

THE CHALLENGE OF MEDICINAL CANNABIS TO THE POLITICAL LEGITIMACY OF THERAPEUTIC GOODS REGULATION IN AUSTRALIA

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The decision by the Commonwealth government to reschedule cannabis for medicinal purposes in August 2016 marked a watershed in the regulation of the drug. It occurred in the midst of pressure for reform by state governments, patients and the media. This article examines the reform period of 2014 to 2018 and asks what it means for the political legitimacy of the regulatory regime for therapeutic goods in Australia. It argues that three distinct voices were present in the debates on medicinal cannabis reforms, each of which expressed different views about regulatory change and the nature of cannabis itself. By applying a perspective on political legitimacy that uses dialogue as a metaphor, the article analyses how the voices of medicinal cannabis reform challenged the legitimacy of Australia's therapeutic goods regime. It concludes that this challenge provides an opportunity for reflection on Australia's therapeutic goods regulatory regime, and a chance to embrace a dialogic approach to political legitimacy.

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Cite as:

Penny Gleeson, ‘The Challenge of Medicinal Cannabis to the Political Legitimacy of Therapeutic Goods Regulation in Australia’
(2019) 43(2) *Melbourne University Law Review* (advance)

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I INTRODUCTION

[T]he [Therapeutic Goods Administration] traditionally has dealt with clear-cut proposals which lead to drugs which can be commercialised ... It would not be a body that would be able to liaise with other state health departments and the like in the way that I believe is going to be essential to get effective control of medical cannabis.¹

On 31 August 2016, the Commonwealth Department of Health effectively determined that Australians could legally access cannabis for medicinal purposes.² The decision was made under the Australian regulatory scheme that applies to all pharmaceuticals and medical devices — collectively referred to as ‘therapeutic goods.’³ The decision followed a significant period of public controversy regarding the medicinal use of cannabis which engaged individu-

¹ Evidence to Senate Legal and Constitutional Affairs Legislation Committee, Parliament of Australia, Canberra, 30 March 2015, 21 (David Penington).

² Therapeutic Goods Administration, Department of Health (Cth), *Final Decisions and Reasons for Decisions by a Delegate of the Secretary to the Department of Health* (31 August 2016) 10 (*‘Final Decisions and Reasons for Decisions’*).

³ *Therapeutic Goods Act 1989* (Cth) s 3 (definition of ‘therapeutic goods’) (*‘Therapeutic Goods Act’*).

al patients and their families, advocacy groups, state and Commonwealth governments, and the media.⁴ While the drug itself was the subject of intense focus, the complex regulatory scheme pursuant to which the decision was made was less so. Yet, as the above quote illustrates, the controversy surrounding medicinal cannabis highlighted doubts about Australia's regulatory arrangements for therapeutic goods. This uncertainty contrasted starkly with the view that the Australian regulator, the Therapeutic Goods Administration ('TGA'), and the regime it administered, had 'an excellent reputation both internationally and domestically'.⁵

This article considers the reforms to the availability of medicinal cannabis between 2014 and 2018 in Australia and the resulting challenge to the political legitimacy of the regulation of therapeutic goods.⁶ The reforms are one of a number of examples of 'difficult' or 'hard' cases that the therapeutic goods regulatory regime has dealt with, and continues to deal with. Others include drugs, like cannabis, that are commonly used recreationally or give rise to contentious ethical or social issues.⁷ As this article illustrates, such 'difficult' case studies are commonly characterised by public controversy and conflict. Case studies like medicinal cannabis reform provide an insight into important aspects and deficiencies of the operation of the established regulatory regime in a way that other, more uniform examples may not.⁸ The aim of this article is

⁴ See below Part IV.

⁵ Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation: Report on the Regulatory Framework for Medicines and Medical Devices* (Report, 31 March 2015) vii.

⁶ While relevant to the reforms around medicinal cannabis, this article will not focus on reforms to the criminal law in relation to the drug: see, eg, Charles Martin, 'Medical Use of Cannabis in Australia: "Medical Necessity" Defences under Current Australian Law and Avenues for Reform' (2014) 21(4) *Journal of Law and Medicine* 875; Victorian Law Reform Commission, *Medicinal Cannabis* (Issues Paper, March 2015) 76–7 ('VLRC Medicinal Cannabis Issues Paper').

⁷ For example, alkyl nitrites, psychedelic drugs (such as MDMA and psilocybin), and the medical abortion drug commonly known as RU486: 'Alkyl Nitrites Consultation: Regulatory Options for Appropriate Access and Safety Controls for Alkyl Nitrites', *Therapeutic Goods Administration* (Web Page, 6 June 2019) <<https://www.tga.gov.au/alkyl-nitrites-consultation>>, archived at <<https://perma.cc/AV3M-V5DE>> ('Alkyl Nitrites Consultation'); Jenny Valentish, 'Opening Minds', *The Saturday Paper* (Melbourne, 23 February 2019) 8; Grant McArthur, 'The Trip of a Lifetime: Push to Allow Psychedelic Drugs for Medical Use', *The Herald Sun* (Melbourne, 14 February 2019) 8; Barbara Baird, 'Medical Abortion in Australia: A Short History' (2015) 23(46) *Reproductive Health Matters* 169.

⁸ See, eg, Julia Black, 'Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes' (2008) 2(2) *Regulation and Governance* 137, 138 ('Legitimacy and Accountability'). See also Robert K Yin, *Case Study Research: Design and Methods* (SAGE Publications, 5th ed, 2014) 40–4, 68.

to analyse the case of medicinal cannabis reform in Australia to draw out these insights and their implications for the therapeutic goods regulatory regime.

Before outlining the contents of this article, it is useful to briefly describe the drug with which it is concerned. Cannabis is the generic name given to three species of plants.⁹ It can be used for a variety of purposes — as a fibre (known as hemp), an oil for fuel, varnish, and soap, and, most relevantly, as a drug.¹⁰ In biological terms, it is the nature and level of cannabinoids, the active components of the cannabis plant, which determine the medical impact of cannabis and its psychoactive affect.¹¹ Cannabis is commonly dried and smoked, but may also be administered as a resin, oil or as food.¹² Claims about the medicinal potential of the cannabis plant appear in texts on folk medicine from around the third to eighth centuries BCE.¹³ This highlights the comparatively contemporary nature of the regulatory debates about the medicinal use of cannabis. The phrase ‘medicinal cannabis’ will be used in this article to refer to cannabis that is ‘used for a medicinal objective’ to achieve ‘a curative or remedial effect’, rather than for ‘recreational’ use.¹⁴

This article asks what the recent reforms around medicinal cannabis indicate about the political legitimacy of the regulation of therapeutic goods in Australia. It begins by providing an overview of the regulation of therapeutic goods. Part III summarises the restrictive historical regulation of medicinal cannabis in Britain, the United States, under international law and in Australia. This historical context is important in setting the scene for the unprecedented reform period from 2014 to 2018. Part IV describes these reforms in the State of Victoria and the Commonwealth and how they emerged. The

⁹ Martin Booth, *Cannabis: A History* (Doubleday, 2003) 2.

¹⁰ *Ibid* 4–5.

¹¹ The cannabinoid delta-9-tetrahydrocannabinol (“THC”) primarily provides the euphoric effect of the drug: see, eg, Mahmoud ElSohly and Waseem Gul, ‘Constituents of *Cannabis Sativa*’ in Roger G Pertwee (ed), *Handbook of Cannabis* (Oxford University Press, 2014) 3, 4; Victorian Law Reform Commission, *Medicinal Cannabis* (Report, August 2015) 20 [2.4] (‘VLRC Medicinal Cannabis Report’).

¹² *VLRC Medicinal Cannabis Report* (n 11) 22 [2.10].

¹³ Ethan Russo, ‘Cannabis in India: Ancient Lore and Modern Medicine’ in Raphael Mechoulam (ed), *Cannabinoids as Therapeutics* (Birkhäuser Verlag, 2005) 1, 2; Lumír O Hanuš and Raphael Mechoulam, ‘Cannabinoid Chemistry: An Overview’ in Raphael Mechoulam (ed), *Cannabinoids as Therapeutics* (Birkhäuser Verlag, 2005) 23, 23.

¹⁴ *VLRC Medicinal Cannabis Report* (n 11) 21 [2.6], citing Jonathan P Caulkins et al, *Marijuana Legalization: What Everyone Needs to Know* (Oxford University Press, 2012) 14. The term ‘cannabis’ will be used in this article to describe both recreational and medicinal cannabis.

reform period is more closely analysed in Part V — in particular, how the debate surrounding the changes to the regulation of medicinal cannabis was permeated by three sets of competing, and at times overlapping, ‘voices’. Each of these voices expressed a different conception about what constituted ‘medicinal cannabis’ and, therefore, views about regulatory reform. Part VI of the article examines what the medicinal cannabis reform period tells us about the political legitimacy of therapeutic goods regulation in Australia. In doing so, it outlines an approach to analysing political legitimacy that emphasises constant dialogue between all parties to a power relationship to reach a shared set of normative values and beliefs. Applying this approach, the article examines how certain ‘voices’ of medicinal cannabis reform challenged the political legitimacy of Australia’s therapeutic goods regulatory regime. The article concludes that the therapeutic goods regulatory regime should embrace a ‘constant dialogic’ approach to political legitimacy to better anticipate and respond to the challenges of its regulatory environment.

II THE REGULATION OF THERAPEUTIC GOODS IN AUSTRALIA: A BRIEF OUTLINE

The regulation of therapeutic goods plays a significant role in Australia’s health system. Therapeutic goods are typically understood as constituting medicines (eg headache tablets), medical devices (eg bandages, gloves), or biologicals (eg tissue- or cell-based products).¹⁵ In Australia, the regulation of therapeutic goods is overseen by the TGA, which is part of the Commonwealth government’s Department of Health.¹⁶ These regulatory arrangements are complemented by schemes for the subsidisation of medicines and medical services via the Pharmaceutical Benefits Scheme and the Medicare Benefits Scheme respectively.¹⁷

¹⁵ ‘What Are “Therapeutic Goods”?’, *Therapeutic Goods Administration* (Web Page) <<http://www.tga.gov.au/what-are-therapeutic-goods>>, archived at <<https://perma.cc/SJF7-QLUQ>>. The *Therapeutic Goods Act* (n 3) defines ‘therapeutic goods’ broadly in a series of provisions: at ss 3 (definitions of ‘therapeutic goods’, ‘therapeutic use’, ‘medical device’, ‘biological’), 32A, 41BD.

¹⁶ The TGA is not established by legislation. However, the *Therapeutic Goods Act* (n 3) confirms the ‘continued ... existence’ of the ‘Therapeutic Goods Administration Account’ for the purpose of public finance administration: at s 45(1).

¹⁷ See ‘What the TGA Doesn’t Do’, *Therapeutic Goods Administration* (Web Page, 2 August 2012) <<http://www.tga.gov.au/what-tga-doesnt-do>>, archived at <<https://perma.cc/WM6S-YCUC>>; *MBS Online: Medicare Benefits Schedule* (Web Page, 31 July 2019) <<http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home>>, archived at <<https://perma.cc/2DB7-F6WQ>>; *PBS: The Pharmaceutical Benefits Scheme* (Web Page)

A complex mix of regulatory tools apply to the manufacture, import, export and supply of therapeutic goods, the most significant of which is the *Therapeutic Goods Act 1989* (Cth) (*'Therapeutic Goods Act'*). For the purpose of this article I will collectively refer to these regulatory tools as the 'therapeutic goods regulatory framework', 'therapeutic goods regulatory regime', 'regulatory framework', or 'regulatory regime'. The Act establishes a cooperative Commonwealth–state regulatory scheme which reflects the respective constitutional powers of the two tiers of government.¹⁸ The Act has two objectives. The first is to establish and maintain 'a national system of controls relating to the quality, safety, efficacy and timely availability' of therapeutic goods that are used in, or exported from, Australia.¹⁹ The second object is to provide a 'framework' for a uniform national approach in relation to poisons.²⁰ In addition to the Act, a range of secondary legislation, guidelines, standards, and the decisions and practices of the executive branch of government also form part of the regulatory framework.²¹ I will outline some of these in relation to medicinal cannabis below. The Act specifies that the key regulatory decision-makers are the relevant Minister and the Secretary of the Department of Health (or, typically, their delegates).²² They are supported in relation to parts of their functions by certain advisory committees.²³

The regulatory framework adopts a risk–benefit-based approach to determine whether a proposed therapeutic good should be made available to the

<<http://www.pbs.gov.au/pbs/home>>, archived at <<https://perma.cc/6LCX-8SC8>>. See generally John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Therapeutic Goods Administration, 2007); Westlaw AU, *The Laws of Australia* (online at 1 September 2019) [20.11].

¹⁸ See VLRC *Medicinal Cannabis Issues Paper* (n 6) 56–7 [4.1]–[4.6], 59–61 [4.17]–[4.24].

¹⁹ *Therapeutic Goods Act* (n 3) s 4(1)(a).

²⁰ *Ibid* s 4(1)(b). A poison is defined as 'an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard': at s 3 (definition of 'poison').

²¹ See, eg, *Therapeutic Goods Regulations 1990* (Cth) (*'Therapeutic Goods Regulations'*); *Poisons Standard June 2019* (Cth) (*'Poisons Standard'*); *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth); *Therapeutic Goods (Articles That Are Medical Devices) Specification 2014* (Cth); *Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines 2010* (Cth).

²² See, eg, *Therapeutic Goods Act* (n 3) ss 7AA, 9A(1), (5). The powers of the Secretary under the Act may be delegated: at ss 3 (definition of 'authorised person'), 7A.

²³ *Ibid* ss 52B (establishing the Advisory Committee on Medicines Scheduling), 52C (establishing the Advisory Committee on Chemicals Scheduling), 63(2)(a) (enabling the Governor-General to make regulations to establish such committees).

public.²⁴ In simple terms, a higher degree of regulatory scrutiny is imposed on higher-risk goods. Before therapeutic goods can be made available, the Secretary of the Department of Health (or, typically, her or his delegate) must evaluate the proposed goods, ‘having regard to ... whether the *quality, safety and efficacy* of the goods for the purposes for which they are to be used have been satisfactorily established.’²⁵

If a particular therapeutic good has been subject to, and passed, the applicable level of regulatory scrutiny, it is included on the Australian Register of Therapeutic Goods (‘ARTG’).²⁶ The Act imposes criminal penalties for the import, export, manufacture or supply of therapeutic goods not approved for inclusion on the ARTG.²⁷ As will be explained, the Act provides that therapeutic goods may, however, be made available when they are not on the ARTG, ‘in response to the needs of particular people or circumstances.’²⁸

The second object of the Act — to facilitate the uniform regulation of poisons throughout Australia — is particularly relevant to the regulation of medicinal cannabis and related reforms.²⁹ The Act enables the making and amendment of the *Standard for the Uniform Scheduling of Drugs and Poisons* (‘*Poisons Standard*’).³⁰ The *Poisons Standard* classifies poisons in one of 10

²⁴ There are, however, regulatory differences between the frameworks for medicine and medical devices: see generally Sansom, Delaat and Horvath (n 5) chs 4–5.

²⁵ *Therapeutic Goods Act* (n 3) ss 25(1)(c), 32DA, 32DE (emphasis added). The Secretary must also consider additional matters (such as compliance with any relevant standard and the quality of any manufacturing steps performed overseas) and may seek a range of information: at ss 25(1)(f), (g), (k), (2)–(2G), 26(2), 31 (in relation to medicines and medical devices). See also at ss 32DA, 32DE (in relation to biologicals).

²⁶ See ‘ARTG Search’, *Therapeutic Goods Administration* (Web Page) <<https://tga-search.clients.funnelback.com/s/search.html?query=&collection=tga-artg>>, archived at <<https://perma.cc/B5P7-9CE5>>. The ARTG is separated into five parts: (1) ‘registered’ and (2) ‘provisionally registered’ goods, which are considered to pose a higher level of risk to human safety; (3) ‘listed’ goods, which are deemed to have a lower risk profile; and finally (4) ‘biologicals’ and (5) ‘medical devices’: *ibid* s 9A(3). See also ‘The Regulation of Medicines in Australia’, *Therapeutic Goods Administration* (Web Page, 18 December 2013) 5 <<https://www.tga.gov.au/medicines-0>>, archived at <<https://perma.cc/X4E7-8WRG>>.

²⁷ Or otherwise deemed exempt or subject to other specified approvals: *Therapeutic Goods Act* (n 3) ss 19B(4)–(4A). More serious criminal penalties apply where the use of the goods has, will, or would be likely to result in ‘harm or injury to any person’: at s 19B(1). See also criminal offences in relation to biologicals: at ss 32BA–32BJ.

²⁸ ‘Australian Register of Therapeutic Goods’, *Therapeutic Goods Administration* (Web Page) <<https://www.tga.gov.au/artg>>, archived at <<https://perma.cc/K3MR-A4X3>>. The availability of goods in these circumstances will be explained further below in relation to medicinal cannabis: see below Part III(C).

²⁹ *Therapeutic Goods Act* (n 3) s 4(1)(b).

³⁰ *Ibid* pt 6-3.

schedules according to their respective level of risk to public health.³¹ It imposes a range of requirements and restrictions on the sale and supply, storage, labelling, advertisement, and disposal of poisons in accordance with that level of risk.³² Schedule 10, for example, includes poisons considered to be of greatest risk and which are consequently prohibited from supply or use.³³ The *Poisons Standard* is therefore central to the control of public access to drugs in Australia.

The Australian Health Ministers' Advisory Council ('AHMAC') determines the policy framework according to which the *Poisons Standard* is made and amended.³⁴ However, it is the Secretary of the Commonwealth Department of Health who makes and amends the *Poisons Standard*.³⁵ In doing so, the Secretary or delegate must have regard to several matters under the Act, its Regulations, AHMAC's policy framework, any advice of the Advisory Committees on Medicines or Chemicals Scheduling, and public submissions.³⁶ Further, the *Poisons Standard* is only enforceable in the states and territories which incorporate it in their statute book.³⁷ Thus, while the regulatory framework is intended to, and largely does, achieve the uniform regulation of poisons across Australia, this is not necessarily the case. Ultimately, uniformity depends on each state's position about any amendment to the *Poisons Standard*.³⁸

III THE REGULATORY CONTEXT AND HISTORY OF MEDICINAL CANNABIS

Cannabis has traditionally been dealt with strictly by Australia's therapeutic goods regulatory regime. This reflects similarly stringent approaches taken

³¹ *Poisons Standard* (n 21) iv–v.

³² *Ibid* pts 2–3. See also Australian Health Ministers' Advisory Council, *Scheduling Policy Framework for Medicines and Chemicals* (January 2018) 5–7 ('*Scheduling Policy Framework*').

³³ *Poisons Standard* (n 21) sch 10.

³⁴ *Scheduling Policy Framework* (n 32) 5.

³⁵ *Therapeutic Goods Act* (n 3) s 52D.

³⁶ *Ibid* ss 52B(4), 52C(4), 52D(2), 52E; *Therapeutic Goods Regulations* (n 21) pt 6 divs 3A–3B, 3D.

³⁷ *Scheduling Policy Framework* (n 32) 6. In Victoria, for example, it is typically incorporated into the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) ('*Drugs Act* (Vic)').

³⁸ See, eg, 'Australian State & Territory Variations from Part 4 of the Poisons Standard', *Therapeutic Goods Administration* (Web Page, 31 May 2019) <<https://www.tga.gov.au/australian-state-territory-variations-part-4-poisons-standard>>, archived at <<https://perma.cc/KP6W-294U>>.

internationally. It is therefore appropriate to briefly set out this broader context before turning to describe Australia's regulatory approach to medicinal cannabis prior to the start of the recent reform period.³⁹

A *The International Context*

Medicinal cannabis first made its appearance in western medical commentary in the early to mid-1800s.⁴⁰ It ushered in a period in which pharmaceutical formulations of the drug were often used and prescribed in Britain, Europe and North America.⁴¹ In Britain, domestic drug control was the subject of regulation and bureaucratisation from the early 1900s.⁴² In 1925, the supply of cannabis in Britain was restricted by amendments to the country's *Dangerous Drugs Act 1920*, which ratified the *International Opium Convention* of the same year.⁴³ A restrictive regulatory approach continued throughout the remainder of that century and assumed greater prominence into the 1960s, with the introduction of additional controls and penalties, and an enhanced focus on drug addiction.⁴⁴ It was an approach that reflected the position of the

³⁹ More extensive accounts of the regulation and control of cannabis in the United Kingdom, the US and under international law can be found in James H Mills, *Cannabis Britannica: Empire, Trade, and Prohibition 1800–1928* (Oxford University Press, 2003) ('*Cannabis Britannica*'); James H Mills, *Cannabis Nation: Control and Consumption in Britain, 1928–2008* (Oxford University Press, 2013) ('*Cannabis Nation*'); Nancy E Marion, *The Medical Marijuana Maze: Policy and Politics* (Carolina Academic Press, 2014); Booth (n 9); Alice P Mead, 'International Control of Cannabis' in Roger G Pertwee (ed), *Handbook of Cannabis* (Oxford University Press, 2014) 44.

⁴⁰ Russo (n 13) 6.

⁴¹ Ibid 6–9; Andrew D Hathaway and Kate Rossiter, 'Medical Marijuana, Community Building, and Canada's Compassionate Societies' (2007) 10(3) *Contemporary Justice Review* 283, 284; Booth (n 9) 89–95. Note the alternative conclusion reached by one commentator in relation to Britain that 'there was very little use of preparations of the plant in the UK in the period 1800–1928': Mills, *Cannabis Britannica* (n 39) 208. The author describes extensively, however, the experimental use of cannabis by the British medical establishment: at 208–10.

⁴² Virginia Berridge, 'Drugs and Social Policy: The Establishment of Drug Control in Britain 1900–30' (1984) 79(4) *British Journal of Addiction* 17, 21–3.

⁴³ *Dangerous Drugs Act 1925*, 15 & 16 Geo 5, c 74 ('1925 UK Drugs Act'); *International Opium Convention*, signed 19 February 1925, 81 LNTS 319 (entered into force 25 September 1928) arts 4–11.

⁴⁴ See, eg, *Dangerous Drugs Act 1965* (UK); *Misuse of Drugs Act 1971* (UK) ('1971 UK Drugs Act'); John Lawrence Jiggins, 'Marijuana Australiana: Cannabis Use, Popular Culture, and the Americanisation of Drugs Policy in Australia, 1938–1988' (PhD Thesis, Queensland University of Technology, 2004) 28; Mills, *Cannabis Nation* (n 39) 6, 82, 91–5, 133; Booth (n 9) 269–70. See also Berridge (n 42) 28.

UK government that the drug had no therapeutic merit.⁴⁵ In the United States, cannabis was transformed from a common therapeutic substance to an illicit one, as federal and state legislators and bureaucrats sought to control the growth, sale and use of cannabis by the 1930s.⁴⁶ This prohibitive approach continued throughout the counter-culture movement of the 1960s and merged with the country's infamous 'war on drugs' of the 1970s and '80s. Despite a renewal of medicinal support for the drug, it was not until the early 1990s that certain state governments took steps to facilitate access to medicinal cannabis in their jurisdictions.⁴⁷

On the international stage, the *International Opium Convention* of 1925 was the first significant step by the international community in relation to drug control.⁴⁸ While its proposed intention was to regulate the opium trade, cannabis was ultimately included at the urging of Egypt.⁴⁹ It was, however, the 1961 United Nations *Single Convention on Narcotic Drugs* ('*Single Conven-*

⁴⁵ Booth (n 9) 274. See *1971 UK Drugs Act* (n 44); *Misuse of Drugs Regulations 2001* (UK) SI 2001/3998. This is a perspective that has changed only very recently in relation to particular medicinal cannabis products: see, eg, Tim Wyatt, 'Cannabis Products Available for Prescription within Weeks, Government Announces', *The Independent* (online, 11 October 2018) <<https://www.independent.co.uk/news/uk/home-news/cannabis-prescription-doctors-nhs-home-office-medical-marijuana-sajid-javid-a8579256.html>>, archived at <<https://perma.cc/RKQ5-2V4U>>; Letter from Sally C Davies, Stephen Powis and Keith Ridge, 31 October 2018, archived at <<https://perma.cc/3RJW-CWZA>>; *The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018* (UK) SI 2018/1055.

⁴⁶ See, eg, *Marihuana Tax Act of 1937*, Pub L No 75-238, 50 Stat 551; Marion (n 39) 21-7; Troy Duster, *The Legislation of Morality: Law, Drugs, and Moral Judgment* (Free Press, 1970) 44.

⁴⁷ Marion (n 39) 27-38. As of July 2019, medicinal cannabis was legal in 33 American states and recreational use legal in 10. At the federal level of government, both medicinal and recreational use of cannabis remains prohibited and highly controlled: 'State Medical Marijuana Laws', *National Conference of State Legislatures* (Web Page, 2 July 2019) <<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>>, archived at <<https://perma.cc/5HNX-AJK8>>; Daniel J Mallinson and Lee Hannah, 'Marijuana Expands into 3 More States, but Nationwide Legalization Still Unlikely', *The Conversation* (online, 8 November 2018) <<https://theconversation.com/marijuana-expands-into-3-more-states-but-nationwide-legalization-still-unlikely-106512>>, archived at <<https://perma.cc/NES5-PXNG>>; Marion (n 39) 37-8.

⁴⁸ *International Opium Convention* (n 43).

⁴⁹ The Egyptian delegation was concerned about the extent of the use of cannabis in its country and urged that the drug should be included in the Convention: Booth (n 9) 117-18. In 1931 and 1936, additional treaties were developed in response to the illicit drug trade and concern about drug addiction: *Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs*, opened for signature 13 July 1931, 139 LNTS 303 (entered into force 9 July 1933); *Convention of 1936 for the Suppression of the Illicit Traffic in Dangerous Drugs*, opened for signature 26 June 1936, 198 LNTS 301 (entered into force 26 October 1939).

tion')⁵⁰ that established what is now recognised as the international regime for the control of illegal drugs. Like its predecessors, the *Single Convention* limited the production and cultivation of drugs, including cannabis, and required signatories to impose domestic licensing and reporting requirements. The *Single Convention* sought to strike a balance between the legitimate availability of drugs for therapeutic purposes and a high degree of state control to combat drug abuse and addiction.⁵¹ It provided that only a 'rational' medical or scientific use of controlled substances such as cannabis could be considered justifiable.⁵² This highly controlled approach to cannabis remains the status quo at international law,⁵³ although there are strong indications of the possibility of reform.⁵⁴

B *The Regulation of Cannabis in Australia before 2014*

The early approach to cannabis in Australia reflected an acceptance of the drug for everyday therapeutic purposes, and it was used medicinally until the start of the 20th century.⁵⁵ According to one commentator, for example, cannabis was an ingredient in the popular, and over-the-counter, pain relief preparation Chlorodyne — 'the country's favourite panacea' — and of cigarettes used widely for asthmatic conditions.⁵⁶ The first significant legal regulation of cannabis in Australia was introduced as an amendment to

⁵⁰ *Single Convention on Narcotic Drugs*, signed 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964) ('*Single Convention*').

⁵¹ Mead (n 39) 47–8.

⁵² *Ibid* 48.

⁵³ Subsequent UN conventions in 1971 and 1988 reinforced the *Single Convention's* regime: *ibid* 48–9. This is despite recent reform by some signatories to facilitate domestic access to the drug, such as Canada: Roojin Habibi and Steven J Hoffman, 'Legalizing Cannabis Violates the UN Drug Control Treaties, but Progressive Countries like Canada Have Options' (2018) 49(2) *Ottawa Law Review* 427.

⁵⁴ Reform at the international level appears possible in light of recommendations by the World Health Organization Expert Committee on Drug Dependence at the end of 2018 for changes to the international control of certain cannabis and cannabis-related substances: 'WHO Endorses Decisions of Expert Committee on Cannabis and Other Substances', *World Health Organization* (Web Page, 2019) <https://www.who.int/medicines/news/2019/ecdd-endorses-decisions-ECDD_cannabis-other-substance/en/>, archived at <<https://perma.cc/TS4P-SBZN>>.

⁵⁵ Jiggins (n 44) 25–8.

⁵⁶ *Ibid* 26–8. Cannabis seeds were brought to Australia upon European settlement with the aim of producing hemp: John Rainford, *Consuming Pleasures: Australia and the International Drug Business* (Fremantle Press, 2009) 161–2.

Victoria's *Poisons Act* in 1927 to make it an offence to possess cannabis, coca leaves and cocaine.⁵⁷ The same set of amendments provided for the regulation of the production, possession and sale of those substances.⁵⁸ Other states adopted a similar approach.⁵⁹ It appears that cannabis was included amongst the emerging nation's prohibited drugs at this point to fulfil its obligations under the 1925 *International Opium Convention*.⁶⁰ The reforms were also influenced by the British Parliament's amendments to its *Dangerous Drugs Act 1925* to restrict the sale of cannabis.⁶¹

The late 1930s marked a turning point in Australia's early acceptance of the drug, influenced by changing public opinion and the impact of international obligations.⁶² By 1956, the Commonwealth government had declared cannabis a prohibited import, and in mid-1960 it broadened the legislative definition of the drug in its customs regulations.⁶³ In the early 1960s, the Commonwealth pressured all states to rewrite or introduce their respective *Poisons Acts*.⁶⁴ The aim was to ensure that each state adopt a uniform schedule of drugs and thereby enable the Commonwealth to meet its obligations under the *Single Convention*.⁶⁵ It also resulted in the classification of cannabis as a prohibited and highly controlled substance.⁶⁶ These regulatory arrangements established the basis of the cooperative legislative scheme between the Commonwealth and the states for drug control.

Despite this prohibitive legislative approach, recreational use of cannabis increased from the second half of the 1960s.⁶⁷ Its use in Australia symbolised a generational gap: 'the pot leaf joined the [anti-Vietnam War] moratorium

⁵⁷ *Poisons Act 1927* (Vic) s 24(3).

⁵⁸ Terry Carney, 'The History of Australian Drug Laws: Commercialism to Confusion?' (1981) 7(3) *Monash University Law Review* 165, 196. Less significant but noteworthy provisions were enacted earlier to regulate the control of a variety of drugs, including cannabis, via food, customs and housing legislation: at 168, 173, 175–6.

⁵⁹ *Ibid* 196 n 226.

⁶⁰ *International Opium Convention* (n 43).

⁶¹ See, eg, Victoria, *Parliamentary Debates*, Legislative Council, 28 September 1927, 1529 (WJ Beckett, Minister of Public Health); Desmond Manderson, *From Mr Sin to Mr Big: A History of Australian Drug Laws* (Oxford University Press, 1993) 9; 1925 *UK Drugs Act* (n 43).

⁶² Carney (n 58) 168–9.

⁶³ *Ibid* 198–9.

⁶⁴ Manderson (n 61) 141–3.

⁶⁵ *Ibid*.

⁶⁶ *Ibid*.

⁶⁷ Predominantly amongst older teenagers and young adults: see, eg, *ibid* 144.

badge as a “revolutionary” symbol’ of the anti-establishment culture.⁶⁸ In this context, cannabis use constituted a challenge to the legal and medical establishments.⁶⁹ Cannabis was soon labelled by the police and popular press as a precursor to heroin use and it became a key target of strict social control.⁷⁰

Until relatively recently, Australia’s therapeutic goods regulatory regime reflected its historical prohibition and control of cannabis. Prior to the recent reforms and consistent with its historical regulation, cannabis was listed as a ‘prohibited substance’ under sch 9 of the *Poisons Standard*.⁷¹ Schedule 9 is the second highest level of classification under the *Poisons Standard*. It recognises that the drugs contained within it ‘may be abused or misused’ and therefore that their ‘manufacture, possession, sale or use ... should be prohibited by law’, except for the purposes of particular medical or scientific research or teaching.⁷² However, a limited number of certain cannabinoid substances used for specific therapeutic purposes, along with ‘processed hemp fibre’, are included in other schedules to indicate a lower level of risk associated with these products.⁷³ In addition, the *Narcotic Drugs Act 1967* (Cth) (*Narcotic Drugs Act*) provides that drugs subject to the Act, including cannabis, can only be produced in Australia if a licence is granted by the Commonwealth Minister for Health.⁷⁴ Historically, the legislation of the states and territories,

⁶⁸ Jiggins (n 44) 38.

⁶⁹ Ibid 38–9; Manderson (n 61) 145–7.

⁷⁰ Jiggins (n 44) 39, 56.

⁷¹ *Poisons Standard October 2017* (Cth) sch 9.

⁷² *Poisons Standard* (n 21) v. In contrast, sch 10 contains ‘[s]ubstances of such danger to health as to warrant prohibition of sale, supply and use’. The less restrictive sch 8 is for controlled drugs which are described as ‘[s]ubstances 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.’

⁷³ *Final Decisions and Reasons for Decisions* (n 2) 8. Included amongst these products, for example, is nabiximol, better known by its brand name Sativex, which is intended for use by multiple sclerosis patients. Sativex is the only biological (non-synthetic) cannabis drug approved for medicinal use in Australia under the therapeutic goods regime: Therapeutic Goods Administration, Department of Health (Cth), *Australian Public Assessment Report for Nabiximols* (Report, 27 September 2013) 189. Sativex subsequently failed to obtain approval under the Pharmaceutical Benefits Scheme and its sponsor withdrew the drug from the Australian market: Ian Freckelton, ‘Medicinal Cannabis Law Reform in Australia’ (2016) 23(3) *Journal of Law and Medicine* 497, 498.

⁷⁴ *VLRC Medicinal Cannabis Report* (n 11) 105 [4.20]–[4.21].

including Victoria, reflected the approach of the Commonwealth with respect to cannabis, treating it as a ‘drug of dependence’ and a ‘poison’.⁷⁵

C Restricted Access to Medicinal Cannabis in Australia

This restrictive regulatory regime meant that medicinal cannabis was effectively prohibited and unavailable in Australia. It is important to appreciate this highly controlled environment in order to understand the drive for reform that arose from it. In order to access medicinal cannabis, patients were left with two main exceptional pathways under the therapeutic goods regime, which remain in place today.⁷⁶ The remaining alternative was the illegal market.

Under one option, patients can obtain access to medicinal cannabis via the therapeutic goods ‘special access’ regulatory arrangements.⁷⁷ This enables a patient to seek, through a clinician, the approval of the Secretary of the Commonwealth Department of Health to obtain a cannabis product that is not listed on the ARTG, commonly through importation.⁷⁸ Applications under these arrangements are assessed against specific criteria.⁷⁹ This pathway is typically considered an exceptional basis on which to obtain access to

⁷⁵ *Drugs Act* (Vic) (n 37) s 4(1) (definitions of ‘drug of dependence’, ‘poison or controlled substance’), sch 8, as enacted. Nevertheless, it has been observed that this ‘thoroughly modern drug law’ was ‘equivocal’ in relation to cannabis because certain offences relating to it were subject to lesser penalties than for other drugs: Manderson (n 61) 185–6. The cultivation, possession or use of cannabis was prohibited in Victoria unless a person was licensed to do so. Typically a license to cultivate, possess and use cannabis was only issued where the drug was needed in relation to a person’s profession or in performing duties under the Act: *ibid* 107 [4.34].

⁷⁶ Therapeutic Goods Administration, Department of Health (Cth), *Access to Unapproved Therapeutic Goods: Personal Importation* (Guidelines, October 2004) 7 (‘*Personal Importation Guidelines*’); *Therapeutic Goods Act* (n 3) ss 18–19. The first pathway is the special access scheme: at ss 31A(1), 31B(2). The second pathway is the authorised provider scheme: at ss 19(5), 31B(3). If patients or prescribers use one of these two pathways, they must also meet certain conditions to import the drug: *Personal Importation Guidelines* (n 76) 9–12. Access may also be obtained through participation in a clinical trial: *Therapeutic Goods Act* (n 3) s 19(1)(b).

⁷⁷ Therapeutic Goods Administration, Department of Health (Cth), *Special Access Scheme: Guidance for Health Practitioners and Sponsors* (September 2017); ‘Access to Medicinal Cannabis Products: Using Access Schemes’, *Therapeutic Goods Administration* (Web Page, 30 August 2019) <<http://www.tga.gov.au/access-medical-cannabis-products-using-access-schemes>>, archived at <<https://perma.cc/R9WM-EBGX>>.

⁷⁸ *VLRC Medicinal Cannabis Report* (n 11) 112 [4.66].

⁷⁹ *Ibid* [4.67].

otherwise unapproved therapeutic goods.⁸⁰ It has been perceived to be a complex process and, even following the reforms, application numbers were initially low.⁸¹ It is important to note that the TGA ‘does not vouch for the quality, safety and effectiveness’ of drugs obtained via the ‘special access’ regulatory pathway.⁸² A second way in which medicinal cannabis may be legally accessed by patients is if their clinician applies to become an ‘authorised prescriber’ of the drug ‘to specific patients (or classes of recipients) with a particular medical condition’.⁸³

Little empirical data is available on the extent and method by which patients access and use medicinal cannabis.⁸⁴ Data that does exist indicates that the illicit nature of the drug in Australia discouraged, or was a concern for, those using or wanting to use medicinal cannabis.⁸⁵ The Victorian Law

⁸⁰ Ibid 113 [4.73]–[4.76].

⁸¹ Ibid 112–13 [4.66]–[4.76]; ‘Medicinal Cannabis “Red-Tape” Pushing Doctors and Patients Back to Illegal Products’, *Lateline* (Australian Broadcasting Corporation, 16 August 2017) <<http://www.abc.net.au/lateline/medicinal-cannabis-red-tape-pushing-doctors-and/8814530>>, archived at <<https://perma.cc/9RYC-9TPA>>. The TGA responded that it was the absence of evidence in relation to the therapeutic use of medicinal cannabis that explained the low levels of prescription under the special access scheme: ‘Responding to Lateline: Accessing Medicinal Cannabis Products’, *Therapeutic Goods Administration* (Web Page, 17 August 2017) <<https://www.tga.gov.au/behind-news/responding-lateline-accessing-medicinal-cannabis-products>>, archived at <<https://perma.cc/B29N-9WMS>> (‘Responding to Lateline’). However, a presentation by the head of the TGA (the Deputy Secretary of the Health Products Regulation Group) in August 2016 stated that imported cannabis products ‘have proven difficult for Australian patients to access’: John Skerritt, ‘Medicinal Cannabis: What’s Happening?’ (Speech, Australian Pharmaceutical Industry Scientific Conference, August 2016) 8 (emphasis omitted). Over time, application numbers have, however, increased significantly, and the application process has been ‘streamline[d]’: ‘Access to Medicinal Cannabis Products’, *Therapeutic Goods Administration* (Web Page, 3 September 2019) <<http://www.tga.gov.au/access-medicinal-cannabis-products-1>>, archived at <<https://perma.cc/NG7K-5XPU>>.

⁸² ‘Access to Medicinal Cannabis Products’ (n 81).

⁸³ Ibid.

⁸⁴ See, eg, Peter Gates, Stephanie Todd and Jan Copeland, ‘Survey of Australians’ Knowledge, Perception and Use of Cannabis for Medicinal Purposes’ (2017) 5(1) *Journal of Addiction and Prevention* 10:1–10.

⁸⁵ A study of epilepsy patients reported that 14% of respondents used or had previously used cannabis products in relation to their condition. Of those participants that did not use cannabis, a large proportion said that access to the drug, including its illegality, was the key reason for not doing so: Anastasia S Surraev et al, ‘An Australian Nationwide Survey on Medicinal Cannabis Use for Epilepsy: History of Antiepileptic Drug Treatment Predicts Medicinal Cannabis Use’ (2017) 70(B) *Epilepsy and Behavior* 334, 336–7. An earlier study found that a significant proportion of users of medicinal cannabis were concerned about the illegal nature of their use. This study contained a relatively small sample size of 128 adults and the authors state that the results may have been affected by selection bias: Wendy Swift, Peter

Reform Commission ('VLRC') concluded in its 2015 inquiry on medicinal cannabis that 'cannabis is currently being used illegally by a wide range of Victorians to attempt to alleviate a broad array of health conditions', and that '[o]thers have informed the Commission that they would use it but are deterred by its current unlawful status.'⁸⁶ Anecdotally it appeared therefore that, at least prior to the recent reforms, it was far more common for patients to access medicinal cannabis illegally than to use the special access or authorised prescriber regulatory routes to import the drug.⁸⁷

IV THE REGULATORY REFORM PERIOD OF 2014–18

Given the apparent demand for medicinal cannabis and its prohibitive regulatory history, it is perhaps not surprising that numerous attempts have been made to reform laws around its access and use.⁸⁸ It was not until 2014, however, that genuine momentum built for change. Consequently, the resulting reforms, driven by the State of Victoria, are significant.⁸⁹ The circumstances that made reform possible were multifactorial. Anecdotal accounts of seriously ill patients and their families who accessed medicinal cannabis illegally played a considerable role.⁹⁰ So too did the media, providing widespread coverage of such stories and supporting enhanced access to the drug. Included amongst the media supporters were outlets with a traditionally conservative perspective on 'law and order' issues, which caveated their position by objecting to 'indiscriminate' recreational use.⁹¹ In contrast to the polarised generational and political environment of the 1960s and '70s, by 2013 more than two-thirds of the Australian population supported legislative

Gates and Paul Dillon, 'Survey of Australians Using Cannabis for Medical Purposes' (2005) 2 *Harm Reduction Journal* 18:1–10.

⁸⁶ *VLRC Medicinal Cannabis Report* (n 11) 23 [2.16].

⁸⁷ *Ibid* xvii–xviii [12]–[14]; Freckelton (n 73) 499. The TGA has acknowledged patient access of illegal products: 'Responding to Lateline' (n 81).

⁸⁸ Freckelton (n 73) 498.

⁸⁹ *Ibid*.

⁹⁰ *Ibid* 498–500.

⁹¹ See, eg, Annika Smethurst, 'Desperate Parents Turn to Medical Marijuana in Last-Ditch Effort to Improve Their Children's Lives', *The Herald Sun* (online, 12 January 2014), archived at <<https://perma.cc/R2S5-TNCR>>; Grant McArthur and Andrea Hamblin, 'Medical Benefits of Cannabis Must Be Examined, Say Health Experts', *The Herald Sun* (online, 25 August 2014), archived at <<https://perma.cc/KPB4-YM64>>; Editorial, 'Time for New Drugs Debate', *The Herald Sun* (online, 25 August 2014), archived at <<https://perma.cc/P5UA-YB77>>.

change to enable the therapeutic use of cannabis.⁹² It is important to also note the relevant party-political and constitutional factors that influenced reform, some of which I will explore shortly.

A *The State of Victoria*

It was against this background that the then Victorian Labor opposition party committed, during the 2014 state election campaign, to ‘seek advice from the Victorian Law Reform Commission on medical cannabis, so it can be used to treat people in exceptional circumstances.’⁹³ Its promise almost mirrored that of the campaign advanced by sections of the media that had preceded the announcement. Labor also rejected legalisation of recreational use.⁹⁴ The then Victorian Coalition government’s position was that this was not an issue for it, as a state government, to determine.⁹⁵ Its view was that this was instead a matter for the Commonwealth Coalition government, and the TGA, to determine according to ‘the best medical advice and science.’⁹⁶ The Victorian Coalition government committed instead to facilitate clinical trials with a view to potentially allowing therapeutic use in the future.⁹⁷ This position reflected that of the existing Commonwealth Coalition government, and that of the TGA.⁹⁸ What the Victorian Labor opposition had achieved politically was to effectively adopt a popular media campaign as its own policy and, in doing so, distinguish itself from both the State and Commonwealth govern-

⁹² Gates, Todd and Copeland (n 84) 1, citing Australian Institute of Health and Welfare, *National Drug Strategy Household Survey Detailed Report 2013* (Drug Statistics Series No 28, 2014) 115. Subsequent studies with lower numbers of participants reported similar or higher levels of support for the legalisation of medicinal cannabis: Freckelton (n 73) 502–3.

⁹³ Daniel Andrews, ‘Labor: Medical Cannabis Should Be Legal’ (Media Release, Victorian Labor Party, 24 August 2014), archived at <<https://perma.cc/W3MM-BQKK>>.

⁹⁴ Ibid; ‘Victorian Labor Party Proposes Legalisation of Medical Cannabis’, *ABC News* (Web Page, 25 August 2014) <<https://www.abc.net.au/news/2014-08-24/labor-party-proposes-legalisation-of-medical-cannabis/5692454>>, archived at <<https://perma.cc/6W85-RGWD>>.

⁹⁵ Michelle Ainsworth, ‘Labor to Seek to Overturn “Outdated” Laws Banning Medical Marijuana [sic]’, *The Herald Sun* (online, 24 August 2014), archived at <<https://perma.cc/P7PE-APCY>>.

⁹⁶ Ibid.

⁹⁷ Melissa Davey, ‘Medical Marijuana to Undergo Clinical Trials in Victoria’, *The Guardian* (online, 28 August 2014) <<https://www.theguardian.com/society/2014/aug/28/medical-marijuana-undergo-clinical-trials-victoria>>, archived at <<https://perma.cc/Z8Q3-G3KJ>>.

⁹⁸ Smethurst (n 91); Matthew Knott, ‘Medical Cannabis Closer to Federal Approval’, *The Sydney Morning Herald* (online, 29 September 2014) <<https://www.smh.com.au/politics/federal/medical-cannabis-closer-to-federal-approval-20140928-10n5rd.html>>, archived at <<https://perma.cc/S77Y-KH4F>>.

ments. Labor was then able to portray the incumbents as ‘out of touch’ with the community.⁹⁹

It was the election of the Victorian Labor government in November 2014 and the fulfilment of its election promise that proved to be the reform ‘tipping point’ for medicinal cannabis in Australia. The new Labor Attorney-General issued terms of reference to the VLRC to report ‘on options ... to allow people to be treated with medicinal cannabis in exceptional circumstances.’¹⁰⁰ In early October 2015, the new State Labor government accepted the vast majority of the VLRC’s recommendations to ‘legalise access to locally manufactured medicinal cannabis products for use in exceptional circumstances.’¹⁰¹ The *Access to Medicinal Cannabis Act 2016* (Vic) was passed with the intention of providing access to medicinal cannabis to Victorians with specific conditions.¹⁰² The Victorian Labor government had therefore quickly signalled its intention to implement reform in Victoria, irrespective of the position of the Commonwealth.¹⁰³ This marked a significant departure from the entrenched cooperative regulatory arrangements that had characterised the regulation of drugs, including medicinal cannabis, up to this point.

B *The Commonwealth*

On 2 December 2015, the Commonwealth Coalition government acted to keep pace with Victoria. The Minister for Health announced amendments to the *Narcotic Drugs Act* to introduce a ‘nationally-consistent licensing scheme regulating the controlled cultivation of cannabis for medicinal or scientific

⁹⁹ Davey (n 97).

¹⁰⁰ Significantly, the VLRC noted that the government was ‘committed’ to this policy and that the VLRC could not, therefore, provide its views on the policy or on broader legalisation: *VLRC Medicinal Cannabis Report* (n 11) 2 [1.2].

¹⁰¹ Daniel Andrews, ‘Medicinal Cannabis to Be Legalised in Victoria’ (Media Release, Victorian Labor Party, 6 October 2015) <<https://www.premier.vic.gov.au/medicinal-cannabis-to-be-legalised-in-victoria/>>, archived at <<https://perma.cc/UP88-J95M>>.

¹⁰² *Access to Medicinal Cannabis Act 2016* (Vic) ss 1(a)(i), 3 (definition of ‘eligible patient’). The Victorian government ultimately announced that it would not be proceeding with the ‘stand-alone’ scheme established by the Act in light of the Commonwealth reforms which followed: ‘Medicinal Cannabis’, *Health.Vic: Victoria’s Hub for Health Services & Business* (Web Page), archived at <<https://perma.cc/9RBK-83P3>>.

¹⁰³ The *Access to Medicinal Cannabis Bill 2015* (Vic) was introduced and first read in the Victorian Parliament on 8 December 2015: Victoria, *Parliamentary Debates*, Legislative Assembly, 8 December 2015, 5340 (Jill Hennessy, Minister for Health).

purposes.¹⁰⁴ The scheme was to be administered by the Commonwealth Office for Drug Control and would ensure that Australia continued to meet its international obligations under the *Single Convention*.¹⁰⁵ The aim of the amendments was to facilitate the availability of medicinal cannabis for patients as determined by each state and territory.¹⁰⁶

Despite claims that the Commonwealth government was delivering the ‘missing piece’ in making medicinal cannabis available,¹⁰⁷ it was apparent that access to the drug remained dependent on its status under the therapeutic goods regulatory regime. In describing the amendments to the *Narcotic Drugs Act*, the Commonwealth Health Minister affirmed that the *Therapeutic Goods Act* and the TGA would continue to regulate the registration of any new medicinal cannabis products (on the ARTG) and the supply of unregistered medicinal cannabis products to ‘specific patients’ (under the special access and authorised prescriber schemes described above).¹⁰⁸ The Commonwealth was therefore placing the ‘Therapeutic Goods Administrator, our drug regulator, at the centre’ of the legal regime for medicinal cannabis in Australia.¹⁰⁹ Regulation under the therapeutic goods regulatory regime was the basis on which the Commonwealth government committed to ‘maintain the same high safety standards for cannabis derived products that [it applies] to any other medicine.’¹¹⁰

¹⁰⁴ Sussan Ley, ‘Medicinal Cannabis to Be Cultivated through Single National Scheme’ (Media Release, 2 December 2015), archived at <<https://perma.cc/BM8Y-J598>>; Narcotics Drugs Amendment Bill 2016 (Cth).

¹⁰⁵ Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth) 17.

¹⁰⁶ Freckelton (n 73) 504.

¹⁰⁷ Sussan Ley, ‘Turnbull Govt Delivers Medicinal Cannabis “Missing Piece”’ (Media Release, 17 October 2015), archived at <<https://perma.cc/7E5D-2EHD>>.

¹⁰⁸ Commonwealth, *Parliamentary Debates*, House of Representatives, 10 February 2016, 1166 (Sussan Ley, Minister for Health, Sport and Aged Care). Applications under these schemes are decided on an individual basis. However, the TGA has subsequently provided a list of medical indications for which applications for medicinal cannabis have been approved, including palliative care and cancer pain: ‘Access to Medicinal Cannabis Products’ (n 81).

¹⁰⁹ Commonwealth, *Parliamentary Debates*, House of Representatives, 10 February 2016, 1168 (Sussan Ley, Minister for Health, Sport and Aged Care).

¹¹⁰ Ibid 1167. The key role of the TGA and its regime was further reflected in the amendments to the *Narcotic Drugs Act 1967* (Cth) (*‘Narcotic Drugs Act’*) that required a decision-maker to refuse an application for a licence to manufacture a medicinal cannabis product where they were not satisfied that the drug would be used in accordance with the *Therapeutic Goods Act* (n 3), or that the drug was already registered on the ARTG: *Narcotic Drugs Amendment Act 2016* (Cth) s 11K.

It was therefore almost inevitable that reforms to the therapeutic goods regime would need to follow. In January 2016, the TGA announced a proposal to amend the *Poisons Standard* to reschedule cannabis from a ‘prohibited substance’ under sch 9 to a ‘controlled drug’ under sch 8.¹¹¹ In explaining the proposal, the TGA stated that it ‘complements’ the (at that stage) intended reforms to the *Narcotic Drugs Act* and ‘aims to simplify access for those qualified for such access.’¹¹² Despite this, and in the midst of the momentum of the respective Commonwealth and Victorian government reforms, the TGA emphasised that any decision to down-schedule cannabis was still to be made by the delegate of the Secretary of the Department of Health and according to established processes, including the receipt of public comments and a recommendation by the Advisory Committee on Medicines Scheduling (‘ACMS’). It therefore invited public submissions on the proposal.¹¹³

On 31 August 2016, a delegate of the Secretary of the Department of Health decided to downgrade cannabis from sch 9 to sch 8 of the *Poisons Standard*, where the substance was for therapeutic use and prescribed by an authorised medical practitioner.¹¹⁴ The decision was consistent with ACMS advice that sch 8 ‘provid[ed] a suitable level of oversight ... and safety.’¹¹⁵ On the issue of the drug’s efficacy, the ACMS concluded that ‘moderate-quality evidence’ was available to support the use of cannabis for ‘chronic pain and spasticity’ and that ‘low-quality evidence of benefit’ existed for a range of other conditions.¹¹⁶ It advised that there was a ‘low risk of dependence’ particularly in relation to other opioids, but noted that cannabis was a potential ‘pathway’ drug.¹¹⁷

The effect of this decision was to amend the *Poisons Standard* so that patients could access medicinal cannabis where it was approved and included on the ARTG or, as had existed previously, as an unapproved drug under the

¹¹¹ ‘Cannabis Re-Scheduling Proposal: Questions and Answers’, *Therapeutic Goods Administration* (Web Page, 20 January 2016) <<https://www.tga.gov.au/behind-news/cannabis-re-scheduling-proposal-questions-and-answers>>, archived at <<https://perma.cc/42MQ-SDMN>>.

¹¹² *Ibid.*

¹¹³ *Ibid.*

¹¹⁴ *Final Decisions and Reasons for Decisions* (n 2) 12–14.

¹¹⁵ *Ibid.* 9.

¹¹⁶ *Ibid.*

¹¹⁷ *Ibid.* The decision further stated that the drug must be for use in products produced, imported or supplied in accordance with the *Narcotic Drugs Act* (n 110) and the *Therapeutic Goods Act* (n 3); *ibid.* 14–16.

‘special access’ scheme or for an approved ‘authorised provider’.¹¹⁸ Despite these reforms to the *Poisons Standard*, no application has yet been made for a new cannabis product to be approved by the TGA for entry on the ARTG.¹¹⁹ For the most part, therefore, patients remain reliant on the ‘special access’ or ‘authorised prescriber’ schemes to obtain medicinal cannabis products that have not been approved for use in Australia, generally by importing those products from overseas markets.¹²⁰ The TGA anticipates the ‘special access’ scheme to be ‘the major route for patient access to medicinal cannabis products over the next few years’.¹²¹

V THE DIFFERENT VOICES OF MEDICINAL CANNABIS REGULATORY REFORM: 2014–18

This section will discuss how the debate surrounding the changes to the regulation of medicinal cannabis from 2014 to 2018 was permeated by three sets of competing, and at times overlapping, ‘voices.’ Each of these voices expressed a different conception about what constitutes ‘medicinal cannabis’, and indeed what cannabis is itself. The ‘dominant’ voice asserted the position of the regulatory status quo to exercise a high degree of social and legal control over cannabis as an illicit substance. A more ‘moderate’, middle ground voice sought to embrace cannabis as both a therapeutic substance and a mechanism of delivering compassion to patients. A third, ‘radical’ voice conceived of cannabis as a mainstream substance for consumption that should be normalised and legalised. These perspectives in turn emphasised different

¹¹⁸ Note that for a medicinal cannabis product to be approved and registered by the TGA, it must meet the requirements of the relevant Order: see, eg, Delegate of the Minister for Health (Cth), *Therapeutic Goods Order No 93 (Standard for Medicinal Cannabis)* (21 March 2017).

¹¹⁹ The TGA states that ‘the only medicinal cannabis product currently registered on the ARTG [Sativex] is not marketed in Australia’: Therapeutic Goods Administration, Department of Health (Cth), *Guidance on GMP Compliance for the Manufacture of Medicinal Cannabis for Supply under ‘Approved Access’ Provisions* (January 2018) 4.

¹²⁰ However, one Australia-based medicinal cannabis company has announced the availability of its products under the ‘authorised prescriber’ and ‘special access’ schemes: Bod Australia Limited, ‘Bod Secures First Medicinal Cannabis Prescription and Enters into Research Collaboration Agreement with Cannabis Access Clinics’ (Media Release, 25 October 2018) <<https://www.investi.com.au/api/announcements/bda/d6e5dfc7-6e7.pdf>>, archived at <<https://perma.cc/AYG3-72E4>>.

¹²¹ ‘Medicinal Cannabis Products: Overview of Regulation’, *Therapeutic Goods Administration* (Web Page, 17 June 2017), archived at <<https://perma.cc/NJP4-U2TA>>. There were increasing numbers of applications from September 2018 to August 2019 under the ‘special access’ scheme: ‘Access to Medicinal Cannabis Products’ (n 81).

epistemological traditions to justify their respective views on the regulation of medicinal cannabis.¹²² The concluding part of this article will explain how these competing voices contributed to challenging the political legitimacy of the regulation of therapeutic goods in Australia.

A *Medicinal Cannabis as an ‘Object’ of Regulation*

In his comprehensive work on the history of Australian drug laws, Desmond Manderson observed that, while diverse social and political historical forces have shaped the regulation of drugs, it is also the way in which a drug is perceived as an *object* of regulation that determines its particular regulatory fate.¹²³ The VLRC’s inquiry, for example, has been analysed as a case study on the construction of medicinal cannabis as an *‘object to be debated, regulated and evaluated’*.¹²⁴ Arguably, there are diverse ways in which medicinal cannabis can be perceived as a regulatory ‘object’, none of which are ‘fixed and given’ but which are instead *‘constructed and hence contestable’*.¹²⁵ Such distinct conceptualisations not only emphasise what medicinal cannabis constitutes, but also effectively silence alternative ways of perceiving the drug. As will be later discussed, this in turn can narrow the scope of discourse about how medicinal cannabis can, and should, be regulated.¹²⁶ It is necessary therefore at this point to articulate the different ‘voices’ present in the reform debates around the regulation of medicinal cannabis and their respective concepts of medicinal cannabis.

B *The Dominant Voice*

The dominant voice shaping the concept and regulation of medicinal cannabis has been predominantly expressed by the TGA, established medical professional bodies and political conservatives. This is the voice of the regulatory

¹²² The term ‘epistemological’ is used broadly here to refer to assertions of knowledge that are typically grounded in a particular disciplinary tradition. For an overview of the philosophy of epistemology, see, eg, Mattias Steup, ‘Epistemology’, *The Stanford Encyclopedia of Philosophy* (Web Page, 14 December 2005) <<https://plato.stanford.edu/archives/win2018/entries/epistemology/>>, archived at <<https://perma.cc/HC4G-T2DQ>>.

¹²³ Manderson (n 61) 12.

¹²⁴ Kari Lancaster, Kate Seear and Alison Ritter, ‘Making Medicine; Producing Pleasure: A Critical Examination of Medicinal Cannabis Policy and Law in Victoria, Australia’ (2017) 49 *International Journal of Drug Policy* 117, 117 (emphasis added).

¹²⁵ *Ibid* 118 (emphasis in original).

¹²⁶ *Ibid*.

status quo. Cannabis from this perspective is an illicit substance, which has little therapeutic value and poses risks to public health. According to this view, cannabis production and use should be prohibited or at least subject to strict regulatory control, including in circumstances where it is to be used medicinally. This view is steeped in the modern historical, international and national regulatory background described earlier, in which cannabis is conceived of as a drug that is unsafe, immoral, and without therapeutic merit.

This dominant voice has been largely used by the TGA. It is a perspective that reflected the TGA's legislative responsibilities to ensure the efficacy, quality and safety of therapeutic goods and fundamental standards dictated by the scientific method.¹²⁷ The dominant perspective echoed the state of the law as it stood prior to the reforms, in which medicinal cannabis was defined as a 'prohibited substance' under the *Poisons Standard*. Accordingly, medicinal cannabis was conceptualised by the TGA as an appropriately classified sch 9 drug with 'no currently established therapeutic value and [as] likely to present a high risk of dependency, abuse, misuse or illicit use.'¹²⁸ Even in the midst of the process to consider the rescheduling of cannabis under the *Poisons Standard*, the head of the TGA stated that '[e]vidence for efficacy [of cannabis] is mixed, and incomplete.'¹²⁹ The then Victorian Coalition government was reluctant to consider any alternatives to the voice of the TGA, advocating that it was the dominant source of expertise on the nature of medicinal cannabis.¹³⁰

This dominant voice was echoed by the medical professional associations. The Victorian branch of the Australian Medical Association ('AMA') told the VLRC that it supported limited law reform 'only where *evidence, safety* and law reform are key considerations.'¹³¹ The AMA called on the newly elected

¹²⁷ *Therapeutic Goods Act* (n 3) s 4(1).

¹²⁸ Australian Health Ministers' Advisory Council, *Scheduling Policy Framework for Medicines and Chemicals* (1 February 2015) 27.

¹²⁹ Skerritt (n 81) 5. Subsequent statements on the 'consumer information & education' section of the TGA's website include that 'there is limited evidence on [medicinal cannabis]' success in treating different medical conditions, or on effective forms and dosages' and that '[t]here is also very limited evidence about how medicinal cannabis reacts with other approved medications': 'Medicinal Cannabis Products: Patient Information', *Therapeutic Goods Administration* (Web Page, 29 May 2018) <<http://www.tga.gov.au/community-qa/medicinal-cannabis-products-patient-information>>, archived at <<https://perma.cc/945Z-4AN8>>.

¹³⁰ Ainsworth (n 95).

¹³¹ Australian Medical Association Victoria, Submission No 38 to Victorian Law Reform Committee, *Medicinal Cannabis Issues Paper* (2015) 1 (emphasis added).

Victorian Labor government to seek further evidence from clinical trials.¹³² It considered that the ‘state of clinical knowledge’ was ‘the primary consideration to ensure that no harm comes to patients as a result of using a substance, the efficacy of which is currently not evidence-based.’¹³³ In its view, ‘there should be no exceptional circumstances or “compassionate considerations” where medicinal cannabis is used to treat a patient until such use is evidence-based.’¹³⁴ The AMA subsequently expressed concern that the Victorian government was reforming the availability of medicinal cannabis in the absence of further results from clinical trials: ‘This deviates from the *usual process of how medications are approved for use* in Australia, where there is either thorough international evidence and/or Australian evidence.’¹³⁵ Other medical professional bodies had publicly expressed similar sentiments, including that the existing therapeutic goods regulatory regime should constitute the way in which any medicinal cannabis products were regulated.¹³⁶

The perspective of the status quo, and its construction of medicinal cannabis, reflects an epistemological background embedded in the scientific tradition and its associated, and almost irrefutable, claims to objectivity.¹³⁷ According to the dominant voice, what medicinal cannabis ‘is’ is determined by evidence as to its efficacy, quality and safety as dictated by the scientific method. This alone is perceived to determine the societal value of medicinal cannabis and, consequently, how it should be viewed by the therapeutic goods regulatory regime.¹³⁸ Consequently, the dominant view provided by the TGA

¹³² Ibid.

¹³³ Ibid.

¹³⁴ Ibid.

¹³⁵ Australian Medical Association Victoria, ‘AMA Victoria’s Response to the VLRC’s Recommendation to Legalise Medicinal Cannabis’ (Media Release, 6 October 2015) (emphasis added) <<https://amavic.com.au/media/Archived-Media-Releases/2015-media-releases/ama-victoria-s-response-to-the-vlrc-s-recommendation-to-legalise-medicinal-cannabis>>, archived at <<https://perma.cc/2DJE-ZUGA>>.

¹³⁶ See, eg, The Royal Australasian College of Physicians, Submission No 52 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (April 2015); Clinical Oncology Society of Australia and Cancer Council Australia, Submission No 37 to Senate Legal and Constitutional Affairs Legislation Committee, *Regulator of Medicinal Cannabis Bill 2014* (March 2015).

¹³⁷ See, eg, Julia Black, ‘Regulation as Facilitation: Negotiating the Genetic Revolution’ in Roger Brownsword, WR Cornish and Margaret Llewelyn (eds), *Law and Human Genetics: Regulating a Revolution* (Hart Publishing, 1998) 29, 63 (‘Regulation as Facilitation’).

¹³⁸ See, eg, Sheila Jasanoff’s rejection of the expertise of ‘technocracy’, including the scientific method, as the sole mechanism through which decisions about contemporary society are

established a sharp dichotomy. Either a drug such as cannabis is determined to constitute a credible ‘therapeutic’ substance according to established regulatory and scientific criteria, or it is a drug without therapeutic merit and constitutes an illicit ‘recreational’ drug subject to a highly restrictive and often criminal law-based regime.¹³⁹ The voice offered by the TGA and its regulatory regime offered no middle ground.

C *The Moderate Voice*

This middle ground was initiated and developed instead by the Victorian Labor government and the VLRC’s 2015 inquiry. What this article will call the ‘moderate’ voice adopted aspects of the dominant position but emphasised strong elements of the need to act compassionately towards seriously ill patients and their carers.¹⁴⁰ The moderate voice constructed its own conception of cannabis as a beneficial therapeutic substance by looking partly to individual anecdotal experience and the medicinal *potential* of the drug. This was despite the acknowledged paucity of clinical evidence in support of medicinal cannabis, and compared starkly with the reliance by the dominant voice on the gold standard of the scientific method.¹⁴¹

Patient experience and need was a key element in constructing the moderate perspective on medicinal cannabis.¹⁴² The Victorian Labor government was motivated by a patient and media campaign that focused on anecdotal experiences of patients and carers using medicinal cannabis to alleviate the symptoms of serious illnesses, including childhood epilepsy.¹⁴³ The credibility attributed to individual patient experiences was inherent in the Victorian Labor government’s request that the VLRC inquiry consider how medicinal

made: Sheila Jasanoff, *The Ethics of Invention: Technology and the Human Future* (WW Norton & Company, 2016) 19–21, 28–9.

¹³⁹ See Lancaster, Seear and Ritter (n 124) who argue that, in the context of the VLRC inquiry, ‘medicinal cannabis’ is ‘constituted as unique and fundamentally different from ... recreational cannabis’ but that medicinal cannabis depends on the concept of ‘recreational cannabis’ for its own definition: at 118. See also Manderson (n 61) who notes that the increase in ‘recreational’ cannabis use by a younger cohort in the 1960s ‘challenged medico-legal drug control’: at 145.

¹⁴⁰ See, eg, Freckelton (n 73) 507–8.

¹⁴¹ Lancaster, Seear and Ritter (n 124) 122.

¹⁴² See, eg, Freckelton (n 73) 498–9.

¹⁴³ See, eg, Andrews, ‘Labor: Medical Cannabis Should Be Legal’ (n 93); Victoria, *Parliamentary Debates*, Legislative Assembly, 10 December 2015, 5528 (Jill Hennessy, Minister for Health); Andrea Hamblin, ‘Parents Face Questions over Marijuana Oil Treatment for Sick Child’, *The Herald Sun* (online, 18 August 2014), archived at <<https://perma.cc/K966-M5VE>>.

cannabis should be made available in ‘exceptional circumstances’.¹⁴⁴ It was strengthened by submissions made throughout the inquiry by patient advocacy groups and specific professional associations.¹⁴⁵ This necessitated that the VLRC identify a means of determining ‘who is eligible and who is not’ for medicinal cannabis, and ‘take certain products *outside of the conventional, evidence-driven* approval and treatment framework’.¹⁴⁶ The VLRC therefore sought to ‘cater to the present-day suffering of patients that is not being adequately alleviated by *conventional forms of relief*’.¹⁴⁷ Illustrative of the advocacy for an alternative to the dominant voice was the submission of the Australian Nursing and Midwifery Federation, which argued for ‘a scheme that is driven by compassionate grounds and which provides treatment options that are not wholly established by orthodox double blind, placebo controlled trials’.¹⁴⁸

The concept of compassion provided the VLRC with an explicit basis on which it could move beyond the dominant and conventional construction of medicinal cannabis and its regulation.¹⁴⁹ Described as ‘empathy and an authentic desire to address another person’s suffering’, compassion provided the foundation on which the VLRC could ‘mitigate the harshness of a wholly evidence-based approach’.¹⁵⁰ The emphasis on compassion reflected the philosophy of international and domestic ‘compassion clubs’.¹⁵¹ Compassion clubs first appeared in Canada and the US as part of the advocacy movement for medicinal cannabis.¹⁵² The clubs were traditionally operated as cooperatives, producing and supplying cannabis and extensive cannabis-related health information to a membership of largely seriously ill individuals.¹⁵³

¹⁴⁴ VLRC *Medicinal Cannabis Report* (n 11) vii.

¹⁴⁵ Australian Nursing and Midwifery Federation (Victorian Branch), Submission No 75 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (4 June 2015) 1 (‘ANMF Submission’); Cancer Action Victoria, Submission No 54 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (2015) 1.

¹⁴⁶ VLRC *Medicinal Cannabis Report* (n 11) 52 [3.1], 53 [3.10] (emphasis added).

¹⁴⁷ *Ibid* 54 [3.15] (emphasis added).

¹⁴⁸ ANMF Submission (n 145) 2.

¹⁴⁹ VLRC *Medicinal Cannabis Report* (n 11) 54–5 [3.12]–[3.21].

¹⁵⁰ *Ibid* 54 [3.12], [3.17].

¹⁵¹ *Ibid* 55 [3.18].

¹⁵² See generally Hathaway and Rossiter (n 41).

¹⁵³ Additional services such as hospice care were commonly a part of the cooperative’s purpose and the communities provided support, acceptance, empathy and a sense of ‘belonging’ to members. On compassion societies in the US and Canada respectively, see, eg, Wendy Chapkis, ‘Legalization and Medicalization in the Marijuana Reform Movement’ (Conference

Further, the moderate voice adopted by the VLRC emphasised the therapeutic potential of medicinal cannabis and therefore the hope it generated for patients. The VLRC recommended that the government establish an independent medical advisory committee to provide advice about the ‘potential efficacy’ of medicinal cannabis for conditions and symptoms on which eligibility for the drug would be determined.¹⁵⁴ This again represented a departure from the dominant voice of orthodox scientific methodology and an endorsement of anecdotal patient stories about the drug’s efficacy.¹⁵⁵ In many respects, the VLRC’s perspective recalls the work by Alan Petersen on the sociopolitical dimension of ‘hope’.¹⁵⁶ Petersen argues that hope has assumed a powerful place in a healthcare environment that increasingly emphasises the role and responsibility of the individual.¹⁵⁷ In this respect, the moderate voice expresses the same ‘rhetoric of hope’ articulated by advocates for new biomedical treatments, including genetic and stem cell medicines.¹⁵⁸

However, the VLRC and the Labor government also drew on clinical evidence and medical expertise to construct their notion of medicinal cannabis and its regulation. The VLRC stated that ‘[c]ompassion demands that individual suffering be taken into account, but not that clinical efficacy be ignored’.¹⁵⁹ It accepted significant and orthodox aspects of the dominant voice and its advocates, including that of the AMA, which argued that ‘compassion should not constitute a licence for undue latitude’ in determining risks to patients.¹⁶⁰ Medicinal cannabis was therefore only to be provided to patients on the prescription of a medical practitioner, and clinicians were to ‘act as “gatekeepers” to the scheme’.¹⁶¹ As a result, the moderate voice constructed its own

Paper, American Sociological Association Annual Meeting, 2013) 2–3; *ibid.* In Australia, see, eg, United in Compassion, an organisation which advocates for access to medicinal cannabis and whose ‘philosophy’ is ‘the dignified alleviation of suffering with compassion [and] empathy’: ‘About Us’, *United in Compassion* (Web Page, 2019) <<http://www.unitedincompassion.com.au/about-uic>>, archived at <<https://perma.cc/5PJT-APCE>>.

¹⁵⁴ *VLRC Medicinal Cannabis Report* (n 11) 75 recommendation 5 (emphasis added).

¹⁵⁵ See, eg, *ibid* 54–5 [3.12]–[3.21].

¹⁵⁶ Alan Petersen, *Hope in Health: The Socio-Politics of Optimism* (Palgrave MacMillan, 2015).

¹⁵⁷ *Ibid* 5. Advocates of medicinal cannabis may contend that they ‘expect[]’ or ‘predict[]’ the drug to provide a health benefit based on past individual experience. Petersen acknowledges that such an ‘expectation’ can be distinguished from a mere ‘feeling’ or ‘desire’ that a positive outcome will result: at 11–12.

¹⁵⁸ *Ibid* 10–11.

¹⁵⁹ *VLRC Medicinal Cannabis Report* (n 11) 52 [3.3].

¹⁶⁰ Freckelton (n 73) 508.

¹⁶¹ *VLRC Medicinal Cannabis Report* (n 11) 52 [3.5].

dichotomy around medicinal cannabis. To the Victorian Labor government and the VLRC, cannabis was, on the one hand, a ‘thoroughly *medical* object’,¹⁶² imbued with hope for desperate patients, posing comparatively little risk to those with a recognised serious illness and serving as a means by which government and society could act compassionately. On the other hand, the drug also had the potential to be used by healthy individuals for recreational pleasure which could not be endorsed and should therefore remain prohibited and controlled.¹⁶³ It has been argued that this position ‘silenced’ alternative voices on the interaction between the medicinal benefit of cannabis and the pleasure obtained from its use.¹⁶⁴ Such a dichotomy arguably restricts more expansive considerations of what ‘therapeutic benefit’ means in this context, and indeed how medicinal cannabis is itself constructed as an object of regulation.¹⁶⁵

D *The Radical Voice*

The ‘radical’ voice is the third conceptualisation of medicinal cannabis that was evident during the recent regulatory reforms. Elements of this voice were present in a range of submissions to the VLRC during its inquiry and to the TGA.¹⁶⁶ There are three key elements to the notion of medicinal cannabis constructed by the radical voice: first, the rejection of cannabis as a substance with a standalone therapeutic identity; second, the notion of cannabis as a ‘natural’ object of human consumption that should be normalised in a social and regulatory context; and finally, the making of cannabis into a political symbol. Although this voice is labelled here as ‘radical’, the elements just described are certainly not. They reflect the historical threads of cannabis

¹⁶² Lancaster, Seear and Ritter (n 124) 120 (emphasis in original).

¹⁶³ See, eg, Victoria, *Parliamentary Debates*, Legislative Assembly, 10 December 2015, 5529 (Jill Hennessy, Minister for Health).

¹⁶⁴ Lancaster, Seear and Ritter (n 124) 118.

¹⁶⁵ *Ibid* 120. Further, such a dichotomy fails to recognise research indicating that users of medicinal cannabis often also use the drug for ‘recreational’ purposes, and that they initially discover the drug’s medicinal qualities through recreational use: Gates, Todd and Copeland (n 84) 9.

¹⁶⁶ See, eg, Michelle O’Dea and a Working Group of the Cannabis Community of Victoria, Submission No 95 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (2015) (‘CCV Submission’); The Australian Lawful Use of Cannabis Alliance, Submission No 35 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (18 April 2015) (‘ALUCA Submission’); Cannabis Social Club Australia, Submission No 15 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (27 March 2015).

regulation outlined earlier — from its ancient beginnings to its identity as a symbol of protest during the 1960s and '70s. Radical is, however, an apt term to describe this conceptualisation in contrast to the dominant and moderate positions set out above.

The radical voice constructs cannabis as a substance that is harmless, naturally derived, and a source of pleasure for the user.¹⁶⁷ This understanding of cannabis merges the notion of cannabis as a 'recreational' and 'therapeutic' substance.¹⁶⁸ According to this perspective, cannabis is a source of relief or 'solace' from suffering in all forms¹⁶⁹ — not just from those conditions and symptoms that traditional scientific and medical methods recognise.¹⁷⁰ The radical voice views the dichotomy established by the dominant and moderate voices of cannabis — as either a 'recreational' drug, on the one hand, or a 'therapeutic' drug on the other — as inimical to the fundamental nature of the drug. Even the moderate voice's attempt to temper the dichotomy with the notion of human compassion is insufficient to embrace the radical view of cannabis as a potential source of human enjoyment. The radical conception of medicinal cannabis blurs the line between 'therapeutic' and 'recreational'.¹⁷¹ It renders these terms, and therefore the very notion of '*medicinal cannabis*', as irrelevant. In constructing cannabis in this way, the radical voice — perhaps inadvertently — challenges the very scientific and medical expertise, and underlying epistemology, that determines and defines the line between 'recreational' and 'therapeutic'.

¹⁶⁷ See generally Lancaster, Seear and Ritter (n 124).

¹⁶⁸ CCV Submission (n 166) 16. See also the suggestion that 'it may also be that distinctions between "medicinal" and so-called "recreational" cannabis become unstable and difficult to sustain once discourses of pleasure are made visible': *ibid* 124.

¹⁶⁹ ALUCA Submission (n 166) 6–7, 11. For a broader analysis of the role of drugs as an object of 'desire' for 'transformation and connection with the imperceptible', see also John L Fitzgerald, *Framing Drug Use: Bodies, Space, Economy and Crime* (Palgrave Macmillan, 2015) 9–12.

¹⁷⁰ Lancaster, Seear and Ritter (n 124) argue that the VLRC alludes to the broader benefits of medicinal cannabis for 'wellbeing' and 'quality of life' in its discussion of anecdotal evidence regarding the drug's impact. Consequently, this may enhance how the capacity of 'medicine' is understood: at 122–3.

¹⁷¹ '[A]ll use of cannabis provides therapeutic benefits, irrespective of the user's intent. Relaxation and stress relief are legitimate therapeutic needs': CCV Submission (n 166) 20. Lancaster, Seear and Ritter (n 124) argue that aspects of the VLRC's discussion of 'medicinal cannabis' results in its 'co-constitut[ion]' with 'recreational cannabis': at 121.

The radical voice refers frequently to cannabis as ‘natural’ — that is, unprocessed and unrefined in comparison to man-made pharmaceuticals.¹⁷² This leads to often-expressed conclusions that cannabis supports human health and wellbeing, is of inherent therapeutic value, and is safe for human consumption. Frequently, such views are supported by anecdotal evidence and appeals to the long history of human cannabis use.¹⁷³ Cannabis is therefore rendered by the radical voice as a normal, everyday object of human consumption. This contrasts with the highly marginalised status assigned to the drug by the dominant voice. The radical position therefore advocates various degrees of legalisation and deregulation. This reflects the contemporary reality of parts of the United States in which cannabis has been legalised and where cannabis production and sale is increasingly commercialised and marketed as a lifestyle brand.¹⁷⁴ Finally, we see the radical voice remain, to some extent, true to its namesake. Many of the submissions to the VLRC inquiry and to the TGA on the rescheduling of medicinal cannabis under the *Poisons Schedule* raised political concerns. These included: criticism of the historical reasons for the prohibition of cannabis;¹⁷⁵ that access to cannabis was a human right;¹⁷⁶ that restrictions on the drug constituted discrimination;¹⁷⁷ and objections to the power exercised by the pharmaceutical industry.¹⁷⁸

The above analysis examines how the dominant, moderate and radical voices of the medicinal cannabis regulatory reform period offered distinct but

¹⁷² See, eg, Delegate of the Secretary to the Department of Health (Cth), *Public Consultation on the Proposed Amendments to the Poisons Standard* (March 2016) pt 2, 4, 12. Emeritus Professor David Penington anticipated that medicinal cannabis would ‘end [up] being designated as a regulated “herbal” product rather than registered under the Therapeutic Goods Act’: David Penington, Submission No 24 to Victorian Law Reform Commission, *Medicinal Cannabis Issues Paper* (14 April 2015) 1.

¹⁷³ See, eg, CCV Submission (n 166) 14–17; ALUCA Submission (n 166).

¹⁷⁴ See, eg, *Oil & Gold Los Angeles: The American Dream* (Web Page) <<http://oilandgold.la/>>, archived at <<https://perma.cc/T3NH-ZR38>>; *Bloom* (Web Page, 2019) <<https://thebloombrand.com/>>, archived at <<https://perma.cc/73JT-T22K>>; Chapkis (n 153) 8.

¹⁷⁵ For example, that ‘[t]he “War on Drugs” is an internationally acknowledged failure’: CCV Submission (n 166) 16; and that ‘[cannabis] proscription was ... propagated throughout the world in furtherance of American national security objectives’: ALUCA Submission (n 166) 4.

¹⁷⁶ See, eg, Delegate of the Secretary to the Department of Health (Cth), *Public Consultation on the Proposed Amendments to the Poisons Standard* (March 2016) pt 3, 20, 28 (*Poisons Standard Public Consultation Part 3*). See also CCV Submission (n 166) 17.

¹⁷⁷ ‘[T]o prosecute and punish people who are DISABLED by their conditions, for seeking relief from their ailments’: *Poisons Standard Public Consultation Part 3* (n 176) 28 (emphasis in original). See also CCV Submission (n 166) 17.

¹⁷⁸ See, eg, *Poisons Standard Public Consultation Part 3* (n 176) 32.

interrelated conceptualisations about the nature of the drug itself. These voices consequently directed debate, recommendations and conclusions about the reforms required in the context of the broader therapeutic goods regulatory framework. The next part of this article will focus on this broader regulatory context.

VI WHAT DOES REGULATORY REFORM OF MEDICINAL CANNABIS TELL US ABOUT THE POLITICAL LEGITIMACY OF THERAPEUTIC GOODS REGULATION IN AUSTRALIA?

This part addresses what the reforms to the regulation of medicinal cannabis between 2014 and 2018 in Australia indicate about the political legitimacy of the therapeutic goods regulatory regime. First, it briefly outlines the relevance of theories of political legitimacy to the regulation of therapeutic goods. It then sets out an approach to political legitimacy called, for the purposes of this article, the ‘constant dialogic’ approach. Applying this approach, it will be argued that the debate regarding, and the reforms to, medicinal cannabis regulation constituted a challenge to the legitimacy of the regulation of therapeutic goods in Australia. This challenge is evident from the public expression of the ‘moderate’ and ‘radical’ voices described above and the alternative bases for regulation they presented. These alternative voices challenged the legitimacy of the ‘dominant’ voice of the therapeutic goods regulatory regime because it did not adopt an approach to legitimacy that embraced all relevant parties and their respective voices.

A *What Is Political Legitimacy?*

The relevant literature offers a diversity of perspectives on what political legitimacy means. Broadly, theories of political legitimacy seek to explain the ‘justification of political authority’.¹⁷⁹ From a philosophical perspective, politically legitimate power may constitute power that is *normatively* ‘rightful’; from a social scientist’s viewpoint, legitimacy may mean power that is empirically ‘*acknowledged* as rightful’.¹⁸⁰ Other commentators have noted that

¹⁷⁹ Steffen Schneider et al, *Democracy’s Deep Roots: Why the Nation State Remains Legitimate* (Palgrave Macmillan, 2010) 2.

¹⁸⁰ David Beetham, ‘Revisiting Legitimacy, Twenty Years On’ in Justice Tankebe and Alison Liebling (eds), *Legitimacy and Criminal Justice: An International Exploration* (Oxford University Press, 2013) 19, 19 (emphasis altered) (‘Revisiting Legitimacy’). See also Black, ‘Legitimacy and Accountability’ (n 8) 144–5.

the concept of legitimacy is tied to notions of trust about the exercise of power.¹⁸¹ Theories of political legitimacy have been used to analyse a range of government roles and functions. These include law enforcement and the court system.¹⁸² In the context of public health, theories of political legitimacy have been applied to critique decisions about the rationing of health care resources and the cost-effectiveness of therapeutic goods in Europe.¹⁸³ As the discussion that follows illustrates, political legitimacy presents a useful lens through which to analyse the regulation of therapeutic goods in Australia in relation to medicinal cannabis reforms.

B *The ‘Constant Dialogic’ Approach to Political Legitimacy*

While acknowledging the diversity of perspectives on political legitimacy, this article adopts an approach to political legitimacy which can, for present purposes, be described as the ‘constant dialogic’ approach. Briefly, this approach suggests that political legitimacy be analysed as a *constant dialogue*, through which a set of *shared normative beliefs and values* are formulated, between *all* parties to a power relationship. As the name indicates, the constant dialogic approach emphasises aspects of the dialogic model of legitimacy. It, in turn, is grounded in the foundational theory of political legitimacy developed by political and social scientist David Beetham.¹⁸⁴ Before returning to the constant dialogic approach, this article summarises Beetham’s framework and its expansion by the dialogic model.

¹⁸¹ Keith Syrett, *Law, Legitimacy and the Rationing of Health Care: A Contextual and Comparative Perspective* (Cambridge University Press, 2007) 98 (*‘Law, Legitimacy and the Rationing of Health Care’*); Keith Syrett, ‘Courts, Expertise and Resource Allocation: Is There a Judicial “Legitimacy Problem”?’ (2014) 7(2) *Public Health Ethics* 112; Keith Syrett, ‘Legitimizing “Fourth Hurdle” Pharmaceutical Regulation in Europe: Learning the NICE Way?’ (2003) 9(4) *European Public Law* 509. However, there is a view that, conceptually, ‘trust’ focuses on feelings about a *future* basis of power, whereas ‘legitimacy’ focuses on the *present* justification of that power: Anthony Bottoms and Justice Tankebe, ‘Beyond Procedural Justice: A Dialogic Approach to Legitimacy in Criminal Justice’ (2012) 102(1) *Journal of Criminal Law and Criminology* 119, 164 (*‘Beyond Procedural Justice’*).

¹⁸² See, eg, Anthony E Bottoms and Justice Tankebe, ‘Police Legitimacy and the Authority of the State’ in Antje du Bois-Pedain, Magnus Ulväng and Petter Asp (eds), *Criminal Law and the Authority of the State* (Hart Publishing, 2017) 47 (*‘Police Legitimacy’*); Tom R Tyler and Yuen J Huo, *Trust in the Law: Encouraging Public Cooperation with the Police and Courts* (Russell Sage Foundation, 2002).

¹⁸³ Syrett, *Law, Legitimacy and the Rationing of Health Care* (n 181) 95–9.

¹⁸⁴ See generally Bottoms and Tankebe, ‘Beyond Procedural Justice’ (n 181) 132–49; David Beetham, *The Legitimation of Power* (Palgrave Macmillan, 2nd ed, 2013).

1 *Beetham's Framework of Political Legitimacy*

At the core of Beetham's concept of legitimacy are the societal values and beliefs that constitute a shared normative justification for power for a specific society at a particular point in time.¹⁸⁵ Beetham's framework outlines three 'dimensions' or 'elements' that are necessary for power to be considered legitimate. The absence or dilution of any one of these constitutes, on its own, a particular deviation from legitimacy. The first element — the 'legality' element — requires that power is obtained and used according to existing rules.¹⁸⁶ The second element relates to beliefs that justify these rules. Beetham has termed this 'normative justifiability', but for ease of reference it will be referred to as the 'normative' element.¹⁸⁷ This element requires that rules of power and their exercise must be justified 'by reference to beliefs shared by both dominant and subordinate' parties to a relationship of power.¹⁸⁸ This is the central element of Beetham's framework. It requires that power must be justified by normative considerations and a congruence between the values or standards held by those in power and those subject to power: that is, that there must be a 'shared moral order' between dominant and subordinate parties in a power relationship.¹⁸⁹ The third dimension of Beetham's framework is the 'consent' or 'acknowledgement' element.¹⁹⁰ This element requires that the subordinate party to a power relationship consents to, or at least acknowledges, the power relationship. Examples of this consent or acknowledgment may include voting in an election or participating in a community consultation process.¹⁹¹ An absence of, or challenge to, this element may be indicated by 'public acts of protest, disobedience, and withdrawal of endorsement or recognition'.¹⁹²

¹⁸⁵ Beetham, *The Legitimation of Power* (n 184) 11.

¹⁸⁶ Ibid 64; David Beetham and Christopher Lord, *Legitimacy and the EU* (Longman, 1998) 3.

¹⁸⁷ Beetham and Lord (n 186) 3.

¹⁸⁸ Beetham, *The Legitimation of Power* (n 184) 16; Beetham, 'Revisiting Legitimacy' (n 180) 20.

¹⁸⁹ Beetham, *The Legitimation of Power* (n 184) 4, 11, 82.

¹⁹⁰ Beetham, however, refers to it as the 'legitimation' element: Beetham, 'Revisiting Legitimacy' (n 180) 20.

¹⁹¹ Beetham, *The Legitimation of Power* (n 184) 14, 18, 91–3.

¹⁹² Beetham, 'Revisiting Legitimacy' (n 180) 26.

2 *The Dialogic Approach to Political Legitimacy*

The dialogic perspective adopts and builds on Beetham's political legitimacy framework.¹⁹³ It essentially considers that legitimacy is a relational concept, developed over the course of a dialogue between those exercising power and those subject to power. Legitimacy can therefore be analysed consistently with Beetham's framework, but from a dialogic perspective. There are three key aspects of the dialogic model. First, it explicitly distinguishes between legitimacy as perceived by different parties to the power relationship — the dominant and subordinate parties, and between different dominant parties.¹⁹⁴ Second, the dialogic model distinguishes between audiences within the subordinate group. It asserts that dominant parties 'claim' to hold and exercise legitimate power by addressing *different* subordinate audiences that are subject to that power.¹⁹⁵ Finally, at the core of the dialogic model of legitimacy is its relational nature. Dominant parties seek to cement and to 'cultivate' an ongoing relationship with subordinate audiences to establish and preserve legitimacy.¹⁹⁶ The dominant party should therefore develop a 'narrative' that cultivates a view amongst the subordinate audience(s) that it is normatively justified to hold power and that it therefore represents social stability and order.¹⁹⁷ Further, it is important to note that a dominant party's 'understanding of their own legitimacy may evolve' in response to the subordinate party.¹⁹⁸

3 *The 'Constant Dialogic' Approach to Political Legitimacy*

The constant dialogic approach emphasises particular aspects of the dialogic model that are most relevant to the regulatory relationships with which this

¹⁹³ Bottoms and Tankebe, 'Beyond Procedural Justice' (n 181) 132–4, 147, citing Jean-Marc Coicaud, *Legitimacy and Politics: A Contribution to the Study of Political Right and Political Responsibility*, tr David Ames Curtis (Cambridge University Press, 2002). Beetham has himself described his model as a 'discursive structure of legitimacy': *ibid* 19–20.

¹⁹⁴ Anthony Bottoms and Justice Tankebe, "'A Voice Within': Power-Holders' Perspectives on Authority and Legitimacy' in Justice Tankebe and Alison Liebling (eds), *Legitimacy and Criminal Justice: An International Exploration* (Oxford University Press, 2013) 60, 63 ('A Voice Within').

¹⁹⁵ Bottoms and Tankebe, 'Beyond Procedural Justice' (n 181) 128–9.

¹⁹⁶ *Ibid*.

¹⁹⁷ Bottoms and Tankebe, 'Police Legitimacy' (n 182) 48–50.

¹⁹⁸ Belén V Lowrey-Kinberg and Grace Sullivan Buker, "'I'm Giving You a Lawful Order': Dialogic Legitimacy in Sandra Bland's Traffic Stop' (2017) 51(2) *Law and Society Review* 379, 385. See also Beetham, *The Legitimation of Power* (n 184) 258, citing Bottoms and Tankebe, 'Beyond Procedural Justice' (n 181).

article is concerned. This approach underscores that legitimacy be analysed as a *constant dialogue*, through which a set of *shared normative beliefs and values* are formulated, between *all* parties to a power relationship. Each of these aspects will now be briefly described. First, the approach emphasises that legitimacy should be analysed as a *constant* dialogue. According to the dialogic approach, political legitimacy is established as ‘a perpetual discussion, in which the content of power-holders’ later claims will be affected by the nature of the audience response’.¹⁹⁹ In certain contexts a ‘discussion’ of legitimacy, and the understanding of the respective parties to a power relationship, must be approached as not just one that occurs repeatedly, but as an *ongoing* or *constant* process.²⁰⁰ This constant perspective on legitimacy is likely to apply to many of the regulatory relationships that exist between the state, institutions, and officials on the one hand, and the community and individual affected parties on the other. It is particularly applicable where regulatory arrangements have a significant and consistent impact on the lives of subordinate parties — for example, in relation to health services, telecommunications and utilities. This element of *constancy* highlights the importance of legitimacy’s relational nature.²⁰¹

Second, the constant dialogic approach emphasises that inherent to the ongoing legitimacy ‘dialogue’ are elements that enhance or diminish a congruence in beliefs and values between parties.²⁰² These elements may

¹⁹⁹ Bottoms and Tankebe, ‘Beyond Procedural Justice’ (n 181) 129.

²⁰⁰ This is a natural conclusion in light of the connection between the legitimation of power and the achievement of social order and stability. Bottoms and Tankebe explain that “the first political question” for any society ... concerns how that society can establish and maintain “order, protection, safety, trust, and the conditions of cooperation” and that this is ‘a perennial question ... [which] needs to be solved “*all the time*”’: Bottoms and Tankebe, ‘Police Legitimacy’ (n 182) 49 (emphasis in original), quoting Bernard Williams, *In the Beginning Was the Deed: Realism and Moralism in Political Argument*, ed Geoffrey Hawthorn (Princeton University Press, 2005) 3. Bottoms and Tankebe further argue that ‘in the social world, order requires the development of “regular and recurrent patterns of [social] interaction”’: Bottoms and Tankebe, ‘Police Legitimacy’ (n 182) 50, quoting Dennis Wrong, *The Problem of Order: What Unites and Divides Society* (Free Press, 1994) 5.

²⁰¹ Bottoms and Tankebe appear to intend that the dialogic model should apply in this ‘constant’ way. However, it is possible to interpret their approach as emphasising the significance of repeated but *distinct* legitimacy discussions or exchanges between parties to a power relationship: see, eg, Bottoms and Tankebe, ‘Police Legitimacy’ (n 182) 73. This arguably leaves the impression that legitimacy should be analysed as a series of time-bounded conversations, rather than as a ‘dialogue’ that never ends and which is favoured here.

²⁰² See, eg, Tal Jonathan-Zamir and Amikam Harpaz, ‘Police Understanding of the Foundations of Their Legitimacy in the Eyes of the Public: The Case of Commanding Officers in the Israel National Police’ (2014) 54(3) *British Journal of Criminology* 469.

include the use of jargon, epistemic traditions, and the feedback received and acted on by the dominant party.²⁰³ These factors may determine whether normative congruence between the parties is achieved, maintained or undermined.

Third, an examination of a power relationship from the constant dialogic perspective highlights the perspectives of, and the conflicts and congruencies between, *multiple parties*. A dominant power-holder may need to interact with a range of subordinate audiences, as well as other dominant parties, who hold a variety of beliefs and values. Perspectives on the legitimacy of a dominant party may be as diverse as those who are involved in a power relationship with that party. In the following section, the constant dialogic approach, and its incorporation of Beetham's model of political legitimacy, will be applied to illustrate how therapeutic goods regulation was challenged by the regulatory reforms to medicinal cannabis.

C *The Challenge of the 'Moderate' and 'Radical' Voices to the Political Legitimacy of Therapeutic Goods Regulation*

Earlier, this article described the competing voices present throughout the 2014 to 2018 medicinal cannabis reforms. The alternatives to the dominant voice were the moderate and radical voices with their respective conceptualisations of medicinal cannabis and views on its regulation. These alternative voices generated considerable media coverage and political comment. They were a source of strong community interest and engagement in the policy and law reform process of that period. In addition, these alternative perspectives contributed significantly to reformist regulatory positions adopted by the Victorian Labor government and ultimately accepted by the Commonwealth. But what did the presence and impact of these alternative voices mean for the political legitimacy of the TGA and the dominant regulatory regime? Beetham's threefold framework of legitimacy, on which the dialogic approach builds, provides an insightful perspective on this question.

According to the second, and central, 'normative' element of Beetham's legitimacy framework, the exercise of power should be justified 'by reference to beliefs shared by both dominant and subordinate' parties to a relationship of power.²⁰⁴ The alternative voices of medicinal cannabis regulation were indicative of an absence of shared beliefs between the dominant regulatory

²⁰³ See *ibid* 483.

²⁰⁴ Beetham, *The Legitimation of Power* (n 184) 16.

position on the one hand, and those who held the moderate or radical perspective on the other. Further, these alternative voices were evidence of an absence of Beetham's third element of political legitimacy — that of consent to a relationship of power. According to Beetham, acts of consent to or acknowledgment of the exercise of power provide a public expression of a legitimate power relationship.²⁰⁵ In relation to medicinal cannabis, however, the Victorian Labor government, non-government organisations and individuals expressed alternative voices through public statements, election commitments, law reform initiatives, draft legislation, consultation submissions, media comment, and the admission of growing, supplying, accessing and using cannabis illegally. These were 'public acts of protest, disobedience, and withdrawal of endorsement or recognition' of the therapeutic goods regulation of medicinal cannabis at that time.²⁰⁶ To the extent that these acts constituted a 'withdrawal' of consent, they arguably, according to Beetham, amounted to delegitimation of the regulatory status quo.²⁰⁷

In an attempt to sustain legitimacy, the TGA, Commonwealth government and their supporters referred frequently to the legal justification for the therapeutic goods regulatory regime.²⁰⁸ This reliance on the first 'legality' element of Beetham's framework recalls the following observation: "The much readier access of the powerful to the law, and the fact that it provides both the source and protection of their power, makes appeal to the law as the ground of legitimacy a particularly favoured strategy for dominant groups."²⁰⁹

As Beetham's framework makes clear, however, the legality of the regulatory status quo is not a sufficient basis to establish and preserve its legitimacy.²¹⁰ Even if it were, the TGA's (and others') reliance on this basis for legitimacy was short-sighted. What the medicinal cannabis regulatory reform debate highlighted was that sites of power, and therefore potential sources of legality, are diverse. This is particularly the case in Australia's federal constitutional system and the cooperative Commonwealth–state regulatory arrangements for therapeutic goods. Consequently, the Victorian government was able to present a possible alternative legal regime for regulation of medicinal cannabis

²⁰⁵ Ibid 18, 91.

²⁰⁶ Beetham, 'Revisiting Legitimacy' (n 180) 26.

²⁰⁷ Ibid 19–20, 26. See also Beetham, *The Legitimation of Power* (n 184) 19–20, 205–6, 209–10.

²⁰⁸ See, eg, Ainsworth (n 95); Smethurst (n 91).

²⁰⁹ Beetham, *The Legitimation of Power* (n 184) 67.

²¹⁰ Ibid 68.

that challenged the role of the TGA.²¹¹ Similarly, in 2014, a cross-party group of Commonwealth Senators, led by the Australian Greens, proposed a Bill to establish new regulatory arrangements for medicinal cannabis that sought to provide an alternative to the TGA.²¹² The introduction of this Bill further highlighted the competition between state and Commonwealth governments and political parties

for the political kudos of being seen as the first to champion the therapeutic benefits of medicinal cannabis and to promulgate schemes which circumvent the processes of the TGA and enable access to Australian-grown forms of the [medicinal cannabis] product.²¹³

The regulatory reforms proposed by Victorian Labor and the Commonwealth Greens embraced alternative voices. Further, they highlighted the short-sightedness of the TGA and others to anticipate alternative sites and sources of legality as a basis for regulatory legitimacy.

The reform debate of 2014 to 2018 exposed the incongruence between the values and beliefs of the regulatory status quo and the moderate and radical voices that sought reform. It also indicated that the legal basis on which the dominant parties relied to justify the existing regulatory arrangements was replaceable in relation to medicinal cannabis. At the very least, this amounted to a challenge to the political legitimacy of the TGA and its regulatory regime's approach to medicinal cannabis.

This challenge can be considered as providing an opportunity to reflect on the therapeutic goods regulatory regime beyond the case study of medicinal cannabis reform. Medicinal cannabis constitutes one of a number of 'difficult' or 'hard' cases with which the therapeutic goods regulatory regime deals as part of its regulatory responsibilities. These are cases, like medicinal cannabis, that are characterised by contentious public debate, controversy, and divergent views on ethical and social issues. Another example of such a 'difficult' case is the medical abortion drug known as RU486, which was the focus of significant public controversy when introduced in Australia.²¹⁴ A more recent

²¹¹ However, it is important to acknowledge the potential limitations of this alternative legal regime: see, eg, *VLRC Medicinal Cannabis Report* (n 11) 114–17 [4.82]–[4.98], recommendation 17.

²¹² Regulator of Medicinal Cannabis Bill 2014 (Cth).

²¹³ Freckelton (n 73) 512.

²¹⁴ See, eg, Anne O'Rourke, Suzanne Belton and Ea Mulligan, 'Medical Abortion in Australia: What Are the Clinical and Legal Risks? Is Medical Abortion Over-Regulated?' (2016) 24(1) *Journal of Law and Medicine* 221. See above n 7.

example is the TGA's proposed changes to the regulation and accessibility of alkyl nitrite, a drug used recreationally, including by the LGBTIQ+ community.²¹⁵ Representatives of that community have publicly criticised the TGA's proposals as discriminatory.²¹⁶ Similarly, recent clinical trials of psychedelic substances such as MDMA (commonly known as 'ecstasy') and psilocybin ('magic mushrooms') to treat mental health conditions are likely to lead to calls for regulatory reform in relation to those drugs.²¹⁷

The analysis of 'difficult' cases provides insights about established regulatory regimes, such as for therapeutic goods, which more 'typical' or non-controversial cases may not. A similar approach is adopted, for example, by Black in her assessment of the legitimacy and accountability of transnational, non-state regulators.²¹⁸ She considers that her arguments are applicable to regulators more broadly.²¹⁹ Transnational regulators, she states, 'are chosen because they provide the "hard case"' which 'brings to the fore critical issues which are often obscured when discussed in the context of comparatively stable constitutional settlements and legal regimes.'²²⁰ The value of analysing single case studies is, more generally, supported by commentators on case-study methodology.²²¹ Accordingly, while medicinal cannabis reform in Australia constituted a 'hard case' for the therapeutic goods regulatory regime, the difficulties it posed provide significant insights into the therapeutic goods regulatory regime and its political legitimacy.

²¹⁵ See above n 7.

²¹⁶ See, eg, 'Regulatory Options for Appropriate Access and Safety Controls for Alkyl Nitrites: Public Meeting Questions and Answers', *Therapeutic Goods Administration* (Web Page, 31 January 2019) <<https://www.tga.gov.au/regulatory-options-appropriate-access-and-safety-controls-alkyl-nitrites-public-meeting-questions-and-answers>>, archived at <<https://perma.cc/NE6L-KXYQ>>.

²¹⁷ See, eg, Valentish (n 7); McArthur (n 7).

²¹⁸ Black, 'Legitimacy and Accountability' (n 8) 138.

²¹⁹ Ibid.

²²⁰ Ibid.

²²¹ For example, Yin (n 8) describes this approach as 'analytic generalization', which is 'the opportunity to shed empirical light about some theoretical concepts or principles ... that go beyond the setting for the specific case' and that 'can take the form of a lesson learned, working hypothesis, or other principle that is believed to be applicable to other situations': at 40, 68. Yin explains that conclusions from the analysis of a case study can have conceptual implications (for example, in relation to public policy), broader than that of the case study: at 40–1. See also Bent Flyvbjerg, 'Five Misunderstandings about Case-Study Research' (2006) 12(2) *Qualitative Inquiry* 219, 229–30; Joachim Blatter and Markus Haverland, *Designing Case Studies: Explanatory Approaches in Small-N Research* (Palgrave Macmillan, 2012).

D *The Failure of Therapeutic Goods Regulation to Embrace the Constant Dialogic Approach to Political Legitimacy*

This challenge to the legitimacy of the therapeutic goods regulatory regime can be largely explained by the absence of a constant dialogic approach to legitimacy. As described earlier, the dialogic approach advocates that regulators and their regimes facilitate a *relational* approach to legitimacy. Specifically, this article has argued that this requires an emphasis on constant dialogue, through which a set of shared normative beliefs and values can be formulated, between all parties to a power relationship. The challenge to the legitimacy of the therapeutic goods regulatory regime makes apparent that neither the TGA nor its regulatory framework facilitated such a dialogue. There are two factors that contributed to this situation.

1 *The Absence of a Constant Dialogue with All Relevant Parties*

First, it appears that the TGA and its supporters did not facilitate or engage in a dialogue over time with *all* relevant parties to the regulatory relationship, including patients, carers and cannabis societies. For example, in an August 2016 presentation, the head of the TGA described consultations ‘within [the] Commonwealth, states and territories’ (presumably with those governments) and with ‘interested growers and manufacturers.’²²² Patients, their families and advocates seem absent. Further, only partial consultation appears to have occurred as part of the process to reschedule medicinal cannabis under the *Poisons Standard*. This process required that the decision-maker consider submissions made by the public. A total of 35 submissions were received.²²³ In comparison, the VLRC received 99 submissions and conducted 32 consultations as part of its inquiry.²²⁴ Further, the reasons for the decision to reschedule medicinal cannabis under the *Poisons Standard* make no substantive reference to the contents of the public submissions.²²⁵ The format and predominant tone of the reasons are legalistic. This is markedly different from the more conversational style of the VLRC inquiry report.²²⁶ The absence of a

²²² Skerritt (n 81) 10.

²²³ *Final Decisions and Reasons for Decisions* (n 2) 8.

²²⁴ *VLRC Medicinal Cannabis Report* (n 11) apps B–C. Although the VLRC inquiry was broader than that of the TGA’s rescheduling process, it was limited to one Australian state.

²²⁵ *Final Decisions and Reasons for Decisions* (n 2) 10–11.

²²⁶ For example, the VLRC summarised the views of experts, patients and their families about a mooted ‘grow your own’ medicinal cannabis scheme and stated that it ‘shares their concerns’: *VLRC Medicinal Cannabis Report* (n 11) xxvi [61]–[65]. The VLRC further suggested that a list of clinical indications for medicinal cannabis should be ‘a basis for further discussion

dialogue between the therapeutic goods regulator and all relevant parties to the regulatory relationship appears to extend to before the reform period. Despite the long historical antecedents of alternative voices, there is no indication that a discourse had previously existed. There was arguably, therefore, no opportunity for the TGA to build on existing relationships for dialogue as pressure for reform arose in Victoria.

The apparent absence of an ongoing, relationship-based discourse with all relevant parties to the regulatory scheme effectively blinkered the TGA and other supporters of the ‘dominant’ voice. It arguably obscured the alternative moderate and radical voices from consideration as part of regulatory reforms to medicinal cannabis. Obscured, therefore, was the existence of incongruent values and beliefs to that of the regulatory status quo. It is consequently unsurprising that the TGA and its supporters relied on legality to advocate its legitimacy. The TGA’s view was that it and its regulatory responsibilities were validly established by enabling legislation and were therefore legitimate. The significance of Beetham’s ‘normative’ and ‘consent’ elements of legitimacy simply did not appear relevant to the dominant parties in reflecting on the political legitimacy of the existing regulatory regime. For example, in announcing the amendments to the *Narcotic Drugs Act* to regulate the cultivation of medicinal cannabis, the Commonwealth Department of Health explained that ‘[t]here are already mechanisms in place to enable access to [unregistered] medicinal cannabis products through the *Therapeutic Goods Act 1989*’.²²⁷ This statement appeared to defend the legitimacy of the existing regulatory arrangements, rather than support the then Commonwealth Health Minister’s attempt to extend sympathy to patients with ‘debilitating illnesses’ and to ‘enable access to the most effective medical treatments available.’²²⁸

2 *The View that Expertise Trumps Discourse*

A second factor which contributed to the absence of a constant dialogic approach to legitimacy was inherent in the TGA’s regulatory aims. These aims require the regulator to prioritise expertise over discourse and therefore discourage it from a dialogic approach to legitimacy. The objects of the

between the government, the medical community and patients’ and that future consultation between government and patients should ensure a means of communication is adopted that is best suited to ‘this disparate and widespread group of people’: at xxi [35], 13 [1.79].

²²⁷ Department of Health (Cth), *Medicinal Cannabis* (Fact Sheet) 1, archived at <<https://perma.cc/MWP8-STCY>>.

²²⁸ Ley, ‘Turnbull Govt Delivers Medicinal Cannabis “Missing Piece”’ (n 107) 1.

Therapeutic Goods Act are to control the quality, safety, efficacy and timely availability of therapeutic goods.²²⁹ The nature of these aims requires the TGA to engage largely with established, technical sources of scientific and medical expertise to the exclusion of additional or alternative sources of relevant information. Expertise is therefore perceived to trump discourse.²³⁰

An earlier section of this article discussed how epistemological traditions associated with quality, safety and efficacy shaped the TGA's conceptualisation of medicinal cannabis.²³¹ Contrary to the expansive approach of dialogic legitimacy, these traditions arguably dictated a narrow perspective on who and what information should contribute to the TGA's role in regulating medicinal cannabis. The TGA therefore approached the reforms by engaging almost solely in a dialogue with established forms and sources of scientific and medical expertise. Again, this can be seen in the process to reschedule medicinal cannabis under the *Poisons Standard*. The decision-maker for the rescheduling proposal was required to consider the advice of the ACMS, the members of which are largely required to possess medical or scientific expertise.²³² It is unsurprising, therefore, that the advice of the ACMS focused on evidence obtained from clinical trials and the need to support related research through rescheduling. Supporters of the TGA, including the then (Coalition) Premier of Victoria, also advocated the TGA's reliance on 'the best medical advice and science' as the basis for its legitimacy.²³³

In contrast, a broader group of stakeholders, including patients, carers and cannabis societies, viewed their own experience and knowledge as also constituting a form of expertise.²³⁴ In their view, this expertise was as valid as that offered by recognised clinicians and scientists. Their stories were embraced by the VLRC inquiry as valid and credible sources of information.²³⁵

²²⁹ *Therapeutic Goods Act* (n 3) s 4(1)(a).

²³⁰ Black observes that 'the scientific voice is that which is granted the status of objectivity, and thus, in the current rules of debate, authority and legitimacy. Lay views are often seen as irrational, based in ignorance, as mere emotions or prejudices': Black, 'Regulation as Facilitation' (n 137) 30.

²³¹ See above Part V(B).

²³² One member 'may have expertise in consumer health issues' and it is possible for members to hold expertise in medical ethics: *Therapeutic Goods Regulations* (n 21) regs 35B(1A)–(1B), (2)(w) (emphasis added).

²³³ Smethurst (n 91).

²³⁴ See *VLRC Medicinal Cannabis Report* (n 11) apps B–C.

²³⁵ Lancaster, Seear and Ritter (n 124) 123:

These 'patients' (along with their families, carers and advocates) were positioned as legitimate and essential voices to be heard within the Commission's review process ... these

This phenomenon — in which ‘the boundaries between lay knowledge and expertise are ... increasingly blurred’ — has been described as emanating from the ‘reflexive society’.²³⁶ Kennedy explores this society and its members in the context of complementary and alternative medicines:

The ‘reflexive individual’ relies less on the traditional authority ... and is more reliant on her own judgement about health matters ... medicine ... must be interrogated: trust must be earned and medicine must learn to accept the relevance of lay and alternative voices ... Consequently, the belief that ‘the doctor knows best’ is increasingly challenged ...²³⁷

Viewed from this perspective, the TGA was not able to adequately justify its power by relying solely on traditional medicinal and scientific expertise. Such expertise was considered an insufficient basis for the TGA to differentiate itself from those expressing alternative perspectives on medicinal cannabis, and therefore for it to exercise legitimate power over those parties.²³⁸ In the context of medicinal cannabis regulatory reform, the TGA arguably employed traditional expertise to *speak to* the community over which it exercised power, rather than to use that expertise as one basis on which to facilitate a *dialogue with* the community. Expertise was therefore elevated above discourse, and the opportunity to establish and maintain legitimacy through a relationship based on constant dialogue was lost.

VII STEPS TOWARDS A CONSTANT DIALOGIC APPROACH TO POLITICAL LEGITIMACY

The analysis of medicinal cannabis reform in Australia provides some fundamental ‘teachable moments’²³⁹ for the therapeutic goods regulatory regime, particularly in relation to ‘hard’ or ‘difficult’ cases. Since the specific reforms described in this article, the therapeutic goods regulatory regime appears to have established a coordinating role in relation to the reformed

‘cannabis users’ become legitimate stakeholders in the policy debate, in possession of valuable expertise and knowledge based on experience ...

²³⁶ Peter Kennedy, ‘Habermas and the Self-Regulation of Complementary and Alternative Medicine (CAM)’ in Mark Murphy (ed), *Habermas and Social Research: Between Theory and Method* (Routledge, 2017) 56, 60 (citations omitted).

²³⁷ *Ibid* 60–1.

²³⁸ See Beetham, *The Legitimation of Power* (n 184) 77–82.

²³⁹ Bottoms and Tankebe, ‘A Voice Within’ (n 194) 62. See Wyatt (n 45).

model of medicinal cannabis regulation throughout Australia.²⁴⁰ This apparent indication that the regulatory regime has weathered this particular challenge to its legitimacy should not, however, justify inaction. In relation to medicinal cannabis reform, future challenges for the regulatory regime are likely to include proposals by minor political parties to extend access to cannabis and applications to include new cannabis products on the ARTG.²⁴¹ To enhance its ability to anticipate and respond to what lies ahead, Australia's therapeutic goods regulatory regime may be best served by considering what steps it can take to adopt an approach to political legitimacy such as that outlined in this article. To that end, this final part briefly outlines steps that the therapeutic goods regulatory regime could take to advance the goals of the constant dialogic approach to political legitimacy.

A starting point for these steps may be found in the commentary on the connection between a power holder's sense of identity and its understanding, or 'inner voice', about its own political legitimacy.²⁴² Arguably, this starting point should constitute a reconceptualisation of the TGA's own sense of its institutional identity. As the above analysis has highlighted, the TGA has traditionally adopted a view of itself as an entity embedded in scientific expertise and methodology, a perspective fortified by its legislative mandate. This has perhaps contributed to an inflexible view by the TGA about the nature and exercise of its power, a perspective which contributed to the TGA's vulnerability to challenge during the medicinal cannabis reform period.²⁴³

A shift in the TGA's sense of identity would not necessarily require, however, that it should adopt the alternative values and beliefs held by subordinate parties to the regulatory relationship (such as the 'moderate' and 'radical' voices described above). Instead, the TGA may be able to reconceptualise its

²⁴⁰ The State of Victoria, for example, has indicated that its pivotal and 'stand-alone medicinal cannabis regulatory scheme' will 'not be proceeding': 'Medicinal Cannabis' (n 102).

²⁴¹ See Australian Cannabis Agency Bill 2018 (Cth). The Bill proposes to regulate 'the production and distribution of recreational cannabis in the Australian Capital Territory and the Northern Territory' and to establish 'the Australian Cannabis Agency': at cl 3. 'Recreational cannabis' is defined in the Bill to exclude 'medicinal cannabis': at cl 5 (definition of 'recreational cannabis'). The Bill was proposed by the Australian Greens: Paul Karp, 'Greens Propose Full Legalisation of Cannabis', *The Guardian* (online, 16 April 2018) <<https://www.theguardian.com/society/2018/apr/16/australian-greens-propose-full-legalisation-of-cannabis>>, archived at <<https://perma.cc/AWJ6-V5ZE>>.

²⁴² See generally Bottoms and Tankebe, 'A Voice Within' (n 194); Rodney Barker, *Legitimizing Identities: The Self-Presentations of Rulers and Subjects* (Cambridge University Press, 2001). It is not, however, the purpose of this article to examine this literature.

²⁴³ See Bottoms and Tankebe, 'A Voice Within' (n 194) 62; Lowrey-Kinberg and Buker (n 198) 384–5.

identity, and sense of political legitimacy, by adopting a role as facilitator of ‘the integration of contending views.’²⁴⁴ The TGA could, for example, adopt the identity of ‘interpreters: of re-translating the views of different groups and putting them into a language that the others can understand.’²⁴⁵ This would be consistent with the dialogical approach to political legitimacy and the goal of achieving a normative congruence between multiple parties to a regulatory relationship.

There are a number of practical steps that could be taken by the therapeutic goods regulatory regime to achieve this revised role. While it is beyond the scope of this paper to set out a comprehensive agenda for reform, two broad steps will be described. The first step is an enhanced acknowledgement by the therapeutic goods regulatory regime of the worthy contribution of different values and beliefs — in particular, those that are not necessarily embedded in the scientific paradigm.²⁴⁶ To do this requires the TGA to expand opportunities for the voices of patients, families and community health advocates to be heard as part of the operation of the regulatory regime.²⁴⁷ There are positive indications that the TGA has begun to do this, including a recent willingness to participate in community forums and the establishment of a social media presence.²⁴⁸ Further, as the constant dialogic approach advocates, this step should be underpinned by efforts to forge ongoing relationships with parties to the regulatory regime. Expanding opportunities for additional voices to be heard may also include prescribing and expanding the number and diversity of lay members appointed to advisory bodies such as the ACMS.²⁴⁹ It is

²⁴⁴ Black, ‘Regulation as Facilitation’ (n 137) 60.

²⁴⁵ Ibid.

²⁴⁶ See *ibid.*

²⁴⁷ See *ibid.* 30–2. The TGA’s first Consumer Survey concludes that consumer ‘[r]esponses relating to feedback and consultation mechanisms reflect a general lack of direct engagement with [the] TGA’: Therapeutic Goods Administration, *TGA Consumer Survey 2018* (December 2018) 11. To some extent, such an opportunity was taken by the VLRC as part of its inquiry into medicinal cannabis reform: *VLRC Medicinal Cannabis Report* (n 11) apps B–C.

²⁴⁸ See, eg, ‘Unfinished Business: National Mesh Implant Forum’, *Health Issues Centre: Consumer Voices for Better Healthcare* (Web Page, 12 February 2019) <<https://www.healthissuescentre.org.au/news/detail/unfinished-business-national-mesh-implant-forum>>, archived at <<https://perma.cc/4V3U-QFJH>>; Therapeutic Goods Administration, ‘TGA Facebook Has Officially Launched’ (Media Release, 3 September 2018) <<https://www.tga.gov.au/media-release/tga-facebook-has-officially-launched>>, archived at <<https://perma.cc/G6MJ-D32R>>.

²⁴⁹ Currently it is at the discretion of the Minister to appoint a member with ‘expertise in consumer health issues’: *Therapeutic Goods Regulations* (n 21) reg 35B(1B). In contrast, the Minister can only appoint other members if they have expertise in one of a number of listed medical fields: at regs 35B(1A)(b), (2). Notably, this includes medical ethics: at reg 35B(2)(w).

important to stress that this step should not mean that scientific evidence should be displaced and ignored by the regulatory regime in favour of alternative views, but rather that lay voices and experiences are recognised, heard, and not perceived as secondary to that of scientific and medical experts. Related to this first step is a second — a willingness to facilitate a discourse with and between all parties to the regulatory relationship. This requires the TGA to actively engage with and understand the values and beliefs of those parties, to comprehend their different ‘voices’, and to be prepared and able to explain or ‘translate’ these voices.²⁵⁰ This step may take a number of forms, including the facilitation of deliberative forums, both in person and online.²⁵¹ The successful implementation of these two steps could be effectively evaluated through additions to the key performance indicators of the TGA.²⁵² Such steps would represent a shift in the identity of the TGA consistent with a constant dialogic approach to the political legitimacy of the regulatory regime.

VIII CONCLUSION

The regulatory reforms to medicinal cannabis in Australia between 2014 and 2018 constituted a watershed moment in Australian drug law and policy. The reform period was also significant because of the insight it provided about the nation’s therapeutic goods regulatory framework. Medicinal cannabis ultimately constituted a challenge to the political legitimacy of the TGA and its regulatory regime. According to the approaches to political legitimacy described here, this was because the ‘moderate’ and ‘radical’ voices that emerged during the reform period expressed values and beliefs incongruent with the ‘dominant’ views of the regulatory status quo. This incongruence can be explained by the absence of a constant dialogic approach to legitimacy by

On the broadening of membership of European regulatory frameworks relating to genetics, see, eg, Black, ‘Regulation as Facilitation’ (n 137) 59–60.

²⁵⁰ Black, ‘Regulation as Facilitation’ (n 137) 68.

²⁵¹ See, eg, Jenny Stewart, *The Dilemmas of Engagement: The Role of Consultation in Governance* (ANU E Press, 2009) 26–8; Dominik Hierlemann, ‘More than Just a Five-Minute Conversation: A Case Study in Civic Engagement from Germany’ in John Wanna and Sam Vincent (eds), *Opening Government: Transparency and Engagement in the Information Age* (ANU Press, 2018) 107; Cynthia Farina et al, ‘Democratic Deliberation in the Wild: The McGill Online Design Studio and the RegulationRoom Project’ (2014) 41(5) *Fordham Urban Law Journal* 1527.

²⁵² See generally ‘Performance Reports’, *Therapeutic Goods Administration* (Web Page) <<https://www.tga.gov.au/publication/performance-reports>>, archived at <<https://perma.cc/RCB2-XJNP>>.

the TGA and its supporters. The failure to embrace a constant dialogue with all relevant parties to the regulatory power relationship blinkered the TGA and others to alternative normative positions. Further, a sole focus on established claims to legality, and on scientific expertise instead of discourse, rendered the regulatory status quo vulnerable to alternative sites of power and, ultimately, to reform. This article has suggested steps that the therapeutic goods regulatory regime could take towards a new approach to political legitimacy. Ultimately, it is hoped that such steps will lead to a new institutional identity for the TGA, which includes the facilitation of ongoing dialogue with and between all parties to the regulatory relationship.