NAME OF THE COMMITTEE:

The Standing Committee on Health, Ageing, Community and Social Services.

THE INQUIRY:

Inquiry into the Exposure Draft of the *Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014* and related discussion paper.

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My name is Nicholas Christodoulou, and I am an undergraduate student at the Australian National University (ANU) College of Law. I have recently completed an internship with the Law Reform and Social Justice program at ANU. As part of my internship I was asked to write a paper, which addresses both the international and domestic barriers, which could impact legislative amendments of medicinal cannabis in the ACT. In my paper I have made suggestions, which if followed, would increase the success of a potential Bill. Below, in an attempt to give some background to my comments on the proposed Bill, I have summarised Australia's international obligations to relevant conventions and also how Commonwealth legislation could potentially affect any attempt to reform medicinal cannabis laws in the ACT. Lastly, I have specified why the discussion paper and exposure draft for the Drugs of Dependence (Cannabis Use for Medicinal Purposes) Amendment Bill 2014 in its current form is legally flawed and is unlikely to be approved.

Introduction

In the latter part of 2014 the ACT Government agreed to join a 'Commonwealth-backed' national medical cannabis trial. Opponents of reform are troubled by the potential public health implications associated with cannabis such as schizophrenia, addiction and the credible risk of carcinoma from smoke inhalation. Consequently, the ACT Government must weigh up potential risks with potential benefits and decide whether medicinal cannabis reform is both in the public interest.

The medical use of crude cannabis has been questioned because of health risks associated with pulmonary administration. Furthermore, pharmaceutical companies are hesitant to assist in the registration of crude cannabis on the

Australian Register of Therapeutic Goods (ARTG) due to the difficulties in patenting a natural plant (Report of the Working Party in the Use of Cannabis for Medicinal Purposes, Parliament of New South Wales, Report of the Working Party in the Use of Cannabis for Medicinal Purposes Volume I (2000) 18).

Pharmaceutical companies have manufactured numerous cannabinoid products (synthetic alternatives to crude cannabis) including Nabilone, Dronabinol and Sativex (Arno Hazekamp et al, 'Evaluation of Vaporizing Device (Volcano®) for the Pulmonary Administration of Tetrahydrocannabinol', (2006) 95(6) *Journal of Pharmaceutical Sciences* 1308, 1308). However, problems associated with these products include the difficulty of using oral medication when suffering from nausea or vomiting, the 'unreliable effects' of oral cannabinoids (Hazekamp et al), and the products' exorbitant price (Alex Wodak and Laurence Mather, *Australia Has no Reason to Disallow Medical Cannabis Use*, (26 March 2014) The Conversation).

If, as a matter of policy, the ACT is inclined to enable the medical use of cannabis, this submission proposes that the supply of crude cannabis is a cost-effective option for many patients, especially if cultivation took place within the ACT. This submission proposes a scheme whereby cannabis could be cultivated, prescribed by doctors and used by patients in the ACT. The model will propose a safer alternative to smoking cannabis, whilst maintaining the benefits of pulmonary administration, and will address the potential legal obstacles that the ACT will need to overcome.

International Obligations

Australia is party to several relevant international conventions, namely the *United Nations Single Convention on Narcotic Drugs 1961*, the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*, and the *United Nations Convention on Psychotropic Substances 1971*. Under the *1961 Convention*, cannabis is classified as a narcotic, in the same class as drugs such as cocaine and heroin. Furthermore, the World Health Organisation has placed cannabis in schedule IV of the *1961 Convention*, because cannabis is considered to be 'particularly liable to abuse and [likely] to produce ill effects' (*1961 Convention* art 2(5)(b), art 4(c)).

The *1961 Convention* permits the 'production', 'manufacture', 'export', 'import', 'distribution', 'trade in', 'possession', and 'use', of a prohibited drug, as long as the above mentioned is deemed necessary by a particular country for 'medical' or 'scientific' purposes. There is no definition of the term 'medical and scientific purposes' in the *1961 Convention*, however 'international legal commentary' suggests that the term is 'sufficiently broad' as to include 'the prescription or certification of cannabis' for medicinal purposes (NSW Parliamentary Research Services, 'Issues Backgrounder: Medicinal Cannabis' (Research Paper No 5, Parliamentary Library, NSW Parliament, 2014) 8.).

Article 28 of the *1961 Convention* specifies that cannabis cultivation must adhere to the same controls as opium production found in art 23, which specifies that only a government agency can designate land for cultivation and issue licences to

cultivators, and that the government agency must 'purchase and take physical possession of such crops as soon as possible' after harvesting.[1]

The *1988 Convention* places obligations on member states to, prevent illicit drug trafficking and cultivation, which could be overcome if medicinal cannabis was legalised in the ACT. The *1971 Convention* was produced to 'control drugs not covered by previous treaties' (Graham Pearson, 'Further Chemical Control Regimes: Narcotic Drugs and Psychotropic Substances'(2001) 51 *CBW Conventions Bulletin* 1, 4), and will not affect any potential cannabis policy amendments in the ACT. These conventions do not prevent Australia from permitting the use, import, export or distribution of cannabis for scientific or medical purposes.

Commonwealth legislation and medicinal cannabis

The following Commonwealth Acts present potential barriers to legalisation of medicinal cannabis in the ACT: *Customs Act* 1901 (Cth); the *Customs (Prohibited Imports) Regulations* 1956 (Cth); the *Therapeutic Goods Act* 1989 (Cth); the *Crimes (Traffic In Narcotic Drugs and Psychotropic Substances) Act* 1990 (Cth) and the *Narcotic Drugs Act* 1967 (Cth). The implications of the Commonwealth Acts and Regulations identified above will depend on the details of the proposed ACT Bill.

The Customs Act 1901

The *Customs Act*, would only be applicable if importation or exportation of cannabis is considered, and will be irrelevant if cultivation occurs within the ACT (Report of the Working Party in the Use of Cannabis for Medicinal Purposes). If external importation was deem the only viable option, s 50(3)(a), provides that the

[1] Ibid arts 23(1), (2).
[2] Ibid s 19(5).

'importation of [illicit] goods is prohibited unless a licence, permission, consent or approval to import goods' is provided.

***Customs (Prohibited Imports) Regulations* 1956**

The *Customs (Prohibited Imports) Regulations* list cannabis as a prohibited item under schedule 4. However, under reg 5(1)(a), importation of a prohibited drug is possible if a licence or permission is granted by the Secretary of the Department of Health and Aged Care (DHAC) or other authorised person. The ACT would be expected to comply with several conditions provided for in reg 5(9)in order to obtain a licence to import cannabis, such as the safe custody of the drug. Cannabis is listed as a Schedule I drug, and reg 5(12) of the *Customs (Prohibited Imports) Regulations* specifies that a maximum amount of the drug that is to be imported into Australia must be determined by the DHAC 'in accordance with Australia's obligations under the *1961 Convention* and be notified annually to the International Narcotics Control Board'. Therefore, it would only be possible for the ACT to import cannabis for medicinal purposes if permission is granted by the Secretary. The ACT must then adhere to the regulations specified under reg 5(9), and then the DHAC must make an estimation of the maximum amount of cannabis that is to be imported to the ACT, which then must be relayed to the International Narcotics Control Board.

Narcotic Drugs Act 1967

The *Narcotic Drugs Act* was enacted to implement Australia's international obligations under the *1961 Convention*, and was designed to regulate the

manufacture of drugs. It does not present any significant barrier to medicinal cannabis legislation.

***Therapeutic Goods Act 1989* (TGA)**

Because s 157 of the *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT), states that 'the commonwealth therapeutic goods laws apply as law of the territory' the TGA will be decisive in relation to any medicinal cannabis policy in the ACT.

The TGA creates the Australian Register of Therapeutic Goods (ARTG) 'which lists all therapeutic goods which are approved for supply in Australia and, but for some limited exceptions, only those goods included in the Register can be legally marketed in Australia' Graham Irvine, *Legalisation of Medicinal Cannabis in New South Wales*, (PhD Thesis, Southern Cross University, 2011) 157. Therefore, in order to supply and use cannabis medicinally in the ACT, registration on the ARTG would be essential (NSW Parliamentary Research Services).

Registration of crude cannabis on the ARTG can only be achieved 'on application by a pharmaceutical company'; this is unlikely, because 'of the difficulties patenting cannabis in its crude form' (Report of the Working Party in the Use of Cannabis for Medicinal Purposes), making it less attractive as a viable product for a pharmaceutical company. There would be minimal incentives for businesses to manufacture cannabis due to the ACT's limited potential market size (Australian National Council on Drugs, *Medicinal Use of Cannabis: Background and Information Paper* (25 August 2014) ANCD: Australian National Council on Drugs, 4). Furthermore, drugs are

approved for the ARTG based on the product's 'quality', 'safety' and 'efficacy' (John McEwen, 'What does TGA approval of medicines mean?' (2004) 27(6) *Australian Prescriber* 156, 156). Because smoking is currently the preferred method of administration for most users, as discussed above, the associated health risks may prevent cannabis from gaining approval for the ARTG (Report of the Working Party in the Use of Cannabis for Medicinal Purposes).

Drugs of Dependence (Cannabis Use for Medicinal Purposes) Amendment Bill 2014

In 2004, draft legislation was submitted amending the *Drugs of Dependence Act 1989* (ACT). The proposal permitted medical practitioners to prescribe cannabis and allowed individuals to 'apply to the Chief Medical Officer for approval to possess and use cannabis' and essentially 'self medicate' (Explanatory Statement, Drugs of Dependence (Cannabis for Medicinal Conditions) Amendment Bill 2004 (ACT) 2). In addition to possession and use, the potential amendments proposed that an individual could apply for a licence to cultivate cannabis for medical purposes. The draft legislation also included various new clauses, providing exemption from prosecution, for persons using or cultivating cannabis that has been issued with a licence. The proposal was rejected for, among other things, not being 'developed in accordance with evidence-based medical and/or treatment guidelines and for ignoring Australia's framework for the regulation of therapeutic goods' (Australian Capital Territory, *Hansard,* Legislative Assembly for the ACT, 25 August 2004, 4129 (Mr Corbell)). It also failed to resolve potential obstacles in the legislative framework relating to Commonwealth importation.

The model in the Drugs of Dependence (Cannabis Use for Medicinal Purposes) Amendment Bill 2014 does not 'attempt to set up a [governmental] system for selling or supplying cannabis to people' (Shane Rattenbury, 'Medicinal Cannabis' (Discussion paper, ACT Greens, July 2014) 2), but instead permits individuals suffering from chronic pain to use, cultivate and self medicate with cannabis.

The draft does not respond to the fatal flaws of the 2004 Bill. It does not address Australia's TGA framework or Commonwealth importation legislation, or anticipate Australia's international obligations, particularly under the *1961 Convention*. Legislation that operates inconsistently with Australia's international obligations could have adverse consequences for Australia. In 1989, when the ACT introduced 'infringement notices' for inconsequential cannabis offences, the U.S. and International Narcotics Control Board 'threatened to cut off international markets for Australia's lucrative morphine industry' (D McDonald, 'What are the Likely Costs and Benefits of a Change in Australia's Current Policy on Illicit Drugs?' (Background Paper for an Australia 21 Round Table, Sydney, 31st January 2012) 17.).

Regulator of Medicinal Cannabis Bill 2014 (Cth)

A Commonwealth Bill, currently before the Senate, proposes to establish a 'Regulator of Medicinal Cannabis' who can approve products to be listed on the 'Register of Regulated Medicinal Cannabis Products'. The Register would operate independently from the TGA; accordingly the TGA would not apply to 'things done in accordance with licences or authorisations issued by the new regulator of medicinal cannabis'.

The Commonwealth Bill addresses cultivation and potential international ramifications of not adhering to the *1961 Convention*, particularly arts 23 and 28. It offers a more practical and viable option for reform than either the 2004 or 2014 ACT Bills because it overcomes barriers associated with the TGA and addresses Australia's international obligations.

The Commonwealth Bill signals a direction the ACT proposals could follow on the issue of medicinal cannabis.

Preferred method of administration

There are moderate health risks associated with smoking cannabis from 'noxious…byproducts' (Hazekamp et al), and so the smoking of crude cannabis should not be seen as an appropriate medicinal method of administration. To avoid pulmonary administration, 'Dronabinol' and 'Nabilone', which contain D-9-tetrahydrocannabinols (THCs), are taken orally in capsule form. However, oral alternatives are seen as impractical because of the 'unreliable effects' of oral THCs, and the difficulties in taking oral medication when suffering from nausea or vomiting (Hazekamp et al). An alternative is the mouth spray 'Sativex', but it costs 'between AUD500 and AUD800 a month', a potentially insurmountable financial barrier for patients and carers (Wodak) that leads many patients revert to smoking cannabis (Hazekamp et al).

An alternative pulmonary method of cannabis administration is through vaporisation. A vaporiser heats 'cannabis plant material at a temperature high enough to volatize the active compounds without reaching temperatures which could cause combustion of the plant material' (Justin Fischedick, Frank Van Der Kooy

and Robert Verpoorte, 'Cannabinoid Receptor 1 Binding Activity and Quantitative Analysis of *Cannabis sativa* L. Smoke and Vapor' (2010) 58(2) *Chemical and Pharmaceutical Bulletin* 201, 201). This method distributes cannabinoids rapidly into the bloodstream, thus limiting the prospect of excessive or insufficient dosage, whilst circumventing noxious byproducts associated with smoking. Research undertaken into the 'gas phase of vapourised cannabis', determined that the vapors produced from the vaporiser, efficiently delivered D-9-tetrahydrocannabinols, without 'significant harmful cancer causing combustion products' (Hazekamp et al). Vaporising appears to be a safer alternative to smoking cannabis, 'while maintaining pharmacokinetic advantages of pulmonary administration' (Fischedick, Van Der Kooy and Verpoorte).

Recommendation

If, as a matter of policy, the ACT is inclined to enable the medical use of cannabis, a viable legal framework needs to be established. A 'flexible interpretation' of drug enforcement conventions has accommodated *recreational* drug de-regulation in the US States of Colorado and Washington, but there is a limit to the pliability of the drug enforcement conventions (International Narcotics Control Board, *Report of the International Control Board for 2013*, (4 March, 2014), 96). The ACT can work within Australia's international treaty obligations if it permits cannabis use for medicinal or scientific purposes, and in a particular manner.

Compliance with the *1961 Convention* represents a significant opportunity for the ACT Government because it would have the 'exclusive right' of 'exporting…[and] wholesale trading…', of cannabis which would not only benefit patients but also the economy of the Territory. Cultivation of cannabis should take place in the ACT, which would be more cost-effective than importation and would

also circumvent any Commonwealth importation legislation. However, subsequent proposals should incorporate comprehensive details of the contemplated system of cultivation, so that international obligations are not breached.

To comply with Australia's international obligations under art 28 of the *1961 Convention*, the ACT Government itself ought establish a 'system for selling or supplying cannabis', similar to the cultivation of opium. A scheme that 'permits individuals to apply for personal cultivation licences (Shane Rattenbury, 'Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014' (Exposure Draft, ACT Greens, 7 August 2014), s 16(1) is likely to be incompatible with Australia's international obligations. A scheme must provide for the ACT Government to take 'physical possession' of the cannabis, for distribution to wholesalers in the ACT.

Further, any proposed scheme must resolve the obstacle of registration on the Australian Register of Therapeutic Goods (ARTG). It is unlikely that crude cannabis could be registered on the ARTG (Report of the Working Party in the Use of Cannabis for Medicinal Purposes, Parliament of New South Wales, Report of the Working Party in the Use of Cannabis for Medicinal Purposes Volume I (2000) 18). The ACT could attempt to work within the framework of the TGA in various ways:

- rely on the Australian orphan drug scheme for drugs that are 'not commercially viable to supply' (*Therapeutic Goods Regulations 1990* pt 3B s 16H(2)(b)) , to absorb some of the costs associated with the production and retail of medicinal cannabis

- rely on s 19(1) of the TGA which provides 'exemptions for special and experimental uses' so that an individual, with the permission of the Secretary, can personally import 'specified therapeutic goods that are not registered goods…for use in the treatment of another person'.

- rely on s 19(5) of the TGA which permits a 'specified medical practitioner', with the permission of the Secretary, to supply therapeutic goods to be used as treatment.[2]

Rather than rely on the discretion from time to time of the Secretary, to the ACT could amend s 157 of the *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT), disassociating the ACT from the TGA and thereby creating the possibility of a separate therapeutic register in the ACT that provides specifically for the registration of medicinal cannabis.

To address health concerns with smoking, crude cannabis should be supplied to patients via a prescription and administered via a vaporiser, meaning that the patients sustain the 'advantages of pulmonary administration',[3] and have access to an affordable a product.

[2] Ibid s 19(5).
[3] Fischedick, above n 49, 201.