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THE ISSUE OF MEDICINAL CANNABIS IN CONTEMPORARY AUSTRALIA

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The primary aim of this paper is to enhance the quality of debate and assist interested parties to consider relevant contemporary issues concerning the reintroduction into Australia of cannabis for medicinal purposes: it thereby builds on our previous work in which we outlined the medical case.¹ A secondary aim is to discuss some of the major areas where strong differences in opinion may currently be obstructing efforts to reform cannabis laws in Australia. It will be clear to the reader that the authors favour the case for legalising the use of cannabis for medicinal purposes by regulation and control, analogous to the means used for other clinically-useful drugs open to non-therapeutic uses.

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¹ Laurence E Mather et al, '(Re)introducing medicinal cannabis' (2013) 199 *The Medical Journal of Australia* 759.

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I INTRODUCTION

'Drugs' or 'medicines' are chemical substances that are ingested essentially to extend our life or improve the way we feel, typically as part of the treatment plan for a medically recognised condition. They usually do this by altering or regulating some or other normal or deranged physiological function. Not many generations ago, drugs or medicines were mainly prepared as mixtures, tinctures, and elixirs from natural sources, typically as extracts from plants or animal parts. Some were pre-prepared proprietary preparations and others were prepared by the pharmacist from non-proprietary formulae. Today, the vast majority are pure chemicals (synthetic or derived from natural products), developed by evidential research, supplied in proprietary ready-to-use forms, and rarely prepared by pharmacists. A great many mixtures, tinctures, and elixirs from natural sources are now sold as proprietary preparations under the catch-all name of 'complementary medicines', although medical claims for these are not allowed to be made, and supporting evidential research may be sparse.

Cannabis, in its various forms, comes from a plant. It is among many substances that have been declared illegal by most governments following international treaties that aim to reduce the availability of specified drugs in order to protect members of society from

their actual or perceived harms. Most substances are therapeutic drugs, or derivatives thereof, that are used non-therapeutically, allegedly as 'recreational' or pleasure-giving mood altering substances, with various degrees of habituating or addicting liability. While legal drugs may be used by people outside of their approved therapeutic uses, the supply of those drugs is closely controlled. In Australia, cannabis use is illegal,² including for treatment of recognised medical conditions; but, despite vigorous efforts to control supply, it remains relatively easy to obtain.³

The chemical quality of legal pharmaceutical drugs, such as paracetamol, is carefully regulated by suppliers in accordance with government agencies: in Australia, this is the Therapeutic Goods Administration (TGA). As a plant, cannabis does not sit comfortably with Australia's regulatory model, and this presents a basis for objection to its use by many people who might otherwise concede that it has some therapeutic value. Like other plants, cannabis contains several hundred chemical substances that regulate the plant's growth and sustenance. Many of these substances demonstrate activity in relevant pharmacological models, including some for which the pharmacological properties of cannabis are recognised.

Moreover, these substances occur in varying concentrations depending on the strain of the plant, its conditions of growth, harvesting, storage, and processing.⁴ Thus 'cannabis' cannot be regarded as a particular drug,⁵ and this creates difficulties with Australian and international standards for the regulation of pharmaceutical products. Recognising the unusual characteristics of cannabis and the recent rapid increase in scientific knowledge

² At present, the only cannabis product registered on the Australian Register of Therapeutic Goods (ARTG) is a proprietary cannabis plant extract with the US Approved Name (USAN) of nabiximols and the trade name of Sativex®. See Department of Health, Australian Government, *Medicinal Cannabis* <<http://www.health.gov.au/internet/main/publishing.nsf/Content/MC14-007515-medicinal-cannabis>>. The New South Wales (NSW) government has announced that it 'has committed clinical trials to further explore the use of cannabis and/or cannabis products...' but the legal framework for such trials has not yet been made public. See also Department of Health, New South Wales, *Clinical Trials: Medical Use of Cannabis* <<http://www.health.nsw.gov.au/cannabis/Documents/fs-cannabis-trials.pdf>>.

³ Natasha Sindicich and Lucy Burns, 'Australian Trends in Ecstasy and Related Drug Markets 2013: Findings from the Ecstasy and Related Drugs Reporting System (EDRS)' (Australian Drug Trends Series No 118, National Drug and Alcohol Research Centre, University of New South Wales, 2015) 101–102.

⁴ David J Potter, 'A review of the cultivation and processing of cannabis (*Cannabis sativa* L.) for production of prescription medicines in the UK' (2014) 6 *Drug Testing and Analysis* 31.

⁵ See A Hazekamp and J T Fisdick, 'Cannabis – from cultivar to chemovar' (2012) 4 *Drug Testing and Analysis* 660; Wendy Swift et al, 'Analysis of Cannabis Seizures in NSW, Australia: Cannabis Potency and Cannabinoid Profile' (2013) 8 *Plos One* e70052.

about it, some countries (most notably the Netherlands),⁶ have created an 'Office of Medicinal Cannabis' separate from their main regulatory body, in order to work through these difficult issues.

II THE BEGINNINGS OF MEDICINAL CANNABIS

Cannabis is an ancient herbaceous plant: its botanical name derives from the Latin for hemp. Various preparations from cannabis foliage and florets have been used for medicinal, dietary, textile fibre-making, religious, spiritual, and recreational purposes, for millennia. Although it is not believed to be a native, cannabis seeds were brought to Australia with the First Fleet to assist with providing for the voracious needs of the Royal Navy for sailcloth and rope. To these ends, the 'climate and soil' of Australia were proclaimed early in colonial history to be 'admirably adapted to the growth of hemp', indeed, so much so that the hemp plant 'was [in 1845] growing wild on the banks' of the Upper Hunter River.⁷

In Australia, as in most Western countries, a variety of proprietary and pharmacopoeial preparations of cannabis were available from early Victorian times. The introduction of cannabis into Western medicine is attributed to Dr W B O'Shaughnessy, Assistant-Surgeon and Professor of Chemistry in the Medical College of Calcutta, who described its botanical and physical characteristics and folkloric medicinal use in October 1838.⁸ He also described his own observations in human patients that included successful symptomatic treatment in cases of pain arising from acute and chronic rheumatism, of paroxysms from hydrophobia (rabies), diarrhoea from cholera, muscular spasms from tetanus, and infantile convulsions (epilepsy). O'Shaughnessy wrote a remarkably comprehensive report, and an account of it by 'Dr Neligan' was picked up by at least one Australian newspaper describing the medicinal benefits of cannabis, along with the prescient remark that it 'may be used as a substitute for opium, in cases for which that drug may be unsuited, from idiosyncrasy or any other cause; and also that it will

⁶ CIBG Ministerie van Volksgezondheid, Welzijn en Sport: The Office of Medicinal Cannabis. See CIBG Broadcast, *Informatieclip BMC English* (27 March 2012) YouTube <http://youtu.be/hE60il2pI_k>.

⁷ Robin Goodfellow, 'Hemp', *Hawkesbury Courier and Agricultural and General Advertiser* (Windsor), 3 April 1845, 1.

⁸ W B O'Shaughnessy, 'On the Preparations of the Indian Hemp, or Gunjah (*Cannabis indica*); Their Effects on the Animal System in Health, and Their Utility in the Treatment of Tetanus and Other Convulsive Diseases' (Speech delivered at the Medical College of Calcutta, October 1839) <<http://www.druglibrary.org/schaffer/history/e1850/gunjah.htm>>.

occasionally succeed in aborting, sometimes in completely removing pain, where this agent totally fails us'.⁹ With such wide-ranging and salutary pharmacological properties, it is not surprising that cannabis, in one form or another, had, by the mid-19th century, become part of the medical armamentarium of many societies.

As cannabis became adopted into the *materia medica* of Western medicine, it was formally described in national pharmacopoeial monographs, including those of Great Britain, the source of Australian standards for drugs and medicines. The British Pharmaceutical Codex (BPC) of 1934, for example, described the physical appearance of the plant and its active ingredient-enriched flowering tops, its action and uses, dosages of different forms, and recipes for making 'extract of cannabis' and 'tincture of cannabis'. Numerous folkloric preparations also abounded.¹⁰

III THE DEMISE OF MEDICINAL CANNABIS

In Australia and elsewhere, cannabis was legally used medicinally well into the 20th century. However, its demise began in the United States from about 1914 with several recognisable influences:¹¹ racial prejudice against (minority) Mexican immigrants in the southern and western states (who referred to it as marijuana), the Bureau of Prohibition, headed by Harry J Anslinger, a bureaucratic desire to justify its continued existence, and the assumption that cannabis (presumed to be an addictive drug) would substitute alcohol at a time of the national prohibition of alcohol.

Additionally, it was claimed by the Egyptian delegation at the Geneva Conventions on Opium and Other Drugs of 1925 that cannabis was as dangerous as opium and should therefore be subject to the same international controls and restrictions (although a subcommittee of that Conference reported that its use should be limited to medical and scientific purposes). No formal evidence was produced and conference delegates had not been briefed about cannabis. The only objections came from Britain and other colonial powers. They did not dispute the claim, but they did want to avoid a

⁹ 'Indian Hemp', *The Perth Gazette and Western Australian Journal* (Western Australia), 15 November 1845, 3.

¹⁰ Ethan B Russo 'History of Cannabis and its Preparations in Saga, Science, and Sobriquet' (2007) 4 *Chemistry & Biodiversity* 1614.

¹¹ Richard J Bonnie and Charles H Whitebread II, 'The Forbidden Fruit and the Tree of Knowledge: An Enquiry into the Legal History of American Marijuana Prohibition' (1970) 56 *Virginia Law Review* 1010.

commitment to eliminating its use in their Asian and African territories.¹² The passage of the *Marihuana Tax Act* in the United States on 1 October 1937 effectively prohibited the medicinal use of cannabis there, despite protests from the American Medical Association.¹³ The anti-cannabis *Reefer Madness*, cum 'sex-drug' propaganda,¹⁴ soon spread to Australia, and resulted in the ban of cannabis importation.¹⁵

The last appearance of cannabis in the BPC, from which it could be legally prescribed as a medicine in Australia, was in 1949, before disappearing in 1971. Its monograph stated that '[c]annabis is too unreliable in action to be of value in therapeutics as a cerebral sedative or narcotic...'.¹⁶ This statement contained the nucleus of the scientific argument for the demise of cannabis pharmacotherapy,¹⁷ and was reflected in many other countries. Nonetheless, medicinal cannabis was not sorely missed, as it was anticipated that most of its uses, in those optimistic times of a burgeoning pharmaceutical industry, would be replaced by more effective medicines.

It is commonly believed that the demise of medicinal cannabis in Australia resulted from Australia signing and ratifying the 1961 United Nations *Single Convention on Narcotic Drugs* (the Convention). But the medicinal use of cannabis was not precluded as a necessary outcome of ratifying this convention. The Preamble of the *Single Convention* proclaims that:

The Parties, [c]oncerned with the health and welfare of mankind, [r]ecognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...¹⁸

¹² Robert Kendell, 'Cannabis condemned: the proscription of Indian hemp' (2003) 98 *Addiction* 143, 151.

¹³ David F Musto, *The American Disease: Origins of Narcotic Control* (Oxford University Press, 2nd ed, 1987) 210–222.

¹⁴ See, eg, *Reefer Madness* (Directed by Louis J Gasnier, G and H Production, 1938).

¹⁵ 'Accomplishing the Impossible: Drug Habit Spreads In U.S.A.', *The Adelaide Chronicle* (Adelaide), 6 June 1946, 12; 'War on the Drug Traffic', *Sydney Morning Herald* (Sydney), 28 May 1954, 14; 'Marihuana Under Import Ban', *Sydney Morning Herald* (Sydney), 19 February 1947, 1.

¹⁶ The Council of the Pharmaceutical Society of Great Britain, *The British Pharmaceutical Codex* (Pharmaceutical Press, 1949). See also Laurence E Mather, 'Medicinal Cannabis—Hoax or Hope?' (2001) 26 *Regional Anaesthesia and Pain Medicine* 484.

¹⁷ *Ibid.*

¹⁸ *Single Convention on Narcotic Drugs*, opened for signature 30 March 1961, 520 UNTS 151 (entered into force 13 December 1964).

The Preamble then sets the scenario for a control regime concerned with the 'serious evil' of 'addiction to narcotic drugs'.¹⁹ Article 2, Part 5 states that:

The drugs in Schedule IV shall also be included in Schedule I and subject to all measures of control applicable to drugs in the latter Schedule, and in addition thereto:

- a) A Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included; and
- b) A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.²⁰

Several points are pertinent. First, 'cannabis and cannabis resin' is (surprisingly) included in Schedule IV, among a list of 17 drugs of which all others are opioids (mostly chemical relatives of fentanyl, itself a highly potent synthetic opioid analgesic agent in widespread clinical use), an entirely different chemical and pharmacological class of drug.²¹ Second, this reads that if a Party to the Convention (ie a country) only has to prohibit cannabis if it decides that 'the prevailing conditions...render [prohibition] the most appropriate means of protecting the public health and welfare'.²² Surely this can only mean that countries that do not believe that prohibition of cannabis is the most appropriate means of protecting the public health and welfare do not have to prohibit the drug, including for medicinal use. Third, the Single and other Conventions do not define 'medical' or 'scientific'. However, the Convention stipulated that '[t]he use of cannabis for other than medical and scientific purposes must be discontinued as soon as possible but in any case within twenty-five years from the coming into force of this Convention as provided in paragraph 1 of article 41', which, nevertheless, included the

¹⁹ Ibid.

²⁰ Ibid art 2(5).

²¹ Ibid Schedule IV.

²² Ibid art 2(5).

right to a signatory party to permit '[t]he use of cannabis, cannabis resin, extracts and tinctures of cannabis for non-medical purposes'.²³

IV WHAT IS MEDICINAL CANNABIS?

Medicinal botanicals are typically complex mixtures of natural chemicals, sometimes lacking a distinct (or recognisable) active principal, and with substantial prior human use. In 1964, the chemical structure of the main active psychotropic ingredient of cannabis, delta-9 tetrahydrocannabinol (THC), was described (in research that was not legal at the time).²⁴ Within three decades, approximately 100 similar and related substances had been identified, along with hundreds of other substances found in cannabis, many of which contribute to the relevant pharmacological activity attributed to cannabis, both salutary and otherwise.²⁵ Moreover, during this time, research on the bodies' own array of 'chemical messengers'²⁶ now included endocannabinoids, substances that are mimicked by various botanical cannabis constituents.²⁷ From this research, a vast array of synthetic and semisynthetic molecules, only some of which are directly or chemically related to the natural phytocannabinoids, were prepared as part of the scientific investigation of cannabis pharmacology,²⁸ but only a small number of these were eventually clinically-approved as medicines.

Nonetheless, a familiar pharmacological sequence was recurring: a history of empirical use of plant derived medicine, scientific experimentation with analogous (phyto)chemical molecules and their analogues, and finally the discovery of the presence and functioning of the body's own system with which those plant-derived molecules were interacting. This is remarkably similar to that of opium and the

²³ Ibid art 49(1)–(2).

²⁴ Y Gaoni and R Mechoulam, 'Isolation, Structure and Partial Synthesis of an Active Constituent of Hashish' (1964) 86 *Journal of the American Chemical Society* 1646.

²⁵ G Appendino, G Chianese and O Tagliatela-Scafati, 'Cannabinoids: Occurrence and Medicinal Chemistry' (2011) 18 *Current Medicinal Chemistry* 1085.

²⁶ These are diverse chemical molecules that cause changes in the functioning of nervous pathways that control body functions such as the beat of the heart and responses to injury.

²⁷ The term 'cannabinoid' refers to the family of substances, regardless of their chemical structures and whether they are natural product or synthetic, that bind to the biological receptors to thereby reproduce various of the pharmacological effects demonstrated by extracts of *Cannabis sativa*. The analogy is 'opioid' referring to morphine-like substances from opium. See also Raphael Mechoulam and Linda A Parker, 'The Endocannabinoid System and the Brain' (2013) 64 *Annual Review of Psychology* 21.

²⁸ Jenny L Wiley, Julie A Marusich and John W Huffman, 'Moving around the molecule: relationship between chemical structure and in vivo activity of synthetic cannabinoids' (2014) 97 *Life Sciences* 55.

endogenous opioid system described a generation earlier.²⁹ But, unlike opium, cannabis had already been removed from the pharmacopoeia, and thus from legal medicinal use — for non-scientific reasons — long before its science was understood.

Botanical cannabis is a complex mixture of phytocannabinoids and other natural product substances. As presently interpreted, 'medicinal cannabis' is an umbrella term used to designate a botanical product harvested from genetically identical cannabis plant clones that meets the reproducibility standards of a product sold for medicinal use; that is, accurately labelled material of known provenance, having reproducible active principal composition, quality of batch consistency, and being free of contaminants such as heavy metals, fungus and pesticides.³⁰ This contrasts with the cannabis of unknown provenance that is commonly sold on the black market. Indeed, it has been reported that the consistency of THC-related phytocannabinoids extracted from a cannabis plant is equivalent to what some drug regulators would accept for synthetic drugs.³¹

The glandular trichomes on the cannabis flower are the richest source of the phytocannabinoids, but their concentration and ratio may vary according to the cultivar (notably, the strain), environmental growing conditions, and storage of the plant and plant products.³² This thereby reinforces the need for regulation and control. Some detractors of 'medicinal cannabis' argue that the presently available cannabinoids obviate further need for botanical cannabis,³³ but there is no valid reason for this assertion.

The concentration and ratio of phytocannabinoids (and, probably, of certain non-cannabinoid ingredients) also play an important role in the pharmacological effects of medicinal cannabis with continually evolving evidence that different compositions can be preferably attuned to different treatments.³⁴ Additionally, contemporary research

²⁹ L E Mather, 'Opioids: A Pharmacologist's Delight!' (1995) 22 *Clinical and Experimental Pharmacology and Physiology* 833.

³⁰ Justin Thomas Fishedick et al, 'Metabolic fingerprinting of Cannabis sativa L., cannabinoids and terpenoids for chemotaxonomic and drug standardization purposes' (2010) 71 *Phytochemistry* 2058.

³¹ Geoffrey Guy in S M Crowther, L A Reynolds and E M Tansey (eds), *The Medicalization of Cannabis* (Wellcome Witnesses to Twentieth Century Medicine, 2010) vol 40, 34.

³² Potter, above n 4, 31.

³³ Drug Free Australia, *Drug Free Australia's position on Medical Marijuana/Cannabis* (July 2014) <http://www.drugfree.org.au/fileadmin/library/Medical_Marijuana/DFA-PositionOnMedicalMarijuana-2014.pdf>.

³⁴ Hazekamp and Fishedick, above n 5, 660.

suggests that the mixture of ingredients of cannabis may have greater therapeutic advantage than any of the principal ingredients alone, often referred to as the ‘entourage’ effect.³⁵

Medicinal cannabis is used in many forms, but only a few are available in ready-to-use preparations. Powdered dried plant material has traditionally been smoked, but can be consumed in other ways, especially via inhalation from a personal vaporiser (a device used to heat the material to release the active ingredients as a vapour), and this has the advantage of giving the user greater control over the effects. Other forms may be swallowed like the majority of medicines, for example, from an oil extract, tablets, capsules, “tea”, alcohol based “tincture”, or included in home-baked goods, typically “cookies”. One particular proprietary cannabis preparation, usually referred to by its proprietary name of Sativex® (or its US Approved Name (USAN) of nabiximols), has received considerable attention in the lay press and elsewhere as it has been used in many research studies sponsored by its originating company.³⁶ Sativex® is botanical cannabis extract from selective strains, thereby being enriched in THC and cannabidiol (CBD), and is sprayed into the lining of the mouth (‘oromucosal spray’) from where some of the dose becomes absorbed whilst some is swallowed.³⁷

V THE RESURGENCE OF MEDICINAL CANNABIS

By the 1990s, an international movement of patients and their advocate groups, health professionals and scientific experts, were questioning the illegal status of cannabis as a medicine, claiming that cannabis has significant medical benefits. Further, it was being claimed that cannabis is preferred to, or is more acceptable than, various conventional medications introduced for treatment of certain conditions, and it was widely acknowledged to be less harmful when consumed ‘recreationally’ than alcohol and tobacco, which were not subject to legal penalties for their use. By the late 1990s, the debate over medicinal cannabis was raised to another level when prestigious scientific

³⁵ Ethan B Russo, ‘Taming THC: Potential Cannabis Synergy and Phytocannabinoid-Terpenoid Entourage Effects’ (2011) 163 *British Journal of Pharmacology* 1344.

³⁶ Geoffrey W Guy and Colin G Stott, ‘The development of Sativex® — a natural cannabis-based medicine’ in R Mechoulam (ed), *Cannabinoids as Therapeutics* (Birkhäuser Basel, 2005) 231.

³⁷ Ethan Russo and Geoffrey W Guy, ‘A tale of two cannabinoids: The therapeutic rationale for combining tetrahydrocannabinol and cannabidiol’ (2015) 66 *Medical Hypotheses* 234; Stott et al, ‘A phase I study to assess the single and multiple dose pharmacokinetics of THC/CBD oromucosal spray’ (2013) 69 *European Journal of Clinical Pharmacology* 1135.

bodies in the United States³⁸ and Great Britain³⁹ published favourable reviews of the existing evidence. These independently agreed that cannabis appeared to be of value in the treatment of certain medical conditions (Table 1), although concluding that further rigorous research was needed to assess the true therapeutic benefits.

TABLE 1: INDICATIONS FOR CANNABINOID PHARMACOTHERAPY

Agreed uses for cannabinoid pharmacotherapy (from various recent inquiries):

- control of nausea/vomiting (eg from cancer chemotherapy);
- appetite stimulation (eg in patients with HIV-related or cancer-related wasting syndrome);
- control of muscle spasticity (eg from multiple sclerosis or spinal cord injury);
- pain management (especially of neuropathic origin); and
- anti-convulsant effects (eg from epilepsy).

Historically recognised uses for cannabinoid pharmacotherapy (from historical publications):

- management of pain of migraine;
- management of painful cramps of dysmenorrhoea;
- glaucoma treatment (temporary relief); and
- bronchodilation (associated with asthma treatment).

Emerging uses for cannabinoid pharmacotherapy (from current research literature):

- antitumorigenic and other direct anticancer treatments; and
- treatment of post-traumatic stress syndrome.

In 1999, New South Wales (NSW) Premier Carr announced the formation of a Working Party on the Use of Cannabis for Medical Purposes, which went on to endorse the uses given in Table 1. The Party made 24 medical, scientific, legal, and political recommendations, including that a trial be set up to explore how to institute a legal mechanism for patients to obtain and use cannabis medicinally. In May 2003, Premier

³⁸ See Janet E Joy, Stanley J Watson Jr and John A Benson Jr (eds), *Marijuana and Medicine: Assessing the Science Base* (National Academy Press, 1999).

³⁹ See Select Committee on Science and Technology, *Science and Technology – Ninth Report*, House of Lords Paper No 151, Session 1997–98 (1998); Select Committee on Science and Technology, *Therapeutic Uses of Cannabis*, House of Lords Paper No 50, Session 2000–01 (2001).

Carr outlined key elements of the plan, including the formation of an Office of Medicinal Cannabis under the auspices of the NSW Department of Health, and stated that a draft exposure Bill would be introduced at the earliest opportunity.

Although the Carr government continued to affirm its support for the project, no further developments occurred.⁴⁰ In fact, no additional significant governmental activity in Australia occurred until 2012 when a NSW Legislative Council inquiry into medicinal cannabis was announced. Following public hearings in March 2013, the multi-party inquiry unanimously recommended (in May 2013), the medicinal use of cannabis along with proposals for making it available to selected patients.⁴¹ In November 2013, the NSW government rejected all but one recommendation.

Between the NSW 2000 and 2013 reports, much of the largely anecdotal evidence for the usefulness of cannabis had been supplanted by robust evidence reported in peer-reviewed scholarly and professional journals. This evidence continues to accrue, a significant portion of it derived from studies using Sativex®. Concurrently, the lay media and the internet has become a vast repository of anecdotal evidence about medicinal uses of cannabis in various forms. For several decades, almost insurmountable barriers to medicinal cannabis research included obtaining funding, gaining ethics approval and sourcing lawful medicinal cannabis that could be used in studies. This form of publication bias is rarely acknowledged.

Over the past several years, a number of companies in Australia, both locally-established and overseas-partnered, including some now listed on the Australian Stock Exchange, are joining an emergent list of legal providers of cannabis-derived and related products in anticipation of changed governmental standpoints on cannabis. The scope, which can partially be gauged from submissions made to the Australian Senate in conjunction with the Regulator of Medicinal Cannabis Bill 2014,⁴² includes medicinal and industrial uses of cannabis products for use within Australia and overseas, as well as ancillary technology for administration of cannabis in approved clinical trials.

⁴⁰ See Rowena Johns, 'Medical Cannabis Programs: A Review of Selected Jurisdictions' (Briefing Paper 10/04, Parliamentary Library, New South Wales, 2004).

⁴¹ See New South Wales Parliament, 'The use of cannabis for medicinal purposes' (Report, No 27, Legislative Council, General Purpose Standing Committee No 4, 15 May 2013).

⁴² Senate Standing Committee on Legal and Constitutional Affairs, *Submissions* (2014) Parliament of Australia

<http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill/Submissions>.

Such commercial interests add to the mainly enthusiast-based list that operates with various degrees of legal approval. Nonetheless, mainstream pharmaceutical companies generally eschew natural products unless they can find and prepare from the natural source a novel pharmacological principal that allows intellectual property and a potential commercial opportunity to be secured. Notwithstanding, myriad patents have been granted to individuals and/or organisations for cannabinoid-related substances, methodologies, preparations, formulations, and medicinal uses, although there are presently few proprietary cannabinoid preparations in clinical use.

VI THE ISSUE FROM A HEALTH PERSPECTIVE

Two of the main matters that are repeatedly raised from a health perspective are the therapeutic efficacy of medicinal cannabis and the possible adverse effects. A number of medicines in current use (including some having Prescription Benefits Scheme (PBS) listing) demonstrate less impressive evidence for therapeutic efficacy and safety than cannabis, even allowing for inconsistencies in the cannabis product studied. This is not to say that any cannabis preparation is free from adverse effects — no medication is — but rigorous studies generally report that the side effects of medicinal cannabis are minimal and acceptable.⁴³ Adverse effects must be weighed against the untreated symptoms of the condition or the adverse effects of other medicines used to treat the condition.⁴⁴

Nor do we argue that medicinal cannabis use will always be beneficial — again, no medication is. As with any therapeutic product, it may not be effective, even when used where indicated. The Australian Register of Therapeutic Goods (ARTG) presently lists one cannabis product, Sativex® for only a single condition — muscle spasticity in multiple sclerosis. Off-label prescribing remains possible, but a recent (widely criticised) paper published in the *British Medical Journal* (curiously) cautioned that doctors ‘should avoid taking this medicolegal responsibility.’⁴⁵

⁴³ Tongtong Wang et al, ‘Adverse effects of medical cannabinoids: a systematic review’ (2008) 178 *Canadian Medical Association Journal* 1669.

⁴⁴ Philip Robson, ‘Abuse potential and psychoactive effects of δ -9-tetrahydrocannabinol and cannabidiol oromucosal spray (Sativex), a new cannabinoid medicine’ (2011) 10 *Expert Opinion on Drug Safety* 675.

⁴⁵ Michael Farrell, Rachele Buchbinder and Wayne Hall ‘Should doctors prescribe cannabinoids?’ (2014) 348 *British Medical Journal* 33.

VII MEDICINAL CANNABIS POLICY REFORM

Many major community and industry organisations support the legalisation of medical cannabis, arguing that it is safe and effective. Some medical bodies are sceptical of the evidence for the therapeutic benefits of cannabis, and are concerned about the prospect of prescribing an unfamiliar product.⁴⁶ However, because medicinal cannabis is not yet legally available in Australia, many people seeking relief (for themselves or their family) purchase cannabis from the black market despite inevitable risks arising from the lack of regulation. As cannabis use remains illegal and all cannabis use is treated the same under law (ie no distinctions are made between medicinal and non-medicinal use), people using cannabis for therapeutic gain may face legal sanctions. They may also be reluctant to share this information with their healthcare professionals, compromising the therapeutic relationship by withholding it. Early attempts by the NSW government to preclude the risk of legal sanctions for patients and carers do not appear to have solved this problem.

All Australian states and territories now have drug-driving legislation enabling roadside testing for THC, methamphetamine and 'ecstasy' (a street name for methylenedioxymethamphetamine or MDMA). The presence of detectable quantities of one or more of these drugs constitutes an offence. No evidence of impairment is required. It is not clear at this stage how patients lawfully using medicinal cannabis will be dealt with once the lawful use of medicinal cannabis is permitted in Australia.

A key issue for policy makers is the possibility of its 'recreational' or non-medical use, and the need to ensure that there is a sufficient difference between the classifications of cannabis for medicinal purposes versus 'recreational' purposes. The recreational aspects of cannabis mean that there is the potential for drug misuse if the policy does not suitably target the appropriate medicinal administration and regulation of its distribution. While some believe the legalisation of medical use could implicitly condone

⁴⁶ Australian Medical Association, *AMA Position Statement: Cannabis and Health* (2014) <https://ama.com.au/sites/default/files/documents/AMA_position_statement_cannabis_use_and_health_2014.pdf>; See also New South Wales Parliament, above n 41; Senate Standing Committee on Legal and Constitutional Affairs, above n 42.

and increase recreational use, others have suggested that its medical status may decrease recreational interest in the drug.⁴⁷

A review tested this hypothesis in 2015, collating data on adolescent cannabis use in the USA over a 24-year period. The researchers found that implementation of medical cannabis laws did not increase recreational cannabis use, although the states that implemented the laws tended to have higher rates of recreational use than those states that did not implement laws.⁴⁸ A successful policy will reconcile the differences in recreational and medical use in order to ensure that the community understands the need for medical prescription and expertise when consuming the drug. There are many potentially positive flow-on effects in the research community following the legalisation of medical cannabis. Whereas a blanket ban can prevent researchers from attempting to evaluate its medicinal use,⁴⁹ there is substantial and increasing international research pertaining to the medicinal use of cannabis where government policy is more lenient.

Another key issue for cannabis policy reform is securing a legal supply. This can cause contradictions in a country's policy if cannabis is illegal outside of a medical framework or if state and federal laws sit at odds with more localised policy initiatives. Having contradictory policy can cause confusion in police interpretation and leave some people (such as medical practitioners in the case of US reform) vulnerable to persecution through policy loopholes. In the Netherlands, outside the medical framework, the production and supply of cannabis is illegal, while the retail sale is not illegal within a controlled licensed "coffee shop" arrangement.⁵⁰

This has created a 'back door problem', where the supply side of the policy is at odds with the legalised retail policy, creating internal contradictions.⁵¹ In Colorado, a state licensing system was established for the production and supply of cannabis to outlets in

⁴⁷ Deborah S Hasin et al, 'Medical marijuana laws and adolescent marijuana use in the USA from 1991 to 2014: results from annual, repeated cross-sectional surveys' (2015) 2 *The Lancet Psychiatry* 601.

⁴⁸ Ibid.

⁴⁹ L E Mather, A D Wodak and W G Notcutt, 'Re: Should doctors prescribe cannabinoids?' (2014) 348 *British Medical Journal*.

⁵⁰ The International Association for Cannabinoid Medicines website lists the legal positions of various countries, amongst other information. For a legal overview of The Netherlands, see C Sandvos, *The Netherlands* (20 March 2014) International Association for Cannabinoid Medicines <<http://cannabis-med.org/index.php?tpl=page&id=235&lng=en&sid=1b35fdd1438521c70b7a145c6cf33ffb>>.

⁵¹ EMCDDA, 'A cannabis reader: global issues and local experiences' (Monograph Vol 1, European Monitoring Centre for Drugs and Drug Addiction, 2008).

order to overcome the difficulties in 'legal supply'.⁵² These are both examples of legal supply for recreational use that can be adapted for medicinal supply. Arguably the best approach to overcoming policy loopholes associated with medicinal supply is demonstrated in Uruguay, where a national, rather than state law was passed to regulate the sale and production of cannabis.⁵³

Medicinal cannabis has been debated in Australia recently as some jurisdictions have considered the increasing evidence for its efficacy and safety. Within the last few years, the ACT, Tasmanian, Victorian and Queensland governments have embarked on courses regarding the legal patient access of medical cannabis. During 2014, two draft Bills were tabled in the NSW Parliament to commence lawful use of medicinal cannabis and/or give *de facto* permission to patients and their carers to possess small quantities for medicinal purposes. These Bills were shelved when, in December 2014, Premier Baird announced the establishment of an expert panel to oversee the conduct of three government supported projects to evaluate cannabis pharmacotherapy in (i) improving the quality of life in adults with terminal illness; (ii) treatment of refractory nausea and vomiting following cancer chemotherapy; and (iii) treatment of intractable epilepsy of childhood.⁵⁴

Additionally, the Commonwealth Parliament has before it the Regulator of Medicinal Cannabis Bill 2014 — a Bill to create a nation-wide framework for regulation and control of cannabis and its preparations for medicinal purposes, with provisions for states and territories to cede their requirements for the regulation of cannabis to the Commonwealth. On 12 February 2015, the Senate referred the Bill to the Legal and Constitutional Affairs Legislation Committee for inquiry.⁵⁵ Not unexpectedly, like previous inquiries, submissions ranged from a few sentences of personal testimony to many pages of referenced research.⁵⁶ This included outright support, especially from patients and/or their carers, overall support from experts based on the evidence,

⁵² John Hudak 'Colorado's Rollout of Legal Marijuana Is Succeeding: A Report on the State's Implementation of Legalization' (2015) 65 *Case Western Reserve Law Review* 649.

⁵³ EMCDDA, 'Perspectives on Drugs: Models for the legal supply of cannabis: recent developments' (Report, European Monitoring Centre for Drugs and Drug Addiction, 2014).

⁵⁴ Department of Health, New South Wales, *Clinical Trials: Medical Use of Cannabis* <<http://www.health.nsw.gov.au/cannabis/Documents/fs-cannabis-trials.pdf>>.

⁵⁵ Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into Regulator of Medicinal Cannabis Bill 2014* (2014).

⁵⁶ Senate Standing Committee on Legal and Constitutional Affairs, above n 42.

tentative support or opposition mainly from professional peak bodies expressing concerns that cannabis is not a pure regulated drug and expressing wariness over the reported adverse effects (often accompanied by claims that there is not enough evidence, or that the evidence is weak, or that there are already sufficient drugs that cater for the pharmacotherapy afforded by cannabis).⁵⁷

Submissions also voiced outright opposition based on the reported adverse effects to individuals and society from the evils of the illicit drug market.⁵⁸ Such diversity indicates a need for policy reform to reconcile the differences in public opinion in the policy selection and implementation phases of the policy cycle. For this to occur, implementation issues around the legal supply and separation of the 'recreational use debate' must be well considered within any implementation plan or consultation strategy.

The multiparty unanimous report, consisting of six recommendations, was brought down on 11 August 2015. Overall, the committee supported the access of medical patients to cannabis products, the establishment of mechanisms to evaluate scientific/medical evidence about cannabis, and the establishment of a national regulatory framework for cannabis products concordant with existing frameworks and treaty obligations. This structure shares elements of the Dutch model, in which the legal production and supply of medicinal cannabis to pharmacies, universities and research institutes is the responsibility of the government Office for Medicinal Cannabis (OMC) within the Dutch Ministry of Health. The OMC works with contracted growers-suppliers to devise preferred cannabis blends for appropriate medical conditions, maintain quality assurance, and ultimately distribute to pharmacies along with advice to pharmacists who dispense to patients upon medical prescriptions.⁵⁹ The model is commendable and it is hoped that Australian legislation will reflect many of its elements. However, as of September 2015, no amendments had been proposed and a timeline for further presentation had not been planned.

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ Cannabis Bureau, *What is the Office of Medicinal Cannabis?* <<https://www.cannabisbureau.nl/english>>.

VIII ISSUES FOR GOVERNMENT POLICY MAKERS

The primary issue is no longer the supportive evidence — that is more than adequate — it is supply. The NSW 2013 inquiry recommended that (restricted amounts of) raw cannabis or cannabis-based products be made available under prescription. The 2015 Senate inquiry called for submissions concerning a Bill to establish:

a Regulator of Medicinal Cannabis to be responsible for formulating rules and monitoring compliance with those rules for licensing the production, manufacture, supply, use, experimental use and import and export of medicinal cannabis; and provides for a national system to regulate the cultivation, production and use of medicinal cannabis products, and related activities such as research.⁶⁰

A federal approach is clearly preferred to separate state and territory approaches, but at this stage, the Bill would permit only opt-in agreements. The issue of supply thus remains unclear and confused. For example, the NSW Minister for Health was reported to have said that the (government sponsored) cannabis trials would not involve the use of ‘crude cannabis’ which has ‘serious potential ill-health effects... this is about looking at derivatives of cannabis that can be useful in treating these conditions’.⁶¹ It is not clear from this what was meant by use of the term ‘derivatives’— was it a misunderstood reference to Sativex®, a botanical cannabis preparation?

We regard Sativex® as an appropriate medicine but are concerned by the high cost and the consequent risk that many patients will obtain their medication from illegal sources, a significant problem in Canada several years ago. Our other concern with Sativex® derives, somewhat paradoxically, from its virtue in being a well-regulated preparation as to the concentrations of its two main phytocannabinoid ingredients (THC and CBD). As previously mentioned, research suggests patients with different conditions may fare better with a range of offerings with phytocannabinoid content in different ratios, as occurs in the Netherlands.

Community support for medicinal cannabis is very strong and has been for some years. The 2013 National Drug Strategy Household Survey found that approximately two thirds

⁶⁰ Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, *Inquiry into Regulator of Medicinal Cannabis Bill 2014* (2014).

⁶¹ Nicole Hasham, ‘States to join NSW medical marijuana trials’, *Sydney Morning Herald* (online), 19 April 2015 <<http://www.smh.com.au/nsw/states-to-join-nsw-medical-marijuana-trials-20150418-1mnwbq.html>>.

of Australians aged over 14 years support a change in legislation permitting the use of cannabis in a medical setting.⁶² This figure has remained relatively constant since 2007,⁶³ showing that, in Australia, there has been widespread public support over the past six years.

Currently, 23 US states and Washington DC legally permit medicinal cannabis. Seven countries — the Netherlands, Italy, Canada, Chile, the Czech Republic, France and Israel — provide medicinal grade cannabis while continuing to prohibit the recreational use of cannabis. Each has introduced a level of state-regulation, although these regulations vary. Cannabis cultivation in Canada is illegal unless a personal use production license or a designated-person production license is issued by the government through the Medical Marihuana Access Regulation Programme, under which one plant may be grown at a time (thereby avoiding supply contradictions).⁶⁴ This allows access to the raw botanical form of the cannabis plant, as does the Chilean, Czech, and Israeli models of medicinal cannabis. Various other countries such as Belgium, New Zealand, and Spain have laws to permit its medical use under special conditions.

IX CONCLUSION

There is adequate evidence to consider cannabis and/or its preparations as reasonable second-line medications for a variety of chronic medical conditions, and not just terminal illnesses. At the same time, there are many misconceptions about the substance, as well as the evidence put forward in the political, legal, medical, and societal discourse. Some have been addressed in the preceding narrative and are summarised in Table 2 below.

⁶² Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey detailed report 2013' (Report, Drug Statistics Series No 28, AIHW, 25 November 2014).

⁶³ Australian Institute of Health and Welfare, '2010 National Drug Strategy Household Survey report', (Report, Drug Statistics Series No 25, AIHW, 27 July 2011).

⁶⁴ Health Canada, 'Statement: Medical Marihuana Access Regulations Update' (Media Statement, 28 March 2014) <<http://www.hc-sc.gc.ca/dhp-mps/marihuana/access-access-eng.php>>.

TABLE 2: SOME COMMON MISCONCEPTIONS ABOUT MEDICINAL CANNABIS

- *What is needed, as is the case for any medications, is strong evidence and not only anecdotal stories.* It is hard to reconcile this view with more than a hundred published and mostly favourable randomised controlled trials.⁶⁵
- *At present there is no comprehensive evidence to address questions such as who may benefit from medicinal cannabis and derivatives.* There is already sufficient evidence for pharmacotherapy for a range of conditions (Table 1), with considerable agreement among different reviewers of the literature.
- *Any benefits accruing to medical users of cannabis will occur at the expense of increases in non-medical cannabis use and related risks and harms.* In US states, medical cannabis schemes have been used as a “Trojan horse” for the legalisation of recreational cannabis use. There is broad concern that sanctioning the medicinal use of cannabis might ‘send the wrong message’ and lead to an increase in recreational cannabis use among adolescents. There are no data to justify this concern.⁶⁶
- *Condoning the use of inhaled cannabis through smoking would also be a retrograde step in terms of efforts to reduce and prevent smoking.* For most adults, inhalation of cannabis vapour is a feasible and preferable alternative to smoking. Some patients may insist on smoking cannabis and their doctors will have to accept that.⁶⁷
- *There are now much more effective drugs available.* Even if cannabis is only used as a second line treatment, when conventional medicines prove ineffective or have unacceptable side effects, it would still provide a worthwhile benefit.
- *Cannabis is curative.* There is insufficient present evidence to confirm or deny curative properties of cannabis.⁶⁸

⁶⁵ Frango Grotenhermen and Kirsten Müller-Vahl, ‘The Therapeutic Potential of Cannabis and Cannabinoids’ (2012) 109 *Deutsches Ärzteblatt International* 495.

⁶⁶ Karen O’Keefe et al, ‘Marijuana Use By Young People: The Impact of State Medical Marijuana Laws’ (Report, Marijuana Policy Project, June 2011); S D Lynne-Landsman, M D Livingston and A C Wagenaar, ‘Effects of State Medical Marijuana Laws on Adolescent Marijuana Use’ (2013) 103 *American Journal of Public Health* 1500; Esther K Choo et al, ‘The impact of state medical marijuana legislation on adolescent marijuana use’ (2014) 55 *Journal of Adolescent Health* 160.

⁶⁷ Mark A Ware et al, ‘Smoked cannabis for chronic neuropathic pain: a randomized controlled trial’ (2010) 182 *Canadian Medical Association Journal* 1.

⁶⁸ C J Fowler, ‘Delta9-Tetrahydrocannabinol and Cannabidiol as Potential Curative Agents for Cancer: A Critical Examination of the Preclinical Literature’ (2015) 97 *Clinical Pharmacology & Therapeutics* 587.

The use of medicinal cannabis should be lawful with neither patients nor their carers at risk of legal sanctions or requiring police discretion. The Dutch model is commendable, involving regulation of the quality of medicinal cannabis and providing it to patients via medical prescription and pharmacy dispensing at an affordable price. A federal approach is preferable to piecemeal state and territory frameworks. Cannabis medications should be legally available for research, as well as available and affordable to patients throughout Australia. The more restricted the system for medicinal cannabis, the higher the proportion using unregulated and black market supplies and vice versa. Although any new system in Australia is likely to start cautiously, and therefore with many restrictions, a more liberal system will reduce the number of patients using unregulated supplies.

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