

Drug Free Australia's position on Medical Marijuana/Cannabis July 2014.

1. What is the stance of Drug Free Australia on the legalisation of cannabis for medical purposes?

Drug Free Australia (DFA) opposes the legalisation of cannabis for medical purposes because:

• Its origins have not come from the medical profession, but rather special interest groups and marijuana companies, that can be likened to 'Big Tobacco', where profit is the main motive.

Groups like the *National Organisation for the Reform of Marijuana Laws* (NORML) have been agitating for medical marijuana for a long time, as has the *Drug Policy Alliance*. However, particular individuals have also put in considerable funds. These include billionaire financier George Soros and insurance magnate Peter Lewis. It is estimated that Lewis alone has spent between \$40 and \$60 million on medical marijuana initiatives since the early 80s.

Soros-watcher Rachel Ehrenfeld has described the Soros strategy as set forth to prolegalisation group *Drug Policy Foundation* in the early nineties:

... in 1993 Soros gave DPF a "set of suggestions to follow if they wanted his assistance: Come up with an approach that emphasizes `treatment and humanitarian endeavors,' he said ... target a few winnable issues, like medical marijuana and the repeal of mandatory minimums." Apparently, they took his advice.

According to Dr Kevin Sabet, University of Florida: 'Special-interest "Big Tobacco"- like groups and businesses have ensured that marijuana is widely promoted, advertised and commercialized in Colorado. As a result, calls to poison centers have skyrocketed, incidents involving kids going to school with marijuana candy and vaporizers seem more common, and explosions involving butane hash oil extraction have risen. Employers are reporting more workplace incidents involving marijuana use, and deaths have been attributed to ingesting marijuana cookies and food items. Marijuana companies, like their predecessors in the tobacco industry, are determined to keep lining their pockets'. "

• Promoters of 'Medical' Marijuana are using the community's compassion for the suffering of sick people; it is emotional blackmail, based on political and economic motives rather than science.

DFA believes that the current trend in this debate in Australia is mirroring a similar campaign carried out some years ago in the United States, when Dr Robert DuPont spoke against medical marijuana and is quoted as saying:

'More people need to see "medical marijuana" for what it is: a cynical fraud and a cruel hoax. The conflict being discussed at this hearing today, in my view, is not about medicine; it is about the political exploitation of the public's compassion for suffering sick people. Legitimizing smoked marijuana as a "medicine" is a serious threat to the health and safety of all Americans'. iv

This is supported by Dr Greg Pike, Adelaide Centre for Bioethics and Culture: 'A dangerous precedent is set by approval processes that are effectively achieved by popular vote of citizens who are not expert judges of medical efficacy, side-effects, abuse potential, or ethics of the doctor-patient relationship. Popular vote is also risky because the public is then at the mercy of pressure from groups who are using medical marijuana as a beachhead for generalised legal access to marijuana'.\(^{\text{V}}\)

• There are important differences between modern scientific medicine that is administered as single chemicals (usually synthetic) by the oral route of administration and smoked herbal marijuana.

For example, the Food and Drug Administration, in the United States (similar to the Australian Therapeutic Goods Administration) states that:

'To be accepted as a medicine, the following criteria must be met:

- (1) The drug's chemistry must be known and reproducible
- (2) There must be adequate safety studies
- (3) There must be adequate and well-controlled studies proving efficacy
- (4) The drug must be accepted by qualified experts
- (5) The scientific evidence must be widely available'.

Cannabis does not meet these criteria.

Other peak organisations such as the Australian Medical Association, the American Medical Association, the American College of Physicians, the American Nurses Association, the American Cancer Society, the American Glaucoma Foundation, the National Multiple Sclerosis Society, the American Academy of Pediatrics and the American Society of Addiction Medicine all support the approval process and have expressed either opposition to or concern over the use of smoked marijuana as a therapeutic product.

It is important that peak bodies like the FDA in the US and the *Therapeutic Goods Administration* (TGA) in Australia are able to maintain their position as the gatekeepers of the regulatory process by which new medicines become available to the public. They are undermined when, by alternate regulatory means, medicines are made available. This is the case in the US where States have enacted legislation that makes smoked marijuana available for medical purposes without FDA approval'.

- There are medications already approved and available to help people who are in pain and suffering that work extremely well. (Refer to Question 3)
- Robust research on the harms of cannabis.

'The scientific verdict is that marijuana can be addictive and dangerous. Despite denials by special interest groups and marijuana businesses, the drug's addictiveness is not debatable: 1 in 6 kids who ever try marijuana will become addicted to the drug, according to the National Institutes of Health. Many baby boomers have a hard time understanding this simply because today's marijuana can be so much stronger than the marijuana of the past.

In fact, more than 450,000 incidents of emergency room admissions related to marijuana occur every year, and heavy marijuana use in adolescence is connected to an 8-point reduction of IQ later in life, irrespective of alcohol use.

Marijuana users also have a six times higher risk of schizophrenia and are significantly more likely to development other psychotic illnesses. It is no wonder

that health groups such as the National Alliance of Mental Illness are increasingly concerned about marijuana use and legalization'. vii

Lack of credible research, especially on smoked marijuana.

For example: Following the establishment of the *Center for Medicinal Cannabis Research* (CMCR) at the *University of California* in 1999, the number of research projects on smoked cannabis has increased. Several clinical studies have been published on neuropathic pain and experimentally induced pain. In general the results show a modest analgesic effect of smoked cannabis over placebo. It is important to note that most of the subjects in these studies were cannabis experienced, so the results may not be able to be extrapolated to cannabis naïve patients. Moreover, because the subjects were cannabis-experienced, it is likely that blinding was compromised and hence the findings should be interpreted with this in mind.

• Abuse of the systems in place, where Medical Cannabis has been legalised:

There seems little doubt that marijuana is being diverted from medical programs for 'recreational' purposes. The *Las Vegas Metropolitan Police Department* recorded an enormous 1200 percent increase in grow site seizures between 2006 and 2010. viii

In Colorado, 48.8 percent of adolescents admitted to substance abuse treatment obtained their marijuana from someone registered to use medically. The authors 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.

In a recent study by Cerda and co-workers, it was found that states with medical marijuana laws had higher rates of use, abuse and dependence.^x

2. Would DFA consider it for any indications e.g. for people who are terminally ill and in intractable pain and for whom conventional medicines have not worked? Or any other patients with distressing symptoms

DFA would not consider cannabis for any indications for the following reasons: As in Australia, there are no sound scientific studies supported the medical use of marijuana for treatment in the United States and no animal or human data supported the safety or efficacy of marijuana for general medical use.

To quote Dr Stuart Reece, Fellow of Drug Free Australia: 'Approved narcotics work very well in these indications, where many combinations are used in palliative care which are very effective in pain relief. To gain therapeutic effects using cannabis high cannabinoid levels need to be achieved, at which the psychotropic / hallucinogenic effects of cannabis become predominant and are not tolerated by patients who are not used to these effects of cannabis'.

In the United States, the Food and Drug Administration also concurs that there are alternative (FDA)-approved medications in existence for treatment of many of the proposed uses of smoked marijuana.

3. If not, what alternatives does DFA support?

'Currently there are 4 formulations of active ingredients, dronabinol (Marinol), nabilone, nabiximols (Sativex) and rimonabant. The first two are THC lookalikes, whereas Nabiximols is a marijuana extract containing both THC and CBD. Rimonabant is a cannabinoid receptor blocker which was initially marketed as an anti-obesity drug in Europe in 2006 before being withdrawn soon after when side effects including serious depression and suicidal ideation were found to be frequent.

Dronabinol was approved by the US *Food and Drug Administration* (FDA) in 1985 for treating chemotherapy-induced nausea and vomiting and AIDS-related wasting, and although proven effective, both dronabinol and nabilone have not become the mainstays of treatment mainly because of their side effects, which include sedation, anxiety, dizziness, euphoria/dysphoria and hypotension, as well as the presence of superior alternatives.

Dronabinol and nabilone have also been shown to produce symptomatic relief of neuropathic pain and the spasticity associated with multiple sclerosis. However, whilst patients report alleviation of spasticity, measures of objective changes are mixed. In a recent study by Kraft and co-workers, an orally administered extract of cannabis containing mainly THC was found to have no beneficial impact on acute pain and may possibly have enhanced pain sensation. This study highlights not only the complex nature of pain itself, but also the importance of identifying specific therapeutic contexts in which THC may or may not be useful.

It should be noted that while these studies are conducted much like other studies on medical agents, a particular problem arises because the psychoactive side effects of dronabinol and nabilone make it difficult to maintain appropriate blinding, which is a basic requirement of a randomized controlled trial. In other words, when the research subjects become aware that they are receiving the active ingredient and not the placebo, their perception of therapeutic value is potentially confounded and a study's claim of therapeutic advantage over placebo may be compromised.

Nabiximols is an interesting example of a novel form of delivery by nasal spray that has the advantage of rapid absorption. By including both THC and CBD together, it may be that CBD limits some of the adverse side effects common with THC alone. It has been licensed for the treatment of cancer pain and neuropathic pain.

The role of CBD in potentially mitigating some of the adverse effects of THC may prove to be a valuable finding. It also highlights why use of the raw herbal product could be even more problematic than already thought, because as new strains have been developed, the amount of THC has risen at the same time as the amount of CBD has declined. In some strains, CBD is virtually absent. When production of cannabis is permitted by the public for medical use, there is no control over the levels of active ingredients and in particular the ratio of THC to CBD.

One final variation on delivery systems involves vaporization of the herbal product. This means of delivery is about as close as possible to smoked marijuana. Some clinical trials are currently underway.

It is important to note that with each of these formulations little is known about the medium to long term adverse effects. However, given that there is evidence for long-term harm arising from studies of those who smoke cannabis regularly, significant caution should be exercised about these formulations of active ingredients'. xi

DFA supports the use of approved alternatives such as Nabiximols (also known as Sativex). If they need to be made more accessible and less costly, Australia has a PBS process that could be employed to assist.

4. Do you think there is a place for medical cannabis if it is strictly controlled e.g prescribed by doctors and dispensed by pharmacists?

DFA's findings from examples in the United States where cannabis has been legalised show that strict controls are not working. For example:

- Increased use of marijuana
- Laws abused
- Taxation benefits lower than expected
- 5. Is DFA comfortable with the use of the drugs morphine, amphetamine, ketamine and cocaine for medical purposes, as allowed now in Australia?

When used for medical purposes, having been authorised by the TGA, these drugs are acceptable. Cannabis however, is far more complex and components far more difficult to control. For example, while opium has been recognised for its medicinal value for many centuries, the active ingredients codeine and morphine have now been extracted and subjected to extensive research and analysis over many years. We now have both in various formulations with known dosage and purity, a body of information on side-effects, known indications and contraindications, knowledge of therapeutic targets, patient populations for whom treatment is appropriate, and knowledge of abuse potential. No medical authority would ever prescribe or even recommend smoking opium, not only because of the availability of formulations of active ingredients which are superior, but also because of the harm of smoking as a delivery system. **ii

- 6. If not, what alternatives does DFA support?

 The use of approved drugs as described in Questions 2 and 3.
- 7. Would DFA support a trial into the use of medical cannabis in Australia?

DFA would not support a trial for the following reasons:

- All of the above. Plus:
- The system that is in place through the Therapeutic Goods Administration should not be bypassed. We have enough ethically and legally authorised pharmaceutical medicines that assist medical responses to pain and suffering available
- As stated in question 1, there is an abundance of research, information and emerging trends with negative outcomes from locations where medical cannabis has been introduced, especially in the United States. Regarding the direct health effects of cannabis, Nora Volkow MD, NIDA, has produced 'Adverse Health Effects of Marijuana Use' gives current data that has been well researched.

This is more than sufficient for Australia to use as a gauge, without having to introduce trials here.

End notes/acknowledgements:

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ⁱ O'Connor C, High Roller: How Billionaire Peter Lewis Is Bankrolling Marijuana Legalization, Forbes Magazine, April 2012 See http://www.forbes.com/sites/clareoconnor

ii Rachel Ehrenfeld, May 1996, The Movement to Legalize Drugs in the United States: Who's Behind It? Downloaded from the Capital Research website www.capitalresearch.com

- viii Raybuck T, Medical Marijuana, Nevada's Big Gamble. *The Journal of Global Drug Policy and Practice* 5(2), 2011
- ix Thurstone C, Lieberman SA & Schmiege SJ, Medical marijuana diversion and associated problems in adolescent substance treatment. *Drug Alcohol Dependence* 118(2-3):489-492, 2011
- ^x Cerda M *et al.*, Medical marijuana laws in 50 states: investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence, *Drug Alcohol Depend.* 120(1-3): 22-27, 2012

For more information go to www.drugfree.org.au

iii http://edition.cnn.com/2014/07/10/opinion/sabet-colorado-marijuana/

iv http://www.ibhinc.org/pdfs/RLDMedMJTestimony031407.pdf

^v Pike G, Medical Marijuana, May, 2013

vi Pike Op Cit 2013

vii Kevin Sabet http://edition.cnn.com/2014/07/10/opinion/sabet-colorado-marijuana

xi Pike, Op. Cit 2013

xii Pike, Op Cit 2013

xiii Nora D. Volkow, M.D., Ruben D. Baler, Ph.D., Wilson M. Compton, M.D., and Susan R.B. Weiss, Ph.D. Adverse Health Effects of Marijuana Use', N Engl J Med 2014; 370:2219-2227June 5, 2014.