INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

Organisation: FamilyVoice Australia

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Submission

on the

Use of Cannabis for Medical Purposes

to the

General Purpose Standing Committee No. 4

Legislative Council Parliament House Macquarie St Sydney NSW 2000

Telephone: 02 9230 2976

Email: gpscno4@parliament.nsw.gov.au

Website: http://www.parliament.nsw.gov.au/gpsc4

by

FamilyVoice Australia GPO Box 9894 Sydney NSW 2001

Telephone: 1300 365 965

Facsimile: 08 8223 5850

Email: office@fava.org.au

Website: www.fava.org.au

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1. Introduction

On 22 November 2012 the Legislative Council of the Parliament of New South Wales referred to its General Purpose Standing Committee No. 4 a reference to inquire into the use of cannabis for medical purposes.

The Committee has invited written submissions addressing these issues. Submissions are due by 15 February 2013.

2. No medical use for marijuana

Beginning with California in 1996 several States of the United States of America have passed laws which permit the use of marijuana (and in some States the cultivation of marijuana plants) by persons who have a certificate from a doctor stating that the person can medically benefit from marijuana use. Some States specify a list of conditions for which such certificates may be issued.

In 2001 the United States Food and Drug Administration usefully summarised its position on the medical use of marijuana.

There is suggestive evidence that marijuana may have beneficial therapeutic effects in relieving spasticity associated with multiple sclerosis, as an analgesic, as an antiemetic, as an appetite stimulant and as a bronchodilator, but there is no data from controlled clinical trials to support a new drug application for any of these indications.

Data of the risks and potential benefits of using marijuana for these various indications must be developed to determine whether botanical marijuana, or any cannabinoid in particular, has a therapeutic role...

In March 1999, the Institute of Medicine (IOM) issued a detailed report that supports the absolute need for evidence based research into the effects of marijuana and cannabinoid components of marijuana, for patients with specific disease conditions.

The IOM report also emphasized that smoked marijuana is a crude drug delivery system that exposes patients to a significant number of harmful substances and that "if there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives."

As such, the IOM recommended that clinical trials should be conducted with the goal of developing safe delivery systems.¹

In its official report titled "Marijuana and Medicine: Assessing the Science Base", the Institute of Medicine highlighted a number of risks to the public health as a result of cannabis consumption:

- Cognitive impairments associated with acutely administered marijuana limit the activities that people would be able to do safely or productively. For example, no one under the influence of marijuana or THC should drive a vehicle or operate potentially dangerous equipment.²
- The most compelling concerns regarding marijuana smoking in HIV/AIDS patients are the possible effects of marijuana on immunity. Reports of opportunistic fungal and bacterial pneumonia in AIDS patients who used marijuana suggest that marijuana smoking either suppresses the immune system or exposes patients to an added burden of pathogens. In

summary, patients with pre-existing immune deficits due to AIDS should be expected to be vulnerable to serious harm caused by smoking marijuana. The relative contribution of marijuana smoke versus THC or other cannabinoids is not known.³

- DNA alterations are known to be early events in the development of cancer, and have been
 observed in the lymphocytes of pregnant marijuana smokers and in those of their newborns.
 This is an important study because the investigators were careful to exclude tobacco
 smokers; a problem in previous studies that cited mutagenic effects of marijuana smoke.⁴
- Three factors influence the safety of marijuana or cannabinoid drugs for medical use: the delivery system, the use of plant material, and the side effects of cannabinoid drugs.
 - (1) Smoking marijuana is clearly harmful, especially in people with chronic conditions, and is not an ideal drug delivery system.
 - (2) Plants are of uncertain composition, which renders their effects equally uncertain, so they constitute an undesirable medication.
 - (3) The side effects of cannabinoid drugs are within the acceptable risks associated with approved medications. [However, a]s with many medications, there are people for whom they would probably be contraindicated.⁵

Recommendation 1:

No consideration should be given to allowing any exemptions from the laws regulating cannabis and marijuana under the guise of medical use.

3. Cannabis derived or related products

The Therapeutic Goods Administration (TGA) has given limited approval for three cannabis derived or cannabis-like synthesised products for use in Australia following its usual processes:

- Nabilone A synthetic cannabinoid used for treatment of anorexia and for its antiemetic effects (e.g. in cancer patients under chemotherapy); its chemical structure is closely related to THC;
- Dronabinol Synthetically produced pure THC applied in multiple sclerosis and pain patients;⁶
- Nabiximols (botanical extract of Cannabis sativa which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.⁷

Dronabinol and nabiximols currently may only be prescribed by a medical practitioner available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health and Ageing under section 19 of the Therapeutic Goods Act 1989 which provides for the limited use of drugs which are not approved for general use in Australia under special circumstances.⁸

On 26 November 2012 the TGA added to the Australian Register of Therapeutic Goods a specific nabiximol product, namely "Sativex Oromucosal Spray, nabiximols 80 mg/mL pump actuated metered dose aerosol", and approved its use as follows:

Sativex is indicated as treatment, for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other antipasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.⁹

Before this product can be used, a change needs to be made to the Poisons Schedule and a consultation on this change is underway. The change would allow any doctor to prescribe Savitex for the indicated condition.

Recommendation 2:

Cannabis-derived or cannabis-like synthesised products should only be approved for use following the same rigorous scrutiny used for all other therapeutic goods. Care needs to be taken that listing such a product would not facilitate its abuse for non-medical purposes.

4. Endnotes

1. Food and Drug Administration, "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act", *Federal Register*, Wednesday, 18 Apr 2001, Vol. 66, p. 20047.

2. Institute of Medicine, *Marijuana and medicine: assessing the science base*, National Academy press, 1999, p 107: http://www.nap.edu/openbook.php?record id=6376&page=1

- 3. *Ibid.*, p 116-117.
- 4. *Ibid.*, p 118-119.
- 5. *Ibid.*, p 127.
- 6. Final Decisions & Reasons for Decisions by Delegates of the Secretary to the Department of Health and Ageing, Department of Health and Ageing, Jul 2011, p 1: https://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CDoQFjAB&url=http%3A%2F%2Fwww.tga.gov.au%2Fword%2Fscheduling%2Fscheduling-decisions-1107-final-a.doc&ei=PngUUZXiA6-wiQfi7IAo&usg=AFQjCNEZV2lqcAEc4nQ8m8ALHWsHGEVbAQ
- 7. Poisons Standard 2012, Schedule 8.
- 8. Poisons Standard 2012, Appendix D, Section 3.
- 9. Theraputic Goods Administration, Sativex Oromucosal Spray, nabiximols 80 mg/mL pump actuated metered dose aerosol: Public summary, Nov 2012: <a href="https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs%2FPublicHTML%2FpdfStore.nsf&docid=80AE3C9BF0BDD408CA257AC2003CB6EF&agid=(PrintDetailsPublic)&actionid=1
- 10. Invitation for public comment ACMS and ACCS meetings, Mar 2013: http://tga.gov.au/newsroom/consult-scheduling-acmcs-1303.htm#notice