Medicinal Cannabis

Integrating this "old drug" into modern evidence-based clinical practice

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waves
Western Australian Veterinary Emergency & Specialty

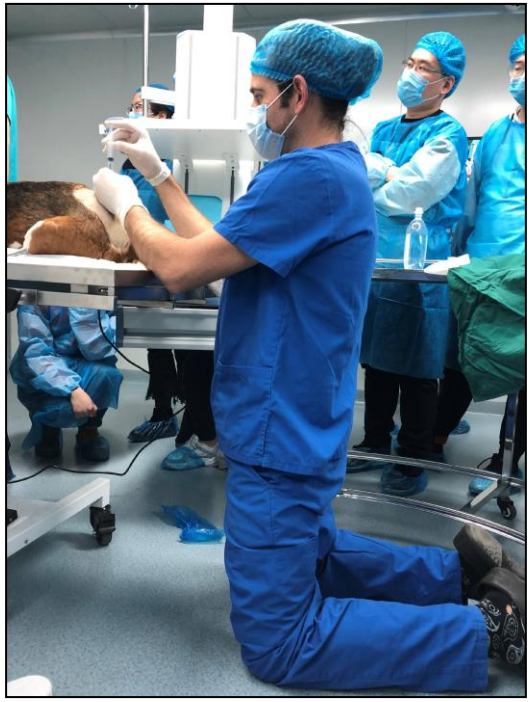
NovaVet DIAGNOSTICS

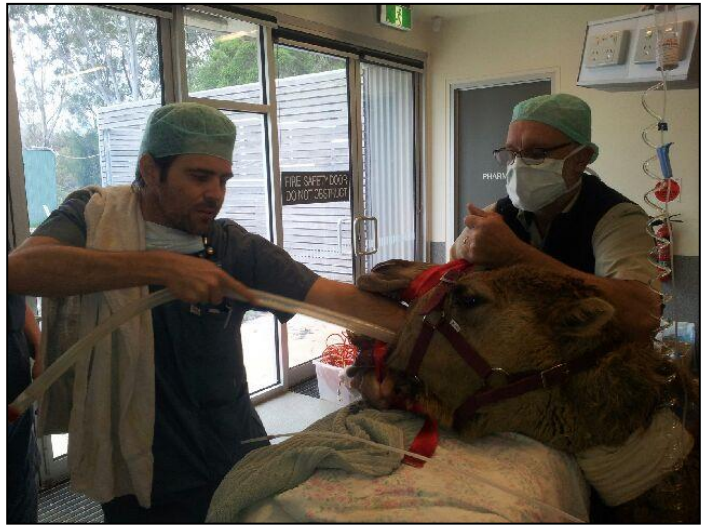
ROYAL CANIN®

Who am I?

BSc(Biol), *BBiomedSc(Hons1)*, *BSc*, *BVMS*, MVS, MANZCVS, Dip.ACVAA, *PhD*

- **Veterinary Anaesthesia & Pain Management**





ACVAA
FOUNDED IN 1975

AMERICAN COLLEGE OF VETERINARY ANESTHESIA AND ANALGESIA

I am an evidence-base clinician

- >20 Peer Reviewed Publications
- 15 years academic & research experience
- Member of Australian College of Veterinary Scientists
- Australasian Veterinary Boards Council registered specialist
- Translational Pain Researcher

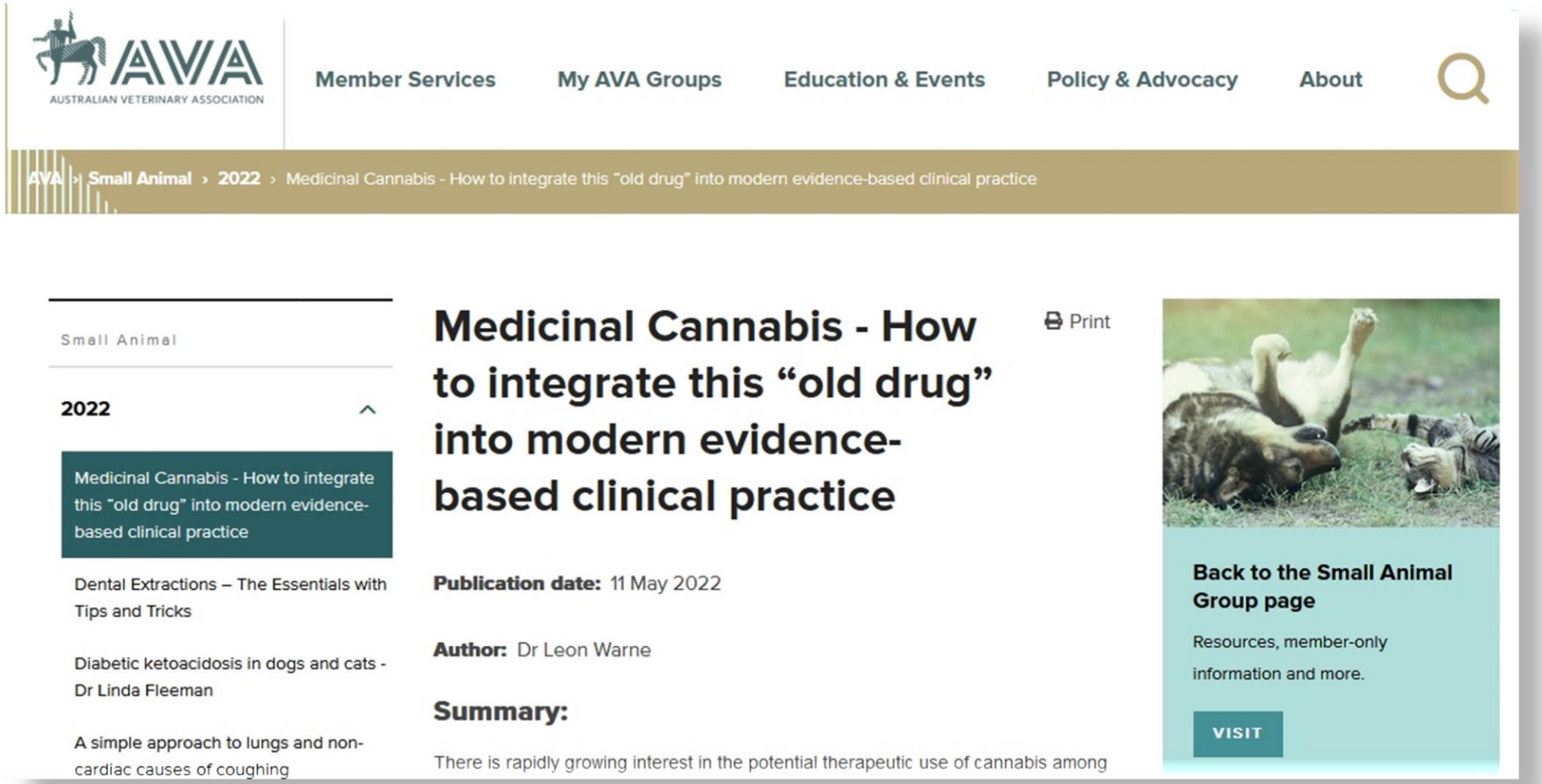
Current Roles

- **Research positions**
  - Curtin University,
  - Murdoch University
  - Southern Cross University

- **Medical Director / Founder**
  - The Vet Pharmacist

- **Director**
  - Veterinary Anaesthesia & Pain Management Australia

Medicinal Cannabis – How to integrate this “old drug” into modern evidence-based clinical practice

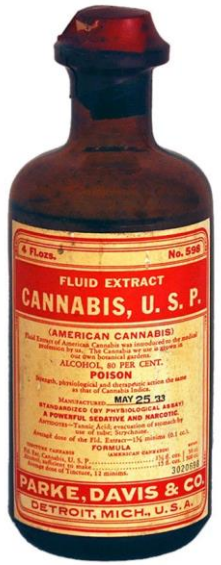


History of Cannabis as a Medicine

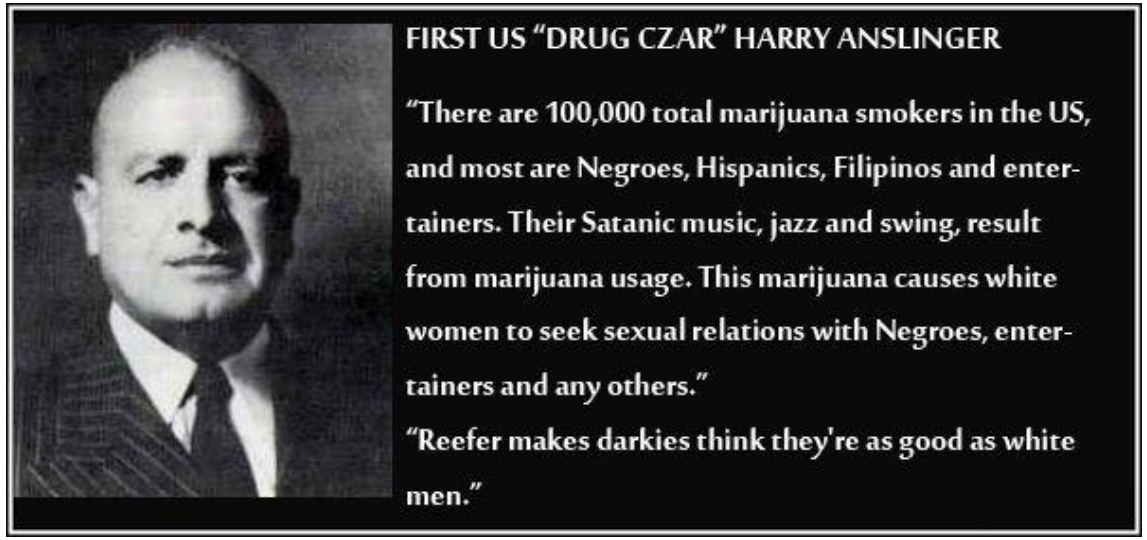
- >5,000 years of medical use of cannabis
  - Mentioned in the Chinese pharmacopeia of Emperor Chen Nung 2,700 BCE

History of Cannabis as a Medicine

- As late as early 20th Century cannabis preparations widely prescribed by ‘Western’ Drs.
  - Bronchitis, epilepsy, burns, hypnotic, analgesia, premenstrual syndrome (PMS)



Cannabis Ban Stemmed from Prejudices in the US



- The practice of smoking cannabis appeared in Texas border towns around 1900 brought in by immigrants who cultivated cannabis as an intoxicant and for medicinal purposes as they had done at home.

- Local police demonized the plant in racial terms as the "drug of immoral populations."

- Harry Anslinger - Commissioner Federal Bureau of Narcotics 1930-1962
  - Marijuana Tax Act 1937

Single Convention on Narcotic Drugs of 1961 (International Treaty)

- Made Cannabis illegal, worldwide

- *A 1962 issue of the Commission on Narcotic Drugs' Bulletin on Narcotics proudly announced that "after a definite transitional period, all non-medical use of narcotic drugs, such as . . . consumption of cannabis . . . will be outlawed everywhere”*

Resurgence in Interest in Medicinal Cannabis

- Interest rekindled in the 1980's
  - Patient/consumer Advocacy – illegal use in community: anecdotal efficacy stories
  - Scientific Research (esp. Israel)
    - Identified endogenous cannabinoids with influence on neurological, immune, gastrointestinal systems

- Synthetic THC developed
  - FDA approved: nausea and vomiting due to chemotherapy
  - Dronabinol 1986 (also AIDS anorexia, Nabilone 2010)

- Compassionate use allowed
  - California 1996……

- Clinical trials launched in NSW 2015
- **Medical** prescribing permitted in Australia 2016

Prescribing Medicinal Cannabis Veterinary Patients, the Law in Australia

- Following amendment of the Narcotic Drugs Act, medicinal cannabis for *human therapeutic use* permitted on 1st November 2016

- Veterinarians are permitted to exercise professional judgement in the ‘off-label’ use of most drugs including those registered for human-use

- Vets are permitted to prescribe medicines manufactured for humans, as ‘off-label’ medicines (i.e., used not in accordance with approved labelling) for animals under certain conditions
  - As there are no medicinal cannabis drugs registered for use in animals; vets only avenue to prescribe CBD is as a “human medication for ‘off-label’ veterinary use”.

Prescribing Medicinal Cannabis Veterinary Patients, the Law in Australia

- Medicinal cannabis products, which contain high levels of THC are for human therapeutic use only. They cannot be prescribed by veterinarians.

- Regarding medicines containing predominantly CBD; veterinarians may prescribe these products if used for therapeutic purposes and where:
  - CBD comprises 98% or more of the total cannabinoid content of the preparation; and
  - Any cannabinoids, other than CBD, must be only those naturally found in cannabis (i.e., not synthetic) and comprise 2% or less of the total cannabinoid content of the preparation.

- Veterinarians are allowed to prescribe unregistered veterinary products containing cannabis for therapeutic use in animals only – provided they comply with the provisions of Schedule 4 of the Poisons Standard and are manufactured outside of Australia. https://apvma.gov.au/node/116471
- *Actually…. its more detailed than that!!* 😉
  - **Cultivation** must occur outside of Australia
  - **Extraction** must occur outside Australia
  - **Manufacture** must occur outside Australia

Prescribing Medicinal Cannabis Veterinary Patients, the Law in Australia

Veterinary Surgeons' Board

MORE ON CANNABIS BASED PRODUCTS

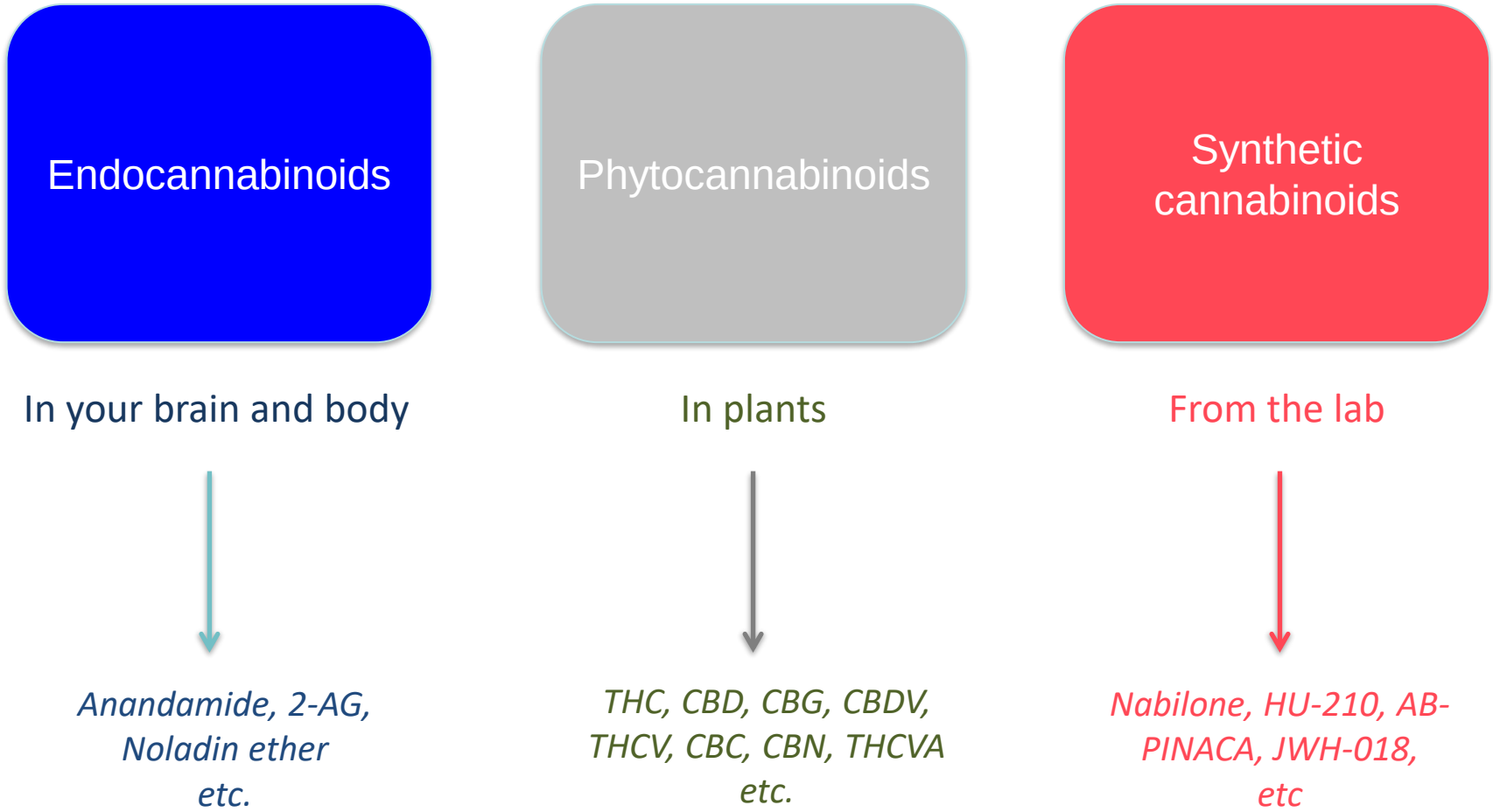
The article on cannabis based products in the last Board newsletter generated a lot of interest and questions. The following information is provided to address the most asked queries.

Most medicinal cannabis products are classed as S8 for human therapeutic use only. Veterinary surgeons have not been given authority to prescribe these products so they revert to S9(Prohibited)

With regard to cannabidiol, that is a schedule 4 product if used for therapeutic purposes (human or animal). Veterinary surgeons may prescribe these products. However, to be classed as cannabidiol, the total amount of cannabinoids present must not exceed 2%. If this is not the case then the product would revert to schedule 9 and be a prohibited drug which cannot be prescribed by a veterinary surgeon.

Any possession of a schedule 4 medicine without a valid prescription is an offence, so if clients are sourcing the oil from the internet they may be committing offences under the *Medicines and Poisons Act 2014*.

Sources of Cannabinoids (Ligands)

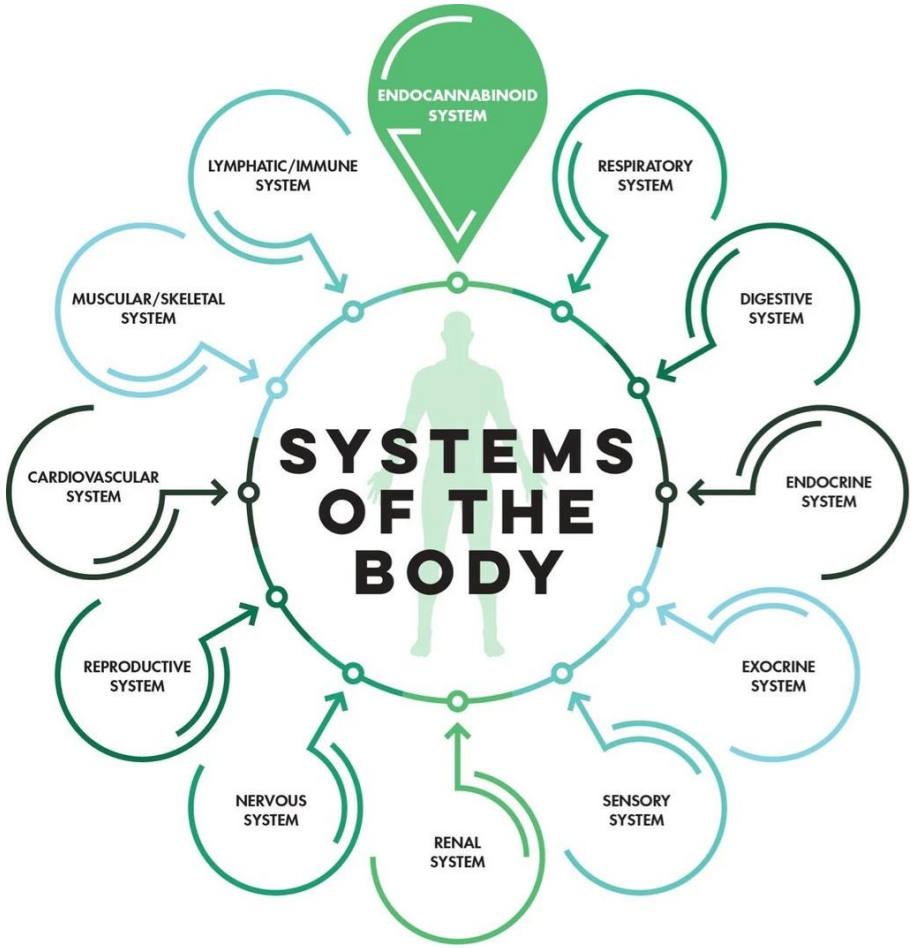


The Endocannabinoid System

- The ECS is a biological system composed of:
  - **Endocannabinoids** (lipid-based neurotransmitters/ligands) that bind to **cannabinoid receptors** (e.g., CB1 and CB2,) that are expressed throughout the vertebrate CNS and peripheral nervous system.

- ECS is implicated in the regulation of mood, appetite, pain, memory, stress, immune responses and gastrointestinal function.

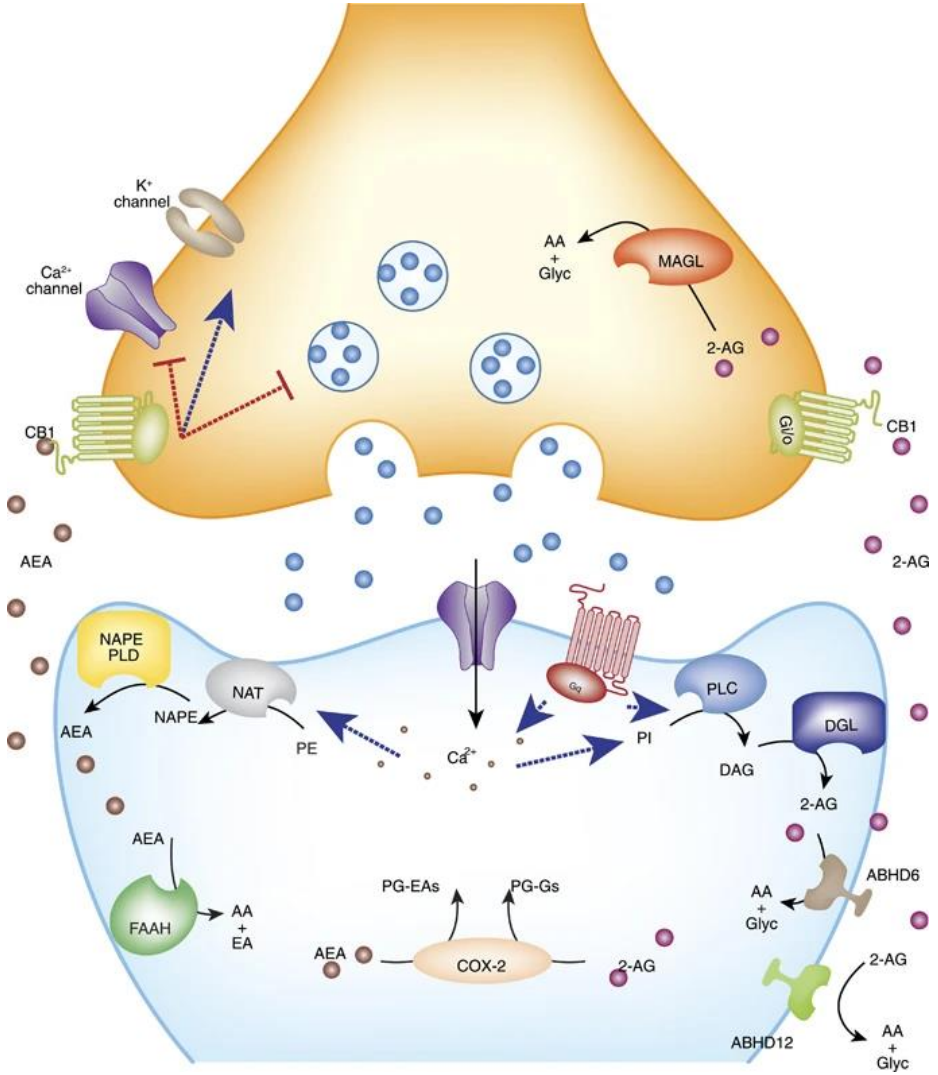
- **The 3 Pillars of the ECS**
  1. Receptors
  2. Endocannabinoids
  3. Regulatory Enzymes



ECS - Receptors

Present on neurons and cells throughout the body

- **G-protein coupled receptors**
  - **CB1**
  - **CB2**
  - GPR 18, GPR 55, GPR 119
- **Ligand-gated ion channels**
  - TRPV1 (nociception), 5-HT3 (serotonin - mood), GlyR
- **Nuclear Receptors**
  - PPARα, PPARγ



CB1 Receptor

- The most abundant protein-based receptor found in the human brain and CNS
  - Also found in: fat cells, liver cells, musculoskeletal tissue, GI tract, cardiovascular system, peripheral nerves, reproductive tract

- Mediates inhibitory action on the release of excitatory and inhibitory dopaminergic, GABA, glutamatergic, serotinergic, noradrenalin and acetylcholine neurotransmitter systems

- **Functions:** Mood, cognition, reduction of pain and inflammation
- Responsible for the psychotropic effects of THC

CB2 Receptor

- Primarily in cells of the immune system
  - Receptors are expressed on T-cells, B-cells, and macrophages
  - Also found in: liver cells, kidney, skin

- **Functions:** Immune modulation and anti-inflammatory effect

Phytocannabinoids
Cannabidiol (CBD) – *Mode of Action*

- Low binding affinity for CB1 and CB2 receptors
- Weak antagonist at both CB1 and CB2 receptor agonists
  - Interaction with CB2 receptors explains its ability to inhibit immune cell migration
  - Also known to be a negative allosteric modulator at CB1, explains its ability to counteract some of the negative effects of THC
- More potent agonist at TRPV1
- Limits anandamide degradation by FAAH
- Allosteric modulator of opioid receptors (mu and delta)

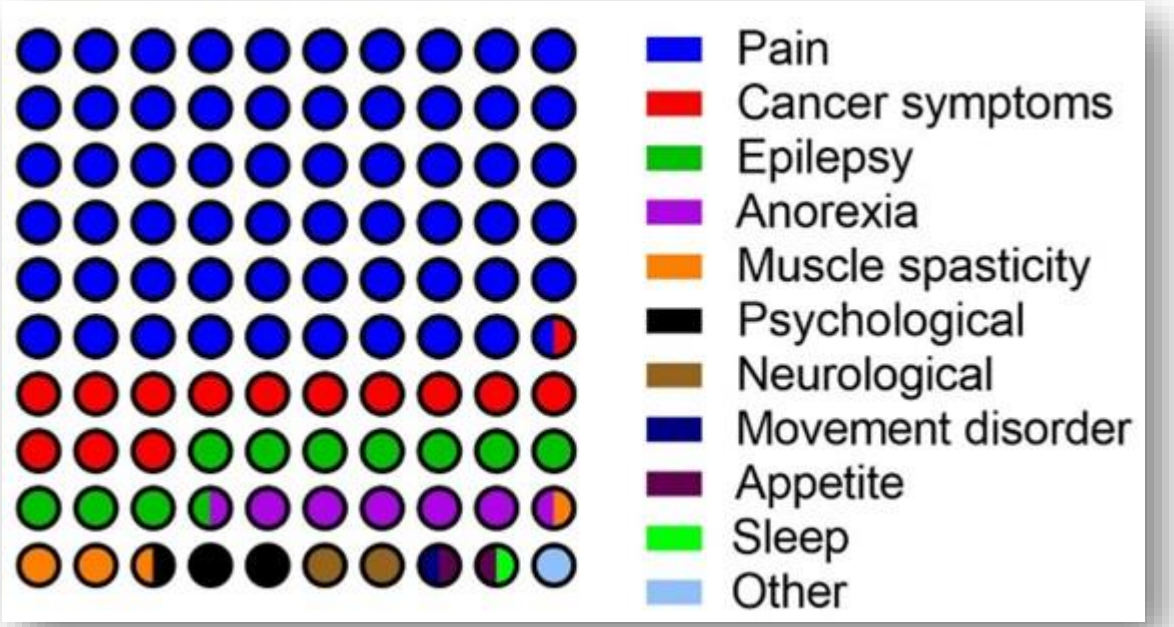
Phytocannabinoids
Tetrahydrocannabinol (THC) – *Mode of Action*

- Partial agonist of CB1 and CB2 receptors
- Phytomimetic of anandamide although has less selective binding
- Binds FABP, limits endogenous anandamide degradation by FAAH
- Psychotropic through binding of CB1 receptors
  - Dogs have higher proportion of CB1 receptors in cerebellum, thus high risk of adverse effect.

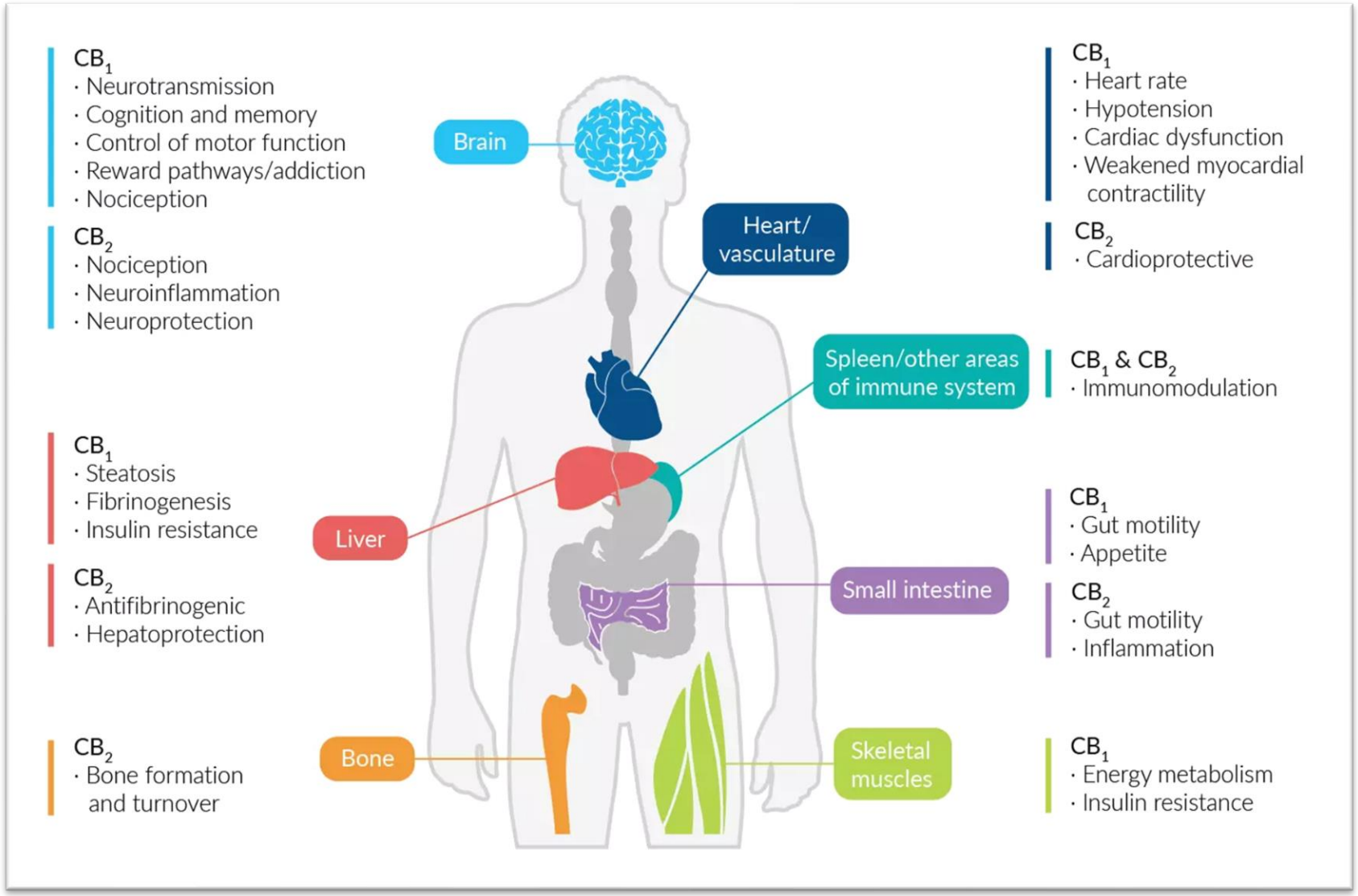
Understanding Cannabis as a Medicine: *A Different Way of Thinking*

- The many phytochemicals of the plant mean that there is the potential for one medication to have multiple effects

Reasons being prescribed:



CB1 & CB2 Receptor Distribution & Mechanism of Action



Understanding Cannabis as a Medicine: *A Different Way of Thinking*

- Treatment with medicinal cannabis is often not about curing the condition, rather it is about alleviating symptoms and improving quality of life.

- DON'T OVERCOMPLICATE IT! You do not need to:
  - have a degree in naturopathy, homeopathy or alternative medicine
  - have lived through the 60's and *inhaled*!

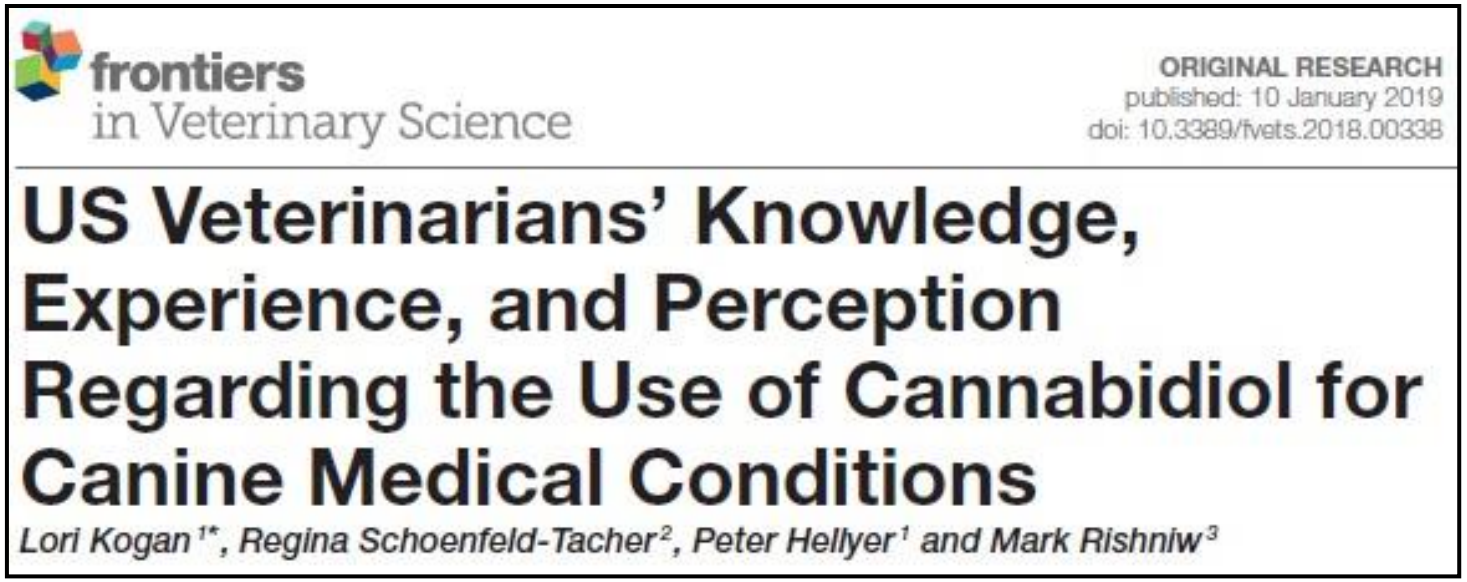
- I say this because;

standardisation of Cannabis *as a medicine* in terms of the quality and validation of the finished product enables you to use this medicine as you would any other pharmaceutical.

Medical Uses for Cannabis in Veterinary Patients

- Analgesia
- Anti-inflammatory
- Antiepileptic adjunctive/primary tx
- Anti-emetic
- Behavioural therapeutic (particularly anxiety/fear) – adjunctive/primary tx

Medical Uses for Cannabis in Veterinary Patients



Conclusion: "*CBD was most helpful in providing analgesia for chronic and acute pain, relieving anxiety and decreasing seizure frequency/severity. The most commonly reported side-effect was sedation.*"

Frontiers in Veterinary Science, 2019 Volume 5, Article 338 pp. 1-11

Cannabis Dosing in Veterinary Medicine

Challengers:

- Rapidly growing interest in therapeutic use of cannabis
  - Pressure from clients; other colleagues
  - Profound lack of knowledge:
    - "*I wasn't taught this at vet school…. What is the endocannabinoid system anyway?*".
  - Fear of patient harm and litigation, or even committing a criminal offence.

- How do I know which products to trust?

- Lack of traditional dosing protocols developed in accordance with manufacturers' pharmacokinetic and pharmacodynamic studies.
  - You won't find a dose in Plumbs or your favourite veterinary formulary

Creating a Cannabis Dosing Plan in 3-Steps

STEP 1: Pick the cannabinoid(s) indicated based on the patients condition

STEP 2: Choose an appropriate product formulation

STEP 3: Search the Literature

Creating a Cannabis Dosing Plan in 3-Steps

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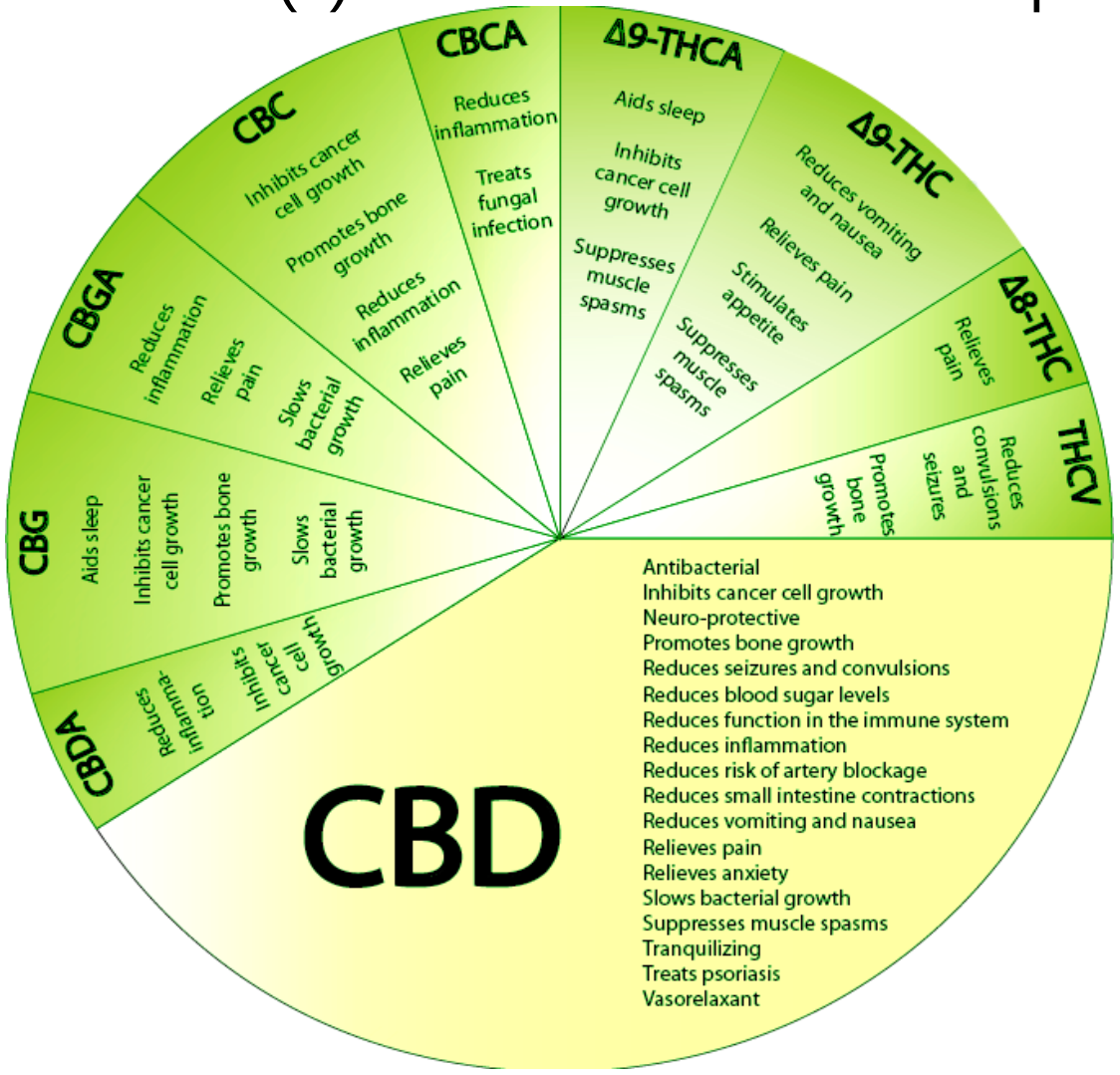

Creating a Cannabis Dosing Plan in 3-Steps

STEP 2: Choose an appropriate product formulation

- **Quality**: Ensure that the product you select has been manufactured under rigorous quality measures (e.g., Good Manufacturing Practices – GMP).
    - Batch-manufacturing guaranteed – active ingredient content (content 90-110% of stated)
    - Known composition (Certificate of Analysis)
    - Stability data / expiration date
    - Unadulterated

    - This GMP manufacture and batch release, is a guarantee of quality standard. It is MUCH more important that an unverifiable Certificate of Analysis (CoA).

- Unfortunately, not all products have the same obligations:
    - Illegally sourced ‘black-market’ products
    - Products bought from overseas via the internet
    - Some imported international (non-GMP) products

❖ ***Hemp seed oil -*** the general public and veterinarians frequently encounter misinformation related to CBD oil and hemp seed oil. FACT, hemp seed oil is made from hemp seeds and does not contain CBD or other cannabinoids

Creating a Cannabis Dosing Plan in 3-Steps

STEP 2: Choose an appropriate product formulation

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Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature

- **The Truth is Out There….. but probably not at these locations:**
  - Google
  - Human medicinal cannabis companies (or compounding pharmacies) posing as veterinary specific
  - Human trained healthcare professionals (Drs, Naturopaths, TCM, etc)
  - Individuals at local markets and travelling fairs
  - Friendly locals who have been “growing” for years.

  - **No.1 Tip:** Beware of people who try to overcomplicate the process!! **YOU GOT THIS!**

Creating a Cannabis Dosing Plan in 3-Steps

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LET'S DIVE INTO THE RESEARCH!

Creating a Cannabis Dosing Plan in 3-Steps

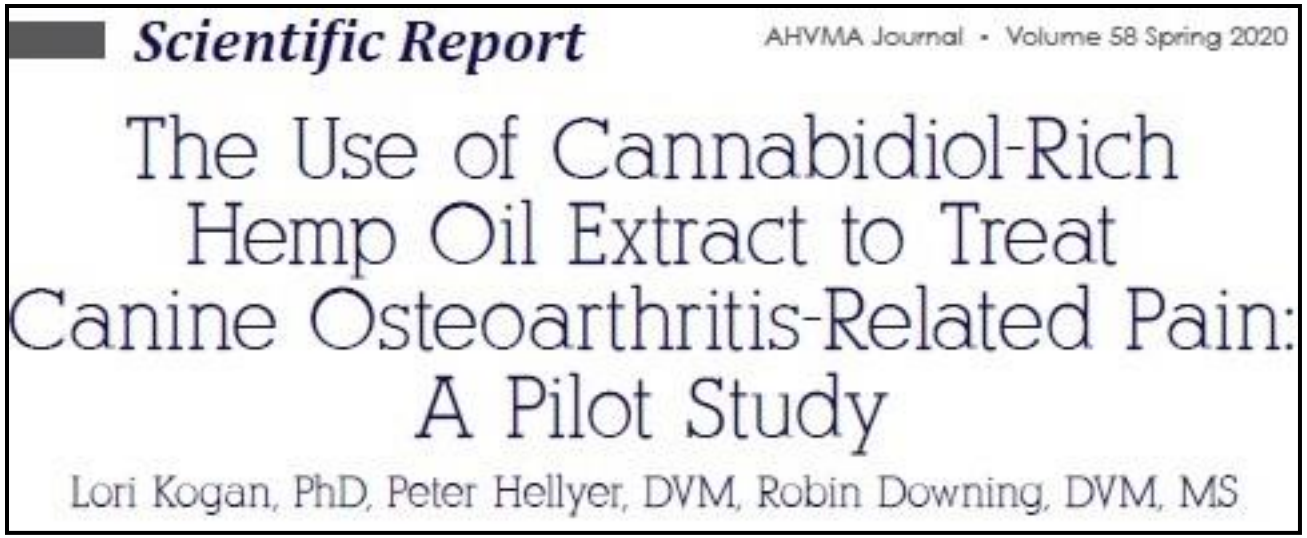
STEP 3: Search the Literature: Analgesia - Osteoarthritis

Findings: "*This pharmacokinetic and clinical study suggests that 2 mg/kg of CBD twice daily can help increase comfort and activity in dogs with OA.*"

Frontiers in Veterinary Science, 2018 Volume 8, Article 165 pp. 1-9

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature : Analgesia - Osteoarthritis

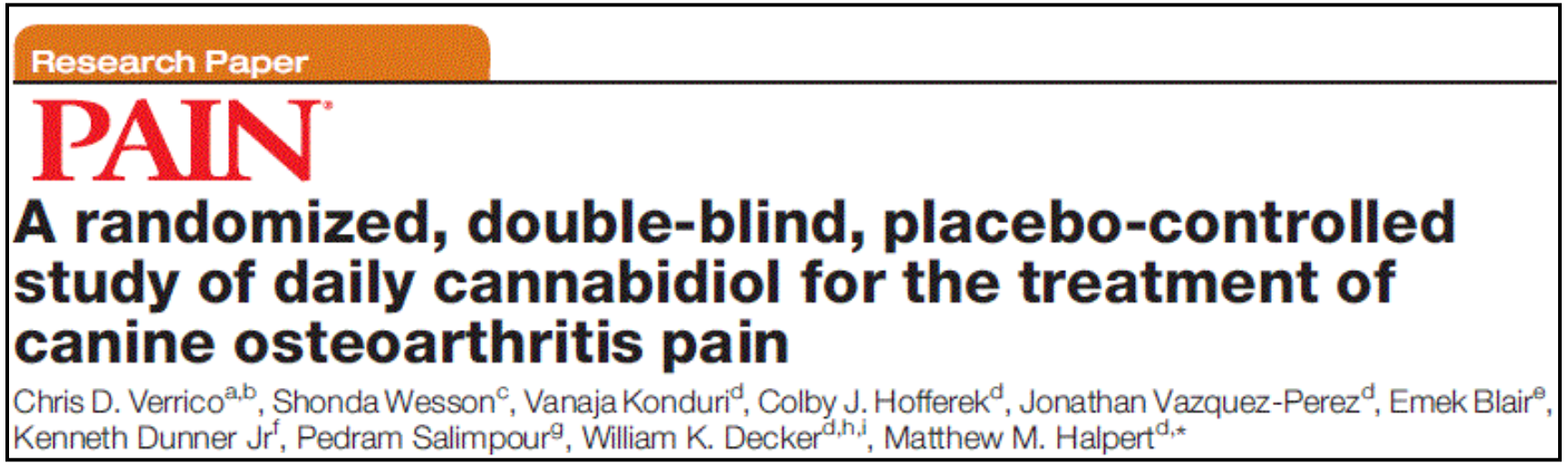


Findings: "*The addition of hemp-derived CBD oil appears to positively affect dogs with chronic maladaptive pain by decreasing their pain, thereby improving their mobility and quality of life.*"

American Holistic Veterinary Medical Association, 2020 Volume 58, pp. 1-10

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature : Analgesia - Osteoarthritis


Research Paper

PAIN

A randomized, double-blind, placebo-controlled study of daily cannabidiol for the treatment of canine osteoarthritis pain

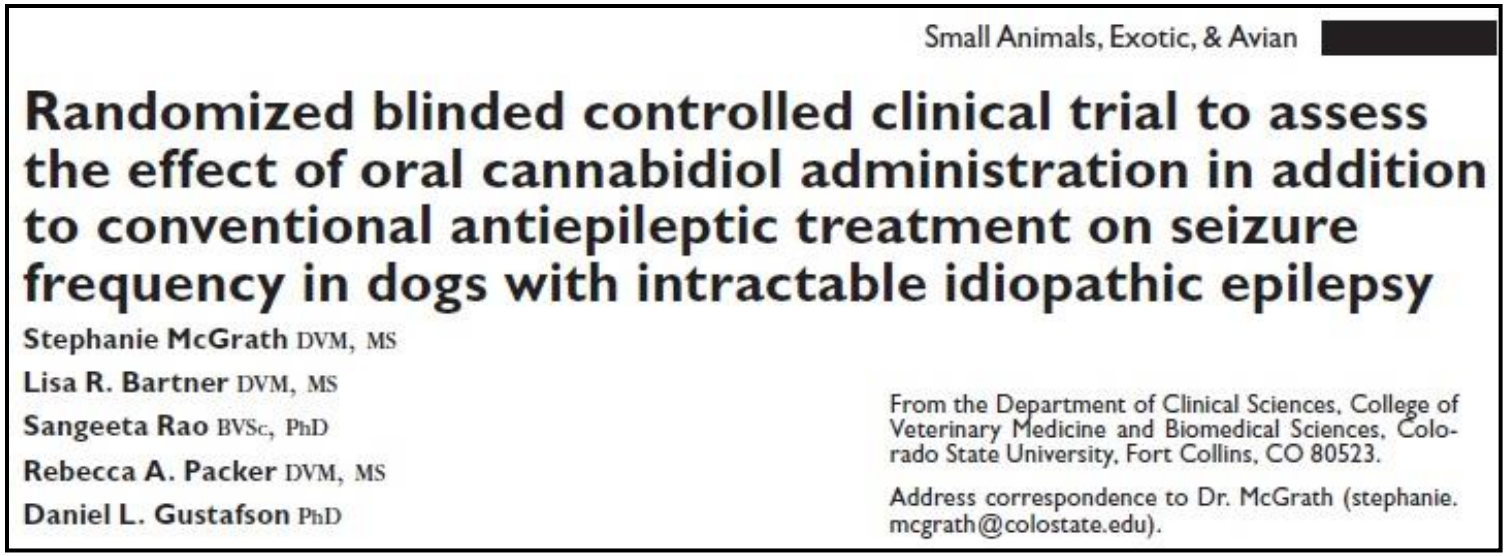
Chris D. Verrico[a,b], Shonda Wesson[c], Vanaja Konduri[d], Colby J. Hofferek[d], Jonathan Vazquez-Perez[d], Emek Blair[e], Kenneth Dunner Jr[f], Pedram Salimpour[g], William K. Decker[d,h,i], Matthew M. Halpert[d,*]

Findings: "*This study supports the safety and therapeutic potential of CBD (1.2 mg/kg/day) for relieving arthritic pain….*"

PAIN, 2020 Volume 161, (9) pp. 2191-2202

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Seizure Reduction – Intractable Epilepsy



Small Animals, Exotic, & Avian

Randomized blinded controlled clinical trial to assess the effect of oral cannabidiol administration in addition to conventional antiepileptic treatment on seizure frequency in dogs with intractable idiopathic epilepsy

Stephanie McGrath DVM, MS
Lisa R. Bartner DVM, MS
Sangeeta Rao BVSc, PhD
Rebecca A. Packer DVM, MS
Daniel L. Gustafson PhD

From the Department of Clinical Sciences, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, CO 80523.

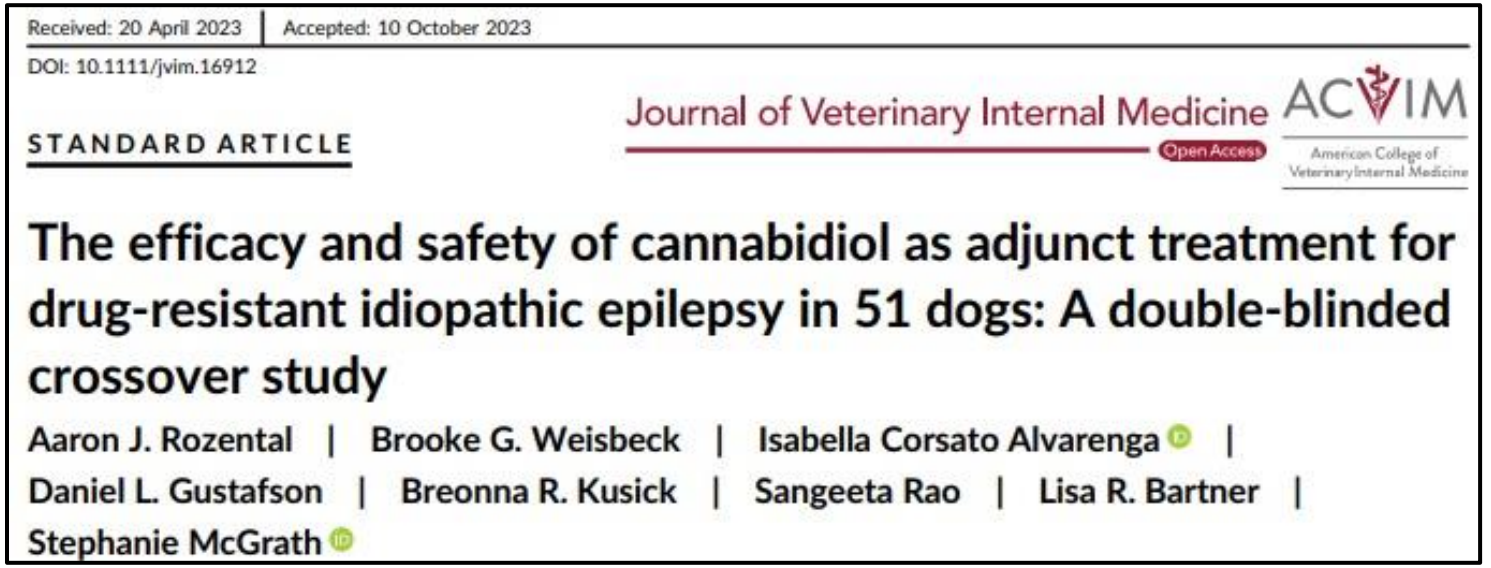
Address correspondence to Dr. McGrath (stephanie.mcgrath@colostate.edu).

Findings: *"Overall, results of the clinical trial reported here indicated that a significant reduction in seizure frequency was achieved in dogs with intractable idiopathic epilepsy by the addition of CBD treatment to conventional AED treatment"*

Journal of the American Veterinary Medical Association, 2019 Volume 254, (11) pp. 1301-1308

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Seizure Reduction – Epilepsy



Received: 20 April 2023 | Accepted: 10 October 2023
DOI: 10.1111/jvim.16912

Journal of Veterinary Internal Medicine ACVIM
Open Access
American College of Veterinary Internal Medicine

STANDARD ARTICLE

The efficacy and safety of cannabidiol as adjunct treatment for drug-resistant idiopathic epilepsy in 51 dogs: A double-blinded crossover study

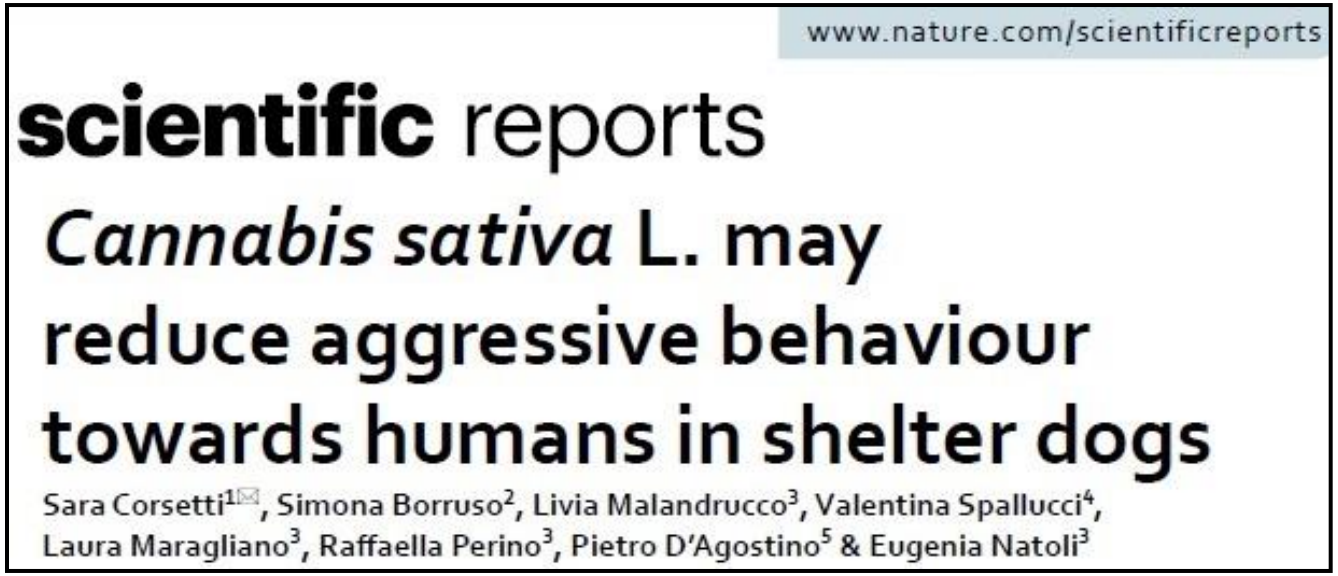
Aaron J. Rozental | Brooke G. Weisbeck | Isabella Corsato Alvarenga | Daniel L. Gustafson | Breonna R. Kusick | Sangeeta Rao | Lisa R. Bartner | Stephanie McGrath

Findings: "*At the 9 mg/kg/day dose, the decrease in total seizure frequency was significant compared with placebo. A 24.1% decrease in seizure days occurred in dogs receiving CBD and a 5.8% increase occurred in dogs receiving placebo (P ≤ .05).*"

Journal of Veterinary Internal Medicine, 2023 https://doi.org/10.1111/jvim.16912

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: <u>Behavioural Therapy - Aggression</u>

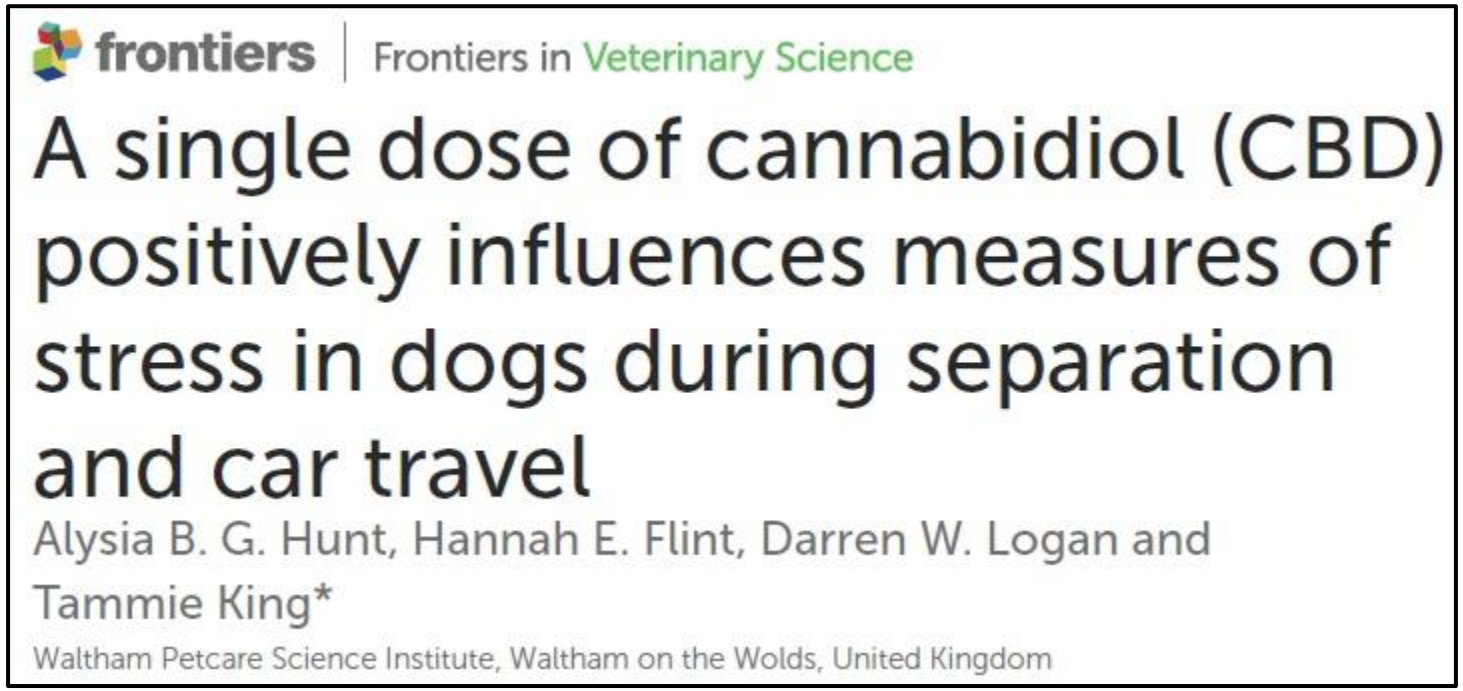


Findings: "*Treated dogs showed reduced aggressive behaviour towards humans following the treatment, but the difference in the decrease of aggressive behaviour between the two groups was not significant*"

<u>Nature – Scientific Reports</u>, 2021, 11(2773) pp. 1-10

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Behavioural Therapy - Anxyolysis

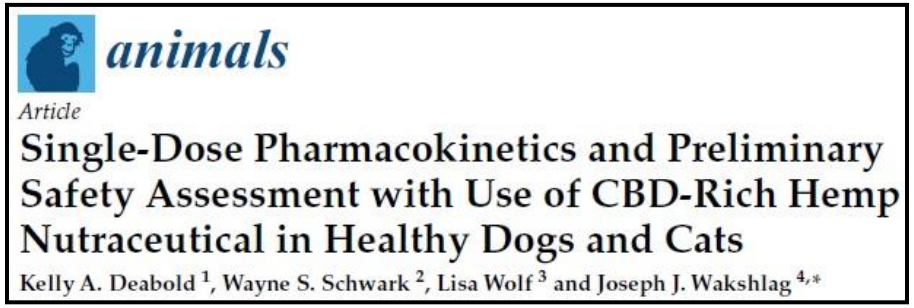


Findings: *"A single dose of 4 mg/kg CBD 2 h prior to exposure to stressful events attenuates some indicators of acute canine stress, which is likely to improve emotional wellbeing."*

Frontiers in Veterinary Science, Feb, 2023, DOI 10.3389/fvets.2023.1112604

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Safety & PK


animals

Article

Single-Dose Pharmacokinetics and Preliminary Safety Assessment with Use of CBD-Rich Hemp Nutraceutical in Healthy Dogs and Cats

Kelly A. Deabold [1], Wayne S. Schwark [2], Lisa Wolf [3] and Joseph J. Wakshlag [4,*]

Animals, 2019, 9(832) pp. 1-13

Dosing Regimen

- CBD 2 mg/kg q12h PO
- *Single-dose PK reported + 12-week safety/AEs*

Max. plasma conc. (C_{max}) of single dose

- Dogs: 301 ng/mL
- Cats: 43 ng/mL

Time to max. plasma conc. (T_{max})

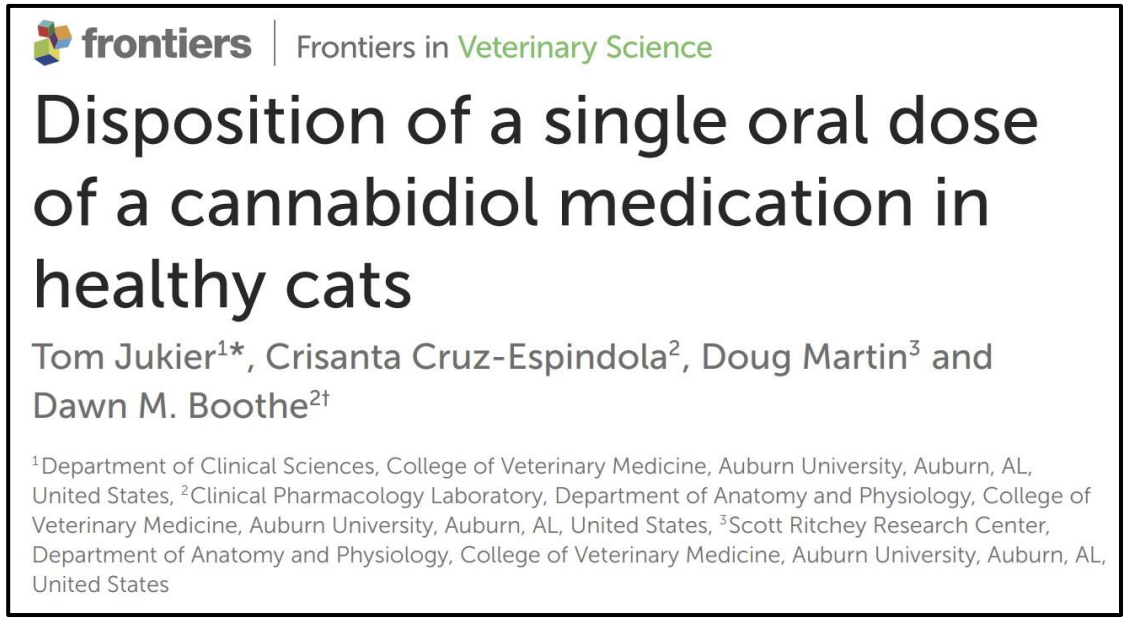
- Dogs: 2 h
- Cats: 1.4 h

Conclusion: *"CBD appear to be relatively safe in healthy populations of dogs and cats, and dogs appear to absorb CBD better than cats."*

"Cats displayed excessive licking and head shaking with administration of the oil".

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Safety & PK Studies



frontiers | Frontiers in Veterinary Science

Disposition of a single oral dose of a cannabidiol medication in healthy cats

Tom Jukier[1]*, Crisanta Cruz-Espindola[2], Doug Martin[3] and Dawn M. Boothe[2†]

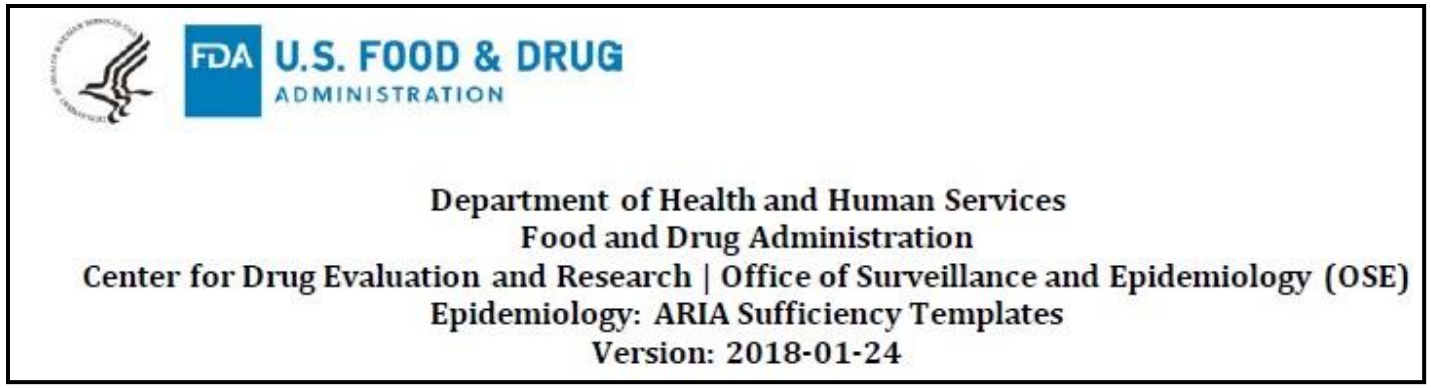
[1]Department of Clinical Sciences, College of Veterinary Medicine, Auburn University, Auburn, AL, United States, [2]Clinical Pharmacology Laboratory, Department of Anatomy and Physiology, College of Veterinary Medicine, Auburn University, Auburn, AL, United States, [3]Scott Ritchey Research Center, Department of Anatomy and Physiology, College of Veterinary Medicine, Auburn University, Auburn, AL, United States

Findings: *"Pharmacokinetic analysis reveals that relative bioavailability of CBD shows a near eleven-fold increase when administered in the fed state compared to the fasted state. Additionally, concentrations achieved at a dose of 5 mg/kg, may be sufficient to explore the therapeutic potential in cats with epilepsy."*

Frontiers in Veterinary Science, May, 2023, DOI 10.3389/fvets.2023.1181517

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Pre-clinical Safety Studies



Findings: *"Preclinical safety studies performed prior to FDA approval of CBD containing medicines, Sativex® and Epidiolex®, indicate* ***no observable adverse effects level*** *(NOAEL) of 100 mg/kg BW of CBD. Reported side effects associated with 10, 50, or 100 mg/kg daily administrations included hepatocellular hypertrophy and weight loss, which were most common in dogs dosed at 100 mg/kg."*

Food and Drug Administration Application 210365Orig1s000, GW Pharmaceuticals, 2018.

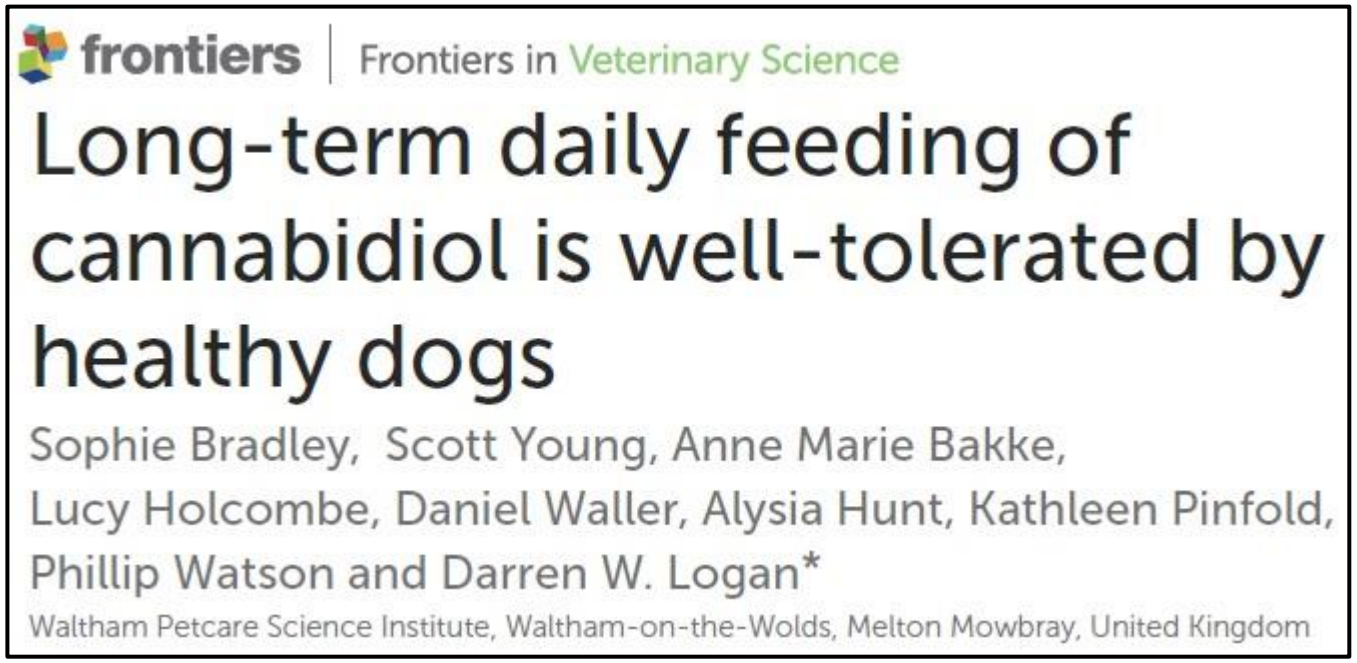
Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Feline Dose Escalation - Safety Studies

Findings: "*Titration to maximum doses of **30.5 mg/kg CBD** (CBD oil), 41.5 mg/kg THC (THC oil) or 13.0:8.4 mg/kg CBD:THC (CBD/THC oil) **was safely achieved in all subjects**. All observed adverse events (AEs) were mild, transient and resolved without medical intervention.*"

Creating a Cannabis Dosing Plan in 3-Steps

STEP 3: Search the Literature: Long-term Safety Studies



Findings: *"A blinded RCT of 20 dogs received daily CBD capsules at a dose of 4 mg/kg CBD daily for 6-months. Biochemistry and hematology showed no clinically significant alterations apart from a transient elevation in ALP (only) in just over half of the dogs receiving CBD. This elevation was in the absence of any adverse effect. Bone-ALP was simultaneously elevated suggesting that total ALP was at least partly due to the bone-derived isoform. This study provides evidence that a once-daily oral dose of 4mg CBD/kg BW is well tolerated in clinically healthy dogs for a duration of 6-months".*

Frontiers in Veterinary Science, Sept, 2022, DOI: 10.3389/fvets.2022.977457

Prescribing Cascade – Canine (OA)

- **1st line**
  - **NSAIDs or Anti-NGF mAb therapy**

- **2nd line**
  - **CBD:** 1.0 - 2.0 mg/kg PO q12h
    - *Consider replacing 1st line NSAIDs with CBD if clinically significant renal/GI disease*

- **3rd line**
  - **Amantadine:** 5 mg/kg PO q24h
    - *May reduce NSAID dose*
  - **Gabapentin:** 5 - 20 mg/kg PO q12-24h

- **4th line**
  - **Amitriptyline:** 1 – 2 mg/kg PO q12-24h
  - **Paracetamol:** 10 - 20 mg/kg PO q12h

Prescribing Cascade – Feline (OA)

➢ 1st line

- **NSAIDs or Anti-NGF mAb therapy**

➢ 2nd line

- **CBD:** 1.0 - 2.0 mg/kg PO q12h
  - ❖ *Consider replacing 1st line NSAIDs with CBD if clinically significant renal/GI disease*
- **Tramadol:** 2 - 3 mg/kg PO or IM q12h

➢ 3rd line

- **Gabapentin:** 5 - 20 mg/kg PO q12-24h

➢ 4th line

- **Amantadine:** 5 mg/kg PO q24h
- **Amitriptyline:** 1 – 2 mg/kg PO q12-24h

Assessing Efficacy of Chronic Disease Interventions

VetMetrica HRQoL Tools

https://www.newmetrica.com/vetmetrica-hrql/

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QUESTIONS?

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www.thevetpharmacist.com

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Clinical Application of CBD - Canine OA

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Need Help?

Please contact: Dr Leon Warne | Specialist in Anaesthesia & Pain Management

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