SmokeFree Tasmania

WORKSHOP:
Choosing Tobacco or Health:
Where to from here?

"Legalisation no Medicalisation of Commercial Marijuana the next threat to health"

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Alcohol & Drug Service, THS

Launceston City Library, 71 Civic Square, Launceston

25 June 2021

Click or hover on
notes & references

Medicinal Cannabis in Context of Tobacco Control

- Today I will discuss community, industry & political pressures to liberalise access to cannabinoids in the treatment of a wide range of medical conditions for which there are scientifically unsupported claims of therapeutic application & benefit, to demonstrate common failures of governance & of leadership in public policy reform & market intervention aimed at addressing avoidable unhealthy commodity-induced health harm across our nation
    - While focusing on the immediate risks of medicalisation I will draw parallels with the idea of legalisation & decriminalisation of cannabis for non-medical purposes
- In this I note the parallel governance & public policy challenges for our State & for our nation in addressing tobacco-induced health harm

Unbridled Enthusiasm

- **Mainstream & social media** accounts are full of **patient stories** suggesting cannabis provides therapeutic benefit for a very long & ever increasing list of medical conditions of vastly differing pathophysiology*
  - Influenced by **impassioned** pleas, anecdotes & narratives to make cannabis more accessible
- Many **politicians** have joined this **advocacy** movement, in the apparent belief that cannabis is a medical panacea, for which there is good scientific evidence when there isn't, clearly in the absence of having done their homework & getting themselves across the necessary scientific detail

- Suddenly, cannabis has gone from the status of being a '**bad drug**' used by '**bad people**' to having almost **saintly** properties
  - Neither view is scientifically erudite or helpful, noting that at present, the evidence supporting the efficacy of medicinal cannabis **falls** way **short** of the usual **standards** required for approval of medicines

Medical Conditions Claimed to Benefit from Cannabis

1. Spasticity, stiffness & pain in multiple sclerosis
2. Chronic nociceptive vs neuropathicpain
3. Chemotherapy-induced nausea, vomiting & anorexia
4. Terminal cancer appetite stimulant
5. Anti-inflammatory e.g., Crohn's Disease
6. Irritable bowel syndrome
7. Treatment of HIV/AIDS related wasting
8. Wasting syndromes more generally
9. Anorexia
10. PTSD
11. Treatment resistant epilepsy In childhood (12 syndromes) including:
    i. Dravet Syndrome (myoclonic epilepsy)
    ii. Lennox-Gastaut syndrome
    iii. Tuberous Sclerosis Complex
12. Neonatal Hypoxic Ischaemic Encephalopathy
13. Aggressive brain tumours (glioma)
14. Breast & skin cancer
15. Hepatitis C
16. Migraine headache
17. ADHD
18. Scleroderma

In view of this irrational retreat from science, it has been facetiously suggested our hospitals serve cannabis for breakfast, lunch & dinner!

19. Amyotrophic Lateral Sclerosis
20. Psoriasis
21. Tourette's Syndrome
22. Motor neuron disease
23. Glaucoma
24. Parkinson's Disease
25. Alzheimer's disease
26. Dementia more generally
27. Type 2 diabetes
28. Diabetic retinopathy
29. 'Aged care'
30. Arthritis ('rheumatism')
31. Fibromyalgia
32. Insomnia
33. Neuro-protectant following stroke or trauma (apoptosis)
34. Preventing opioid overdose
35. Opioid sparing action in pain Mx
36. Treatment of cannabis dependence
37. Neonatal hypoxic ischaemic encephalopathy
38. Schizophrenia
39. Sickle Cell Disease…

CART BEFORE HORSE

Anecdotally > 250 claimed conditions now'!

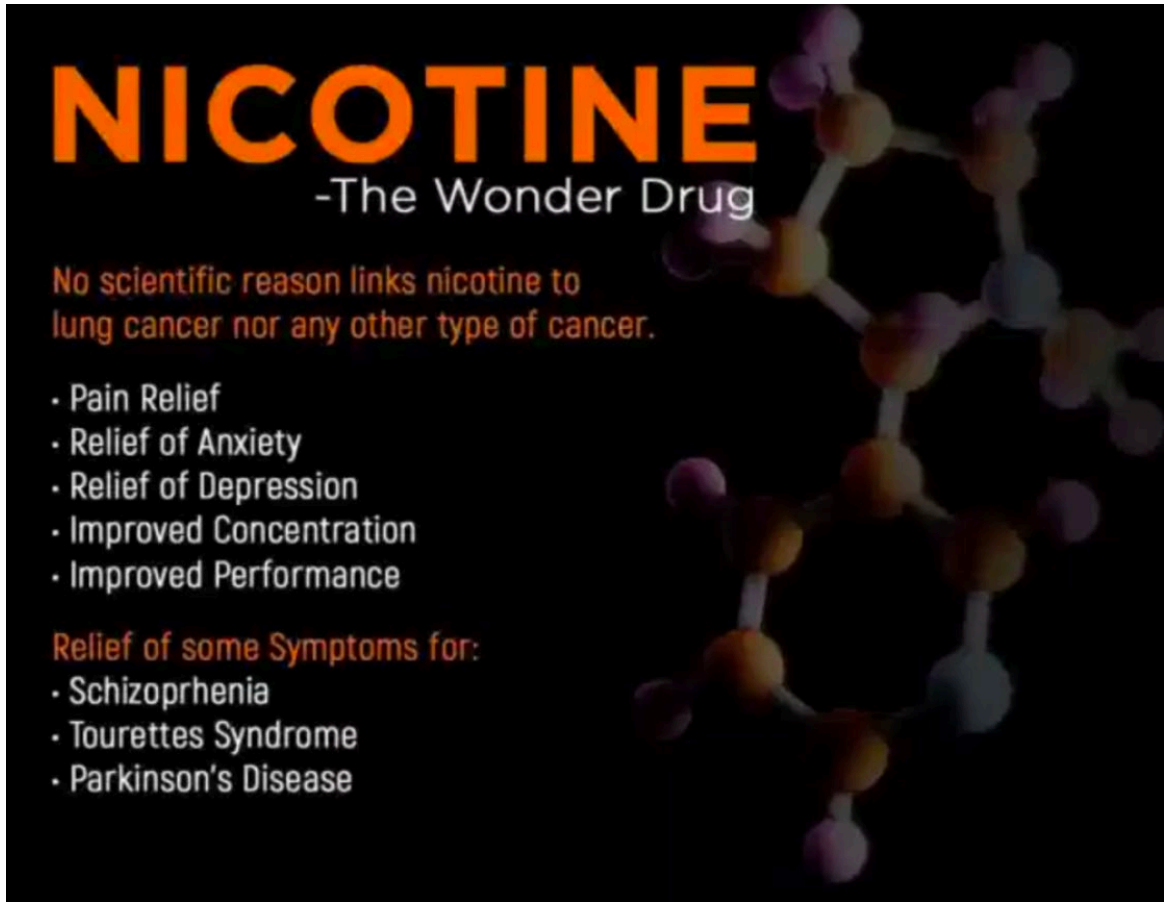
Personal Beliefs Trumping Science

- In a demonstration of commonplace ‘academic freeloading’ & a signal of what we are observing increasingly in Australia & internationally through social media, mainstream media & other avenues of communication:

  - *“I have no training or recognised & relevant tertiary qualifications in science or medicine, I have not done the hard yards of many years of undergraduate & post-graduate study in relevant areas of Medicine & Science, I am not an expert & I have not read all or even any of the salient scientific literature nor do I understand it but my personal opinion is as good as any expert’s knowledge, evidence & analysis…no, better & I demand governments, health professionals & society listens to & follows my opinion…& I will criticize, abuse & seek to publicly denigrate any medical or other expert who disagrees with me”*

Note the Analogous Behaviours: Nicotine, e-Cigs & Medicinal Cannabis

- This is the same kind of uninformed, misleading & reckless nonsense we see peddled through social & other media by those who clearly have no clue what they are talking about, however, in just making things up to suit they demonstrate they are willing to place the community at serious risk in pushing their own unfounded beliefs & self-interests on others, thereby further degrading already low levels of science, health & health policy literacy



What is Going on Here & Where is this Headed?

- A fledgling cannabis industry is now rapidly expanding in Australia & internationally, gearing up for a projected hundreds of billions of dollars annual revenue, globally
- In doing so, this new industry is running way ahead of the evidence to support its commercial claims & commercial aspirations, drawing upon contemporary best practice in marketing to tap into & manipulate a large & highly vulnerable audience

    - This explosion of industry product manufacture & marketing in the absence of usual standards of required medical evidence of effectiveness & safety is unprecedented & represents a cavalier & brazen disregard for an evidence-based, quality use of medicines framework usually expected if not medico-legally demanded by citizens, & quite reasonably so

PROHIBITION PARTNERS

This commercial behavior, supported by some governments & others, is pathognomonic of an all-too-common disrespect for & indeed, retreat from science

Race to Bring Cannabis to Market

- The current industry race to bring cannabis to the marketplace across the globe with industry sales & profit projections of a quantum beyond the hitherto wildest dreams of many (forecast **medicinal cannabis market €55.2b, recreational cannabis market €60.3b** & industrial cannabis market value of €180m in 2028), in the absence of anything close to good evidence to support what is occurring
- This again demonstrates the disconnect between understanding, valuing & respect for science, the evidence-indifference & the greed shown by vested commercial interests
  - Since when do we build a medicines market, yet alone one of massive proportions, for a wide range of medical interventions, well before we have anything resembling high quality, replicated peer reviewed published evidence to support this?

Usual Scientific Process Being Bypassed

- The usual scientific process of demonstrating safety & therapeutic efficacy is being bypassed in order to provide rapid access to products containing cannabinoids in patients suffering from terminal illness & certain chronic & complex diseases, on compassionate grounds *(Martin et al, 2018)*
  - Sounds familiar?

  - When I witness these behaviours, I don't just think about the clinical dimension, I think foremostly about the commonality of low science, health & health policy literacy in the Australian community & about governance structures, systems & processes for critical public policy decision making & their performance in regulating often quite bizarre, predatory & harmful human behaviour

Elected Representatives Unable to Manage Industry Pressures & Running for Cover

- Australian, State & Territory Governments are presumably feeling under pressure to endorse this commercial activity given substantial & growing behind the scenes industry inducements & coercion we must all assume, & given the 'advocacy' arising from poor health & related suffering & poorly informed community hopes & magical beliefs in the healing powers of cannabis products & under those additional pressures from a new industry with billion dollar signs in its eyes
  - As we observe historically, our parliaments & those in public administration are struggling (as they are internationally) with the (scientific) *'detail'* while so often crumbling to the *'retail'* in such matters
  - In the Australia case, the Australian government has elected to run for cover while trying to handball responsibility to the medical profession to prescribe these products, as they have with e-Cigarettes
  - Disturbingly, a small number of medical practitioners also appear to have responded in ways that are contrary to what they were taught about 'good science', 'safe, good medical practice' & the ethical duty of care obligations that arise from these two principles
    - Leading me to ask: have they carefully read & interrogated the scientific literature?

Pressures on Doctors to Prescribe

- I observe the medical profession should never be asked or expected to engage in clinical guessing or prescribing substances based on unfounded claims or wants or dollar signs in the eyes of new start up industry or of ill-informed & inappropriate political advocacy…
  - While recognising that patients are often desperate for new treatments given the present limitations of medicine in treating some complex & distressing chronic medical conditions
- Nor should the medical profession be expected to be a policy regulator or sentinel of access to unproven & potentially unsafe substances when our parliaments don't feel able or want to say '*no*' to unhealthy commodity industry & to community advocates …
- More appropriate would a response along the following lines:

Governments Must Govern for the People

"No, we cannot approve these products until we have good evidence that specific cannabinoid products meet good agricultural & good manufacturing standards & are safe & effective in the treatment of specifically studied medical conditions, prescribed in a specified formulation administered by a particular route, within a defined dose range & dosing interval for a particular medical condition & therapeutic purpose, including when taken in conjunction with other medicines or substances that may interact pharmacodynamically &/or pharmacokinetically & influence systemic availability, risk & incidence of adverse events; while noting right now, the clinical safety & efficacy concerns do not justify their undefined use in medicine"

- And to thus, do their job in alignment with scientific evidence & in support of expert medical advice

One State Stood Tall, Then Tripped Over Itself

- Until recently, one State stood out in listening to medical experts & in holding the line with its Cannabis Access Scheme (2016), requiring a disease specific non-GP medical specialist, if they saw merit based on limited existing scientific evidence, to prescribe unregistered cannabinoid products to citizens with a serious or chronic illness for which cannabinoids have been 'shown to be effective', subject to a process of clinical-regulatory review, however…
    - Without consulting medical experts in relevant fields including Pain Medicine & Addiction Medicine, & clearly without consulting the medical evidence, the Premier of that State announced its GPs would 'soon be able to prescribe cannabis', bringing that State into alignment with the other States & Territories & their unstructured & non-evidence guided position on this matter

One State Stood Tall, Then Tripped Over Itself

- It authorised GP prescribing & wider pharmacy dispensing from 01 July 2021; while noting that only two medicinal cannabis products are listed on the ARTG, Sativex (nabiximols) which is used to treat certain patients with multiple sclerosis & Epidyolex (cannabidiol) which is used for patients with certain epileptic conditions, notwithstanding the absence of good evidence to support those indications at this time & to demonstrate they deliver high value/ low risk treatment
- However, there are at present no low dose CBD or other cannabinoid products listed on the ARTG that could be supplied by pharmacies under Schedule 3, raising questions about how & why untested products might soon be so registered & why State governments acted before the facts
    - Only Schedule 4 cannabis products can be supplied by prescription at present if wanting to remain within the law

Must We Continue to Repeat the Errors of History?

- Have we learned nothing from the opioid epidemic, the COVID-19 pandemic, the adverse health, social & economic impacts of other unhealthy commodity industry behaviours & from OTC CACC (codeine) reforms managed so well by the TGA?
  - We can & simply must perform better than this in government & in governance if we are to prosper to our potential as a nation, into the future

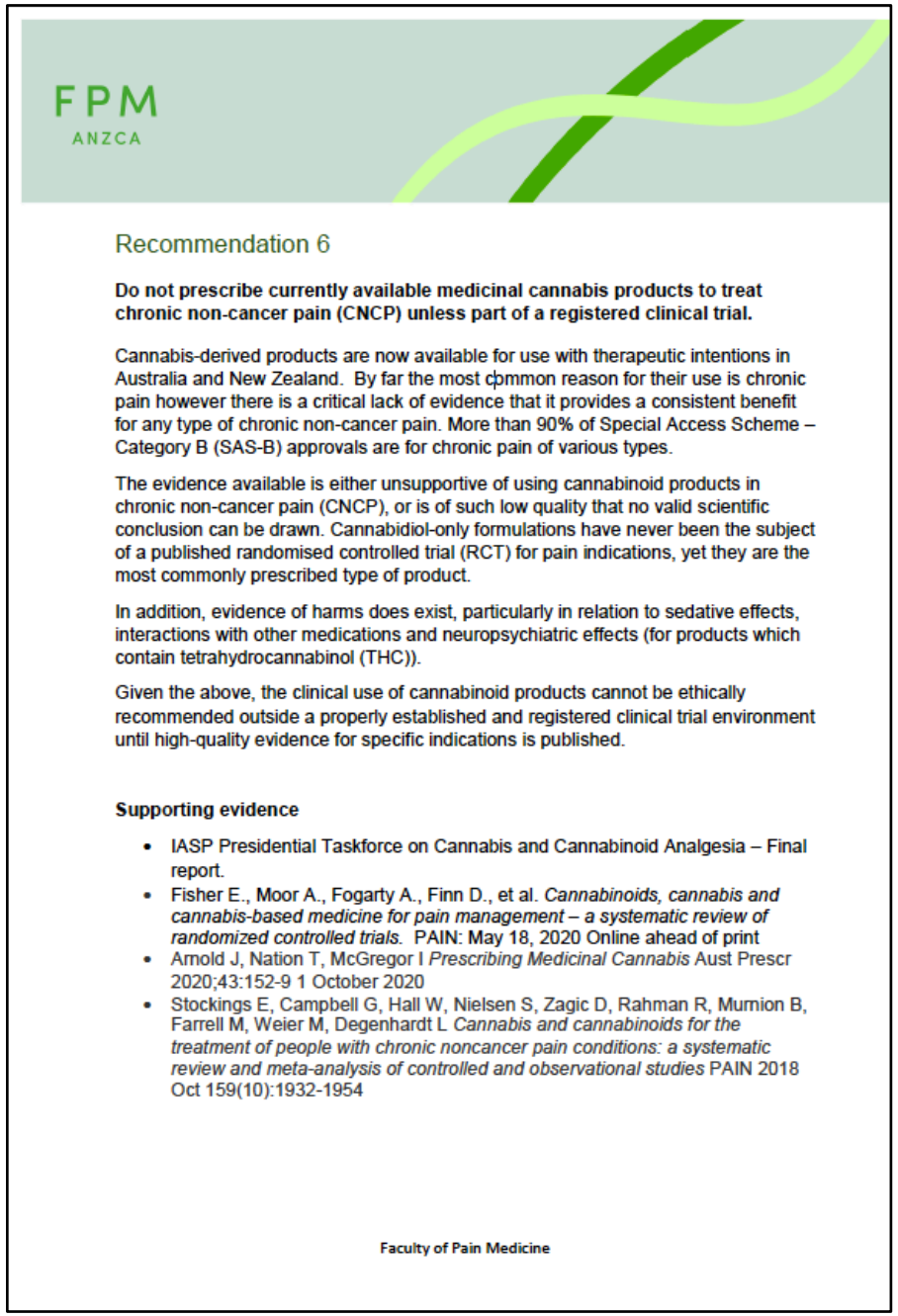
No Product Available Anytime Soon?

- Given the need for a ‘sponsor’ to provide significant data (in the absence of existing good data) demonstrating quality, safety & efficacy & given this demands high quality systematic review (AMSTAR-2) of high quality randomised & non-randomised studies demonstrating meaningful clinical benefit & low risk & harm associated with a specific cannabinoid for each & every medical condition where there are hopes or claims of therapeutic benefit…
- We cannot expect any cannabinoid to be added to the ARTG any time soon given the absence of compelling evidence for any cannabinoid in delivering such benefit for any medical condition
  - …that is, unless the TGA substantially lowers required standards …& I trust & expect that would only occur if inappropriate political pressures or directions were to be applied

FPM
FACULTY OF PAIN MEDICINE
ANZCA

FPM Position Statement 2021

- *"Prescribing 'medicinal cannabis' for CNCP is not supported by current evidence"*



FPM
ANZCA

Recommendation 6

Do not prescribe currently available medicinal cannabis products to treat chronic non-cancer pain (CNCP) unless part of a registered clinical trial.

Cannabis-derived products are now available for use with therapeutic intentions in Australia and New Zealand. By far the most common reason for their use is chronic pain however there is a critical lack of evidence that it provides a consistent benefit for any type of chronic non-cancer pain. More than 90% of Special Access Scheme – Category B (SAS-B) approvals are for chronic pain of various types.

The evidence available is either unsupportive of using cannabinoid products in chronic non-cancer pain (CNCP), or is of such low quality that no valid scientific conclusion can be drawn. Cannabidiol-only formulations have never been the subject of a published randomised controlled trial (RCT) for pain indications, yet they are the most commonly prescribed type of product.

In addition, evidence of harms does exist, particularly in relation to sedative effects, interactions with other medications and neuropsychiatric effects (for products which contain tetrahydrocannabinol (THC)).

Given the above, the clinical use of cannabinoid products cannot be ethically recommended outside a properly established and registered clinical trial environment until high-quality evidence for specific indications is published.

Supporting evidence

- IASP Presidential Taskforce on Cannabis and Cannabinoid Analgesia – Final report.
- Fisher E., Moor A., Fogarty A., Finn D., et al. *Cannabinoids, cannabis and cannabis-based medicine for pain management – a systematic review of randomized controlled trials.* PAIN: May 18, 2020 Online ahead of print
- Arnold J, Nation T, McGregor I *Prescribing Medicinal Cannabis* Aust Prescr 2020;43:152-9 1 October 2020
- Stockings E, Campbell G, Hall W, Nielsen S, Zagic D, Rahman R, Murnion B, Farrell M, Weier M, Degenhardt L *Cannabis and cannabinoids for the treatment of people with chronic noncancer pain conditions: a systematic review and meta-analysis of controlled and observational studies* PAIN 2018 Oct 159(10):1932-1954

Following a comprehensive review by the world's peak pain body, the **International Association for the Study of Pain** [**IASP**], said in its March 2021 Position Statement:

"There is a lack of sufficient evidence to endorse the general use of cannabinoids for the treatment of pain"

FPM Position Statement 2021

- The FPM (ANZCA) has presented the medical profession of Australia & New Zealand with explicit advice:
  - "Do not prescribe currently available medicinal cannabis products to treat chronic non-cancer pain (CNCP) unless part of a registered clinical trial"
- It does so, based on its analysis of available international evidence for the effectiveness & safety or otherwise of the cannabinoids in treating chronic noncancer pain. The FPM (ANZCA) concludes:
  - "The clinical use of cannabinoid products cannot be ethically recommended outside a properly established & registered clinical trial environment until high-quality evidence for specific indications is published"

Majority of TGA Cannabis Approvals are for CNCP

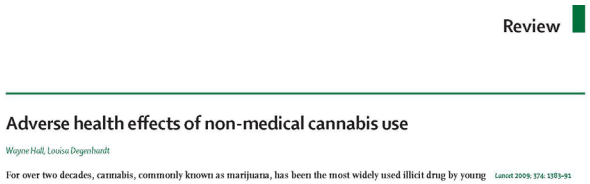
- The FPM assessment & recommendations stand in serious tension with an observation that about 90% of TGA approvals to date, over 120,000 as of 31 May 2021, have been for the prescribing of cannabis products under the Special Access (SAS-B) Scheme in the treatment of chronic non-cancer pain

  - Prescribing a class of substances that on current evidence *'do not work' or 'work very well'* & that are a source of '*significant risk of significant health harm'* is anything but compassionate good care & makes no sense
    - Since when does a enlightened & caring society allow those who are not cardiologists to make critical decisions about the best treatment of complex cardiac conditions; or who are not engineers & architects to design bridges & buildings so they perform as required & do not fall over?**
    - But that is exactly what we are commonly witnessing

Most Common Adverse Health Effects

- Cannabis use, whether prescribed or illicit, is associated with a range of potentially serious health harms
- The most common acute adverse effects are **anxiety**, **panic** reactions, & **psychotic** symptoms, all of which are most often reported by naïve illicit cannabis users
- Independent of cigarette smoking, continued cannabis use during pregnancy appears associated with significant reductions in infant gestational age at birth, birthweight & length, & head circumference, as well as increased frequency of **severe neonatal morbidity**
- While research is unfolding, cannabinoids may have profound effects on the metabolism & safety of many prescribed drugs through drug-drug interactions…& …
- Increased risks of cardiovascular events in cannabis smokers (elevated blood pressure, AMI, CVA)

- Hall & Degenhardt, 2009


Review

Adverse health effects of non-medical cannabis use

Wayne Hall, Louisa Degenhardt

For over two decades, cannabis, commonly known as marijuana, has been the most widely used illicit drug by young Lancet 2009; 374: 1383–91

Medicinal Cannabis a Potential Gateway to Worse Life Prognosis?

- There are concerns about the potential for ‘medicinal cannabis’ as gateway to cannabis smoking & to illicit drug use, noting that when smoked, cannabis is commonly mixed with tobacco, enhancing many health risks due to additional toxicity & due to more risky dynamics associated with this common way of using cannabis

    - One now quite dated publication reported that smoking cannabis entails a two thirds larger puff volume, a one third larger inhaled volume, a fourfold longer time holding the breath & a fivefold increase in concentrations of carboxyhaemoglobin

- Henry et al, 2003

Good Evidence of Harm

Panel 1: **Acute and chronic adverse effects of cannabis use**

Acute adverse effects

- Anxiety and panic, especially in naive users
- Psychotic symptoms (at high doses)
- Road crashes if a person drives while intoxicated

Chronic adverse effects

- Cannabis dependence syndrome (in around one in ten users)
- Chronic bronchitis and impaired respiratory function in regular smokers
- Psychotic symptoms and disorders in heavy users, especially those with a history of psychotic symptoms or a family history of these disorders
- Impaired educational attainment in adolescents who are regular users
- Subtle cognitive impairment in those who are daily users for 10 years or more

– *Hall & Degenhardt, 2014*

Possible Adverse Health Effects of Cannabis Smoking

- Respiratory cancers
- Depressive disorders, mania, and suicide
- Use of other illicit drugs by adolescents

- Hall & Degenhardt, 2014

Cannabis Dependence

- **Cannabis dependence** appears to be a most under-appreciated risk & harm
  - This is no small matter…though some say otherwise…
- In Australian studies it has been estimated that the **lifetime risk** of developing a cannabis dependence is **9%** while the risk rises to one in six (~**17%**) among those who initiate use during adolescence
- **NASEM** (2017) reports that of 22.2 million cannabis users in a survey, 4.2 million described symptoms consistent with the presence of a cannabis use disorder (CUD as per DSM 5)
  - That is **19%** developing a **CUD**

- Anthony, 2006; Hall & Degenhardt, 2009

- While adding in the context of this workshop that almost all tobacco & e-Cig users become nicotine dependent

Drug Dependence Diminishes Human Agency

- Drug dependence characteristically diminishes the affected individual's **life opportunities** & **life chances** & adversely alters their **life choices, life course** & **life outcomes**
  - While noting there are differences between drug classes & those with rich personal, financial & social resources may manage their lives & 'fly beneath the radar' for many years in the face of this problem … until one day they do not
- Most drug dependence axiomatically diminishes an affected individual's **autonomy, human agency & opportunity to flourish** in life to the best of their abilities & social context
- Even when people are entering a terminal phase of any serious illness, they generally want to remain as **active** as possible, be able to fully engage in & enjoy life to the maximum & engage & communicate meaningfully with family & friends
  - Drug dependence can render that difficult to achieve, as does 'affect modulation' or sedation, & any medical problems arising from substance use leading to consequential impairment, disability & handicap

Key Statements

No Clinically Significant Effects Yet Demonstrated

Key Statement 1:

- There are presently no medical conditions for which any cannabinoid can be considered first line treatment…
- …but more importantly, there are no conditions for which there is good evidence of clinically moderate to high value clinical benefit & low risk of harm based on independent, peer reviewed & replicated high quality scientific studies
  - i.e., no studies showing more than small effect sizes of statistical & clinical significance in context of many studies demonstrating risk & harm (including NASEM, 2017)

No Medically Endorsed Guidelines in Australia

Key Statement 2:

- There are currently no medical professional body endorsed clinical guidelines in Australia that support the use of any unregistered medical cannabis product …
- … prescribed in any specified formulation administered by a particular route, within a defined dose range & dosing interval for a particular medical condition & therapeutic purpose, including when taken in conjunction with other medicines or substances that may interact pharmacokinetically* & influence systemic availability
  - Quite simply, there isn't adequate data & evidence of clinical benefit & safety to support prescribing of cannabinoids in the manner that we see emerging in Australia & internationally, from a scientifically & medically supportable & responsible perspective

Defining Effective (Quality) Care

- Prescribing any medicine is difficult to justify where there are unclear clinical benefits, particularly in the face of obvious, common & serious adverse outcomes
- In its report *Addressing unwarranted variation: literature review on methods for influencing practice*, the Health Quality & Safety Commission New Zealand (2014) stated that: **effective care is defined as interventions for which the benefits far outweigh the risks** (p.4)
  - Compare & contrast this with current common policy & practice!

General Prescribing Considerations: Risks vs Benefits

- The AHPRA Code of Conduct for Medical Practitioners requires them to consider 'the balance of benefit & harm in all clinical management decisions'…

- … & only to recommend a treatment 'when there is… a reasonable expectation of clinical efficacy… for the patient'
- Clinical Guidelines have a role in 'establishing competent professional practice' & medico-legally provide 'persuasive evidence that the doctors were practising in accordance with widely held peer professional opinion…'
  - Compare & contrast this with current common policy & practice!

Our Duty of Care Obligations as Doctors

- *"It could be said that the Government has placed the medical profession in a difficult situation by its actions, but the medical profession is not 'helpless' . . .*

- *. . . As a profession, not only are we ethically bound to promote quality safe & effective patient care, we are also duty bound to do so in law – which is clearly stated in the AHPRA (Medical Board) Code of Conduct. As Governments fall over themselves to remove themselves from the advocates' firing line, it will be up to the medical profession to advocate passionately for its patients, providing non-judgmental, supportive advice based on a dispassionate, considered & balanced review of the facts. And then to hold the line. We do it every day in our practices. The public health practice is no different"*

- *Sarma, 2017*

Unethical Behaviours

- What we are witnessing unfolding here is, based on current scientific knowledge, serious **commercial fraud** of an unprecedented nature & scale
  - The lessons of medical history have again been forgotten or wittingly discarded

  - I present it is unethical for Australian governments & clinicians alike to be engaging in **dualities of interest** and **conflicts of interest** in tacitly supporting, let alone opening the flood gates to commercial industry peddling low value-high risk products & prescribing in ways that can, based on current evidence, can only mislead & harm the community & provide false hopes for cannabinoids in treating a wide range of often serious medical conditions while at the same time, placing the broader community at increased health risk now & into the future
    - That is, assuming we really care as a nation about continuously striving to meet the highest of possible standards in every aspect of medicine & in public policy, legislation & regulation for health & healthcare. If not, let us please be honest & transparent about that in our communications with the people of Australia

Professional & Ethical Cautions

- Clear separation from false & misleading industry advocacy & promotion is critical for medical practitioners & researchers alike, noting it is no longer sufficient to provide (repeated) declarations of a duality or conflict of interest as if this exonerates the practitioner or researcher from ethical & medico-legal responsibility after having engaged in industry sponsored research; & as if that disclosure deals appropriately & adequately with the duality or conflict of interest when it clearly does not
  - Medical practitioners & researchers must ensure they have **no dualities or conflicts of interest** into the future, noting the now burgeoning & unfortunate problems of common research methodological design & implementation flaws, publication bias & market manipulation by the pharmaceutical industry**(see notes)
  - They must ensure they do not engage in such **research** or **medical fraud** into the future
  - Article 5.3 of the WHO FCTC has a similar purpose of preventing all government officials from being party to industry influence on tobacco control policies, though few demonstrate they understand, accept & are willing to abide by the legal obligations of our nation as signatory to the Convention

Serious Legal Consequences Likely to Follow

- If the behaviour of the opioid pharmaceutical industry & its recent & numerous **criminal & class action legal challenges** & associated adverse legal outcomes are anything to go by, equally, if not larger class actions & serious medicolegal & criminal consequences are likely to follow the cannabinoid industry & those engaged in inappropriate & misleading research, clinical practices & public policy decisions into the future

    - I am advising my colleagues to be very careful to avoid being swept up by advocates & vested commercial interests & engaging in such professionally & personally compromising practices

Medical Profession Strongly Advised Against Prescribing Cannabinoids for any Medical Condition at this Time

- The position statement of the Faculty of Pain Medicine is strongly supported
  - The medical profession & medical bodies will quickly lose control if they fail to act soon & with decisiveness & conviction
- Based on current evidence & the repeated lessons of medical history & regardless of the recent policy decisions of the Australian government & TGA…
- The medical profession of Australia is advised in the strongest possible way that it must not prescribe any cannabis product for pain or for any other medical condition regardless of these decisions, unless part of a registered clinical trial
  - Just as we are advising the medical profession not to prescribe e-Cigarettes & nicotine containing liquids at this time…
  - … for similar reasons of absence of evidence of benefit & significant reason for concern about potentially serious clinical & population level harms

Many Elected Representatives Struggle to Read Understand & Value Evidence

- While we all appreciated, admired & shall never forget Ivan Dean's thoughtful, caring & heroic efforts to win the support of his parliamentary colleagues, the recent TFG & T21 parliamentary debates highlighted for us all how members of parliament can '*box at shadows*'* & appear to struggle in placing appropriate value on or in reading & making sense of the scientific literature & expert advice made available to them, giving more weight it often seems to unscientific personal opinions & populist beliefs & wants, influenced we are inevitably led to assume by commercial industry lobbying & other influential behind the scenes activity

Many Elected Representatives Struggle to Understand & Value Evidence

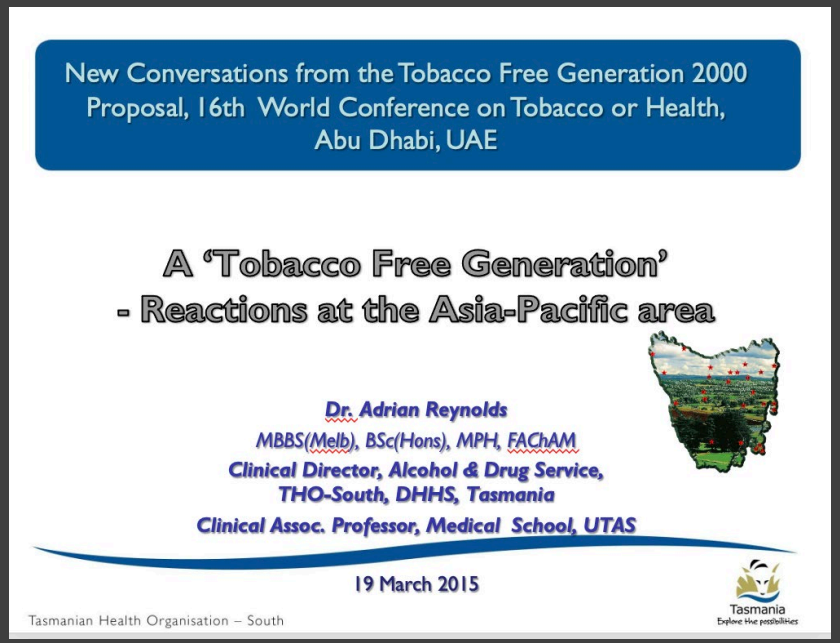
- It is one thing for our parliaments to continue as they have over many decades to ignore evidence & expert advice to address the tragic though substantially avoidable unhealthy commodity industry impacts on health, social well being & our future global economic best interests
- But allowing new unhealthy commodity (e.g., e-Cigarette & 'medicinal cannabis') industries to unleash their commercial trickery on the people can only further damage public & population health while the people remain blissfully unaware, they are being played by industry
  - This is exactly what we are witnessing now with those two industries
- As a doctor, I am alarmed & deeply distressed by this; & I present all health professionals of Australia should be equally concerned

Is This Where We Are Headed?

Free Markets Trumping Evidence of Quality, Safety & Effectiveness? Corporate Capture of Harm Minimisation?

"With the support of government free market policy: if you believe it will help & if you want it – you can have it. Now available at your convenience from your local street market or vending machines. Or go online to request our free home delivery service"

Is this really where we wish to head as a nation?



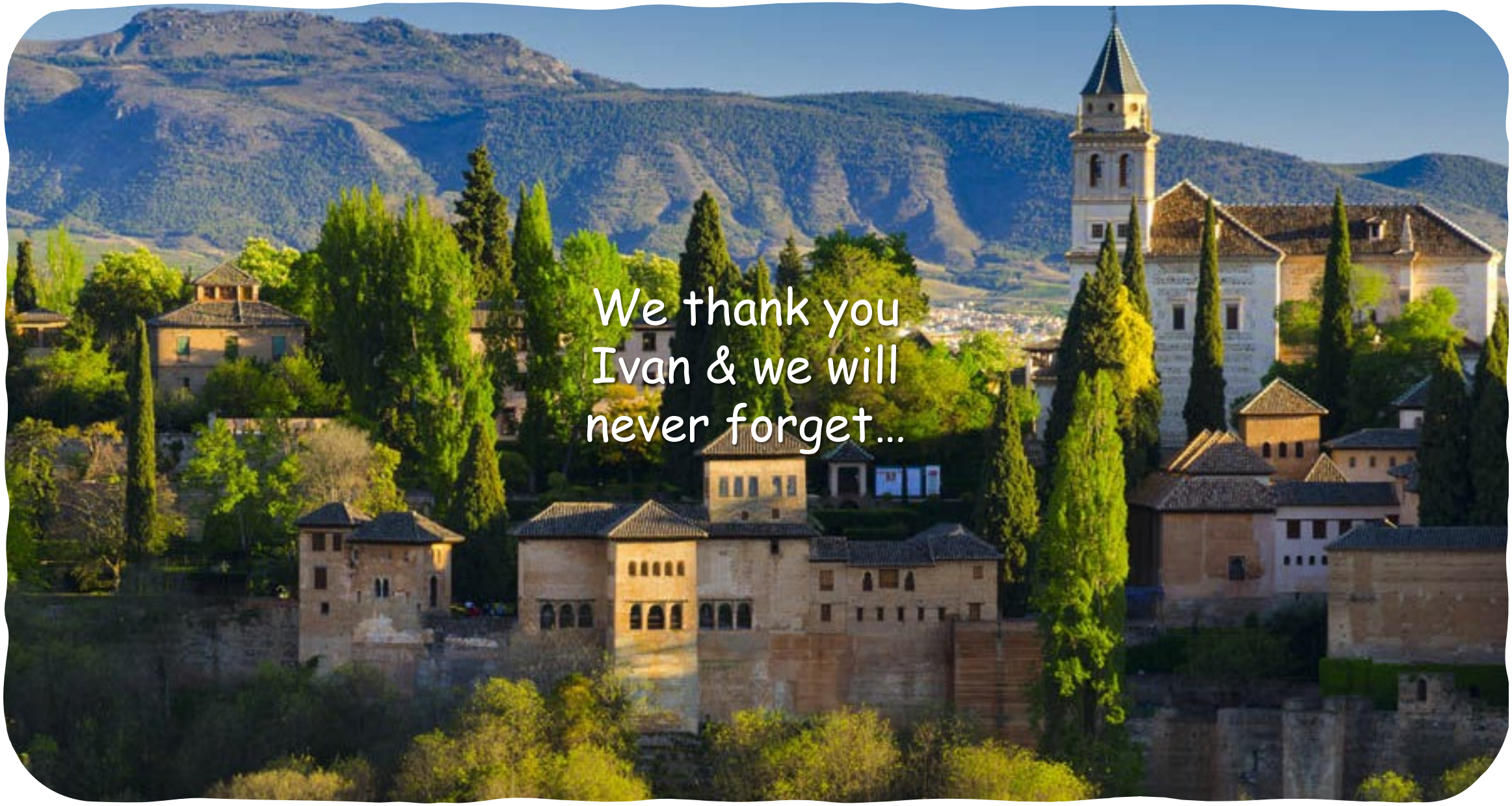
Dr Margaret Chan, DG WHO; Prof Jon Berrick & Dr Adrian Reynolds, WHO WCTOH, 20 Mar 2015

Ivan Dean, we salute & thank you for everything you did for 'health' & for the people

- It was my great honour & pleasure to present your TFG Bill & to talk about it & show your picture along side the picture of Jon Berrick, the architect of this brilliant idea, at the 16th World Conference on Tobacco or Health, Abu Dhabi, UAE in 2015
  - It was also an honour for Jon & I to meet with the Director General of the WHO, Dr Margaret Chan & in response to a prior plenary question from leading Singapore surgeon Dr HN Koong, to hear her say to the large international audience of 2,300 delegates representing 103 countries, *"a tobacco free world & a Tobacco Free Generation proposal should be supported very strongly, very strongly"*
  - *Dr Margaret Chan answering Dr HN Koong plenary question on TFG, WHO WCTOH Abu Dhabi 20 Mar 2015.mp4*

Acknowledging the Hon Ivan Dean for His Extraordinariness in the Face of Ordinariness

- I wish to acknowledge & thank you Ivan for your health policy leadership in the Tasmanian parliament
- You stood up & you spoke in support of an important public health principle & legislative reform when only two other members in the parliament would do so
- You understood the tragedy that is nicotine dependence & smoking, when others did not & you fought for important tobacco policy reform in the face of the ordinariness that is our Westminster & political party system of governance
- You did something most others would not – you drew upon the power of scientific knowledge, power that strikes fear in the hearts of tobacco industry & its advocates, reaching out to the vast array of experts in health & in tobacco control in Tasmania & beyond, some of whom are here in this room today, listening carefully & then delivering in spades
- In this, you were extraordinary while sadly as you have described so clearly, your parliamentary colleagues chose to be ordinary & in this, failed the people they are trusted to protect, not to forget the health & human service workers who are confronted by the human tragedy of smoking every day in their work


We thank you
Ivan & we will
never forget…

Appendix

- Adding more detail to the retail…

Clinical Significance: NNTB & NNTH

- Based on available & credible published data, Stockings et al (2018) calculate that 24 persons with CNCP need to be treated for one person to get a **30 % (pain relief) benefit** (**$NNTB_{30}$ = 24**) (CI:15-61)
  - Across RCTs, pooled event rates (PERs) for 30% reduction in pain were 29.0% (cannabinoids) vs 25.9% (placebo)
  - **Pooled change in pain intensity (standardised mean difference: 20.14, 95% CI 20.20 to 20.08) was equivalent to a 3 mm reduction on a 100 mm visual analogue scale greater than placebo groups,** well below the minimum 30 mm reduction regarded to represent a clinically important difference in pain intensity
- For **50% reduction** in pain, PERs were 18.2% vs 14.4%; no significant difference was observed
  - It is significant that no evidence for a 50% reduction in pain can be demonstrated while noting debates about whether 50% reduction in pain intensity is a standard for meaningful chronic pain relief or lesser reductions are meaningful (e.g., Holliday et al, 2018; Olsen et al, 2017)
- In comparison, 6 persons need to be treated for 1 person to suffer harm (**NNTH = 6**)

❖NNTB = **1/ ARR** (Absolute risk reduction) OR;
❖ = 1/ (E-P) (experimental – placebo intervention)
❖NNTBs for effective treatment usually in range of 2–4
❖The $NNTB_{50}$ for paracetamol 500mg + ibuprofen 200mg = 1.5

NNT < 2.3 are considered large effects, NNT of 2.4 - 3.6 are considered to be moderate or typical effects & NNT >8.9 are considered small effects (Kramer et al, 2003)

Clinical Significance: NNTB & NNTH

- So, for every patient who experiences a small but perhaps meaningful benefit (30% reduction in pain), based on these calculations, 4X as many will experience an adverse event
  - **Stated alternatively, for every 100 people treated with cannabinoid, ~5 may benefit by a small margin while ~16 will experience an adverse event (from minor to serious)**
  - This seems a marginal benefit among a very small proportion of treated patients that carries a substantial risk of being harmed in some way
  - Noting also that placebo may also provide a 20-30% benefit
    - So, on basis of current evidence, the cannabinoids look like **"low value/ high risk medicines"** in the clinical management of CNCP

- Whiting et al, 2015; Stockings et al , 2018

Harm May be High if Legalised

- On the basis of the above referenced systematic review & meta-analysis, deriving a **NNTB = 24** & a **NNTH = 6** but without taking into account the risk of cannabis dependence*, the likelihood of being harmed in a policy environment of regulated legalisation could well be even higher than **1 in 6**, perhaps 1 in 3 or **1 in 2 in daily users** (when addiction is included in the calculus of harm)**(see notes)
  - Does any country really want that for its people where alcohol & the drugs are already associated with substantial though avoidable acute & chronic health & social harm?
    - Is any government really willing to trade this frequency & level of potential harm for commercial profit & tax receipts that won't likely come close to fully funding the economic externalities?
    - While 'harm reduction' remains a pivotal principle of our National Drug Strategy, as it must
      - We must be careful to remember what works in public policy for public health (public regulation & market intervention) & take care to avoid the traps of '*corporate capture*' & '*clinician capture*' of the principle

Cost-Effectiveness Considerations

Cost-Effectiveness Considerations

- What does all of this mean? While back of envelope calculations should not be taken too literally for obvious health economic complexity reasons, consider the following:
- Cannabinoid treatment currently costs up to **$2,000** to **$2,500 per month** (2018)
- Across all CNCP conditions, for **one patient** to experience a 30% reduction in CNCP, 23 will experience no measurable relief & this currently costs up to $2000 x 12 x 24 = **$576,000 per year**
- Who will be brave (& foolish) enough to try to explain & justify this expenditure to the people of Australia, yet alone to clinicians & health managers in great need of more resources to deliver evidence based care to a numerally (far) greater number of people suffering from medical illness??

"Our national health resource is limited so it must be used wisely. We can ill-afford ill-informed advocates & public policy decision-makers who do not grasp this reality & who do not demonstrate a commitment to learn & act on this principle & available knowledge"

Cost Effectiveness Considerations

- Government is expected to pick up the tab for this expensive Rx but in the end, the Australian taxpayer bears much of the cost of funding cannabis in the absence of usual required standards of evidence of benefit, good investment & safety
  - Cost effectiveness considerations are important wrt best spending of finite public resources, regardless of how we structure the payments system, which is the purpose of the PBAC…there is no way the PBAC could include cannabinoids on the PBS based on current evidence, unless government were to direct it to abandon its core decision making principles
  - Sadly, that is more than a remote possibility based on the governance we are witnessing right now!

Tony Abbott PM Backs Legalisation of Medical Cannabis

- Term ‘legalisation’ is being used in a new way to refer to access to cannabinoids for medicinal purposes

    - *“If a drug is proven to be safe abroad & is needed here, it should be made available”,* said the PM Tony Abbott

- *The Age, 17 September 2014*

- In this, our former PM displayed a distinct lack of understanding & disregard for a fundamental bedrock of medicine in Australia & our fierce attention to detail (medical evidence) in our independent scientific analysis & pursuit of highest standards in medicines regulation
    - Noting many other countries are failing to adopt highest possible standards in medicines research, legislation & regulation, it would in my assessment be a fatal error of judgment if our nation were to dissolve our own research & evidence driven policy & regulatory capability & commitment

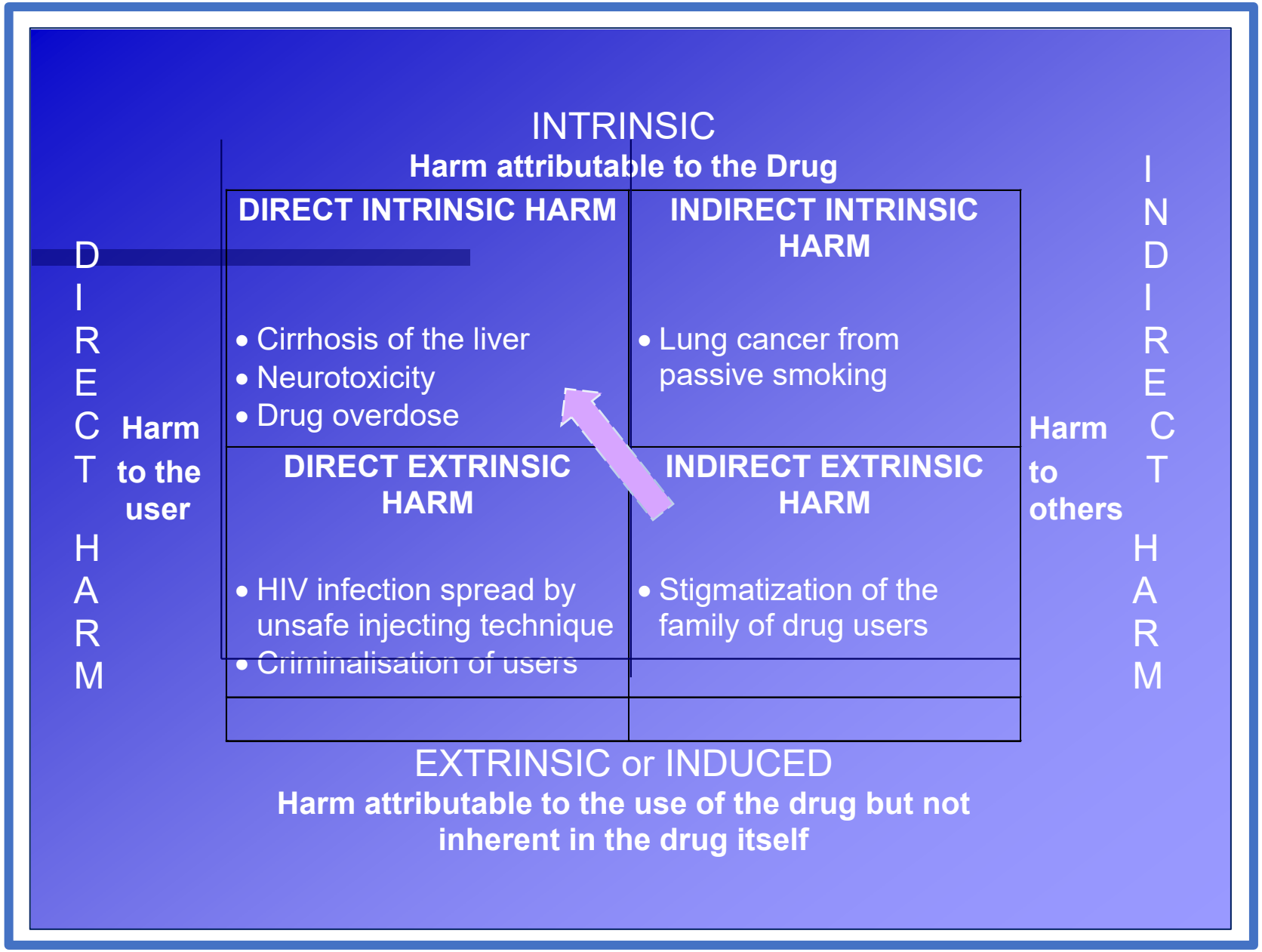
Comparing Cannabis Policy Options

- ***Decriminalisation*** as commonly described does not mean that people can use drugs with impunity
  - Instead, it may mean that possessing small [or in some cases, any amount(s)] no longer leads to a criminal penalty including severe monetary penalties or a jail sentence
- By contrast, ***legalisation***, means that 'users' & those who supply the market for personal gain face no disincentive or penalty at all
- In a legalised environment, a cannabis industry can markedly & quickly increase access, advertise, promote, encourage & enculturate ('normalise' & 'commercialise') use & derive profits by maximising sales, while governments can earn revenue from taxation arising from the sale of cannabis products in the same way they do from alcohol & tobacco
  - That is in substantial part why legal drugs (alcohol, tobacco, prescription drugs) contribute to or cause most of the drug related health, mortality, social & economic harm in Australia

Legalisation is An Entirely Different Matter

- **Legalisation** opens the gates to industry to take full advantage of the unwitting & unknowledgeable community in promoting & enabling consumption on a wide scale, for profit & governments may believe they are achieving a win-win through legalisation given the consequential new taxation revenue stream & free market support for unfettered industry activity to maximise sales, consumption & profit

    - This stands to replicate the errors of history where governments have allowed industry to promote & maximise the sale of unhealthy commodities in order to achieve increased taxation receipts, unaware (or ignoring expert advice regarding a net loss to revenue over time (as is the case for alcohol & tobacco products) arising from consequential increased health & social burdens


INTRINSIC
Harm attributable to the Drug
DIRECT INTRINSIC HARM
• Cirrhosis of the liver
• Neurotoxicity
• Drug overdose
INDIRECT INTRINSIC HARM
• Lung cancer from passive smoking
DIRECT HARM
Harm to the user
Harm to others
INDIRECT HARM
DIRECT EXTRINSIC HARM
• HIV infection spread by unsafe injecting technique
• Criminalisation of users
INDIRECT EXTRINSIC HARM
• Stigmatization of the family of drug users
EXTRINSIC or INDUCED
Harm attributable to the use of the drug but not inherent in the drug itself

Drug Harms Policy Framework?

- A legalised, commercialised & normalised taxation model will likely increase use, potentially substantially so, with the potential benefit of reducing some but not all induced extrinsic (legal) harm while unfortunately at the same time, increasing direct & indirect intrinsic health & social harms to users & others (e.g., through MVAs & adverse impacts on families)

Rethinking Policy & Legislative Frameworks

- So, the question arising is this…
- How can governments alternatively, though carefully crafted policy, legislative & regulatory reform, address the avoidable induced, indirect (legal) harms without increasing use & without increasing direct, intrinsic health harms?

    - Noting that while a range of improvements in policy & legislative design & implementation are required, Australia has less unkind & unjust drug laws than many countries of the world

Fuelling the Flames of Harm

- Political responses to expressed public concerns about conflicts of interest are as we can see in this new item & associated undesirable official behaviour, commonly defended on the basis of '*legality of product'*
- This is as lamentable as it is quite candidly, ill-informed, simple minded & without apparent moral compass, noting it is the legal drugs (alcohol, tobacco & prescription drugs) that are far & away responsible for most drug-induced & drug-related harm in Australian society

Big tobacco backs Nats

THE National Party has received more than $200,000 in donations from tobacco giant Philip Morris International in the past five years.

The Labor Party ceased accepting donations from "Big Tobacco" in 2004 and the Liberal Party in 2014.

Nationals MP Barnaby Joyce said it was "a legal product and if they want to donate to a party they can".

"If you don't get support, you can't run a political party, you can't pay staff and put ads on with feelings and well-meaning ideas," he said.

"If it's legal, it is legal and if you don't like it, ban it. I'm not advocating people smoke, far from it, but if it is a legal product, alcohol is a legal product, tobacco is a legal product."

Likely Legalisation Outcomes?

- Based on evidence arising from recent research & its analysis, legalisation for recreational, non-medical use will expand the list of unhealthy commodity industry commercial successes & market failures
  - It will most certainly add to the significant, likely & avoidable morbidity & mortality arising from a prominent new (legal) unhealthy commodity
  - I will most certainly add to the impacts on our bursting health system, in an environment where health professionals are exhausted & where they are exasperated by the failure of our parliaments to do their job in adopting upstream preventative policy reforms that protect & promote the health & well being of the Australian people
- But legalisation is the real prize for a cannabis industry, noting that many citizens are claiming need on a medical basis when it is the psychotropic drug effects they seek & noting that if allowed through the gate, recreational use will vastly overwhelm use for medical purposes & hence demand, sales & profit into the very near future

Legalised Medicinal Cannabis & the Laws of Commerce

- As Coughlin et al (2021) have accordingly pointed out, legalised medicinal cannabis will follow the laws of commerce
- Any new revenue stream through taxation receipts will create a strong incentive in government to allow commercial industry to heavily market their products & compete with others by lowering prices & increasing availability & accessibility, in order to maximise sales & profit

    - Increased supply inevitably drives increased demand & use
    - Based on current knowledge, increased use in turn predicts an increase in health harm, albeit in the absence of objective & clinically meaningful 'therapeutic benefit'
    - Will elected representatives of the future continue to trot out the same lines as they do in defending political donations from alcohol, tobacco & gambling interests – "it is legal", when before they may have called for severe punishments?

Legalisation as a Trojan Horse

- If a commercially & personally driven imperative to have access to cannabis is about using the medical profession as a Trojan Horse for the legalisation of cannabis, that is a dishonorable tactic & cannot be respected
  - The **legal status (legalisation or decriminalisation) is a separate matter that must be considered & prosecuted on its own scientific & societal value merits…**
  - … though the medical profession would naturally have a professional responsibility to ensure that any well-intended efforts to remove or diminish societally unhelpful or unjust induced legal harms are assessed & managed in a way that avoids a substantial commercially driven increase in cannabis use leading to inevitable increased health risks & harms, as described earlier

Medical Profession Must Now Decide What It Will & Will Not Prescribe

- Accordingly, & as alluded to already, I have been involved in discussions with medical leadership in Tasmania & we have agreed to now embark upon educational communications with colleagues across the state & also nationally, strongly advising medical colleagues against the prescribing of any medicinal cannabis products in the absence of compelling, high-quality evidence to support this & in the presence of evidence to significant risk of significant harm
    - The same will occur in relation to the prescribing of e-cigarettes

Medical Profession Must Now Decide What It Will & Will Not Prescribe

- Given the inability of the Australian government to consistently demonstrate it understands & respects medical evidence & is willing to listen to experts in the field & respond accordingly, the medical profession is left with no option other than to demonstrate policy & clinical leadership in now taking charge of the clinical & public health situation
    - While recognising there will always be a few mavericks like those doctors who operated the OxyContin ‘pill mills’ in Florida & the ‘medical marijuana burger shops’ in Venice Beach CA, who will choose to go outside the framework of evidence-based, ethical & professional medical practice & prescribe