Medicinal cannabis policy reforms in contemporary Australia

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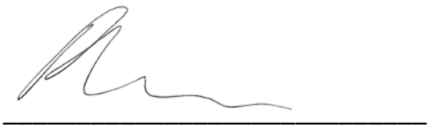
Abstract

The 2016 federal legalisation of medicinal cannabis in Australia was a significant development in drug policy that was, according to much of the literature, primarily caused by effective lobbying from patient advocacy groups. The policies that were initially implemented to facilitate access to medicinal cannabis have since undergone substantive reforms. This thesis examines the conditions that led to legalisation, the policies that were initially implemented, and the ongoing role that advocates have played in reforming these policies. This is done through a combination of documentary research on legislative and regulatory changes from 2014 to 2020, and in-depth semi-structured interviews with six prominent patient advocates.

Using Baumgartner and Jones' theory of punctuated equilibrium this thesis shows that, while advocates were successful in securing federal legalisation, this was not the end of the reform process. Legalisation was followed by a volatile series of policy changes across federal and state governments, as competing interest groups contested the expansion of patient access. Advocates adapted their lobbying strategies which contributed to the intervention of senior federal policymakers in 2018. The government created a new online portal which has significantly streamlined and expedited access. Advocates now report more collaborative relationships with governments, and have become increasingly incorporated into policymaking processes, suggesting the formation of a new policy status-quo.

Statement of Originality

This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself. Ethical approval for this study was granted by the University of Macquarie Human Research Ethics Committee (#52021950425259)



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1. Introduction

Cannabis is a plant. It is also a medicine, an intoxicating drug, and a politically contentious social issue. Although cannabis has been widely used for nutritional, medicinal and spiritual purposes across multiple cultures for thousands of years, its status as a recreational drug rose to prominence in the early 20th century. This led to its near-total prohibition for both medicinal and non-medicinal purposes (Booth, 2005; Lee, 2012; Mead, 2019) after which it became the most-used illicit drug in the world, particularly in developed countries (Decorte and Potter, 2015). Scientific research into the intoxicating effects of cannabis in the 1990s led to new discoveries in cannabis pharmacology and physiology and its medicinal effects, which bolstered the arguments of pro-cannabis advocates who had been campaigning for it to be legalised for medicinal purposes (Vitiello, 1997).

Since 1996, successful campaigns for medicinal legalisation have been made across numerous US states. In the last decade alone, medicinal cannabis has been legalised in diverse ways in dozens of countries, including Australia in 2016, as well as for recreational purposes in some countries and US states (Decorte, Lenton and Wilkins, 2020; Seddon and Floodgate, 2020). The recent global proliferation of cannabis law reforms represents a historic shift in the management of drugs and medicines, and has spurred new research into the implications for public health, economics, and criminology. The emerging literature has also examined the social and political forces behind various campaigns for legalisation, and their impacts on public policy. Australia is a useful case study in the dynamics of medicinal cannabis policy change for several reasons. It is one of the earlier examples of federal legalisation globally, allowing a longer-term historical analysis than many other jurisdictions, and its legal medicinal cannabis framework is now accessed by tens of thousands of patients, making it one of the largest, federally-legal access schemes in the world (MJBizDaily, 2021).

Research on the dynamics of cannabis policy faces some particular methodological challenges. Legal cannabis frameworks are new, numerous, and often in flux (Seddon and Floodgate, 2020). The historical lack of any major reforms in this area means that newly-legal cannabis frameworks tend to be diverse and can interact in complex and unpredicted ways with the broader regulatory environment (Babor, 2018). There are also challenges in theorising such sudden departures from the regulatory status-quo. While the recent global wave of cannabis reforms could be simply explained by the emergence of new medical scientific evidence informing more rational policies, this is rarely the case for politically contentious social issues, especially for policies regarding drugs (Ritter and Bammer, 2010; Monaghan, 2011).

Cannabis policy research is also complicated by the fact that many of the social movements advocating for reform have been loose, grass-roots coalitions (Bone, Potter and Klein, 2018), whose less-visible efforts to affect change may go undocumented, especially once legalisation has been achieved in a

particular jurisdiction. This is particularly relevant for the Australian case, where legalisation initially produced confusing and restrictive patient access policies that have since been reformed.

To attempt to overcome these challenges, this thesis takes the Australian case study and explores two questions: how and why have policies regarding access to medicinal cannabis in Australia changed since legalisation, from the perspective of patient advocates? And is there evidence to suggest that a new approach to medicinal cannabis policy is forming in Australia, one that better incorporates advocates and their demands?

Medicinal cannabis advocates have already been identified in the Australian literature as key agents in the successful campaign for legalisation (Freckelton, 2016; Lancaster, Seear and Ritter, 2017; Caldicott *et al.*, 2018; Hall and Farrell, 2018; Gleeson, 2019; Adler, 2020), so their perspectives should prove useful in understanding ongoing changes in this area. Therefore, this thesis draws significantly on the lived experiences of six prominent medicinal cannabis advocates, captured through semi-structured interviews, combined with documentary analysis of legislative and regulatory reforms.

Overall, this research finds that for advocates, legalisation was a fleeting victory that failed to provide the outcomes they expected and, left unchanged, seemed unlikely to meaningfully expand legal access to medicinal cannabis in Australia. This frustration led to new and intensified conflicts with policymakers. Reforms that advocates perceived to be made in response to these new conflicts, while receiving less attention than legalisation itself, have since significantly expanded access. This has partially satisfied advocates, who now report more collaborative government relationships as they have become increasingly accommodated by policymakers. In this case, while federal legalisation in 2016 is seen as the most significant change to patient access policy, other reforms (especially since 2018) have been important in determining the scale, speed, and ease of access to medicinal cannabis in Australia.

This thesis begins with a review of the literature concerning drug policy and theories of policy change in Chapter 2. This establishes that drug policy operates in the "political realm" (Lenton, 2004, p. 223), and is best analysed using approaches that recognise policymaking as more than just the technical application of new evidence (Gstrein, 2018). One such approach is Baumgartner and Jones' punctuated equilibrium theory (PET) (Baumgartner, Jones and Mortensen, 2018), which is also well suited to explaining sudden changes following long periods of policy stasis, and has been increasingly used by drug policy theorists (Rychert and Wilkins, 2018; Monaghan, Wincup and Hamilton, 2021). Its potential application to changes in medicinal cannabis policy is discussed.

This is followed by Chapter 3 on methodology. Changes to patient access policies at the federal and state levels between 2014 and 2020 were analysed to develop a chronology of policy change, and to identify key events. A map of the patient advocacy community and its central actors was developed through a systematic analysis of media stories, presentations at advocacy events, submissions to

government inquiries, and parliamentary transcripts. From this, eight advocates likely to possess unique insights into key policy changes were identified and sampled purposively (Tansey, 2007; Robinson, 2014). Six completed a single, in-depth semi-structured interview (Charmaz and Belgrave, 2012, p. 348) lasting about one hour. Interview questions and the coding of transcripts were guided by the two combined theoretical approaches underpinning PET: policy communities and agenda setting (Cairney, 2012, pp. 175–6). Interviews and further documentary analysis were conducted iteratively, producing a theoretically-grounded periodisation of policy change, around which the findings chapters of this thesis are structured.

These three chapters roughly correspond to a policy trajectory consistent with PET: a long period of policy stasis that is disrupted by the re-framing of a policy issue, attracting the intervention of powerful, previously uninvolved actors; volatile and contested changes that continue for some time; and finally, the establishment of a new status-quo aligned with the new policy frame and a reduction in conflict.

Chapter 4 'Punctuation' explores the formation of the patient advocacy community and the agenda-setting strategies that advocates used to challenge the established policy image of medicinal cannabis, such as direct lobbying and media engagement. It shows how this put significant public pressure on governments to act and, by targeting multiple policy venues, found initial success with some state governments which helped lead to federal legalisation in 2016.

Chapter 5 'Disruption' analyses how legalisation was actually implemented, the volatile series of policy changes that ensued, the complex interactions between state and federal processes, and the barriers to patient access these presented. Legalisation did not satisfy advocate demands, but shifted the site of conflict from the highly-visible political realm to various bureaucratic policy sub-systems responsible for administering access to medicinal cannabis. Sustained advocacy and an intensification of conflict then provoked further attention from senior policymakers, which saw the federal government intervene to significantly reform patient access processes at the federal and state levels from 2018.

Chapter 6 'Harmonisation' discusses how this intervention has expanded access, both through streamlining administrative processes and motivating state governments to remove restrictions on patient and prescriber eligibility. It shows that advocates have responded positively to these changes and now report more collaborative relationships with governments, indicating the formation of a new status-quo better aligned to advocates and their demands. Some outstanding issues, and potential threats, to patient access are then discussed.

In Chapter 7, the conclusions of this thesis are summarised and future lines of inquiry are proposed.

A chronological list of legislative and regulatory changes is provided in Appendix 1.

Defining 'legalisation'

For the purposes of this thesis, the 'legalisation' of patient access to medicinal cannabis refers to federal amendments made to *The Standard for the Uniform Scheduling of Medicines and Poisons* (Cwth) (the 'Poisons Standard') in November 2016 that allowed cannabis for medicinal purposes to be regulated as a controlled drug rather than as a prohibited substance (this distinction is explained in Chapter 5). The Poisons Standard is "central to the control of public access to drugs in Australia" (Gleeson, 2019, p. 565). This change was made with the explicit intention of allowing prescription access to medicinal cannabis (Decorte, Lenton and Wilkins, 2020, p. 344) and "effectively determined that Australians could legally access cannabis for medicinal purposes" (Gleeson, 2019, p. 559).

Very limited access to medicinal cannabis was possible prior to November 2016. The Poisons Standard had previously been amended in 2012 to include nabiximols (a pharmaceutical cannabis product) as a controlled drug, and in 2015 to include cannabidiol (a non-intoxicating active ingredient found in cannabis) as a prescription-only medicine. However, the November 2016 amendment best represents the 'legalisation' of patient access in Australia.

Defining 'access'

This thesis frequently refers to the concept of 'access' to medicinal cannabis. While clarified and contextualised throughout the thesis, it is worth briefly highlighting the importance of this concept and its particular relevance to this case study. It is used here as a qualitative term that refers to more than just the binary legal possibility of a prescription. It describes and encompasses a broad range of interrelated concerns that advocates have about access to medicinal cannabis, but centrally: speed, ease, cost, and eligibility.

2. Theory and literature review

This chapter begins by situating medicinal cannabis within the discipline of drug policy and identifies some of the challenges particular to drug policy research. Then a review of the international literature specifically addressing changes in cannabis policies is provided, including some limited work on the case of medicinal cannabis legalisation in Australia. The main theoretical approaches to understanding drug policy change are explored, following a categorisation from Stevens and Ritter (Stevens and Ritter, 2013). The utility of theories of 'structured interaction' for the purposes of this thesis is explained, and one such theory, Baumgartner and Jones' 'punctuated equilibrium theory' (PET), is explained in greater depth.

In the final section of this chapter, the literature most specific to the Australian case is summarised. This includes a limited number of publications that engage explicitly with theories of policy change, as well as some more descriptive accounts from the medical-scientific disciplines. The chapter concludes by

arguing that the legalisation of medicinal cannabis in Australia has distinctive characteristics that make it a potentially fruitful case study for understanding how drug policies change, and sets out research questions that are further developed in the following chapter on research methodology.

Medicinal cannabis and drug policy

An examination of medicinal cannabis policy should be at least partly situated within the broader literature on drug policy. This is because, despite medicinal cannabis (in some jurisdictions) now being legally distinct from its recreational counterpart, their shared cultural and political history ensures they remain intrinsically linked. This is evident in how the literature on cannabis policy considers medicinal cannabis legalisation as the beginning of a longer-running trend towards recreational legalisation (Babor, 2018, p. 247), or as a sub-type of cannabis policy change in general (Seddon and Floodgate, 2020). Medicinal legalisation in Australia has been characterised as the "third wave" of cannabis policy reforms (Decorte, Lenton and Wilkins, 2020, p. 434), following prohibition and police diversion programs for recreational use. And, as identified by Lancaster et al, the very definition of 'medicinal' cannabis has been socially constructed in opposition to its recreational counterpart (Lancaster, Seear and Ritter, 2017).

Drug policy is an interdisciplinary field "at the cross roads of public policy and public health … [that] focuses on exploring the processes and outcomes of policy making in relation to illicit drugs" (Gstrein, 2018, p. 75). While much of this research focusses on illicit drug production/distribution networks, and the impacts of drug use and drug policies on public health, the field is also interested in how drug policies (both illicit and licit) are made, influenced and changed (Stevens, 2010; Ritter, 2021). This research has significant overlaps with the disciplines of criminology, sociology, and public policy, which is of particular relevance to this thesis.

The proliferation of cannabis law reforms, especially over the last decade, has been of much interest to drug policy researchers. The global cannabis policy landscape is now "undergoing a process of profound change" (Decorte, Lenton and Wilkins, 2020, p. 1). And although the most prominent reforms that appear in the literature are concerned with recreational legalisation in the Americas, changes in other jurisdictions, particularly the legalisation of cannabis for exclusively medicinal purposes, has "challenged the underlying ideology of cannabis prohibition" (Decorte, Lenton and Wilkins, 2020, p. 1) and points to the beginning of "a global paradigm shift in how we regulate cannabis" (Seddon and Floodgate, 2020, p. 16).

These new cannabis frameworks can be difficult to research. The pace of these changes, their historical novelty, and the ever-growing number of jurisdictions experimenting with such reforms means that cannabis policy is often messy (Decorte, Lenton and Wilkins, 2020, p. 436). This is especially the case for medicinal cannabis. As identified by Belackova et al. in their efforts to map the regulatory options for

medicinal cannabis legalisation in Australia, "due to the way cannabis has historically been understood politically, socially and legally, designing schemes that regulate access to medicinal cannabis for patients (but not access for other purposes) represents a complex and controversial policy challenge" (Belackova et al., 2018, p. 403).

This complexity is further compounded when the outcomes of a policy change do not clearly reflect the stated intentions of policymakers. As per Belackova et al., "it should not be taken for granted that the policy is implemented as per the law, because often practice does not reflect the actual laws" (Belackova et al., 2018, p. 410). So, not only can the legal and regulatory aspects of medicinal cannabis frameworks be difficult to research, understanding the outcomes of these frameworks and how they actually operate in practice can also present challenges to drug policy researchers. For example, while legislation, regulation and policy governing access to medicinal cannabis may not formally restrict certain healthcare professionals from pursuing access, such restrictions may (and have been) implemented by government departments at their discretion (RACGP, 2018b). One way to overcome this challenge is by seeking insights from stakeholders who have lived experience of policy outcomes, which is the approach taken in this thesis. There are, of course, many different ways to analyse cannabis policies, as will now be explained.

International accounts of cannabis policy change

The drug policy literature specifically addressing legal cannabis policies has grown considerably in recent years, including several publications that cover a range of case studies across multiple jurisdictions. Notable contributions include Seddon and Floodgate's *Regulating Cannabis, a Global Review and Future Directions* (Seddon and Floodgate, 2020), Decorte et al.'s *Legalizing Cannabis; Experiences, Lessons and Scenarios* (Decorte, Lenton and Wilkins, 2020), and Corva and Meisel's *The Routledge handbook of post-prohibition cannabis research* (Corva and Meisel, 2021). Overall, this literature provides valuable insights on the design and performance of cannabis policies, but how policy change comes about is less thoroughly explored.

The research presented in Decorte et al. (Decorte, Lenton and Wilkins, 2020) covers a number of international case studies of cannabis reform in great detail. The book is rooted in the discipline of public health, and cannabis policies are interrogated for their social and economic impacts on communities, with the intention of advancing policies that insulate reforms from the potential harms of commercial markets. The introduction identifies Australia as somewhat of an outlier, stating that, "unlike in other countries, the laws are very restrictive with strict controls over cultivation, product manufacture, product range and patient access" (Decorte, Lenton and Wilkins, 2020, p. 3).

Hughes' chapter on Australian cannabis policy touches briefly on medicinal legalisation, noting that, despite some changes to patient access in 2018, "access to the drug is still severely restricted two years

after medicinal use was legalised nationally" (Hughes, 2020, p. 345), suggesting that medicinal cannabis legalisation in Australia was initially more conservative than in other places. But, as will be demonstrated shortly, it has since liberalised considerably. This indicates that legalisation was in this case the *beginning* of a period of change, rather than the end of one. Building on Hughes' research, this thesis aims to more closely explore the nature of these changes, how they came about, and how they have subsequently impacted patient access. To do this, it is necessary to analyse not just how the old policy monopoly was dismantled, but also the tumultuous periods of contestation that have followed.

Seddon and Floodgate (Seddon and Floodgate, 2020) provide a sweeping global overview of cannabis policy reforms, their historical trajectories and impacts on economies and societies. Their main theoretical contribution is to frame cannabis policies as business regulation and propose a future interdisciplinary research agenda informed by theories of global value chains. They argue that many of the regulatory decisions involved in cannabis legalisation, "rest on choices about the type of society we wish to live in and the matters that we want to prioritise or value. Yet this *normative* dimension is largely missing from research on cannabis regulation" (Seddon and Floodgate, 2020, p. 123). This can become especially challenging for medicinal cannabis regulation:

> "Stating the obvious, if a particular product is defined as a medicine, it will be regulated as one. We have seen in the last couple of years in the UK and elsewhere that this can lead in practice to very limited accessibility to medicinal cannabis products … better regulation is not simply a matter of finding the right legislative model but in fact requires the various stakeholders … to be participants in an integrated and multi-faceted regulatory strategy" (Seddon and Floodgate, 2020, p. 127)

These arguments support a deeper analysis of the Australian case, where an initially limited access scheme has been gradually reformed by the inclusion and legitimation of previously uninvolved stakeholders, including patient advocates.

Corva and Meisel's publication (Corva and Meisel, 2021) examines cannabis legalisation through the lenses of political economy and critical sociology. The disciplines of the contributions are diverse, ranging from neo-colonialism, to labour studies, to clinical pharmacology. Most relevant to this thesis is the chapter by Bone and Potter on medicinal cannabis patient access policy in the UK (Bone and Potter, 2021). While not engaging explicitly with theories of policy change, the authors explain how patient advocates were disappointed by legalisation as it did not facilitate meaningful levels of access. They question whether legalisation represents, "the thin edge of a wedge that will, over time, see greater access to legal medical cannabis, or … a political sop in response to media and public pressure" (Bone and Potter, 2021, p. 87).

A similar conclusion is reached by Monaghan et al., in their analysis of medicinal cannabis policy in the UK (Monaghan, Wincup and Hamilton, 2021). Despite legalisation, patient access in the UK remains limited, and they suggest that legalisation may "prove to be only a minor punctuation to the equilibrium surrounding UK medicinal cannabis policy" (Monaghan, Wincup and Hamilton, 2021, p. 7). They argue that a significant change of some kind occurred through the dismantling of a previously stable policy monopoly, resulting in the legalisation of medicinal cannabis, but provided no substantive change in its accessibility. This is very similar to the first few years of the Australian medicinal cannabis framework although in Australia further changes have since produced substantive access. This raises the question: how did legalisation – Australia's initial, significant change – open up further possibilities for ongoing reforms? And is there evidence to suggest that a new approach to medicinal cannabis policy is forming in Australia, one that better incorporates advocates and their demands, in a way that has yet to occur in other places?

Theories of policy change

There are a multitude of theoretical approaches to analysing how drug policies change. Several influential approaches such as Monaghan (Monaghan, 2011) and Ritter (Ritter, 2011) have categorised theories of drug policy-making based on the nature and role of 'evidence'. One such categorisation from Stevens and Ritter (Stevens and Ritter, 2013) neatly summarises the theoretical field into three broad groups. The first group, 'authoritative choice', is characterised by the central role of government action, and of policymaking being a "technical process of solving official problems" (Stevens and Ritter, 2013, p. 169). The second group, 'social construction', understands policymaking as a process that constructs, rather than simply responds to problems, and "creates an understanding of what the problem is, whose problem it is and how that problem gets framed" (Stevens and Ritter, 2013, p. 271). The third, 'structured interaction', focuses on how evidence is used strategically by competing stakeholders who operate within and between various networks, institutions and policy systems.

Theories that prioritise the narrative of authoritative choice see policymaking as the rational actions of actors, usually governments, which seek out objective information to inform better policies (Monaghan, 2011, p. 27). While providing simple explanations of policy change, such approaches face several challenges, not least of which is the endurance of policies that consistently fail to achieve their stated goals, and the assumption that unbiased policy-relevant knowledge can be produced at all (Cairney and Oliver, 2017). Such approaches have been rigorously critiqued in the drug policy literature (Bennett and Holloway, 2010) and are not a focus of this thesis.

Theories of social construction focus on how the 'problems' of drugs are discursively created. Although Stevens and Ritter note that the "flirtation with epistemological relativism" (Stevens and Ritter, 2013, p. 171) in these theories may limit their practical utility for informing policy choices, they are useful for understanding how drug policies are made. Gstrein's review of constructivist theories in the drug policy

literature (Gstrein, 2018) provides a good overview of how these approaches have been applied to a variety of case studies. Theories of social construction are particularly useful for analysing processes of agenda setting (Lancaster, Seear and Ritter, 2017) and the role of the media in drug policy debates (Lancaster *et al.*, 2011), which are important aspects of policy change. While drawing on these approaches, this thesis relies more heavily on theories of structured interaction, which are better placed to analyse how individuals and groups compete with each other in pursuit of specific policy changes and outcomes.

Theories of structured interaction are interested in how groups with shared policy interest are formed and maintained, and how these groups compete with each other within institutional contexts to pursue policy goals. The most prominent theory with this focus is Sabatier's advocacy coalition framework (Sabatier, 1988), which theorises that actors with shared beliefs form coalitions and attempt to defeat or influence the beliefs of competing groups in pursuit of their common policy objectives. Kindgon's multiple stream heuristic also features heavily in the drug policy literature (Kingdon, 2014). This approach theorises that entrepreneurial individuals or groups participate in the development of policy ideas, take advantage of political conditions, and try to gain attention for their policy issues. Change comes about when entrepreneurs are able to link the three 'streams' together by joining a viable policy solution to an identified problem under favourable political conditions, creating a short-term window of opportunity for policy change.

Kindon's approach emphasises the circumstances required for policies to change. Baumgartner and Jones' punctuated equilibrium theory (PET) (Baumgartner, Jones and Mortensen, 2018), while also combining theories of policy communities and agenda setting, shifts the emphasis to examine not just moments of change but also the long periods of policy stasis that are typical of drug policy. In PET, dominant policy communities protect their positions by maintaining the status-quo, allowing only incremental change to occur over long periods of time, in what is termed a 'policy monopoly'. But if competing groups successfully challenge that power through re-framing the policy issue and involving previously absent actors, major and ongoing policy changes can occur until a new monopoly is secured.

The drug policy literature has been heavily influenced by both Kingdon and Sabatier, thanks in part to how they acknowledge the role of evidence in policymaking, while rejecting the ""naïve" assumption that policy making can be de-politicised by the judicious application of science to societal problems" (Gstrein, 2018, p. 78). Punctuated equilibrium theory (PET), while influential in the broader public policy literature, has so far been largely absent from much drug policy research (Gstrein, 2018, p. 82). PET has been used to analyse several examples of drug legalisation, such as the implementation and repeal of alcohol prohibition in the United States (Schrad, 2007) and the legalisation of Novel Psychoactive Substances in New Zealand (Rychert and Wilkins, 2018). Of particular relevance is work by Monaghan et. al., who used PET to explain the sudden emergence of medicinal cannabis as a high-priority political

issue and its subsequent legalisation in the UK (Monaghan, Wincup and Hamilton, 2021). Monaghan et al. argue that by drawing public and political attention to their cause, advocates re-framed the issue of cannabis regulation and challenged the dominant policy monopoly, producing a punctuation in the form of legalisation.

Punctuated equilibrium theory

PET is most simply described as the combination of two other public policy approaches: policy communities and agenda setting (Cairney, 2012). Policy communities research is primarily about identifying "close relationships between interest groups and public officials, based on the exchange of information for influence" (Cairney, 2012, p. 165). Policy communities frame issues in such a way as to maintain the community's position of power over a particular area. This can be achieved by framing the issue as one that has already been resolved, too technical for others to engage in, or too dull to warrant widespread attention. As policy decision-makers cannot pay attention to all issues simultaneously (Cairney, 2012, p. 176), this creates 'negative' policy feedback where the only changes that occur are incremental ones which are consistent with the current definition of the policy issue. This situation is termed a 'policy monopoly', where a group maintains a "monopoly on political understandings" premised on maintaining a "dominant image of the policy problem" (Cairney, 2012, p. 179) and can remain relatively stable for long periods of time (Baumgartner, Jones and Mortensen, 2018, p. 60).

Agenda setting can both maintain the status-quo and produce the conditions for sudden change. Competing communities with different objectives may attempt to dismantle policy monopolies through re-framing their policy issue in a way that generates a desire for other institutions and actors to intervene (Monaghan, Wincup and Hamilton, 2021). Such a re-framing may be the outcome of a 'focussing event' that brings public attention to the issue (Birkland, 1998). Non-dominant policy communities may also appeal to powerful external actors and attempt to change their minds about a policy issue, or engage in 'venue shopping' by bringing the issue to a different institution or jurisdiction to seek a more amenable audience.

Should there be a successful challenge to the policy monopoly, and the issue is re-framed as one requiring the intervention of powerful policy decisionmakers, the system undergoes a 'punctuation'. The existing policy monopoly is dismantled, previously excluded groups are legitimised, and new institutions and actors become involved. This disruption creates 'positive' feedback, and a period of significant change that may last for some time, until a different configuration of actors is able to secure a new policy monopoly. After which the system returns to incremental changes (Stevens and Ritter, 2013, p. 353) consistent with the institutional reinforcement of the new 'policy image' (Cairney, 2012, p. 198).

This thesis draws on Sabatier and Kingdon, as they each provide useful lenses through which to analyse policy communities and their competitive interactions, but building on Monaghan et al. it is structured

primarily around PET. These theories are broadly complementary in the way they understand the role of agenda setting under conditions of bounded rationality, and the overall strategies and tactics that actors have at their disposal to exert influence in a policy field. PET's combination of policy communities and agenda setting, its explicit application to contentious policy issues, and its theoretical focus on long periods of stasis followed by sudden and ongoing change, make it well suited for analysing drug law reforms. For the Australian case, the sometimes-extensive period of change that may follow a punctuation (Cairney, 2012, p. 177) makes PET particularly relevant, rather than explaining this as a time-limited window of opportunity, as per Kingdon, or the result of changes in policy community composition or beliefs, as per Sabatier.

It should also be noted, however, that, for the purpose of this thesis, these theories are being used heuristically rather than as predictive models. Unlike some studies utilising PET (Schrad, 2007; Monaghan, Wincup and Hamilton, 2021), no attempts have been made to quantify or measure the frequency of medicinal cannabis appearing in news media or government debates. Although this may be a fruitful line of inquiry, the escalation of this policy issue is sufficiently established in the literature to direct the kind of in-depth analysis that is the focus of this thesis.

Having surveyed the theoretical literature on policy change, and some of the explanatory gaps left by international accounts of medicinal cannabis legislation, the next section provides a more detailed analysis of the Australian case. It demonstrates why this thesis has centred patient advocates as a policy community, and the importance of the incremental but substantive policy changes that have followed legalisation. Having surveyed the main theoretical approaches to understanding drug policy change in general, we can now explore some of the ways in which the field has approached cases of cannabis policy change in particular.

Medicinal cannabis policy change in Australia

This thesis builds on the small body of literature that has attempted to explain the legalisation of medicinal cannabis in Australia so far. While much of this literature comes from the medical-scientific disciplines and is focused on analysing the clinical utility of medicinal cannabis as opposed to explaining its legalisation, there are four notable exceptions. First is Gleeson's research on how medicinal cannabis legalisation challenged the legitimacy of the regulation of Therapeutic Goods Administration in Australia (Gleeson, 2019). As a legal scholar, Gleeson examines the 2014-2018 'reform period', analyses the legislative and regulatory changes, and provides a theoretical categorisation of the competing policy groups. These are the 'radical voice' of activists who supported more widespread reforms such as the legalisation of personal cultivation; the 'dominant voice' of the regulatory status quo, which opposed facilitating access to medical cannabis, even on compassionate grounds; and the 'moderate voice' which balanced evidence and compassion, exemplified by the Victorian Law Reform Commission.

Gleeson argues that organisations of the 'dominant voice' maintained "a sole focus on established claims to legality, and on scientific expertise instead of discourse, [which] rendered the regulatory status quo vulnerable to alternative sites of power and, ultimately, to reform" (Gleeson, 2019, p. 604). The sites of power underpinning this regulatory status quo included sections of the medical community such as the Australian Medical Association; federal and state health department bureaucracies; and international drug control treaties. Legalisation was achieved by the 'moderate voice', while the 'dominant voice' was forced to partially concede in the face of imminent defeat.

Gleeson's analysis captures how the regulatory status quo was successfully challenged by pro-reform advocates, which might be described as the dismantling of a pre-existing policy monopoly. In the time since Gleeson's research, further developments have emerged that make it difficult to define legalisation as the final outcome of a time-limited policy window, as per Kingdon, or the result of shifting beliefs in these various policy communities, as per Sabatier. The volatile period following legalisation is best characterised as one of 'positive' policy feedback, as the reforms championed by the 'moderate voice' were insufficient to satisfy the demands of advocates.

As will be shown in Chapter 5, following legalisation in 2016 the expansion of access that legalisation was meant to facilitate was resisted by the same sections of the medical community and various state and federal health department bureaucracies that constituted Gleeson's regulatory status quo, resulting in a complex and restrictive access framework. This led to an intensification of conflict with advocates who, in 2018, were successful in again attracting the intervention of senior federal policymakers to streamline and simplify the framework. This was done through the creation of a single online access application portal and associated regulatory and policy changes. Advocates now report more collaborative and less combative relationships with governments, and have become more incorporated into policymaking processes, suggesting the formation of a new policy monopoly.

Another contribution to the case study literature is Lancaster et al., who use Carol Bacchi's poststructuralist approach to analyse how medicinal cannabis was socially constructed by advocates during the Victorian Law Reform Commissions' 2014/15 inquiry into the proposed legalisation of medicinal cannabis in Victoria (Lancaster, Seear and Ritter, 2017). They found that when illicit drug users, normally excluded from any policy debate, framed their drug use as medicinal, they became empowered as "legitimate political subjects" (Lancaster, Seear and Ritter, 2017, p. 123). But also, as "'patients' in need of 'care' and 'supervision' … [requiring] the oversight of qualified, professional, authoritative and expert health practitioners" (Lancaster, Seear and Ritter, 2017, p. 123). Lancaster et al.'s analysis helps explain why advocates reported being frustrated by legalisation, as it did not immediately produce their desired outcomes of quick, simple, and easy access. The social construction of 'medicinal' cannabis shifted the site of conflict from the visible realm of public politics, where

advocates had secured significant support, to health department bureaucracies, some of which were resistant to expanding access.

Lancaster et al.'s findings are supported by Adler, the third contribution to the Australian case study (Adler, 2020). Adler conducts a thematic analysis of strategic communication and media framing used by Australian medicinal cannabis advocates, both before and following legalisation. Their work illustrates the complexity of these policies, the frustration that has been felt by advocates, and their efforts to affect policy change. Adler's work primarily focuses on advocate's strategic communication strategies. This thesis builds on Adler to explore the outcomes of these strategies and how they influenced legislative and regulatory reforms. The methodology of this thesis also draws from Adler by gaining novel insights from patient advocates through conducting in-depth semi-structured interviews. Two of Adler's subjects participated in interviews for this thesis.

The fourth contribution of note is Lewis and Flood's content analysis of articles in Australian professional medical publications between 2000 and 2019 regarding medicinal cannabis (Lewis and Flood, 2021). This research shows that the number of articles published about medicinal cannabis per year rose sharply from 2012 to 2014, when the issue first rose to public prominence in Australia, and has since continued to accelerate. The three most common 'frames' found in these articles were "MC a legitimate therapeutic option"; "Process for accessing and prescribing is complex"; and "MC driven by community (patients)". This further supports the argument that patient advocates have been the driving force behind patient access policy reforms, and that the regulatory frameworks put in place following legalisation were restrictive, at least in part due to their complexity.

Moving then to the medical-scientific literature on medicinal cannabis policy in Australia, this literature concurs that legalisation was caused by patients and their advocates successfully campaigning for policy change. Patient access following legalisation is generally characterised as constrained yet expanding, although there are disputes as to whether this is appropriate or desirable, as per the preferences of the authors. What is largely missing from the literature, partly due to its recency, is an examination of the various regulatory changes that have led to the significant expansion of patient access since 2018, and the role that patient advocates played in securing those changes. It is this gap in particular that this thesis attempts to fill.

The influential role of patient advocates is identified by Freckelton, who characterises the campaign for legalisation as being "driven by individuals – patients whose plight became publicly known and who engaged considerable sympathy and thereby galvanised the impetus for reform to the law" (Freckelton, 2016, p. 498). Freckelton even refers to various government-funded medicinal cannabis clinical trials by the names of the patients who drew attention to that specific medical condition, with the adult cancer clinical trial being the "Dan Haslam category" (Freckelton, 2016, p. 500). Others have described legalisation as occurring "in response to consumer demand and … widespread community support"

(Lintzeris *et al.*, 2018, p. 211), or as a result of "parents of children with cancer or intractable forms of epilepsy … [who have] persuaded state and federal governments to permit access to cannabis based products for medical use" (Hall and Farrell, 2018, p. 209).

Depending on the policy preferences of the authors, patient access following legalisation tends to be characterised as constrained (if the preference is for expansion) or expanding too quickly (if the preference is for constraint). This tension is captured by a 2017 article authored by Skerritt, representing the Commonwealth Therapeutic goods Administration, the year after legalisation. Skerritt acknowledged the frustration of patients struggling to access medicinal cannabis, saying "there is a strong preparedness to respond to the wish by sections of the community to improve patient access to medicinal cannabis. However, the regulatory system is complex for a number of reasons" (Skerritt, 2017b). Skerritt then explains how few cannabis medicines have undergone normal drug approval processes; the clinical evidence supporting medicinal cannabis is limited; and patient access must be approved by both the federal and state governments.

In an exchange that exemplifies the contentious nature of medicinal cannabis policy in 2018, Martin et. al., writing on behalf of the Royal Australasian College of Physicians, argued that patient access should be restricted in order to protect public health, and that "the pace and scale of the introduction of medicinal cannabis are unprecedented" (Martin, Bonomo and Reynolds, 2018). This provoked a response from McGregor, who called Martin et. al.'s piece "a patronising and scaremongering diatribe" and noted that "for the vast majority of Australian patients, medicinal cannabis is little more than a pipe dream" (McGregor, 2018). That same year, an article in the Medical Journal of Australia by Hall and Farrell asserted that "the best public policy response to patient demands for medical cannabis is that which has been adopted by the federal and several state governments" (Hall and Farrell, 2018). While Caldicott et. al. argued that "obstacles continue to thwart the creation of an efficient, patient-oriented system, despite intentions of Federal legislation" (Caldicott *et al.*, 2018).

The expansion of patient access, especially since 2018 with the federal government intervening to create the online application portal, has also been remarked upon. Writing in 2020, Arnold et al. described the rise in patient access approvals as "exponential", but warned that despite this, "surveys suggest that many Australians continue to self-medicate with illicit cannabis. Indeed, the National Drug Strategy Household Survey recently reported that 600,000 Australians use cannabis for medicinal purposes, but only 3.9% obtain it via legal pathways" (Arnold, Nation and McGregor, 2020, p. 157). And the Commonwealth Department of Health, in their submission to a 2020 Senate inquiry into barriers to patient access to medicinal cannabis, noted that "the cumulative number of individual patients accessing medicinal cannabis … continues to rise, with a 600 percent increase from 2018 to 2019" (Australian Government Department of Health, 2020, p. 13). While advocates continue to lobby for further improvements to patient access, there is a consensus that medicinal cannabis is now much

easier and quicker to access than it was just following legalisation. This is due to a series of policy changes that began in 2018, as will be explored further in Chapters 6. While patient advocates are credited with securing legalisation, their role in these post-legalisation reforms remains largely unexplored.

Conclusion

This chapter has situated medicinal cannabis within the broader drug policy field, provided a review of the literature concerning theories of policy change, and how they might be used to analyse the case of patient access policy change in Australia. It has summarised the drug policy literature relevant to medicinal cannabis policies globally, and the more limited literature on Australia specifically, identifying some explanatory gaps that warrant further research. It has demonstrated that, while Australia's medicinal cannabis framework has been characterised as restrictive, this is partly due to a focus on the initial policy features of legalisation circa 2016 and their immediate effects. In contrast to how the Australian case has been discussed in the literature, patient access has since expanded considerably, but this has been due to a series of substantive changes beginning in 2018 that have so far received little academic attention. Advocates were key to securing legalisation, but their role in subsequent, less visible, reforms remain largely unexplored. It is likely that members of this policy community possess unique insights relevant to the study of this case in particular, and to drug policy change in general. It is on this basis that the research methodology for this thesis was developed, as will be explained in the following chapter.

3. Methodology

In order to analyse the role of advocates in post-legalisation changes to medicinal cannabis patient access policy, two research methods were used: documentary analysis and qualitative interviews. Documentary analysis was used to determine that these policies have actually changed in ways that meaningfully expanded access, and to locate when and how these changes occurred. Qualitative interviews were used to uncover how the patient advocacy community experienced and contested these policies. Interviews were also used to identify if, and to what extent, patient advocates and their preferences have been incorporated into policymaking processes in the years following legalisation, in order to point to some future directions for medicinal cannabis policy in Australia, and to explore the possible formation of a new policy monopoly.

Documentary analysis

Research began by conducting an analysis of changes to medicinal cannabis patient access policies at the federal and state levels across Australia from 2014 to 2020. Guided partly by my a-priori[1] understanding of the field, a list of policy changes most relevant to patient access were identified. This analysis focused on policies directly related to the authorisation and facilitation of patient access to medicinal cannabis in each jurisdiction, such as restrictions on the types of healthcare professionals, patients, and products eligible for access; significant changes to access application and approval processes; and new government commitments to policy outcomes such as improving application approval timeframes.

36 documents were identified, including various bills; existing, new and amended acts and regulations; policy changes; and announcements from ministers and government agencies. For analytical clarity, documents that dealt exclusively with the import/export of medicinal cannabis products, the provision of clinical guidance information, and commercial licensing were excluded. Additional events were added or removed in response to findings from the interviews. This was used to produce a chronological list of 29 events, and a brief summary of their effects and relevance (included as Appendix 1).

As the purpose of this exercise was to construct a time-line of how and when policies changed, these documents were analysed descriptively (Owen, 2014, p. 15) and were not subject to coding or textual analysis. These documents are important for clarifying how and when medicinal cannabis policies have changed and are referred to throughout the thesis in order to provide historical context for the experiences reported by patient advocates.

[1] I have worked in the Australian medicinal cannabis sector since 2016, mostly as a commercial consultant, and have advocated for patient access policy reforms. I therefore possess some relevant a-priori knowledge that has informed this thesis.

This exercise informed the structure of my research in two ways. First, the chronology informed a geographical focus on the states of Queensland, New South Wales, and Victoria, which were all early-movers in patient access reforms. These jurisdictions have also undergone the most significant liberalisations of access, and now account for the vast majority of medicinal cannabis prescriptions nationally. Second, it provided a periodisation of policy change that was developed further during the interviews and used to structure the findings chapters.

Documentary analysis showed that patient access policies have changed in three chronologically-ordered stages that roughly conform to a trajectory described by punctuated equilibrium theory: first, a long period of policy stasis was suddenly disrupted by the dismantling of a previously dominant policy monopoly, resulting in federal legalisation in 2016. Second, this disruption was followed by a volatile series of patient access reforms, which variously restricted or expanded patient access across federal and state levels. Third, the implementation of more liberal access policies from 2018 points to the partial incorporation of previously excluded policy communities, and the formation of a new policy monopoly. As per Fisher et al., this chronological sequence of events was used to guide interview questions (Yanow, 2007, p. 411) and was compared to the experiences of advocates, as will be explained further on in this chapter.

Following this policy history analysis, I conducted some preliminary research to identify the patient advocates and advocacy groups that have participated most in these debates and reforms. This research drew from the academic literature, news media, legislation and regulation, policy announcements, the grey literature, and parliamentary transcripts and reports. While hundreds of people have, in one way or another, participated in medicinal cannabis advocacy in Australia, this was narrowed down to a few dozen of the most-involved individuals and groups. This section of the community is relatively cohesive, and members tend to speak at the same events and government inquiries, lobby the same stakeholders, and belong to the same advocacy groups.

Participant sampling

As this research aimed to more fully understand how patient advocates engaged in a particular series of reforms, interview participants were sampled purposively, rather than randomly or theoretically. This is a method of participant selection where “the study's purpose and the researcher's knowledge of the population guide the process” (Tansey, 2007, p. 770). Purposive sampling allows the researcher to leverage their prior knowledge of a research topic to identify participants most likely to facilitate research outcomes, so they can ask “theoretically guided questions” that “probe beyond official accounts and narratives” (Tansey, 2007, p. 767).

Participant sampling was performed with three objectives in mind. The first was to identify individuals who had gained access to senior policymakers and participated significantly in policymaking processes.

The second was to include individuals with a variety of backgrounds to capture diverse perspectives of policy reform processes. Some of the most prominent advocates have become involved in lobbying for patient access without having previously engaged with politicians, bureaucrats, medical experts, or the media. Others already possessed significant technical and professional expertise. These differences may also have influenced advocates' perceptions of policy change, and the extent to which they become incorporated into any new policy monopoly. I also considered which participants would be most likely to provide the kinds of insights that would be relevant to the research. The third was to include a sufficient number of participants while ensuring that individual cases retained a "locatable voice within the study … [allowing] an intensive analysis of each case to be conducted" (Robinson, 2014, p. 29).

From the initial map of the policy community, eight participants were identified. After considering the potentially contentious nature of the research, which was likely to touch on issues such as the attitudes and conduct of policymakers and bureaucrats, one participant was excluded because they now work in government and I determined that, should they agree to participate, the lack of anonymity would restrict their candour.

Seven participants were invited and all of them agreed to contribute, although one participant ceased corresponding before an interview could be scheduled and did not respond to further requests. Given the time constraints of this research, I did not attempt to find a replacement. The exclusion of this participant slightly shifted the focus of these interviews away from the role of grass-roots activism towards the experiences of more technical/professional advocates.

Ethical considerations

Ethical approval for this study was granted by the University of Macquarie Human Research Ethics Committee [#52021950425259]. All participants were provided with an information sheet explaining the research project, and signed a consent form confirming their informed intent to participate. Participants were given the option of being referred to by a pseudonym in published work, but were advised that this would be unlikely to ensure their anonymity. All participants who contributed to this research consented to being identified.

As I was already known to the participants, in order to ensure that participation was voluntary, interview invitations were sent by the research supervisor. Consideration was also given to my personal commercial circumstances, being the sole director of a company that consults to the medicinal cannabis industry. Participants were informed of this, and assured that no data or information received as part of the research would be shared with any clients, employees or subcontractors the company, nor used for any commercial purposes.

Participants

The six participants who contributed to this research, including a very brief outline of their relevance to medicinal cannabis advocacy, are listed below. Their personal contexts and relationships to each other will be further explained in Chapter 4. To illustrate the relative cohesiveness of this policy community, some examples of their shared organisational affiliations has been provided. For the sake of clarity, only organisations and affiliations that were current as of October 2021 have been included. The list is not exhaustive, and a brief description of these organisations is provided below the table.

Participant	Advocacy work	Shared affiliations
Lucy Haslam	Lucy is Australia's most prominent patient advocate. The bill legalising medicinal cannabis was named "Dan's law" after her son, Daniel Haslam, who passed away from bowel cancer in 2015.	Founder, United in Compassion (UIC) Chair, Australian Medicinal Cannabis Association (AMCA)
Lanai Carter	Lanai is the mother of Lindsay Carter, who lives with a brain tumour and intractable epilepsy. Lindsay was one of the first legally-prescribed medicinal cannabis patients in Australia and Lanai has extensive experience of this early time period.	No shared affiliations
Justin Sinclair	Justin has worked closely with Lucy Haslam, especially on the education of healthcare professionals, since 2015. Justin is now a PhD candidate at the NICM Health Research Institute at Western Sydney University, and the Chief Scientific Officer at an Australian medicinal cannabis company.	Scientific Advisor, UIC Board member, AMCA
Teresa Nicoletti	Teresa is a doctor of medical science and a Partner at Mills Oakley law firm and has provided legal, regulatory and commercial advice to the medicinal cannabis industry. Teresa began collaborating with Lucy Haslam in 2016 and has provided pro-bono legal advocacy for several patients attempting to legally access medicinal cannabis.	Company Secretary, AMCA

Iain McGregor	Iain is a Professor of Psychology and the Academic Director of the Lambert Initiative for Cannabinoid Therapeutics at the University of Sydney and has been a prominent figure in public debates about cannabis science and patient access.	Academic Director, Lambert Initiative Board member, Medicinal Cannabis Industry Australia's Medicinal Cannabis Health Advisory Council (MCIA Council)
Carol Ireland	Carol is the CEO of Epilepsy Action Australia, one of the country's primary patient support and advocacy organisations. In 2016 Carol was the only patient advocate invited to join the newly-formed Australian Advisory Council on the Medicinal Use of Cannabis, which reports to the federal health minister.	Board member, MCIA Council Board member, Lambert Initiative External Advisory Board

Organisations: United in Compassion (UIC) is a patient advocacy charity; Australian Medicinal Cannabis Association (AMCA) is an industry and community association; The Lambert Initiative for Cannabinoid Therapeutics (Lambert Initiative) is a philanthropically-funded medical research centre; Medicinal Cannabis Industry Australia is an industry association; MCIA's Medicinal Cannabis Health Advisory Council (MCIA Council) is an affiliated independent entity.

Interview methods

Participants were invited to complete a single, in-depth, semi-structured interview lasting around one hour. To protect against possible interruptions from COVID-19 lockdowns, interviews were conducted and recorded online using Zoom and then transcribed. The interviews were structured around a list of questions that were provided to participants in advance (see Appendix 2), along with an explanation of the nature and focus of the research. Interviews were intended to facilitate a "detailed exploration of an aspect of life in which the interviewee has substantial experience and, often, considerable insight" (Charmaz and Belgrave, 2012, p. 348). As such the questions were open-ended, and participants were verbally invited to consider them as prompts for a wide-ranging conversation, with limited interruptions from the researcher.

Interview questions were informed by the two combined theoretical approaches which underpin punctuated equilibrium theory: policy communities and agenda setting (Cairney, 2012, pp. 175–6). In addition to their overall involvement with medicinal cannabis policy in Australia, participants were asked

about their objectives and challenges, and the agenda setting strategies that they used to pursue their goals. This included direct lobbying of policymakers, using social and mass media to generate public pressure, and seeking out new institutional venues, such as different levels of government, to find support. Participants were also asked about their experiences with the formation and interaction of policy communities, which included connecting and collaborating with allies, and identifying and engaging with oppositional groups and their interests. Participants were asked about the chronology of significant events relevant to patient access policy changes. These accounts were tested against the timeline developed in the documentary analysis in an iterative fashion – during the interviews, as participants were invited to provide their own periodisations, and during the analysis of interview transcripts.

The analysis of interview transcripts was guided by the principles of constructivist grounded theory (Strauss and Corbin, 1997; Charmaz and Belgrave, 2012, p. 355), using 'process coding': action-oriented words or short phrases (Saldaña, 2014). Subsequent rounds of analysis related these codes to the conceptual categories of punctuated equilibrium theory, which was then used to develop initial assertions about the experiences reported by advocates. These were iteratively checked against prior assumptions, new interview data, and documentary evidence (Roulston, 2014, p. 305). Data was also reviewed for 'negative' cases that might complicate or contradict emergent findings (Roulston, 2014, p. 306).

This clarified that patient access policies have evolved in three distinct stages, which are reflected in the structure of the findings chapters:

In Chapter 4 'Punctuation', advocates spoke about the remarkable levels of public and political support they were able to generate in the lead-up to legalisation. Advocates publicly campaigned through the media and met directly with politicians, with the former often leading to the latter. As advocates were very much 'outside' policymaking processes during this period, they tended to rely on applying external public pressure. Advocates pursued their cause across several policy venues and were initially successful in achieving reforms in some states, which put pressure on senior federal policymakers. Punctuated equilibrium theory refers to this tactic as 'venue switching', and it featured prominently in the interviews.

Venue switching helped overcome the regulatory status-quo that advocates believed was sustained by various professional medical associations; federal and state health department bureaucracies; and political economic interests such as pharmaceutical opiate manufacturers and the regulation of narcotics through international drug control treaties. These sites of opposition reported by advocates suggested a pre-existing policy monopoly that was eventually overcome through legalisation. Despite resistance, advocates managed to shift the policy image of medicinal cannabis, framing it an issue of urgent medical necessity, leading to its legalisation in 2016.

In Chapter 5 ‘Disruption’, following legalisation advocates were confronted by an unexpectedly complex and difficult regulatory environment that did not satisfy their demands. State governments in particular introduced new access requirements, in addition to those at the federal level, which differed (often substantially) between states, constraining and delaying access. Legalisation had been broadly supported by senior politicians, but the actual implementation of legalisation involved various federal and state health department bureaucracies and professional medical communities, many of which were not prepared to facilitate quick and easy access to medicinal cannabis.

In response, advocates continued to use the media to apply public pressure. But in contrast to the campaign for legalisation, they lobbied for more specific policy reforms and began to engage directly with senior bureaucrats. This indicates that advocates shifted the emphasis of their lobbying efforts towards more ‘internal’ strategies as they become increasingly familiar and involved with policymaking processes. In 2018, advocates succeeded in getting senior federal policymakers to intervene in the administration of patient access by creating a new online portal. This automated and expedited access applications, limited the extent to which health departments could impose ad hoc conditions on applications, and motivated some states to make further legislative, regulatory and policy reforms to expand access.

In Chapter 6 ‘Harmonisation’, following the 2018 changes, patient access has improved considerably. There are outstanding issues that advocates continue to lobby for, and disagreement on what actions should be taken, but advocates report that they now enjoy more collaborative relationships with governments and other stakeholders. The uneven introduction and removal of barriers to access across multiple jurisdictions that followed legalisation appears to conform to what punctuated equilibrium theory describes as ‘positive’ feedback; a period of volatile change that follows the dismantling of a policy monopoly. As advocates and their demands have become incorporated into policymaking processes, this has led to a reduction in volatility and conflict, potentially indicating the formation of a new policy monopoly. Some emerging issues caused by the liberalisation of patient access were also identified by advocates, which are flagged as potential future threats to the stability of this new policy monopoly.

Limitations

As demonstrated in Chapter 2, advocates have been credited with achieving legalisation, which is supported by the findings from these interviews. It is interesting to note however that, unlike other contentious health policy issues with significant levels of popular support (such as euthanasia) (Hanrahan, 2018), advocates did not appear to face much concerted political opposition to their cause. This raises questions about how the social construction of medicinal cannabis, and the material conditions and power relations involved with it, differs to other issues, which is not fully explained by the interview data.

The knowledge that advocates possess is, of course, limited to their personal experiences. They undoubtedly influenced both the 2016 legalisation of medicinal cannabis and the 2018 policy reforms to some extent, and they possess unique perspectives regarding why and how these reforms were contested, and by whom. But a more comprehensive investigation into the dynamics of these policy changes would benefit from including other relevant perspectives, especially from groups that advocates identified as being important, such as the medical community and health department bureaucracies, and the medicinal cannabis industry, which did not feature prominently in the interviews.

Regardless of which groups are interviewed about their experiences, it is important to acknowledge that the interview as a research methodology is "not so much a neutral conduit or source of distortion as an occasion for constructing accounts" (Gubrium and Holstein, 2012, p. 32). Interviewees are not passive vessels from which objective information can be extracted, but are collaborative participants in the development of a narrative. It is therefore appropriate to treat these interviews not as immutable facts, but as retrospectively constructed accounts, to which we should attend "more to whether [the] participants' accounts are theoretically plausible than whether they have constructed them with unassailable accuracy" (Charmaz and Belgrave, 2012, p. 351).

4. Punctuation

Introduction

This chapter begins by explaining the personal contexts of patient advocates and the formation of their policy community in their own words. It then shows, with some illustrative examples, how advocates relied primarily on the media in pursuit of popular support, which provided access to senior politicians who they were then able to influence. Using both interviews and documentary research, it shows how advocates targeted multiple policy venues to find support, which likely contributed to successful reforms in some states, including the legalisation of medicinal cannabis cultivation in the state of Victoria. This threatened the federal control of medicines regulation, and could have put Australia in violation of international drug control laws. In response to this, and in the face of significant public demand, the federal government legalised medicinal cannabis in 2016.

Chapter 5 then explores how legalisation was actually implemented, including a detailed explanation of federal and state patient access processes, and new barriers to access that were implemented by some states in response to federal legalisation. The resistance that advocates experienced from some sections of the medical community and state health department bureaucracies is examined, as well as the ways that advocates adapted their lobbying efforts in response to these challenges. This was followed by another federal intervention in 2018 which created an online patient access portal that simplified and expedited access, and put pressure on state health departments to make additional reforms.

Community formation

Advocates noted 2014 as being a pivotal year for their involvement in medicinal cannabis policy. Lanai Carter and her family were living in the USA, where her son Lindsay had been recommended medicinal cannabis to treat his brain tumour and associated seizures. They started regularly returning to Australia from 2014, and were concerned about being able to continue Lindsay's treatment.

> "And I did start reaching out to some [Australian] politicians from the US and started talking to people like Lucy [Haslam]. I had also made contact with organisations like Epilepsy Action when I was in the US. And then just basically when we came back, I got involved in it [advocacy] in a more, sort of, I guess almost full time […] trying to make things happen for Lindsay and for other patients like him." (Carter, 2021)

Lanai was one of the growing numbers of concerned parents that reached out to Epilepsy Action Australia around that time, spurred by recent media reports of epileptic children being treated with medicinal cannabis (AAP, 2014). Carol Ireland, the CEO of Epilepsy Action Australia, remembers,

> "That was the very first thing I think we heard, the phone calls, emails, inquiries. And the inquiries were around, is this true? Is there anything to it? And how can I get it?" (Ireland, 2021)

For Lucy Haslam, 2014 was the year in which her son Dan began to use medicinal cannabis to assist with the side-effects of his cancer treatment. When Lucy noticed how much cannabis was helping Dan, she felt compelled to do something.

> "So, I decided without any kind of light bulb moment, I just decided that I had to do something about it. And for some strange reason, I thought the best way to start was to talk to my local members, both state and federal members." (Haslam, 2021)

Lucy created the charity United in Compassion and, later that year, held a Symposium in Tamworth NSW, the first of what would become a series of conferences aimed at educating people about medicinal cannabis and lobbying for reform. Justin Sinclair had been interested in the therapeutic potential of cannabis for many years, and first met Lucy when he attended the 2014 Symposium. At the end of the event,

> "I remember going over and introducing myself and what I did, and thanking her for putting this on, and being really inspired by her and Dan and the rest of the family for what they were doing, and that I'd love to help. And […] gave her my card, essentially, and then the rest is history […] I started working very closely with her and still do to this day." (Sinclair, 2021)

Iain McGregor had spent many years studying the effects of cannabis, although mostly its potential harms. While discussing some of his recent research on a TV news segment, he was asked by a journalist about his thoughts on cannabis for medicinal purposes.

> "And I said, you know, people are suffering, if they're in pain, if they've got conditions that otherwise aren't being helped by prescription meds, why would you deny them the opportunity to try medicinal cannabis for their condition? And it just so happened that Lucy Haslam was watching the ABC that night […] and invited me to this symposium that she was organising up in Tamworth." (McGregor, 2021)

Iain and some of his colleagues attended and spoke at the event, which is where they met Michael Lambert, whose parents would end up donating $35 million to the University of Sydney to establish the Lambert Initiative for Cannabinoid Therapeutics in 2015.

Teresa Nicoletti's interest began with her parents. Her mother had developed Alzheimer's Disease, for which there was some emerging pre-clinical evidence that cannabis might be beneficial. Her father later developed metastatic prostate cancer. Being a lawyer, she felt unable to source cannabis to help with his cancer symptoms, as it was still illegal.

> “And so, I watched him die in excruciating pain. So, I became an advocate for those reasons, but also because I had independently reviewed a lot of the evidence and thought that this was a really potentially quite important treatment modality.” (Nicoletti, 2021)

Teresa kept abreast of the issue and provided legal services to various early-stage Australian cannabis companies. After attending the second Symposium that was held in 2016, Teresa offered to help Lucy with any pro-bono cases of patients struggling to access medicinal cannabis.

> “I was so, I guess, emotionally affected by some of the patient cases that I said to Lucy, look, y'know, I've got a pretty good legal skill set. Let me help some of these patients, send them to me.” (Nicoletti, 2021)

The formation of this policy community happened alongside the growing popular support for action to be taken on medicinal cannabis legalisation. Advocates came to know each other through events, public hearings at government inquiries, and media appearances, and began to collaborate on lobbying efforts. They met with politicians and bureaucrats, provided submissions and testimonies to government inquiries, shared their stories with the media, and ran educational events aimed at reducing the stigma associated with cannabis and promoting the emerging scientific research supporting the use of cannabis as medicine.

Policy stasis

Historically, cannabis had been constructed exclusively as a harmful recreational drug. The routine management of cannabis in Australian society was administered by various policy sub-systems concerned with technical aspects of criminal law and public health, attracting "minimal external interest or a limited ability of outsiders to engage” (Cairney, 2012, p. 177). In 2014, despite the emergence of some medical scientific research demonstrating the therapeutic potential of medicinal cannabis, the common-sense understanding was that legalising the production of and access to medicinal cannabis was unlikely to happen.

For example, in 2013, an inquiry into the use of cannabis for medical purposes was conducted by the NSW Legislative Council. The recommendations from that inquiry mostly dealt with establishing legal protections for people with terminal illnesses who were using illicitly-sourced cannabis, as opposed to legalising access to regulated products. In response to these findings, the NSW government – with Jillian Skinner as health minister – agreed to express in principal support for more research into medicinal cannabis, but rejected all other recommendations (NSW Government, 2013).

By 2014, through her direct lobbying efforts, Lucy Haslam had developed a relationship with NSW Nationals Senator Trevor Khan, who was a member of the committee which conducted the inquiry. Even

though Khan supported the recommendations that Skinner had rejected, he expressed scepticism about the potential for any major policy change. Lucy Haslam recalls,

> "I said to him [Kahn], would it be worth opposing her [Skinner], going out against her? And he said you can try, we'll certainly support you if you do, but from us, there's nothing we can do about it. That's just the way these things work." (Haslam, 2021)

Shifting the policy image

The escalation of medicinal cannabis to the top of the political agenda was sudden, and largely driven by advocates who pursued a wide range of strategies. The personal accounts of the suffering being experienced by patients and their advocates were emotive and compelling. Beginning in 2014, medicinal cannabis went from being a non-issue to one of national, public importance (Freckelton, 2016). The role of the media, particularly in the lead-up to legalisation, in communicating these messages was emphasised strongly by all advocates. Media coverage brought the general public, who had not previously been involved with medicinal cannabis policy, into the debate. And, according to advocates, following the public came the politicians, who soon recognised it as a political issue.

In addition to appearing in the media, advocates directly lobbied politicians at state and federal levels. All advocates reported having multiple meetings with various politicians and senior bureaucrats in the lead-up to legalisation. Most advocates were inexperienced at lobbying and had a limited understanding of political and policy processes. Despite this, they managed to gain direct access to many senior decisionmakers. Lanai Carter believed that most of these people were genuinely moved by her efforts, and that they "did see the need and they understood […] they were compassionate enough to do something" (Carter, 2021). Carol Ireland recalls,

> "We did start to advocate for people through their governments, state-based governments and the different structures that had been developed. I can recall dealing with a number of state governments and in one situation got myself all the way to a table with the Premier in Queensland and met with the Chief Medical Officer and the Premier and a parent." (Ireland, 2021)

Lucy Haslam's lobbying efforts are well captured by Adler (Adler, 2020) but it is worth noting that, within a few months of deciding to publicly advocate for medicinal cannabis, Lucy had developed political allies in the NSW Premier, Mike Baird; the leader of the federal Greens Party, Richard Di Natale; the leader of the federal National Party, Barnaby Joyce; and the powerful media figure Alan Jones of 2GB Radio Sydney, among many others. As the salience of medicinal cannabis as a policy issue reached its crescendo, Lucy recalls,

> "All the politicians were sort of clamouring to be, you know, in front of cameras with people. I remember Bill Shorten was the head of the Australian Labor Party at the time. He ended up on my doorstep one day, just out of the blue, and ended up going out and having a media opportunity with the Dell family. You know, it was it was kind of sickening." (Haslam, 2021)

Iain McGregor recalls that "change was in the air" and that it felt as though governments were suddenly "taking this really seriously" (McGregor, 2021). Policymakers began to face insurmountable public pressure. According to Justin Sinclair,

> "There was volatility and that volatility was splashed all over the media […] And then we started seeing huge shifts in public opinion. And you know, what, 90 plus percent of the Australian population supported medicinal cannabis? No politician in their right mind is ever going to fight against that. But how it was actually then implemented and rolled out is a different idea." (Sinclair, 2021)

Media coverage amplified advocate calls for action which, combined with their lobbying efforts, appeared to influence policymakers that something had to be done. Although it was still unclear what that action should consist of.

State reforms

Punctuated equilibrium theory describes how actors switch their lobbying efforts from one policy venue to another in order to find receptive audiences. Advocates reported that they were initially most successful in lobbying state governments, rather than the federal government. The regulation of medicines in Australia, especially narcotics such as cannabis, is closely intertwined with both state and federal laws (Gleeson, 2019), which can restrict and complicate the ability for states to undertake major reforms unilaterally. Prior to federal legalisation, a series of reforms were made at the state levels aimed at satisfying community demands in the absence of a federal approach, although the legalisation of medicinal cannabis was also a live issue in that policy venue, as will discussed later.

In December 2014, the NSW government created the Terminal Illness Cannabis Scheme (later re-named the Medicinal Cannabis Compassionate Use Scheme), which encouraged police to not arrest or prosecute terminally ill people using illicit cannabis for medicinal purposes. This was one of the recommendations from the 2013 NSW Legislative Council inquiry that had been rejected by the government only the year before, and was achieved in large part thanks to Dan and Lucy Haslam's lobbying of Premier Mike Baird (Thomsen, 2014; New Zealand Drug Foundation, 2016). The NSW government also struck agreements with Victoria and Queensland to fund and run several large clinical trials investigating the efficacy of medicinal cannabis for people with epilepsy, cancer, and terminal illness (AAP, 2014; ABC News, 2014).

In Queensland, Lindsay Carter's doctor was trying to import medicinal cannabis products from overseas. But this was prevented by state law as, at that time, medicinal cannabis was still a prohibited substance. Lanai Carter lobbied for these laws to be changed and eventually threatened legal action. In December 2015, the government implemented the Health (Drugs and Poisons) Amendment Regulation (No. 1) 2015 (Qld), which permitted Lindsay's doctor to prescribe him a prohibited substance. But the issue was far from over. Lanai recalls,

> "Once we got through that, we then had to deal with delays at a TGA [Therapeutic Goods Administration] level and we had to start a legal review process there. And then that got resolved. And then that didn't end it because once the TGA approved it, the [Queensland] health department decided that they were going to start to apply processes from a proposed bill that hadn't even passed parliament, so further delays. And when we realised this, we actually started another legal process with the state health department, put them on notice to take it to court. And we had to then engage the media, 60 Minutes at that time it was […] to basically keep them honest. Arming the media with copies of applications, showing all the data that they had on file at the health department, and questioning as to why there should possibly be any reason to delay it any further." (Carter, 2021)

Lanai's experience illustrates how advocates contributed to the acceleration of what might otherwise have been incremental changes by switching policy venues between state and commonwealth governments, and by using a variety of tactics to maintain public attention and political pressure through meeting with politicians, appealing to the media, and threatening legal action. It also suggests that both advocates and policymakers may have been unclear about what kinds of regulatory changes were necessary or sufficient to achieve policy outcomes, or even what those outcomes should be.

Despite the level of support advocates received from many senior politicians at the time, there was still no move towards broader legalisation. Some advocates believed that bureaucrats within government health departments were opposed to medicinal cannabis reforms and were working behind the scenes to thwart substantive progress. Lanai Carter recalls that policymakers were nervous about moving too far, too quickly,

> "In those early days, I remember a comment from the adviser to the [Queensland] health minister saying something along the lines of, as far as medical legalisation […] they didn't want to be at the front of the bus, they didn't want to be at the back of the bus. They wanted to be in row 2b with the seatbelt securely fastened." (Carter, 2021)

The resistance to reform, particularly within the NSW health department, was remarked upon by several advocates. For example, in 2014 Dan Haslam was undergoing chemotherapy at Tamworth Hospital. That day, the NSW health minister Jillian Skinner was visiting the hospital. Lucy had tried unsuccessfully to get

Skinner to visit Dan while she was there, so as Dan was leaving, he took it upon himself to approach Skinner as she was finishing a press conference,

> "He just put his hand out, shook her hand and said, "I'm Dan Haslam and I'd like to talk to you about medical cannabis", and she said "oh, I know all about you, Daniel Haslam". And he started to tell her the story about how he was using it, how it helped him, and she was listening to him. And I thought, this is going well, she's listening. And then at the end of it, she put a hand on his shoulder and she said, "you know, Daniel, that smoking is going to give you lung cancer" […] I was speechless and Dan said, "well, I've already got lung cancer so I guess it doesn't matter". And after that, I didn't know what to say. I just was so unprepared for that […] And I said to Mike Baird afterwards, I said, "don't you ever let me near that Jillian Skinner ever again."" (Haslam, 2021)

Advocates reported that they advanced their cause in the face of this kind of resistance by maintaining public pressure through strategic use of the media. In Victoria, Lucy recalls receiving a phone call around July 2014 from another advocate who told her that Cassie Batten was being arrested for giving illicit medicinal cannabis to her young epileptic son, Cooper Wallace. Lucy immediately contacted Helen Kapolos, a journalist who had recently visited Lucy in Tamworth.

> "I phoned Helen and said, Helen, this is happening. Can you get round there with a camera? And she did, and so that made the news. Helen was able to be there in five or ten minutes to film Cassie being arrested as a nine-month pregnant lady and fingerprinted. And so, off the back of that, Daniel Andrews was pressured into approving it for people like Cooper. That then became his election promise." (Haslam, 2021)

While there were certainly other factors which contributed to this outcome, Lucy Haslam's account demonstrates the deeply held belief shared by many advocates that the media can be a powerful tool for policy change. The Victorian Labor Party won the November 2014 election and the new Premier, Daniel Andrews, instructed the Victorian Law Reform Commission (VLRC) to investigate how to legalise medicinal cannabis, with or without federal action. In October 2015, the Andrews government accepted the 40 recommendations from the inquiry (Victorian Law Reform Commission, 2015) and followed through on the election commitment of legalising the cultivation, manufacture, and patient access of cannabis medicines by tabling the Access to Medicinal Cannabis Bill 2015 (Vic).

The Bill was intended to tightly restrict patient access only to children with paediatric epilepsy (such as Cooper Wallace), who would be exclusively provided with purified cannabidiol products[2] in the form of oral oils. Over time, more clinical indications and product types could be added, but only condition-specialist doctors, such as neurologists, and not general practitioners, would be able to prescribe. The

[2] Cannabidiol is a non-intoxicating active ingredient found in cannabis

proposal for strict restrictions on the eligibility of prescribers and patients influenced subsequent laws and regulations in other states, as will be discussed in the following chapters.

Federal reforms

Alongside these changes in the states, the federal government was also debating the legalisation of medicinal cannabis. A point of focus for these debates was the Regulator of Medicinal Cannabis Bill 2014 (Cwth) from the federal Greens Party that had been introduced to the senate in November 2014. The Bill sought to legalise medicinal cannabis and establish a stand-alone regulator separate to the Therapeutic Goods Administration (TGA) to oversee cultivation, production and patient access. The Bill was referred to a senate committee, which held public hearings in March and April 2015. Lucy Haslam, Lanai Carter, Iain McGregor and Carol Ireland attended or spoke at the public hearings and expressed support for the Bill.

The committee report, published in August 2015 (Australian Legal and Constitutional Affairs Legislation Committee, 2015), recommended that the Bill be passed, but only once various conflicts were resolved regarding existing legislation. Creating a new medicinal cannabis regulator would have been an unprecedented departure from Australia's established approach to the regulation of therapeutic goods. The committee also voiced concerns that the Bill could result in Australia breaching international drug control laws.

Government officials and politicians advised advocates that breaching international drug control laws could, in turn, threaten Australia's ability to continue as the world's largest exporter of poppy-derived narcotics. Some advocates saw this argument as evidence of the corrupting influence of the pharmaceutical industry, working behind the scenes to prevent the legalisation of a product that could threaten the profits of opiate manufacturers. Whatever the cause, there were political and economic constraints that limited what reforms were possible. According to Teresa Nicoletti,

> "I remember in the early days being told at a government level that it wasn't as simple as removing the barriers to access because there were significant economic and policy considerations to weigh into whatever decisions were made. Now to me, that's political. And I think we'd be naive to think that economic considerations around the broader pharmaceutical industry and the broader regulatory requirements that have been in place for, say 30 or 40 years, should be disregarded because this new treatment modality comes in and we need to bend the rules and uphold different standards for that.
>
> It's an invidious position for the regulator to be in, to have to weigh in – and not just the regulator, but government to have to resolve – when they've got the public beating down their door saying we want access, but not understanding the economic, political and policy considerations that weigh into their decision making." (Nicoletti, 2021)

By 2015, it seemed that demands for federal legalisation would need to be accommodated in one way or another. Queensland had already amended laws to allow the prescription of prohibited substances such as medicinal cannabis, while NSW had taken steps to legally protect terminally ill people who were using illicit cannabis and had invested heavily into clinical trials. What finally appeared to force the federal government's hand was Victoria's introduction of the Access to Medicinal Cannabis Bill 2015 (Vic), which would have legalised the licensed cultivation and manufacture of medicinal cannabis at the state level. This would have put Australia in contravention of various United Nations drug treaties which require narcotics production to be controlled by national governments (Collins, 2020).

Legalisation

Under considerable pressure from the general public, in the few months between when Victoria's Access to Medicinal Cannabis Bill 2015 (Vic) was tabled in November 2014 and passed into law in April 2016 as the *Access to Medicinal Cannabis Act 2016* (Vic), the federal government proposed its own legislation. In February 2016, the Narcotic Drugs Amendment Bill 2016 (Cwth) was introduced and passed. This made amendments to the *Narcotic Drugs Act 1967* (Cwth), legalising the cultivation and manufacture of medicinal cannabis at the federal level. The explanatory memorandum of the Narcotic Drugs Amendment Bill 2016 (Cwth) specified that federal legalisation was necessary partly because,

> "There is a risk that Commonwealth legislation could be inconsistent with that of the states and/or territories. In such a case, the Commonwealth is potentially in breach of its international obligations under the Single Convention with at least one state unilaterally moving to permit cultivation of cannabis for medicinal purposes." (Australian Government, 2016, p. 9)

The Narcotic Drugs Amendment Bill 2016 (Cwth) passed both houses in record time with universal political support. As reported by Adler (Adler, 2020, p. 34), Lucy Haslam helped expedite the process by encouraging the Labor Party to vote for the Bill without first sending it to a senate committee. The Bill passed on the anniversary of Dan Haslam's death and was named "Dan's law" in his honour. It was followed later that year by associated amendments to *The Standard for the Uniform Scheduling of Medicines and Poisons November 2016* (Cwth) (the 'Poisons Standard'), which legalised patient access to medicinal cannabis. Lucy was initially optimistic,

> "Naively, I thought that people would be able to go to their doctor and get a script for cannabis and go to the chemist and get it filled, at reasonable cost and with minimal effort. That's what I thought was the right way to treat people that were often chronically ill or very disabled or terminally ill." (Haslam, 2021)

But this was not to be the case. Iain McGregor recalls how, in the months following legalisation,

> "It became very rapidly apparent that this was a crock, you know, or it was a fraud. I mean, it was really difficult to understand the motivations. They'd rolled out this scheme, which became, I guess, instantly unpopular because we realised that it was almost designed to ensure that nobody could get medicinal cannabis." (McGregor, 2021)

Advocates switched policy venues and secured support across various state governments, apparently generating significant political pressure, which contributed to policy change at the federal level. But this did not immediately produce the outcomes that advocates were hoping for. While political support for medicinal cannabis legalisation had been near-universal at the federal level, advocates found that politicians and bureaucrats differed in their views on what legalisation should actually look like. Legalising medicinal cannabis at the federal level also allowed senior policymakers to turn their attention to other issues, leaving the actual implementation of patient access largely up to federal and state health department bureaucracies, which were reportedly less receptive to advocate's demands, as will be explored in Chapter 5.

Conclusion

Chapter 4 has shown that patient advocates formed a relatively coherent policy community from around 2014. Advocates were able to generate significant public and political support through strategic use of the media and by directly lobbying policymakers across multiple policy venues. This contributed to a shift in the policy image of medicinal cannabis, framing it an urgent and important policy issue. Advocates believed they found initial success with some state governments, leading to the legalisation of medicinal cannabis cultivation in Victoria that threatened federal control of medicines and compliance with international drug control treaties. This appeared to provoke federal action, resulting in legalisation in 2016.

Chapter 5 unpacks the regulatory complexity of legalisation, the policy volatility that followed, and how this frustrated advocates as they encountered new and unexpected barriers. It explores how legalisation required the participation of new policy sub-systems and communities, such as health department bureaucracies and prescribers, which had not previously administered medicinal cannabis and were resistant to expanding access. It shows how advocates attempted to overcome these barriers by adapting their strategies as they became more familiar with the policymaking processes, engaging with detailed regulatory issues and lobbying for specific reforms. This was followed by a second intervention from senior federal policymakers in 2018, which created a new online portal to streamline and expedite access, and put pressure on the states to also reform their access requirements.

5. Disruption

Introduction

This chapter begins by exploring what federal legalisation actually entailed and how federal and state governments managed patient access. It examines the processes, conditions and constraints that were implemented, and the fragmented nature of these regulations across the country. It demonstrates that, for advocates, achieving federal legalisation shifted the site of conflict from the highly visible political realm to various policy communities and sub-systems responsible for administering access to medicinal cannabis, such as health department bureaucracies and prescribers. This presented advocates with new and unexpected barriers, especially at the state levels, as some applications for access were rejected or delayed.

Although advocates continued to rely on 'outsider' strategies such as using the media to put pressure on senior politicians, they also adapted their efforts to engage directly with health department bureaucrats and to lobby for specific reforms to existing policies. During this time, advocates became more incorporated into policymaking processes, for example by having a patient advocate join a federal body advising the minister for health. Advocates launched a new campaign to reform patient access in 2018, which appeared to provoke the intervention of senior federal policymakers. The federal government implemented a new online patient access portal, which simplified and expedited access processes, and pressured state health departments to make further reforms.

Chapter 6 discusses how the creation of the online portal in 2018 has impacted patient access. It shows that the portal immediately improved the ease and speed of access, and has since motivated further reforms in some states, to the satisfaction of advocates. Although issues with patient access remain, advocates report that since the creation of the portal, they have developed more productive working relationships with governments and feel they can better contribute to positive reforms in the future, indicating the formation of a new policy monopoly.

The Poisons Standard

Despite the Narcotic Drugs Amendment Bill 2016 (Cwth) being named "Dan's law", it was primarily concerned with commercial licensing and not patient access. It set out the legal framework in which Australian companies could be licensed to cultivate and manufacture cannabis medicines in accordance with domestic and international laws. Although "Dan's law" in and of itself did not impact patient access, it demonstrated the government's commitment to do so. According to Gleeson, "it was therefore almost inevitable that reforms to the therapeutic goods regime would need to follow" (Gleeson, 2019, p. 576).

Patient access reforms were achieved through amendments to the *The Standard for the Uniform Scheduling of Medicines and Poisons November 2016* (Cwth) (the *'Poisons Standard'*), which categorises medicines and poisons into different 'Schedules' based on risk, and specifies among other things federal-level rules about how these substances should be stored, advertised, and sold (TGA, 2021b). The Schedule of a medicine can impact how easily it can be prescribed, which healthcare professionals can prescribe it, and to whom. Changes to the *Poisons Standard* are usually automatically incorporated into state regulations, although these jurisdictions can choose to differ from the Commonwealth (Gleeson, 2019).

In November 2016, in the same month that the government began accepting commercial cultivation and manufacturing license applications, the TGA amended the *Poisons Standard* and created a new entry for medicinal cannabis in Schedule 8, making it a controlled drug (*Poisons Standard November 2016*, Cwth). This meant that cannabis now appeared in three Schedules: cannabis for non-therapeutic use was still a Schedule 9 prohibited substance. For therapeutic use, cannabis became a Schedule 8 controlled drug. Purified cannabidiol – a non-intoxicating active ingredient found in cannabis – was already a Schedule 4 prescription only drug, thanks to amendments made in June 2015 (*Poisons Standard June 2015*, Cwth) although, for a number of reasons, this had not yet facilitated meaningful access to such products. Amending the *Poisons Standard* automatically made it possible to prescribe medicinal cannabis products in most states, although this was complicated by various other factors, including new cannabis-specific state laws and regulations, as will be explained shortly.

Changes to the *Poisons Standard* were not accompanied by any formal restrictions on product, patient, or prescriber eligibility at the federal level. This stood in contrast to statements previously made by the then health minister, Susan Ley, (Yaxley, 2015) who had announced that only orally-ingestible medicinal cannabis products (as opposed to products that could be vapourised or inhaled) would be permitted.

These changes to the *Poisons Standard* also stood in contrast to the Victorian *Access to Medicinal Cannabis Act 2016* (Vic) that had been recently passed into law, which only permitted condition specialist medical doctors to prescribe a limited range of products exclusively to children with treatment-resistant epilepsy. In 2015, the Victorian approach was progressive in comparison to the absence of reforms in any other Australian jurisdiction but by 2016, federal legalisation made it appear conservative. In response the Victorian government chose to not implement the *Access to Medicinal Cannabis Act 2016* (Vic) and placed no restrictions on access to medicinal cannabis, above and beyond those already in place for other medicines. This illustrates the speed at which policies were changing, and the momentum that would continue past federal legalisation as regulations continued to be created, contested, and reformed.

Commonwealth requirements

Although the *Poisons Standard* had been amended to allow easier access to medicinal cannabis products, no products had yet undergone the clinical research necessary to prove their safety and efficacy. Normally, medicines must demonstrate safety and efficacy to the TGA in order to become 'registered' on the Australian Register of Therapeutic Goods, before they can be prescribed (Skerritt, 2017a, 2017b). This meant that all of the medicinal cannabis products that might be accessed in Australia were 'unregistered' medicines, which are generally only made available in exceptional circumstances (Donovan, 2017)[3]. Unregistered medicines are also not eligible for government subsidies through the Pharmaceutical Benefits Scheme, which means they are often expensive.

Unregistered medicines can only be prescribed to patients participating in clinical trials, or through one of the TGA's several 'special access' pathways (TGA, 2021a). Although each of these pathways has a similar intent – to facilitate access to unregistered medicines in exceptional circumstances – they differ in their operation, and in their interaction with state requirements. A more detailed explanation of these pathways can be found elsewhere (Skerritt, 2017b; O'Rourke, 2018; Arnold, Nation and McGregor, 2020), including how the federal government prohibited cannabis from being accessed via the pathway exclusively reserved for medical emergencies and the terminally ill (Davey, 2017), claiming it would have allowed people to bring "bags of weed" into the country (Esposito, 2017). But essentially, the 'unregistered' nature of medicinal cannabis products meant that both the TGA and state governments could impose conditions on access.

For the vast majority of situations (depending on the access pathway used) an access approval required a prescriber to submit an application to the TGA requesting permission to treat a specific patient with a specific product. Prescribers had to justify their request to use a cannabis medicine, and the TGA had to approve their application before treatment could commence (Skerritt, 2017a). Although the TGA did not impose any formal restrictions on product, prescriber, or patient eligibility, some restrictions were imposed on a case-by-case basis. For example, the TGA could determine that a general practitioner should seek endorsement from a condition specialist, or that the prescriber should attempt the use of other drugs before commencing treatment with medicinal cannabis (Australian Government Department of Health, 2020).

State requirements

In addition to the various approvals necessary to navigate patient access at the federal level, most states implemented their own additional requirements, with entirely separate application and authorisation processes to the TGA. By 2017, most states had passed new laws, changed regulations, or announced

[3] Since 2016, two cannabis medicines have been registered, and can be prescribed without TGA approval (Centre for Medicinal Cannabis Research and Innovation, 2021)

policies that in some way put conditions on the kinds of patients, prescribers or products eligible for access. Most also chose to implement their own case-by-case clinical assessments of access applications, in addition to the clinical assessments made by the TGA, and often exercised broad discretion in approving access. Teresa Nicoletti recalls,

> "You were required to obtain approval under either the Special Access Scheme or Authorised Prescriber Scheme, but then each state had their own assessment processes whereby someone within each department of health would separately review applications and determine whether a patient should or should not have access. And it was quite concerning that some of the reviewers of those applications really didn't have the requisite expertise to be making clinical decisions in the interests of patients." (Nicoletti, 2021)

To illustrate, here are three such examples of the regulatory situation in 2017:

In Victoria, the *Access to Medicinal Cannabis Act 2016* (Vic), which was intended to restrict access to condition specialist prescribers, children with treatment-resistant epilepsy, and purified cannabidiol products, was abandoned. This meant that, in addition to TGA approval, prescribers required a treatment permit from the state health department prior to commencing treatment with a Schedule 8 cannabis medicine, as was the case for all Schedule 8 drugs in Victoria (Government of Victoria Department of Health, 2021). This was a relatively simple application process that did not involve an in-depth clinical assessment. No state approval was required for Schedule 4 (purified cannabidiol) medicines.

Meanwhile in NSW, amendments were made to the Poisons and Therapeutic Goods Regulation 2008 (Nsw) in August 2016. This required prescribers to seek state authorisation before prescribing any Schedule 8 cannabis medicines (NSW Legal and Regulatory Services, 2016). Unlike Victoria, the NSW authorisation process involved an in-depth clinical assessment, which could delay the access process by several weeks. Some applications were rejected outright, and some general practitioners were instructed to seek the endorsement of a condition specialist before re-applying. Advocates felt this was inappropriate, especially for disabled patients or those undergoing palliative care, who lacked the money and time to fulfil these requirements. Schedule 4 products could be prescribed with TGA approval alone.

In Queensland, the *Public Health (Medicinal Cannabis) Act 2016* (Qld) was passed into law in March 2017. Similar to the changes in NSW, this meant that the state health department conducted in-depth clinical assessments before permitting access and could require general practitioners to seek endorsement from a condition specialist. But, unlike in NSW or Victoria, this applied to both Schedule 8 and Schedule 4 medicinal cannabis products.

These new reforms at the state level caused significant confusion for patients, advocates and healthcare professionals (RACGP, 2018a). Each jurisdiction had different prescriber, patient, and product eligibility requirements, which could be explicit or informal (RACGP, 2018b). They also had different application processes, paperwork, and processing times. Some applications that were approved by the TGA were rejected by the states (Cohen, 2017). Others were held up for months in lengthy deliberations between prescribers and health departments (Esposito, 2018). Medicinal cannabis had been legalised, but it was far from accessible. Advocates became increasingly angry as they come into contact with these unexpected new obstacles. Lucy Haslam recalls,

> "Once we saw how it was going to work, that it wasn't going to work, I stopped feeling like I had achieved something and I started feeling like I'd been cheated. I guess I felt like it had been derailed, and it was then I realised that politicians don't always mean what they say. It's all about the optics. It's all about looking like you're doing something and keeping conversations in closed rooms, you know, keeping people happy. It was like the unseen people that you knew were actually driving it were having the upper hand and, you know, I was kind of a bit sick, to be honest. I felt really bad about how it played out." (Haslam, 2021)

New policy communities

The campaign for legalisation had been largely fought by advocates at the political level – by using the media to put public pressure on senior politicians to change the law. But now that legalisation had been achieved, medicinal cannabis became incorporated into the broader framework of medicines regulation. The political problem of medicinal cannabis legalisation appeared to have been resolved, allowing senior politicians to turn their attention to other issues. Prescribers became wholly responsible for pursuing patient access, while eligibility assessments and access approvals were delegated to the various policy sub-systems within government health departments. These two policy communities – healthcare professionals and health department bureaucracies – became central points of focus for patient advocates.

Prescribers

Prescribers who were interested in considering medicinal cannabis were caught between a complex and unfamiliar access scheme on one hand and, on the other, increasing demands from their patients who believed that medicinal cannabis was now legally available. A survey of 640 general practitioners conducted by the Lambert Initiative in 2017 found that the majority had fielded at least one patient inquiry about medicinal cannabis in the prior three months (Karanges *et al.*, 2018). A majority of prescribers believed that medicinal cannabis should be available on prescription, but fewer than 10% said they understood the regulatory approach or how to prescribe it. Justin Sinclair recalls,

> “The poor old doctors at this point are just like, “well, I don't know anything about this, we haven't been really involved in consultation in this process”. And not a great deal of consultation has really taken place, I think it's fair to say, when it comes to the regulatory changes that were happening in the medicinal cannabis space. And this is just me, but I wonder if that was part of the decision-making process, of putting the gatekeeper position onto the doctors, knowing that this would further slow things down.” (Sinclair, 2021)

There were a few doctors prepared to pursue medicinal cannabis on behalf of their patients, some of whom reached out to patient advocates for guidance and support. After Lindsay Carter became one of the first Australian patients to successfully access a prescription medicinal cannabis product, Lanai was contacted by a doctor who asked her to help him navigate the patient access system,

> “That was quite alarming to me because I thought, you know, he's a specialist [...] and he wants his patient to have this medicine. They have no, no idea how to start the process and how to navigate it. And he was able to successfully get an approval, but it just made me realise how many more doctors and specialists out there might be in that situation.” (Carter, 2021)

While advocates reported that they found allies in the Royal Australian College of General Practitioners and the Australian Nursing and Midwifery Federation, they experienced resistance from many sections of the medical community. Advocates reported that they came into particular conflict with the Australian Medical Association, the Australian and New Zealand College of Anaesthetists, and the Royal Australasian College of Physicians; organisations that had all voiced concerns about expanding access to medicines that had not been assessed for safety or efficacy (Martin, Bonomo and Reynolds, 2018).

Advocates were quick to identify how important it was for prescribers to have access to information, not just on how to navigate the access processes, but also on the emerging medical scientific evidence justifying the use of medicinal cannabis. The education of healthcare professionals soon became a core focus for advocates, alongside their efforts to change patient access policies at the federal and state levels.

Heath department bureaucracies

Advocates felt they had been successful in their lobbying efforts up to this point primarily by influencing senior politicians. But following legalisation, the actual administration of patient access was largely left up to government health departments. The experiences of advocates during this time suggests that there were groups within health department bureaucracies that were opposed to the legalisation of medicinal cannabis, or that had competing interests.

In Lucy Haslam’s experience, the kinds of government representatives who attended meetings with her began to change after 2016. The direct access she previously enjoyed with many senior politicians became diluted with health department bureaucrats.

> "It was like, well, it was bureaucratic, I guess. It was, you know, some of these faceless people that you never normally hear of who seemed to be running the show […] There were quite a few patients that we ended up going to New South Wales Health about, physically going and meeting them and sort of being met with this room full of more extras than Quo Vadis, the likes of [Chief Health Officer] Kerry Chant and the Chief Pharmacist." (Haslam, 2021)

Teresa Nicoletti believed that the patient access processes were both unworkable and unusual, and she made pro-bono representations to federal and state governments on behalf of patients. In her opinion,

> "They were empathetic to the issues we were raising, but there were deeper policy considerations and government considerations that we weren't privy to. And without them telling me that, I knew that. And I don't think we can begin to understand the deeper discussions that were had at the government level around why they adopted the approach they had taken, and maybe a lot of that was just the level of comfort with medicinal cannabis as a treatment just wasn't there." (Nicoletti, 2021)

Some of this resistance was also likely due to the fact that medicinal cannabis had only recently been legalised after decades of prohibition and, despite the new policy image, many people still held established beliefs about its status as a harmful recreational drug. Responding to legalisation by introducing new approval processes could also represent attempts by these sub-systems to suppress policy change that might have threatened to destabilise their position within other power structures or policy images. Advocates continued to engage with health department bureaucrats, but failed to make significant progress in expediting or expanding patient access.

New rounds of conflict

Medicinal cannabis had been legalised and was *technically* available, yet patients continued to struggle to access it. Confronted with these difficulties, advocates returned to the lobbying strategies that had previously proven successful, including telling their stories through the media, holding events, and meeting with government officials. According to Justin Sinclair,

> "Advocate groups were quite vocal in just saying yes, we've got the law changed. Yes, that's great. But what does this mean? Patients still can't access. It's not streamlined. Doctors don't know how to do this. And putting that constantly into the media, which was, I think, essentially providing a pretty good amount of pressure." (Sinclair, 2021)

By this time, the Lambert Initiative had commenced several research projects aimed at understanding the nature of illicit medicinal cannabis use in the Australian community. One of these was the PELICAN study (Suraev *et al.*, 2018), which involved interviewing families of children with severe paediatric epilepsy and analysing the medicinal cannabis products they were providing to their children. Iain

McGregor recalls,

> "I remember two Sydney Morning Herald articles probably in 2017, 2018 where I just really let fly at the TGA, the federal government, the NSW government, all of them. And we became very stern critics. It was around this time that we were running the PELICAN study, so we were going out into the community and talking to a lot of families who had children with severe epilepsy. And most of them were having to break the law to get cannabis products. And you know, that spelled out really starkly how poor the scheme was that had been introduced and how unworkable it was. And that drove the fury that we present in the media.
>
> And there was a very willing audience that wanted to hear this, and Lucy and her organization was taking off. People were puzzled and journalists were puzzled, baffled that, you know, I remember talking to [ex-Prime Minister] Tony Abbott and he thought that it was legal and that everyone could get it just by going to the doctor. There was just this kind of broad disconnect between what people thought was going on and what was actually going on." (McGregor, 2021)

Although medicinal cannabis remained a live political issue, the federal government appeared reluctant to take responsibility for a situation that they claimed was being caused by the states. During federal senate estimates hearings in March 2017, A/Prof John Skerritt, Department of Health Deputy Secretary, provided an update on the performance of the medicinal cannabis framework (Commonwealth of Australia, 2017).

Senators questioned why patients were reporting that applications to access medicinal cannabis were taking several weeks to process. Skerritt explained this was usually due to prescribers providing incomplete information in their applications to the TGA, in addition to whatever delays might be occurring at the state level, noting, "I hear very different timelines for states, ranging from a couple of weeks to longer. But it is really something the Commonwealth cannot influence" (Commonwealth of Australia, 2017, p. 192).

But these kinds of explanations, involving health system regulations and the differences between federal and state responsibilities, failed to cut through against the new policy image of medicinal cannabis: that it was legitimate, legal, and should be made available. Public pressure to fix access continued to mount in the months following legalisation. At the same time, the federal government's approach to patient access appeared to be reconfiguring into one more conducive to the demands of advocates, who became increasingly incorporated into policymaking processes.

Venue switching

To assist the minister for health with the implementation of the medicinal cannabis scheme – which included both patient access as well as commercial licensing and import/export – the federal

government established the Australian Advisory Council on the Medicinal Use of Cannabis (the Council). Carol Ireland was the first and, at the time, only patient representative invited to sit on the Council. The Council's first Communique from its inaugural meeting in April 2017 raised the issue of patient access, commenting that,

> "The Council has noted that differences in regulatory policy and patient access between jurisdictions are likely to add confusion to an already complex and emerging scheme. The Council will work through the Department of Health to look at how such differences could be addressed." (Australian Advisory Council on the Medicinal Use of Cannabis, 2017)

In May 2017 the Council created the Cannabis Patient Access Working Group, of which Carol Ireland was also a member. This working group was primarily focused on harmonising patient access requirements across the various jurisdictions and reducing the complexity of access processes. According to Carol, this exercise was extremely difficult. The diversity of stakeholders, their competing priorities, and their beliefs about the benefits and risks of medicinal cannabis posed a significant challenge. Carol recalls,

> "I was sitting around a fairly large table and there were representatives from the pharmaceutical industry, from medicine, from the Australian Federal Police, there was a QC. It was a really, really diverse group. And oh, my goodness, on the one hand it might be a good thing coming from really diverse backgrounds, but on the other, it's not easy to find common ground." (Ireland, 2021)

These difficulties were multiplied by the number of jurisdictions that needed to be considered and brought into some kind of agreement on a nationally-consistent access framework.

> "First of all, I think it's one of the curses of federation that when we come to deal with any issue that affects the population at large and probably affects them in the same way, then we've got different states and territories, governments and their bureaucrats that are actually taking different approaches. And honestly, I think it came down to that, you know, you had people at different levels of acceptance and awareness and their own existing state- or territory-based processes.
>
> And therefore, everyone took a different approach. They were all on board. They were all at the table in one way or another. But different states and territories were far more progressive than others. And, you know, again, from a consumer point of view, when we're representing Australians across the country, that was problematic. Probably can't go any deeper into that." (Ireland, 2021)

In December 2017, a year after legalisation, the Council's fourth Communique made no mention of harmonisation efforts, or of the challenges being faced by patients at the state levels. The Communique discussed federal approval processes and timeframes only, which were framed in a positive light.

> “There has been a ten-fold increase in applications in 2017 (from 38 in 2016 to 380+ in 2017). Where approval is given, it is given in 1 working day or less in a third of cases and three-quarters of approvals are given in 10 working days or less. Terminally ill patients are accessing medicinal cannabis through SAS Cat B in a timely fashion. Where there are delays, this rests entirely with doctors who are not responding for requests for basic medical information in a timely fashion.” (Australian Advisory Council on the Medicinal Use of Cannabis, 2018a)

Carol Ireland’s experience suggests that there were diverse policy communities across a number of jurisdictions, with different attitudes towards medicinal cannabis. Legalisation had dismantled the previously-stable policy monopoly, producing a volatile series of reforms as these communities vied for the institutionalisation of their preferred policy outcomes.

New punctuations

In January 2018, the federal health minister, Greg Hunt, issued a media release promoting upcoming regulatory amendments that would permit Australian-made medicinal cannabis products to be exported (Australian Government Department of Health, 2019). In further comments made to the media, Hunt stated that "there are now no real government barriers at all to accessing medicinal cannabis" (Clarke, 2018) and that “it is up to individual doctors – governments shouldn’t interfere in the prescribing practices of individual doctors” (AAP, 2018).

The day after those comments, a separate media story about medicinal cannabis was published (Barro, 2018). The story included comments from Dr Teresa Towpik, a general practitioner from NSW, who had been declined an approval for one of her patients by the TGA because the TGA had determined that, in this case, the endorsement of a condition specialist was required. After securing the endorsement of the specialist and subsequently receiving the TGA approval, Dr Towpik’s application was rejected by the NSW Health Department.

A TGA spokesperson quoted in the article rejected the assertion that the current system was “protracted and difficult” (Barro, 2018). To illustrate the protected and difficult nature of Australia’s medicinal cannabis access framework, a flowchart [Figure 1] was included in the article that demonstrated the different steps that had to be taken in each jurisdiction to pursue a medicinal cannabis prescription at the time.

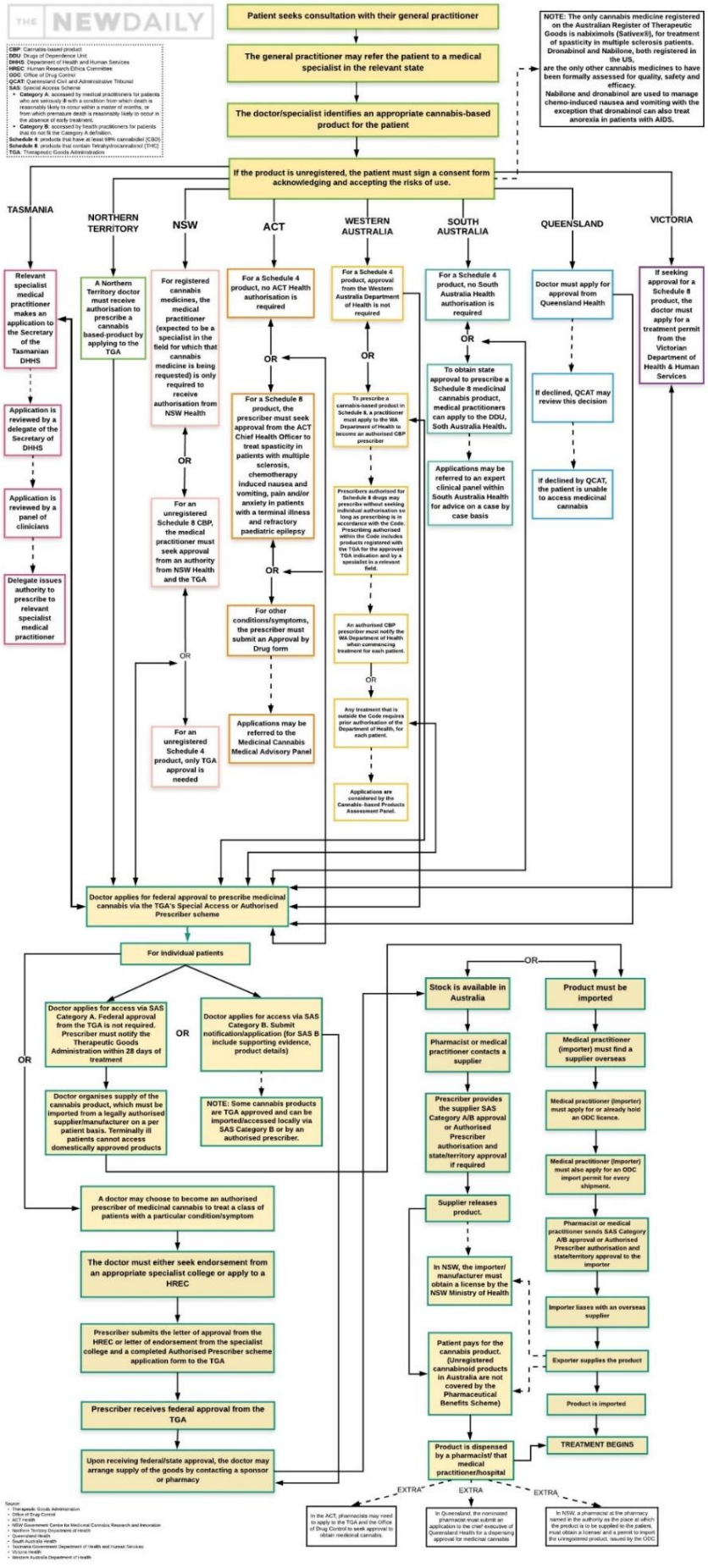

Figure 1 - patient access flowchart

In reaction to Hunt's comments to the media, Lucy Haslam convened a meeting of medicinal cannabis advocates, clinicians and scientists to build consensus on policy priorities and lobbying activities, forming a group that was termed the "Australian Medicinal Cannabis Alliance" (Barro, 2018; Bath, 2018; Esposito, 2018). The meeting was held within days of Hunt's comments, and was hosted by Mills Oakley law firm, where Teresa Nicoletti was a Partner. Chatham House rules were in effect, which prevents identifying specific individuals who attended, but it marked a turning point in how advocates approached policy reform. 'Outsider' strategies such as using the media to put pressure on senior politicians continued to be used but the Alliance meeting demonstrated that advocates, as a policy community, were organised and capable of attracting different kinds of political power in addition to the blunt instrument of public support.

The streamlining of patient access, which had been absent from the most recent Communique of the Australian Advisory Council on the Medicinal Use of Cannabis, rose to the top of the agenda. The Council met in February 2018, the month after the Alliance meeting, and "discussed public frustration with access to medicinal cannabis, and noted the potential duplication in Commonwealth and state and territory approval processes as an area of concern", and stated that Hunt had "written to the state and territory health Ministers to seek support from his colleagues to address challenges faced by patients in accessing medicinal cannabis" (Australian Advisory Council on the Medicinal Use of Cannabis, 2018b).

In March, Hunt announced that the federal government would be working with NSW to streamline patient access processes (Laurence, 2018). In-depth clinical assessments of applications would no longer be conducted by NSW, which would speed up processing times and greatly reduce the ability of the state health department to reject or delay applications. Hunt also announced the federal government was working with all states to harmonise access processes. There was still some resistance to these changes from state health bureaucracies, but this was soon overcome. Teresa Nicoletti recalls one such case regarding a patient seeking access to medicinal cannabis.

> "There had been federal approval, but it had been obstructed at the state level. And I wrote quite forcefully to both the federal health minister and the state health minister, at a time when both governments had decided that they would agree to streamlining, but were still stalling it. That was probably one of the most forceful occasions where I said to them, "if this isn't done in a week, I'm just going public with it because there's no reason to keep stalling it". And three days later, they gave the approval and they dispensed with the state regulation. And I don't like doing that, but that's an example of strong advocacy for my patient, for the patient I was acting for." (Nicoletti, 2021)

In April 2018, the Health Council of the Council of Australian Governments met, and representatives from every Australian jurisdiction agreed to support a new, single, online patient access application portal (COAG Health Council, 2018). This launched in July, initially for NSW, Victoria and Queensland

(Australian Advisory Council on the Medicinal Use of Cannabis, 2017), expanding to South Australia, Western Australia and the Northern Territory from September (Australian Advisory Council on the Medicinal Use of Cannabis, 2019a). The Australian Capital Territory joined later that year, while Tasmania eventually joined in July 2021 (Premier of Tasmania, 2021).

In March 2019, the Australian Advisory Council on the Medicinal Use of Cannabis "acknowledged the portal had been reflected positively in the press" (Australian Advisory Council on the Medicinal Use of Cannabis, 2019b). Although several jurisdictions initially maintained some sort of state approval requirement and/or clinical assessment, the portal greatly simplified the application process. Instead of having to submit two separate applications, with different information requirements, to both the federal and state governments, prescribers only needed to complete a single online form tailored to their jurisdiction. Crucially for advocates, this also came with the commitment that complete applications would take less than 48 hours to be assessed by both state and federal authorities. After signing onto the portal and committing to a 48 hour turnaround, some states then further reduced barriers to patient access, which will be discussed in more detail in Chapter 6.

Conclusion

Chapter 5 has shown that federal legalisation alone was not sufficient to produce the outcomes that advocates expected. Following legalisation, advocates confronted new policy communities and sub-systems that did not share their objectives, some of which acted to constrain patient access. Advocates responded by both adapting and intensifying their lobbying efforts, maintaining public media pressure while also engaging directly with senior politicians and bureaucrats. Conflict between advocates and governments escalated in early 2018 which motivated the launch of a new advocacy campaign. This was followed by the intervention of senior federal policymakers which resulted in a new online portal intended to streamline and expedite patient access. Despite some opposition from state health departments, the portal was successfully implemented across most states within a matter of months.

Chapter 6 discusses the 2018 reforms in more detail, including how the implementation of the online portal produced further reforms to patient access policies in several states. It shows that advocates responded positively to these changes, which have greatly expanded access, leading to more collaborative relationships between advocates and governments. It provides evidence that advocates have become incorporated into a new policy monopoly, and provides insights from advocates about the dynamics of policy change. It concludes by identifying some outstanding policy issues, and potential threats to this new policy monopoly.

6. Harmonisation

Introduction

This chapter explores how the creation of a streamlined approach to patient access exposed state governments and health department bureaucracies to significant external pressure. It analyses the impacts that federal intervention had on access processes, how this was followed by additional reforms across the states, and how advocates responded positively to these changes. It provides evidence to suggest that a new policy monopoly is forming, partially incorporating advocates and their demands. Outstanding issues that advocates still have with patient access are discussed, as well as some potential threats to the future of patient access to medicinal cannabis in Australia. This is followed by the conclusion to the thesis, which summarises the findings and proposes future research directions.

Expansion of patient access

The creation of the portal described in the previous chapter placed state governments in a position where they could either sign up to the portal and its expedited access processes, or be identified as opposing improvements to patient access, making them political targets for advocates and other pro-reform groups. It also demonstrated that the federal government was prepared to engage with the states and their health department bureaucracies to ensure that access processes were overhauled. This brought significant and sustained external attention to bear on what were otherwise relatively hidden policy sub-systems.

States could only sign up to the portal if they committed to processing applications in a timely fashion, which limited their ability to require in-depth clinical assessments, and reduced the extent to which applications could be subject to ad hoc conditions. Some states, such as NSW, initially failed to comply with this commitment (Esposito and Hennessy, 2019), but eventually fell into line. According to Teresa Nicoletti, this greatly improved patient access,

> "If you consider what the framework was like in the beginning, some of the pro bono cases I dealt with […] were taking six to nine months to get access. And a lot of lobbying and a lot of writing backward and forward to regulatory authorities to get those approvals. And if you look at it now, when we're processing applications in 24 to 48 hours, it's extraordinary progress that we've made in the space of the five years since legalisation." (Nicoletti, 2021)

After the creation of the portal in 2018, several states went on implement additional policies expanding access. For example, by no longer conducting in-depth clinical assessments at the state level; by entirely removing the requirement for prescribers to seek approval from the state for most of their patients; or by allowing general practitioners to prescribe medicinal cannabis without requiring a condition specialist endorsement.

Empowering general practitioners to prescribe without needing specialist endorsement has been particularly impactful. From 2017 to 2019, the number of medicinal cannabis prescribers in Australia grew from 108 to 1,465, with approximately 55% of those being general practitioners (Australian Government Department of Health, 2020, p. 14). From 2017 to 2019, the cumulative number of approvals for medicinal cannabis access grew from 457 to over 18,000 (Australian Government Department of Health, 2020, p. 15). Accurately estimating the number of patients – as opposed to approvals – is difficult, due to the nature of how this data is collected, but the cumulative number of approvals has since grown to over 200,000 as of November 2021 (Therapeutic Goods Administration, 2021).

Although patient access regulations in several jurisdictions have remained unchanged since 2016 (such as South Australia, the Northern Territory, and Victoria), others have undergone significant reforms. For example, in 2016, Queensland's *Public Health (Medicinal Cannabis) Act 2016* (Qld) required prescribers to get state approval before prescribing Schedule 8 or Schedule 4 medicinal cannabis products, and often required general practitioners to have the endorsement of a condition specialist. The state also conducted in-depth clinical assessments of applications which could take weeks to complete. In 2019, the Health Legislation Amendment Regulation (No. 2) 2019 (Qld) repealed the Act and removed all of those conditions. Since 2018, NSW, Tasmania, Western Australia, and the Australian Capital Territory have also expanded access (see Appendix 1). According to Iain McGregor,

> "It all got very federal all of a sudden because the states bowed out of access, and in a way that was a tremendous relief." (McGregor, 2021)

This suggests the primary policy venue for medicinal cannabis advocacy has shifted back to the federal government. Policies remain nationally uneven, and some states have been quicker to liberalise access than others. But prescribers in more permissive states can consult with and prescribe medicinal cannabis to patients across state lines. This has resulted in an uneven distribution of access, with most approvals originating in the more permissive states. For example, approvals for Queensland prescribers now account for approximately half of all approvals nationally (Therapeutic Goods Administration, 2021), and many of those approvals are likely for patients living in other states.

A new policy monopoly?

If the series of reforms to patient access made following legalisation indicates the formation of a new policy monopoly, we should expect to see a reduction in conflict between advocates and other stakeholders, and a stabilisation of policy change. This would indicate that certain groups have been able to secure a "monopoly on political understandings" premised on maintaining a "dominant image of the policy problem" (Cairney, 2012, p. 179). While advocates believe there is much more work to be done, there is evidence of a growing political consensus about what patient access should look like.

For example, Iain McGregor reports that,

> “We've all become a little bit more grown up and a little bit more relaxed about where we are. Not too relaxed, there's still huge amounts of work to do. But I'm certainly in a much happier place than I was back at the beginning of this journey.” (McGregor, 2021)

For Teresa Nicoletti,

> “I think many of us that have worked in this industry from the outset can say that we enjoy a much more collaborative relationship with all the regulatory authorities that are involved. And that's been quite a rewarding journey in some respects because you don't feel like you've constantly got targets on your back or that it's irreparably harmed relationships with the people that you deal with professionally every day.” (Nicoletti, 2021)

For Lanai Carter,

> “It's been a really interesting experience, seeing the prescribed model evolve. But I've also seen all of the limitations, and I guess the thing is, it's nice to see that the government is kind of allowing this to evolve to a degree. But there's still so much more that's needed for the patients.” (Carter, 2021)

For Justin Sinclair, the interview process provided an opportunity to reflect on just how much patient access policies have changed, and to put these changes into perspective.

> “It's very easy, I think, for us to focus on the negatives because they're the things that sometimes have the biggest impact on us. But you've actually, with the questions that you've asked, allowed me to actually see where we started and where we are. And I think, as I said, you know, I've never really reflected on how much […] Australia has actually been able to achieve. To facilitate patient access to quality, standardised medicinal cannabis, with protections around what that quality should look like. Yeah, that's pretty cool, I think.” (Sinclair, 2021)

Perhaps the most compelling evidence that advocates have been incorporated into a new policy monopoly comes from Lucy Haslam. While Lucy has maintained a consistently critical assessment of patient access policy, and continues to lobby for its improvement, her attitude regarding government engagement has begun to shift. Despite Lucy’s assertions that her lobbying has been ineffective, and that policy makers “can’t stand me and probably go, oh not that woman again” (Haslam, 2021), there are signs that she is becoming more collaboratively engaged in government policy development.

> “I want Dan's legacy to be something that he would be proud of and I don't think I'm proud of it yet. I think [the expansion of access] happened in spite of the government, not because of the government […] For me, I think success will be when we actually have a compassionate access scheme that is effective and where governments aren't interfering and where, you know,

everybody is patient-focused […] Hopefully we'll have something to announce at the Symposium in that regard. We are just taking the first steps to engage with government on making that a reality, and government being part of the process rather than running interference. So, I think we've all grown up a bit and we're hoping that, even though we've got a shitty system, that we can start to influence the shitty system so it's a little less shitty." (Haslam, 2021)

How policies change

Through their involvement with medicinal cannabis policy reforms, advocates have developed perspective about how policies change, which are relevant to this case study and potentially to other drug law reform efforts. Advocates attribute the scale and speed of these changes to a number of factors, including the impact of patient stories and direct lobbying efforts, which accelerated the acceptance of medicinal cannabis in the minds of key policy communities. But engaging productively in this kind of advocacy can be challenging. According to Carol Ireland,

> "You start with understanding and knowing what your consumers want and you're able to express that. But it needs to be expressed in a way that doesn't alienate some of the other key stakeholder groups. You know, you've got key stakeholder groups in government and the medical sector here for a start. And if you alienate them, I think they will stop listening. You've got to find the common ground where there's respect and they will listen. That's not easy." (Ireland, 2021)

In addition to effective stakeholder lobbying, advocates pointed to the overall 'normalisation' of medicinal cannabis as an important factor behind policy reforms. Iain McGregor asks,

> "Can sociologists or policy wonks describe a typical trajectory where, you know, there's years and years of struggle followed by normalisation, the realisation that people hear it enough – medicinal cannabis, medicinal cannabis – that it just gets normalised and then suddenly it's there and people just don't realise that there was a time when it wasn't?" (McGregor, 2021)

Both normalisation and direct lobbying brought stakeholders closer to a shared understanding of medicinal cannabis, how it may help people, and how it should be managed. In Lucy Haslam's words,

> "People are getting more educated whether they like it or not. Including doctors, including bureaucrats." (Haslam, 2021)

For Teresa Nicoletti, change has come about through the combined efforts of multiple advocates engaging in largely uncoordinated ways with different parts of the policy system.

> "I don't think any of us had a strategic plan at the outset for how the scheme would evolve, and I don't think there's a textbook process that people should follow if they want to affect policy change. I think what did it for us is cogent arguments that we all presented to government and a

> movement of advocates who all had experience and skills to affect that change. So, if you look at it, we've had scientists, we've had lawyers, we've had nurses, we've had doctors, we've had patients that have all been advocates in a positive way. And each of them has tackled this issue from a different angle." (Nicoletti, 2021)

This assessment is shared by Lanai Carter, who attributes a few key advocates with particular influence,

> "The Greens obviously, I would have to rate pretty highly as, you know, as being very instrumental in a lot of things. And Lucy, Justin Sinclair, the Lambert Initiative, all the team there. Carol Ireland and Epilepsy Action Australia. I mean, they were really incredible." (Carter, 2021)

According to Justin Sinclair, while many advocates have contributed to policy reforms, patients have been the most influential,

> "They really don't know how much impact they had. And yes, it started with Dan, it started with Lucy. But there's been a lot of others that have stepped out. And it's painful to watch them get ridiculed or suffer in the public domain because it puts a focus on you. And many of them are actually very private people, but they're doing it because they thought it was the right thing to do, and it was the one thing that they could do – the only thing that they felt empowered that they could do – to make change." (Sinclair, 2021)

Future reforms

While patient access has improved considerably, issues remain for advocates. A federal senate inquiry into barriers to patient access to medicinal cannabis, led by the Greens, tabled its report in March 2020 (Australian Community Affairs References Committee, 2020). Lanai Carter made a submission, while the other advocates interviewed for this research made submissions and testified at the public hearing. The inquiry produced 20 recommendations, including that more education and training on medicinal cannabis be made available to healthcare professionals, and that additional reforms should be made to further streamline patient access approvals, both at the federal and state levels.

Laws covering driving were flagged as a barrier to patient access, as random roadside drug testing conducted by state governments can penalise legally-prescribed medicinal cannabis patients for driving with the presence of cannabis in their saliva, even while they are not impaired (Perkins *et al.*, 2021). Financial costs to patients were also identified as a barrier: unregistered medicinal cannabis products are not eligible for government subsidies, and when patients struggle to find a prescriber who is educated about and willing to consider medicinal cannabis, they are often forced to rely on private 'medicinal cannabis clinics', which can charge hefty consultation fees (Australian Community Affairs References Committee, 2020, p. 76).

In the 2020 senate inquiry report, these clinics were characterised as expensive but largely benign companies that provide a much-demanded service. But both Teresa Nicoletti and Carol Ireland raised concerns about these clinics during their interviews, and the potential risks that some of them pose to the new policy monopoly grounded in the shared political understanding that barriers to patient access should be reduced. Carol Ireland explains,

> "There's still a lot of frustration. I mean, the fact that most of the cannabis that is available via prescription is still unapproved product, is still costly, that people go to clinics to get the product. I've got some recent examples of parents I'm talking to with very young babies now. There's one that I've been talking to that has an 11-month-old, there's another one that has a two-year-old.
>
> Now, I would have told you back a year or two ago that they would not get a script. Their neurologist would not have been prescribing and nor would anyone else touch that area of very young children, paediatrics. They've actually got scripts now and they've got those scripts through a clinic. But through conversations, I'm still really aware that they don't have the medical supervision that they really should have. The government's approving the product, it's getting through. These are families that can pay for it. Some can't, these can. But that paediatric specialty is not there." (Ireland, 2021)

Teresa Nicoletti also commented that, should access become so unrestricted that it risked public health, the consequences could be significant.

> "I have to say that I have deep concerns, ongoing deep concerns about some of the clinic setups and the lack of proper patient oversight in decision making. And that can't be a good thing all around for the regulatory scheme. Because if there are public health and safety risks, patient health and safety risks, then it will undermine the scheme. And then you'll start to get regulatory barriers being reintroduced. So, it's in our interests, as an industry, to play a role in ensuring that every aspect of patient access is carried out to the highest standards." (Nicoletti, 2021)

Punctuated equilibrium theory can help explain how patient access policies have been expanded, but also how those changes might be reversed. Rychert and Wilkins, writing about the regulation of novel psychoactive substances in New Zealand, remind us that "policy reversals are not impossible, but are to be expected. After all, the possibility of change is a major implication of their [Baumgartner and Jones'] theory … PET offers one possible explanation for the reversal: the extent of mobilization of criticism" (Rychert and Wilkins, 2018, p. 2137). Policy monopolies are not just the institutionalisation of stakeholder preferences. They represent the constant efforts of communities building and maintaining consensus around a policy image. A monopoly might be relatively stable for long periods of time, but

there is always the potential for it to be contested. As advocates continue their work to expand access, they remain vigilant for future developments that may threaten the progress made so far.

Conclusion

Chapter 6 has explored how the creation of a streamlined approach to patient access exposed state governments and health department bureaucracies to significant external pressure. It analysed the impacts that federal intervention had on access processes, how this was followed by additional reforms across the states, and how advocates responded positively to these changes. It provided evidence to suggest that a new policy monopoly is forming, partially incorporating advocates and their demands. Issues that advocates still have with patient access were discussed, as well as some potential threats to the future of medicinal cannabis in Australia. In Chapter 7, the conclusion to this thesis, the overall findings are summarised and some future research directions are proposed.

7. Conclusion

Cannabis policies are changing. In just the last few years, access to cannabis for medicinal purposes has been legalised in dozens of countries, including Australia in 2016. Many US states and several countries have also legalised access for non-medicinal purposes. These changes represent a historic shift in drug policy. While it is crucial to investigate the impacts that these various newly-legal frameworks may have on societies, it is also necessary to inquire into the dynamics of these policy changes, and to ask how and why they have come about. This kind of research can be challenging, not least because many new reforms are continuing to emerge worldwide. For some drug policy scholars, this has permitted only a cursory examination of various case studies which, as a result, tends to prioritise highly-visible policy changes such as federal legalisation. While such events are, of course, highly relevant, this can mean that more subtle reforms following legalisation may be missed. This is particularly relevant for the Australian case, where the initially restrictive framework that was implemented has undergone significant change.

This thesis has explored two questions: how and why have policies regarding access to medicinal cannabis in Australia changed since legalisation, from the perspective of patient advocates? And is there evidence to suggest that a new approach to medicinal cannabis policy is forming in Australia, one that better incorporates advocates and their demands?

These questions were addressed by using theoretical and methodological approaches that are sensitive to complex and ongoing policy changes. A review of the literature confirmed that patient access policies have changed in the years following legalisation. It also identified patient advocates as key actors in the legalisation of medicinal cannabis. Building on previous approaches to drug policy research, theories of structured interaction were used to examine documentary research on changes to patient access policies. This developed a periodisation that was best explained by Baumgartner and Jones' theory of punctuated equilibrium (Baumgartner, Jones and Mortensen, 2018). A purposively-sampled group of patient advocates were identified and participated in in-depth semi-structured interviews. Iterative analysis of interview data and documentary research clarified the stages of policy change around which the findings chapters have been structured.

Overall, this thesis found that medicinal cannabis patient access policy in Australia has evolved in three stages. First, advocates campaigned for federal legalisation and, through strategic use of the media that framed their issue as one of urgent medical necessity, were able to attract significant public support. Advocates believe that this public pressure led to political action and, despite resistance from some sections of the medical community and health department bureaucracies, and also due to political economic constraints related to the regulation of pharmaceutical opiates, legalisation was secured in 2016.

But legalisation was not the end of the reform process. It was a highly visible punctuation that was followed by a series of volatile changes and further rounds of contestation, as policy communities vied for their preferred outcomes. Frustrated by these new and unexpected barriers, advocates intensified their lobbying efforts and modified their strategies as they became familiar with the machinery of government, and better incorporated into policymaking processes. This was followed by a second intervention from senior federal policymakers in 2018 and the streamlining of patient access through a new online portal. Following the 2018 intervention, patient access has improved considerably, and advocates report less conflict with competing stakeholders and more collaborative relationships with government, indicating the formation of a new policy monopoly.

The findings presented in this thesis, and the theories and methods used, all invite further scrutiny. While the evolution of medicinal cannabis patient access policy in Australia appears to be well explained by punctuated equilibrium theory, other approaches, such as the ones identified in Chapter 2, may prove to have greater explanatory power, or reach findings that support or contradict those developed here. The recency of the Australian case may also present difficulties, as future events could also challenge these findings.

This thesis has focused on the role of patient advocates in influencing policy change, and is drawn substantially from their lived experiences. These are individual perspectives, retrospectively constructed through the interview process, and not definitive facts. There have, of course, been other factors that have contributed to these changes. Other policy communities, such as the medicinal cannabis industry, have lobbied for improvements to patient access policies. The cannabis industry's role in driving policy change was not often raised by advocates, despite these communities being well known to each other. This might indicate that advocates were ignorant of industry lobbying activities, or that the relatively small, new industry lacked the kind of influence that advocates developed. Understanding the role of the industry during this time period may contrast with advocate's perspectives and should be considered for future research.

The role of healthcare professionals and prescribers also warrants further inquiry. These communities are central to patient access and advocates continue to make considerable efforts to influence their beliefs and behaviours. Advocates identified what they believed were clear points of conflict between groups within these communities, with condition specialist physicians and their professional associations often holding opposing views to those in general practice and nursing. This apparent schism and its relationship to medicinal cannabis, and to other kinds of drug policy change, would also benefit from more research.

Political and bureaucratic policy communities have featured prominently in this thesis, but from the perspectives of advocates, who generally encountered them as opponents to be won over or defeated. A deeper analysis of these groups and institutions, and their relationships to other sites of power such

as the pharmaceutical industry and systems of international drug control, could be a fruitful line of inquiry, both to develop a better understanding of the dynamics of medicinal cannabis policy, and of drug law reform in general.

Appendix 1 – documentary analysis

This table summarises changes to legislation, regulation, and policy, as well as some announcements and government reports, between 2014 and 2020 (inclusive) that are related to patient access to medicinal cannabis in Australia. A brief description of each event and its relevance is provided. The list is non-exhaustive.

Year	Month	Jurisdiction	Type	Title	Description
2014	Nov	Cwth	Bill	Regulator of Medicinal Cannabis Bill 2014 (Cwth)	Proposes the legalisation of production and patient access to medicinal cannabis, managed by a regulatory authority separate from the TGA.
	Dec	NSW	Policy	Terminal Illness Cannabis Scheme (TICS) and clinical trials (AAP, 2014; New Zealand Drug Foundation, 2016)	TICS allows people with terminal illnesses to register as illicit medicinal cannabis users, encouraging police discretion in prosecution. $7m in government funding is announced for three medicinal cannabis clinical trials.
2015	Jun	Cwth	Legislation	*Poisons Standard June 2015* (Cwth)	Makes purified cannabidiol (a non-intoxicating cannabinoid) a Schedule 4 prescription-only medicine. Amendments to the Poisons Standard are automatically incorporated by most states, but the effects on patient access processes can vary considerably between states.

Year	Month	Jurisdiction	Type	Title	Description
	Aug	Cwth	Senate committee report	Inquiry into the Regulator of Medicinal Cannabis Bill 2014 (Australian Legal and Constitutional Affairs Legislation Committee, 2015)	Recommends the Bill be significantly amended to ensure compliance with international drug control laws and maintain TGA-control over patient access.
	Oct	VIC	Report	VLRC Medicinal Cannabis Report (Victorian Law Reform Commission, 2015)	Recommends VIC legalise the commercial production and patient access to medicinal cannabis.
	Nov	VIC	Bill	Access to Medicinal Cannabis Bill 2015 (Vic)	Follows recommendations from VLRC Report to legalise commercial production and patient access to medicinal cannabis. Access will be limited to: • Paediatric patients with intractable epilepsy • Condition specialist prescribers • Schedule 4 cannabidiol products
	Dec	QLD	Regulation	Health (Drugs and Poisons) Amendment Regulation (No. 1) 2015 (Qld)	Permits the state to approve the prescription of medicinal cannabis as a Schedule 9 poison.
2016	Feb	Cwth	Legislation	Narcotic Drugs Amendment Bill 2016 (Cwth)	Referred to as “Dan’s Law”. Amends the Narcotic Drug Act 1967.

Year	Month	Jurisdiction	Type	Title	Description
					Legalises the commercial cultivation and manufacture of medicinal cannabis. Production and import/export managed by Office of Drug Control, patient access managed by the Therapeutic Goods Administration.
	Apr	VIC	Legislation	*Access to Medicinal Cannabis Act 2016* (Vic)	Enacts the Access to Medicinal Cannabis Bill 2015. Act is passed but not implemented, and is later repealed.
	Jul	NSW	Regulation	Poisons and Therapeutic Goods Amendment (Designated Non-ARTG Products) Regulation 2016 (Nsw)	Prescribers must seek state authority to prescribe Schedule 8 medicinal cannabis products. State conducts in-depth clinical assessments and may impose requirements including endorsement by a condition specialist.
	Nov	Cwth	Legislation	*Poisons Standard November 2016* (Cwth)	Makes medicinal cannabis a Schedule 8 controlled drug, unless captured in other Schedules. Amendments to the Poisons Standard are automatically incorporated by most states, but the effects on patient access processes can vary considerably between states.
	Nov	Cwth	Regulation	Therapeutic Goods and Other Legislation (Narcotic Drugs) Regulation 2016 (Cwth)	Allows companies to be issued with cannabis cultivation, manufacture and research licenses. Also restricts patient access through the SAS-A pathway.

Year	Month	Jurisdiction	Type	Title	Description
	Nov	ACT	Announcement	ACT Medicinal Cannabis Scheme (ACT Health, 2018)	Prescribers must seek state authority to prescribe Schedule 8 medicinal cannabis products if used for more than 2 months, or if the patient is drug dependent. State conducts in-depth clinical assessments and may impose requirements, including endorsement by a condition specialist.
2017	Jan	WA	Regulation	Medicines and Poisons Regulations 2016 (Wa)	Prescribers must seek state authority to be designated as a 'cannabis-based medicine prescriber' to prescribe Schedule 8 medicinal cannabis products. State conducts in-depth clinical assessments. Condition specialists must be involved in co-treatment with general practitioners.
	Mar	QLD	Legislation	*Public Health (Medicinal Cannabis) Act 2016* (Qld)	Prescribers must seek state authority to prescribe Schedule 8 and Schedule 4 medicinal cannabis products. State conducts in-depth clinical assessments and may impose requirements including endorsement by a condition specialist.
	Apr	SA	Announcement	Patient access pathway (SA Health, 2017)	Clarifies patient access pathways created by Cwth Poison Standard amendment. Prescribers must seek state authority to prescribe Schedule 8 medicinal cannabis products if used for more than 2 months, or if

Year	Month	Jurisdiction	Type	Title	Description
					patient is drug dependent. No authority required for patients 70 years or older, or who are Notified Palliative Care Patients. State conducts in-depth clinical assessments and may impose requirements including endorsement by a condition specialist.
	Jun	Cwth	Regulation	Disallowance of items 1 and 4 of the Therapeutic Goods and Other Legislation (Narcotic Drugs) Regulation 2016 (Cwth)	Disallows items that prevented patient access via the SAS-A pathway.
	Sep	TAS	Policy	Controlled Access Scheme (Premier of Tasmania, 2017)	Prescribers must seek state authority to prescribe medicinal cannabis products. Only Schedule 4 medicinal cannabis products are permitted. Only condition specialists may apply. Products are subsidised by the state. No other access outside the Scheme is permitted.
	Sep	Cwth	Legislation	The Medicinal Cannabis Legislation Amendment (Securing Patient Access) Bill 2017 (Cwth)	Attempts to re-instate access via the SAS-A pathway. Bill is passed by the senate but not the house.
	Oct	ACT	Regulation	Medicines, Poisons and Therapeutic Goods (Category	Prescribers may apply for a 'category 6' medicinal cannabis approval, which reduces the frequency at which state authorities are required for Schedule 8 products, limited by indication.

Year	Month	Jurisdiction	Type	Title	Description
				Approval) Determination 2017 (No 3) (Act)	
2018	Mar	Cwth, NSW	Policy	NSW streamlining announcement (Laurence, 2018)	NSW ceases in-depth clinical assessments to expedite access approvals.
	Apr	Cwth, states	Announcement	COAG Health Council communique (COAG Health Council, 2018)	COAG announces unanimous support for streamlining patient access through a single online application process managed by the TGA.
	Jul	Cwth, states	Policy	TGA medicinal cannabis access portal launches (Therapeutic Goods Administration, 2018)	Portal launches with NSW, VIC and QLD prescribers first. SA, WA and NT are added within 6 months. TAS is added in 2021.
	Nov	NSW	Regulation	Poisons and Therapeutic Goods Amendment (Cannabis and Unregistered Drugs of Addiction) Regulation 2018 (Nsw)	Prescribers must now seek state authority to prescribe Schedule 8 medicinal cannabis products for new patients only, not continuing patients.
2019	Jul	QLD	Legislation	Health Legislation Amendment Regulation (No. 2) 2019 (Qld)	Repeals the Public Health (Medicinal Cannabis) Act 2016. Prescribers must now seek state authority to prescribe Schedule 8 medicinal cannabis products to drug-dependent patients only. No condition specialist endorsement is required.

Year	Month	Jurisdiction	Type	Title	Description
	Sep	NSW	Regulation	Poisons and Therapeutic Goods Amendment (Cannabis Medicines) Regulation 2019 (Nsw)	Prescribers must now seek state authority to prescribe Schedule 8 medicinal cannabis products to children and patients who are drug-dependent only. No condition specialist endorsement is required.
	Oct	VIC	Legislation	*Health Legislation Amendment and Repeal Bill 2019* (Vic)	Repeals the Access to Medicinal Cannabis Act 2016.
	Nov	WA	Policy	Medicines and Poisons Amendment Regulations 2019 (Wa)	Prescribers must now seek condition specialist endorsement to prescribe Schedule 8 medicinal cannabis products to children and patients who are drug dependent only.
2020	Mar	Cwth	Senate committee report	Current barriers to patient access to medicinal cannabis in Australia (Australian Community Affairs References Committee, 2020)	Report produces 20 recommendations to improve patient access, including further streamlining of state and TGA approval processes.

Appendix 2 – interview agenda

Thank you for contributing your time to this research project. This interview will take around one hour.

The objective of this research is to better understand how medicinal cannabis policy reforms happened in Australia. You have been included in this research due to your involvement with the development of Australia's medicinal cannabis framework.

Below are a series of questions that ask about your role in the policy reform process, with a focus on the groups and networks you built, participated in, or engaged with during this time.

We might not get to all of these questions, and we might end up discussing things that are not directly related to any of these questions in particular. These questions will serve as a guide for our conversation, and you are welcome to focus on some more than others.

After the interview is concluded, you can request a copy of the recording.

Interview questions:

- How did you first get involved with medicinal cannabis policy reforms in Australia?
- What is your general impression of how medicinal cannabis is currently managed in Australia?
- In what capacity did you engage with the policy reform process, and what was that like for you?
- What were some of your key objectives and concerns throughout this process?
- What were the main barriers or challenges you had to overcome to achieve your objectives?
- Which people or groups do you think shared similar objectives and concerns to yourself?
- Were there other stakeholders who you feel had different objectives or competing interests to you and your group?
- How did you collaborate with likeminded people to engage with stakeholders who were pursuing competing interests?
- How effective do you think you were in achieving your goals?
- In your opinion, what are the most significant things (people, events, political/economic conditions etc.) that have shaped Australia's medicinal cannabis framework?
- Are there any other lessons or reflections from this experience you would like to add?

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