

## Online submission to the Victorian Law Reform Commission

### MEDICINAL CANNABIS REFERENCE

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The risks posed in the face of legalising the medicinal use of cannabis far outweigh any potential benefits alleged by zealous advocates of the substance. These risks are not only medical risks, but political and social risks. It is important in the legislative process to analyse the risks and benefits to the delivery of healthcare associated with such a reform. Not all costs and benefits are reasonably foreseeable, particularly in the context of economic, legal, social and political responses in the healthcare sector.

The various proposed models of legalisation and regulation are a valiant attempt by the political left to liberalise the provision of unconventional medicine in the name of autonomy and informed consent to treatment. However, none so far adequately counter-balance the heavy-weighted threats to public health, diversion and the medical profession in general, that such reform poses. It is of paramount importance that the legislature consider not only medical ramifications of implementing these reforms, but also the potential risks which fall outside the realm of medical science.

#### The Risks

There are vast numbers of legal drugs available to the medical practice that are both potentially lethal, and at the same time, indispensable for modern day treatment. Drugs such as morphine, codeine, and other opiates can also be highly addictive. Although cannabis has not been known to cause death by overdose, there are inherent risks with the drug which must be weighed with potential benefits in order for it to be considered a legitimate course of treatment. These inherent risks include, but are not limited to: cognitive impairment, a higher risk of developing mental illness (including a pre-disposition to developing schizophrenia), exacerbated symptoms of pre-existing mental illness, and a heightened risk of developing pulmonary cancer (if smoked).

There are also policy and ethical risks associated with the legalisation of the drug for medicinal use, such as the risk of inadequately informed use of the drug, the risk of the drug being diverted into an illegal market, and the risk of compromising the doctor/patient relationship.

#### Risk of Inadequately Informed Medicinal Use

There is a significant risk associated with the lack of conclusive evidence in support of the therapeutic use of cannabis as treatment for Multiple Sclerosis, Pediatric Epilepsy, chronic pain, and other illnesses. As noted in the issues paper, there is increasing evidence which suggests that a purely anecdotal understanding of its benefits as a treatment to these conditions is prolific, and widely influential, with little or no scientific or clinical basis.

This concern is reflected in the submissions made both by Medicines Australia, and The Royal Australasian College of Physicians (“RACP”) on the Regulator of Medicinal Cannabis Bill 2014. In particular, the RACP expressed their reluctance to support the proposals in bill, inter alia, due to a lack of evidence proving its efficacy. It also remains unconvinced that the function of the Therapeutic Goods Act is broad enough in scope to monitor and regulate the quality and safety of potential medicinal cannabis products.

Andrew Saxon and Kendall Browne state that the idea of physicians prescribing medicinal cannabis as a treatment to chronic pain is “fraught with a number of concerns”, all attributed to the known side-effects of using, and lack of research on the potential benefits and detriments of the substance. Until such research is conducted, Saxon and Browne emphatically deny any wisdom and safety in prescribing medicinal cannabis for chronic pain. The ethical responsibility of government in prohibiting unproven treatments was emphasised in the case of *United States v Rutherford*, where the U.S. Supreme Court determined that the protection of the terminally ill from unproven treatment was of no less importance than the protection of other patients.

Some of the most prevalent users of medicinal cannabis have typically been sufferers of glaucoma, multiple sclerosis, and cancer, however, U.S. medical organisations representing sufferers from those conditions, such as the American Glaucoma Society, National Multiple Sclerosis Society, and the American Cancer Society, have been outspoken in their opposition to using cannabis as treatment for them. The government agencies which regulate the prohibition on medicines and substances – the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) – have also emphatically objected to the medicinal use of cannabis, on the basis of a lack of evidence in support of its efficacy.

The same apprehension should be adopted by the legislature in Australia. The RACP, although supporting the intent of the bill, emphasized the need for further research to determine the efficacy of medicinal cannabis, and that it should be subject to the same scrutiny as any other medicine. This sentiment was echoed by the President of the Australian Medical Association (“AMA”), Brian Owler. Notwithstanding the significance placed on personal autonomy and informed consent to treatment in Australia, it is a matter of public health that unproven, uninformed use of cannabis be prohibited until it is categorically approved as an effective, legitimate form of treatment by the relevant research and drug attestation authorities.

#### Risk of Diversion

There is an inherent risk with legalising the medicinal use of cannabis that such a widely-used illegal recreational drug will be diverted from the legal (authorised) market, to the illegal (unauthorised market). A drug already so attractive to such a large illegal market will arguably become a target for illegal users under the excuse of “medical reasons”. The approval of it for medical treatment would likely cause a fall in the stigma attached to its use in general, and may even cause patients who would not normally be drawn to such a drug, to be more inclined to experiment with it in a legal or illegal manner.

In 2011, the most common indication qualifying patients for medical marijuana in California was self-reported chronic pain, on a self-reported scale. At the time, there was no requirement under state law that the pain be associated with medical conditions such as cancer or some

other distinguishable condition. Further, over 20% of the patients studied neglected to try conventional prescription medication before turning to marijuana. The ease of access to cannabis products created simply by legalising them for medicinal use will cause a proliferation of access to the drug in illegitimate cases, and illegal cases.

This is especially a concern when distribution mechanisms become more widely dispersed, and the regulatory framework of distribution is diluted, subsequently diminishing public confidence in the framework. The model of legalisation commonly known as ‘grow your own’ licenses have attracted a particularly strong risk of diversion, evidenced by the scheme used in Canada which was eventually phased-out for that reason in 2014.

In the United States, diversion risk is somewhat mitigated in some states through the keeping of inventories, and tracking measures implemented to monitor the dispensation and cultivation of cannabis products grown residentially for personal medical use. Whilst these measures may indeed mitigate the prolific diversion of the product in to the illegal market, they cannot be said to eliminate the risk completely. Especially considering the availability of the product on the illegal market already, mere administrative measures such as these would arguably be easily overcome as obstacles to the exploitation of the product for illegal capital gain.

#### Risk of Relationship Compromise

The legalisation of medical cannabis products may pose an additional threat to the sensitive, trust-based relationship between a doctor and patient. A formidable concern is that undue pressure will be placed on doctors to use the treatment experimentally, if a patient does not receive a desired response from more conventional treatment. The AMA expressed further Concern about the requirement that patients and their carers be authorised to use medicinal cannabis at the request of their medical practitioner, as this may allow undue pressure to be put upon doctors to support applications for authorisation, purely as a means to accessing cannabis.

The concern is that such pressure may pose a risk to the doctor/patient relationship, and that this was a unique concern surrounding the use of cannabis, as opposed to a doctor choosing not to prescribe prescription medication because it is not clinically appropriate for the patient. This is exacerbated by the apparently growing popularity and anecdotal support for the use of cannabis. The differences in popular opinion and professional opinion on the medical use of marijuana presents an unprecedented, and in many cases “polarising”, tension between its advocates and opposition.

From an ethical point of view, the Hippocratic Oath, although considered outdated by some, remains highly influential and informative on medical practice. The themes of a duty to “do no harm”, and “do good”, provide informative maxims upon how to render medical services generally. In the context of prescribing medicinal cannabis, the health professional is faced with the dilemma of whether prescribing a relatively untested form of treatment is inconsistent with the duty to “do no harm”. Furthermore, with the rising support for its use, it is important that the doctor is no way swayed to favour the use of it simply through the persuasion of “popular votes”.

This risk also poses a threat to the authenticity of the doctor/patient relationship. A patient, in full knowledge that medical cannabis is at the disposal of a doctor, would arguably able to

quite easily fabricate symptoms or responses to treatment with the motivation of requesting that their doctor resort to prescribing medical cannabis. Granted - this risk is inherent with most medical treatments - however, it is of unique significance to the prescription of cannabis, due to its wide illegal, unauthorised usage in society already. The Californian study mentioned above illustrates how potentially easy gaining access to cannabis products through a medical practitioner may be, in that patients who complained of “chronic pain”, without linking it to any identifiable condition, were able to gain access to medicinal cannabis in most cases.

In 2010, an undercover reporter in Oregon undertook an investigation into how easy it was to gain access to medical marijuana through a medical practitioner. Notwithstanding prior treatment of back pain with massage therapy, the doctor found that she qualified and would benefit from medical marijuana. Further studies suggest that this is not an isolated case. In Arizona, between April and October of 2011, the state denied access to just seven out of 14,925 applicants for marijuana registration cards. This not only poses a threat to diversion of the product to the illegal market, but undermines the role of the doctor ethically and professionally, as a gatekeeper to such treatments.

#### Modes of Legalisation, and Proposed Answers to Associated Risk

As evidenced above, a range of legalisation methods have been trialed in North America. It is evident that whilst some methods see elements of success, there remains significant questions surrounding the ease of access, and rate at which the substance is used legitimately, without diversion. Nevertheless, as noted in the Issues Paper, there remains a large zealous advocacy for the legalisation of cannabis for medical treatment. This raises the question of whether there are methods of liberalising the use of cannabis for medical treatment, without compromising the political and social concerns of public health, diversion and weakening the doctor/patient relationship.

#### State-Controlled Registrations/Licenses, ‘Grow Your Own’ methods

A state-controlled registration or license system, such as that rolled-out in California, and a number of states in the U.S. is often cited to perform an effective role in controlling the proper use of medicinal cannabis. However, most of these inevitably require the assessment of health professionals, often Doctors, to determine whether a patient is eligible for treatment due to a qualifying condition or illness. Some jurisdictions in the U.S allow individuals who are not Doctors of Medicine – such as homeopaths and naturopaths - to authorise such treatment. Many of these jurisdictions use registration and licensing to allow patients to possess a certain quantity of cannabis plants for their own medicinal use.

Needless to say, the practical variability of access to medicinal cannabis where such programs are in force is vast. However, most jurisdictions in the U.S. who have adopted such schemes allow access to the substance if there is self-reported chronic pain, regardless of whether it is symptomatic of another identifiable condition (such as cancer or muscular dystrophy). In this sense, a lack of symptomatic evidence does not prevent a patient from gaining access to medicinal cannabis through their doctor, and would be easily exploited for illegitimate use. A state-controlled registration or license system cannot be said to adequately mitigate against risks of diversion or compromising the doctor/patient relationship. Further, as noted in the Issues paper, the popularity of ‘grow your own’ distribution models has been strongly linked to

a proliferation of illicit cannabis trafficking. Such an easily abused mechanism should not be deemed as legitimate for medical purposes in Australia.

### 'When All Else Fails'

A more restrictive approach is to only allow medicinal cannabis to be provided when all other conventional methods of treatment have either failed, or are unavailable. As stated in the issues paper, the VLRC suggests that this approach would allow a person with a debilitating but common medical condition to use medicinal cannabis if it is the most effective option for the person. Requiring patients to use clinically tested and approved treatments before proceeding to a less predictable or effective treatment may even work to improve public health. The doctor/patient relationship may be somewhat protected in a scheme requiring all other conventional methods of treatment to be exhausted prior to proceeding with medicinal cannabis, especially when a doctor in question may not be confident in its efficacy.

However, as stated above, this scheme may cause tension with a doctor's ethical duty to "do no harm", in the sense that there is very little clinical evidence in support of its efficacy, and substantial evidence of adverse side-effects. A doctor may be reluctant to recommend cannabis for treatment, even when all other treatments have been exhausted. Further still, this method does not mitigate the risk of patients fabricating symptoms with the intention of attaining licenses or prescriptions to use or possess cannabis illegitimately. It therefore does not adequately address the risk of diversion, or compromise of the doctor/patient relationship.

### The Unavoidable Risk – Uninformed Use

As of the present day, there is a critical lack of evidence supporting the efficacy of medicinal cannabis, which cannot be overcome by different legalisation schemes or roll-out methods. The risk of uninformed use remains inherent in all models of legalisation – the lack of evidence in support of medicinal cannabis efficacy undermines the justification for legalising medicinal cannabis in general. This can only be resolved by continued clinical trials in the field – a practice which has been encouraged by a number of Australian and international medical organisations who have stated their current opposing status to legalisation of medicinal cannabis. However, as of the present day, there is a critical lack of evidence supporting the efficacy of medicinal cannabis, which cannot be overcome by different legalisation schemes or roll-out methods.

The typical proposed models of state-controlled provision and "grow your own" schemes provide very few comprehensive answers to the remaining questions surrounding the risks to public health, diversion, and the doctor/patient relationship. Even a more restrictive "if all else fails" concept is unable to satisfactorily protect the interests of the public, or the medical profession. In any case, zealous advocacy in the name of autonomy and liberalism is hardly persuasive for reform in the medical field without being supported with clinical evidence. The legislature has a responsibility to enforce the interests of public health over the liberty of individuals in their assertion of autonomy and free choice of treatment.

## Conclusion

In considering whether medicinal cannabis should be legalised for medical purposes, it is essential that the risks associated with the side-effects of the substance are realistically weighed, in conjunction with the risks to public health, diversion, and the doctor/patient relationship. The medical risks are significant in themselves, however, the medical risk of a Treatment is not disqualifying on whether it may nevertheless be beneficial and appropriate. It is evident that the non-medical risks associated with the use of cannabis are severe.

Legalisation may be detrimental to public health, in that the use of an inadequately researched, unproven treatment, will become widely available and attractive to potential candidate patients. Diversion risks have shown to be high in most forms of distribution around the world, and almost any level of government restriction less than prohibition is evidently incapable of satisfactorily mitigating that risk. Research into the use of the substance ought to continue, however, leaps of policy on the back of zealous advocacy will only work to reinforce the power of the uninformed activist.