

**Submission
No 75**

INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

Organisation: Adelaide Centre for Bioethics and Culture

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The Adelaide Centre for Bioethics and Culture supports investigation into the potential of cannabinoids derived from cannabis to be used medicinally. The Centre supports rigorous medical scientific inquiry that takes proper account of efficacy, side-effects, abuse potential and alternatives. To ensure protection for patients, the precautionary principle ought also apply. The process of development of potential cannabinoid based medicines should be similar to the process for other medicines and regulated through the TGA.

The use of smokable cannabis as a medicine does not fit within this paradigm and hence should not be permitted.

Furthermore, governments have a responsibility to promote the proper use of medicines and diligently develop strategies to minimise abuse. Taking account of the risks from any particular strategy to the more vulnerable members of the community, particularly children, should be paramount, and minimized accordingly.

! Adelaide Centre for
Bioethics
and Culture

SUBMISSION

BY

ADELAIDE CENTRE FOR BIOETHICS AND CULTURE

TO

NSW LEGISLATIVE COUNCIL PARLIAMENTARY INQUIRY INTO THE MEDICAL
USE OF CANNABIS

The Adelaide Centre for Bioethics and Culture welcomes the opportunity to make a contribution to this Inquiry.

The primary interests of the Centre with regard to this issue relate to the proper care of people suffering from various ailments, the process by which new medicines become accepted therapeutic agents in modern medicine, and the distinction between use and abuse of substances.

Cannabis could be delivered by smoking the raw product as happens in 'recreational' use, by nasal sprays or pills or patches of plant extracts, or by using specific pure active agents or combinations of them delivered by sprays, pills or patches.

What method may or may not be permitted or endorsed by medical authorities is a central element of this issue.

Whether cannabis ought to be made available for medicinal use rests upon an understanding of modern medicine and its role in advancing human health and well-being. All of the medical codes of ethics endorse the central principle 'do no harm', as well as the need to place the interests of the patient first, and secondary to any interests of science or society. Therefore, any potential medicinal use of cannabis, its extracts or active ingredients must be kept clearly separate from its abuse for 'recreational' purposes, an illegal activity.

Modern medicine has developed standard protocols by which new medicines come to the market. The process involves animal studies to assess efficacy as well as toxicity and side effects. Studies then progress through the various phases of clinical trials until a point is reached where it is clear that an agent is suitable for therapeutic application – typically as one active chemical agent, but sometimes as extracts or mixtures. It is the role of medical research to assess efficacy and side-effects. But this is not the end of the story. Governments and their agencies then need to assess abuse potential and balance that against what alternatives exist that might also satisfactorily serve patients' needs.

On the question of efficacy, there has been shown to be some clinical benefit from the active ingredients in cannabis. The typical approach taken by modern inquiry into

potential pharmaceuticals is to isolate active ingredients and subject them to analysis. Given that smoking a raw product is a known harmful delivery system, studies should focus on specified chemical agents or extracts. This is the process by which morphine and codeine and related opiates came to be used medicinally and not opium. Opium is 19th century medicine, not 21st century medicine. Likewise smokable cannabis is inappropriate for 21st century medicine. Unfortunately, some research has indeed used smoked cannabis.

Studies using either smoked cannabis leaf or active ingredients cannot be effectively conducted using the gold standard of modern medical research, that is, as properly blinded studies where the recipient does not know whether they are receiving an active ingredient or a placebo. The psychoactive properties of cannabis make this very difficult and hence studies are rendered potentially biased. Moreover, where studies use cannabis-experienced subjects who have been using cannabis for some time, there is an incentive for providing self-reported benefits. Where subjects experience a positive cognitive effect it becomes difficult to separate this from any actual therapeutic effect on whatever condition is being examined. Hence, each study needs to be carefully assessed on its merits taking proper account of its shortcomings. It is not clear whether some or many of the studies using smoked cannabis are of sufficient rigour.

On the question of side-effects, things become somewhat complicated. There is a solid body of research on the harmful effects of smoked cannabis which includes harm from the fact that the product is smoked as well as from the active ingredients. This research is increasing at a rapid rate but the long term effects will take some time to ascertain. However, already there is cause for serious concern that the cognitive effects, particularly regarding psychosis, may be serious enough to make use by patients problematic. Since it is the active ingredients that have the adverse cognitive effects, rather than the well known deleterious substances in inhaled smoke, any isolated active ingredient like THC, CBD, CBN, THCV or CBG, will need to be carefully independently assessed.

On the question of abuse potential, it is well-established that cannabis is the most commonly abused illicit drug in Australia and worldwide. Cannabis is known to be addictive and with increasing potency the impact upon young people in particular is clearly worrisome. Given the crucial role of governments to protect the more vulnerable members of the community, particularly teenagers, great care must be taken to ensure that any potential medical use of cannabis does not exacerbate its abuse.

The abuse of substances is well-recognised in medicine as a significant problem that is growing. The medical paradigm approves the value of substances to provide therapy for people and disapproves of their abuse. Some of the more serious problems being experienced right now relate to the abuse of legally available pharmaceuticals; for example, benzodiazepines like Xanax, opiates like Morphine and Oxycodone, antipsychotics like Seroquel, and amphetamines like Ritalin and Adderall.

It is important that there is no blurring of the distinction between legitimate use of a therapeutic agent and its abuse. If cannabis were to be made legally available as a smokable product for medical use, not only would this be perhaps the only medicine delivered by smoking, but the distinction between use and abuse would be seriously blurred. By confounding smoking cannabis to get high with smoking cannabis for medicine, authorities would be risking confusing particularly the young, and potentially affecting their perception of the legitimacy of smoking cannabis 'recreationally'.

There is an important corollary question here about the role of governments in assessing the potential use of medicines. The question must be asked, “Is it the role of a State Government to decide about the medical value of a particular substance, or is it more properly the role of the TGA?” In the United States, many states have approved smokable cannabis for medicinal purposes. It is a very odd thing that a public process of voluntary voting should determine whether something is a safe medicine. That is a task for experts in the field. In the US context that process was open to serious influence by drug legalisation advocates who saw medical marijuana as a beachhead for liberalising policies on ‘recreational’ use of cannabis. Their bankrolling of the initiatives in several states enabled the subversion of the careful process of evidence based scientific review of the efficacy and safety of medicines that is so vital for the protection of the public’s health. We are fortunate that such a process is not possible in Australia; however, the fact that public inquiries are occurring here rather than via the process for all other medicines is cause for concern.

The experiences of some of the US states with regard to medical marijuana are worth considering, particularly with regard to separating therapeutic use from abuse. What is the risk of diversion for recreational use from the medical cannabis dispensaries, and what is the risk of individuals accessing medical sources of cannabis when in fact they have no objectively measurable condition? For example, given that one of the medical uses of cannabis is for pain control, how is it possible to assess whether in fact the individual involved is seeking cannabis to treat pain, (assessed subjectively) or to use recreationally?”

In Colorado, 48.8 percent of adolescents admitted to substance abuse treatment obtained their marijuana from someone registered to use medically. The authors of a recent paper examining Colorado’s experience with medical marijuana conclude,

Diversion of medical marijuana is common among adolescents in substance treatment. These data support a relationship between medical marijuana exposure and marijuana availability, social norms, frequency of use, substance-related problems and general problems among teens in substance treatment.¹

Those registered for medical marijuana in Colorado can do so for a range of conditions including cachexia, cancer, chronic pain, nervous system disorders, muscle spasticity, and nausea. However, 94% of users are registered for the control of severe pain.² There is no definitive way of knowing whether a person is experiencing pain and at what level, and given that a select few doctors are involved in most recommendations for medical marijuana, the possibility of abuse of the system is likely. Indeed the relationship of the patient to the physician is a curious one.

The medicalization of marijuana in Colorado includes a narrowed account of the relationship between a patient and a physician, in which a physician gives permission to use an otherwise illegal substance without the usual fiduciary

¹ Thurstone C, Lieberman SA & Schmiede SJ, Medical marijuana diversion and associated problems in adolescent substance treatment. *Drug Alcohol Dependence* 118(2-3):489-492, 2011

² Colorado Department of Public Health and Environment. Center for Health and Environmental Information and Statistics. Registry Program Update 31 December 2012. See <http://www.colorado.gov/cs/Satellite/CDPHE-CHEIS/CBON/1251593017044>

responsibilities of a physician.³

In summary, the Adelaide Centre for Bioethics and Culture supports investigation into the potential of cannabinoids derived from cannabis to be used medicinally. The Centre supports rigorous medical scientific inquiry that takes proper account of efficacy, side-effects, abuse potential and alternatives. To ensure protection for patients, the precautionary principle ought also apply. The process of development of potential cannabinoid based medicines should be similar to the process for other medicines and regulated through the TGA.

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Yours Sincerely

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³ Nussbaum AM & Thurstone C, Mile High Macarons: The Medicalization of Marijuana in Colorado. *The Journal of Global Drug Policy and Practice* 5(2), Summer 2011. See <http://www.globaldrugpolicy.org/Issues/Vol%205%20Issue%202/Mile%20High.pdf>