, 2007; in submission 46, p 8.

⁴⁶ Podda and Constaninescu, 2012; in Submission 46, p 9.

⁴⁷ Submission 46, p 9.

- 2.26** Before considering the evidence on this issue, it is important to note that most studies on cannabis safety have been carried out on a sample of recreational users, and there are few studies or clinical trials designed to assess risk for medical users.

Side effects

- 2.27** Patients who received cannabinoids in therapeutic trials reported a variety of side effects including dizziness, dysphoria (a state of feeling unwell or unhappy), depression, hallucinations, paranoia and impairment in psychomotor performance.⁴⁸
- 2.28** A 2008 review of the side effects of medical cannabis observed that cannabis and cannabinoid induced side effects were minor and that cannabinoid drugs were *not* found to create a higher risk of serious adverse effects than placebo.⁴⁹
- 2.29** The 2008 review supported the conclusion drawn by the US Institute of Medicine in 1999 that the adverse side effects caused by the use of medical cannabis were ‘within the risks tolerated for many medications’ and patients could potentially develop tolerance to many of these effects with continued use.⁵⁰
- 2.30** In summary, evidence suggested that, in the short term, it is sufficiently safe to use cannabis to control nausea and vomiting in cancer treatment, to stimulate appetite and to relieve post-surgery acute pain.⁵¹
- 2.31** It is noted that although the side effects were not severe enough to disqualify cannabis from being used in medical treatment, given the impact cannabis has on psychomotor performance, medical experts advised that patients should avoid driving when under the influence of cannabis.⁵²

Potential harm through prolonged use

- 2.32** Possible long term adverse effects of medical cannabis use include: developing cardiovascular or respiratory diseases or cancers, dependence and precipitating psychotic disorders.⁵³
- 2.33** It is important to note that such long term effects might not concern patients with terminal illness or a short life expectancy.

Cardiovascular or respiratory diseases or cancers

- 2.34** Cannabis use has been linked to cardiovascular and respiratory diseases and cancer. Medical research has suggested that these side effects are generally associated with the practice of

⁴⁸ Submission 46, p 10.

⁴⁹ Wang and colleagues’, 2008; in Submission 46, p 10.

⁵⁰ Submission 46, p 10.

⁵¹ Submission 46, p 10.

⁵² Submission 46, p 10.

⁵³ Submission 46, p 11; Professor Michael Cousins, University of Sydney, and Director, Pain Management Research Institute, Royal North Shore Hospital, Evidence, 18 March 2013, p 14.

smoking cannabis.⁵⁴ Cannabis smoke contains harmful carcinogens similar to those in tobacco⁵⁵ which, when smoked in a large quantity and for a long period of time, cause damage to the lungs and upper respiratory system.⁵⁶ In addition, the incidence of cardiovascular or respiratory diseases or cancer among cannabis smokers may be due to the fact that many cannabis smokers also smoke tobacco or mix tobacco in their cannabis preparations.⁵⁷

Long term dependence

- 2.35** Another possible long term adverse effect of using medical cannabis is dependence. However, it has been suggested that cannabis related dependence is not a physiological dependence, but rather a psychological one.⁵⁸ Other evidence has suggested that cannabis use can result in dependence and withdrawal syndrome.⁵⁹
- 2.36** A 2011 review of Sativex reported that cannabis abuse or dependence ‘is likely to occur in only a very small proportion of recipients’ and that tolerance did not develop in patients who used nabiximols.⁶⁰

Psychotic disorders

- 2.37** As a psychoactive drug, cannabis has been widely studied for its effects on mental health and its potential to exacerbate psychotic disorders. While there is evidence suggesting that cannabis use may precipitate psychotic disorders in young people or people with a predisposition to or history of psychiatric conditions,⁶¹ it has not been proven that cannabis use causes psychiatric conditions that would not have occurred in its absence.⁶²
- 2.38** In relation to a link between cannabis use and mental illness in young people, in 2006 the Mental Health Council of Australia noted that young people between age of 12 and 19 were at a stage of life when their brain is developing. The report expressed concern over the use of cannabis at that stage of life.⁶³
- 2.39** Room et al (2008) suggested that people in the following subpopulation groups should avoid using cannabis: those aged 17 years old or younger, young people with conduct disorders and people with a predisposition to psychiatric condition or a family history of psychosis.⁶⁴
- 2.40** However, there is insufficient evidence to show a correlation between cannabis use and psychotic disorders in older people who do not have a high risk of developing such disorders.⁶⁵

⁵⁴ Submission 56, p 16.

⁵⁵ Lamarine, 2012; in Submission 29, p 10.

⁵⁶ Submission 4, p 4.

⁵⁷ Submission 46, p 12.

⁵⁸ Submission 21, p 7.

⁵⁹ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 10.

⁶⁰ Submission 14, p 14.

⁶¹ See Submission 21, p 9; Room et al, 2008; in Submission 29, pp 8-9.

⁶² NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 11.

⁶³ Submission 95, Alcohol and other Drugs Council of Australia, p 5.

⁶⁴ Room et al, 2008; in Submission 29, pp 8-9.

Toxicity

- 2.41** Cannabis is considered as having low toxicity.⁶⁶ It has a higher ‘margin of safety’ (the margin between the therapeutic dose and the toxic dose of a drug) than most other potent drugs. Its side effects are milder than those of opioid analgesics or antidepressants or indeed, the effects of severe medical conditions left untreated.⁶⁷
- 2.42** Cannabis does not cause any immediate life-threatening side effects, even if consumed in excessive doses.⁶⁸

History of cannabis use: from medical treatment to banned drug

- 2.43** This section documents key historical developments in relation to the use and regulation of cannabis. It starts with the accepted use of cannabis as a medical treatment in the nineteenth and early twentieth centuries, the later ban on cannabis use in the 1960s, followed by the more recent calls to introduce cannabis as a medicine.

Cannabis use in the nineteenth and early twentieth centuries

- 2.44** During the nineteenth century, cannabis products played a significant role in western medicine, notably in the form of tinctures.⁶⁹ In addition, cannabis has a long history of use in India and the Middle East for the treatment of pain, convulsions, spasms, nausea and to induce sleep.⁷⁰ During the early twentieth century, the development of more effective analgesic drugs, along with difficulties in standardising oral cannabis preparations for medical use, led to a significant decrease in medical use of cannabis.⁷¹
- 2.45** In 1961, cannabis was included in the United Nations’ *Single Convention on Narcotic Drugs* as a controlled drug, at a time when there was a widespread recreational use of cannabis amongst young people in the United States.⁷²

Calls to introduce cannabis for medical use from late 1990s

- 2.46** In late 1990s, a number of international medical institutes investigated and reported on the potential medical use of cannabis. These included the Health Council of the Netherlands, American Medical Association House of Delegates, British Medical Association and World Health Organisation. The two most influential reports published during this wave of research

⁶⁵ Submission 46, p 11.

⁶⁶ Submission 120, Dr Andrew Katelaris, p 2.

⁶⁷ Submission 14, p 15.

⁶⁸ Submission 14, p 15.

⁶⁹ Kalant (2001); in Submission 46, p 4.

⁷⁰ Grinspoon (1993), Nahas (1984), Mechoulam (1986); in Submission 46, p 4.

⁷¹ Kalant (2001); in Submission 46, p 4.

⁷² Submission 46, p 4.

2.47 into medical cannabis were produced by the House of Lords Select Committee on Science and Technology in the United Kingdom in 1998 and the Institute of Medicine in the United States in 1999.⁷³

NSW Working Party on the Use of Cannabis for Medical Purposes

2.48 In New South Wales, there were similar calls from the late 1990s to permit the medical use of cannabis. In October 1999, the then NSW Premier, Hon Bob Carr MP, established a Working Party on the Use of Cannabis for Medical Purposes (hereafter the Working Party) to investigate and report on the feasibility of using cannabis for medical purposes. Premier Carr referred to the Report released by the House of Lords Select Committee on Science and Technology as well as calls from the Australian Medical Association that cannabis may have some therapeutic value for treating a certain range of medical conditions. Professor Wayne Hall, the then Executive Director of the National Drug and Alcohol Research Centre, was appointed to lead the investigation.⁷⁴

2.49 In August 2000, the Working Party delivered its report (hereafter the Report).⁷⁵ The Report found that some cannabinoids may have value in treating HIV related wasting, chemotherapy induced nausea, muscle spasm in some neurological disorders and pain that was unrelieved by conventional treatments. The Report recognised the need for more scientific research in this area and expressed a view that crude cannabis could not, and was unlikely ever to be, prescribed in Australia. It acknowledged that there were commercial and regulatory obstacles to medical prescription of synthetic cannabinoid substances in Australia.⁷⁶

2.50 The Report made 24 recommendations, including that the NSW Government:

- conduct more scientific research to evaluate the medical benefits of cannabis
- identify more effective and safer ways to administer cannabis [that is, other than smoking or consuming the plant directly]
- develop a compassionate scheme in the interim to provide access to cannabis to provide relief to patients with serious medical conditions.⁷⁷

2.51 The Report also recommended a two year trial of medical cannabis, under which possessing, growing and using cannabis by approved people with certain medical conditions would be exempted from criminal prosecution.⁷⁸ The Report's findings and recommendations were consistent with the Institute of Medicine and the House of Lords Select Committee on Science and Technology reports.⁷⁹

⁷³ NSW Parliamentary Library Research Service, Briefing Paper No 11/99, p 1.

⁷⁴ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 14.

⁷⁵ Working Party on the Use of Cannabis for Medical Purposes, Report of the Working Party on the Use of Cannabis for Medical Purposes, August 2000, Vol. I and Vol 2.

⁷⁶ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, pp 14–15.

⁷⁷ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 15.

⁷⁸ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 15.

⁷⁹ Submission 14, p 12.

- 2.52** The Report was subsequently released for public comment. In July 2001, the NSW Government published the *Report on Consultation on the Findings and Recommendations of the Working Party on the Use of Cannabis for Medical Purposes* which showed that 72 per cent of the responses supported the medical use of cannabis.⁸⁰
- 2.53** In May 2003, Premier Carr announced his intention to launch a four year trial of the medical use of cannabis. This proposal included the establishment of the Office of Medicinal Cannabis, which would regulate and support matters related to the supply and use of medicinal cannabis. Eligible patients would be requested to register with the Office of Medical Cannabis on a yearly basis and provide medical certificate from their regular doctors. People excluded from the trial were are young people under 18, pregnant women, people convicted of an illicit drug offence in any jurisdiction (other than for a minor personal use offence) and offenders on parole. Offences and penalties would apply for any who contravene the provisions.⁸¹
- 2.54** This proposal was supported by the then Opposition on the condition that the cultivation and distribution of cannabis and the eligibility criteria for participants were kept under tight control. However, the proposed trial of the medical use of cannabis did not proceed.⁸²

Moves to introduce Sativex in Australia

- 2.55** In May 2008, Premier Carr's successor, Hon Morris Iemma MP, sought permission from the Commonwealth Government to import Sativex into Australia.⁸³
- 2.56** In November 2012, Sativex (also referred to as nabiximols), was entered into the Australian Register of Therapeutic Goods as a controlled drug, available on prescription to treat multiple sclerosis related spasticity.⁸⁴

Regulation of cannabis in Australia

- 2.57** The following section sets out the regulatory system for cannabis use in Australia and New South Wales. First, it outlines the Commonwealth Government's regulation of cannabis, then briefly describes the legislation governing the supply of all medical products, including medical cannabis. Finally, it summarises the NSW Government's legislative framework for cannabis use.

⁸⁰ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 15.

⁸¹ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 16.

⁸² NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 16.

⁸³ Drug Policy Modelling Program, The University of New South Wales, The Australian (illicit) drug policy timeline: 1985-2013, The University of New South Wales, accessed 10 April 2013, < [http://www.dpmp.unsw.edu.au/DPMPWeb.nsf/resources/timeline/\\$file/57361209.pdf](http://www.dpmp.unsw.edu.au/DPMPWeb.nsf/resources/timeline/$file/57361209.pdf)>

⁸⁴ Therapeutic Goods Administration, Department of Health and Ageing (Cth), Public Summary [of nabiximol], accessed 17 April 2013, < [https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=80AE3C9BF0BDD408CA257AC2003CB6EF&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=80AE3C9BF0BDD408CA257AC2003CB6EF&agid=(PrintDetailsPublic)&actionid=1)>.

Australia

2.58 Australia is a signatory to two international agreements overseen by the United Nations restricting the use of cannabis: the *Single Convention on Narcotic Drugs (1961)* and the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)*.⁸⁵ These agreements require the Commonwealth to limit the cultivation, trade and use of cannabis to medical or scientific purposes.⁸⁶ Any cultivation, possession and use of cannabis plants or pharmaceutical cannabis (except Sativex provided on prescription, or cannabis products accessed via the Special Access Scheme discussed below in paragraph 2.60) is illegal in Australia and all its states and territories.

2.59 Relevant Commonwealth legislation limiting the use of cannabis includes:

- *Customs Act 1901*
- *Customs (Prohibited Imports) Regulations 1956*
- *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990*
- *Narcotics Drugs Act 1967*
- *Therapeutic Goods Act 1989*.

Therapeutic Goods Act 1989

2.60 The *Therapeutic Goods Act 1989* sets out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (ARTG).⁸⁷ The ARTG records goods approved for therapeutic use. The only cannabis product listed on the ARTG at the moment is Sativex, which is classified as a controlled drug and is only available on prescription from a medical practitioner authorised by the Secretary of the Commonwealth Department of Health and Ageing.⁸⁸

2.61 Patients with serious medical conditions or at the end stage of their life may request access to cannabis products or other unapproved therapeutic goods through the Therapeutic Goods Administration under the provision of the Special Access Scheme.⁸⁹ For example, dronabinol was once imported to treat HIV related wasting under the Scheme, however, the accompanying high costs prevented eligible patients from accessing the treatment.⁹⁰

⁸⁵ Submission 4, p 4.

⁸⁶ Correspondence from Ms Jane Halton, Secretary, Department of Health and Ageing, to Chair, 15 April 2013, p 2.

⁸⁷ Department of Health and Ageing, Therapeutic Goods Administration, Legislation & legislative instruments, accessed 24 April 2013, < <http://www.tga.gov.au/industry/legislation.htm>>.

⁸⁸ Correspondence from Ms Halton, to Chair, 15 April 2013, p 2.

⁸⁹ Therapeutic Goods Administration, Department of Health and Ageing, Special access scheme, access 16 April 2013, < <http://www.tga.gov.au/hp/access-sas.htm>>.

⁹⁰ NSW Parliamentary Library Research Service, Issues backgrounder, No 1, p 8.

New South Wales

- 2.62** Cannabis offences within Australia are enforced by state and territory laws. In New South Wales, it is a criminal offence to cultivate, possess and distribute cannabis. However, under the Cannabis Cautioning Scheme, introduced in 2000, NSW police have the discretion to either press criminal charges or issue up to two cautions against a person for the possession or use of up to 15 grams of cannabis products or equipment for the administration of cannabis.⁹¹
- 2.63** Relevant state legislation includes:
- *Drug Misuse and Trafficking Act 1985*
 - *Poisons and Therapeutic Goods Act 1966*
 - *Hemp Industry Act 2008* (which authorises and regulates the cultivation and supply of low THC hemp for various uses, including commercial).
- 2.64** State and territory related laws could potentially be overwritten by Commonwealth laws, if they were found to contravene the Commonwealth's international obligations.⁹²

Regulation of cannabis in overseas jurisdictions

- 2.65** This section sets out the legal frameworks operating in three of the countries that have legalised medical cannabis: the Netherlands, Canada and the United States. The Netherlands represents the most liberal regulatory system where possession of a small amount of cannabis for personal use is tolerated. Canada has established a special cannabis access program to supply medical cannabis but prohibits any cannabis use for non-medical purposes,⁹³ while the United States has a two-tier Federal/State regulatory system for cannabis use. Each of three countries are signatories to The United Nations *Single Convention on Narcotic Drugs*.⁹⁴

The Netherlands

- 2.66** Cannabis is an illegal substance in the Netherlands. However, any possession of up to 5 grams per person for personal use is not prosecuted by the Dutch government.⁹⁵ Cannabis is available from special 'coffee shops' which were designed to separate young recreational cannabis users from the use or trade of hard drugs.⁹⁶

⁹¹ NSW Parliamentary Library Research Service, Issues backgrounder, No 1, p 2.

⁹² NSW Parliamentary Library Research Service, Issues backgrounder, No 1, pp 20-21.

⁹³ Health Canada, About the Marihuana Medical Access Program, accessed 29 April 2013, <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/index-eng.php>>.

⁹⁴ United Nations, Single Convention on Narcotic Drugs 1961, accessed 29 April 2013, <http://www.unodc.org/pdf/convention_1961_en.pdf>.

⁹⁵ Library of Canada, Parliament of Canada, National Drug Policy: The Netherlands, accessed 16 April 2013, <<http://www.parl.gc.ca/Content/SEN/Committee/371/ille/library/dolin1-e.htm#D>. Why is the Dutch System Different?>.

⁹⁶ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 22 and p 24.

- 2.67** In relation to the medical use of cannabis, the Dutch Government introduced a program in 2003 to supply medicinal cannabis, in crude plant form⁹⁷ to seriously ill persons. Patients can obtain government supplied cannabis from pharmacies, pharmacy holding general practitioners and hospitals.⁹⁸ Patients are warned against smoking cannabis and advised to inhale cannabis using a vaporiser or drink it as a herbal tea.⁹⁹
- 2.68** The cultivation, production and supply of medicinal cannabis is regulated by the Bureau voor Medicinale Cannabis (BMC). The BMC also licensed prospective cannabis growers, who are required to sell the entire harvest to the BMC and destroy any surplus plants.¹⁰⁰

Canada

- 2.69** Cannabis is neither legal nor approved as a therapeutic good in Canada. However, patients may apply for permission to possess and use crude cannabis for medical purposes under the *Marihuana Medical Access Program*.¹⁰¹
- 2.70** Applicants must be certified by a licensed medical doctor for conditions that either are treated as part of end of life care or fall within a certain range of medical indications, or any other medical symptoms that have debilitating conditions. The applicant and the doctor must declare that conventional treatments have been tried or considered, but have been found ineffective or inappropriate in treating patient's condition.¹⁰²
- 2.71** Approved patients can purchase cannabis from the government, grow their own or delegate someone else to grow it for them. The amount of cannabis that a patient can purchase, grow or possess at any one time depends on the daily dosage recommended by the doctor, with a maximum supply of 30 days. Growers must be over 18 years of age. However, there is no restriction on supplying cannabis treatment to children.¹⁰³
- 2.72** Cannabis is also available from some unlicensed 'cannabis clubs', which operate on a compassionate and not for profit basis. Local police tolerate these operations but can inspect and lay criminal charge against them.¹⁰⁴
- 2.73** Problems associated with the Canadian model include the high cost and unsatisfactory quality of government supplied cannabis, poor patient registration and medical associations discouraging doctors from signing the health declaration for patients.¹⁰⁵

⁹⁷ Bedrocan, Products, accessed 16 April 2013, <<http://www.bedrocan.nl/english/products.html>>.

⁹⁸ Office for Medicinal Cannabis, Home, Accessed 16 April 2013, <<http://www.cannabisbureau.nl/en/>>.

⁹⁹ Bedrocan, The use, accessed 16 April 2013, <<http://www.bedrocan.nl/english/the-use.html>>.

¹⁰⁰ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 23.

¹⁰¹ Health Canada, Cannabis/Marijuana (also hash, hash oil and hemp), accessed 15 April 2013, <<http://www.hc-sc.gc.ca/hc-ps/drugs-drogués/learn-reseigne/cannabis-eng.php>>.

¹⁰² Health Canada, Are you Eligible? Accessed 15 April 2013, <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/how-comment/eligible-admissible-eng.php>>.

¹⁰³ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 27.

¹⁰⁴ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, p 29.

¹⁰⁵ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, pp 29-32.

United States

- 2.74** In the United States, cannabis use is illegal at the federal level. However, 18 states have legalised the medical use of cannabis (eleven via citizen-initiated referenda).¹⁰⁶ Each state's framework for the regulation of cannabis differs in:
- the source of supply (permission to grow by patients or carers or accessible via a central outlay such as cannabis buyers' clubs)
 - requirements for medical assessment (proof of medical conditions, advice given to patients in relation to the risks of cannabis use)
 - medical conditions approved for cannabis use
 - conditions of use and possession (consumption in the public area or at the workplace, quantity allowed for possession at any one time).¹⁰⁷
- 2.75** Pharmaceutical cannabis products such as dronabinol and nabilone have been approved for therapeutic use since 1985. Sativex is still pending approval for use in cancer related pain relief.¹⁰⁸
- 2.76** There are several problems with the US approach. Firstly, the inconsistency between federal and state laws means that cannabis suppliers (including medical practitioners who prescribe cannabis) might not be protected against federal criminal charges. Secondly, it is difficult for patients to secure a legal supply of cannabis. Patients often have to purchase from the black market or through compassionate clubs who obtain cannabis from the same source. This creates a 'quasi legal' system for cannabis production and distribution in some states, and some medical cannabis is sold to recreational users. Thirdly, in allowing cannabis to be supplied on prescription, but in the absence of sufficient medical study of cannabis, medical practitioners can find it hard to know what amount to prescribe or for what medical conditions. Lastly, studies suggest that most cannabis users in the most liberal Californian system are unlikely to be people with severe cancer or neurological diseases. This finding raises questions as to whether these 'medical cannabis programs' are meeting their purposes.¹⁰⁹

¹⁰⁶ Submission 46, p 14.

¹⁰⁷ NSW Parliamentary Library Research Service, Briefing Paper No 10/04, pp 33-53.

¹⁰⁸ Submission 4, p 6.

¹⁰⁹ Submission 46, pp 14-16.

Chapter 3 **Pharmaceutical cannabis products**

The previous chapter provided the background to this report by documenting factual information about cannabis and cannabis products, their efficacy and risks, and the present Commonwealth and State legal framework for them. The present chapter and the following one form the main body of the Committee's report by reflecting, analysing and making recommendations on the evidence we received from inquiry participants as to whether cannabis and cannabis products should be made legally available for medical use.

In Chapter 2 we noted the key distinction between pharmaceutical cannabis products and crude cannabis products, which emerged as distinct areas for debate among inquiry participants, with correspondingly distinct implications for law and policy. In this chapter we focus principally on pharmaceutical products, while the following chapter focuses on crude cannabis. This chapter commences, however, with participants' broad views about the potential use of cannabis - in its general sense - for medical purposes. Here it examines participants' views on the priority to be afforded to the issue, ideological considerations and the risks and harms that might arise from the use of cannabis for medical purposes.

The chapter then examines participants' views on pharmaceutical cannabis products, noting a number of important advantages of cannabis in this form, before turning to the critical issue of whether there is now sufficient scientific evidence to justify the expanded use of pharmaceutical cannabinoids and for which medical conditions. The Committee makes a number of findings, including that in general terms medical cannabis has potential as an effective treatment for certain medical conditions, with appropriate safeguards in place.

Views on the potential use of cannabis for medical purposes

- 3.1** A broad range of inquiry participants expressed their support for the potential use of cannabis for medical purposes, referring to cannabis products generally, without making a distinction between pharmaceutical and crude forms.
- 3.2** Professor Michael Cousins, Director of the Pain Management Research Institute, Royal North Shore Hospital, and of the University of Sydney, underscored his support for the potential use of cannabinoids for pain management by reporting an urgent need to expand the menu of pain treatments:

The most important thing I am going to say is that there is an urgent need for more options for patients with pain. This includes patients with acute pain, such as pain after surgery or trauma, patients with cancer pain and patients with a very wide range of conditions that are associated with chronic non-cancer pain. There just simply are not enough options to cover the situations that a wide range of patients present with. Some of the current options work for some patients, but they do not work for all of them.¹¹⁰

- 3.3** Generally, participants' support was based on the recognition of the scientific evidence for the efficacy of cannabis products in treating various conditions documented in the previous

¹¹⁰ Professor Michael Cousins, University of Sydney, and Director, Pain Management Research Institute, Royal North Shore Hospital, Evidence, 13 March 2013, p 11.

chapter. In its submission, for example, the Cancer Council NSW identified certain circumstances where there may be potential benefits to patients:

Cancer Council NSW acknowledges that cannabis may be of medical benefit to cancer patients where conventional treatments are unsuccessful, in the following circumstances:

- in relieving nausea and vomiting in patients undergoing chemotherapy;
- as an adjunctive analgesic in patients with moderate to severe pain; and/or
- as an appetite stimulant for cancer patients experiencing weight loss and muscle wasting.¹¹¹

3.4 The consumer group Cancer Voices expressed strong support for the potential use of cannabis for the treatment of medical conditions, with appropriate safeguards in place, identifying two aspects of their utility for cancer patients:

- as an antiemetic, reducing vomiting and gastrointestinal discomfort caused by treatment, and
- as an analgesic to control or reduce chronic pain, caused by the progression of the disease.¹¹²

3.5 The Australian Drug Law Reform Foundation (hereafter ADLRF) cited numerous research papers to demonstrate that internationally, there is growing interest in harnessing the therapeutic potential of cannabis, possibly as a result of improvements in botanical drug development and the discovery of the human endocannabinoid system. It noted that scientists, medical authorities and major pharmaceutical companies in several countries are actively researching the cannabis plant and many of its psychoactive extracts.¹¹³ The ADLRF argued that cannabis should be available for provision within a doctor-patient relationship for medical purposes, determined by the current criteria for regulation of all medicines - most especially efficacy, safety and cost-effectiveness¹¹⁴ - and went on to summarise the present evidence on efficacy:

There is now little doubt that rigorous evidence exists to support the conclusion that medicinal cannabis can be an effective medication for some medical conditions. At present it does not appear to be a first line drug for any condition but it is sometimes a very useful second or third line drug providing considerable benefit to some unfortunate patients with intolerably severe symptoms from some conditions, including some patients with a short life expectancy where more conventional medications have already proved ineffective or accompanied by unacceptable side effects. These conditions include: (i) intractable nausea and vomiting following cancer chemotherapy; (ii) severe wasting in advanced HIV infection; (iii) disseminated sclerosis accompanied by severe spasticity; and (iv) selected cases of severe chronic non-cancer pain.¹¹⁵

¹¹¹ Submission 4, Cancer Council NSW, p ii.

¹¹² Submission 7, Cancer Voices, p 2.

¹¹³ Submission 54, Australian Drug Law Reform Foundation, p 6.

¹¹⁴ Submission 54, p 2; Mr Evert Rauwendaal, Member, Australian Drug Law Reform Foundation, Evidence, 11 March 2013, p 61.

¹¹⁵ Submission 54, p 2.

- 3.6** Correspondingly, the ADLRF recommended that the NSW Government accept that ‘the evidence for effectiveness and safety of medicinal cannabis for certain conditions warrants this agent being legally provided in NSW’, and that it ‘commence allowing medicinal cannabis in patients with severe and distressing symptoms unrelieved by conventional medication’.¹¹⁶
- 3.7** Mr Nicholas Parkhill, Chief Executive Officer of ACON clearly outlined the support of his organisation, as well as that of Positive Life NSW, the Australian Federation of AIDS Organisations, and National Association of People with HIV:

As raised in our submission, we support the availability of cannabis for medical use ... We want to see a system that allows reasonable availability to a small number of people who are in specific circumstances. Any system that is implemented must be: Economically accessible to people who are already experiencing a high economic burden due to their treatment; safe, in relative terms of their existing health conditions; and one that makes it easy for people to understand their position with regard to the law.¹¹⁷

- 3.8** Evidence of the efficacy of cannabis was also emphasised by two members of the former Working Party on the Use of Cannabis for Medical Purposes (hereafter the Working Party) that reported to the NSW Government in August 2000 (see Chapter 2). Emeritus Professor Lawrence Mather of the Department of Anaesthesia and Pain Management at the University of Sydney, an academic medical research scientist with substantial expertise on cannabis and cannabinoids, emphasised that recognition of the efficacy of cannabis was consistent with an evidence based approach to medicine:

There is now much evidence for the usefulness of cannabis/cannabinoid medications. Modern medicine is committed to an evidence based adoption of practice and these standards should also form the basis of the political deliberations about this issue.¹¹⁸

- 3.9** In addition, in his joint submission with Professor Michael Farrell, Director of the National Drug and Alcohol Research Centre (NDARC), the Chair of the Working Party, Professor Wayne Hall, of the University of Queensland Centre for Clinical Research, concluded that the present research evidence points to a valuable but limited role for cannabinoids:

Controlled clinical trials indicate that cannabinoids have some efficacy in controlling emesis [or vomiting] in cancer patients, in stimulating appetite in AIDS patients and in relieving pain. Much of this evidence comes from studies that are 30 years old and for many of these indications the medical need for cannabinoids has been reduced by the development of more effective drugs. If the cannabinoids have a medical role in these indications, it is as second or third line treatments, or as an adjunctive treatment.¹¹⁹

- 3.10** During her evidence, Professor Jan Copeland of the University of New South Wales observed that this is an under-researched area and reported that the available research indicates that

¹¹⁶ Submission 54, p 3.

¹¹⁷ Mr Nicholas Parkhill, Chief Executive Officer, ACON, Evidence, 18 March 2013, p 52.

¹¹⁸ Submission 14a, Emeritus Professor Lawrence Mather, p 2.

¹¹⁹ Submission 46, Professor Wayne Hall, Deputy Director (Policy), University of Queensland Centre for Clinical Research and Professor Michael Farrell, Director, National Drug and Alcohol Research Centre, University of New South Wales, p 19.

cannabinoids are of positive but modest benefit, whilst noting that cannabinoids also have unexplored potential in the treatment of various medical conditions:

I do think that the cannabinoid family of drugs is well and truly under-researched and certainly some of them have potential for medical application. I think the current state of evidence is not particularly strong; I think it is modest at best for two or three conditions and then only as a second line or adjunctive medication. But that does not mean that in the future—I think particularly the two cannabinoids of most interest to me in my research are CBD, cannabidiol, and THCV, cannabivarin. They are both less potent agonists of the cannabinoid system but have some interesting potentials as antianxiety, antipsychotic and other indications. But we are so far from having evidence at this point but, yes, I think they have potential.¹²⁰

3.11 Professor Copeland went on to note that her conclusion reflected her reading as a scientist, of the scientific literature, acknowledging that while the effect is modest from that perspective, ‘that does not mean clinically it might not be very effective for some patients’.¹²¹

3.12 While the majority of the discussion during the inquiry was on the use of cannabis to manage the symptoms of various illnesses or effects of treatment - primarily pain and nausea - the Committee also heard that there is emerging evidence for the efficacy of cannabis in the management of other conditions, and in the use of cannabis derived products for the active treatment of diseases such as cancer. Dr Andrew Katelaris, for example, stated in evidence that there is a large body of evidence on the ‘anti-tumour’ properties of cannabis, and spoke of his own laboratory based research on the efficacy of cannabinoids attacking cancer cells:

There is a large literature based on animal models and cell culture work looking at the mechanisms by which cannabis exerts, or the cannabinoids exert, their anti-tumour effect, right? There is a vast amount ... [W]hen I was doing my Doctor of Medicine [MD] thesis at St Vincent's Hospital, I studied the process of apoptosis, which is an energy-dependent cell suicide. It appears that the cannabinoids are a unique class of selective apoptosis-inducing agents. So in the tissue culture which has been done in labs all around the world, if you put tumour cells and normal cells together and then add some tetrahydrocannabinol and cannabidiol, you can watch the apoptosis selectively removing the tumour cells.¹²²

3.13 In addition, in its submission Botanic Medical Australia cited a number of publications to report that there is evidence to support the use of cannabinoids in cancer including breast cancer, diabetic retinopathy, gastrointestinal disorders, HIV, Hepatitis C, migraine headaches, and morning sickness, as well as being a ‘neuroprotectant’ that limits damage following stroke or trauma, and in the treatment of neurodegenerative diseases such as Alzheimer’s disease and Parkinson’s disease.¹²³ Cannabis Science Australia cited evidence for the effectiveness of hemp oil in treating skin cancers.¹²⁴

¹²⁰ Professor Jan Copeland, University of New South Wales, Evidence, 18 March 2012, p 17. Professor Copeland gave evidence as an individual, not as a representative of an organisation.

¹²¹ Professor Copeland, Evidence, 18 March 2012, p 17.

¹²² Dr Andrew Katelaris, Evidence, 18 March 2013, p 64.

¹²³ Submission 52, Botanic Medical Australia Pty Ltd, p p 1-2.

¹²⁴ Submission 78, Cannabis Science Australia, p 3.

- 3.14** While we take this evidence at face value we concentrated our investigations to the use of pharmaceutical cannabis products to treat the indications outlined in Chapter 2.
- 3.15** While the Australian Medical Association (AMA) NSW acknowledged that there is some evidence for the efficacy of cannabis as medicine, it called for more research to examine these benefits, in light of cannabis' recognised harmful effects.¹²⁵
- 3.16** On the other hand, Professor Cousins argued that there is sufficient evidence on the efficacy of cannabinoids in relieving pain to justify acting now:

I think it is known, yes. I think in terms of getting started, making it possible for patients to gain access to the benefits of cannabinoids, we should be doing something now. There is enough evidence there that pain relief can be obtained with manipulation of the cannabinoid system, if I can put it that way, and we can argue probably all day about what would be the best agent to use for that ... I agree with what was said in the 2000 [Working Party] report. There is enough evidence, and there is more evidence now. There are at least another two very good studies, well designed, that leave little doubt that pain relief will be obtained by at least some people. In view of the lack of options we currently have, I think it is very important that we take advantage of this option.¹²⁶

A priority issue?

- 3.17** While as noted above, Professor Cousins called for the urgent development of cannabinoids to treat pain, representatives of the NSW Ministry of Health advised the Committee in evidence that the use of cannabis for medical purposes had not emerged as a priority in its consultations with clinicians in the Chronic Pain Network convened by the Agency for Clinical Innovation (ACI). Mr Christopher Shipway, Director of Primary Care and Chronic Services with the Ministry's Agency for Clinical Innovation, told the Committee:

In providing that advice the medicinal use of cannabis never emerged as an issue from that clinical network that needed to be included in that advice to the Government. That is not to say that there are not potentially benefits there—there is certainly research that would indicate that—but our sounding of two or three of the clinical leaders of that pain network prior to attending this hearing was that while there is evidence, it is not sufficiently robust at this stage for the network to consider the medicinal use of cannabis for pain management as a critical area of activity or priority.¹²⁷

- 3.18** Ms Lesley Brydon, Chief Executive of Painaustralia, reported that from her perspective, 'this is one small consideration in the whole sphere of issues around the management of chronic pain'.¹²⁸

¹²⁵ Dr Saxon Smith, Vice President, Australian Medical Association NSW, Evidence, 18 March 2013, pp 2 and 5.

¹²⁶ Professor Cousins, Evidence, 13 March 2013, p 12.

¹²⁷ Mr Christopher Shipway, Director, Primary Care and Chronic Services, Agency for Clinical Innovation, NSW Ministry of Health, Evidence, 11 March 2013, p 5. See also p 2, 8 and 9.

¹²⁸ Ms Lesley Brydon, Chief Executive, Painaustralia, Evidence 11 March 2013, p 28.

- 3.19** In respect of interest among palliative care clinicians, the Ministry of Health advised in answers to questions on notice that while some members of the ACI Palliative Care Network are aware of the potential benefits of medicinal cannabis, especially in relation to reducing pain and nausea and increasing appetite, ‘this topic has not been considered a priority within the Palliative Care Model of Care.’¹²⁹
- 3.20** On the other hand, Ms Sally Crossing, Deputy Chair of Cancer Voices NSW reported that as a consumer organisation focused on a range of issues affecting people with cancer, including pain, ‘It is one of many issues but it is an important issue’. She further suggested that medical use of cannabis may not have emerged as a priority issue for clinicians because it has not been one for the Ministry, which finds legal issues such as this relatively challenging. She indicated that at present, self-medication with cannabis by patients is taking place under the radar without the Ministry being aware of it.¹³⁰
- 3.21** Dr Alex Wodak, President of the ADLRF and Emeritus Consultant at the Alcohol and Drug Service, St Vincent’s Hospital, suggested that this might not be a high order issue within the pain management clinical community because unlike in several other countries, cannabis has not yet been recognised as a potential avenue of treatment in Australia, so clinicians would not be reading and hearing about it.¹³¹
- 3.22** Other inquiry participants indicated that the medical use of cannabis was a salient issue for them. Dr Saxon Smith, Vice President of the AMA NSW reported that it is discussed with some regularity within his organisation,¹³² while the Cancer Council NSW indicated that individuals regularly seek advice from it about cannabis:

[Cancer Council NSW] regularly receives public enquiries regarding the potential therapeutic benefits of cannabis for advanced cannabis patients, leading us to the conclusion that this is an issue which generates public concern.¹³³

- 3.23** Mr Parkhill reported that medical use of cannabis is an important issue for people living with HIV/AIDS, despite it not being a high priority for policy in recent years:

It does get discussed by clients who we are interfacing with, if you like. In respect of where it sits in the policy schedule of priority for us, it has not been a lead policy issue for us over recent years because there has not been that space, if you like, put forward by government for this issue to be discussed. That is why, absolutely, this process is a very welcome process for us. While it might not be making headlines, I think it is still very much a community issue, particularly for those people who are in need of medical cannabis. I am sure you would all appreciate that policy runs in cycles or can run in cycles. The 1999 Drug Summit created a space for this and there was some movement in this area. There has been a level of frustration on our behalf that that

¹²⁹ Answers to questions on notice taken during evidence 11 March 2013, NSW Ministry of Health, Question 3, p 5.

¹³⁰ Ms Sally Crossing, Deputy Chair, Cancer Voices NSW, Evidence, 11 March 2013, p 28.

¹³¹ Dr Alex Wodak, President, Australian Drug Law Reform Foundation, Evidence, 11 March 2013, p 65.

¹³² Dr Smith, Evidence, 18 March 2013, p 9.

¹³³ Submission 4, p i.

did not move towards the next phase. Also, that statement is laid with the context that the needs of positive people are changing with advances in treatment. Having said all of that, it is still a policy issue in great need of attention for us.¹³⁴

- 3.24** Both the ADLRF and Cancer Council NSW noted that there are high levels of community support for the use of cannabis for medical purposes, as reflected in the Australian Institute of Health and Welfare's 2010 National Drug Strategy Household Survey, which found that 69 per cent of those surveyed supported legislative change to permit the medical use of cannabis, while 74 per cent supported clinical trials to investigate the benefits of cannabis for the treatment of medical conditions.¹³⁵

Ideological issues

- 3.25** A number of inquiry participants observed the long history of the use of cannabis for medical purposes in both western and non-western cultures.¹³⁶ Some also suggested that 'ideological' interpretations of cannabis as a drug inevitably impact upon the debate about cannabis for medicinal purposes.
- 3.26** As noted in Chapter 2, cannabis has a long history of use for medical purposes in India and the Middle East, and in western countries during the nineteenth century. According to Professors Hall and Farrell, its declining use in western medicine in the twentieth century 'was accelerated by the somewhat arbitrary inclusion of cannabis under international drug control treaties ... as a drug that had no medical use and whose use posed similar risks as heroin and cocaine.'¹³⁷ They further observed that an effect of the widespread recreational cannabis use by young people in the United States in the 1960s and 1970s has been that the medical use of cannabis has been entangled in policy debates about how to deal with nonmedical cannabis use.¹³⁸ Professors Hall and Farrell suggested that, 'One consequence of this entanglement has been major difficulties in allowing medical cannabis use while prohibiting adult use of cannabis for any nonmedical purpose.'¹³⁹
- 3.27** Similarly, Professor Mather argued that the removal of cannabis from medical practice some 50 years ago was neither a scientific nor medical decision, but an ideological one, as there was virtually no scientific information about it at the time. He suggested that while a dramatic upsurge in scientific research in the last 20 years has corresponded with a greater recognition of the 'pharmacotherapeutic potential' of cannabis products, ideological considerations are still very much at play. He contended, for example, that this is expressed in the emphasis placed on the harms of cannabis, and the fact that in many countries it is only possible to obtain research funding to investigate those harms, rather than the 'possible benefits and uses' of cannabis.¹⁴⁰ Professor Mather further argued that it is crucial to separate medical from non-medical use:

¹³⁴ Mr Parkhill, Evidence, 18 March 2013, p 56.

¹³⁵ Submission 4, p 5; Submission 54, p 4; Mr Rauwendaal, Evidence, p 61.

¹³⁶ See for example Submission 120, Dr Andrew Katelaris, p 2.

¹³⁷ Submission 46, Professor Wayne Hall and Professor Michael Farrell, p 4.

¹³⁸ Bostwick, 2012, in Submission 46, p 4.

¹³⁹ Submission 46, p 4.

¹⁴⁰ Submission 14a, p 1.

As with opioid analgesics used for pain management, it is crucial that the medical and non- medical uses of cannabinoids be divorced, but that the connection be respected. Regrettably, this distinction is often not made ... Because cannabis is associated with an illicit 'recreational' drug culture, it is adversely prejudged by sections of society and this, no doubt, makes reform-minded politicians nervous. For over two decades, cannabis has received considerable press attention, especially by patients and their advocate groups who await law changes to make their medical supply-lines legal, by those who see medical cannabis as the "thin end of the wedge" to breach or avoid issues of the legality and/or criminality of recreational cannabis, and by those who see the side effects as too big a risk for any use.¹⁴¹

- 3.28** In addition to resistance based on ideology, Professor Mather suggested that resistance can also be expected from those who emphasise cannabis' association with possible mental health and/or other side effects, and by others who naturally resist change. He argued that in the face of such resistance, allowing the medical use of cannabis would be a courageous step that has the potential to improve patients' quality of life:

Reintroducing a readily affordable cannabis product for legal medical use, albeit with more efficacious methods of administration than when it was last a legal preparation, would be a valiant move ... On the other hand, reintroduction of cannabis pharmacotherapy may change the quality of peoples' lives, especially for medical conditions that are presently poorly treated.¹⁴²

- 3.29** In evidence, Professor Cousins concurred with Professor Mather's view that there has been too great an emphasis on the potentially negative effects of cannabinoids in the media, also observing a parallel with opioids, which he argued remain a very valuable analgesic despite their risk of misuse and their negative side effects.¹⁴³

- 3.30** Perhaps alluding to the influence of ideologies, the ADLRF noted in its submission that many medicines such as morphine and cocaine are used today and with great benefit although their recreational use is prohibited. It went on to argue that that, 'The failure to use cannabis medicinally because recreational use is prohibited is therefore bizarre'.¹⁴⁴

- 3.31** Cancer Voices cautioned against arguments about the use of cannabis for medical purposes based on religious or political views and beliefs, contending:

This issue is neither a political or religious matter – it is about deciding how to allow access to a medicine, with due care to restrict such access to those who will benefit from it, as with any other drug used for medical purposes.¹⁴⁵

¹⁴¹ Submission 14, p 20.

¹⁴² Submission 14, p 22.

¹⁴³ Professor Cousins, Evidence, 13 March 2013, pp 12-13.

¹⁴⁴ Submission 54, p 2.

¹⁴⁵ Submission 7, p 2.

- 3.32** In his evidence, Dr Wodak underscored the evidence for the community's acceptance of cannabis for medical purposes, noting that many ordinary people agree with the desirability of compassionate responses to disease:

I am sure, if there was a willingness to do it, it would be possible to do it. We are talking about people's grandmothers and grandfathers, and uncles and aunts, and mums and dads. As Evert [Rauwendaal] mentioned, 69 per cent of the Australian people want this ... I think a lot of Australian people these days want to see something sorted out. Our submission is for a very modest beginning, so that people who are opposed to this, for whatever reason, can see that this is a sensible, reasonable and compassionate thing to do, and we should do it. In 2013, if Australia is a compassionate, civilised country, we should be looking after people who need this to lead a more comfortable life.¹⁴⁶

Risks and harms of legalising medical cannabis

- 3.33** Some inquiry participants voiced a concern that legalising the medical use of cannabis might have the unintended consequence of legitimising recreational use. For example, the NCPIC submission argued that in the context of permissive laws on medical marijuana in many parts of the United States, 'very powerful and well-funded pro-cannabis lobby groups have had a marked influence on the community perception of the harms associated with cannabis use among American adolescents', such that the levels of use among high school students in that country has increased markedly.¹⁴⁷ The submission went on to argue that these same messages are being promulgated in Australia:

The messages emphasising cannabis' safety are also echoed by Australian lobby groups for the cause of legal and/or medicinal cannabis. As these also include prominent and credible members of the Australian legal, academic and medical communities they must be balanced with evidence regarding harms and consideration of the negative as well as any putative positive consequences of regulated availability.¹⁴⁸

- 3.34** The risk of inadvertently undermining the message of the harms of recreational use was also emphasised in evidence by representatives of FamilyVoice Australia. Dr David Phillips, President, referred to evidence that recreational use of cannabis in permissive US states is approximately double the level of use in restrictive states.¹⁴⁹ Mr Graeme Mitchell, State Officer, put it in these terms:

¹⁴⁶ Dr Wodak, Evidence, 11 March 2013, p 62.

¹⁴⁷ 'Marijuana use continues to rise among US teens, while alcohol use hits historic lows', *Monitoring the Future*, University of Michigan News Service, 14 December 2011, cited in Submission 56, p 2.

¹⁴⁸ Submission 56, National Cannabis Prevention and Information Centre, p 2.

¹⁴⁹ Dr David Phillips, National President, FamilyVoice Australia, Evidence 18 March 2013, p 40; FamilyVoice Australia subsequently detailed the 2012 findings of Cerda et al, that 3.5 per cent of people in states without legal medical marijuana use had used marijuana in the previous year, compared with 7.13 per cent of people in states where marijuana use was legal: Cerda M, Wall M, Keyes KM, Falea, S and Hasin, D, 'Medical marijuana laws in 50 states: investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence', *Drug and Alcohol Dependence*, 2012, Vol 120, FamilyVoice Australia, Answers to questions on notice, 18 March 2013, Question 1, p 1.

There is evidence that legalised medical marijuana is associated with a lower perception of riskiness in society and higher rates of marijuana use amongst adolescents—that is what I think it is important to consider.¹⁵⁰

- 3.35** Whilst not necessarily endorsing the view, Mr Shipway of the Ministry of Health acknowledged the concern among some stakeholders that allowing medical use of cannabis might be taken by some members of the community to infer that using cannabis ‘might be good for your health or have some efficacious purpose’.¹⁵¹ He suggested that while that risk could be mitigated through appropriate communication strategies, it does need to be taken into account in this debate.¹⁵² In evidence and their submission, AMA representatives underscored the desirability of an effective education campaign targeting both medical professionals and the general community on harmful effects to address this risk, should medicinal cannabis become legally available.¹⁵³
- 3.36** The risk of diversion of medically intended crude cannabis products for recreational use is discussed in detail in Chapter 4, as is the issue of the various harms associated with cannabis.
- 3.37** Dr Wodak addressed the issue of harms in his evidence, by noting that all medicines have potential harms, which must be balanced against their potential benefits when determining their therapeutic potential, and these harms are more able to be controlled in a medical context:

There are always harms in medicinal agents. The real question when you are trying to evaluate the possible place of a medicine in the pharmacopeia is not whether it has harmful side effects but how severe those harmful side effects are, how frequent and what the balance is, most importantly, between benefits and harms. When cannabis is used medicinally there is far more control over it than when it is used recreationally. We should not simply translate from what is said about the harms of recreational cannabis use and extrapolate that to medicinal use because it is likely to be used in smaller quantities, with more purity and more consistency and with the patient instructed as to how to take it.¹⁵⁴

Views on pharmaceutical cannabis products

- 3.38** Having explored the views of inquiry participants in relation to the potential use of cannabis in the treatment of medical conditions, this chapter now moves to its major focus: the potential use of cannabis products in pharmaceutical form.
- 3.39** Notwithstanding the risks observed by some inquiry participants documented above, there was a near consensus among stakeholders in accepting the potential use of pharmaceutical products derived from cannabis in the effective treatment of certain conditions. Even among those who argued very strongly against any sanctioning of crude cannabis for medical use,

¹⁵⁰ Mr Graeme Mitchell, State Officer (NSW and ACT), FamilyVoice Australia, Evidence, 18 March 2014, p 51.

¹⁵¹ Mr Shipway, Evidence, 11 March 2013, pp 2-3.

¹⁵² Mr Shipway, Evidence, 11 March 2013, p 3.

¹⁵³ Dr Smith, Evidence, 18 March 2013, p 3; Submission 21, Australian Medical Association NSW, p 18.

¹⁵⁴ Dr Wodak, Evidence, 11 March 2013, p 61.

most accepted that cannabinoid pharmaceuticals were or could be acceptable.¹⁵⁵ This broad support appears to be based at least in part on stakeholders' acceptance of the evidence for the effectiveness of synthetic and/or naturally occurring cannabinoids (as documented in Chapter 2). At the same time, there was variation in the extent to which stakeholders believed the evidence was currently sufficient to proceed with allowing the use of pharmaceutical cannabinoids in New South Wales.

- 3.40** Set out in the following sections are participants' views on two specific aspects of the possible introduction of pharmaceutical cannabis products: the prescription of such products by medical practitioners and the regulation of such products as therapeutic goods. We then explore the apparently greater acceptability of pharmaceutical products over crude cannabis, noting the various advantages identified by stakeholders with regard to the former. The chapter then discusses participants' views in relation to the research evidence on the risks and side effects accompanying pharmaceutical cannabinoids. Noting the present pharmaceutical industry context in which these medicines are now emerging, we then document participants' views in relation to the product Sativex. Next, we turn to the key issue of whether there is sufficient evidence to allow the use of medicinal cannabinoids, and for which groups, before documenting a number of participants' concerns about the affordability of such medicines.

Prescription by medical practitioners

- 3.41** Implicit within a pharmaceutical model is an understanding that such products are prescribed by medical practitioners within the context of a therapeutic relationship with a patient. Accordingly, this issue was raised by few inquiry participants, with the notable exception of Professor Cousins, who told the Committee that as a clinician, he advocated that prescription of standardised, dose-controlled cannabinoid products such as Sativex would necessarily take place on the basis of a proper 'biopsychosocial' assessment of a patient, that is, one which examines the physical, psychological and environmental factors at work in that patient. He also stressed that such assessment should be conducted by medical practitioners with appropriate education and training, noting that these same provisos would hold for other medications to treat conditions such as chronic pain. Professor Cousins further argued that such assessment should be regularly repeated with a focus not just on whether the medication stopped the pain, but also its effect on the patient's functioning, such as in terms of its impact on their family relationships, their ability to work and participate in other activities, and their quality of life.¹⁵⁶
- 3.42** Related to this, in its submission Painaustralia pointed out that should such medications be made available, it will be essential to ensure that appropriate clinical guidelines are developed and promulgated.¹⁵⁷

¹⁵⁵ See for example Submission 34, Drug Free Australia, p 13 and Submission 55, Drug Advisory Council of Australia, p 55.

¹⁵⁶ Professor Cousins, Evidence, pp 11 and 13.

¹⁵⁷ Submission 27, Painaustralia, p 2.

Regulation as therapeutic goods

3.43 Numerous inquiry participants emphasised that any cannabinoid based medications would necessarily be regulated under the same regime as other pharmaceutical products, that is, the Therapeutic Goods Administration (TGA) system documented in Chapter 2.

3.44 For FamilyVoice Australia, this was crucial. In its submission it recommended that, ‘Cannabis-derived or cannabis-like synthesised products should only be approved for use following the same rigorous scrutiny used for all other therapeutic goods ...’.¹⁵⁸ Elaborating on this point in evidence, Dr Phillips first underscored the necessity for any potentially therapeutic components to be extracted or synthesised and to be subject to proper clinical trials, with their side effects understood and minimised.¹⁵⁹ Explicitly opposing smoking as a delivery method, and then legalisation of any crude cannabis products, he went on to argue that any provision of cannabinoids for medical purposes must occur within the TGA system:

[I]n relation to the question of any of the cannabinoid family that prove to be beneficial for medicinal purposes, the development, the testing, exploration and control of availability and so on should be done through the Therapeutic Goods Administration [TGA] under Federal law, and State governments should not seek to bypass Therapeutic Goods Administration of tests, trials and anything else. The State Government should not get involved in trying to undermine the proper pharmacological processes and testing that is done under the auspices of the Therapeutic Goods Administration.¹⁶⁰

3.45 Stakeholders including PainAustralia, Professors Hall and Farrell and Professor Mather also recommended that any provision of pharmaceutical cannabis products take place within the existing regulatory regime.¹⁶¹

Greater acceptability of pharmaceutical products over crude products

3.46 Many stakeholders expressed a strong preference for pharmaceutical cannabis products over crude, and for some, as for FamilyVoice Australia, this was expressed as an openness to or acceptance of pharmaceutical products matched with an outright rejection of crude cannabis. Others were open to both forms for medical use. Participants’ views in relation to crude cannabis products are examined in detail in the following chapter.

3.47 Stakeholders identified a number of advantages of pharmaceutical products over crude cannabis, often putting this in terms of why they would support such products. While these perceived advantages are interrelated and overlapping, they are broadly categorized below as being safer; enabling standardization and dosage control; minimising unwanted effects; being more personally acceptable; and being able to be differentiated from unlawful cannabis products.

¹⁵⁸ Submission 31, FamilyVoice Australia, p 3.

¹⁵⁹ Dr Phillips, Evidence 18 March 2013, pp 40-41.

¹⁶⁰ Dr Phillips, Evidence 18 March 2013, pp 40-41 and 48.

¹⁶¹ Submission 27, p 1; Professor Wayne Hall, Deputy Director (Policy), University of Queensland Centre for Clinical Research, Evidence, p 73; Professor Michael Farrell, Director, National Drug And Alcohol Research Centre p 73; Submission 14, p 15.

Safety

- 3.48** A number of participants emphasised the greater safety of pharmaceutical products. Like FamilyVoice Australia, the AMA NSW explicitly decried smoking as a delivery method because of its health risks. It also underscored the ready ability to manage, deliver and measure cannabinoid medications, as opposed to crude forms of cannabis.¹⁶²
- 3.49** The NCPIC submission shared the concern about smoking cannabis, making a link between the ability to regulate pharmaceuticals and a number of aspects of reducing harm, both to the individual and the broader community:

Considering the results of the many clinical and experimental studies in humans involving pharmaceutical preparations of cannabis extracts it is logical that selected and targeted manipulation of the cannabinoid system is preferable to treatment with a whole, unregulated, variable dose and contaminated cannabis product with an unsafe delivery system ... Pharmaceutical preparations of cannabis extracts on the other hand can be delivered safely, are tested and subjected to strict regulatory control both in preparation and administration, thereby reducing the harm potential both to the user and the wider society.¹⁶³

- 3.50** Representatives of the NSW Police Force also emphasised that such approved pharmaceutical products would necessarily be therapeutic and safe to use.¹⁶⁴
- 3.51** Sharing her consumer perspective, Ms Crossing of Cancer Voices stated in evidence her support for both crude and pharmaceutical products, whilst also noting that her personal preference would be for the latter because she regards them as safer.¹⁶⁵

Standardisation and dosage control

- 3.52** Linked to the issue of safety, numerous participants highlighted the ability to standardize the contents of pharmaceutical products and thereby control their dosage.
- 3.53** Professor Copeland observed that these considerations were very important to medical practitioners, who would be responsible for prescribing such medications:

I think if you wish a doctor to prescribe a medication, they would want to know what is the composition of that drug, what is the potency, what are the contaminants and that it has been provided in a consistent way. So from one dose to the next the person they would know what medication they were taking. It is a fairly standard medical and pharmaceutical approach that you be aware of what it is you are providing.¹⁶⁶

- 3.54** Similarly, Dr Smith of the AMA NSW argued that pharmaceutical preparations enable the manipulation of dosages to target the best outcomes for patients in clinical trials, as well as

¹⁶² Dr Smith, Evidence, 18 March 2013, p 4.

¹⁶³ Submission 56, p 18.

¹⁶⁴ Superintendent Patrick Paroz, Commander, Drug and Alcohol Coordination, NSW Police Force, Evidence, 11 March 2013, pp 42 and 48.

¹⁶⁵ Ms Crossing, Evidence, 11 March 2013, p 27.

¹⁶⁶ Professor Copeland, Evidence, 18 March 2013, p 22.

enabling ‘post-surveillance’ mechanisms that monitor and record adverse outcomes that can be communicated to the medical profession.¹⁶⁷

- 3.55** From a consumer perspective, Ms Brydon of Painaustralia stressed that dosage control is very important for patients, as is a user-friendly delivery system, stating, ‘I think it is really important that the delivery system is really simple, particularly for people who are ill and they know what dose they are getting. That is critical.’¹⁶⁸

Controlling unwanted effects

- 3.56** The Cancer Council NSW argued that pharmaceutical products are preferable because they enable the minimisation of unwanted effects. It noted for example that nabiximols provide symptom relief without the unwanted psychological effects of tetrahydrocannabinol (THC), and that the Sativex oral spray form of nabiximols is more acceptable delivery method for patients who have difficulty swallowing or digesting tablets.¹⁶⁹ Ms Brydon also reported that avoiding the psychotropic effects of smoked cannabis products is important to many patients, who may worry about the risks of using cannabis in crude form.¹⁷⁰

- 3.57** The NPCIC submission verified that manipulation of the cannabinoid content in pharmaceutical products has enabled the investigation of benefits whilst controlling unwanted effects – in the research context at least:

Pharmaceutical preparation of the plant for research and clinical purposes has enabled the constituent components to be adjusted for research purposes to investigate which combinations of the constituents might provide the best treatment for differing conditions. This is critical as it is the psychoactive components and the balance of the constituents and the route of administration of the drug that create the largest risk of harm to self and others (dependence, cognitive impairment, psychological impairment in terms of paranoia, anxiety and impaired judgment when driving or working, hepatic, respiratory and cardiac disease).¹⁷¹

- 3.58** In addition, Professor Cousins observed that one of the reasons why there is growing interest in the therapeutic use of cannabinoids is that the acute side effects seem to be less than those of opioids.¹⁷²

Personal acceptability to patients

- 3.59** Linked to a number of these perceived advantages is the suggestion that many patients would feel personally uncomfortable with smoking cannabis or using it in another crude form, and are correspondingly more comfortable with and trusting of orthodox medications. Ms Brydon

¹⁶⁷ Dr Smith, Evidence, 18 March 2013, p 4.

¹⁶⁸ Ms Brydon, Evidence, 11 March 2013, p 27.

¹⁶⁹ Submission 27, p i and 7. See also Submission 46, Professor Wayne Hall and Professor Michael Farrell, pp 19-20 and Submission 14, p 9.

¹⁷⁰ Ms Brydon, Evidence, 11 March 2013, p 68.

¹⁷¹ Submission 56, p 4

¹⁷² Professor Cousins, Evidence, 18 March 2013, p 15. See also Submission 10, Mullaways Medical Cannabis, p 3.

put it in these terms: 'I personally would not want to smoke a joint, for example. I find that abhorrent'.¹⁷³

- 3.60** Representatives of the Help End Marijuana Prohibition (HEMP) Party acknowledged that pharmaceutical cannabinoids will be more personally palatable to those people who have had little contact with crude cannabis, and noted their support for such products if they are what a patient's treating physician recommends.¹⁷⁴

Differentiation from unlawful products

- 3.61** Representatives of the NSW Police Force offered a different but important perspective, that the inherent differentiation of pharmaceutical cannabis products from crude would be important for law enforcement. Superintendent Pat Paroz, Commander, Drug and Alcohol Coordination stated in evidence:

One of the things that New South Wales police would be looking for were this to progress is that the medicated form would have to be easily identifiable and differentiable from the normal product, otherwise that would make any enforcement issue very difficult if they were similar but if it was packaged differently, set up differently, used differently, such as the nasal spray type process, then obviously there are clear differences.¹⁷⁵

The pharmaceutical industry context

- 3.62** The Committee was interested to understand the present pharmaceutical industry context in which medicinal cannabinoids are now emerging.

- 3.63** In their submission, Professors Hall and Farrell reported that there is a relatively small market for therapeutic cannabinoids, and noted that while the synthetic cannabinoids dronabinol and nabilone have been available in the United States for some 30 years, their take-up by patients has been poor because, as noted earlier, patients find it difficult to titrate their doses and avoid negative side effects. Pharmaceutical companies have been slow to develop newer cannabinoids that overcome these problems because there are substantial disincentives to them doing so. Such disincentives include that:

- natural cannabis products cannot easily be patented, and the costs of developing and registering synthetic drugs are very high¹⁷⁶
- the small market for such medicine is not seen to justify the costs, as the indications for cannabinoids are uncommon and more effective drugs have emerged to treat conditions such as nausea and vomiting¹⁷⁷

¹⁷³ Ms Brydon, Evidence, 11 March 2013, p 27.

¹⁷⁴ Mr James Moylan, National Campaign Director, The HEMP Party, New South Wales Branch, Evidence, 11 March 2013, p 58; Mr Michael Balderstone, President, The HEMP Party, New South Wales Branch, Evidence, 11 March 2013, p 58.

¹⁷⁵ Superintendent Paroz, Evidence, 11 March 2013, p 42.

¹⁷⁶ Institute of Medicine (US), Division of Neuroscience and Behavioral Health, *Marijuana and Medicine: Assessing the Science Base*, Washington, DC, National Academy Press, 1999, cited in Submission 46, p 18; see also Submission 14, p 9.

- in the United States, pharmaceuticals derived from or chemically related to prohibited substances must meet strict regulatory requirements in order to be registered.¹⁷⁸

Sativex

3.64 As the inquiry proceeded, significant attention coalesced around the nabiximols spray marketed as Sativex, which is now approved or recommended for approval in 21 countries.¹⁷⁹ According to Professors Hall and Farrell, in this context, the development of this product by GW Pharmaceuticals and its registration in various countries has been highly significant:

The current best hope of new pharmaceutical cannabinoids lies with Sativex, the sublingual cannabis extract that has been developed and trialled in the UK over the past decade. The manufacturers of Sativex have been able to patent the plant clones and the process used to produce their extract rather than the natural extract itself. Sativex has been registered for clinical use in Canada, Czech Republic, Denmark, Germany, New Zealand, Spain, Sweden and the UK. Sativex has not yet been registered for use in Australia. Until it has been registered, Australian patients who wish to use cannabinoids for medical purposes have to smoke cannabis.¹⁸⁰

3.65 In evidence, Professor Hall elaborated on the significance of this development, indicating that these events changed the landscape that existed when the Working Party handed down its report in 2000. As there had been no promising pharmaceuticals on the horizon at the time, the Working Party's recommendations were focused on encouraging research and on making cannabis available in its crude form for patients who sought it, in the context of international drug control treaties and the pharmaceutical regulatory system.¹⁸¹ Professor Hall went on to suggest that Sativex could potentially address a number of the problems identified by the Working Party in making cannabinoids available for medical use, whilst acknowledging that this would be dependent on availability of this product, its cost to consumers, and indeed whether the pharmaceutical company that owns Sativex wishes to have it approved and registered in Australia.¹⁸²

3.66 Noting the attention paid to Sativex during the hearings, one inquiry participant, Mr Andrew Kavasilas raised questions about the product in a supplementary submission with regard to

¹⁷⁷ Hall W, Lynskey MT and Degenhardt L, *The Health and Psychological Effects of Cannabis Use*, Canberra, Commonwealth Department of Health and Ageing, 2001, and Institute of Medicine 1999, cited in Submission 46, p 18.

¹⁷⁸ Cohen SP, 'Cannabinoids for chronic pain - Are effective but research is needed to decide who benefits most', Editorial, *British Medical Journal*, 2008, Vol 336, No 7637, pp167-8, Institute of Medicine, 1999, Bostwick JM, *Blurred boundaries: the therapeutics and politics of medical marijuana*, Mayo Clinic Proceedings, 2012, Vol 87, No 2, pp 172-86, cited in Submission 46, p 18.

¹⁷⁹ Answers to questions on notice taken during evidence 11 March 2013, NSW Ministry of Health, Question 1, pp 1 and 3.

¹⁸⁰ Submission 46, pp 13-14, with citations given for: Iversen LL, *The Science of Marijuana*, 2nd ed, Oxford, Oxford University Press, 2007; Russo E and Guy GW, 'A tale of two cannabinoids: The therapeutic rationale for combining tetrahydrocannabinol and cannabidiol', *Medical Hypotheses*, 2006, Vol 66, No, pp 234-46; GW Pharmaceuticals, Sativex, <<http://www.gwpharm.com/Sativex.aspx>>.

¹⁸¹ Professor Hall, Evidence, 11 March 2013, pp 68 and 72.

¹⁸² Professor Hall, Evidence, 11 March 2013, p 72.

‘how the Sativex tincture became lawful in the first place, the simplicity of its manufacture ... why it is so expensive and why couldn’t a similar product be produced here for evaluation’.¹⁸³ He further suggested that many people describe Sativex as very similar to the tinctures available through ‘compassion clubs’ in Australia and that it is very easy to misuse.¹⁸⁴

Current availability

- 3.67** Like Professor Hall, Professor Mather recognised Sativex as a significant opportunity for making pharmaceutical cannabinoids available to patients. He advised the Committee that GW Pharmaceuticals announced in April 2011 that it has entered into an exclusive licence agreement for the multinational pharmaceutical company Novartis Pharma (Australia) to commercialise Sativex in Australia and New Zealand, among other countries, and that it is expected to be available in Australia in the second half of 2013.¹⁸⁵
- 3.68** Mr Bruce Battye of the NSW Ministry of Health advised the Committee in evidence that Sativex has now been accepted on the Australian Register of Therapeutic Goods (ARTG) for specific indication only and that ‘the company, the sponsor, is now grappling with the process of how that is going to be regulated’.¹⁸⁶
- 3.69** The Committee sought advice from the Commonwealth Department of Health and Ageing as to the present status of Sativex in respect of the ARTG. The Department advised that Sativex is now registered as follows:

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

Advice on the medicines scheduling for Sativex was obtained from the Advisory Committee on Medicines Scheduling in March 2013. That committee recommended that in addition to its Schedule 8 classification, Sativex also be included in Part 1 of Appendix D of the Poisons Standard.

The Poisons Standard consists of decisions of the Secretary or a delegate of the Secretary regarding the classification of poisons into nine different Schedules signifying the degree of control recommended to be exercised over their availability to the public. Medicines included in Schedule 8 are Controlled Drugs. This means they are substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Inclusion in Appendix D means that additional specified controls apply on possession or supply. For Sativex the additional control that was recommended is

¹⁸³ Submission 62a, Mr Andrew Kavasilas, p 1.

¹⁸⁴ Submission 62a, p 1.

¹⁸⁵ Submission 14, p 21.

¹⁸⁶ Mr Bruce Battye, Deputy Chief Pharmacist, Pharmaceutical Services, Legal and Regulatory Services Branch, NSW Ministry of Health, Evidence, 11 March 2013, p 3.

that Sativex be available only from or on the prescription or order of an authorised medical practitioner.¹⁸⁷

3.70 The case study of Ms Sue Hodges on the following page details her endeavours to access Sativex to treat her multiple sclerosis muscle spasticity and pain, prior to it becoming registered in Australia.

Case study: Statement by Ms Sue Hodges

As a person who lives with Multiple Sclerosis (MS), I thank the Committee for this opportunity to put forward a statement to the Inquiry. Regrettably, I am unable to appear in person.

I was diagnosed with MS in 1983, and the relentless pain has been with me now for 7 years. It has destroyed my quality of life and the only time I have relief is when I am asleep.

My left leg is badly affected-the tightness/spasm is particularly painful from the knee to the buttock muscle. It is therefore difficult to lift this leg and to walk. Because of this, my balance has now been affected and any attempt at exercise only makes my condition worse.

I have been prescribed a range of medication: pain blockers, analgesics and muscle relaxants, none of which have helped me. Some have had very severe and intolerable side effects.

I became aware of clinical trials that have been conducted in the United Kingdom with compound products derived from natural extracts of the cannabis plant.

The trials which have demonstrated positive results in treating spasticity and associated pain in patients with MS, involved an oral spray called Sativex.

I discussed the possibility of obtaining a prescription for the medication with my Neurologist, who investigated the evidence and availability of the medication on my behalf.

Our enquiries revealed that Sativex has been approved for use in the treatment of MS spasticity in some 20 countries. However, it is not legally able to be prescribed in Australia.

On the evidence available to us, I believe there is a very good chance that a cannabinoid product could help improve my condition, and importantly help alleviate my pain.

As a law-abiding citizen, I have no wish to attempt to obtain the medication illegally. I would certainly not wish to self-administer any such medication without appropriate medical supervision.

I am grateful to the NSW Legislative Council for opening up this inquiry. I sincerely hope the Committee will give very serious consideration to the plight of people like me whose lives are affected, and often ruined, by this debilitating disease.

Over 23,000 Australians live with MS. A high proportion of us suffer from some form of spasticity and pain. In many cases, the pain is mild to severe.

I appeal to the Committee to recommend that appropriate regulation be put in place in Australia to allow access to approved, evidence-based, therapeutic cannabis products for medicinal purposes, and in particular, for the treatment of spasticity and pain in people with MS.

* Ms Sue Hodges, Statement incorporated into transcript of evidence, 11 March 2013, pp 24-25.

¹⁸⁷ Correspondence from Ms Jane Halton, Secretary, Department of Health and Ageing, to Chair, 8 April 2013, p 1.

Clinical trials

- 3.71** The Cancer Council NSW drew on a number of online articles to outline the current clinical trials of Sativex:
- Following Phase IIa and IIb trials demonstrating the effectiveness of nabiximols in relieving advanced cancer pain, GW Pharmaceuticals has commenced a Phase III trial of Sativex for relieving persistent pain in patients with advanced cancer. This study is taking place in Europe, North America, Latin America, and Asia, and is anticipated to be completed by August 2014.¹⁸⁸
 - GW Pharmaceutical is also currently running an international clinical trial of Sativex, including in 11 Australian research sites. The trial aims to determine the efficacy of Sativex as an adjunctive medication in relieving persistent chronic pain in advanced cancer patients, and is estimated to be completed in December 2015.¹⁸⁹
- 3.72** Ms Brydon of Painaustralia advised the Committee that Australian trial sites in relation to cancer related pain include the palliative care departments of Royal Melbourne, Peter MacCallum and John Hunter Hospitals. She further indicated that Painaustralia is not aware of any trials with respect to other forms on non-cancer chronic pain.¹⁹⁰

Is there sufficient evidence to expand the use of pharmaceutical cannabinoids in Australia?

- 3.73** In the context that the use of a pharmaceutical cannabinoid for one specific indication is now approved, a key issue for this inquiry is whether there is sufficient evidence to justify the expanded use of these pharmaceuticals, and for which target groups.
- 3.74** Professor Mather argued that there is sufficient evidence available to justify the permitted use of cannabis pharmacotherapies at this time.¹⁹¹ He explained that in 2000 the Working Party concluded that while there was insufficient rigorous scientific evidence at that time to support the unequivocal introduction of cannabinoids in clinical practice, there were sufficient signals for efficacy, particularly when more conventional treatments had failed. In the absence of a rigorous research base, the Working Party recommended further research be undertaken. Professor Mather went on to report that some 13 years later, ‘the peer-reviewed medical and scientific literature on cannabinoids has expanded enormously and a much stronger evidence base, mainly with standardisation of cannabinoid preparations, is now accruing.’¹⁹²
- 3.75** Professor Mather suggested that whilst not perfect, Sativex ‘is the best controlled dosage form presently available’, and other forms may become available in the future.¹⁹³ He went on to contend that further trials are unnecessary:

¹⁸⁸ Submission 4, pp 7-8.

¹⁸⁹ Submission 4, pp 8.

¹⁹⁰ Ms Brydon, Evidence, 11 March 2013, p 24.

¹⁹¹ Submission 14, p 2.

¹⁹² Submission 14, p 21.

¹⁹³ Submission 14, p 2.

In the decade since the 2000 Report, the commercial botanical product Sativex has already been found useful in so many trials that further local trials of its usefulness are superfluous.¹⁹⁴

3.76 Professor Mather suggested instead that this pharmaceutical ‘be introduced under controlled conditions with data collection by an appropriate regulation agency’.¹⁹⁵

3.77 Perhaps more cautiously, Professors Hall and Farrell suggested that the Committee advocate further clinical trials of nabiximols:

You could advocate for and encourage trials of Sativex or Sativex type products, because there are others under development in Australia, and perhaps look to government funding some clinical trials of those substances to see what interests there might be amongst patients with some of these conditions.¹⁹⁶

3.78 Having documented the research evidence on nabiximols and their advantages in terms of safe delivery and their ability to be standardised, tested and regulated,¹⁹⁷ the NCPIC submission recognised Sativex as ‘the most promising cannabinoid preparation for clinical research - and if proven safe and effective - for medical prescription under supervision’.¹⁹⁸ It went on to argue that ‘the mixed results of many studies particularly those examining pain in MS and some of the unwanted effects call for much more research to be undertaken on the safety and efficacy of these products’.¹⁹⁹

For which groups?

3.79 There was significant debate among inquiry participants about which groups of patients pharmaceutical cannabis products should appropriately be made available to.

3.80 Professor Mather argued that there is sufficient evidence to introduce cannabinoid pharmacotherapy for the following conditions:

- control of nausea/vomiting (e.g. from cancer chemotherapy)
- appetite stimulation (e.g. in patients with HIV-related wasting syndrome)
- control of muscle spasticity (e.g. from multiple sclerosis and spinal cord injury)
- pain management (e.g. for neuropathic pain, and possibly anti-inflammatory treatment)
- anti-convulsant effects (e.g. from epilepsy)
- bronchodilation (asthma treatment).²⁰⁰

3.81 Professor Hall explained to the Committee that the greatest evidence on Sativex’s effectiveness (which has in turn governed its registration for use) is in respect of neuropathic pain arising from multiple sclerosis, as a result of a commercial decisions by GW Pharmaceuticals. This was the primary therapeutic target for early Sativex trials because there

¹⁹⁴ Submission 14, p 2.

¹⁹⁵ Submission 14, p 21.

¹⁹⁶ Professor Hall, Evidence, 11 March 2013, p 74; Professor Farrell, Evidence, 11 March 2013, p 74.

¹⁹⁷ Submission 56, pp 13-14.

¹⁹⁸ Submission 56, p 18.

¹⁹⁹ Submission 56, p 17.

²⁰⁰ Submission 14, p 13.

are no other effective treatments for multiple sclerosis related neuropathic pain. By contrast, as advances in alternative treatments had emerged for nausea associated with cancer as well as AIDS-related wasting had emerged, the company did not apply to register the product for that use. Professor Hall went on to suggest that there might be a case for the use of Sativex as a second line treatment for other conditions such as nausea, for those patients for whom the newer medications prove ineffective.²⁰¹

3.82 A particular debate emerged as to whether pharmaceutical cannabis products should be used to treat chronic pain, including among patients with multiple sclerosis, as distinct from people with pain in the terminal stages of disease such as cancer.

3.83 There was a wide recognition among participants that a compassionate approach in the context of palliative care was entirely appropriate.

3.84 In its submission, Cancer Voices argued that it would be wrong to deny people relief at the very end of their lives:

We also note that health concerns raised by those opposing this move are largely related to long term use by young and healthy people. For people with cancer, there is no suggestion that use of cannabis for medical reasons would pose a long term health risk, for obvious reasons, as it would be prescribed and used for specific symptoms only. It could be argued that if a person is dealing with severe and chronic pain due to late stage metastatic cancer, it would be hypocritical and misguided to suggest that they be denied such relief because of a very small chance of mild long-term damage.²⁰²

3.85 Painaustralia expressed the view that access should be restricted to those at the extreme end of the spectrum, for whom there are few treatment options:

The priority would be to have the cannabis products available to those people who perhaps really need them and that is at the far end of the spectrum where either they are in the terminal stages or whether they have a form of cancer with intractable pain, HIV-AIDS, various MS or various conditions where there are no other options or very few other options for them. We are certainly not advocating it for broader use.²⁰³

3.86 In evidence, Ms Brydon expressed a particular reservation about the use of pharmaceutical cannabinoids for chronic non-cancer pain.²⁰⁴

3.87 Professor Cousins explained to the Committee that the concern about use for chronic pain arises from the absence of evidence on the long term use of cannabinoids. He reported that he ‘would be very comfortable with use in the palliative setting [for] ... [s]omeone who has an incurable disease and clearly reduced life expectancy’, going on to say that chronic non-cancer pain (including that arising from multiple sclerosis) is a more difficult area:

As far as chronic non-cancer pain is concerned, sadly, although such people have a severe chronic disease that is life threatening—some of them commit suicide because of the severity of the pain—some of them will lead a normal length of life. They

²⁰¹ Professor Hall, Evidence, 11 March 2013, pp 68-69.

²⁰² Submission 7, p 2.

²⁰³ Ms Brydon, Evidence, 11 March 2013, p 30.

²⁰⁴ Submission 27, p 1.

certainly will not lead a normal life, but they will lead a normal length of life. I have some concerns about the use of cannabinoids, except in a very well-controlled manner, as to the long-term effects they could have on such individuals. I just highlight that aspect.²⁰⁵

- 3.88** Whilst acknowledging this dilemma, Professor Cousins reported that he would be prepared to use cannabinoids for people in this target group based on careful and ongoing ‘biopsychosocial’ assessment referred to earlier in this chapter:

But I would be comfortable in that setting with very careful assessment of individuals who might benefit and then appropriate frequent reassessment to assess in particular pain but also improvement in their mental and physical functioning and quality of life and if that is going downhill despite the use of cannabinoids, well then I think there should be a reassessment of whether that should be continued. So in whatever system is set up I think those requirements should be in some way included.²⁰⁶

- 3.89** Professor Cousins went on to emphasise that such monitoring of the positive and negative effects of treatment on patients’ functioning is standard medical practice:

But we have to do this all the time. We have to take patients off one drug or another, either because it is not working or there are side-effects that have become intolerable. Cannabis would fit into that sort of paradigm.²⁰⁷

- 3.90** The Commonwealth Department on Health and Ageing advised on the process by which the indications for Sativex could be extended:

For Sativex to be considered for approval by the TGA for use in other [non multiple sclerosis] medical conditions would require that the TGA receive an application to extend the indications for use of Sativex. The application should contain evidence to support the safety and efficacy of Sativex for its intended additional indication. The TGA would evaluate that evidence and if it was considered adequate the proposed additional indication would be approved.²⁰⁸

Cost

- 3.91** A final and noteworthy issue that emerged in evidence concerned the affordability of any pharmaceutical products, should they be registered in Australia. As the Committee explores further in Chapter 4, this is a particular issue if the cost of crude cannabis relative to pharmaceutical cannabis, is low.

- 3.92** Participants such as Mr Kevin Charlesworth, Advisor to Mullaways Medical Cannabis, advised the Committee that in New Zealand, Sativex costs \$500 per month, amounting to \$6,000 per year, underscoring that is a great deal of money for a person who is sick.²⁰⁹ Mr Kavisilas reported that a friend of his paid \$880 for a month’s supply of 4 x 5.5 ml bottles.²¹⁰ The

²⁰⁵ Professor Cousins, Evidence, 13 March 2013, p 11.

²⁰⁶ Professor Cousins, Evidence, 13 March 2013, pp 14-15.

²⁰⁷ Professor Cousins, Evidence, 13 March 2013, pp 14-15.

²⁰⁸ Correspondence from Ms Halton to Chair, 8 April 2013, p 1.

²⁰⁹ Mr Kevin Charlesworth, Advisor, Mullaways, Medical Cannabis, Evidence, 11 March 2013, p 32.

²¹⁰ Submission 62a, p 1.

Ministry of Health advised that reports from the UK vary according to level of subsidy or whether the product is paid for privately. Average prices reported on patient feedback websites indicate a cost of £11, equating to approximately \$AUS16, per day.²¹¹

3.93 Ms Brydon of Painaustralia agreed that it was important that cost not be a barrier to patients accessing pharmaceutical products.²¹²

3.94 Speaking in the context of the ADLRF's proposal for a system of authorised supply of medical cannabis in crude form (discussed in detail in the following chapter), Dr Wodak argued that medicines for this target group must be affordable:

But if people with advanced cancer or advanced HIV are going to be asked to pay those sorts of sums I think they are not going to have that kind of money available. We should not really ask people at that stage in their life to fork out money of that sort of size essentially when they are dying. I think we should try and keep them comfortable at affordable prices²¹³.

3.95 Professor Hall advised that affordability to the patient could be addressed by having Sativex listed on the Pharmaceutical Benefits Scheme. He explained that this involves assessment of the cost-benefits of a medicine, based on extensive evidence of efficacy, by the Commonwealth Government's Pharmaceutical Benefits Advisory Committee.²¹⁴

Committee findings

3.96 The Committee considers that in general terms medical cannabis has potential as an effective treatment for some medical conditions with appropriate safeguards in place. Our reading of the evidence gathered during the inquiry – including rigorous scientific evidence – is that cannabis products are emerging as a promising area of medicine, most notably in respect of a number of painful conditions that do not respond to existing treatments. Given this evidence, a compassionate approach is appropriate here.

3.97 While we recognise the risks and negative effects of crude cannabis use particularly via smoking, and by no means do we endorse the recreational use of cannabis, we agree that there is sufficiently robust scientific evidence to indicate that cannabis products can be an effective treatment for certain conditions in very specific circumstances.

3.98 We recognise that particular attitudes have perhaps prevented us from recognising and harnessing the therapeutic potential of cannabinoids in Australia to date. Such attitudes include those about the harms of illicit drugs, along with concerns about how progress in regard to medical cannabis might be perceived by the public and media.

3.99 The Committee notes public opinion in relation to medical cannabis, with 69 per cent of people in a recent Australian Institute of Health and Welfare survey indicating that they

²¹¹ Answers to questions on notice taken during evidence 11 March 2013, NSW Ministry of Health, Question 1, p 3.

²¹² Ms Brydon, Evidence 11 March 2013, p 24.

²¹³ Dr Wodak, Evidence, 11 March 2013, p 62.

²¹⁴ Professor Hall, Evidence, 11 March 2013, p 73.

support legislation to allow medical use of cannabis, matched with 74 per cent of participants showing support for clinical trials investigating the benefits of cannabis for medical conditions.

- 3.100** We consider that on the present medical evidence, cannabis-based treatments will only be appropriate for a small number of people in specific circumstances, and under the supervision of medical practitioners with suitable expertise. Those patients would necessarily be people with severe and distressing symptoms that are not able to be addressed by existing medications.
- 3.101** While we are not convinced that allowing medical use of cannabis will lead to greater non-medical use, we do recognise that government needs to be cautious about the messages it sends to the broader community in such a sensitive area of policy, but we are confident that appropriate communication strategies can be developed in this respect.
- 3.102** While we take seriously the harms associated with cannabis, we note the point made in evidence that all medicines have harms that must be balanced against benefits in order to determine their therapeutic potential. We have a robust system in place to make these judgments – the Therapeutic Goods Administration (TGA) regime – and consider any such harms are more able to be controlled in a therapeutic context.
- 3.103** Turning specifically to pharmaceutical cannabis products, we see this as a promising and workable area of reform, not least because such products are by definition subject to a robust regulatory system. Their active ingredients and doses are standardised and their unwanted effects are able to be controlled. In addition, pharmaceutical cannabis products are more acceptable to many individual patients, to the broader community and of course from a law enforcement perspective. Significantly, the product nabiximols (under the trade name Sativex) has demonstrated effectiveness is now available for prescription in Australia for the treatment of a highly specific condition, muscle spasticity arising from multiple sclerosis. While the Committee explicitly does not endorse any particular pharmaceutical product, we recognise that this is presently the only pharmaceutical cannabis product on the horizon for which there is an evidence base that can be recognised by the TGA.
- 3.104** In relation to side effects, we are sufficiently reassured by the available evidence that short term use of pharmaceutical cannabinoids is reasonably safe. It will be very important to build up the evidence base in respect of risks arising from long term use.
- 3.105** While there is clear support for a compassionate approach to the use of pharmaceutical cannabis medications by people in the terminal stages of illness, like Professor Cousins, we recognise the dilemma in providing them to people over a long period in the absence of studies on the effects of long term use. This needs to be balanced with the desirability of relieving serious and distressing symptoms. And again like Professor Cousins, we feel comfortable with the provision of pharmaceutical cannabis products to such patients over a longer period within the context of careful and ongoing biopsychosocial assessment of the patient by a medical practitioner with recognised expertise in pain management, as is good medical practice and occurs with other medications.
- 3.106** The Committee also notes Professor Cousins' views regarding the urgent need for more options to treat pain, as well as those of Professor Mather, that there is ample scientific evidence to justify the introduction of cannabis pharmacotherapies. At the same time, we

appreciate the need for such products to be subject to standard regulatory processes. As a committee of the NSW Parliament we urge in the strongest possible terms that action proceed as quickly as possible to enable access by various groups of patients to medicine which could have a profoundly relieving effect.

- 3.107** The Committee respects that other target groups will be appropriately determined over time, according to the proper evidence based processes of the TGA. At the same time, we underscore that there is strong evidence on efficacy in relation to a range of conditions, and consider that access by patients should not be determined by the commercial decisions of pharmaceutical companies alone.
- 3.108** We thus strongly encourage the expansion of the evidence base across a range of treatment groups, as well as the development of products by other companies. We are especially mindful here of people suffering from chronic pain for whom existing pain management is not effective.
- 3.109** Finally, the Committee underscores that the affordability of pharmaceutical cannabis products will be a critical determinant of patient access, and like numerous inquiry participants, we observe that many patients who would benefit from these products are of very limited means at a most vulnerable time of their lives. We agree that the affordability of such products would appropriately be addressed via the Pharmaceutical Benefits Scheme.
- 3.110** The Committee notes that the NSW Government's role in this regulatory area is extremely limited, and that we are unable to make recommendations to the Commonwealth Government. We consider it appropriate, however, for the NSW Minister for Health to write to the Commonwealth Minister for Health and Ageing, expressing in principal support for the timely, evidence based expansion of access to approved pharmaceutical cannabis products by additional patient groups including those suffering from chronic pain for whom existing pain management is not effective, for further clinical trials of pharmaceutical cannabis products to continue to build this evidence base, and for approved pharmaceutical cannabis products to be affordable to patients.

Recommendation 1

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

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

Chapter 4 Crude cannabis products

While there was general agreement among inquiry participants about allowing use of pharmaceutical cannabis products for medical purposes in certain circumstances, the use of crude cannabis products such as plant material, resin or liquids was understandably more controversial.

This chapter explores participants' views on whether and how the use of crude cannabis products for medical purposes might be decriminalised. First, it presents the arguments put forward by a number of inquiry participants that a pharmaceutical approach, as proposed in the previous chapter, will not be sufficient to address this policy issue at this time. The chapter then paints a picture of current use of crude cannabis for medical purposes, and notes participants' comments on the present legal consequences of such use. The Committee then charts participants' arguments for and against reform, before setting out the alternative models for reform presented to us which would provide for the legal use of crude cannabis for medical purposes. Two broad options emerged in evidence: legalised supply of medical cannabis to a defined group; and exempting a defined group from arrest and prosecution for the possession and use of cannabis for medical purposes.

Will a pharmaceutical approach be sufficient?

- 4.1** In the previous chapter the Committee found that in general terms, medical cannabis has potential as an effective treatment for some medical conditions, with appropriate safeguards in place. Our reading of the scientific evidence is that cannabis products are emerging as a promising area of medicine, most notably in respect of painful conditions which do not respond to existing medications. A compassionate approach is one that avails itself of all reasonable options, and we consider this one to be reasonable. Specifically with regard to pharmaceutical cannabis products, we see these as an especially promising and workable way forward. One cannabinoid product is currently available under the Therapeutic Goods Administration (TGA) regime for use with one specific patient group, and may well be approved for other groups over the course of time.
- 4.2** Notwithstanding the consensus of support for pharmaceutical cannabis products under certain strict conditions, many inquiry participants also called for reform to allow the use of crude cannabis products for medical purposes.
- 4.3** In evidence, Professor Wayne Hall, Deputy Director (Policy) at the University of Queensland Centre for Clinical Research, noted that in the absence of any viable pharmaceutical products at the time, the recommendations of the Working Party on the Use of Cannabis for Medical Purposes 'were really about making cannabis available in crude form for individuals who wanted to use it, mindful of international drug control treaties and pharmaceutical regulatory obstacles'.²¹⁵ Fifteen years on, with no significant policy developments having occurred in this area, Professor Hall maintained this position. While he expressed a preference for a pharmaceutical model, he nonetheless advocated reform to provide for those who will choose raw products:

I think the preference would be for pharmaceutical products, which would eliminate a lot of problems that arise in attempting to produce a medicinal form of cannabis

²¹⁵ Professor Wayne Hall, Deputy Director (Policy), University of Queensland Centre for Clinical Research, Evidence, 11 March 2013, p 68.

plant, particularly if it is smoked. Generally, I think there is a need to meet the needs of individuals who are seriously ill with these conditions who might want to smoke cannabis ... It is just a question of how many and what sort of costs the government might be prepared to bear to make the drug available.²¹⁶

4.4 The Australian Drug Law Reform Foundation (ADLRF) submission identified several problems with a pharmaceutical only model:

- There are no provisions of compassionate access until a pharmaceutical product is approved for use.
- Seriously or terminally ill patients who may benefit from cannabis right now may not have time to wait.
- Cannabis based pharmaceutical products may not be listed under the Pharmaceutical Benefits Scheme and may therefore be prohibitively expensive to seriously ill and dying patients.
- Approval of pharmaceutical products can take many years.
- Synthetic versions of cannabis may be inferior to natural whole plant based cannabis.²¹⁷

4.5 Dr Alex Wodak, President of the ADLRF noted in evidence that numerous countries have now provided for the legal use of crude medical cannabis, and suggested that while there have been criticisms about such moves, no serious problems have emerged.²¹⁸

4.6 Dr Andrew Katelaris, a physician who has treated many patients who used cannabis for medical purposes, argued that the TGA system is a flawed one, with numerous approved drugs having gone on to produce adverse patient outcomes.²¹⁹ He went on to propose that it is morally wrong to sanction only access to a commercial pharmaceutical product when an affordable and effective alternative that patients can easily manage is available:

I have a very strong position against an exclusive manufactured base for medical cannabis. GW [Pharmaceuticals] has done a great deal of good work scientifically to bring a product to the market, but it is a very simple matter to assay the potency of cannabis and give people the dose that they want. As I said, they can find it very simply, even from a block of chocolate in a two-day titration trial.²²⁰

4.7 In light of the concerns about the harmful effects of smoking cannabis (noted in paragraph 2.34 and discussed in detail in paragraphs 4.47 to 4.54), several participants pointed out that there are different ways to use crude cannabis aside from smoking it, including vapourisation, tinctures and ingestion via food products containing leaf or cannabinoids extracted from plants (see Chapter 2).²²¹

²¹⁶ Submission 14a, Emeritus Professor Lawrence Mather, pp 1-2.

²¹⁷ Submission 54, Australian Drug Law Reform Foundation, p 12.

²¹⁸ Dr Alex Wodak, President, Australian Drug Law Reform Foundation, Evidence, 11 March 2013, pp 62 – 63.

²¹⁹ Dr Andrew Katelaris, Evidence, 18 March 2011, p 58.

²²⁰ Dr Katelaris, Evidence, 18 March 2011, p 61. See also Submission 120, Dr Andrew Katelaris, pp 2 and 6.

²²¹ See for example Dr Katelaris, Evidence, 18 March 2013, pp 60-61; Submission 10, Mullaways Medical Cannabis, p 15.

- 4.8** Mr Paul O’Grady, who is HIV positive and has been treated for cancer, reported that he used cannabis to treat pain caused by radiation therapy and to address HIV related wasting. He suggested that smoking cannabis facilitates titration of dosages, owing to its immediate effects, then went on to argue for a range of choices to be available to patients:

I suppose if you smoke it you are more conscious of the immediate impact—eating and digestion is much harder to gauge and liquid is something that really I do not think I ever quite mastered ... [It is] different horses for different courses. Obviously, you would be better not to smoke it from a lung perspective. When I was crook, that was actually something that was really hard because my body was so fragile. I believe that you should have a system that suits the individual and that you can create a system whereby you seek to assist the person in the most productive way, whichever way that might be.²²²

- 4.9** Drs Wodak and Katelaris also argued for patient choice, with the latter observing that different products will work better for some people than others.²²³ Dr Katelaris further argued that patients should be trusted to decide for themselves:

It is not for us to say how they should do it. There has been this sanctimonious, nanny-state idea that we have to control this vile impulse of dying people no matter what they want to do. Is one better than another? It depends on the patient. The tincture is ideal, for instance, for people in a nursing home, where they would find it almost impossible to smoke pot or to use a vapouriser ... Eating—in America there is a subset of medical cannabis patients that prefer brownies, right? Who are we to say what they are to prefer? So it really is an individual choice.²²⁴

- 4.10** Others who argued for reforms to allow the medical use of crude cannabis included Emeritus Professor Lawrence Mather,²²⁵ ACON, Positive Life NSW, Australian Federation of AIDS Organisations and the National Association of People with HIV Australia,²²⁶ Hepatitis NSW,²²⁷ Australian Drug Law Reform Initiative at the University of New South Wales (hereafter ADLRI UNSW),²²⁸ Emeritus Professor Ian Webster,²²⁹ Cancer Voices,²³⁰ the NSW Council for Civil Liberties,²³¹ Dr Graham Irvine,²³² and many individuals who made written submissions to the Committee, a number of whom presently use cannabis for medical purposes.

²²² Mr Paul O’Grady, Evidence, 18 March 2013, p 27.

²²³ Dr Wodak, Evidence, 11 March 2013, p 64.

²²⁴ Dr Katelaris, Evidence, 18 March 2011, p 61.

²²⁵ Submission 14, Emeritus Professor Lawrence Mather, p 17.

²²⁶ Submission 73, ACON, Positive Life NSW, Australian Federation of AIDS Organisations and the national Association of People with HIV Australia, p 2.

²²⁷ Submission 68, Hepatitis NSW, p 2.

²²⁸ Submission 69, Australian Drug Law Reform Initiative, pp 1-3.

²²⁹ Submission 108, Emeritus Professor Ian Webster, School of Public Health and Community Medicine, University of New South Wales, p 2.

²³⁰ Submission 7, Cancer Voices, p 1.

²³¹ Submission 58, NSW Council for Civil Liberties, p 1.

²³² Submission 51, Dr Graham Irvine, p 2.

Current use and legal consequences

- 4.11** The Committee heard that at present, the use of crude cannabis products for medical purposes, although against the law, is fairly widespread among people with serious illness.
- 4.12** According to Ms Sally Crossing, Deputy Chair of the consumer group Cancer Voices, there is a large number of people who self medicate with cannabis under the radar: ‘they do not talk about it very much – they just do it.’²³³
- 4.13** Mullaways Medical Cannabis manufactures standardised tinctures from cannabis plants and dispenses them at no cost to patients who present with a signed letter from their doctor certifying that the patient has a medical condition and that the doctor is monitoring their treatment and use of cannabis for medical purposes.²³⁴ Its submission states that thousands of patients and carers have sought assistance from the company, such that it has been unable to meet demand:
- Mullaways has encountered thousands of Australians in chronic and debilitating pain asking for help, many asking questions wanting to educate themselves before trying certain methods of receiving Cannabis therapeutically, and many simply asking to receive the Mullaways Cannabinoid Tincture for medical relief, either for themselves or a loved one.
- Mullaways has tried to facilitate as many chronically ill and dying Australians with its Cannabinoid Tincture as possible. But [we] simply cannot produce the required amount of medicine to supply these people until a license is received from the NSW Government so that a Cannabinoid Research Centre and Manufacturing Plant can be built (to TGA standards) to do the required scientific research and eventually produce the amounts of safe, quality Cannabis medicines required, and to be made accessible through Pharmacists and licensed Dispensaries.²³⁵
- 4.14** Representatives of the Help End Marijuana Prohibition (HEMP) Party advised that their Hemp Embassy receives several phone calls each day from people with cancer asking about cannabis for medical use.²³⁶ At the Committee’s request it also forwarded data on the frequency of traffic to its website.²³⁷
- 4.15** Dr Andrew Katelaris reported that as well as overseeing the use of crude cannabis products, he dispensed Mullaways Medical Cannabis tincture to people with a wide range of conditions, primarily people with terminal cancer, and that he too could not keep up with demand.²³⁸
- 4.16** With regard to people living with HIV, ACON, Positive Life NSW, Australian Federation of AIDS Organisations and the national Association of People with HIV Australia reported that

²³³ Ms Sally Crossing, Deputy Chair, Cancer Voices NSW, Evidence, 11 March 2013, p 25.

²³⁴ Submission 10, p 13.

²³⁵ Submission 10, p 34. See also Mr Tony Bower, Director, Mullaways Medical Cannabis, Evidence, 11 March 2013, p 36.

²³⁶ Mr Michael Balderstone, President, HEMP Party, New South Wales Branch, Evidence, 11 March 2013, p 54.

²³⁷ Answers to questions on notice taken during evidence 11 March 2013, HEMP Party, p 1.

²³⁸ Dr Katelaris, Evidence, 18 March 2011, p 60.

a national survey of Australians living with HIV found that 18 per cent reported using cannabis as a complementary medicine, separate to recreational use.²³⁹ Hepatitis NSW noted anecdotal evidence that some people living with the hepatitis C virus use cannabis to relieve the side effects of interferon based treatment, as well as more broadly in relation to symptom relief of chronic hepatitis C itself.²⁴⁰

- 4.17** Dr Monica Barrett and Professor Simon Lenton of the National Drug Research Institute forwarded preliminary findings from an online survey of Australian cannabis growers, over half of whom (54 per cent) reported that they grew cannabis for their own medical use. The Institute reported to the Committee:

The most commonly treated conditions were reported as: depression and other mood disorders (49%), anxiety or panic disorders (47%), inflammation of the joints (arthritis) (36%), chronic pain (35%), migraines and headaches (27%), bowel problems (18%), post-traumatic stress disorder (18%), and attention deficit hyperactivity disorder (12%). Almost all medical users (93%) reported that at least one of their diagnoses (that they were treating with cannabis) was diagnosed by a doctor or medical professional.

Of those who reported using cannabis to treat a condition diagnosed by a doctor or medical professional, we asked whether the doctor had suggested or recommended the use of cannabis. The most common response was that the doctor did not suggest or recommend cannabis and was not aware of the respondent using it for this purpose (52%). Interestingly, 19% reported that the doctor suggested or recommended use of cannabis as a medicine, while 6% said the doctor advised against its use and another 6% said the doctor refused to recommend it upon request.²⁴¹

- 4.18** In her submission, on which the following case study is based, Lilly reported significant relief from chronic, severe pain after using cannabis.

Case study: Lilly (not her real name)

Lilly has suffered from severe spinal and leg pain due to Degenerative Disc Disease for the last three years. Despite two operations, her pain persisted. Her surgeon told her that he would not perform any more operations and that there was nothing more he could do to help her.

Until recently, Lilly had been taking a range of medications: 16 mg of Jurnista (morphine), reduced from 32 mg over a year; Fentanyl 25 mcg patch every three days; Oxycontin 10 mg three times a day as needed; pethidine injections ten per month; and Lyrica, Panadeine Forte, Valium and Stillnox, all as needed. Lilly was addicted to these medications. Every time when her doctor tried to reduce her medication, she went through withdrawal.

Lilly had also developed severe migraines, so severe she was once hospitalised for a week. Her doctor

²³⁹ Submission 73, p 2. See also Mr Nicholas Parkhill, Chief Executive Officer, ACON, Evidence, 18 March 2013, pp 52-54.

²⁴⁰ Submission 68, p 2.

²⁴¹ Submission 30, Dr Monica Barrett and Professor Simon Lenton, National Drug Research Institute, p 1.

was concerned that her medications may be causing the migraines and also damaging her liver and kidneys.

After a friend suggested Lilly try cannabis to treat her pain, she bought some and made cannabis butter and cookies. After three days on the cookies, Lilly cut out all other medications except for the Jurnista, which she cut down to 2 mg every other day, and expects to soon be off entirely. According to Lilly, her pain is now under control, she is no longer worried about damage to her internal organs and her depression because of her chronic pain has also gone.

* Submission 16, Name suppressed.

4.19 In his submission, Professor Webster referred to cannabis as ‘the poor man’s analgesic’, reporting that ‘in clinical practice it is common to encounter patients with unremitting pain who use cannabis to deal with pain, its sequelae and associated health problems’.²⁴² Professor Webster highlighted a number of commonalities among the patients he has seen over the years:

The clinical problems are complex involving – serious physical conditions, unremitting pain and disorders/disturbances in mental health ... The patients come from low socio-economic backgrounds and have no private health insurance and have poor access to specialist services. The environments are where medical and mental health services are under-resourced; in which general access to all levels of health care are difficult. For example, relatively few general practitioners ‘bulk bill’ and the practices which do are overwhelmed. Continuing care of intractable problems is difficult to achieve. Cannabis is easily available in their communities ... Each patient managed their drug use in order to relieve or ameliorate pain and/or the modulation of the distress, anxiety and dysphoria secondary to continuing pain. They were fully aware of the negative aspects of drug use and used cannabis sparingly.²⁴³

4.20 The case study below, included in the Australian Drug Foundation’s submission with the permission of the woman who wrote it, illustrates that crude cannabis is being used to self-medicate for very serious conditions which are otherwise untreatable by people who would not in other circumstances use an ‘illicit substance’.

Case study: Mary (not her real name)

At age thirteen, Mary was diagnosed with Emery-Dreifuss muscular dystrophy (EDMD). It is a rare childhood-onset degenerative muscle disease characterised by early-onset, contractures, very slow progressive muscle weakness and degeneration involving the upper arms and lower legs, and cardiac (heart) muscle disease.

Mary commented that, “from a young age I have had problems with back pain due to scoliosis...This causes ongoing pain and discomfort. Straining my shoulder muscles is a common problem with me and when this happens I am required to be hospitalised to maintain the pain with strong pain medication. The pain can continue for up to a month for the muscle to recoup. This consists of Endone, every 3 to

²⁴² Submission 108, p 2.

²⁴³ Submission 108, p 3.

4 hours, Panadol and ibuprofen. This pain is unbearable and my body reacts in vomiting and nausea.”

Mary said that taking Endone for a long period of time had caused major problems because the only way for her to cope day to day when taking Endone is to sleep and stay in bed. Although the medication did relieve her pain, it was only for a short period of time. Mary was also concerned because Endone is a potent medication and is easily addictive.

For this reason, Mary decided to try cannabis which she has found to be effective in managing her pain, because the effects last longer in her body and she can function without wanting to sleep and vomit from the treatment.

Mary said that in the past she had considered cannabis a ‘no no’ in her life. But when she could not tolerate any other form of pain medication, she decided to give cannabis a go. Mary said: “I don’t like the fact that I am breaking the law and sneaking around but if it is the only way to be able to treat my pain in a manner that allows me to function in everyday life I will. I advocate strongly for Marijuana to be legalised in the treatment of pain.”

* Submission 29, Australian Drug Foundation, pp 14-16.

4.21 There was some discussion in evidence about the present criminal provisions for medical use of cannabis, as set out in paragraphs 2.61 to 2.63. Ms Penny Musgrave, Director of Criminal Law Review with the Department of Attorney General and Justice, advised the Committee that the extent of prosecution in these circumstances is not known.²⁴⁴ Superintendent Nicholas Bingham, Commander of the NSW Police Force’s Drug Squad, advised that police activities focus on suppliers of cannabis, and vary rarely target drug users. He did, however, acknowledge that individual users can get caught in Drug Squad operations, or may be caught via drug sniffer operations at festivals and so on.²⁴⁵

4.22 As noted in Chapter 2, individuals in possession of up to 15 grams of cannabis may be subject to the Cannabis Cautioning Scheme, and may receive up to two warnings before arrest. Superintendent Bingham emphasised the diversionary and informative intentions of the scheme,²⁴⁶ advising how it generally operates in practice:

But generally speaking, when someone is found with a small amount of cannabis on them they pretty well admit to it straight away that it is for their personal use and they are entitled to a cannabis caution, depending on their background.²⁴⁷

4.23 In answers to questions on notice the NSW Police Force provided the following figures for the number of cannabis cautions issued in New South Wales from 2010 to 2012. No breakdown on the purposes for which the cannabis is intended is recorded.²⁴⁸

²⁴⁴ Ms Penny Musgrave, Director, Criminal Law Review, Department of Attorney General and Justice, Evidence, 11 March 2013, p 21.

²⁴⁵ Superintendent Nicholas Bingham, Commander, Drug Squad, NSW Police Force, Evidence, 11 March 2013, p 47.

²⁴⁶ Superintendent Bingham, Evidence, 11 March 2013, p 49.

²⁴⁷ Superintendent Bingham, Evidence, 11 March 2013, p 44.

Table 1 Number of cannabis cautions issued in 2010, 2011 and 2012

Year	First cannabis cautions	Second cannabis cautions
2010	4,698	464
2011	5,269	542
2013	5,500	597

Source: Answers to questions on notice taken during evidence 11 March 2013, NSW Police Force, Question 1, p 2.

- 4.24** In evidence, Mr Ben Mostyn of the ADLRI UNSW highlighted the discretionary element of the Cannabis Cautioning Scheme, citing findings from a recent performance audit review by Auditor General's Office that police exercise their discretion differently in different areas of the State.²⁴⁹
- 4.25** For those individuals who are arrested and found guilty of possession, Ms Musgrave advised that the intended use of the cannabis for medical purposes can be used successfully as a mitigating factor in sentencing. She reported that a number of sentencing options could be applied, including that no conviction be recorded. When asked by a Committee member, Ms Musgrave further advised that the consequence of there being no explicit exemption from prosecution under current law, is that, once arrested, a person must proceed to court.²⁵⁰
- 4.26** According to Mr Michael Balderstone, President of the HEMP Party, increasingly magistrates are lenient towards people who provide a letter from their doctor verifying their use for medical purposes.²⁵¹

Arguments for reform

- 4.27** Aside from, and perhaps underpinning participants' arguments that a pharmaceutical model will be insufficient to address the issue of medical use of cannabis, stakeholders' reasons for reforms to allow the medical use of crude cannabis fell into several broad areas: the desirability of a compassionate regime; the undesirability of criminalising those who are sick; and that it is preferable for people to use cannabis with their doctor's knowledge. As was the case in Chapter 3, generally, participants' support was predicated on perceptions of efficacy.

Compassionate access to treatment

- 4.28** Compassionate access to effective and accessible treatments was a key argument for legal reform advocated by various participants.
- 4.29** As noted above, the Working Party recommended a regime for limited compassionate provision of [crude] cannabis to patients who may benefit from its use. Its report stated:

²⁴⁸ See also Answers to questions on notice taken during evidence 11 March 2013, Department of Attorney General and Justice, Question 4, pp 3-4.

²⁴⁹ Mr Ben Mostyn, Australian Drug Law Reform Initiative, University of New South Wales, Evidence, 18 March 2013, p 35.

²⁵⁰ Ms Musgrave, Evidence, 11 March 2013, p 21.

²⁵¹ Mr Balderstone, Evidence, 11 March 2013, p 60.

The Working Party ... recommends the introduction in NSW of a compassionate regime to assist those suffering from [a range of illnesses] ... to gain the benefits associated with the use of cannabis without facing criminal sanctions, pending the development of safer and more efficient methods to deliver cannabinoids.²⁵²

4.30 While Emeritus Professor Lawrence Mather of the Department of Anesthesia and Pain Management at the University of Sydney, strongly argued for a pharmaceutical approach, consistent with the recommendations of the Working Party (of which he was a member), he also called for provision to be made for compassionate use of crude products.²⁵³ So did Dr Katelaris.²⁵⁴

4.31 Ms Crossing, a cancer survivor herself, argued for an approach that embodied ‘common sense and kindness’²⁵⁵ by facilitating ease of access to effective treatment:

Pain killing drugs, as Lesley [Brydon, Chief Executive of PainAustralia] said, are very strong chemical potions with usually quite severe side effects. I do not think you should force somebody who needs to have either their gastrointestinal vomiting or pain symptoms addressed, to have to go through those very strong drugs before they get to the stage where there is nothing left and they are finally allowed to have a bit of medical cannabis. I think that the cannabis should be available at the same time because there is a lot of anecdotal evidence, although no hard data unfortunately as we heard this morning ... [I]f there is something that can do the job without substantial side effects, why don't we offer it to people?²⁵⁶

4.32 The following case studies of Andrew and Stuart are typical of many stories told to the Committee by people calling for compassionate access to a treatment that they have found effective in addressing symptoms not addressed by mainstream medications.

Case study: Andrew (not his real name)

Andrew had always been against the use of non-pharmaceutical drugs. He lost a friend to drug use and had witnessed adverse outcomes from it in his past employment. However, he is now convinced that cannabis has a legitimate place in the treatment of severe medical conditions.

Some twenty years ago, Andrew was the victim of a vicious attack, leaving him with a fractured skull, brain damage and Post Traumatic Stress Disorder. A few years later, he was also diagnosed with Crohn's Disease, for which there is no known cure, and which gave him abdominal pain, diarrhoea and a range of other symptoms including fever and weight loss.

To treat his medical conditions, Andrew participated in medical trials for many years but nothing eased his symptoms. He says that Azathioprine, the last drug he tried, almost killed him. After all these unsuccessful treatments, a gastrologist told Andrew he had nothing more to offer him.

²⁵² Working Party on the Use of Cannabis for Medical Purposes, *Report*, Volume 1, Executive Summary, August 2000, p 30.

²⁵³ Submission 14, p 17.

²⁵⁴ Dr Katelaris, Evidence, 18 March 2013, p 64.

²⁵⁵ Ms Crossing, Evidence, 11 March 2013, p 23.

²⁵⁶ Ms Crossing, Evidence, 11 March 2013, p 23.

In desperation Andrew searched for alternative treatments on the internet and found an article suggesting that cannabis based drugs could help his medical conditions. After using cannabis tincture for a week he found he had less abdominal pain and insomnia, even despite discontinuing using valium. His bowel motions had reduced from around 20 times a day to around four times a day, and he was less irritable and anxious.

The biggest problem for Andrew now is how to maintain a consistent supply of his ‘medication’. According to Andrew, “This is extremely frustrating to a person who has to live with an incurable disease whose symptoms mainstream medicine cannot even relieve ... Sometime in the not too distant future I look forward to being free to use cannabis as a medicine without discrimination and being viewed as a criminal. I find the present situation totally immoral and against my human rights. In my opinion, my choice to medicate with a natural herb to treat my symptoms should be an inalienable right, especially considering it has been the only medicine that has gained me any relief from what are extremely debilitating symptoms.”

* Submission 5, Name suppressed.

Case study: Stuart

Stuart has terminal cancer with a life expectancy of six to twelve months. He is currently on a large number of medications including 150 mg of Fretnal (Morphine patch) and up to 250 ml of Odrine (Morphine syrup). He stated in his submission:

“Our whole life as a family has changed, our children have has to watch the decline of my health and my wife now needs to care for me 24/7. When you are put into our position you will look at anything that might help or make life easier.”

“I broke the law and acquired some marijuana for my own usage. We found it helped tremendously with pain, nausea and appetite, two of the biggest problem when in palliative care.”

“Why do I need to commit a criminal act to help myself when so many countries ... have embraced the values of marijuana for medical purposes? If the politicians won’t let me die with dignity, at least let me live with some.”

* Submission 89, Mr Stuart Parr.

Criminalising sick people

4.33 A number of participants argued that it is wrong that current laws criminalise sick people for using medicines that they find helpful to them.

4.34 Professor Webster, for example, argued that, ‘persons, who out of necessity and with some benefit use cannabis, need to be protected by legislation rather than being criminalised by existing law’.²⁵⁷

²⁵⁷ Submission 108, p 2.

4.35 Both the HEMP Party and Mullaways Medical Cannabis highlighted the harmful outcomes of such criminalisation. Mr Balderstone underscored the stigma attached to cannabis use, along with the stress that accompanies hiding it from family and friends and being labelled a ‘criminal’ or a ‘druggie’ for self medicating.²⁵⁸ Mullaways Medical Cannabis emphasised that those who use cannabis for medical purposes respect the law, but in the face of their own or their loved one’s debilitating pain, will pursue all reasonable alternatives, including via the black market and even though such products are unregulated and carry greater health risks. In this context, Mullaways Medical Cannabis called for the development of safe, quality alternatives, as well as decriminalisation of cannabis for medical purposes:

Until such time as the production of safe, quality therapeutic Cannabis based medicines such as tinctures, patches, creams, oils, edibles and/or a medical grade form of therapeutic Cannabis is available in Australia many chronically ill and dying Australians, their carers and family's will continue to be unfairly punished for simply trying to relieve the severe pain the only way they find possible through Cannabis, and by obtaining the Cannabis the only way they find possible through street dealers ... [S]omething must be done to ensure protection against criminal prosecution of patients whom require Cannabis for medical relief, and the carers of said patients.²⁵⁹

4.36 Both Mr Parkhill of ACON and Ms Margaret Hall of the ADLRI UNSW agreed in evidence that obtaining and using an illegal medication adds a layer of stress to people who are very unwell.²⁶⁰ Dr Katelaris highlighted the stress associated with police interdiction, of having to find and purchase the product, the cost of the product, and of losing their supply when they are found in possession of it.²⁶¹

4.37 While the Australian Medical Association (AMA) NSW was very clear that it did not endorse the use of crude cannabis, it nevertheless cited a number of studies to draw attention to the ‘profound’ negative health effects of criminalisation. It argued that there is no evidence that criminal penalties act as a deterrent to drug use, and that the presence of a criminal record can severely limit employment prospects, leading to poor health. It further argued that drug prohibition contributes significantly to the health costs of illicit drug use, and hinders harm minimisation.²⁶²

Use under medical supervision

4.38 ACON and its submission coauthors argued that is preferable that people use cannabis under the direction of their doctor:

The parties to this submission believe that the decriminalisation of personal use for medical purposes would facilitate more honest and open discussion between [people

²⁵⁸ Mr Balderstone, Evidence, 11 March 2013, p 60. See also Submission 85, Mr Michael Balderstone, p 4.

²⁵⁹ Submission 10, p 37. See also Mr Kevin Charlesworth, Advisor, Mullaways, Medical Cannabis, Evidence, 11 March 2013, p 36.

²⁶⁰ Ms Margaret Hall, Australian Drug Law Reform Initiative, University of New South Wales, Evidence, 18 March 2013, p 34.

²⁶¹ Dr Katelaris, Evidence, 18 March 2011, p 62.

²⁶² A Macintosh, *Drug Law Reform: Beyond Prohibition*, cited in Submission 21, Australian Medical Association, NSW p 12.

living with HIV] and their doctors about the possible benefits and risks of its use. It could also see further research being undertaken in NSW due to a more open regulatory framework.²⁶³

- 4.39** Mr Parkhill of ACON agreed in evidence that this would be safer than patients self-medicating, especially in the context of their use of multiple other medications, as is often the case with HIV.²⁶⁴

Affordability

- 4.40** In the previous chapter that Committee noted the extremely high cost of the pharmaceutical Sativex at present. Several participants' contended that some patients would find it much more affordable to purchase cannabis on the black market or grow their own cannabis.
- 4.41** Mr James Moylan of the HEMP Party for example, estimated that the effect achieved through a bottle of Sativex could be gained for significantly less in raw cannabis at black market prices. He estimated that for affordability reasons, many would in fact grow their own.²⁶⁵
- 4.42** Ms Hall of the ADLRI UNSW argued that she would be very reluctant to compound the stress for patients by imposing the significant costs of pharmaceutical products when cannabis can be produced very cheaply.²⁶⁶ Like others, she highlighted that anecdotally, Sativex is not as effective as crude cannabis and restricted in its availability.²⁶⁷

Arguments against reform

- 4.43** A small number of inquiry participants including Drug Free Australia,²⁶⁸ the Drug Advisory Council of Australia²⁶⁹ and the Christian Democratic Party²⁷⁰ were adamant in their opposition to the use of cannabis for medical purposes. These views were exemplified by FamilyVoice Australia, which recommended that no consideration be given to 'allowing any exemptions from the laws regulating cannabis and marijuana under the guise of medical use'²⁷¹ on the basis that this would lead to significant individual and social problems:

Legalising marijuana for medical use combines the risks of increasing availability and normalising of drug-taking behavior, leading to a greater frequency of marijuana-

²⁶³ Submission 73, p 2.

²⁶⁴ Mr Parkhill, Evidence, 18 March 2013, p 55.

²⁶⁵ Mr James Moylan, National Campaign Director, HEMP Party, New South Wales Branch, Evidence, 11 March 2013, p 58.

²⁶⁶ Ms Margaret Hall, Australian Drug Law Reform Initiative, University of New South Wales, Evidence, 18 March 2013, p 34.

²⁶⁷ Ms Hall, Evidence, 18 March 2013, p 37.

²⁶⁸ Submission 34, Drug Free Australia, p 5.

²⁶⁹ Submission 55, Drug Advisory Council of Australia, p 2.

²⁷⁰ Submission 70, Christian Democratic Party, p 1.

²⁷¹ Submission 31, FamilyVoice Australia, p 2. See also Dr David Phillips, National President, FamilyVoice Australia, Evidence 18 March 2013, p 48.

taking at an earlier age, increase abuse and dependency, and more ‘conduct disorder’ symptoms among adolescents.²⁷²

- 4.44** Participants’ arguments against the sanctioning of crude cannabis products for medical use fell into two broad areas: health risks and harms; and the risk of diversion of cannabis products intended for medical use for recreational use. A third important area, the risk of normalising or legitimising cannabis for recreational use, was explored in detail in Chapter 3. A snapshot of the research evidence in respect of risks and harms was provided in Chapter 2. Here, the Committee focuses on the debate among participants, documenting the different viewpoints expressed about the issues during the inquiry.

Health risks and harms

- 4.45** Several participants voiced concerns about the health risks and harms associated with crude cannabis use. The National Cannabis Prevention and Information Centre (NCPIC) submission provided a detailed account of these risks and harms, reporting that cannabis has been proven to be an addictive drug, its consumption has been shown to cause cognitive impairment and increasing vulnerability to psychological harms among users, and smoking cannabis is associated with cardiac and respiratory tract morbidity. Summing up, it emphasised the harms for both individual and public health:

There is now a large and growing evidence base demonstrating that regular use of cannabis in either smoked or eaten form has serious implications for the individual and for society. These implications involve adverse psychological, physical, financial and interpersonal effects for the user and adverse consequences for public health and society in terms of the burden of disease on the public purse and the public health systems.²⁷³

- 4.46** By contrast, other participants such as Dr Graham Irvine, whose PhD thesis examined the medical use of cannabis, argued that cannabis is very safe. He asserted, ‘Cannabis is a particularly safe drug. In the annals of medical history there has never been a death attributable to cannabis alone and adverse effects are relatively trivial.’²⁷⁴

Smoking cannabis

- 4.47** Numerous stakeholders highlighted the toxic effects of smoking cannabis, including some who nonetheless advocated a compassionate approach to its use in certain circumstances.
- 4.48** Professors Hall and Farrell, for example, reported that smoking cannabis delivers carcinogens and other toxic substances to the lungs, whilst noting that smoking is the preferred delivery method of cannabis use among users because it enables them to titrate their dose.²⁷⁵

²⁷² Answers to questions on notice taken during evidence 18 March 2013, FamilyVoice Australia, Question 1, p 2.

²⁷³ Submission 56, National Cannabis Prevention and Information Centre, p 7.

²⁷⁴ Submission 51, p 2.

²⁷⁵ Submission 46, Professor Wayne Hall, Deputy Director (Policy), University of Queensland Centre for Clinical Research and Professor Michael Farrell, Director, National Drug and Alcohol Research Centre, University of New South Wales, pp 12 and 13.

- 4.49** Similarly, both the AMA NSW²⁷⁶ and Cancer Council NSW²⁷⁷ highlighted the detrimental health effects of smoking as a delivery method, and like Hall and Farrell, suggested that this means that crude cannabis is unlikely ever to be approved for medical use.²⁷⁸ The NSW Ministry of Health²⁷⁹ expressed strong concerns about smoking, as did FamilyVoice Australia,²⁸⁰ Drug Free Australia,²⁸¹ and the Drug Advisory Council of Australia.²⁸²
- 4.50** In evidence Mr Balderstone argued that the real health risk associated with smoking cannabis lies in mixing it with tobacco, particularly in terms of addiction.²⁸³ Dr Katelaris endorsed this view and contended that medical cannabis smokers are likely to be using very small amounts. He further argued that any purported cardiovascular risks are not relevant among those who use it to relieve symptoms at the very end of their lives.²⁸⁴
- 4.51** While Dr Alex Wodak, President of the ADLRF and Emeritus Consultant at the Alcohol and Drug Service, St Vincent's Hospital, noted his professional disinclination towards the smoking of cannabis, like others, he made the case that such risks are acceptable among those patients with short life expectancy.²⁸⁵
- 4.52** The ADLRF, like several other participants,²⁸⁶ went on to highlight the use of vaporisers as an alternative and safer delivery method:
- The administration of a medicine mixed with smoke inhaled into the lungs is medically unacceptable except in patients with a short life expectancy. However, administration by inhalation of cannabis vapour is now available, effective and relatively inexpensive. Inhalation has some advantages compared to oral ingestion.²⁸⁷
- 4.53** According to Professor Hall, while there are insufficient studies on the risks arising from vapourisation compared with that of smoking, 'it is plausible that there would be a substantial reduction in risk'.²⁸⁸
- 4.54** In his submission, Mr Andrew Kavasilas, who has conducted research involving the sourcing, cultivation and laboratory analysis of high tetrahydrocannabinol (THC) cannabis plants,

²⁷⁶ Dr Saxon Smith, Vice President, Australian Medical Association NSW. Evidence, 18 March 2013, p 2.

²⁷⁷ Submission 4, Cancer Council NSW, p ii and 4.

²⁷⁸ Submission 4, p ii; Submission 46, p 13.

²⁷⁹ Mr Christopher Shipway, Director, Primary Care and Chronic Services, Agency for Clinical Innovation, NSW Ministry of Health, Evidence, 11 March 2013, p 7.

²⁸⁰ Dr Phillips, Evidence 18 March 2013, pp 40-41. See also Submission 31, p 2.

²⁸¹ Submission 34, pp 3-4 and 7-8.

²⁸² Submission 55, p 1.

²⁸³ Mr Balderstone, Evidence, 11 March 2013, p 57.

²⁸⁴ Dr Katelaris, Evidence, 18 March 2011, p 61.

²⁸⁵ Dr Wodak, Evidence, 11 March 2013, pp 61-62. See also Submission 54, p 2.

²⁸⁶ Dr Katelaris, Evidence, 18 March 2011, p 61; Submission 14, p 17; Mr Balderstone, Evidence, 11 March 2013, pp 52-53; Submission 10, p 4.

²⁸⁷ Submission 54, p 2.

²⁸⁸ Professor Hall, Evidence, 11 March 2013, p 70.

emphasised that various techniques exist to provide cannabinoids in ‘good, clean standardised products’:

I have come to understand that most people who would benefit from the use of cannabinoids for medical purposes have never used cannabis, will never need to smoke it, and will never need dosages above recognised levels of intoxication.²⁸⁹

Effects on mental health and cognitive functioning

4.55 Views expressed to the Committee on the effects of cannabis use on mental health were especially polarised.

4.56 The NPCIC submission emphasised the evidence that cannabis has an adverse impact on mental health:

The psychological effects of cannabis use in the research literature include psychosis and psychotic symptoms, paranoia, depression and anxiety. In terms of the individual and psychological consequences the birth cohort studies (based on 20 years of data) and the studies of targeted cohorts of adolescent as well as various other studies have been able to demonstrate definitively the relationship between cannabis use and the development of psychosis. The literature demonstrates both that using cannabis leads to greater vulnerability for mental health disorders and that people with a vulnerability to mental health disorders use cannabis to self-medicate for those conditions.²⁹⁰

4.57 FamilyVoice Australia highlighted the effect of cannabis use on cognitive ability, referring in evidence to a study which found a reduction in intelligence quotient (IQ) of about eight points among cannabis users.²⁹¹ In answers to questions on notice it verified that this longitudinal study from New Zealand found that ‘the most persistent adolescent-onset users evidenced an average 8-point IQ decline from childhood to adulthood’.²⁹² The NPCIC submission also highlighted a robust association between cannabis use and lesser educational attainment.²⁹³

4.58 In its submission, Drug Free Australia emphasised the addictiveness of cannabis and also addressed its association with mental health disorders. In addition to the link to psychosis, it also reported a link with depression and related disorders, as well as to suicide:

The link between cannabis and mental health has been well documented and includes research into the onset of psychosis and schizophrenia. Other mood disorders occur, they include depression, bi-polar disorder and amotivational syndrome. Research has also explored the links to suicide, especially in young people. For instance, Professor Jenny Williams states that the regular use of cannabis can trigger suicidal thoughts in some users, particularly young men, according to the results of a 30-year study that

²⁸⁹ Submission 62, Mr Andrew Kavalas, pp 1 and 2.

²⁹⁰ Submission 56, pp 7-8.

²⁹¹ Dr Phillips, evidence, 18 March 2013, p 40.

²⁹² Meier MH, Caspi A, Ambler A, Harrington H, Houts R, Keefe RSE, McDonald K, Ward A, Poulton R and Moffitt TE, ‘Persistent cannabis users show neuropsychological decline from childhood to midlife’, *PNAS*, Vol 109, No 40, cited in Answers to questions on notice taken during evidence 18 March 2013, FamilyVoice Australia, Question 2, p 2. The same study was referred to in Submission 56, p 8.

²⁹³ Horwood et al, cited in Submission 56, p 9.

experts say strengthens the need for stronger warnings about the drug, particularly for adolescents and young adults.²⁹⁴

4.59 In contrast to the NCPIC and Drug Free Australia submissions, Dr Katelaris cited evidence published in the *British Journal of Psychiatry* that there is no evidence that cannabis causes long term psychiatric problems.²⁹⁵

4.60 Dr Hudson Birden of the University Centre for Rural Health, North Coast cited a number of studies to report that the evidence regarding cannabis and psychosis or schizophrenia is not conclusive. He advised that while there is evidence that cannabis can cause deterioration in a person already prone to psychosis, cannabis also appears to have a role in treating schizophrenia. At the same time, he went on to concur that there is compelling evidence that heavy regular early use interferes with brain development, as does alcohol, such that cannabis use should be discouraged among adolescents.²⁹⁶

4.61 In evidence, Professor Michael Farrell, Director of the National Drug and Alcohol Research Centre, and a psychiatrist by background, advised the Committee that the relationship between cannabis use and mental illness is very controversial. He went on to state that he does not see it as a critical issue in the context of the debate on medical use of cannabis by adults, and went on to argue that any such effects should be weighed against the long term effects of other medications:

In terms of major mental illness the risks are pretty modest ... The psychosis risk, particularly in the adult population, I would not see in any way as a determining factor. The issues around anxiety, mood disorders and subjective unpleasant experiences are much more likely to influence people to decline use rather than major mental health issues. The major mental health issue data we have relates particularly to people starting use before 15 and having a positive family history of psychosis. The issue for us here probably is going to be if we see efficacy around neuropathic pain—and we are seeing significant problems around the use of opioids and other medication—it may be that some of the cannabinoids become substantially preferable to some of the long term side effects of some of the existing medication. If that were the case it would give quite a big push to some of the cannabinoid options.²⁹⁷

Other health risks

4.62 FamilyVoice Australia also highlighted the unknown composition of crude cannabis, suggesting that, ‘Plants are of uncertain composition, which renders their effects equally uncertain, so they constitute an undesirable medication’.²⁹⁸

4.63 While not arguing against reform, Mr Kavasilas, highlighted the contaminants that may be present in street sourced cannabis. He also pointed to the imperative to educate and inform

²⁹⁴ Submission 34, p 7.

²⁹⁵ Dr Katelaris, Evidence, 18 March 2011, p 59.

²⁹⁶ Submission12, University Centre for Rural Health, North Coast, p 1.

²⁹⁷ Professor Michael Farrell, Director, National Drug And Alcohol Research Centre, Evidence, 11 March 2013, p 74.

²⁹⁸ Submission 31, FamilyVoice Australia, p 2.

existing and potential users of cannabis for medical purposes, who are already ill, about these contaminants, and to provide quality, safe products for medical use.²⁹⁹

- 4.64** In the same vein, the ADLRF pointed to the medical cannabis regime operating in the Netherlands to argue that modern horticultural techniques mean that plants cultivated for medicine can be grown and harvested in controlled, contaminant free conditions to produce consistent, high quality pharmaceutical products.³⁰⁰

Use for chronic pain

- 4.65** In answers to questions on notice, the NSW Ministry of Health addressed the issue of whether the use of crude cannabis for chronic pain was desirable, stating:

In relation to chronic pain management, while there may be a place for medical cannabinoids use in palliation or comfort care towards the end of life, there is no evidence that cannabis has a role in non-cancer pain medicine. The analgesic effect is no better than paracetamol. Regular use interferes with Cognitive Behavioural Therapy (CBT) and other self-management techniques ... [and] with interpersonal relationships; and [its anti-anxiety] effect [is] better managed by other methods. Its legal availability will have a significant negative effect on pain medicine.

Moreover, there is evidence that tetrahydrocannabinol (THC) is toxic to the nervous system with sustained use.

One clinician has advised, “In my clinical experience, I have never seen a single patient do well with [cannabis] use for non-cancer pain. Its use is always a flag for poor prognosis. The demotivating effect of [cannabis] is a major problem in this context. Having made the above points, it is possible, but I suspect unlikely that future research may see the development of a refined cannabinoid component that might have a reasonable balance of benefit and harm. So research in non-cancer pain could be considered in a tightly controlled setting”.³⁰¹

Risk of diversion

- 4.66** A second key argument against reforms to allow the medical use of cannabis was that it risks the product being diverted for recreational use. This scenario was highlighted by the NSW Ministry of Health, which argued that it could lead to negative health outcomes and counteract measures to reduce cannabis use:

From a health perspective, a key risk of any program using cannabis for medical purposes would be the potential for diversion for illicit use. This could increase the risk of health impacts and undermine current government efforts to reduce the use of cannabis in the broader community.³⁰²

²⁹⁹ Submission 62, p 2.

³⁰⁰ Submission 54, p 6.

³⁰¹ Answers to questions on notice taken during evidence 11 March 2013, NSW Ministry of Health, Question 4, pp 5-6.

³⁰² Submission 117, NSW Ministry of Health, p 1.

- 4.67** In evidence, representatives of both the Ministry for Health and the Police Force referred to the system operating in many parts of the United States. Mr Christopher Shipway, Director of Primary Care and Chronic Services with the Agency for Clinical Innovation, NSW Ministry of Health, suggested that unlike a pharmaceutical product, a smoked product which is used the same way recreationally as medicinally needs to be considered in terms of its potential for diversion.³⁰³ Superintendent Bingham, Commander of the NSW Police Force's Drug Squad, argued that diversion has occurred in the United States,³⁰⁴ and went on to suggest that the street value of cannabis in Australia is such that should medical use of cannabis be decriminalised, some patients will divert their product for illicit use.³⁰⁵ His colleague, Superintendent Pat Paroz, Commander of Drug and Alcohol Coordination, reported that South Australia, where it is legal for people to grow up to five plants for personal use, has encountered significant problems with diversion.³⁰⁶
- 4.68** FamilyVoice Australia representatives were very concerned about diversion. In evidence, Mr Graeme Mitchell, State Officer, referred to research suggesting that around 74 per cent of subjects in a Colorado study of adolescents in substance abuse treatment had used someone else's medical marijuana.³⁰⁷ Dr Phillips referred to a United States study which found that 3.5 per cent of people in states where marijuana use is illegal had used cannabis in the previous year, while 7.1 per cent of people in states where marijuana use is legal had used the substance in the previous year.³⁰⁸
- 4.69** On the other hand, in his evidence Mr Evert Rauwendaal, Member of the ADLRF, cited publications that found very little evidence of diversion in the United States:

The evidence we have is from the *Annals of Epidemiology*. They found from their study, which was performed in 2012, very little evidence that passing medical marijuana laws increased reported use among adolescents or any other age group. There were also some figures published by the *California Paediatrician*, and they indicated that the data is very reassuring that in almost all cases, medical marijuana legalised for adults does not lead to an increase in the recreational use of marijuana by adolescents. The American Medical Association states that trends in emergency room visits for marijuana do not support the view that State authorisation for medical cannabis leads to an increased sequence of substance misuse.³⁰⁹

³⁰³ Mr Shipway, Evidence, 11 March 2013, pp 11-12.

³⁰⁴ Superintendent Bingham, Evidence, 11 March 2013, p 41.

³⁰⁵ Superintendent Bingham, Evidence, 11 March 2013, p 45; Superintendent Patrick Paroz, Commander, Drug And Alcohol Coordination, NSW Police Force, 11 March 2013, p 45.

³⁰⁶ Superintendent Bingham, Evidence, 11 March 2013, p 45.

³⁰⁷ Mr Graeme Mitchell, State Officer (NSW and ACT), FamilyVoice Australia, Evidence, 18 March 2014, p 46. See also answers to questions on notice taken during evidence 18 March 2013, FamilyVoice Australia, Question 1, p 2.

³⁰⁸ Dr Mitchell, Evidence, 11 March 2013, p 40; Cerda M, Wall M, Keyes KM, Falea, S and Hasin, D, 'Medical marijuana laws in 50 states: investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence', *Drug and Alcohol Dependence*, 2012, Vol 120, cited in answers to questions on notice taken during evidence 18 March 2013, FamilyVoice Australia, p 1.

³⁰⁹ Mr Evert Rauwendaal, Member, Australian Drug Law Reform Foundation, Evidence, 11 March 2013, p 66.

- 4.70 Professor Farrell reported that he was not aware of evidence in either direction as to whether access to medical cannabis has led to an increase in recreational consumption of cannabis. He suggested that in the United States it may have created problems by ‘medicalising the load of access to recreational cannabis use’, but whilst also highlighting that the US model is very different to that explored in the United Kingdom and Australia.³¹⁰ Professor Hall concurred that the Californian system is especially liberal.³¹¹
- 4.71 In evidence, Dr Wodak suggested that crude cannabis is already easily obtained in Australia:
- [D]espite the fact that cannabis is prohibited in Australia, it is relatively easy to obtain. The Commonwealth Department of Health commissions a survey every year that is conducted among drug users, and they ask them how easy or difficult it was to obtain heroin, cocaine and amphetamine, and they also include cannabis in that survey. The 2011 figures were that 94 per cent of respondents in that sample said that cannabis was easy or very easy to obtain—that is hydroponic cannabis—and 78 per cent said that bush cannabis was easy or very easy to obtain ... It is hard to imagine that its availability could be increased.³¹²
- 4.72 Finally, Mr James Moylan, National Campaign Director of the HEMP Party, argued that the present diversion of certain pharmaceutical drugs is a much greater concern than any potential diversion of medical cannabis. He noted that while overdose from such medications can cause death, it is not possible to overdose from cannabis.³¹³

Reform alternatives

- 4.73 While the appropriateness of crude cannabis products for medical purposes was the more controversial aspect of the inquiry, overall, the significant balance among inquiry participants was in favour of some form of reform to allow such use in certain circumstances. The chapter now sets out the various proposals for reform proposed by inquiry participants, before concluding with the Committee’s findings and recommendations for reform. The proposals fell into two broad categories: those that focused on legalising supply to patients, and those that focused on exemption from prosecution for possession and use.

Legalised supply

- 4.74 Several participants proposed models providing for the legal supply of cannabis products to qualifying patients, including the HEMP Party, the ADLRF, the ADLRI UNSW and Mullaways Medical Cannabis. A number of these were adapted from the systems operating in other jurisdictions, which were set out in Chapter 2.
- 4.75 Mr Kavasilas’ submission highlighted that the critical issue for every regime seeking to regulate the medical use of cannabis is that of supply, or obtaining cannabis from a ‘lawful source’ in

³¹⁰ Professor Farrell, Evidence, 11 March 2013, p 69.

³¹¹ Professor Hall, Evidence, 11 March 2013, p 71.

³¹² Dr Wodak, Evidence, 11 March 2013, p 66; See also Submission 54, pp 2 and 10.

³¹³ Mr Moylan, Evidence, 11 March 2013, p 55.

the context of inflexible and ambiguous international drug conventions placing strict requirements on signatory nations.³¹⁴

HEMP Party – dispensary model

- 4.76** While it stated a preference for the legalisation of all cannabis use, the HEMP Party recommended a model, based on the Californian and to some extent Canadian systems, for cannabis products that are grown and also dispensed for medical use under license. A patient would qualify for purchasing cannabis from a dispensary on the basis of a letter from their doctor, according to strict criteria.³¹⁵ The HEMP Party submission proposed:

It is essential that any Cannabis Dispensary (trial or otherwise) only provide cannabis to those particular patients meeting the precise requirements dictated as sufficient to obtain a prescription. Prescription verification procedures must be mandatory and defined in regulation. Any leakage or illegal provision of cannabis to non-patients will act to discredit the dispensary model and will undoubtedly be counterproductive in a number of ways.

All cannabis stocked within a Dispensary Pharmacopoeia must be of a defined strength (potency), type (strain), and weight. Every gram must be traceable directly, via a paper trail, back to the grow-up process. This paper trail must be plainly reviewable and amenable to audit.

Procedures, regulations, and rules, overseeing Dispensary operations should be formulated in association with medical advice and this process largely guided by the best-practice of institutions currently operating dispensaries in California and Canada.³¹⁶

- 4.77** As noted in an earlier section, Professors Hall and Farrell expressed concerns in evidence about the Californian model being too liberal³¹⁷ – although it appears from the above quote that the HEMP Party envisages a higher level of regulation than occurs there.

Australian Drug Law Reform Foundation – Netherlands model

- 4.78** The ADLRF proposed a model replicating the key features of the system operating in the Netherlands. These features included that the growing of highly standardised ‘medical grade’ cannabis would be licensed by government, with the cannabis prescribed by doctors and dispensed by pharmacists. Patient access would be determined by an expert panel on the recommendation of a treating doctor. Experts could recommend which medical conditions would be accorded priority and determine the minimum criteria to qualify.³¹⁸ The ADLRF submission proposed:

³¹⁴ Submission 62, p 3.

³¹⁵ Mr Moylan, Evidence, 11 March 2013, p 54; Mr Balderstone, Evidence, 11 March 2013, pp 54-55. Submission 28, Hemp Party Australia, NSW Chapter, pp 25-26.

³¹⁶ Submission 28, pp 25-26.

³¹⁷ Professor Hall, Evidence, 11 March 2013, p 71. See also Submission 46, pp 18-19 for further criticisms of the North American models.

³¹⁸ Submission 54, p 4; Dr Wodak, Evidence, 11 March 2013, p 63 and 66.

Approved patients could be made exempt from criminal sanction ... A patient would be approved for this purpose if recommended by the Director General of the NSW Ministry of Health on advice from the Department of Health. A doctor registered in NSW would first have to apply on behalf of a NSW patient confirming the presence of a condition accepted for medicinal cannabis and also confirming the severity of the condition. If the application was approved, the doctor would write a prescription. The patient would then be provided by a pharmacist with supplies of raw, dried or whole cannabis products ... Authorisations to use cannabis could be time limited and subject to periodic review. Permits to cultivate and supply cannabis could also be registered by patients or a nominated caregiver and subject to similar regular review.³¹⁹

- 4.79 Professor Mather also recommended the Netherlands' model.³²⁰ In addition, Professor Hall endorsed it as the model that comes closest to the standard regulatory system for pharmaceuticals in Australia. He went on to note that the high level of regulation built into this model makes it very expensive to operate.³²¹ In his submission, Professor Macciza Macpherson recommended a model along these lines, with the active involvement of the CSIRO in monitoring, control and research.³²²

Australian Drug Law Reform Initiative UNSW – authorised supply

- 4.80 The ADLRI UNSW proposed a similar model to that put forward by the HEMP Party, again drawing on the US system, with the primary difference being that its legal basis be provided under an exemption for clinical research trials provided under section 10(2)(b) of the *Drug Misuse and Trafficking Act 1985* (DMTA).³²³ Patients would qualify on the basis of medical certification, and cannabis grown under license would be provided to trial participants, who would also be allowed limited self supply. Participants would be issued with a photo identification card that would also provide for exemption from prosecution:

These conditions could be specified in legislation or regulations. Once a patient is diagnosed with one of these conditions by a medical practitioner, they could issue patients a registration card. Possession of the card would then provide an exemption to prosecution for possession and use of a prescribed amount. It is recommended that this amount be adopted as the possession limit in NSW. Of relevance, a "small amount" under the DMTA is defined as 30 grams ... In order to implement a medical cannabis scheme, minimal amendments to NSW law would be required. A clinical trial program could still operate with patients having an exemption from prosecution under the DMTA on producing evidence in the form of a photo identification card.³²⁴

- 4.81 In answers to questions on notice, the DAGJ verified that the above exemption could be used as a defence where the person acts in accordance with an authority granted by the Secretary of the Department of Health, where the Secretary is satisfied that the possession of the prohibited drug is for the purpose of scientific research, instruction, analysis or study. It went on to suggest:

³¹⁹ Submission 54, p 3.

³²⁰ Submission 14, pp 19-20.

³²¹ Professor Hall, Evidence, 11 March 2013, pp 71-72.

³²² Submission 87, Professor Macciza Macpherson, p 2.

³²³ Mr Mostyn, Evidence, 18 March 2013, p 35; Ms Hall, Evidence, 18 March 2013, p 37.

³²⁴ Submission 69, p 2.

It may therefore suffice for the purposes of a trial of medical cannabis for the Secretary of the Department of Health to issue authorisations to participants. The same defence applies to other offences under the Act, including offences relating to the cultivation and supply of prohibited plants or drugs (s.23 and 25, respectively). Consequently, no amendment of the DMTA would be necessary for a trial of medical cannabis authorised by the Secretary of the Department of Health.³²⁵

Mullaways Medical Cannabis – special access scheme

- 4.82** Mullaways Medical Cannabis advocated a model that differentiated itself by emphasising the range of products to be supplied to patients and carers by licensed dispensaries under a ‘special access scheme’ utilising a photo based card that also exempted qualifying patients from prosecution. It envisaged the provision of ‘safe, quality therapeutic cannabis based medicines such as tinctures, patches, creams, oils, edibles and a medical grade form of therapeutic cannabis for those who would continue to smoke’.³²⁶ Mullaways invested particular thought in its proposed identification card:

The most important part of this regime must be the issuing of Special Access Scheme Card(s), for medical Cannabis (SAS-MC Card) to qualifying patients or designated caregivers. A SAS-MC Card would protect a medical Cannabis patient from getting a criminal record and would solve a huge problem for law enforcement.³²⁷

- 4.83** The purpose of the card would be to assist law enforcement officers, health professionals and dispensaries to identify and verify that cardholders are medical users of cannabis, assisting to ensure the security and non-diversion of medical cannabis products.³²⁸ Mr Kevin Charlesworth explained how this would work:

What we would like to see in legislation is that people get a medical cannabis card so they aren’t criminalised and the police do not waste their time chasing medical cannabis patients around and putting them through the court system. This is not right. This is simple to do ... A little card, that is all we need. They can swipe it, they then know the person is registered with the government and they go on their way.³²⁹

Exemption from arrest and prosecution

- 4.84** While it is implicit in each of the above models that their proponents’ preference was for a model of authorised supply, each of the models also incorporated an element of exemption from arrest and prosecution for qualifying patients for the possession and use of cannabis. There was some discussion of such a provision during the Committee’s hearings.
- 4.85** Many participants agreed that it was highly desirable to introduce exemption from arrest and prosecution as a compassionate provision for patients with certain medical conditions. This support was common to even very cautious participants such as the Cancer Council NSW:

³²⁵ Answers to questions on notice taken during evidence 11 March 2013, Department of Attorney General and Justice, Question 2, p 1.

³²⁶ Submission 10, p 38.

³²⁷ Submission 10, p 24.

³²⁸ Submission 10, p 24.

³²⁹ Mr Charlesworth, Evidence, 11 March 2013, p 38.

Cancer Council NSW supports limited exemptions from criminal prosecution, such as those provided by the Cannabis Cautioning Scheme, for cancer patients who have been certified by an approved medical practitioner as having particular conditions, and who have been counselled by such a practitioner about the risks of smoking cannabis.³³⁰

- 4.86** Similarly, Professor Copeland who was otherwise very careful not to support the liberalisation of current arrangements, saw that for a very targeted group, a compassionate approach could be justified:

I think for that group who are in palliative care and who are not getting relief from the mainstream medications or even from Sativex-type preparations whose only psychological relief because they strongly believe that smoked cannabis is the thing that works for them, I think having some kind of compassionate scheme where that is used as an excuse if you like—I cannot imagine people want to prosecute people in that situation. If there is some way legally to have that as an exemption for that small group, I think no normal person would want to take that option away from people. But, as a general cause, I think if cannabinoids are going to be made available they should be in pharmaceutical preparations where there is a known dose and no impurities.³³¹

- 4.87** Professor Hall stated in evidence that ‘allowing medical use as a defence against criminal prosecution is a reasonable step to take. It is within the prerogative of State governments to take that step’.³³² Professor Farrell agreed, while arguing that people with chronic conditions who find benefit from cannabis should not be subject to ‘the heavy hand of the law’.³³³

- 4.88** Asked by Committee members about the Working Party’s recommendations and why they have not been acted upon since 2000, Professor Hall explained that a range of medical experts had advised the Working Party that they did not feel comfortable prescribing crude cannabis because it is not subject to the Commonwealth’s regulatory regime. In light of this, the Working Party recommended exemption from prosecution based on the certification of a medical practitioner, on the understanding that patients be left to obtain and cultivate cannabis as they can. He reported that this recommendation was not acted upon by the Government at the time, but went on to outline significant limitations with the alternative of authorised supply:

We were implicitly saying, “Well, it’s out there, it’s on the black market, people could purchase at their own risk.” But I think the then Premier and other senior people in the Government were concerned that this was encouraging people to resort to the black market and they preferred to provide the cannabis directly to patients, which is pretty much what has happened in Canada [and the Netherlands]. The problem with that system is that, as I think I said in answer to an earlier question, it gets to be very expensive for government to control cultivation, supply, preparation, oversight and distribution of the cannabis.³³⁴

³³⁰ Submission 4, p ii.

³³¹ Professor Jan Copeland, University of New South Wales, Evidence, 18 March 2012, p 24.

³³² Professor Hall, Evidence, 11 March 2013, p 74.

³³³ Professor Farrell, Evidence, 11 March 2013, p 74.

³³⁴ Professor Hall, Evidence, 11 March 2013, pp 71-72.

- 4.89** Other participants who advocated exemption from arrest and prosecution for a well defined group included ACON and the coauthors to its submission, along with Hepatitis NSW.³³⁵
- 4.90** The ADLRF acknowledged that exemption from prosecution might be the simplest option, potentially involving the removal of criminal sanctions for purchase, use and home cultivation of cannabis below designated threshold quantities for medicinal reasons. It went on to identify two key disadvantages: that seriously ill or disabled patients may be unable to source or cultivate their own cannabis or afford the inflated black market prices; and that patients may ask their caregivers to source or cultivate cannabis, who would then be at risk of arrest and prosecution.³³⁶ In evidence, Dr Wodak emphasised that many patients will not be capable of growing their own cannabis, arguing instead for legalising prescribed supply.³³⁷
- 4.91** The Australian Drug Foundation also argued that until such time as suitable pharmaceutical products are available, patients with a designated medical condition could be exempted from the criminal law to grow cannabis for their own use. It argued that this compassionate approach would ensure patients with debilitating conditions could gain a supply of cannabis without coming into contact with the black market and avoid the fear of arrest or legal sanctions. It proposed that as many patients will not have the capacity to cultivate their own cannabis, they should be allowed to nominate another person to cultivate a supply only for the purpose of treating the patient's conditions. Any diversion for another use would be an offence.³³⁸

Legal changes

- 4.92** Ms Hall of the ADLRI UNSW advised the Committee that there are strong precedents for exempting those who use cannabis for medical purposes from prosecution:

There is lots of precedent for it historically. It has certainly been used in medical areas and that is the main focus in the case law in the last probably 10 or 20 years. Certainly the legislature could tighten that up and make sure that it applies in that more limited way.³³⁹

- 4.93** In evidence, Ms Musgrave of the Department of Attorney General and Justice agreed that it would be relatively straightforward to decriminalise possession and use of small quantities of cannabis by people with terminal illnesses:

Yes. You could do it very quickly using existing exemptions under the trial provisions of the Drug Misuse and Trafficking Act. If it was not a trial, it would require an amendment to the Drug Misuse and Trafficking Act to put in some sort of authorisation scheme. So you would need to have a system where somebody makes a decision that a certain person falls within a class of people who are eligible to have the drug, and a system of identification.³⁴⁰

³³⁵ Submission 73, p 3; Submission 68, p 1.

³³⁶ Submission 54, p 12.

³³⁷ Dr Wodak, Evidence, 11 March 2013, p 63.

³³⁸ Submission 29, Australian Drug Foundation, p 12.

³³⁹ Ms Hall, Evidence, 18 March 2013, p 36.

³⁴⁰ Ms Musgrave, Evidence, 11 March 2013, p 14.

- 4.94** Ms Musgrave further noted that a similar outcome could be achieved via a policy position that police will not prosecute individuals in such circumstances, but went on to argue that this would be less desirable as it would provide less certainty than legislative amendment, which would be secure, explicit and transparent, with its parameters clearly set out.³⁴¹ This legislative amendment would serve as a complete defence from prosecution.³⁴²
- 4.95** Both Ms Musgrave and Police Force representatives confirmed that carers or others who supply cannabis for another person's medical use are presently subject to criminal law. Superintendent Bingham verified that present penalties are higher for supply than for possession for personal use, while Ms Musgrave suggested that, 'Any amendments would have to cover both the person who is suffering the terminal illness and someone who was administering that or cultivating it for them'.³⁴³
- 4.96** In answers to questions on notice, the Department of Attorney General and Justice verified that there are three options open to the Committee to authorise the use of medical cannabis without conflicting with Commonwealth Law. Option 1 is for a research trial, consistent with the evidence of the ADLRI UNSW, by utilising a defence provided under section 10(2)(b) of the *Drug Misuse and Trafficking Act* (DMTA), as noted above. Option 2 would involve amendments to that legislation to provide a permanent defence for a class of persons. Option 3, for prescription through the Australian Register of Therapeutic Goods, was explored in detail in Chapter 3.
- 4.97** In relation to Option 2, the Department advised:
- Amendments exempting persons from prosecution for the use or possession of cannabis for medical purposes would require only minor amendments to the DMTA, such as an addition to existing defences for use and possession in order to cover the authorised medical use of cannabis. It is noted that the DMTA includes provisions exempting people for drug offences committed at a licensed injecting centre as long as they are not in possession of more than a prescribed quantity of drugs. Legislative amendment creating the regime under which medical use of cannabis would be authorised will be only slightly more complex ... A patient diagnosed with one of [certain] conditions could be issued with an authorisation by a medical professional, which would enliven the new defence to use and possession offences. It may be necessary to further regulate or oversee the authorisation by medical professionals. Advice on this issue should be sought from NSW Health.³⁴⁴
- 4.98** The Department further advised that in relation to this option (as well as Option 1), section 313.1 of the Commonwealth Criminal Code provides that it is a defence to drug offences under the Code (excluding import/export offences) that the conduct giving rise to the offence was justified or excused by a law of a State or Territory. Thus the existence of a legitimate defence in New South Wales will provide a defence for those who possess and administer the cannabis, to Commonwealth offences.³⁴⁵

³⁴¹ Ms Musgrave, Evidence, 11 March 2013, p 14.

³⁴² Ms Musgrave, Evidence, 11 March 2013, pp 16-17.

³⁴³ Ms Musgrave, Evidence, 11 March 2013, p 20.

³⁴⁴ Answers to questions on notice taken during evidence 11 March 2013, Department of Attorney General and Justice, Question 2, pp 1-2.

³⁴⁵ Answers to questions on notice taken during evidence 11 March 2013, Department of Attorney General and Justice, Question 2, p 2.

- 4.99** The Department went on to consider the interface with the *Therapeutic Goods Act 1989* (Cth) in this scenario, which would have implications for anyone providing seeds, equipment and so on to the patient who cultivates their own cannabis, as well as a carer or another person cultivating the cannabis on behalf of the patient:

[T]he personal cultivation and use of cannabis for medical purposes could be permitted in NSW without Commonwealth involvement. However, patients growing their own cannabis for lawful medical use would need to obtain seeds, plants, and possibly equipment and instructions. The act of supplying those things may contravene the Therapeutic Goods Act. “Therapeutic goods” include goods which are used to manufacture therapeutic goods.

Where authorised medical users were to be lawfully provided cannabis by another (which may be necessary, as many patients who would benefit from the use of medical cannabis may not be in a physical condition to cultivate their own), the person supplying would be in breach of the Therapeutic Goods Act.³⁴⁶

- 4.100** Ms Musgrave underscored the problematic issue of supply in evidence:

What [the medical practitioner] may actually be doing is simply certifying that that person falls within a class and then the legislation says that people within that class are allowed to possess a quantity of leaf and/or plants and so it comes back to the supply issue. The medical practitioner is not supplying it as a therapeutic good, a commercial organisation is not supplying it to the people as a therapeutic good; they are growing the therapeutic good themselves. But at some point someone has to supply something to those people, i.e. seeds. That is why I suspect all these inquiries have always come to the point of supply.³⁴⁷

- 4.101** In terms of how the scope of the patient group would be reflected in law, Ms Musgrave advised that if the target group were finite (for example people who are terminally ill) it might be possible to define this group in the legislation. If a wider group (such as those with longer term illnesses for whom it is claimed that medical cannabis may be beneficial), she suggested a further layer of authorisation such as an expert panel or review committee may need to be built into the legislation:

Essentially you have two possible models: a defined group in the legislation, say someone who has been certified as terminally ill, or, if a wider group is preferred you could have an authorisation from a class of people, that is, medical specialists or certain practitioners who are applying a set of criteria that are set by the Department of Health or an advisory panel or something like that.³⁴⁸

- 4.102** Finally, Ms Musgrave noted that some jurisdictions use a photo identity card, which means that the legality of their possession and use is resolved at the point of enquiry by a police officer, rather than at the point of a court hearing.³⁴⁹

³⁴⁶ Answers to questions on notice taken during evidence 11 March 2013, Department of Attorney General and Justice, Question 2, p 2.

³⁴⁷ Ms Musgrave, Evidence, 11 March 2013, p 45. See also Submission 62, p 3.

³⁴⁸ Ms Musgrave, Evidence, 11 March 2013, p 15.

³⁴⁹ Ms Musgrave, Evidence, 11 March 2013, pp 17-18.

Education

- 4.103** In the discussion of the potential use of cannabis products for medical purposes in Chapter 3, the Committee documented participants' views about the desirability of effective communication strategies to minimise any possibility of legitimising recreational use (see paragraphs 3.33 to 3.35). Added to this, Professor Copeland agreed in evidence that it would be important for additional community education to accompany any reforms to decriminalise medical use of cannabis:

Certainly greater prevention and public health messaging around cannabis would be an important corollary of increased access even for a very small group so there is a clear understanding in the community what is happening.³⁵⁰

- 4.104** Mr Parkhill of ACON also agreed that any new scheme be accompanied by targeted education to address community understanding of what the changes mean.³⁵¹ ACON et al's submission elaborated on this point:

The provision of information and education to communities that are likely to utilise and benefit from the medical use of cannabis would also be valuable. This should include the engagement of community, service providers and doctors to ensure that reliable information is available to consumers and that potential harms are reduced, for example, by paths for less harmful methods of consumption than smoking.³⁵²

Committee findings

- 4.105** The Committee agrees with the argument put forward by the majority of inquiry participants that provision be made for a very small and specific group of patients to use crude cannabis products for medical purposes legally.
- 4.106** Ideally, pharmaceutical cannabis products would be of sufficient efficacy and safety as to provide relief to patients who experience severe and distressing symptoms that do not respond to existing medications, most especially people in the end stage of terminal illness. However, the only pharmaceutical cannabis product currently approved for use is allowed for a single specific indication, namely muscle spasticity arising from multiple sclerosis. As the TGA approval process is lengthy, it is likely to take years before the use of Sativex for other conditions might be approved. In addition, we are very mindful that unless subsidised by the taxpayer under the Pharmaceutical Benefits Scheme, this product would be unaffordable to many, who as we noted in the previous chapter, will be of very limited means at a most vulnerable time in their lives. We further recognise that the effectiveness of pharmaceutical cannabinoids will vary from individual to individual. In these and other understandable circumstances, some patients will use crude cannabis products.
- 4.107** Indeed, it is a given that some patients are already using crude cannabis for medical purposes, and we received evidence that this is often occurring with the knowledge of their doctor, and sometimes at his or her recommendation.

³⁵⁰ Professor Copeland, Evidence, 18 March 2013, pp 24-25.

³⁵¹ Mr Parkhill, Evidence, 18 March 2013, p 52.

³⁵² Submission 73, p 2.

- 4.108** The Committee agrees with the argument put forward by inquiry participants that a compassionate approach that recognises individual needs and choices is highly desirable and morally justified. We have some sympathy for the argument that patients can be trusted to make the best decisions for themselves, and that it is preferable that they do so under the guidance of their doctor.
- 4.109** The Committee considers that provision should be made to allow medical use of cannabis by patients who have been advised by their treating specialist that they have end stage terminal illness, and those who have moved from HIV infection to AIDS.
- 4.110** We believe, like almost all inquiry participants, that people with terminal illness who take measures to relieve their severe pain should not be criminalised. While presently the Cannabis Cautioning Scheme provides a ‘safety net’ in these circumstances, it is a very limited and discretionary one. The Committee considers it important to protect this small and highly vulnerable group from any criminal justice consequences for their end stage health condition. Such individuals should not be subject to the humiliation and stress of arrest and appearing in court, and indeed, should be able to rest in the knowledge that they are actively protected from such consequences.
- 4.111** Thus we consider that a system which qualifies this group for the use of cannabis for medical purposes should be established by providing a complete defence from arrest and prosecution. We believe that this could be achieved via amendment to the *Drug Misuse and Trafficking Act*, by adding a complete defence to the list of present defences for use and possession, so as to cover the authorised medical use of cannabis.
- 4.112** We recommend that in order to qualify for the exemption that we are envisaging, a patient would need to be certified by their treating specialist medical practitioner as having been diagnosed with a specific incurable condition. Such a certificate would make the person and their carer eligible for inclusion on a register of ‘authorised patients and carers’ held by the NSW Ministry of Health. Registration would make the patient eligible to possess up to 15 grams of dry cannabis or equivalent amounts of other cannabis products,³⁵³ and to use but not supply cannabis. Upon registration, the patient and their carer would be issued with a photo identification card, linked to the register, which he or she would produce for inspection in the event that they are found by police to be in possession of cannabis. It is the Committee’s intention that police take no action in respect of such possession or use, but that if arrest and charge do occur, the defence would protect the individual from criminal sanction. It will be important for Police to receive training which makes clear this intention.
- 4.113** The Committee is satisfied that providing an exemption from arrest and prosecution for personal possession and use would not in itself conflict with Commonwealth law. However, the supply of seeds, plants and equipment to a patient, whether by a carer or another third party, may contravene the *Therapeutic Goods Act*. We believe that provision should be made to exempt carers from arrest and prosecution for possession and supply (in order to provide a product to the patient) under New South Wales law, but note that they would remain vulnerable under Commonwealth law. We trust that Commonwealth law enforcers will adopt a compassionate approach to such persons, who are categorically different to other ‘suppliers’ as are captured by Commonwealth law.

³⁵³ As noted in Chapter 2, individuals in possession of up to 15 grams of dry cannabis may be subject to the Cannabis Cautioning Scheme.

- 4.114 At the same time, the Committee recognises that the issue of supply needs further careful and detailed consideration, as it was not possible for the Committee to examine it in sufficient detail within the timeframe for this inquiry. We believe that it would be preferable for patients and carers to purchase crude cannabis products, seeds and equipment legally. We recognise that this may not be realistic in the present environment.
- 4.115 The Committee acknowledges the many powerfully argued submissions made to us by people with chronic debilitating pain who wish to use cannabis legally to treat their medical conditions. We empathise strongly with them and take at face value that cannabis is an effective treatment for them. However, owing to the present absence of evidence on the long term effects of cannabis use, and the risks associated with smoking it, the Committee considers that at this stage, the target group for this provision should not include people with chronic conditions. This exclusion would apply to people with multiple sclerosis, although we note that in certain circumstances they can now access the pharmaceutical cannabinoid Sativex.
- 4.116 We further consider that the legislative amendments would appropriately exclude the use and supply of cannabis in a public place, and that a three year review of the amendment be written into the legislation. It would be valuable for the Ministry of Health to proactively prepare for this review by collecting qualitative and quantitative data, including from medical practitioners, patients and carers, from the commencement of the register.

Recommendation 2

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

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

Recommendation 3

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

Recommendation 4

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

- 4.117** We believe that provision for the legal use of cannabis for medical purposes within the context of an ongoing therapeutic relationship with a specialist medical practitioner will ensure two things: first, that eligibility is well guarded; and second, that the appropriate level of clinical oversight is afforded to this cannabis use. As with certain pharmaceutical products, we envisage that such specialist medical practitioners would necessarily provide ongoing ‘biopsychosocial’ assessment of the patient, noting the impact of this particular treatment on patients’ pain and holistic functioning.
- 4.118** The Committee considers the risk of diversion arising from our recommendations to be minimal, given the very tight restrictions that we envisage on eligibility and on the amount of cannabis that might be possessed, as well as the present availability of cannabis within the community. We believe that the community will be prepared to tolerate this small risk on compassionate grounds, in light of the potential benefits to a very restricted group of eligible patients, not all of whom would pursue this option anyway.
- 4.119** We believe that the cost of regulating this system would not be significant, and would be offset to some extent by the police not taking action with respect to this group, as well as the court system not having to adjudicate such matters. We also consider that such a move is unlikely to normalise or legitimise broader cannabis use within the community. Nor is it intended to glamourise cannabis to potential recreational users.
- 4.120** Finally, we recommend that the Government accompany these reforms with an education strategy informing the medical profession, community and relevant patient groups about the changes to be brought about. This should include information for patients on the possible harms of smoking cannabis and on other methods of cannabis consumption than smoking.
-

Recommendation 5

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

Appendix 1 Submissions

No	Author
1	Name suppressed
2	Name suppressed
3	Name suppressed
4	Cancer Council NSW
5	Name suppressed
6	Name suppressed
7	Cancer Voices NSW Inc
8	Name suppressed
9	Mr Andrew Graham
10	Mullaways Medical Cannabis Pty Ltd
11	Name suppressed
12	University Centre for Rural Health, North Coast
13	Confidential
14	Emeritus Professor Laurence Mather
14a	Emeritus Professor Laurence Mather
15	Ms Jakh Heremia
16	Name suppressed
17	Name suppressed
18	Mt Barker South Surgery
19	Mrs Nowell Trovato
20	Mr Albert Fish
21	Australian Medical Association, NSW Branch
22	Name suppressed
23	Name suppressed
24	Name suppressed
25	Name suppressed
26	Name suppressed
27	Painaustralia
28	HEMP Party Australia, NSW Branch
29	Australian Drug Foundation
30	National Drug Research Institute
31	FamilyVoice Australia

No	Author
32	Name suppressed
32a	Name suppressed
32b	Name suppressed
33	Name suppressed
33a	Name suppressed
34	Drug Free Australia
35	Mr Damien Blackman
36	Mr Gregory Howard
37	Name suppressed
38	Confidential
39	Ms Catherine Norman
40	Mrs Janine Thurgood
41	Name suppressed
42	Mr Ben Collins
43	Mr Grant Webster
44	Name suppressed
45	Name suppressed
46	National Drug and Alcohol Research Centre
47	Mr Andrew Ongley
48	Name suppressed
49	Name suppressed
50	Confidential
51	Dr Graham Irvine
52	Botanic Medical Australia Pty Ltd
53	Mr James Kingsbury
54	Australian Drug Law Reform Foundation
55	The Drug Advisory Council of Australia Inc
56	National Cannabis Prevention and Information Centre
57	Name suppressed
58	NSW Council for Civil Liberties
59	Name suppressed
60	Confidential
61	Name suppressed
62	Mr Andrew Kavasilas
62a	Mr Andrew Kavasilas

No	Author
63	Name suppressed
64	Mr Mark Heinrich & Mr Nevil Schoenmakers
65	Mr Damon Adams
66	Ms Avril Barrett
67	Name suppressed
68	Hepatitis NSW
69	Australian Drug Law Reform Initiative
69a	Australian Drug Law Reform Initiative
70	Christian Democratic Party
71	Name suppressed
72	Ellomo Medical Cannabis Pty Ltd
73	ACON, Positive Life NSW, National Association of People with HIV Australia and Australian Federation of AIDS Organisations
74	Name suppressed
75	Adelaide Centre for Bioethics and Culture
76	Bolt Findlay Solicitors & Mediators
77	The Pharmaceutical Society of Australia, NSW Branch
78	Mr Anthony O'Leary
79	Cannabis Science Australia
80	Name suppressed
81	Name suppressed
82	Name suppressed
83	Mr Michael Tamits
84	Name suppressed
85	Mr Michael Balderstone
85a	Mr Michael Balderstone
86	Name suppressed
87	Professor Macciza Macpherson
88	Name suppressed
89	Mr Stuart Parr
90	Mr Daniel van Rensburg
91	Mr Anthony Collins
92	Name suppressed
93	Mr Phil O'Grady MPS
94	Murrumbidgee Local Health District, Drug and Alcohol Services

No	Author
95	Alcohol and Other Drugs Council of Australia (ADCA)
96	Mr John Reeves
97	Mr Jason Budden
98	Name suppressed
99	Name suppressed
100	Reverend Boris Kleiner
101	Name suppressed
102	Mr Roger Seccombe
103	Name suppressed
104	Name suppressed
105	Mr Andy Putnam
106	Name suppressed
107	Mr Michael Fane
108	Emeritus Professor Ian Webster AO
109	Cannabis Cures
110	Ms Beth Shelley
111	Mr Bradley Ryan
112	Name suppressed
113	Mr Burri Jerome
114	Name suppressed
115	Confidential
116	Ms Trish Seaton
117	NSW Ministry of Health
118	Name suppressed
119	Names suppressed
120	Dr Andrew Katelaris MD
121	Ms Trisha Ellis
122	Industrial Hemp Association NSW
123	Mr Jason Olbourne

Appendix 2 Witnesses at hearings

Date	Name	Position and Organisation
Monday 11 March 2013 Jubilee Room Parliament House	Mr Bruce Battye	Deputy Chief Pharmacist Legal and Regulatory Services Branch NSW Ministry of Health
	Ms Jenni Johnson	Manager, Pain Management Network, Agency for Clinical Innovation NSW Ministry of Health
	Mr Chris Shipway	Director, Primary Care & Chronic Services, Agency for Clinical Innovation, NSW Ministry of Health
	Ms Penny Musgrave	Director, Criminal Law Review Department of Attorney General and Justice
	Ms Lesley Brydon	Person living with chronic pain and Chief Executive Officer, Pain Australia
	Ms Sally Crossing AM	Cancer survivor and Deputy Chair Cancer Voices NSW
	Mr Tony Bower	Director, Mullaways Medical Cannabis
	Mr Kevin Charlesworth	Advisor, Mullaways Medical Cannabis
	Superintendent Pat Paroz	Commander, Drug and Alcohol Coordination, NSW Police Force
	Superintendent Nicholas Bingham	Commander, Drug Squad NSW Police Force
	Mr James Moylan	National Secretary and Campaign Director The HEMP Party (NSW Branch)
	Mr Michael Balderstone	President The HEMP Party (NSW Branch)
	Dr Alex Wodak AM	President, Australian Drug Law Reform Foundation
	Mr Evert Rauwendaal	Member, Australian Drug Law Reform Foundation
	Ms Vivienne Moxham-Hall	Secretary, Australian Drug Law Reform Foundation
Professor Michael Farrell	National Drug and Alcohol Research Centre	
Professor Wayne Hall	University of Queensland Centre for Clinical Research	

Date	Name	Position and Organisation
Monday 18 March 2013 Macquarie Room Parliament House	Dr Saxon Smith	Vice President Australian Medical Association NSW
	Mr Andrew Took	Director, Medico-Legal and Employment Relations Australian Medical Association NSW
	Professor Michael Cousins	Director, Pain Management Research Institute, Royal North Shore Hospital and Board Member Pain Australia University of New South Wales
	Professor Jan Copeland	Individual
	Mr Paul O'Grady	Member
	Ms Margaret Hall	Australian Drug Law Reform Initiative
	Mr Ben Mostyn	Founding Member Australian Drug Law Reform Initiative
	Mr Graeme Mitchell	NSW State Officer FamilyVoice Australia
	Dr David Phillips	National President FamilyVoice Australia
	Mr Nicholas Parkhill	CEO, ACON
Mr Dean Price	Policy Advisor, ACON	
Dr Andrew Katelaris MD	Individual	

Appendix 3 Tendered documents

Monday 11 March 2013

Public hearing, Jubilee Room, Parliament House

- 1 Written statement from Ms Sue Hodges, dated 5 March 2013, *tendered by Ms Lesley Brydon*.
- 2 Declaration of Montreal, *tendered by Ms Lesley Brydon (publicly available document)*.
- 3 Images of fences restricting access to opium poppy farms, *tendered by Mr Tony Bower*.
- 4 Document entitled 'The dispensary project – A discussion paper' by J Moylan and M Balderstone, 2009, *tendered by Mr Michael Balderstone (publicly available document)*.

Monday 18 March 2013

Public hearing, Macquarie Room, Parliament House

- 5 Document entitled 'Medical marijuana laws in 50 states: Investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence', *Drug and Alcohol Dependence*, Vol 120, pp 20-27, 2012, by Cerda M, Wall M, Keyes KM, Galea S and Hasin D, *tendered by Mr Graeme Mitchell (publicly available document)*.
- 6 Document entitled 'Medical marijuana use among adolescents in substance abuse treatment', *Journal of the American Academy of Child and Adolescent Psychiatry*, Vol 51, No 7, pp 694-702, July 2012, by Salomonsen-Sautel S, Sakai J, Thurstone C, Corley R and Hopfer C, *tendered by Mr Graeme Mitchell (publicly available document)*.
- 7 Document entitled 'No evidence that cannabis causes long term psychiatric problems', unnamed publication citing Thomas H, *British Journal of Psychiatry*, Vol 163 p 141, 1993, *tendered by Dr Andrew Katelaris (publicly available document)*.
- 8 Document entitled 'New billion-dollar crop', *Popular mechanics*, 1938, *tendered by Dr Andrew Katelaris (publicly available document)*.
- 9 Reproduction of letter from the American Medical Association to the Committee on Finance, United States Senate, opposing the tax on cannabis, its preparations and derivatives, dated 10 July 1937, *tendered by Dr Andrew Katelaris (publicly available document)*.
- 10 Pamphlet entitled 'Improve your Health with Hemp Seed' by Bio-Logical Products, *tendered by Dr Andrew Katelaris (publicly available document)*.
- 11 Document entitled 'Psychiatric effects of Sativex', 18th Annual Symposium of the International Cannabinoid Research Society, Abstract 38, 2008, Robson P, and Etges, T, *tendered by Dr Katelaris (publicly available document)*.

Appendix 4 Answers to questions on notice

The Committee received answers to questions on notice from:

- Australian Drug Law Reform Foundation
- FamilyVoice Australia
- NSW Ministry of Health
- NSW Department of Attorney General and Justice
- NSW Police Force
- The HEMP Party

Appendix 5 Minutes

Minutes No. 14

Thursday 22 November 2012

General Purpose Standing Committee No. 4

Members' Lounge, Parliament House, at 1.00 pm.

1. Members present

Mrs Mitchell (*Chair*)

Mr Borsak

Ms Fazio (*Ms Voltz*)

Mr Lynn

Mr Khan

Mr Searle

Mr Shoebridge.

2. Substituting member

The Chair advised of the following substitution:

- Ms Fazio for Ms Voltz.

3. Previous minutes

Resolved, on the motion of Mr Shoebridge: That Draft Minutes No. 13 be confirmed.

4. Correspondence

The Committee noted the following items of correspondence:

- 21 November 2012 – From the Chair to Minister for Police and Emergency Services, informing the Minister of the advice received from Mr Bret Walker SC regarding the powers of the Legislative Council committees and that no further supplementary hearings will be held for the portfolio of Police and Emergency Services.

5. Consideration of Chair's draft Report

Resolved, on the motion of Mr Searle: That the report be the report of the Committee, and that the Committee present the report to the House, together with transcripts of evidence, answers to questions on notice, minutes of proceedings and correspondence relating to the Budget Estimates Inquiry.

6. Inquiry into the medical use of cannabis

The Committee considered referral by the House of a new Inquiry into the medical use of cannabis.

Resolved, on the motion of Ms Fazio: That the Committee adopt the following timeline for the management and administration of the Inquiry:

- 29 November 2012: Advertisements in major Sydney daily newspapers
- 15 February 2013: Closing date for submissions to the Inquiry
- March 2013: Hearings to commence from Monday 11 March
- 14 May 2013: Report to be furnished to the House.

Resolved, on the motion of Ms Fazio: That advertisements calling for submissions be placed in the *Sydney Morning Herald* and *Daily Telegraph*.

Resolved, on the motion of Ms Fazio: That a media release announcing the Inquiry and calling for submissions be issued on Monday 26 November 2012.

Resolved, on the motion of Ms Fazio: That the closing date for submissions be 15 February 2013.

Resolved, on the motion of Ms Fazio: That the Secretariat email members with a list of stakeholders to be invited to make written submissions, and that members have until 5pm, Thursday 29 November 2012, to nominate additional stakeholders.

Resolved, on the motion of Ms Fazio: That the Committee potentially hold two Sydney hearings from the week beginning 11 March 2013, and set aside a third reserve hearing date, on a date to be determined by the Chair after consultation with members regarding their availability.

Resolved, on the motion of Ms Fazio: That the Committee authorise the publication of all submissions to the Inquiry into the medical use of cannabis, subject to the Committee Clerk checking for confidentiality, adverse mention and other issues.

The Chair advised that she has been notified that Dr Kaye would be substituting for Mr Shoebridge, and Ms Fazio would be substituting for Ms Voltz, for the duration of the Inquiry into the medical use of cannabis.

7. Adjournment

Sine die.

Rachel Callinan

Clerk to the Committee

Minutes No. 15

Monday 11 March 2013

General Purpose Standing Committee No. 4

Jubilee Room, Parliament House, at 9.30 am

1. Members present

Mrs Mitchell (*Chair*)

Mr Borsak (*Deputy Chair*) (*from 10.45 am*)

Ms Fazio (*Ms Voltz*)

Dr Kaye (*Mr Shoebridge*)

Mr Khan

Mr Lynn

Mr Searle

2. Previous minutes

Resolved, on the motion of Mr Khan: That Draft Minutes No. 14 be confirmed.

3. Inquiry into the use of cannabis for medical purposes

3.1 Correspondence

The Committee noted the following correspondence received:

- 30 January 2013 – From Mr Richard Baron, FirstEye Films, to Committee Secretariat, seeking permission to film hearings on 11 and 18 March 2013 for the purpose of a documentary.
- 14 February 2013 – From Mr Paul O’Grady, to Committee Secretariat, requesting to make a verbal submission to the inquiry.

Mr O’Grady’s request to give evidence

Resolved, on the motion of Mr Searle: That Mr Paul O’Grady be invited to appear as a witness at the hearing on 18 March 2013.

FirstEye Films' request to film hearings on 11 and 18 March 2013

Resolved, on the motion of Mr Searle: That the Committee agree to the request from

3.2 Submissions**Public**

Resolved, on the motion of Dr Kaye: That the Committee note that submissions no. 4, 7, 9, 10, 12, 14, 15, 18 – 21, 27 – 31, 34 – 36, 40, 42, 43, 46, 47, 51 – 56, 58, 62, 64 – 66, 68-70, 72, 73, 75 – 79, 83, 85, 89 – 91, 93 – 97, 100, 102, 105, 107 – 111, 113, 116, 117 and 120 – 122 were published by the Committee Clerk, subject to checking for confidentiality, adverse mention and other issues, under the authorisation of an earlier resolution.

Name suppressed

Resolved, on the motion of Ms Fazio: That the Committee note that submissions no. 1 – 3, 5, 6, 8, 11, 16, 17, 22, 23, 25, 26, 32, 32a, 32b, 33, 33a, 37, 39, 41, 44, 45, 48, 49, 57, 59, 63, 67, 71, 74, 80 – 82, 84, 86 – 88, 92, 98, 99, 101, 103, 104, 106, 112, 114, 118 and 119 were published by the Committee Clerk under the authorisation of an earlier resolution, with the exception of the authors' names. Further, that the Committee keep confidential the authors' names at the request of the submissions' authors.

Name suppressed and partially confidential

Resolved, on the motion of Ms Fazio: That the Committee note that submission no. 24 was published by the Committee Clerk under the authorisation of an earlier resolution, with the exception of the author's name and information that could potentially identify a third party. Further, that the Committee keep confidential the author's name and the information that could potentially identify the third party.

Partially confidential

Resolved, on the motion of Dr Kaye: That the Committee note that submission no. 39 was published by the Committee Clerk under the authorisation of an earlier resolution, with the exception of information that could potentially identify a third party. Further, that the Committee keep confidential the information that could potentially identify the third party.

Confidential

Resolved, on the motion of Dr Kaye: That submissions no. 13, 38, 50, 60, 61 and 115 remain confidential at the request of the author.

3.3 Witnesses

Resolved, on the motion of Ms Fazio: That that the following additional witnesses be invited to appear on 18 March 2013: a clinician recommended by Pain Australia, and Dr Andrew Katelaris, author of submission no. 120. Further, that the Committee note that the Cancer Council was invited to appear as a witness but declined the invitation, and that Ms Bridget Whelan is unwell and is unable to appear on 11 March 2013.

3.4 Allocation of time for questions during hearings

Resolved, on the motion of Ms Fazio: That the timing of questioning for the hearings be divided evenly amongst Opposition, Crossbench and Government members with questions asked in that order.

3.5 Return of answers to questions on notice

Resolved, on the motion of Mr Khan: That for all hearings, witnesses be requested to return answers to questions on notice and/or supplementary questions from members within 14 days of the date on which questions are forwarded to the witnesses by the Secretariat, and that members have two days after a hearing to provide supplementary questions.

3.6 Extension to reporting date

Resolved, on the motion of Mr Lynn: That the Chair seek the agreement of the House to extend the reporting date to Friday 17 May 2013.

3.7 Public hearing

Witnesses, the public and the media were admitted at 9.35 am.

The following witnesses from NSW Ministry of Health were sworn and examined:

- Mr Bruce Battye, Deputy Chief Pharmacist, Pharmaceutical Services, Legal and Regulatory Services Branch
- Mr Chris Shipway, Director, Primary Care and Chronic Services, Agency for Clinical Innovation
- Ms Jenni Johnson, Manager, Pain Management Network, Agency for Clinical Innovation.

The evidence concluded and the witnesses withdrew.

The following witness from the Department of Attorney General and Justice was sworn and examined:

- Ms Penny Musgrave, Director, Criminal Law Review

Mr Borsak joined the meeting.

The evidence concluded and the witness withdrew.

The following witnesses were sworn and examined:

- Ms Lesley Brydon, Person with chronic pain, Pain Australia
- Ms Sally Crossing, CancerVoices.

Ms Brydon tendered the following documents:

- Written statement from Ms Sue Hodges
- Declaration of Montreal.

The evidence concluded and the witnesses withdrew.

The following witnesses from Mullaways Medical Cannabis were sworn and examined:

- Mr Tony Bower, Director
- Mr Kevin Charlesworth, Advisor.

Mr Bower tendered a document 'Images of fences restricting access to opium poppy farms'. The evidence concluded and the witnesses withdrew.

The Committee adjourned for lunch.

The hearing resumed.

The following witnesses from NSW Police Force were sworn and examined:

- Superintendent Pat Paroz, Commander, Drug and Alcohol Coordination, Commander, Drug Squad
- Superintendent Nicholas Bingham.

The evidence concluded and the witnesses withdrew.

The following witnesses from The HEMP Party (NSW Branch) were sworn and examined:

- Mr James Moylan, National Secretary and Campaign Director
- Mr Michael Balderstone, President.

Mr Balderstone tendered a document entitled *'The dispensary project – A discussion paper'* by J. Moylan & M. Balderstone, 2009.

The evidence concluded and the witnesses withdrew.

The following witnesses from the Australian Drug Law Reform Foundation were sworn and examined:

- Dr Alex Wodak AM, President
- Mr Evert Rauwendaal, Member
- Ms Vivienne Moxham-Hall, Secretary.

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Professor Michael Farrell, Director, National drug and Alcohol Research Centre
- Professor Wayne Hall, University of Queensland Centre for Clinical Research.

Dr Kaye left the meeting at 4.55 pm.

The evidence concluded and the witnesses withdrew.

The public hearing concluded at 5.10 pm.

The public and the media withdrew.

3.8 Tended documents

Resolved, on the motion of Ms Fazio: That the Committee accept and publish the following documents tendered during the public hearing:

- Written statement from Ms Sue Hodges, tendered by Ms Brydon
- Declaration of Montreal, tendered by Ms Brydon (publicly available document)
- Images of fences restricting access to opium poppy farms, tendered by Mr Bower
- Document entitled *'The dispensary project – A discussion paper'* by J. Moylan & M. Balderstone, 2009, tendered by Mr Balderstone.

3.9 Correspondence to the Commonwealth government

Resolved, on the motion of Mr Lynn: That the Committee write to the Commonwealth government seeking informational on pertinent Commonwealth legislation and its interaction with state legislation.

3.10 Additional witness

Resolved, on the motion of Mr Searle: That the ACON be invited to appear on 18 March, together with the co-authors of their submissions.

4. Adjournment

The Committee adjourned at 5.20 pm until Monday 18 March 2013, 10.00 am, Macquarie Room, Parliament House (*public hearing*).

Merrin Thompson
Committee Clerk

Minutes No. 16

Monday 18 March 2013

General Purpose Standing Committee No. 4

Macquarie Room, Parliament House, at 10.10 am

1. Members present

Mrs Mitchell (*Chair*)

Mr Borsak (*Deputy Chair*) (*from 10.15 pm*)

Ms Fazio (*Voltz*) (*from 1.35 pm*)

Dr Kaye (*Shoebridge*)

Mr Khan (*from 10.15 am*)

Mr Lynn

Mr Searle (*to 3.30 pm*)

2. Previous minutes

Resolved, on the motion of Dr Kaye: That Draft Minutes No. 15 be confirmed.

3. Inquiry into the use of cannabis for medical purposes

3.1 Correspondence

The Committee noted the following correspondence:

Received

- 12 March 2012 – From Mr Ewert Rauwendaal, Member, Australian Drug Law Reform Foundation to Secretariat, forwarding three journal articles referred to in his evidence on 11 March 2013
- 13 March 2013 – From Mr Kevin Charlesworth, Advisor, Mullaways Medical Cannabis to Secretariat, requesting to correct a figure cited in his evidence on 11 March 2013 and attaching three articles on issues raised in his evidence
- 13 March 2013 – From Mr James Moylan, National Secretary and Campaign Director, the HEMP Party (NSW) to Secretariat, forwarding further information on issues raised in his evidence on 11 March 2013
- 13 March 2013 – From Mr Phil O’Grady to the Chair, requesting to give evidence to the inquiry and attaching the report, *Cannabis with Care: A call for a trial of synthetic cannabinoids*
- 15 March 2013 – From Mr Mark Heinrich to the Chair regarding issues in relation to the operation of the inquiry.

Sent

- 13 March 2013 – From the Chair to Ms Jane Halton, Secretary, Department of Health and Ageing, seeking information on pertinent Commonwealth legislation and its interaction with state legislation.

Resolved, on the motion of Mr Searle: That the figure ‘five million’ on page 34 of the transcript of evidence of 11 March 2013 be amended to ‘two million’ at the request of Mr Kevin Charlesworth of Mullaways Medical Cannabis.

Resolved, on the motion of Mr Searle: That the Secretariat reply to Mr Heinrich's correspondence regarding issues in relation to the operation of the inquiry.

3.2 Submissions

Resolved, on the motion of Mr Searle: That the Committee authorise the publication of supplementary submission no. 14a.

Resolved, on the motion of Dr Kaye: That submission no. 61 be published, while keeping confidential the author's name at the request of the submission author.

Resolved, on the motion of Dr Kaye: That submission no. 87 be published in full.

Mr Borsak and Mr Khan joined the meeting.

3.3 Public hearing

Witnesses, the public and the media were admitted.

The following witnesses from Australian Medical Association were sworn and examined:

- Dr Saxon Smith, Vice-President
- Mr Andrew Took, Director, Medico-Legal and Employment Relations.

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Professor Michael Cousins, Pain Management Research Institute, Royal North Shore Hospital and Board Member, Pain Australia.

The evidence concluded and the witness withdrew.

The following witness was sworn and examined:

- Professor Jan Copeland, University of New South Wales.

The evidence concluded and the witness withdrew.

Ms Fazio joined the meeting.

The following witness was sworn and examined:

- Mr Paul O'Grady.

The evidence concluded and the witness withdrew.

The following witnesses from the Australian Drug Law Reform Initiative were sworn and examined:

- Ms Margaret Hall, Member
- Mr Ben Mostyn, Founding Member.

Mr Mostyn tendered a supplementary submission.

The evidence concluded and the witnesses withdrew.

The following witnesses from FamilyVoice Australia were sworn and examined:

- Dr David Phillips, National President
- Mr Graeme Mitchell, NSW State Officer, FamilyVoice Australia.

Mr Mitchell tendered the following documents:

- Cerda M, Wall M, Keyes KM, Galea S and Hasin D, 'Medical marijuana laws in 50 states: Investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence', *Drug and Alcohol Dependence*, 2011, Vol 120, 20-12, pp 20-27
- Salomonsen-Sautel S, Sakai J, Thurstone C, Corley R and Hopfer C, 'Medical marijuana use among adolescents in substance abuse treatment', *Journal of the American Academy of Child and Adolescent Psychiatry*, 2012, Vol 51, No 7, pp 694-702.

The evidence concluded and the witnesses withdrew.

Mr Searle left the meeting.

The following witnesses from ACON were sworn and examined:

- Mr Nicolas Parkhill, Chief Executive Officer
- Mr Dean Price, Policy Advisor.

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Dr Andrew Katelaris MD.

Dr Katelaris tendered the following documents:

- 'No evidence that cannabis causes long term psychiatric problems', unnamed publication citing Thomas H, *British Journal of Psychiatry*, 1993, Vol 163 p 141,
- 'New billion-dollar crop', *Popular mechanics*, 1938
- Reproduction of letter from the American Medical Association to the Committee on Finance, United States Senate, opposing the tax on cannabis, its preparations and derivatives
- Pamphlet entitled *Improve your Health with Hemp Seed* by Bio-Logical Products
- Robson P, Etes, T, 'Psychiatric effects of Sativex', 18th Annual Symposium of the International Cannabinoid Research Society, Abstract 38, 2008.

The evidence concluded and the witness withdrew.

The public hearing concluded at 5.00 pm.

The public and the media withdrew.

3.4 Tendered documents

Resolved, on the motion of Ms Fazio: That the Committee accept and publish the following documents tendered during the public hearing:

- Supplementary submission no. 69a, tendered by Mr Mostyn
- Cerda M, Wall M, Keyes KM, Galea S and Hasin D, 'Medical marijuana laws in 50 states: Investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence', *Drug and Alcohol Dependence*, 2011, Vol 120, 20-12, pp 20-27, tendered by Mr Mitchell (*publicly available document*)
- Salomonsen-Sautel S, Sakai S, Thurstone C, Corley R and Hopfer C, 'Medical marijuana use among adolescents in substance abuse treatment', *Journal of the American Academy of Child and Adolescent Psychiatry*, 2012, Vol 51, No 7, pp 694-702, tendered by Mr Mitchell (*publicly available document*)
- 'No evidence that cannabis causes long term psychiatric problems', unnamed publication citing Thomas H, *British Journal of Psychiatry*, 1993, Vol 163 p 141, tendered by Dr Katelaris (*publicly available document*)
- 'New billion-dollar crop', *Popular mechanics*, 1938, tendered by Dr Katelaris (*publicly available document*)

- Reproduction of letter from the American Medical Association to the Committee on Finance, United States Senate, opposing the tax on cannabis, its preparations and derivatives, tendered by Dr Katelaris (*publicly available document*)
- Pamphlet entitled *Improve your Health with Hemp Seed* by Bio-Logical Products, tendered by Dr Katelaris (*publicly available document*)
- Robson P, Etges, T, 'Psychiatric effects of Sativex', 18th Annual Symposium of the International Cannabinoid Research Society, Abstract 38, 2008, tendered by Dr Katelaris (*publicly available document*).

4. Adjournment

The Committee adjourned at 5.05 pm, *sine die*.

Merrin Thompson
Committee Clerk

Minutes No. 17

Wednesday 20 March 2013

General Purpose Standing Committee No. 4

Members' Lounge, Parliament House, at 1.00 pm

1. Members present

Mrs Mitchell (*Chair*)
Mr Borsak (*Deputy Chair*)
Dr Kaye (*Mr Shoebridge*)
Mr Khan
Mr Lynn
Mr Searle

2. Minutes

Resolved, on the motion of Dr Kaye: That Draft Minutes No. 16 be confirmed.

3. Inquiry into the use of cannabis for medical purposes

The Committee noted the following correspondence sent:

- 18 March 2013 – From Secretariat to Mr Mark Heinrich, responding to Mr Heinrich's correspondence regarding issues in relation to the operation of the inquiry.

Resolved, on the motion of Mr Searle: That the Chair write to the Secretary of the Commonwealth Department of Health and Ageing seeking advice on:

- The status of Sativex with respect to the Australian Register of Therapeutic Goods, including for which target group(s) it has been approved
- What if any steps are to be taken by both Commonwealth and state governments before it is available for prescription to the defined target group(s)
- The process for determination of other target groups.

Mr Khan joined the meeting.

4. Discussion of the possible content of the Chair's draft report for the inquiry into the use of cannabis for medical purposes

Debate ensued.

5. Adjournment

The Committee adjourned at 1.50 pm, until Friday 10 May 2013, 9.30 am, Room 1153, Parliament House (*report deliberative*).

Merrin Thompson
Committee Clerk

Draft Minutes No. 18

Friday 10 May 2013

General Purpose Standing Committee No. 4

Room 1153, Parliament House, Sydney at 10.05 am

1. Members

Mrs Mitchell, *Chair*
Mr Borsak, *Deputy Chair*
Ms Fazio (*Ms Voltz*)
Dr Kaye (*Mr Shoebriidge*)
Mr Khan
Mr Lynn
Mr Searle

2. Minutes

Resolved, on the motion of Mr Searle: That Draft Minutes No. 17 be confirmed.

3. Inquiry into the use of cannabis for medical purposes

3.1 Correspondence

The Committee noted the following correspondence received:

- 15 March 2013 – From Belinda Dover, Research Assistant, on behalf of the Chair, Revd the Hon Fred Nile MLC, attaching the journal article ‘Medicinal use of marijuana’, *New England Journal of Medicine*, Vol 368, No 9, pp 866-8, 28 February 2013
- 26 March 2013 – From Mr Kevin Charlesworth, Advisor, Mullaways Medical Cannabis, attaching the journal article, ‘Medical marijuana: A status report’, *Harvard Catalyst*, 6 December 2011
- 4 April 2013 – From Ms Sally Crossing AM, Deputy Chair, Cancer Voices NSW, advising that an answer to the question taken on notice, to survey of their members on ‘how widespread is this experience that relief from pain is costly and/or unsatisfactory because of other health effects’, would require additional resources in order to be provided
- 8 April 2013 – From Ms Jane Halton PSM, Secretary, Department of Health and Ageing, responding to questions from the Committee regarding Sativex
- 11 April 2013 – From Ms Jane Halton PSM, Secretary, Department of Health and Ageing, providing responses to questions from the Committee regarding the interface between Commonwealth and State law and seeking advice as to how the supply of cannabis is regulated by the *Therapeutic Goods Act 1989*
- 10 May 2013 – From Professor Laurence Mather, to the Chair, clarifying the definition of synthetic cannabis.

3.2 Answers to questions on notice

The Committee noted the following answers to questions on notice received which had been published by the Committee Clerk under the authorisation of an earlier resolution.

- Ms Penny Musgrave, Director, Criminal Law Review, NSW Department of Attorney General and Justice

- Superintendent Pat Paroz, Commander, Drug and Alcohol Coordination, NSW Police Force
- Superintendent Nicholas Bingham, Commander, Drug Squad, NSW Police Force
- Mr James Moylan, National Secretary and Campaign Director, the HEMP Party
- Dr Alex Wodak, President, Australian Drug Law Reform Foundation
- Mr Christopher Shipway, Director, Primary Care and Chronic Services, Agency for Clinical Innovation, NSW Ministry of Health
- Dr David Phillips, National President, FamilyVoice Australia.

3.3 Submissions

Public

Resolved, on the motion of Dr Kaye: That the Committee note that submissions nos. 62a and 85a were published by the Committee Clerk, subject to checking for confidentiality, adverse mention and other issues, under the authorisation of an earlier resolution.

Partially confidential

Resolved, on the motion of Mr Searle: That the Committee note that submission no. 123 was published by the Committee Clerk under the authorisation of an earlier resolution, with the exception of the name of a third party. Further, that the Committee keep confidential the name of the third party.

3.4 Consideration of the Chair's draft report

The Chair tabled her draft report entitled *The use of cannabis for medical purposes*, which having been previously circulated, was taken as being read.

Chapter 1 read.

Chapter 2 read.

Resolved, on the motion of Mr Searle: That the subheading before paragraph 2.9 be amended by omitting the word 'Routes' and inserting instead the word 'Forms'.

Resolved, on the motion of Dr Kaye: That paragraph 2.11 be amended by inserting the words 'many of' after the word 'without' and before the word 'the risks'.

Resolved, on the motion of Dr Kaye: That paragraph 2.75 be amended by omitting the words '(70 per cent were male with an average age of 32 years old)' after the words 'neurological diseases'.

Chapter 3 read.

Resolved, on the motion of Dr Kaye: That the second paragraph in the introduction of Chapter 3 be amended by:

- omitting the words 'the former' and inserting instead the words 'pharmaceutical products' after the words 'we focus principally on', and
- omitting the words 'the later' and inserting instead the words 'crude cannabis' after the words 'following chapter focuses on'.

Resolved, on the motion of Dr Kaye: That paragraph 3.27 be amended to clarify reference to Professor Mather's evidence, if necessary.

Resolved, on the motion of Ms Fazio: That paragraph 3.108 be amended by inserting the sentencing 'We are especially mindful here of people suffering from chronic pain for whom existing pain management is not effective.' after the first sentence.

Resolved, on the motion of Ms Fazio: That Recommendation 1 be amended by inserting the words ‘, including those suffering from chronic pain for whom existing pain management is not effective’ after the words ‘additional patient groups’ in the first dot point.

Chapter 4 read.

Resolved, on the motion of Mr Searle: That paragraph 4.112 be amended by:

- omitting the words ‘that may benefit from treatment with the use of cannabis’ after the words ‘a specific incurable condition’ in the first sentence
- omitting the word ‘cannabis’ after the words ‘register of authorised’ and before the words ‘patients and carers’ in the second sentence
- inserting a footnote noting that up to 15 grams is the amount of cannabis allowed under the Cannabis Cautioning Scheme.

Resolved, on the motion of Mr Searle: That paragraph 4.113 be amended by inserting the words ‘arrest and’ after the words ‘providing an exemption from’ and before the words ‘prosecution for’.

Resolved, on the motion of Mr Khan: That references to providing an ‘exemption from prosecution’ be amended to refer to an ‘exemption from arrest and prosecution’ where appropriate.

Resolved, on the motion of Mr Searle: That Recommendation 2 be amended by:

- omitting the words ‘consider introducing’ and inserting instead the word ‘introduce’ after the words ‘the NSW Government’
- omitting the word ‘permanent’ and inserting instead the word ‘complete’ after the words ‘to add a’
- omitting the word ‘may’ and inserting instead the word ‘would’ after the words ‘this system’
- omitting the words ‘and may benefit from treatment with cannabis’ after the words ‘diagnosed with a specified condition’.

Resolved, on the motion of Mr Searle: That Recommendation 5 be amended by omitting the word ‘routes’ and inserting instead the word ‘forms’ after the word ‘alternative’ and before the words ‘of administration’.

The Committee noted that the Committee Secretariat is empowered to correct any typographical, grammatical and formatting errors prior to tabling.

Resolved, on the motion of Mr Borsak: That the draft report, as amended, be the report of the Committee and that the Committee present the report to the House.

Resolved, on the motion of Ms Fazio: That the transcripts of evidence, submissions, tabled documents, answers to questions on notice, minutes of proceedings and correspondence relating to the inquiry be tabled in the House with the report.

Resolved, on the motion of Mr Khan: That upon tabling, all transcripts of evidence, submissions, tabled documents, answers to questions on notice, minutes of proceedings and correspondence relating to the inquiry not already made public, be made public by the Committee, except for those documents kept confidential by resolution of the Committee.

Resolved, on the motion of Dr Kaye: That the Committee thank the Committee Secretariat for their work during the inquiry and in preparing the draft report.

Resolved, on the motion of Mr Khan: That Chair’s foreword and the Executive Summary be amended to emphasise the unanimous nature of the report.

The Committee noted that the Executive Summary and the Chair's foreword will be amended to reflect the changes and circulated to Members.

The Chair indicated that she would hold a media conference on Wednesday 16 May at 11 am upon the tabling of the report.

4. Adjournment

The Committee adjourned at 11.30 am, *sine die*.

Merrin Thompson
Committee Clerk