ANMF
TASMANIAN BRANCH

Australian Nursing & Midwifery Federation (Tasmanian Branch)

Inquiry into the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes

Submission August 2014

Australian Nursing & Midwifery Federation (ANMF)

Organisation Overview

The Australian Nursing and Midwifery Federation (ANMF) is both the largest nursing and midwifery union and the largest professional body for the nursing and midwifery teams in Tasmania. We operate as the State Branch of the federally registered Australian Nursing and Midwifery Federation. The Tasmanian Branch represents over 7,100 members and in total the ANMF across Australia represents over 240,000 nurses, midwives and care staff. ANMF members are employed in a wide range of workplaces (private and public, urban and remote) such as health and community services, aged care facilities, universities, the armed forces, statutory authorities, local government, offshore territories and more.

The core business of the ANMF is the industrial and professional representation of nurses, midwives and the broader nursing team, through the activities of a national office and branches in every state and territory. The role of the ANMF is to provide a high standard of leadership, industrial, educational and professional representation and service to members. This includes concentrating on topics such as education, policy and practice, industrial issues such as wages and professional matters and broader issues which affect health such as policy, funding and care delivery. ANMF also actively advocates for the community where decisions and policy is perceived to be detrimental to good, safe patient care.

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As a nurse, we have the opportunity to heal the heart, mind soul and body of our patients, their families and ourselves.

They may forget your name, but they will never forget how you made them feel. (Maya Angelou)

The ANMF (Tas Branch) welcomes the opportunity to contribute to the Legislative Council Government Administration Committee "A'' inquiry on the use of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.

Summary of Submission

The support for the use of cannabinoids is now gaining momentum among many representative groups and there is growing community support.[1] The Cancer Council NSW, as an evidence based organisation, has since 2012 strongly supported the use of cannabis under medical supervision to treat pain, nausea and weight loss. The American Medical Association in 2009 recommended rescheduling cannabinoid medicines to allow them to be prescribed and there is a stronger medical consensus emerging.[2] The NSW Nurse and Midwives Association has also supported the recommendations of the NSW Legislative Council General Purpose Standing Committee No.4 report on the inquiry into the safety and efficacy of cannabis for medical purposes (2013). Medicinal Cannabis is now legally available in 20 states in the United States of America, Canada and the United Kingdom.
The therapeutic benefits of medicinal cannabis and cannabinoids are substantial. Although not without risks and adverse effects, on balance the advantages outweigh the risks of not being able to provide alternative treatment options for those with conditions known to be remediated with medicinal cannabis and cannabinoids. The ANMF (Tas Branch) would submit that no longer are the medicinal properties of cannabis still only delineated by anecdotal reports but that it is clear cannabis has genuine medical utility. However this has largely been overlooked, with research and the community gaze directed toward the hazards of recreational use rather than the benefits for medicinal use.

- The ANMF (Tas Branch) strongly supports the decriminalisation of cannabis and cannabinoids for medical use.
- The ANMF (Tas Branch) strongly advocates affordable, equitable access to information and medicinal cannabis and cannabinoids if and when it is available
- The ANMF (Tas Branch) strongly supports the introduction of clinical trials to establish the efficacy of cannabis and cannabinoids
- The ANMF (Tas Branch) does not support indiscriminate access to cannabis in any form and would expect any supply chain to have effective quality control mechanisms in place.

[1] Australian Institute of Health and Welfare. 2010 National Drug Strategy Household Survey Report. Canberra.
[2] Adler,JN & Colbert, JA 2013, Clinical decisions: medicinal use of marijuana-polling results. *N Eng J Med*, 368 e 30

- The ANMF (Tas Branch) does not support the smoking of medical cannabis however a dose specific vaporised cannabinoid approach is.

The ANMF (Tas Branch) forwards this submission after consultation with members and governance committees and believes this submission is consistent with the definition of nursing by the International Council of Nurses.

Nursing encompasses autonomous and collaborative care of individuals of all ages, families, groups and communities, sick or well and in all settings. Nursing includes the promotion of health, prevention of illness, and the care of ill, disabled and dying people. Advocacy, promotion of a safe environment, research, participation in shaping health policy and in patient and health systems management, and education are also key nursing roles. (ICN)

Terms of Reference

1. ***The Efficacy and safety of natural botanical medicinal cannabis flower and extracted cannabinoids for medical purposes.***

   The therapeutic properties of cannabis have been recognised for thousands of years. Physicians in ancient China used it to relieve constipation, loss of appetite, and pain during childbirth. The use of cannabis for medicinal purposes is well documented and the primary use of cannabis and cannabinoids is relief of symptoms rather than cure of underlying disease. With the development of synthetic drugs in the 20th century, herbal remedies in general fell into disuse.

   The research related to the value of cannabis as a medicine has proliferated over the last 20years.yet the value of cannabis as a medicine is still disputed. Whilst a major review by Zimmer and Morgan (2002) concluded that 'marijuana's therapeutic uses are well-documented in the modern scientific literature'[3]the medicinal properties of cannabis are still mainly delineated by the anecdotal reports of those who believe their symptoms are relieved by its use and these accounts are often dismissed as wishful thinking or even mischievous.[4] The ANMF (Tas Branch) would submit that no longer are the medicinal properties of cannabis still only delineated by anecdotal reports but that it is clear cannabis has genuine medical utility. However this has largely been overlooked, with research and the community gaze directed toward the hazards of recreational use rather than the benefits for medicinal use. [5],[6]

   It is to the evidence that social and legal reforms must look to ensure: the benefits outweigh the risks, clinical efficacy, safety and cost effectiveness and superiority in therapeutic outcomes for users.

   This submission will focus on the conditions and symptoms most represented in the research literature under controlled conditions:

   a) ***Chronic Pain*****:** The conclusions drawn from two exhaustive literature reviews on the analgesic properties of medicinal cannabis were highly favourable.[7],[8]. A comprehensive literature review conducted by Atha of 134 studies concluded there was an overwhelming body of research on both animal and human models to demonstrate an increased tolerance to pain from the administration of cannabis or individual cannabinoids.[9]
   b) ***Nausea and Vomiting****:* Nissar Darmani, a researcher who has contributed significantly to the reliable research related to the use of cannabinoids in treating nausea, has identified significant evidence to support the selective use of cannabinoids as a beneficial adjunct to the management of nausea and vomiting, particularly associated with chemotherapy treatment for

[3] L Zimmer and J Morgan, *Marijuana Myths, Marijuana Facts* (2002) 127.
[4] ibid
[5] Nutt, DJ, King, LA, Nichols, DE 2013, Effects of Schedule 1 drug laws on neuroscience research and treatment innovation, *Nat Review Neuroscience*, 14:577-585
[6] Gross, M 2013, Drugs prohibition is criminals 'gain, neuroscience's loss, *Curr Biol,* 23: R585-R588
[7] Walker, J & Huang.S 'Cannabinoid Analgesia' (2000) 95 (2)*Pharmacology and Therapuetics* 127–135.
[8] Vaughan C, & Macdonald, J 2005, 'Mechanisms of cannabinoid analgesia', Chapter 5 in Grotenhermen and Russo (eds) *Cannabis and Cannabinoids: Pharmacology, Toxicology, and Theraputic Potentia.l*
[9] Atha, M 2006, *Cannabis and Pain Relief: A Literature Review,* London UK, Independent Drug Monitoring Unit

cancer.[10] Amar's[11] extensive review of the literature related to the therapeutic potential of medicinal cannabis confirms 29 out of 31 studies demonstrated significantly superior effects of medicinal cannabis as an anti-emetic to other drugs. In addition Parcher (2006) conducted a literature review which concluded medicinal cannabis was a"… *highly efficacious therapeutic agent, in cases of nausea and vomiting resistant to more conventional medications".*[12]

c) ***Chemotherapy Induced Nausea and Vomiting (CINV***): is often resistant to conventional treatments, adds significantly to the burden of disease and is universally accepted as having a significant impact on patient's quality of life. [13] but chemotherapy is widely accepted as an integral modality for cancer treatment. Tramar et al (2001) [14] distilled 30 randomised comparisons between various cannabinoids, conventional anti-emetics and placebos, and found that the cannabinoids were generally more effective antiemetics than the conventional formulary. However, the author cautions about the side effects when taken in both short and long term use related to sedation, drowsiness, constipation, euphoria and a "high"' feeling. The authors did however concede that this side effect may have a vicarious beneficial effect.

d) ***Spasticity*****:** There have been a number of studies of the therapeutic use of cannabis to reduce spasticity in people with multiple sclerosis (MS). The findings of 3 research studies conducted in 2006 found favourable results advocating the use of cannabis to relieve the spasticity associated with MS, however recommending the results should be confirmed in further larger scale clinical trials.[15]

e) ***Seizures:*** There is small but growing research activity related to the use of cannabinoids and compounds in severe forms of epilepsy in children. The language used to describe the findings of the pre-clinical trials as "*profound and highly encouraging".*[16]

f) ***Appetite and wasting*****:** One of the most debilitating effects of many acute and chronic conditions is the cachexia and loss of appetite experienced by sufferers, whether through the manifestations of the disease process or from the treatment options available. Smith (2002) completed a literature review of seventy-two controlled studies and reached the conclusion that cannabinoids exhibited therapeutic potential as anti-emetics and appetite stimulants particularly in debilitating diseases of cancer and AIDS.

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[10] Darmani, N 2005, in E Onaivi (ed), *Marijuana and Cannabinoid Research: Methods and Protocols* (2006)and Grotenhermen in F Grotenhermen and E Russo (eds), *Cannabis and Cannabinoids: Pharmacology,Toxicology and Therapeutic Potential* (2005).

[11] Amar ben A 2006 'Cannabinoids in Medicine: A review of Their Therapeutic Potential', *Journal of Ethnopharmacology*, *105*, 1–25

[12] Parcher, P 2006, 'The Endocannabinoid System as an Emerging Target of Pharmacotherapy' 58 *PharmacologyReview* 389–462

[13] Grunberg, SM, Slusher, B, Rugo, HS. Emerging treatments in chemotherapy-induced nausea and vomiting. *Clinical Advances in Hematology & Oncology*, 11 (2 Suppl 1) :1-18

[14] Tramar et al

[15] Parcher, Ibid.

[16] Whalley, B 2013, AHP Theraputic Compendium: Cannabis in the Management and Treatment of Seizures and Epilepsy: *A Scientific Review.*

g) ***Neurological disorders*:** The chronic disability suffered as a consequence of neurological conditions such as, Parkinson's disease, Multiple Sclerosis (MS), Motor Neurone Disease and Tourette's syndrome have been well described. An extensive review of 135 research studies since 1998, (Atha, 2006)[17] revealed a proliferation of studies on the effects of cannabinoids on MS with the vast majority showing a therapeutic effect. MS is now a condition approved for the prescription of medicinal cannabis in the jurisdictions of the United Kingdom, Canada, several states of the United States where the use of medical cannabis is legal. Significant benefits have also been demonstrated in those with Tourette's syndrome, particularly providing relief from the debilitating and exhausting tics and behavioural problems.[18]

h) ***Huntington's Disease-*** Less well known is the significant effects, THC may have on slowing the progress of this disease as well as improvement of symptoms in already symptomatic patients[19]

The efficacy and safety of cannabis use for medical purposes has research findings significantly weighted in favour of considerations. This is particularly demonstrated in its therapeutic use to manage neurological diseases, the relief of pain and the debilitating effects of CINV. In evaluating the evidence it is important to consider the reports of adverse effects reported in the research. A Canadian study reviewed the medicinal cannabis literature and found 31 studies which collectively reported 4779 side effects of which 99.6% were not serious. There were 164 effects described as serious including relapse of MS (12.8%) and vomiting (9.8%). The conclusions were drawn that short term use increased the risk of non-serious adverse effects but long term use risks were poorly defined and required further research trials.[20] Wang et al. however suggest that the risk of adverse effects associated with short term use is minor.[21] There has been also been significant research related to the psychological harms associated with cannabis use. However this research has been conducted in relation to recreational users rather that medicinal applications and these studies have been dominated by those considered 'heavy'' users. The conclusions warned against extrapolating this data to assume that the findings predicted psychological harms in medical use.[22] The risks for ongoing dependence would be no greater that that posed already by the use of opiates.

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[17] Atha, ibid

[18] Killestein et al, 2002, 'Cannabinoids in Multiple Sclerosis: Urgent Need for Long Term Trials' *Neurology, 58,* 1404–1407 and D Wade et al, 'A Preliminary Controlled Study to determine whether whole plantcannabis extracts can improve intractable neurogenic symptoms' (2003) 17(2) *Clin Rehabil* 21–29.

[19] Peggy C. Nopoulos, Elizabeth H. Aylward, Christopher A. Ross, James A. Mills, Douglas R. Langbehn, Hans J. Johnson, Vincent A. Magnotta, Ronald K. Pierson, Leigh J. Beglinger, Martha A. Nance, Roger A. Barker, Jane S. Paulsen, and the PREDICT-HD Investigators and Coordinators of the Huntington Study Group (2011) Loss of striatal type 1 cannabinoid receptors is a key pathogenic factor in Huntington's disease. Brain 2011 134: 119-136.

[20] L Degenhardt and W Hall, 'The Adverse Effects of Cannabinoids: Implications For Use of Medical Marijuana' (2008) 178 *Canadian Medical Association Journal*

[21] T Wang et al, 'Adverse Effects of Medicinal Cannabinoids: a Systematic Review' (2008) 178 *Canadian Medical Association Journal* (3) 1669–1678, 1669.

[22] Idid, 19

2. If, and how, natural botanical medicinal cannabis flower and extracted cannabinoids could/and/or should be supplied for medical use.

The ANMF (Tas Branch) does not support indiscriminate access to cannabis in any form and would expect any supply chain to have effective quality control mechanisms in place. However the balance between access, supply and patient availability must be carefully balanced to ensure equity, affordability and continuity. The considerations here are two fold: the distribution pathway and the supply chain and modes of administration.

The Distribution Pathway

The logistics pathway of distribution should be regulated through licensing, and with rigorous compliance expectations. Models of this already exist in Tasmania through the Tasmanian Poppy industry hence the distribution of medicinal cannabis should not differ from other botanical therapeutic agents. Further studies should be implemented to review the capacity for cultivation of own use supplies for those registered as ''authorised cannabis users and carers''. Failure to provide appropriate distribution pathways may lead to the growth in unscrupulous sources of supply and the potential for illegal activity by the patients themselves. However it is unlikely a patient relying on the medicinal cannabis for symptom control is likely to be engaged in this type of activity. The distribution of cannabinoids in any form must be consistent with the research which suggests that a regulated chemical content of THC and CBD in proportion should be the minimum standard.

The Supply Chain and modes of Administration

Medicinal grade cannabis should remain within the purview of a prescribed medication for specific use. This not only ensures appropriate patient education is provided at point of supply but the monitoring of patient outcomes. The challenge for dosing with medicinal cannabis is titration. There is no pharmaco-therapeutic dose and not dissimilarly with opiates, requires a balance between efficacy and unwanted side effects. The supply through a qualified pharmacist would enable the most efficacious dose to be explored. The pharmacist in collaboration with others in the health team including nurses would then be able to provide an inter-professional team approach to care. The relationship between the patient and doctor should have primacy in the consideration of ongoing symptom management. The current situation where doctors are able to prescribe with clear guidelines would appear to be the most appropriate as it is in the fiduciary relationship where the moral and legal obligations lie.[23]

The clinical trial as proposed by Tasman Health Cannabinoids Pty Ltd. in collaboration with the University of Tasmania afforded a significant opportunity to add to the evidence base related to medical use of cannabis and to use the excellence of a local company and institution to explore the issue. This is a missed opportunity to provide a significant contribution to evidence based research, position Tasmania as a

[23] Hazenkamp, A & Heerdink ER, 2013, The prevalence and incidence of medicinal cannabis on prescription in the Netherlands. Eur J Clin Phamacol:69; 1575-1580

source of international expertise and provide a substantial opportunity for the Tasmanian economy.

The mode of administration has been an issue of consternation primarily through the relationship of both medicinal and recreational cannabis use and smoking. The smoking of medical cannabis is not supported by ANMF (Tas Branch) and may not be acceptable to many patients. There are significant challenges in the administration of cannabinoids due to their phytochemical properties related to water insolubility. However the most common alternative modes of administration are: trans mucosal, per oral and trans pulmonary using vaporisation. The use of vaporisation provides rapid absorption and therefore maximum benefit. Vaporised cannabinoid approach has been successfully employed in research[24] and clinical trials.[25] This mode of delivery has been demonstrated to have wide application and is well tolerated and mitigates the stigma and health implications of smoking. There are also significant cost reductions in comparison with parenteral and oral administration. The administration of medicinal cannabinoids via vaporiser may also have implications for successful therapeutic use in children with CINV where the modes of administration of medications may be problematic.[26]

3. The legal implications and barriers to the medicinal use of natural botanical medicinal cannabis flower and extracted cannabinoids in Tasmania

The nursing profession is a regulated profession and operates in high regulated environments where there is often a tension which exists between compliance with regulatory and legal frameworks and the ethical values of advocacy, beneficence and autonomy of patients. The use of medicinal cannabis poses particular issues for nurses as they are the profession most often engaged in therapeutic relationships with patients across all contexts of healthcare practice. Nursing practice is premised on ensuring patients have access to the best available evidence and therapeutic guidelines enacted through evidence-based practice. Access and equity to information and treatment options is strongly advocated. The legal implications for nurses currently are that any assistance provided by them to support patient access or administer medicinal cannabis not only is illegal but places them at risk of de-registration. The stakes are high. The ANMF (Tas Branch) strongly supports the decriminalisation of cannabis and cannabinoids for medical use. This affords both protection for nurses as advocates and care providers and ensures patient's rights are protected. The Tasmanian *Poisons Act 1971* (the Act) and the *Poisons List* classify cannabis as a Prohibited plant and cannabinoids as Prohibited Substances. The legal implication for members of the community who currently access and use cannabis derivatives to manage symptoms of terminal conditions or chronic disease is profound. This additional burden is unconscionable in a modern world where the relief of suffering is a human issue not a political one and where policy should not

[24] Wilsey, B & Marcotte, T, Deutsch et al. 2013, Low dose vaporized cannabis significantly improves neuropathic pain, *J Pain*,14: 136-148

[25] Earleywine, M, & Barnwell, SS 2007, Decreased respiratory symptoms in cannabis users who vaporize. Harm Reduc J 4(1), 11.

[26] Abrahamov A, Mcchoulam, R 1995, An efficient new cannabinoid antiemetic in paediatric oncology. *Journal of the International Hemp Association* 2(2):76-79.

have the vicarious effect of criminalising behaviour with substantial penalties under the Criminal Code.

S. 52 of *Poisons Act 1971* (the Act) does however afford protection for the growing and cultivation of a prohibited plant under licence by the Minister, S.16 of the Act enables the manufacture of products and S. 53 of *The Act* does enable the Minister discretion in granting or refusing a licence. The ANMF (Tas Branch) would argue the Minister should use this discretion to grant a licence to enable the progression of clinical trials. The Therapeutic Goods Administration regulatory authority ensures the Australian community has access to therapeutic goods which are safe and efficacious. The responsibility of the authority is to weight the benefits against their risks in the public interest. The failure to enable the clinical trials of natural botanical cannabis in Tasmania is a missed opportunity to add to the evidence base related to the therapeutic use of cannabinoids and due deliberations by the Therapeutic Goods Administration.

The *Poisons Regulations 2008* already provides a regulatory framework for the possession, administration and storage of a prohibited substance by authorised officers including nurses and other health professionals. The ANMF (Tas Branch) strongly supports the extension of the existing *Poisons Regulations 2008* to include the possession of cannabinoid substances used for medical purposes.

Tasmania currently has a substantial poppy industry which operates safely in a regulated environment with stringent compliance expectations. A review conducted in July 2013[27] confirmed the existing regulatory framework combined with the Commonwealth *Narcotic Drugs Act 1967* was sufficient in scope to protect the community and ensure compliance with relevant obligations across jurisdictions. The ANMF (Tas Branch) suggests the existing regulatory frameworks should be extended to include natural botanical cannabis flower and extracted cannabinoids.

[27] Ramsay, J 2013, *Review of the Tasmanian Poppy Industry Regulation*, Report.