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Dr Chris Bourke MLA
Chair
Standing Committee on Health, Ageing, Community and Social Services
ACT Legislative Assembly
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Dear Dr Bourke *Chris*

I am writing to you in your capacity as Chair of the ACT Legislative Assembly Standing Committee on Health, Ageing, Community and Social Services (the Committee).

Please find attached the ACT Government Submission (the Submission) to the Committee Inquiry into the Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 and related discussion paper.

The issues associated with the medical use of cannabis products are extremely complex and require detailed and compassionate consideration. I trust that the attached Submission will assist the Committee in its deliberations regarding this important issue.

For further information in relation to the Submission, please contact the ACT Chief Health Officer, Dr Paul Kelly, on 6205 0883.

Yours sincerely

Simon Corbell MLA
Minister for Health

13.2.15

ACT LEGISLATIVE ASSEMBLY

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ACT
Government

ACT GOVERNMENT SUBMISSION

to the ACT Legislative Assembly Standing Committee on Health, Ageing, Community and Social Services 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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INTRODUCTION

The release in July 2014 of the Exposure Draft of the Drugs of Dependence (Cannabis Use for Medical Purposes) Amendment Bill 2014 (the Draft Bill) has generated significant public interest and debate. The ACT Government supports the compassionate intent behind the Draft Bill as outlined in the associated discussion paper. However, it is important that the following issues and perspectives be considered through the Inquiry process:

- a) Medical Perspective – including clinical need, effectiveness, toxicity and indemnity concerns;
- b) Law Enforcement Perspective – including impact on crime, driving and enforcement issues associated with approvals;
- c) Regulatory Issues – including alignment and conflict with local, national and international law;
- d) Public Health Perspective – including the role of the Chief Health Officer and public health risks;
- e) National & Cross Jurisdictional Issues – including the introduction of a Bill at the national level, potential clinical trials and transport across jurisdictions; and
- f) International Experience – lessons to be learnt from frameworks in place overseas.

MEDICAL PERSPECTIVE

CLINICAL NEED

In preparing this submission, clinicians from a variety of specialties were consulted. These specialties include:

- Pain;
- General Practice;
- Neurology;
- Sexual Health;
- Oncology;
- Anaesthetics; and
- Addiction medicine.

These specialties were consulted with a view to assessing the potential clinical need for medicinal cannabis. Consideration should also be given to the possible impact on clinical practice of increased presentations by patients who abuse cannabis in areas such as Emergency Medicine, rehabilitation and mental health services.

Although clinicians are aware that some patients are already using cannabis (either recreationally or medicinally), it is felt that there is very limited clinical need and perceived demand for access to medicinal cannabis.

There is also a general reluctance to recommend cannabis use. This is primarily due to the lack of a quality controlled supply, dosing standards and the absence of approval from the Therapeutic Goods Administration (with the exception of the cannabis extract Sativex®). Patients and clinicians must be confident that what they are using or recommending is a known substance with known effects.

EFFECTIVENESS

There is a paucity of high quality evidence demonstrating the effectiveness of cannabis use in the treatment of the conditions and symptoms outlined in Table 7 of the Draft Bill. Several large scale reviews of the evidence available in scientific literature have highlighted the need for additional research.^{1,2,3,4}

The two most studied cannabinoids are Δ 9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is associated with the psychoactive effects of cannabis consumption, and it appears that CBD plays an important role in moderating the effect of THC. In small scale observational studies, THC has shown some potential as an analgesic while CBD has shown some potential as an antiepileptic and antispasmodic agent. However, there is no conclusive evidence that this effect is greater than the effect of other pharmaceutical medicines.⁵

While it is true that some formulations of cannabinoids show potential in relieving some symptoms in some people, there is a clear need to obtain more definitive evidence of efficacy. In the absence of definitive evidence of efficacy, the vast majority of clinicians are unlikely to consider cannabis as an option for treatment.

TOXICITY

While the therapeutic effects of cannabis remain unclear, there is strong evidence that cannabis use has unpredictable effects on mood and anxiety and deleterious effects on cognition.^{6,7}

Symptomatic relief is generally obtained at doses where patients also experience the psychoactive effects of cannabis. These psychoactive effects include: distorted perception of time, short term memory impairment, euphoria, increased appetite and physical manifestations such as increased heart-rate. These can be viewed as side-effects, in which case cannabis has a negative risk-benefit profile compared to conventional medications, or as a therapeutic effect, in which case cannabis has desirable benefits. Existing studies do not distinguish between the psychoactive action of the drug on pain perception and a potential direct analgesic effect.

Reviews of existing medicinal cannabis programs indicate that many people who find cannabis medically useful have pre-existing or concurrent recreational use which implies acceptance of the psychoactive effects of cannabis.⁸ The acceptance and utility of cannabis as a treatment in those who have not previously been exposed is less well explored.

Most trials conducted to date indicate that cannabis use for medicinal purposes (for periods of 8-12 months) may result in mild to moderate adverse effects and that overdose is associated with less mortality than opiate overdose. However, there are some concerns about possible drug interactions, sensitivities and the toxicity associated with long term cannabis use.⁵

The concentrations of THC and CBD vary significantly among different varieties of cannabis. A recent study of cannabis seizures in NSW indicated extremely high levels of THC and extremely low levels of CBD.⁹ This is likely the result of selective breeding within the recreational use community, as high levels of THC are associated with much stronger psychoactive effects which are sought by recreational users.

Further to the variable concentrations of THC and CBD, the uncontrolled production of cannabis in various preparations (dried to be smoked or ingested in food, in oils to be applied or eaten etc), can result in vastly different concentrations of the cannabinoid compounds in each product. As such, it is difficult to predict what pharmacologic response any cannabis product is likely to elicit.

INDEMNITY ISSUES

Legal advice indicates that under the scheme proposed in the Draft Bill, clinicians who provide a medical declaration in support of an application may be liable for any adverse events that take place as a result of the use of cannabis. This is an unsatisfactory position for clinicians, as in the absence of a quality controlled supply pathway there is no way for clinicians to reliably determine what a patient may be consuming. Given the personal risk involved, it is very unlikely that clinicians would be willing to provide medical declarations in support of applications.

In the event that cannabis use for medicinal purposes is legalised, clinicians will need significant educational support.

LAW ENFORCEMENT PERSPECTIVE

CULTIVATION AND CRIME

Division 2.3 of the Draft Bill describes the process by which persons may apply for and be granted a license to cultivate cannabis. Permitting cannabis to be cultivated at a residential address presents an array of difficulties for law enforcement and has the potential to enable criminal influence on the production, supply, transportation and administration of cannabis. Although section 16(4) of the Draft Bill calls for security measures to be in place, it does not specify what these measures must be or how such requirements are to be enforced.

In addition, it is expected that ACT Policing would receive increased contact from the public through Crime Stoppers and Neighbourhood Watch in relation to the cultivation of cannabis at residential properties. Increased police resources will need to be directed to determining whether or not cannabis is being cultivated legally or otherwise.

CANNABIS AND DRIVING

Cannabis use has a generally negative and profound effect on the skills required for driving. These effects include:

- decreased car handling ability;
- impaired motor skills;
- impaired sustained vigilance;
- reduced perception skills;
- slowed reaction time;
- dulled reflexes;
- impaired time and distance perception; and
- reduced capacity to respond quickly in stressful situations.

Under section 20 of the *Road Transport (Alcohol and Drugs) Act 1977*, it is an offence for a person to drive a motor vehicle on a public street or in a public place if that person has a prescribed drug present in their blood or oral fluid. Motorists are currently tested for a number of drugs including THC. There is no prescribed concentration level applied to this offence.

Section 77 of the *Road Transport (Driver Licensing) Regulation 2000* provides that a person must not drive a motor vehicle if the person's ability to drive safely is impaired by the effects of treatment for any illness, injury or incapacitation. In addition, if a person who is the holder of a driver's licence suffers any permanent or long-term illness, injury or incapacity that may impair their ability to drive safely, the person must tell the Road Transport Authority (RTA) as soon as practicable, but within seven days.

It is a defence to the prosecution of a person for an offence under this section if the person establishes that they were unaware that their ability to drive safely was impaired or they had a reasonable excuse for contravening the section. As cannabis can remain detectable for a long period after it is ingested or inhaled, it is plausible that someone who has consumed cannabis for a medical purpose could unwittingly commit a drug-driving offence due to detectable amounts of cannabis in their body, and this issue will need to be addressed in further detail.

The proposed legislation to legalise the use of cannabis for medical purposes does not change the existing drug-driving laws. Any medicinal cannabis scheme will need to consider educating patients about the importance of road safety when using cannabis. This includes information that refers to the fact that patients who use medicinal cannabis would not be permitted to drive while the drug is detectable in their system.

Information about the use and effects of cannabis would also need to be provided to health practitioners. In March 2012, the National Transport Commission provided a publication on 'Assessing fitness to drive for commercial and private vehicle drivers'. This publication is designed to guide and support assessments made by health professionals regarding fitness to drive for licensing purposes and is used by practitioners treating any patient who holds a driver licence whose condition may impact on their ability to drive safely. This publication may be relevant to assessments of any patient involved in a medicinal cannabis scheme in the ACT.

The RTA can undertake a medical review of the person's license status. As an alternative, a participant's driver's licence could be subject to a condition while they are consuming medicinal cannabis. Ensuring both the safety of the participant and the community is paramount.

CANNABIS USERS AND LAW ENFORCEMENT

ACT Policing has significant experience in dealing with mental health consumers affected by cannabis who as a result of their consumption become a risk to public safety. There are cases when such individuals have become violent towards attending police, at times with tragic results. It is important, therefore, that any scheme to legalise the use of cannabis for medicinal purposes does not exacerbate the pre-existing conditions of vulnerable members of society.

FORM OF APPROVAL

The Draft Bill does not specify the form that an approval issued by the Chief Health Officer (CHO) will take. It is felt that this should be included in the legislation to assist with enforcement and regulatory activities. A requirement to have a photographic identification or 'licence' issued as part of an approval would assist law enforcement in identifying those who have acquired cannabis legally.

REGULATORY ISSUES

INTERNATIONAL LAW

The *Single Convention on Narcotic Drugs 1961* (the 1961 Convention) is an international treaty signed by Australia on 22 November 1972. The 1961 Convention prohibits the production and supply of specific drugs, except under licence for specific purposes, such as medical treatment and research. The 1961 Convention affirms the importance of medical use of controlled substances and specifies measures of control to permit the cultivation of cannabis plants or resin. Article 28 permits the cultivation of the cannabis plant or cannabis resin, on the basis that a system of controls is adopted in accordance with Article 23.

Article 23 permits the cultivation of cannabis on the basis that one or more government agencies are maintained or established to carry out the following functions:

- a) the Agency shall designate the areas in which, and the plots of land in which, cultivation shall be permitted;
- b) the Agency shall licence cultivators to engage in the cultivation;
- c) each licence is to specify the extent of land on which cultivation is permitted; and
- d) all cultivators are to deliver their total crops to the Agency, as soon as possible, but not later than four months after the end of the harvest.

The Draft Bill does not meet the system of controls set out by the 1961 Convention. For the Draft Bill to be effective and achieve its stated purpose, changes would be required to include a system of controls to regulate the production and supply of cannabis for medicinal use under licence.

COMMONWEALTH LAW

In addition to International Conventions, consideration needs to be given to ensure any approach adopted in the ACT is consistent with existing Commonwealth law.

Cannabis is listed as a "border controlled plant" under section 314.5 in part 9.1 of the *Commonwealth Criminal Code Act 1995*. The *Customs (Prohibited Imports) Regulations 1956* (the Prohibited Imports Regulation) establishes a system of licences and permissions to allow the authorisation of the importation of cannabis for medical or scientific reasons.

The Prohibited Imports Regulation makes it illegal to import into Australia a drug that is prohibited, unless a licence to import is received and permission granted by the Secretary of an authorised person under the Regulation.

Permission to import a drug will not be granted unless (in the case of a drug included in schedule 1 to the 1961 Convention) the drug is required by the applicant for medical or scientific purposes. If approved for such purposes, the Minister may then approve the importation of the drug into Australia.

Further, a permission to import must specify a quantity of a drug that does not exceed the amount determined to be the maximum that may be imported into Australia. This maximum amount is determined by the Commonwealth Department of Health in accordance with Australia's obligations under the 1961 Convention and is notified annually to the International Narcotics Control Board (INCB). According to a report published by the INCB, as of September 2011, Australia had notified the INCB of an estimated maximum amount of 1,500 grams of

cannabis. One of the reasons for this notification process is to prevent a build up of stocks in excess of those required for medical and scientific purposes.

The Draft Bill is largely silent on the issue of supply, and this is a matter that must be addressed in accordance with national and international legal obligations.

ACT LAW

The Draft Bill attempts to exclude the possession of cannabis from existing criminal offences. However, the Draft Bill fails to effectively deal with this issue in relation to the possession, cultivation and supply of cannabis in ACT laws. Criminal liability currently arises under the following legislation:

- a) *Drugs of Dependence Act 1989* (the DoDA); and
- b) *Criminal Code 2002* (the Criminal Code).

The DoDA prohibits the cultivation, supply and possession of 'prohibited substances'. Cannabis, cannabis oil and cannabis resin are listed as a 'prohibited substance' as defined under the *Drugs of Dependence Regulation 2009*.

The DoDA includes a provision that a person shall not possess a prohibited substance at section 171 (Possessing prohibited substances). At present, section 171 does not apply if the person in possession of the prohibited substance is authorised to possess the substance under the *Medicines, Poisons and Therapeutic Goods Act 2008* or another territory law. The Draft Bill proposes an amendment that would see authorisations under the DoDA also excluded from the offence provision at section 171.

The criminal offence at section 164 (sale or supply) of the DoDA specifically excludes cannabis from the definition of prohibited substances. Instead, the Criminal Code prohibits the selling of a cannabis plant. The sale of cannabis is a criminal offence that carries a maximum penalty of three years imprisonment, a \$45,000 fine or both. This is relevant because the scheme proposed in the Draft Bill provides for the cultivation of cannabis by a person who does not hold a licence for the medicinal use of cannabis.

The Draft Bill limits applications for cannabis cultivation licences to people who hold an authorisation to use cannabis for medicinal purposes. However, the Draft Bill includes scope for an applicant to nominate another person to cultivate cannabis. This provision recognises that a person who holds an authorisation for possession and use of cannabis may not be able to cultivate cannabis (for medical reasons or as a result of a lack of knowledge and expertise related to cultivation).

However, the Draft Bill does not give a person nominated under a cultivation licence immunity from prosecution for supplying cannabis to the person with a medical cannabis approval.

Other issues may also arise from the intersection of the Draft Bill and more serious drug offences. This is particularly the case with offences in part 6.4 (cultivating controlled plants) in the Criminal Code. The Draft Bill does not propose amendments to exclude medical cannabis cultivation licence holders from offences in the Criminal Code.

Section 618 (Cultivating controlled plants) of the Criminal Code makes it an offence to artificially cultivate one to two cannabis plants or cultivate (artificially or otherwise) three or more cannabis plants.

A medical cannabis cultivation licence must include conditions about:

- a) The number of plants; and
- b) The maximum amount of cannabis (not more than 300 grams) that may be kept at any time.

It is possible that cultivation of cannabis may yield an amount in excess of the prescribed 300 gram maximum that may be possessed. This would place a licensee in a position where they are trafficking in cannabis as a result of the statutory presumptions in part 6.2 (trafficking in controlled drugs) of the Criminal Code.

Further consideration of how a medicinal cannabis scheme would impact on drug offences and serious drug offences is required to ensure any proposed scheme gives users and cultivators protection from criminal prosecution.

PUBLIC HEALTH PERSPECTIVE

ROLE OF THE CHIEF HEALTH OFFICER

The Draft Bill is problematic for the Chief Health Officer (CHO) both because of the administrative role it proposes for the CHO and because of the wider risks to public health entailed by the medicinal cannabis scheme it proposes.

The Draft Bill proposes that the CHO approve applications submitted by patients (following a medical declaration from a doctor) endorsing the use, possession and cultivation of cannabis for medicinal purposes. The CHO must approve these applications unless he has concerns about the veracity of the information provided. The CHO must also maintain a register of approvals and licenses for the use and cultivation of medicinal cannabis.

As with clinicians, the CHO has no basis for knowing the quality or content of illegally supplied or domestically grown cannabis supplied under an approval. This piece of information is key to making an informed decision about whether the treatment proposed in an application is appropriate. For example, in the treatment of epilepsy a high CBD content may be desirable while most 'street' cannabis has high THC to produce a strong psychoactive effect sought by recreational users.

PUBLIC HEALTH RISKS

The proposed scheme poses a number of potential risks to public health. Where illegally or self-grown cannabis has been legalised for medicinal use there have been problems with vulnerable patients interacting with drug dealers including violence and financial exploitation. Additionally, patients have reported frustration with not being able to obtain cannabis once it is prescribed where they lack the skills, time or material to grow the crop themselves. This has led to demand for growers collectives, or an organised sponsorship of supply for patients.

Under the scheme outlined in the Draft Bill, children would be eligible to use cannabis under Category 1 or 2 application. There are serious concerns about the use of cannabis by a child and the possible impact on a child's brain (including in-utero), development and learning, and passive exposure or access to cannabis prescribed to a child's parent or carer. In addition, the issue of access and use by a parent or carer of a child's cannabis has not been addressed.

ROUTE OF ADMINISTRATION

The route of administration for unregulated medicinal cannabis could pose a risk to health. Tinctures and other secondary processing of cannabis can pose a risk of fire or explosion when prepared, but further complicate any assessment of the potential clinical effect of the product. Processing of botanical cannabis can significantly change the composition of the final medicinal product.

Long term smoking of cannabis carries risks of damage to a patient's lungs, infection and allergic reactions to ingredients in the smoke and is not recommended except where a patient's life expectancy is limited.⁷

REGISTER

The maintenance of a Register will require significant additional resources and is a 'red-tape' solution which would produce negligible gains for public health. ACT Health is moving away from application-based regulation for opiate drugs as use (and abuse) is better tracked through electronic monitoring of prescriptions. The introduction of an approval and license register as proposed in the Draft Bill is viewed as a regressive approach.

NATIONAL & CROSS-JURISDICTIONAL ISSUES

NATIONAL SCHEME

On 27 November 2014, the Regulator of Medicinal Cannabis Bill 2014 (the National Bill) was introduced into the Commonwealth Senate. The National Bill establishes a Regulator of Medicinal Cannabis (the National Regulator). The National Regulator would be responsible for formulating rules for licensing the production, manufacture, supply, use, experimental use and import and export of cannabis for medicinal purposes. The National Bill outlines a scheme that is similar to the model currently in place in the Netherlands.

INTERGOVERNMENTAL COMMITTEE ON DRUGS

The issue of medicinal cannabis is currently being considered by the Intergovernmental Committee on Drugs. All jurisdictions have schemes that divert minor offenders into health education and treatment, and/or allow for fines to be imposed for the possession of small quantities of cannabis. A number of jurisdictions are exploring the role of medicinal cannabis.

CLINICAL TRIALS

On 16 September 2014, the NSW Premier announced that a working group would be formed to develop options for the conduct of clinical trials involving cannabis. ACT Health representatives have participated in this working group.

In recognition of the national importance of this issue, Australian Health Ministers discussed the issue of medicinal cannabis at their meeting on Friday 10 October 2014 and indicated their support for better information about the potential benefits of cannabis as a medicine. While NSW will be leading work on a clinical trial(s), a collaborative inter-jurisdictional approach will

be taken. The ACT Government supports the involvement of all jurisdictions in this collaborative approach.

INTERSTATE TRANSPORT

Consideration needs to be given to the implications of an approved applicant (per the Draft Bill) transporting cannabis across jurisdictional borders (e.g. during periods of travel). Although it is recognised that this cannot be directly addressed in the Bill itself, it must be considered in the implementation phase.

INTERNATIONAL EXPERIENCE

While it remains illegal in the majority of countries around the world, some countries and states have moved to legalise the possession, cultivation, supply and use of cannabis for medicinal purposes. Countries such as the Netherlands, Canada, Israel and Spain and over 20 states in the USA have legalised the medicinal use of cannabis. There are a wide variety of schemes and legislative frameworks in place in these jurisdictions.

The scheme outlined in the Draft Bill has some similarities with the scheme that has been implemented in Rhode Island, USA. A published review of the Rhode Island Medical Marijuana Program indicates that many patients were dissatisfied with not being able to obtain cannabis safely and reliably once prescribed.¹⁰ The criminal exploitation of patients seeking cannabis, both financially and through violence, was also reported.

Canada and several US states including Colorado, California and Oregon have established schemes that allow patients to nominate third parties to grow cannabis for their medical use. In practice, this has led to the growth of cannabis “clubs” and dispensaries. Data from the US experience have indicated a failure of doctors to maintain a gate-keeping role, leading to an improbably large number of prescriptions for cannabis to treat chronic pain in a predominantly young age group.¹¹ A low percentage of prescriptions were written for cancer pain or other chronic medical conditions.

In these US jurisdictions, cannabis clubs and dispensaries have grown into a substantial industry which appears to be marketing to consumers despite the technical requirement to obtain a medical endorsement to use the product. This has led to regulatory failure and defacto legalisation for all uses, which has recently become formalised in Colorado and Washington State.

In the Netherlands, medicinal cannabis is available on prescription and dispensed through pharmacies. Several different varieties of cannabis products are available, each with a specified content of active ingredients and grown in a standardised fashion under controlled circumstances. A published review of this scheme¹² indicated that a higher proportion of prescriptions were written for cancer or non-chronic pain indications and the age of users was higher, which is more likely to be indicative of use in serious medical conditions. The overall use of prescription cannabis was lower in the Netherlands than when compared to the US schemes.

CONCLUSION

The ACT Government supports the compassionate intent behind the Draft Bill as outlined in the associated discussion paper. However, the practical implementation of the scheme as proposed in the Draft Bill would be extremely challenging. Prior to any such scheme being implemented, the following issues must be addressed:

- Supply – there is a need for a reliable, quality controlled supply framework to be developed. This issue is currently not addressed by the Draft Bill, and is central to clinical, public health and public safety/law enforcement concerns. As noted above, the National Bill proposes a scheme that is very similar to the model currently in place in the Netherlands. This model addresses the concerns around supply and reflects the preferred approach of the ACT Government.
- Prescribed Medical Conditions – there is a need to further consider the clinical indications for the categories for approval currently listed in Table 7 of the Draft Bill. This should be developed with the direct input of the clinical community and based upon the best available evidence. The definition of each prescribed medical condition should be drafted with close attention to the potential for a broad interpretation to support misuse or diversion.
- Legal – the scheme proposed in the Draft Bill does not meet the requirements set out in the 1961 Convention. Additionally, issues of liability for clinicians, the Chief Health Officer and those issued with licences to cultivate cannabis need to be explored and appropriate protections provided under related ACT legislation.
- Operation of plant and machinery – there is a need to ensure that the safety of the community is protected. Issues arising from the use of cannabis by those issued with a driver's licence must be resolved. The preferred approach would be to embed a process by which the RTA is notified when an authorisation is provided. The RTA can then undertake a medical review of the person's licence status during the course of cannabis treatment.
- Criminal Diversion – there is a need to ensure that subversive criminal elements do not impact on the conduct of any medicinal cannabis program. It is recommended that cannabis cultivation not be permitted at residential addresses, and that any licences issued contain photographic identification of the individuals in question.

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