

**Submission
No 54**

INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

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Australian Drug Law Reform Foundation

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(With assistance from
Professor Desmond
Manderson regarding the
history of medicinal cannabis
in Australia)

[SUBMISSION ON MEDICINAL CANNABIS FOR NSW PARLIAMENT]

Medicinal cannabis, previously used in Australia, should be permitted again in NSW. The evidence for medicinal cannabis being useful for reducing severe and distressing symptoms in certain conditions has been clear for more than a decade. This evidence is growing. The risks of cannabis used medicinally in small quantities under some medical control are acceptable. Data on cost effectiveness are not available but medicinal cannabis may be cost effective. Other drugs (e.g. morphine, cocaine) are used medicinally today while recreational use is prohibited. We recommend that NSW commences cautiously with (i) a limited number of approved conditions; (ii) a system for considering and approving for a period applications from NSW doctors; (iii) supplies of plant cannabis purchased from the Netherlands government be provided to patients by pharmacists where a valid prescription has been issued; (iv) some subsidy may be needed as many patients approved for medicinal cannabis are likely to be unable to afford paying the full costs of their medicine; and (v) an independent evaluation should be commissioned within 1-2 years with a view to possible revision and expansion of this scheme if this appears to be warranted.

Executive Summary:

The use of cannabis for medicinal purposes should be based on the standard current criteria for regulation of all medicines – especially effectiveness and safety. These days, cost-effectiveness is also considered an important criterion. There is now little doubt that rigorous evidence exists to support the conclusion that medicinal cannabis can be an effective medication for some medical conditions. At present it does not appear to be a first line drug for any condition but it is sometimes a very useful second or third line drug providing considerable benefit to some unfortunate patients with intolerably severe symptoms from some conditions, including some patients with a short life expectancy where more conventional medications have already proved ineffective or accompanied by unacceptable side effects. These conditions include: (i) intractable nausea and vomiting following cancer chemotherapy; (ii) severe wasting in advanced HIV infection; (iii) disseminated sclerosis accompanied by severe spasticity; and (iv) selected cases of severe chronic non-cancer pain. There may be a case for also considering compassionate use in selected cases. There are some indications that efficacy may be greater for the whole plant than for extracts. This has significant implications for regulation of cannabis as a medicine.

The safety of medicinal cannabis is acceptable, especially when used in the provision of palliative care to patients with a poor life expectancy. Medicinal cannabis will be safer if used consistent with best medical practice (of using the lowest dose and shortest duration required to achieve the desired medical outcome). The administration of a medicine mixed with smoke inhaled into the lungs is medically unacceptable except in patients with a short life expectancy. However, administration by inhalation of cannabis vapour is now available, effective and relatively inexpensive. Inhalation has some advantages compared to oral ingestion. Nabiximols (Sativex[®]) is a commercially available form of medicinal cannabis sprayed on to the bucal mucosa (lining of the mouth) with an almost 50:50 combination of the slightly stimulatory cannabinoid (THC) and a slightly depressant cannabidiol (CBD). However, this formulation is likely to be far more expensive than unmilled plant cannabis and may prove to be inferior. Many medicines (e.g. morphine, cocaine) are used today and with great benefit although their recreational use is prohibited. The failure to use cannabis medicinally because recreational use is prohibited is therefore bizarre. Recreational cannabis has been readily available for decades. High proportions recently reported that availability is 'easy' or very easy' (94% for hydroponic cannabis and 76% for bush cannabis). Therefore there is virtually no risk that medicinal cannabis will be diverted and thereby increase the availability of recreational cannabis.

We recommend a cautious and evolutionary approach to the regulation of medicinal cannabis. Small changes should be made and then evaluated. If benefit and minimal adverse consequences have been achieved, an expansion of access should then be considered. Experts should be invited to recommend which conditions should be the highest priority to commence medicinal cannabis in NSW. This list should be reviewed by experts and recommendations made to the Chief Health Officer at least annually. Expert advice should also be sought regarding minimal criteria required for the diagnosis of the above conditions and evidence of sufficient severity of the condition. The Dutch government purchases pharmaceutical grade cannabis produced under stringent and secure conditions from an authorized agricultural company. We recommend that NSW source medicinal cannabis from this or a similar provider. Exemption from prosecution might be the simplest and least expensive way to commence medicinal cannabis in NSW but ultimately an officially acceptable form of supply will be required. A committee might consider applications from NSW medical practitioners regarding NSW patients along the lines of the Medical Committee Under the NSW 1966 Poisons Act. In Australia medicinal cannabis currently has strong community support and research into medicinal cannabis even stronger support.

Recommendations of the Submission by ADLRF

Recommendation 1:

That the NSW Government accepts that the evidence for effectiveness and safety of medicinal cannabis for some conditions warrants this agent being legally provided in NSW;

Recommendation 2:

That NSW should commence allowing medicinal cannabis in patients with severe and distressing symptoms unrelieved by conventional medication;

Recommendation 3:

That initially medicinal cannabis should be only permitted in cases of: (i) intractable nausea and vomiting following cancer chemotherapy; or (ii) severe wasting in advanced HIV infection and cancer; or (iii) disseminated sclerosis accompanied by severe spasticity; or (iv) selected cases of severe chronic non-cancer pain;

Recommendation 4:

That doctors registered in NSW could apply to the NSW Ministry of Health for approval for 12 months to prescribe medicinal cannabis for patients resident in NSW whom they believe to meet the criteria;

Recommendation 5:

That applications would be considered by an expert committee appointed by the NSW Ministry of Health;

Recommendation 6:

That the expert committee would then make a recommendation to the Director General of the NSW Ministry of Health;

Recommendation 7:

That if the Director General approves this recommendation for a time limited period, the patient's doctor would then write a prescription which would be dispensed to the patient by a pharmacist;

Recommendation 8:

That NSW would obtain medicinal cannabis from the Department of Health of another country (e.g. the Netherlands);

Recommendation 9:

That the objectives of this policy would be to (a) relieve severe and distressing symptoms for patients with a serious illness; (b) maintain the integrity and excellent reputation of the Australian system of regulating medicines; (c) maintain the integrity and excellent reputation of the Australian medical profession; (d) maintain the excellent reputation of the NSW Ministry of Health;

Recommendation 10:

That an independent review would be conducted in 1-2 years to establish if: (a) patients with severe and distressing symptoms from a serious illness gained significant relief; (b) protocols had been followed; (c) the nature, extent and severity of any unintended negative consequences; (d) worthwhile benefits were achieved for costs (individual and NSW); (e) medicinal cannabis should also be allowed for other conditions; (f) the conditions of the system should be relaxed; (g) other sources of supply should be arranged.

'It is beyond my comprehension that any humane person would withhold such a beneficial substance [cannabis] from people in great need simply because others use it for different purposes'
-Stephen Jay Gould
Professor of Zoology, Harvard University National Academy of Science

[1] History of medicinal cannabis in Australia

The use of cannabis for medicinal purposes is said to have been very common in Australia in the nineteenth and early twentieth century. But this is poorly documented. Pharmacists usually made up medicinal cannabis as a tincture, often combined with opium, chloroform and morphine. Cannabis cigarettes, often referred to as 'Joys', were popular until after World War II and used in the treatment of asthma.

Irvine states that although 'there had been attempts by state parliamentarians to ban or restrict the legal use of cannabis as medicine going back to the 1900s, medicinal cannabis remained legal in New South Wales until the passage of the Police Offences Amendment (Drugs) Act 1954 (NSW), which in turn was repealed and replaced by the Poisons Act 1966 (NSW). This 1966 Act introduced even harsher penalties for the use of cannabis in any form, whether for medicinal purposes or otherwise' ^[1].

In Australia medicinal cannabis was supported by 69% of the community and research into medicinal cannabis by 74% of respondents in a recent study commissioned by the Commonwealth Department of Health ^[2]. Australia has been moving towards reform around the use of Marijuana. ^[3]

As will be outlined within this submission, there is now a large bulk of evidence that demonstrates the effectiveness and safety of medical cannabis prescribed by a doctor.

[2] History of medicinal cannabis in other countries:

In the nineteenth century the line between the medical and non-medical uses of drugs was neither clear nor particularly important. The cannabis plant has been used for medicinal purposes for thousands of years ^{[1][2][19]} and preparations laced with alcohol or opium were freely available from chemists and grocers. Indeed, Australians had the highest consumptions of patent medicines in the world. Warner's 'non-alcoholic' cure for 'kidney and liver diseases' was as strong as brandy; cough medicines were combined with opium, morphine, or (later) heroin. And amongst many similar products, the so-called Cigares de Joy promised 'immediate relief in cases of asthma, cough, bronchitis, hay-fever, influenza and shortness of breath.' They were marijuana cigarettes. Like the history of other drugs, attitudes to marijuana changed decisively in this country during the first half of the twentieth century. It did so under two main influences.

First, the puritan obsessions of the United States led to the rigorous control of first one drug then another. Acting under US pressure, the 1925 *Geneva Convention* initially limited the manufacture, distribution, and use of cannabis 'exclusively to medical and scientific purposes.' The prohibition of non-medical use in Australia shortly thereafter took place at a time in which the drug was largely unknown. But propaganda films like 'Marijuana—Weed of Madness', produced and circulated by the US Federal Bureau of Narcotics in the 1930s, purveyed myths of its criminal potency far more extreme and deceitful than the myths of its medical efficacy purveyed by patent medicine manufacturers. By the time cannabis use started to grow in Australia in the 1960s, particularly amongst the young, a climate of moral hysteria was already firmly in place.

Second, the modernisation of the medical profession dramatically changed our access to drugs. Between the wars, grocers were steadily forbidden from selling most drugs while chemists were prevented from producing and prescribing their own products. A modern structure of gate-keeping was put in place; only doctors could from now on prescribe scheduled drugs, only chemists could dispense them. But in the course of this transition from a *laissez-faire* model to a model of tight medical control, cannabis like heroin was excluded from use altogether.

After cannabis began to be prohibited in the 1920s, medicinal use of cannabis decreased for a variety of reasons including advances in modern medicine. There is now growing interest in exploiting the therapeutic potential of cannabis ^{[19][20][21][22][23][24]} perhaps because of increasing further improvements in botanical drug development and the discovery of the human endocannabinoid system ^{[25][26]}. Scientists, medical authorities and major pharmaceutical companies in several countries are actively researching the cannabis plant and many of its psychoactive extracts ^[25]. Examples from around the globe are summarised below.

Plant based cannabis medicines have been officially approved for use in more than a dozen countries including the UK, Denmark, the Czech Republic, Austria, Sweden, Germany, Spain,

Canada, Italy, Israel and New Zealand^[3]. Medicinal cannabis is now available in the USA in eighteen states and Washington DC (covering more than 40% of the national population).

Modern horticultural techniques ensure that plants cultivated for medicine can be grown and harvested in controlled, contaminant free conditions to produce consistent, high quality pharmaceutical products (sometimes called 'phytopharmaceuticals' or botanical drug substances)^{[4][9][11]}. Doctors and medical societies in countries like Israel, the US and Canada can now recommend 'medical marijuana' (including a low THC formulations for children) to thousands of patients. In some countries a thriving government authorised industry has emerged^{[5][6][10][11][15][16][17][18]}. In 2003, a company from the agricultural sector was contracted by the Dutch government to produce and supply medicinal Cannabis^[9]. In the Netherlands, cannabis comes in standard packaging and is labelled similar to other medicinal products^{[8][9][12]}. The Dutch government recommends that medicinal cannabis is prepared as a tea or inhaled using a vapouriser to avoid exposure to smoke^[12]. Specific arrangements for use or supply differ in the US states where 'medical marijuana' laws allow physicians to recommend the use of cannabis and in some instances permit patients to cultivate cannabis plants at home or on someone else's behalf^{[7][14]}. In a 2011 study of over 1,700 patients receiving medicinal cannabis in California, evaluating physicians recommended use of cannabis most commonly for pain, insomnia and anxiety^[27]

[3] Major official enquiries into medicinal cannabis:

(i) NSW, Australia

Report of the Working Party on the Use of Cannabis for Medical Purposes August 2000

The following is a summary of the key points of this NSW study:

Cannabis is a crude plant product, which contains a complex mixture of many chemicals. This makes production of a standard cannabis product extremely difficult, as it is not clear which chemicals are responsible for particular therapeutic effects. Cannabis smoke also contains a variety of substances that are dangerous to health.

In Australia, cannabis use for medical purposes is reported to be common among gay men who are HIV positive and people with cancer.

The health risks of cannabis use need to be considered. These include the adverse effects of cannabis on motor skills and on the mental health of vulnerable individuals. These health risks should not rule out the use of cannabis for medical reasons, but they must be taken seriously, particularly if long-term cannabis use is being considered for the treatment of a chronic condition.

Several submissions noted that the use of cannabis by smoking posed health risks; others noted that smoking allowed better dose titration than other routes of administration, such as eating. Many submissions recommended that other ways of taking cannabis for medical purposes, or alternative cannabinoid products, should be developed.

- Submissions which advocated medical use of cannabis did so on the basis that cannabis may be appropriate as:
 - an anti-nausea agent during chemotherapy when first-line treatments have failed;
 - a treatment for wasting conditions and appetite loss among patients with cancer and HIV/AIDS;
 - a treatment for chronic pain.
- There were conflicting ideas on the use of cannabis in multiple sclerosis and chronic conditions involving muscle spasticity.
- There was little support for the use of cannabis to treat glaucoma, because of the high doses required and the need for chronic use to control the underlying disease process.
- Several submissions recommended that cannabis be supplied for medical purposes and gave the following comments/suggestions:
 - obtaining an illegal substance placed an additional burden upon ill persons;
 - registered growers/buyers' co-operatives were proposed as a supply source;
 - legislative changes were suggested to remove legal sanctions against medical cannabis users.
- Several groups supported the idea that cannabis should be prescribed by authorised practitioners.
- Those who were opposed to the medical uses of cannabis were concerned about the social implications, particularly the possibility that medical use may promote recreational use.
- Almost all submissions supported further research and clinical trials to obtain more information about the medical benefits of cannabis use.

The full report is available at:

<http://ndarc.med.unsw.edu.au/resource/report-working-party-use-cannabis-medical-purposes-vol-1>

(ii) United States of America.

Marijuana and Medicine: Assessing the Science Base.

Institute Of Medicine. National Academy. United States of America. 1999.

This reports states that:

The accumulated data indicate a potential therapeutic value for cannabinoid drugs, particularly for symptoms such as pain relief, control of nausea and vomiting, and appetite stimulation. The therapeutic effects of cannabinoids are best established for THC, which is generally one of the two most abundant of the cannabinoids in marijuana. (Cannabidiol is generally the other most abundant cannabinoid.)

The effects of cannabinoids on the symptoms studied are generally modest, and in most cases there are more effective medications. However, people vary in their responses to medications, and there will likely always be a subpopulation of patients who do not respond well to other medications

The conclusions and full list of recommendations can be found at:

http://www.nap.edu/openbook.php?record_id=6376&page=3

(iii) United Kingdom.

Science and Technology, Ninth Report, House of Lords, United Kingdom, 1999

Recommendations of the UK Parliament, House of Lords are listed as follows:

- (i) Clinical trials of cannabis for the treatment of MS and chronic pain should be mounted as a matter of urgency (paragraph 8.3).
- (ii) Research should be promoted into alternative modes of administration (e.g. inhalation, sub-lingual, rectal) which would retain the benefit of rapid absorption offered by smoking, without the adverse effects (paragraph 8.4).
- (iii) The Government should take steps to transfer cannabis and cannabis resin from Schedule 1 to the Misuse of Drugs Regulations to Schedule 2, so as to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine and on the named-patient basis, and to allow doctors and pharmacists to supply the drug prescribed (paragraph 8.6).
- (iv) The Government should consult the Advisory Council on the Misuse of Drugs on this matter at once, and respond to this report only after receiving and considering their advice (paragraph 8.8).
- (v) The Government should raise the question of rescheduling the remaining cannabinoids with the WHO in due course (paragraph 8.10).
- (vi) If doctors are permitted to prescribe cannabis on an unlicensed basis, the medical professional bodies should provide firm guidance on how to do so responsibly (paragraph 8.16); and safeguards must be put in place by the professional regulatory bodies to prevent diversion to improper purposes (paragraph 8.17).
- (vii) Cannabis and its derivatives should continue to be controlled drugs (paragraph 8.22).

The full report can be downloaded from:

<http://www.parliament.the-stationery-office.co.uk/pa/ld199798/ldselect/ldsctech/151/15110.htm - a28>

[4] Major reviews of evidence for efficacy of medicinal cannabis

Three major reviews of the therapeutic potential of cannabinoid based medicines (randomized, double blinded, and placebo-controlled trials) have been published:

1. Ben Amar, M. (2006). [Cannabinoids in medicine: A review of their therapeutic potential](#). *Journal of ethnopharmacology*, 105(1), 1-25.
2. Hazekamp, A., & Grotenhermen, F. (2010). [Review on clinical studies with cannabis and cannabinoids 2005-2009](#). *Cannabinoids*, 5, 1-21.
3. Grant, I., Atkinson, J. H., Gouaux, B., & Wilsey, B. (2012). [Medical Marijuana: Clearing Away the Smoke](#). *The Open Neurology Journal*, 6, 18-25.

These reviews demonstrate that the evidence for the use of medicinal cannabis for certain specified conditions is now unquestionably impressive. Historically, the benefits of cannabis have resided not merely in the precise dosage and percentage of THC imbibed but in less quantifiable advantages that are inseparable from the strictly medicinal benefits—even for cancer patients—including reducing anxiety about death and dying and possible placebo effects. For example, ondansetron may be generally more effective for controlling nausea and vomiting secondary to cancer chemotherapy but is more expensive, require an intravenous drip in hospital while a patient taking medicinal cannabis could be at home and without an intravenous drip.

'In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating 10 raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death. Marijuana in its natural form is one of the safest therapeutically active substances known to man. By any measure of rational analysis marijuana can be safely used within the supervised routine of medical care.'

*[DEA Administrative Law Judge - 1988]
— Francis Young*

[5] Major reviews of evidence for safety of medicinal cannabis:

The Chief Administrative Law Judge for the U.S. Drug Enforcement Agency, Francis Young, stated in 1988 that “Marijuana in its natural form, is one of the safest therapeutically active substances known”^[1]. Whilst the use of cannabis for medicinal purposes is likely to have side-effects associated with long term use, like other medicines, the issue is the balance of benefits compared to risks. A systematic review published in 2008 which reported on the adverse effects of medical cannabinoids stated that “most of the events were not serious” and that “none of the reported adverse events was unexpected”^[2]. If used mainly in patients with a short life expectancy, long-term risks are of limited consequence. Overall, the benefits of cannabis far outweigh risks. Therefore medicinal cannabis should be considered ‘safe’. The risk of substantial quantities of medicinal cannabis being diverted to the black market are low because cannabis is readily available in Australia today.

[6] The cost-effectiveness of medicinal cannabis

As a therapeutic drug, plant cannabis should be relatively inexpensive to produce and administer. Considering that the therapeutic effects of medicinal cannabis are most effective when used in patients who have severe chronic diseases, such as HIV and cancer, a low-cost drug could bring relief to thousands of patients in NSW who are currently burdened by the high cost of state of the art drugs. As a cost-effective alternative, medicinal cannabis would reduce out-of-pocket expenses related to chronic diseases in often indigent patients who never quite seem to be covered by the Medicare system^{[1][2][3]}

[7] Options for providing medicinal cannabis

A number of approaches should be considered for providing medicinal cannabis.

1. Authorised supply

Approved patients could be made exempt from criminal sanction (see below). A patient would be approved for this purpose if recommended by the Director General of the NSW Ministry of Health on advice from the Department of Health. A doctor registered in NSW would first have to apply on behalf of a NSW patient confirming the presence of a condition accepted for medicinal cannabis and also confirming the severity of the condition. If the application was approved, the doctor would write a prescription. The patient would then be provided by a pharmacist with supplies of raw, dried or whole cannabis products. This would closely resemble the models adopted in Canada, the Netherlands, Israel and many states in the USA. Authorisations to use cannabis could be time limited and subject to periodic review. Permits to cultivate and supply cannabis could also be registered by patients or a nominated caregiver and subject to similar regular review.

Examples:

Canada - permits home cultivation of cannabis and supply of cannabis by a registered caregiver. Dried cannabis and cannabis seed can be purchased directly from Health Canada. These cannabis products are sourced by Health Canada from an authorized Canadian biopharmaceutical company.

Further information about the Canadian model are available on the Health Canada website:
<http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/supply-approvis-eng.php>

The Netherlands – Cannabis may be used on medical grounds under the supervision of a doctor and pharmacist. The Office of Medicinal Cannabis has exclusive rights to oversee the supply and production of dried medicinal cannabis, which is sourced from an authorized agricultural company:
<http://www.bedrocan.nl/english/home.html>

Video and fact-sheets about the Dutch model can be viewed on the government's website:
<http://www.cannabisbureau.nl/en/press/default.asp>

This link contains an excellent and brief explanation of the meticulously pharmaceutical approach to medicinal cannabis taken in the Netherlands.

Israel– Requests for permits to use medicinal cannabis can be obtained from the Israeli Ministry of Health. The Ministry of Health have authorized a company called Tikun Olam to cultivate medicinal grade cannabis: <http://www.tikun-olam.co.il/>

Caregivers can be involved in administration of cannabis for the severely disabled as seen in this video: http://youtu.be/07_f2F84B3k

More information:

http://www.health.gov.il/English/Services/Citizen_Services/Pages/kanabis.aspx

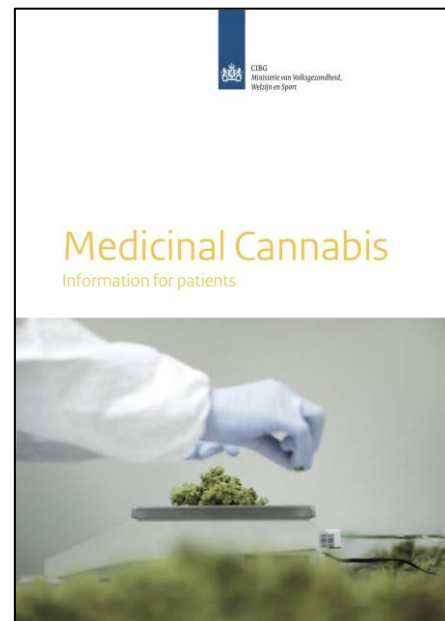


FIG 1: Front cover the Patient Information brochure provided to patients by the Office of Medicinal Cannabis (Netherlands)

The Czech Republic – A system has only recently been approved by parliament in the Czech Republic. [Early news reports](#) indicate that the government may begin to import medicinal grade cannabis from the Netherlands and Israel until it can establish a local distribution framework.

USA – There are significant differences between the systems in the 18 states (and Washington DC) which permit medicinal cannabis. It is beyond the scope of this paper to summarize. More information on individual state law is available here: <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>

A position paper published by the American College of Physicians [ACP] in 2008 stated the:

“ACP strongly supports exemption from federal criminal prosecution; civil liability; or professional sanctioning, such as loss of licensure or credentialing, for physicians who prescribe or dispense medical marijuana in accordance with state law. Similarly, ACP strongly urges protection from criminal or civil penalties for patients who use medical marijuana as permitted under state laws.”

2. Exemption from prosecution

When safety belts were introduced in Australia, taxi drivers and pregnant women were exempt from prosecution. This approach could serve as a model

This approach could involve removing criminal sanctions for the purchase, use and home cultivation below designated threshold quantities of cannabis for medicinal reasons.

The drawback of this model is that:

- Seriously ill or disabled patients may be unable to source or cultivate their own cannabis or afford the inflated black market prices
- Seriously ill patients may ask their caregivers to source or cultivate cannabis which may place them at risk of arrest and prosecution

3. A pharmaceutical model (this model is not recommended)

This model would not permit home cultivation, purchase or supply of cannabis unless the supplier was a registered pharmaceutical company providing a registered pharmaceutical product.

The drawbacks of this model are that:

- There are no provisions of compassionate access until a pharmaceutical product is approved for use.
- Seriously or terminally ill patients who may benefit from cannabis right now may not have time to wait.
- Cannabis based pharmaceutical products may not be listed on the PBS and may therefore be prohibitively expensive to seriously ill and dying patients
- Approval of pharmaceutical products can take many years
- Synthetic versions of cannabis may be inferior to natural whole plant based cannabis.

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