Dr Graham Gulbransen

General Practitioner

Kingsland Family Health Centre

Auckland

Sunday, June 11, 2017

9:20 - 9:45 Medical Marijuana - Sorry No Samples!

Medical Marijuana
Sorry No Samples

Graham Gulbransen

GP & Addiction Specialist, Kingsland, Auckland

Rotorua GPCME 11 June 2017

Medicinal Cannabis 101 for GPs

Graham Gulbransen

GP & Addiction Specialist, Kingsland, Auckland

Rotorua GPCME 11 June 2017

Themes

After this talk you will be better placed to support your patients who use medicinal cannabis.

My messages:

- Don’t be afraid of cannabis
- Case histories – you will have similar patients
- How does medicinal cannabis work?
- Personalised medicine & evidence based medicine
- Evidence for cannabis benefits/harms
- Compassion
- Current NZ situation – how you can prescribe.

Peter 58

- MULTIPLE SCLEROSIS
- Left hemiparesis
- Disease modifying therapy: tecfidera
- Muscle spasms: baclofen inadequate.

We will treat these conditions at the end of this presentation.

Lynda 67

- Terminal pancreatic cancer
- Palliative care; chemotherapy nothing more to offer
- Smoked cannabis during chemo
  - Less nausea
  - Better appetite, but lost weight
  - Less pain
  - But – hated smoking, illegal
- Sativex approved – easy to take, control dose, no choking, eases abdo discomfort, huge appetite stimulant, regaining weight!

Barbara 35

- Severe endometriosis, 18 surgeries, full pelvic clearance
- Chronic pain, central sensitisation disorder
- Past misuse of prescription and illicit drugs to manage chronic endometriosis pain (pseudoaddiction)
- Currently using cannabis most evenings for analgesia

- Requests legal cannabis prescription

Nick 20

- Autism spectrum disorder, global development delay, blind, epilepsy with uncontrolled prolonged seizures about twice a week

Jo 61

- Multiple systems atrophy, cerebellar type
- (chronic progressive debilitating neurological condition)
- Quadraparesis, confined to bed, dystonia, muscle spasms, contractures, depressed
- Clonazepam, levodopa/benserazide: minimal relief

- Requests medicinal cannabis

Prof Nick Lintzeris
Uni of Sydney

All slides used with permission.
Some modified.

Cannabis as Medicine in Australia

Presented at

International Medicine in Addiction Conference, Sydney 26/3/17

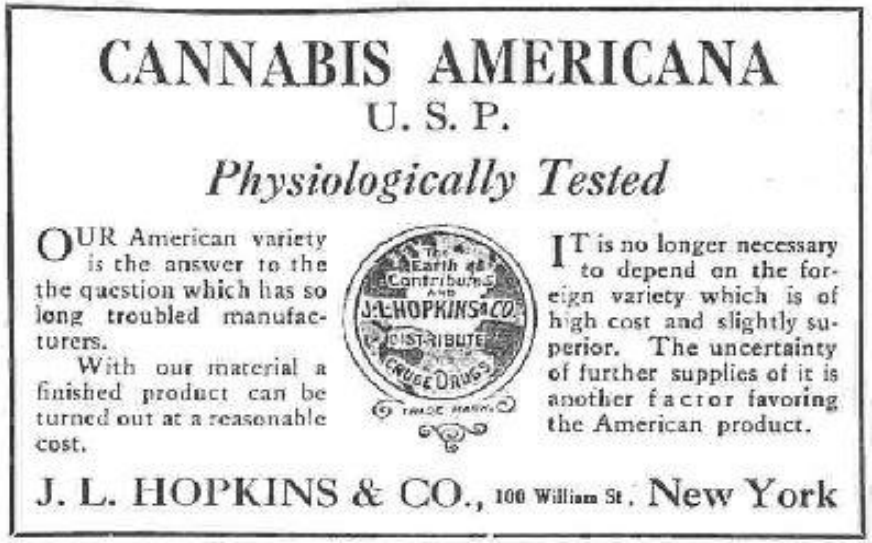
Prof Nicholas Lintzeris MBBS, PhD, FAChAM

Director D&A Services, SESLHD

University of Sydney, Division Addiction Medicine

History of medical cannabis

- >2000 years therapeutic use
- Widely used until early 20th century
  - bronchitis, epilepsy, hypnotic, analgesia, ‘nerve tonic’
- Prohibition: abandoned as therapeutic agent
- Interest rekindled since 1990’s
  - Consumer advocacy
  - Scientific developments



Cannabis Prohibition in NZ

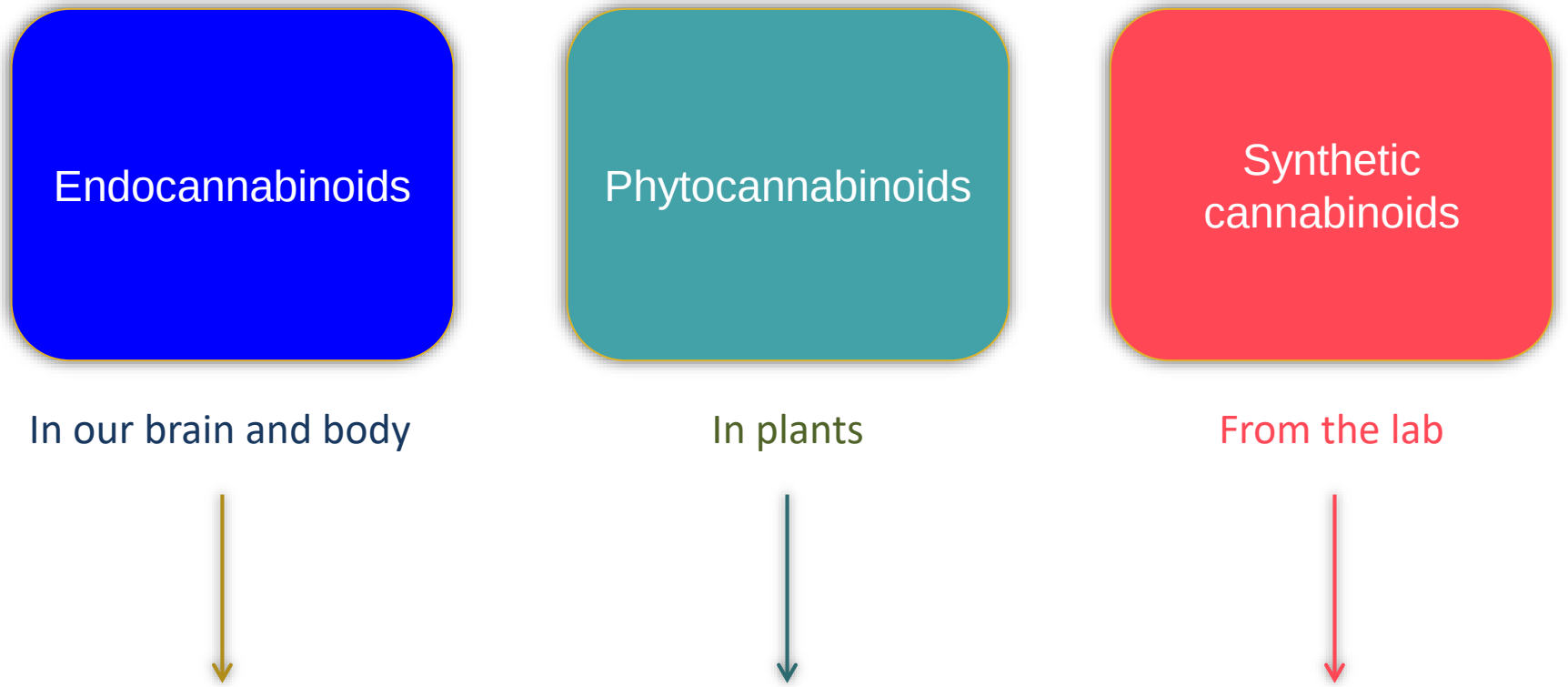
1965 Narcotics Act

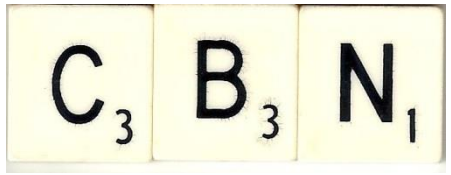
Cannabis oil Class B Misuse of Drugs Act (MoDA) 1975

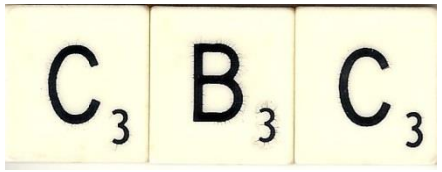
[Definition: Class B drugs pose a high risk of harm]

Cannabis plant Class C, moderate risk of harm.

Varieties of Cannabinoids







Phytocannabinoids

>100 cannabinoids in cannabis plant. Most non-psychoactive.

Each cannabinoid has its own pharmacological actions and therapeutic potential.

Plus … terpenes

“Entourage” effects: whole plant vs single molecules

Table 1. Timeline of cannabis pharmacology.

1964	Identification of Δ^9-THC as the main psychoactive compound of cannabis
1980	Development of synthetic cannabinoids
1988	Identification of the CB_1 receptor
1990	Cloning of the CB_1 receptor
1992	Identification of the CB_2 receptor Discovery of the endogenous ligand anandamide
1993	Cloning of the CB_2 receptor
1994	Development of a CB_1 antagonist
1995	Discovery of endocannabinoids 2-AG and palmitoylethanolamide
1997	Development of a CB_2 antagonist
1998	Evidence of the analgesic properties of endocannabinoids Development of knockout mice lacking the gene expressing CB_1 receptor
2000	Development of knockout mice lacking the gene expressing CB_2 receptor

(Adapted from Beaulieu & Rice, 2002)

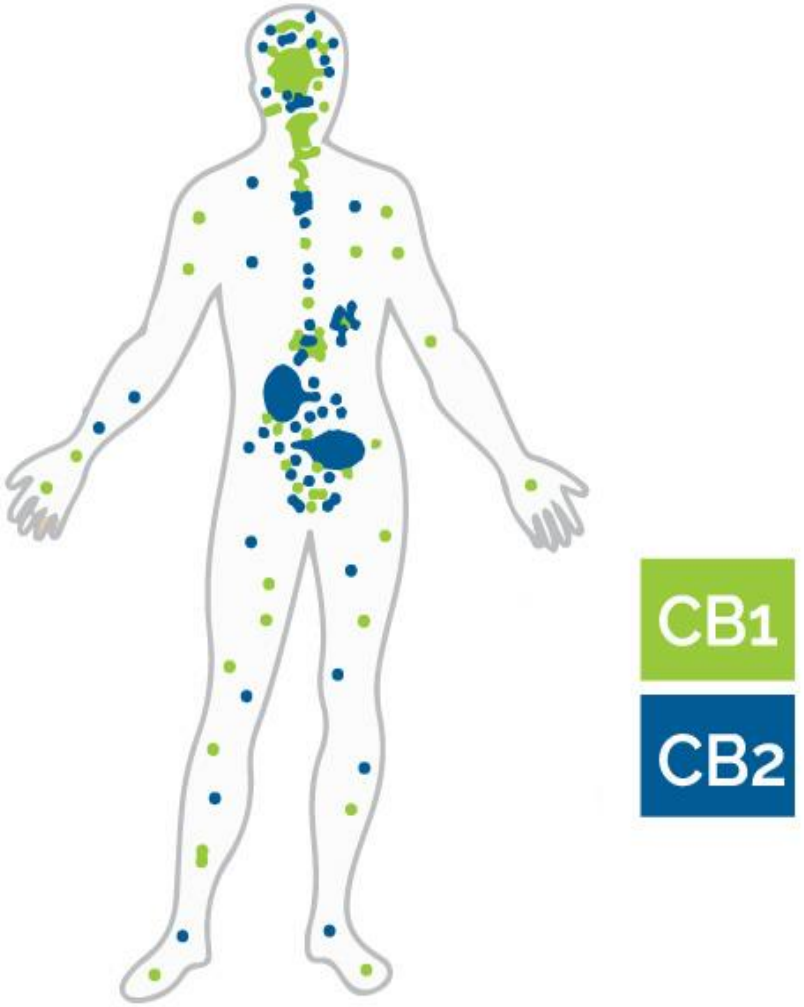
Biological Plausibility: ECS

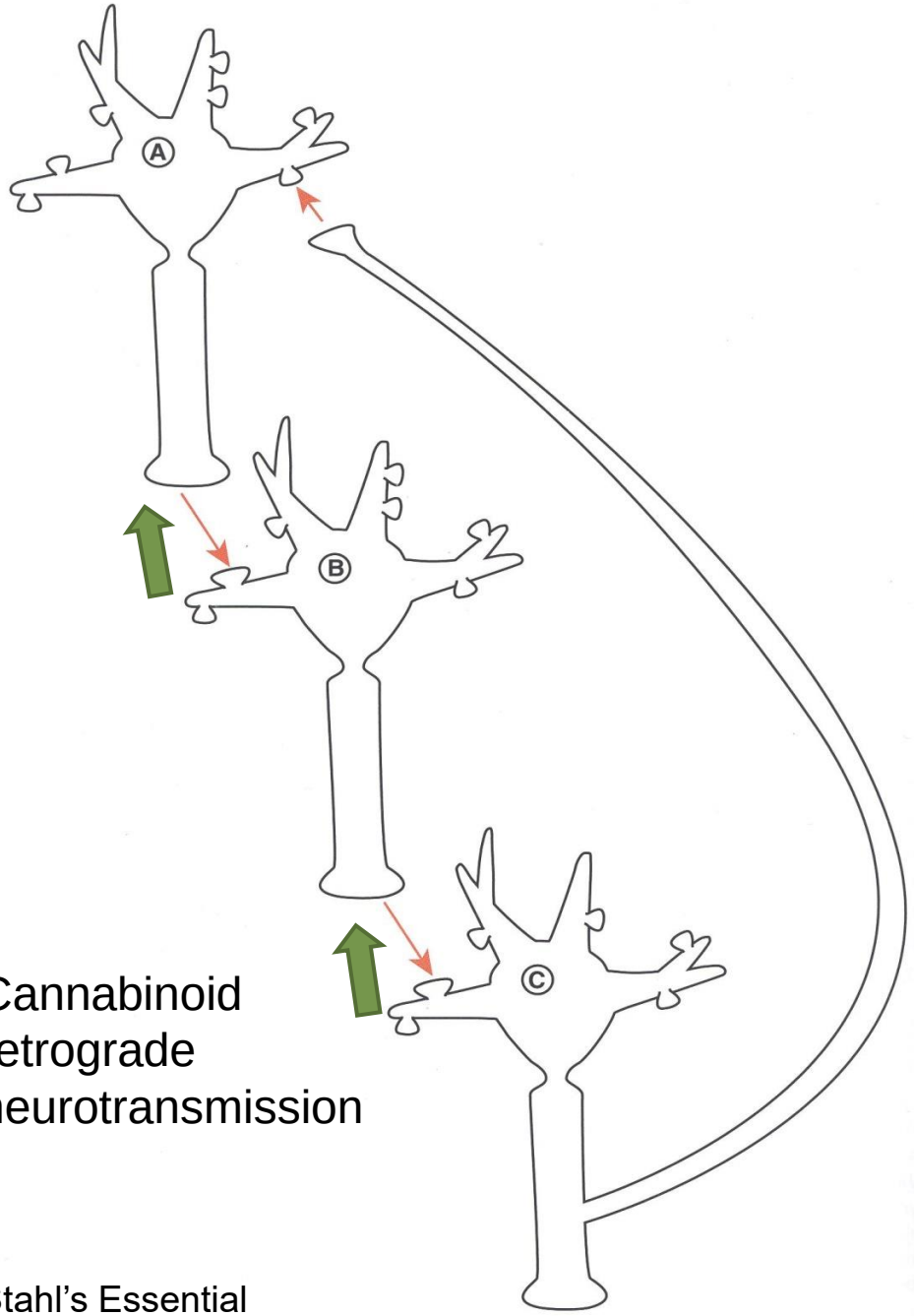
- Theres a reason cannabis works
- The Endocannabinoid System
- Present in all vertebrates, in most animals from sea squirts to humans
- Regulates fundamental processes
  - sexual behaviour
  - male fertility
  - embryo implantation
  - fetal development
  - breastfeeding
- And more…

Viola Brugnatelli - Neuroscientist
Hemp Expo Sydney May 2017 & https://naturegoingsmart.com/understanding-endocannabinoid-system/

Endocannabinoid System
= Homeostasis

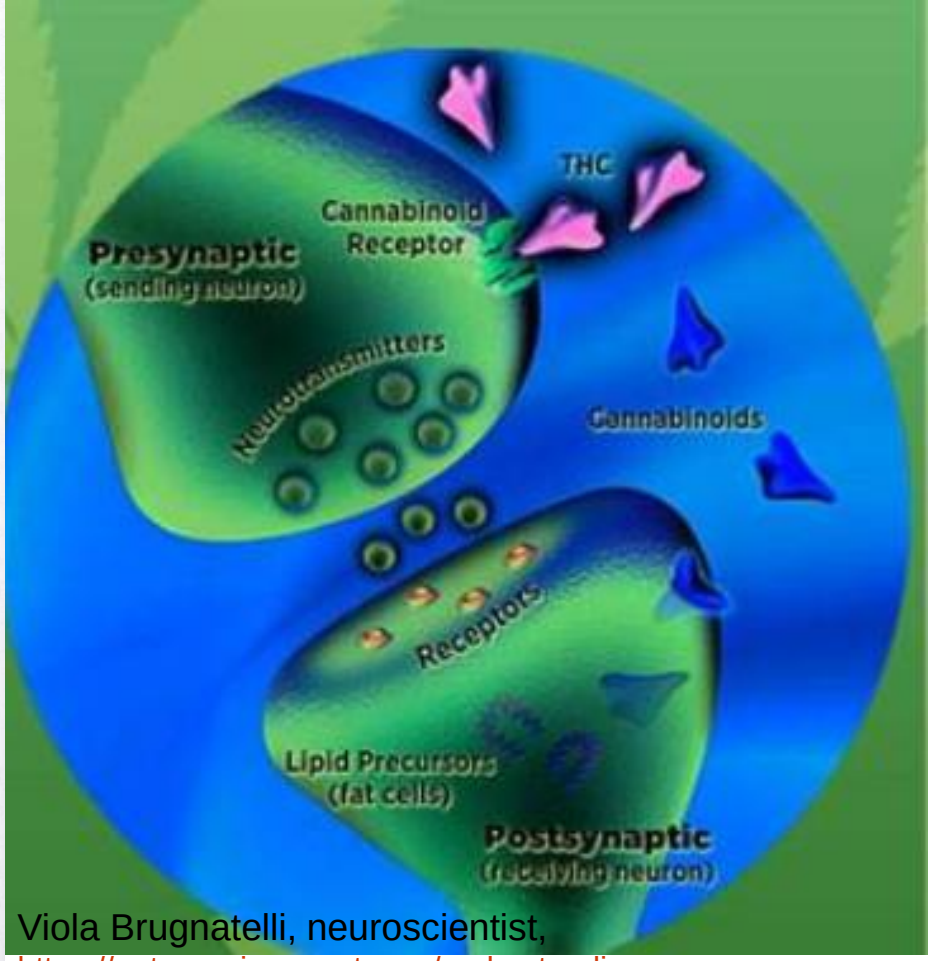
- CB1 receptors:
  - Brain: cortex, basal ganglia, hippocampus, cerebellum
  - Modulate: memory, mood, executive function, cognition, analgesia, movement
  - GI: appetite, lipolysis
  - Respiratory
- CB2 receptors
  - Immune system: regulate inflammation, neuropathic pain
- CB3 & many other receptors under investigation





Cannabinoid retrograde neurotransmission

Stahl's Essential Psychopharmacology, p56



Viola Brugnatelli, neuroscientist, https://naturegoingsmart.com/understanding-endocannabinoid-system/ 2017

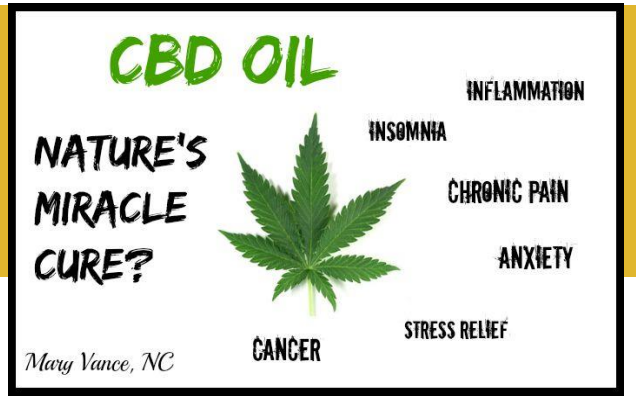
Cannabinoids regulate neurotransmission.

Think overactive CNS regulated by CBD.

- Pain
- Epilepsy
- Anxiety, PTSD

	THC	CBD	CBG	CBN	CBC	THCV	CBGA	CGCA	CBCA	THCA	CBDA
Relieves pain Analgensic	●	●		●	●		●				
Suppresses appetite/Helps with weight loss Anorectic						●					
Kills or slows bacteria growth Antibacterial		●	●						●		
Reduces blood sugar levels Anti-diabetic		●									
Reduces vomiting and nausea Anti-emetic	●	●									
Reduces seizures and convulsion Anti-epileptic		●				●					
Treats fungal infection Antifungal									●		
Reduces inflammation Anti-inflammatory		●	●		●		●	●		●	●
Aids sleep Anti-insomnia				●							
Reduces risk of artery blockage Anti-ischemic		●									
Inhibits cell growth in tumors/cancer cells Anti-proliferative		●	●		●					●	●
Treats psoriasis Anti-psoriatic		●									
Tranquilizing, used to manage psychosis Antipsychotic		●									
Suppresses muscle spasms Antispasmodic	●	●		●						●	
Relieves anxiety Anxiolitic		●									
Simulates appetite Appetite Stimulant	●										
Promotes bone growth Bone Stimulant		●	●		●	●					
Reduces function in the immune system Immunosuppressive		●									
Reduces contractions in the small intestines Intestinal Anti-prokinetic		●									
Protects nervous system degeneration Neuroprotective		●									

Cannabidiol (CBD)



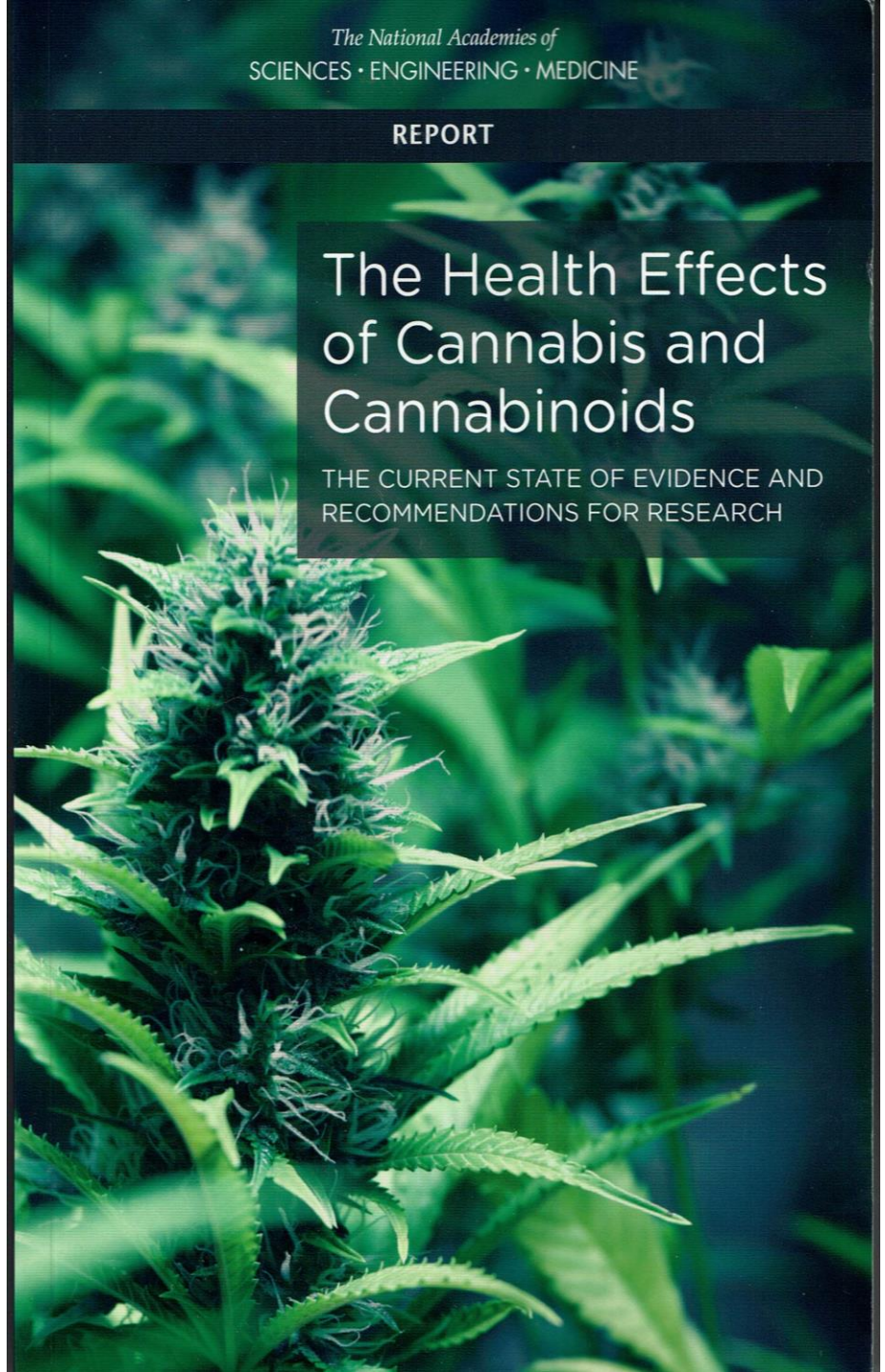
- A non-intoxicating cannabinoid
  - Anticonvulsant effects
  - Anxiolytic, antipsychotic
  - Neuroprotective: ?dementia
  - Analgesia: THC+CBD > THC or CBD alone; synergistic
- Hepatic metabolism:
  - CYP 3A4, 2D9 inhibition: ?clinically relevant
- Doses:
  - ?200-1200mg oral / day prescribed
  - 10-50mg oral / day OTC for ‘wellness’

Conditions the internet can treat with cannabis (medicalmarijuana.com)

- Acute Gastritis; Adenomyosis; Alzheimer's; Amyloidosis; Amyotrophic Lateral Sclerosis (ALS); Anaphylactic or Reaction; Angelman Syndrome; Anorexia; Arthritis; Arthropathy (Gout); Asperger Disorder; Asthma; Attention Deficit Disorder (ADD); Autism
- Back Pain; Bell's Palsy; Bipolar Disorder; Bruxism; Bulemia
- Cachexia; Cancer; Carpal Tunnel Syndrome; Cerebral Aneurysm; CFS; Chronic Pain; Cluster Headaches; CMT Disease; Colitis; Colitis/Ulcerative Colitis; Colon Diverticulitis; Crohn's disease; CVS; Cystic Fibrosis; Cystitis/Urethritis;
- Darier's Disease; Depression; Diabetes; Diarrhea; Dravet Syndrome; Dupuytren's Contracture; Dyspepsia; Dystonia
- Eczema; Ehlers Danlos; Emphysema; Endometriosis; Epilepsy/Seizure Disorder
- Felty's syndrome; Fibromyalgia; Friedreich's Ataxia
- GastroEsophgeal Reflux Disease; Glaucoma; Graves' disease
- Hemophilia A; Henoch-Schonlein Purpura; Herpes; HIV / AIDS; Hydrocephalus; Hypertension (High Blood Pressure); Hyperventilation; HYPOGLYCEMIA-MMj Treatment
- Incontinence; Inflammatory Bowel ; Insomnia; Interstitial Pneumonia; Irritable Bowel Syndrome
- Limbic Rage Syndrome; Liver Disease; Lupus; Lyme Disease;
- Macular Degeneration; Marfan Syndrome-; mastocytosis; MD; Medical Marijuana as Pain Treatment for Patellofemoral Pain Syndrome; Medical Marijuana Treatment for Addiction; Melorheostosis; Meniere's Disease; Menopausal Syndrome; Migraines; Motion Sickness; Movement Disorders; MRSA; Multiple Sclerosis (MS); Muscle Spasm; Muscle Spasms; Myofascial Pain
- Nausea; Nephritis; Neurodegenerative Disorders; Neurofibromatosis; Neuropathy; Nightmares; NPS
- Osgood-Schlatter; Osteogenesis imperfecta;
- Palmar Hyperhydrosis; Pancreatic Cancer; Pancreatitis; Panic Attacks; Panic Disorder; Pectus carinatum (Pigeon breast/chest); Pemphigus; Peptic Ulcer; Peutz-Jehgers; Polyarteritis Nodosa; Polycythemia vera; Porphyria—Alternative Symptom Treatments; Post Concussion Syndrome; Post Traumatic Stress Disorder; PPS-Post Polio Syndrome; Prostate Cancer; Pruritus
- Psoriasis; Pylorospasm reflux
- Radiation Therapy; Raynaud's phenomenon; Reactive Arthritis; RLS-MMj Treats Symptoms
- SAD; Schizophrenia(s); Scleroderma; Scoliosis; Selectivemutism; Shingles; Sinusitis; Sjogren's Syndrome; Sleep Apnea; Spina Bifida; Sturge-Weber; Syringomyelia
- Tenosynovitis; Testicular Cancer; Testicular Torsion; Thoracic Outlet Syndrome; Tic Douloureux; Tietze's Syndrome; Tinnitus; Tourette Syndrome and Cannabinoids; TTM
- Wolff-Parkinson-White Syndrome

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

REPORT



The Health Effects of Cannabis and Cannabinoids

THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH

Evidence of Benefit

- 2017 National Academies of Science, Engineering, Medicine, USA reviewed 10,700 clinical studies
- Neuroscientists have huge non-clinical data-base
- Few high-quality RCTs available:
  - Prohibition restricts supply and standardisation of cannabis
  - Cannabis plant has hundreds of compounds to study separately and individually, different ratios
  - Plants cant be patented, reduces funding sources
- EBM vs Personalised Medicine: GPs know RCTs are a guide but not real-world, we personalise Rx
- Patients' experience of illicit cannabis useful guide.

Systematic review Cannabinoids
Whiting et al JAMA June 2015

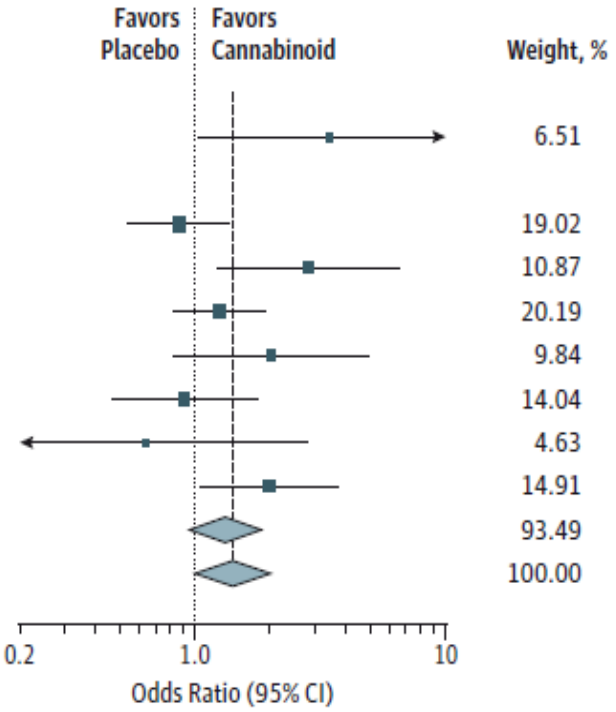
Condition	# studies	Strength of evidence	Conclusion
Nausea & vomiting	3 RCTs	Low	THC or THC/CBD > placebo
Weight gain in HIV/AIDS	1 RCT	Low	THC > placebo
Spasticity in MS / paraplegia	14 RCTs	Moderate	THC/CBD > placebo
Depression	3 RCTs	Low	Placebo > THC/CBD
Anxiety	1 RCT	Low	CBD>placebo
Sleep	12 RCTs	Low	THC/CBD, THC > Placebo
Psychosis	1 RCT	Low	CBD = amisulpiride
Tourette Syndrome	1 RCT	Low	THC > placebo
Glaucoma	1 RCT	Low	THC=CBD=placebo
Epilepsy	Not completed	N/A	CBD

Cannabinoids in chronic pain

Systematic review: Whiting et al JAMA June 2015

Figure 2. Improvement in Pain

Improvement in Pain With Cannabinoid vs Placebo by Study	Cannabinoid Events No.	Cannabinoid Events Total No.	Placebo Events No.	Placebo Events Total No.	Odds Ratio (95% CI)
Tetrahydrocannabinol (smoked)					
Abrams et al,[77] 2007	13	25	6	25	3.43 (1.03-11.48)
Nabiximols					
GW Pharmaceuticals,[22] 2005	54	149	59	148	0.86 (0.54-1.37)
Johnson et al,[69] 2010	23	53	12	56	2.81 (1.22-6.50)
Langford et al,[65] 2013	84	167	77	172	1.25 (0.81-1.91)
Nurmikko et al,[76] 2007	16	63	9	62	2.00 (0.81-4.96)
Portenoy et al,[67] 2012	22	90	24	91	0.90 (0.46-1.76)
Selvarajah et al,[70] 2010	8	15	9	14	0.63 (0.14-2.82)
Serpell et al,[88] 2014	34	123	19	117	1.97 (1.05-3.70)
Subtotal I^2 = 44.5%, (P = .0.94)	241	660	209	660	1.32 (0.94-1.86)
Overall I^2 = 47.6%, (P = .0.64)	254	685	215	685	1.41 (0.99-2.00)



Odds indicate 30% or greater improvement in pain with cannabinoid compared with placebo, stratified according to cannabinoid. The square data markers indicate odds ratios (ORs) from primary studies, with sizes reflecting the statistical weight of the study using random-effects meta-analysis. The horizontal lines indicate 95% CIs. The blue diamond data markers represent the subtotal and overall OR and 95% CI. The vertical dashed line shows the summary effect estimate, the dotted shows the line of no effect (OR = 1).

Compared to other medicines we use to treat pain

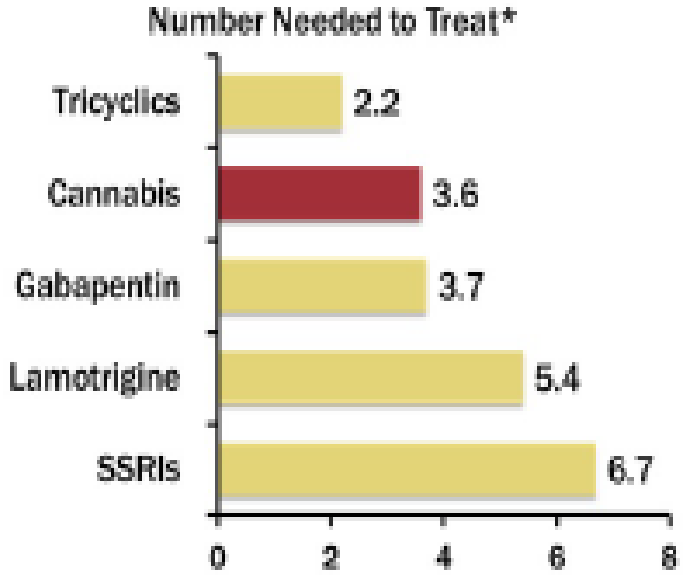


Figure 1. Common analgesics for neuropathic pain.
*to achieve a 30% reduction in pain.
Number needed to treat (NNT) = 1/(E-P), where E is the proportion improved in experimental condition and P is the proportion improved on placebo. Example: If 60% "improve" (according to a given definition) in the experimental condition, while 30% "improve" in the placebo condition, then NNT = 1/(.6-.3) = 3.3. Data adapted from Abrams et al. [3] and Ellis et al. [4].

Grant I, AMA Journal Ethics. 2013

Targeting cannabinoids for people with CNCP

- Pain, substance use, mood and sleep disorders often co-occur, and individually difficult to address
- Childhood trauma is a common link

- Role of cannabinoids for this population?
  - Cannabinoids target the ‘distress’ of pain > pain ‘severity’
  - Cannabinoids involved with mood, sleep, substance use
  - Safer profile than many other medicines used by pain patients

- Could cannabinoids be a useful strategy in addressing ‘high risk’ medication in pain patients - or will they contribute to the problem?
  - All CB RCTs for pain to date have excluded ‘addiction comorbidities’

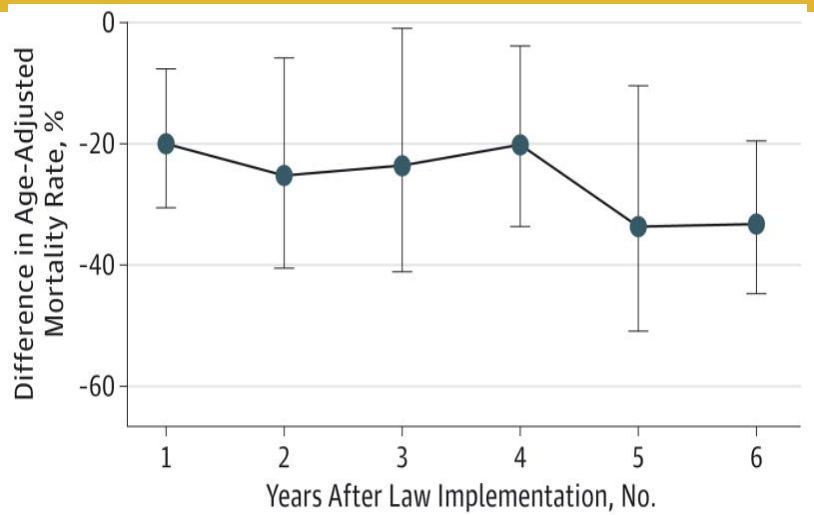
Medical cannabis & opioid related deaths

Bachhuber et al 2014. Medical cannabis laws and opioid analgesic overdose mortality in the United States, 1999-2010. JAMA Int Med 174:1668-73.

- "Medical cannabis laws are associated with significantly lower state-level opioid overdose mortality rates. Further investigation is required to …"

Review of opioid-sparing role of cannabinoids – animal and clinical studies: suggestive but not conclusive

(Nielsen et al Neuropsychopharmacology accepted)

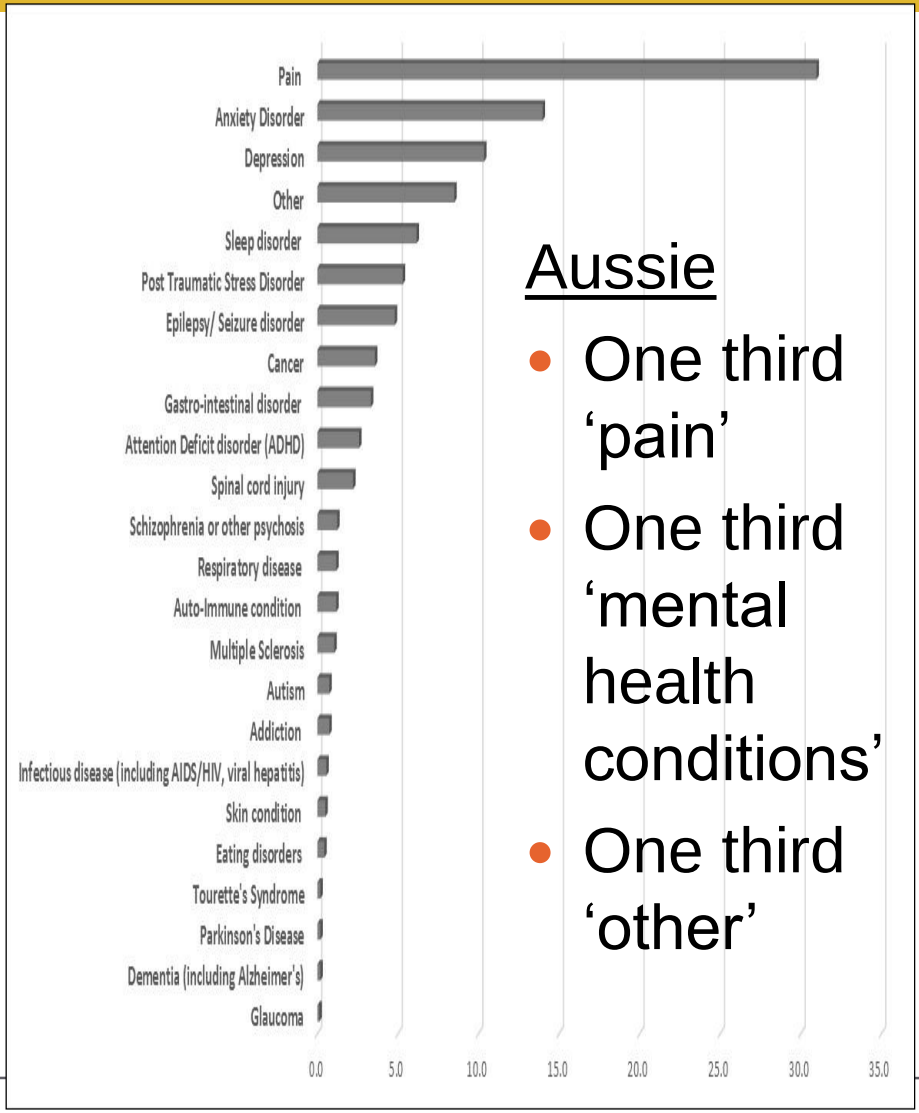


Cannabinoids for other addictions: ‘exit drug’

- Cannabis
  - Sativex (Nabiximols) vs placebo RCT underway in NSW
- Alcohol
  - CBD (and other CBs) for alcohol withdrawal, relapse prevention, cravings
- Opioids
  - CBs (THC) for opioid withdrawal
  - Opioid sparing in pain management
- Amphetamines
  - Promising animal research re: CBD

CAMS-16:
Reason for use (n=1624)

NZ Health Survey
2012/13 (n=13,009)



Aussie

- One third ‘pain’
- One third ‘mental health conditions’
- One third ‘other’

NZ

- 11% used cannabis in past year
- 5% used cannabis medicinally
- Of those
  - 40% for pain
  - 27% for anxiety
  - 26% for depression
  - 11% for nausea

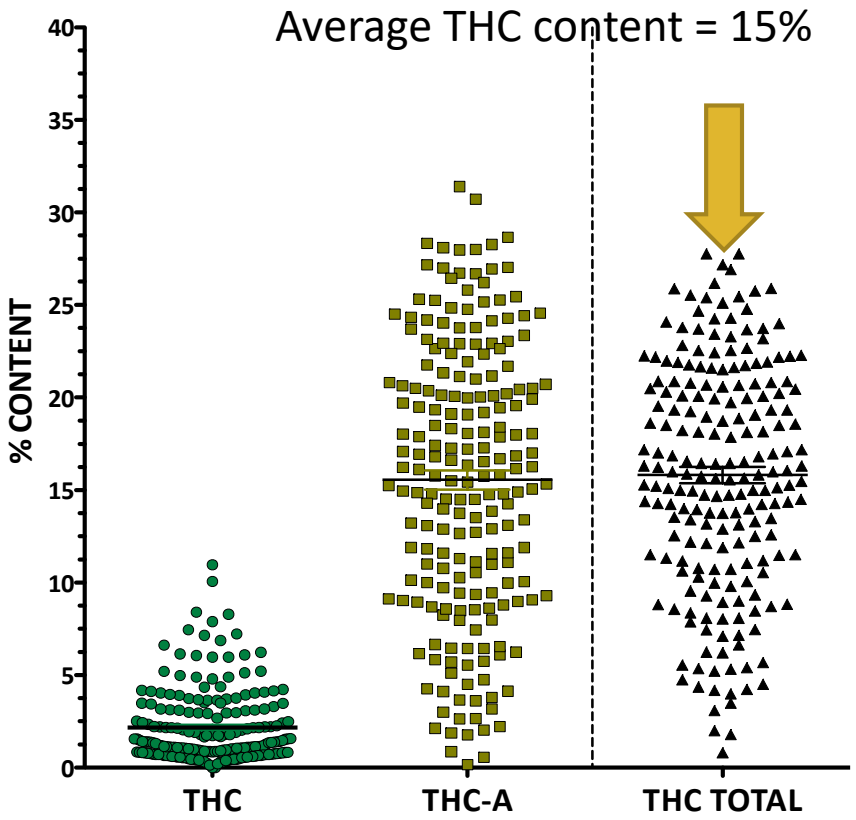
CAMS:16 (preliminary data only)

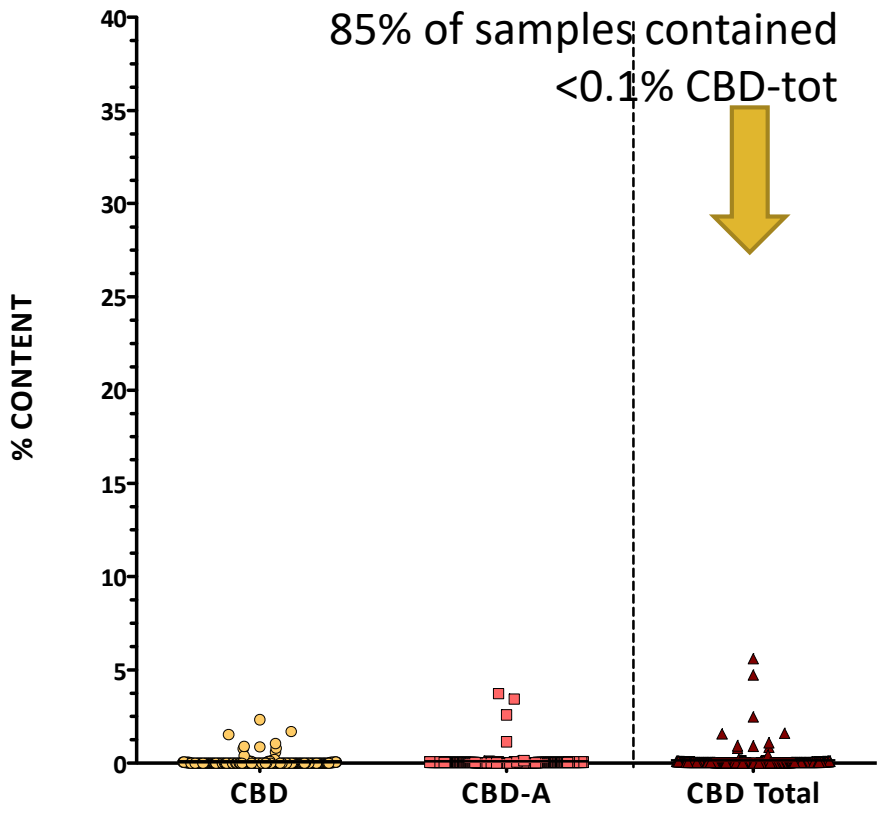
LAMBERT INITIATIVE
FOR CANNABINOID THERAPEUTICS

- Male 68%, Mean age: 38; 62% employed / student
- Using CAM for 10 yrs (mean)
  - ~ half using cannabis for other reasons before 'medical' use
  - ~ half not using cannabis (2/3^{rds} any prior use, 1/3rd never used)
- Median levels of use: 20/28 days; 3gm/day, $72 / week
- Source:
  - Recreational dealer: 42%; Friends/family 33%; grow own 13%; medical cannabis supplier 10%
- Route:
  - Smoked 63% ("Bong"/ pipe 43%; "joint" 19%; "dabbing" 1%)
  - Vaporiser: 14%
  - Oral: 21%

Potency of NSW police seized cannabis: high THC and low CBD

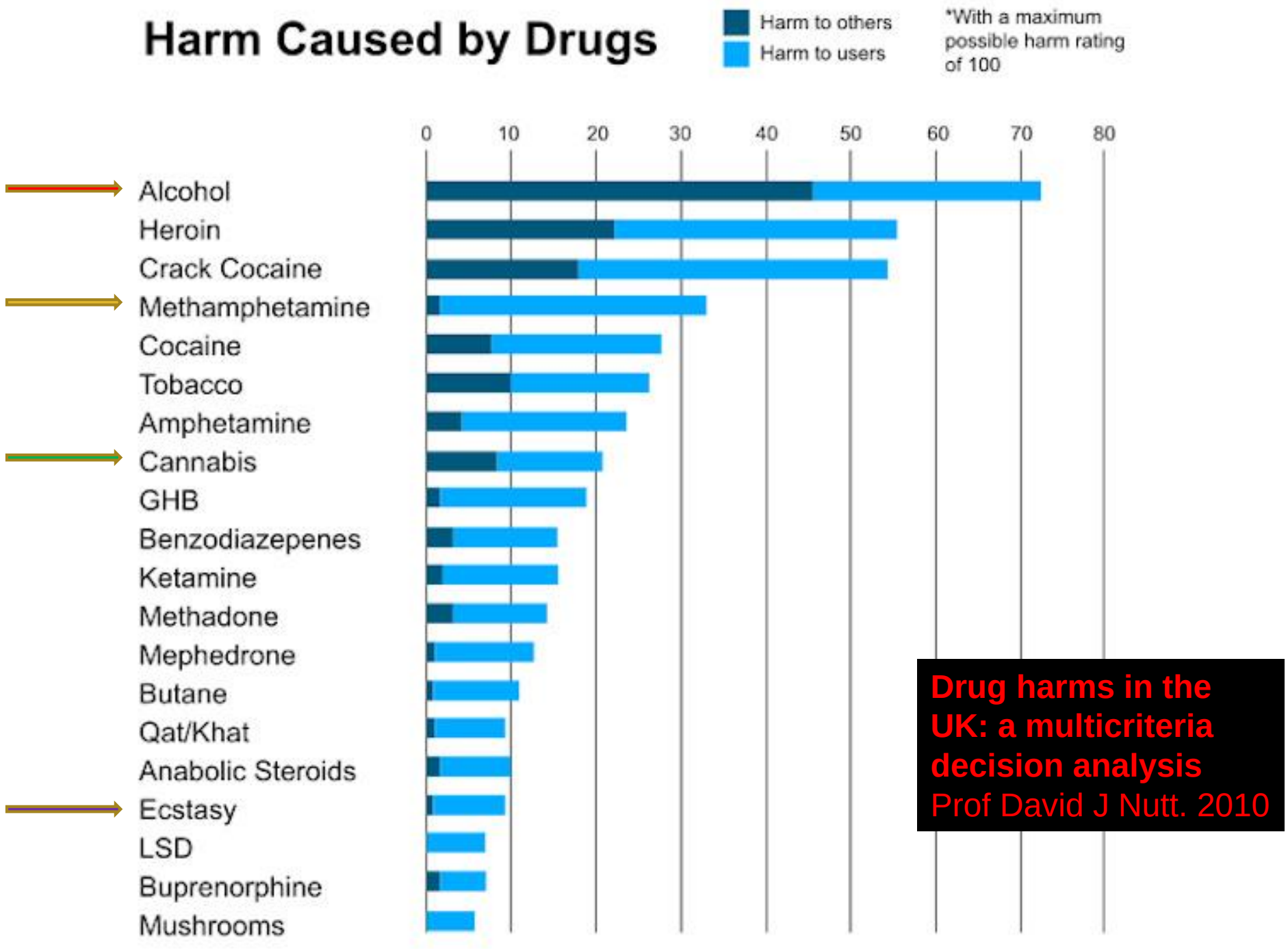
Swift et al PLoS One 2013





THC: psychoactive, sedation, analgesia, antiemesis, antispasmodic

CBD: not psychoactive, anxiolytic, antipsychotic, anticonvulsant, protective against memory loss

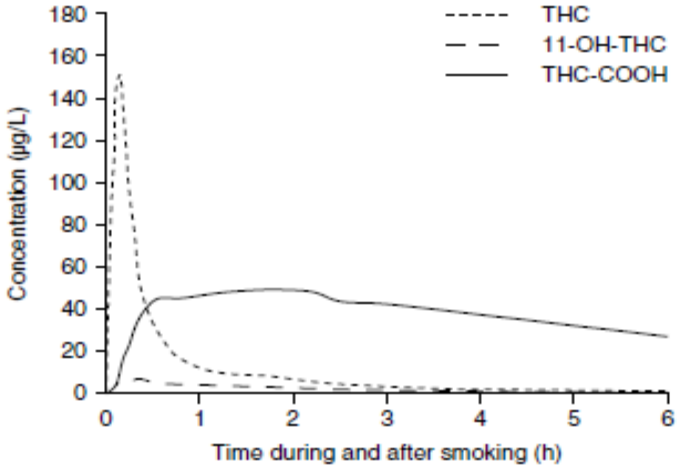

Harm Caused by Drugs
Harm to others
Harm to users
*With a maximum possible harm rating of 100
0
10
20
30
40
50
60
70
80
Alcohol
Heroin
Crack Cocaine
Methamphetamine
Cocaine
Tobacco
Amphetamine
Cannabis
GHB
Benzodiazepenes
Ketamine
Methadone
Mephedrone
Butane
Qat/Khat
Anabolic Steroids
Ecstasy
LSD
Buprenorphine
Mushrooms
Drug harms in the UK: a multicriteria decision analysis
Prof David J Nutt. 2010

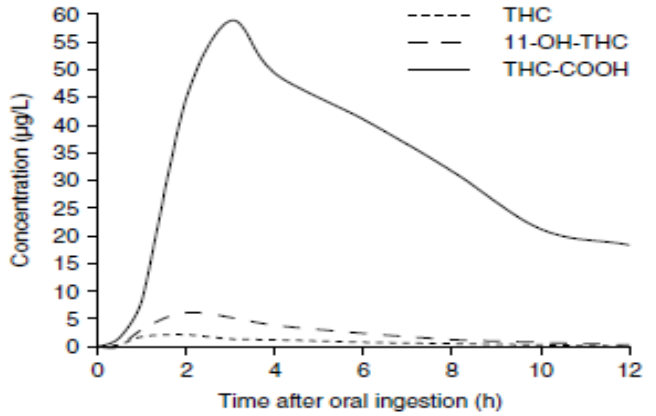
Potential harms / AEs of cannabis (high THC)

- Cognition & performance
  - Sedation and mild cognitive impairments in attention, memory, learning, psychomotor functions. Most effects reversible with abstinence, although may persist in heavy adolescent users
  - Intoxication related injuries (e.g. driving, falls)
- Mental health
  - Increased risk of psychoses OR = 2.09 (95%CI 1.54 to 2.84) & linked to genetic predisposition
  - Adolescent cannabis use associated with increased anxiety
- Dependence: estimated at 1 to 10% illicit users
- Physical effects
  - Hypotension, tachycardia, dizziness, dry mouth, respiratory
- Drug-drug interactions: CBD (THC) is CYP_{450} inhibitor

Using THC

- Higher bioavailability inhaled
  - 10-35% inhaled
  - 5-15% oral (hepatic CYP 2C8/9/19)
- Peak effects:
  - Inhaled:10-90 minutes after use
  - Oral: 60- 240 minutes after use
- Vaporising: similar to ‘e-cigarettes’
  - heats cannabis at lower temperature
  - fewer ‘toxins’, higher bioavailability
  - no side stream smoke (fewer concern re: passive smoking)
  - TGA-compliant devices: Volcano, Mighty Medic





Vaporisers: The Hemp Store
www.hempstore.co.nz

Vaporite digital desktop

Herb chamber

mouthpiece

Arizer Air handheld

Focus handheld

BEDROCAN®

Bedrocan is featuring 22% THC, with a CBD-level below 1%.

BEDROBINOL®

Its THC-level is standardised at 13.5%, with a CBD-level below 1 %.

BEDIOL®

Bediol has a balanced ratio of THC 6.3% and CBD 8%.

BEDICA®

Bedica contains 14% THC with less than 1% CBD.

BEDROLITE®

Bedrolite is a CBD-only product, with less than 1% THC and 9% CBD.

LIQUID CAPSULES

Available in Sativa, Indica, Hybrid and two varieties of CBD for easy ingestion and precise dosage.

DROPS

Available in Sativa, Indica, Hybrid and two varieties of CBD for convenient ingestion. These products also give patients the option of infusing cannabis into many foods of their choice.

VAPORIZER OIL

Available in two varieties of CBD for inhalation and ease of use via vaporization, which is an alternative to smoking.

ORAL SPRAY

Available in Sativa, Indica, Hybrid and two varieties of CBD for quick onset of relief; both convenient and fast-acting.

TOPICAL OIL

Available in Hybrid and two varieties of CBD for direct skin application and localized use.

50+ STRAINS

Tilray has sourced 50+ strains of high quality medical cannabis from British Columbia and around the world, with some of the highest concentrations of THC and CBD available on the market.

What is Sativex®?

Sativex® is a cannabis-based product classified as a Schedule 2, Part 1 (Class B1) controlled drug product under the Misuse of Drugs Act 1975. Sativex® is an oromucosal (mouth) spray administering a metered, actuated dose containing the cannabis extracts delta-9-tetrahydrocannabinol (THC) (2.7 mg/spray) and

cannabidiol (CBD) (2.5 mg/spray)

[+ traces of terpenes and other cannabinoids].

Sativex

Each spray THC 2.7mg, CBD 2.5mg, ethanol, peppermint oil

COST
$950 - $2500
For a 3-pack
3x90 sprays.
$3.50 –
$9 per spray

How do GPs Prescribe cannabinoids?

4 ways

1. What is Sativex® approved for?

- In New Zealand Sativex® is approved for use as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to Multiple Sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

Restriction on the Supply of Sativex—Approval to Prescribe, Supply and Administer (Approval No. 2016/AP305)

- Medical practitioners with a vocational scope of practice of Internal Medicine (specialising in neurology), registered with the Medical Council of New Zealand under the Health Practitioners Competence Assurance Act 2003, for the treatment of multiple sclerosis; or
- any other medical practitioner registered with the Medical Council of New Zealand when acting on the written recommendation of one of the medical practitioners with the vocational scope described above, for the condition specified. The name of the recommending medical practitioner with the appropriate vocational scope must be endorsed on the prescription form.
- The prescriber is required to state the condition being treated (ie "**multiple sclerosis**") on the prescription form.

2. Sativex ‘unapproved use’

- Form 2
- 6 pages
- GP & Specialist signatures
- Process time 1 – 4 weeks.

- SPECIAL AUTHORITY FORM – My proposal for an efficient approval system!!!

- However, as GPs we know that evidence based medicine doesn’t work for everyone, we work in ‘zones of therapeutic uncertainty’

Form 2

FORM 2

Application for
APPROVAL TO PRESCRIBE SATIVEX® FOR AN UNAPPROVED USE under Regulation 22 of the Misuse of Drugs Regulations 1977

A completed and signed copy of this form must be submitted for each application for Ministerial approval to prescribe Sativex® for an **unapproved use** in a specified patient.

Please refer to the current New Zealand Sativex® data sheet when completing this form (see http://www.medsafe.govt.nz/profs/Datasheet/s/sativexspray.pdf)

Please note that Sativex® is currently **not** funded by PHARMAC.

Form 2

4. SPECIALIST ENDORSEMENT

NOTE: SPECIALIST ELIGIBILTY CRITERIA
Specialist assessment and endorsement of the proposal to use Sativex®, and the proposed patient management plan, **must** be issued by a practitioner who is registered with the New Zealand Medical Council as being competent in the scope of practice appropriate to the management of the *specified condition* to be treated. For example, treatment for cachexia related to cancer should be endorsed by a registered oncologist or palliative care specialist.

Specialist endorsement is limited to oncologists, neurologists, anaesthetists and palliative care specialists.

NOTE: PROPOSED USE
To be eligible for approval to prescribe Sativex® for an unapproved use the patient **must** have a *specified condition* as follows:

- nausea, anorexia and wasting (cachexia) associated to cancer and AIDS; or
- chronic pain (including cancer pain) for which other pain relief treatments are ineffective or have significant/severe adverse side-effects; or
- neuropathic pain (associated with conditions including multiple-sclerosis, stroke, cancer, spinal cord injury, severe physical trauma, and peripheral neuropathy resulting from diabetes); or
- muscle spasm and spasticity associated with spinal cord injury.

NOTE: FAILURE OF OTHER PRESCRIPTION MEDICINES OR CURRENTLY AVAILABLE TREATMENTS
To be eligible for approval to prescribe Sativex® for an unapproved use the patient **must** have trialled adequate doses of standard treatments for the *specified condition* for appropriate periods of time without sufficient therapeutic benefit, or the standard treatments are not tolerated by the patient, or are contraindicated in the patient.

3. Application for Ministerial approval to prescribe a pharmaceutical grade cannabis-based product without consent for distribution in New Zealand under Regulation 22 of the Misuse of Drugs Regulations 1977

Please note that the Government does not support the use of unprocessed or partially processed cannabis leaf or flower preparations for medicinal use.

http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/prescribing-cannabis-based-products

a.application from an appropriate specialist
b.a manufacturer has demonstrated a commitment to the development of the product as a pharmaceutical or
c.the product has been prepared pharmaceutically and the characteristics and formulation are clearly described and defined
d.the product has completed animal studies demonstrating proof of concept and potential clinical benefit
e.the product is undergoing an appropriately designed Phase II clinical study or
f.the product has completed clinical trials and is marketed overseas but is not approved for distribution in New Zealand
g.the product is available for use
h.the following are met where relevant:

i. evidence that there will be close follow up of patient by a prescriber
ii. evidence that a wide range of conventional treatments have been trialled and symptoms are still poorly controlled
iii. condition is an approved condition for use or
iv. condition is one for which there is some evidence of efficacy, preferably in clinical trials
v. Ministry clinicians assess application is appropriate if for non-approved use
vi. no history of abuse or diversion of controlled drugs
vii. the patient has no known contraindication to the use of the product
viii. initial approvals usually for 6 months
ix. baseline clinical indicators generally required and evidence of improvement before a new approval is given.

MINISTRY OF HEALTH
MANATŪ HAUORA

Application for Ministerial approval to prescribe a pharmaceutical grade cannabis-based product without consent for distribution in New Zealand under Regulation 22 of the Misuse of Drugs Regulations 1977

A completed and signed copy of this form must be submitted for each application for Ministerial approval to prescribe a pharmaceutical grade cannabis-based product without consent for distribution in New Zealand for a specified patient.

IMPORTANT INFORMATION FOR APPLICANTS
Applications to prescribe pharmaceutical grade cannabis-based products without consent for distribution in New Zealand are considered on a case by case basis. Please review the guidelines used for assessing applications listed on the Medicines Control section of the Ministry of Health website.

1. PRODUCT

Name of the product:

Do you have a Certificate of Analysis?

- ☐ No
- ☐ Yes – please attach details

Please attach any evidence of potential benefits of the use in the product in the condition(s) to be treated and known adverse effects.

2. PATIENT INFORMED CONSENT

"I, the patient named above, am willing to use the product named in the application and I am aware that it is a pharmaceutical grade cannabis-based product without consent for distribution in New Zealand. I have been fully informed of the potential dangers associated with its use. I am aware that if the product is abused or diverted then this application and approval is no longer valid and that future applications will be declined."

Signature of above named patient *Date*

3. APPLICANT DETAILS

NOTE: APPLICANT ELIGIBILTY AND POTENTIAL EXCLUSION CRITERIA
The application must be completed by a specialist who is managing the condition that the product is to treat. The specialist must be registered with the New Zealand Medical Council as being competent in the scope of practice appropriate to the management of the condition to be treated, for example oncologists, neurologists, anaesthetists and palliative care specialists.

Health professionals with a documented history of abuse or diversion of controlled drugs, or who have had their rights to prescribe controlled drugs limited under the Misuse of Drugs Act 1975 may be ineligible to prescribe. The applicant should not have any previous complaints against them for drug or alcohol abuse, and Medicines Control (Ministry of Health) should have no outstanding investigations or concerns about their prescribing pattern of Drugs of Misuse.

4. Alternatives to Sativex

‘In practical terms the changes mean CBD would be able to be prescribed by a doctor to their patient and supplied in a manner similar to other prescription medicine.’

Peter Dunne, Associate Minister of Health, 2/6/17.

In Conclusion

- On both medical and compassionate grounds I would like our government to make available a wide variety of CBD/THC medicinal cannabis products, preferably made in NZ.

- I wish to pay my respects to Helen Kelly, Alex Renton, Paul Holmes, Martin Crowe, Huana Hickey and thousands of unnamed New Zealanders who have risked prosecution or inconvenience and expense to experience the benefits of medicinal cannabis.

~NGA MIHI NUI~