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# MEMORANDUM

DATE	March 28, 2022
то	Multidisciplinary Advisory Committee (MDC)
FROM	Cannabis Subcommittee
	Richard Sullivan, DVM, Chair
	Christina Bradbury, DVM
SUBJECT	Agenda Item 7. Discussion and Possible Action Regarding Board Guidelines for Veterinarian Discussion of Cannabis Within the Veterinarian-Client-Patient Relationship

## **Background**

During the January 2022 Board meeting, the Board was provided a written request from former MDC Member, Jeff Pollard, DVM to consider updating the Board's <u>Guidelines for</u> <u>Veterinarian Discussion of Cannabis Within the Veterinarian-Client-Patient Relationship</u> (Guidelines) within the Veterinarian-Client-Patient Relationship to reflect the present use and current legislation regarding cannabis products (attached). The Board requested the MDC review the request and bring recommendations back to the Board at a future meeting. MDC Chair Richard Sullivan, DVM, and Christina Bradbury, DVM, formed a subcommittee to complete this task.

### Subcommittee Research and Recommendations

Medical cannabis has a long history in California in human medicine with the Compassionate Use Act in 1996, which was passed via Proposition 215. The legality of the Compassionate Use Act was litigated in *Conant v. McCaffrey* (1997) 172 F.R.D. 681, and affirmed in 2002 by the United States Court of Appeals for the Ninth Circuit in *Conant v. Walters* (2002) 309 F.3d 629. In *Conant v. McCaffrey*, the court had the dilemma of resolving the Medical Oath, which states that it is the moral and ethical duty of a physician to prevent pain and suffering versus the fact that marijuana was a Schedule I drug and prohibited from use under any circumstances. In the *Conant v. Walters* appeal of the permanent injunction issued in *Conant v. Walters*, the court resolved this dilemma by saying that a physician's license could not be disciplined for the sole fact of recommending marijuana, but they could not prescribe, dispense, or administer the drug.

In the concurrence appendix of *Conant v. Walters*, the following was written:

From 1978 to 1992, the federal government conducted its own medical marijuana program. Today, the government continues to supply individuals who participated in this program with marijuana under its Compassionate Care program; they are among the few people in the country who can use the drug legally." Four people in this program with various medical conditions participated in an amicus brief in support of

the plaintiffs. (Conant v. Walters (2002) 309 F.3d 629, 648.)

In 2018, Assembly Bill (AB) 2215 (Kalra, Chapter 819, Statutes of 2018) was passed by the California State Legislature and allowed veterinarians to "discuss" with clients the use of cannabis on an animal patient for medicinal purposes without the risk of disciplinary action but did not allow veterinarians to prescribe, dispense, or administer the drug.

Then came the federal Agriculture Improvement Act of 2018, also known as the Farm Bill of 2018, which removed hemp, defined as cannabis (Cannabis sativa L.) and derivatives of cannabis with extremely low concentrations of the psychoactive compound delta-9tetrahydrocannabinol (THC) (no more than 0.3 percent THC on a dry weight basis), from being classified as a Schedule I drug under the federal Controlled Substances Act. Hemp seed products that do not naturally contain cannabidiol (CBD) or THC can be legally used in food products and are regulated by the federal Food and Drug Administration. However, the Federal Food, Drug, and Cosmetic Act does not allow food products that contain an added substance that is an active ingredient in an approved drug or a substance for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. (21 USC § 331(II).) The FDA has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food, including hemp products, containing THC or CBD. (U.S. Food & Drug Administration, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-andcannabis-derived-products-including-cannabidiol-cbd#food [as of Mar. 29, 2022].)

California has since enacted AB 45 (Aguiar-Curry, Chapter 576, Statutes of 2021), which allows hemp CBD products to be added to pet foods.

This year, AB <u>1885</u> (Kalra, 2022) was introduced and is still moving through the California State Legislature. If enacted, AB 1885 would prohibit the Board from disciplining a Board licensed veterinarian for discussing or recommending the use of cannabis on an animal for potential therapeutic effect or health supplementation purposes. The bill also would require the Board, by January 1, 2024, to adopt guidelines for veterinarians to follow when recommending cannabis within the veterinarian-client-patient relationship and post those guidelines on the Board's website.

During the Board's January 19-20, 2022 meeting, the Board asked the MDC to update the cannabis Guidelines to specifically allow veterinarians to recommend and administer hemp derived products.

After reviewing the history of this issue and reading the material supplied, including the relevant laws, the Subcommittee makes the following recommendations.

- Since hemp CBD is an over-the-counter (OTC) product, there is no need or legal precedent requiring the Board to establish guidelines for it. If a client files a complaint against a licensee about a recommendation for the use of a hemp CBD product, the Board will approach the case as it would any other OTC product.
- 2. The Subcommittee reviewed AB 1885, which is still moving through the California State Legislature, and believes that it is premature to write guidelines related to this

bill. The bill also states that if passed, the Board has until January 21, 2024, to write guidelines.

Therefore, it is the recommendation of the Subcommittee that currently there is no need for the MDC, or subsequently the Board, to do anything.

# Action Requested:

If the MDC agrees with the Subcommittee, please entertain a motion to recommend the Board *not* update its Guidelines at this time to include guidelines for hemp CBD products.

January 03, 2022

Executive Officer California Veterinary Medical Board 1747 N. Market Blvd Suite 230 Sacramento, CA 95834

Dear Ms. Sieferman,

As past Chair of the California Veterinary Medical Board's Multidisciplinary Advisory Committee (MDC), I helped formulate cannabis use guidelines for veterinarians based on the legislation, AB 2215. These guidelines, published in January 2020, need to be updated to reflect the present use and current legislation regarding cannabis products.

#### **TIMELINE of US & CA Legislation:** (see TVB article)

Jun 2018 US FDA approved Epidiolex, a cannabis derived drug containing CBD Sep 2018 CA AB 2215 passed Oct 2018 CVMB assigned cannabis guidelines to MDC Dec 2018 US Agriculture Improvement Act passed (aka, Farm Bill<sup>1</sup>) Jan 2019 MDC/VMB meetings at UC-Davis, first public discussions Sep 2019 CA SB 627 failed Jan 2020 Cannabis guidelines posted on VMB website Aug 2020 CA AB384 failed May 2021 NV AB 101 passed Oct 2021 CA AB 45 passed Pending US legislation: HR 841<sup>2</sup>, S 1698<sup>3</sup> (Note: sponsor of HR 841 is a DVM)

CA AB 45, signed by Governor Newsom October 6, 2021, permits the inclusion of hemp and cannabinoids in food, beverages, dietary supplements, cosmetics, and pet food. AB 45 has testing, labeling, and licensing requirements. It includes a "truth in advertising"<sup>4</sup> component. It amends the Adult Use of Marijuana Act (AUMA<sup>5</sup>) by changing the definition of industrial hemp to include cannabis plants with less than 0.3% THC. This legislation provides a unique opportunity for consumers and veterinarians to utilize hemp-derived cannabis products in a safer and more effective manner (see CA AB 45).

In Nevada, veterinarians can now talk about cannabis products containing less than 0.3% THC with pet owners, explain which products are appropriate, offer recommendations and dosing advice, and even administer the products (see NV AB 101).

Nationally, 36 U.S. states and four territories have legalized cannabis as medicine for people. 18 states, 4 territories and the District of Columbia allow general use of cannabis by adults.

Plumb's, the most widely utilized veterinary formulary, now has a drug monograph for CBD. Like its other drug listings, it includes prescriber highlights, uses/indications, pharmacology, pharmacokinetics, contraindications/precautions, adverse effects, reproductive/nursing safety, overdose/toxicity, and drug interaction information (see attached drug monograph).

As a practicing veterinarian, I regularly field questions from consumers regarding hempbased CBD products which are widely available over-the-counter. Consumers are desperate for information on how to use cannabis to help their pets. No profession is more qualified to provide medical guidance regarding the treatment of animals than veterinarians. Yet, veterinarians have been hesitant to discuss cannabis with consumers for fear of state board disciplinary action. The result of restricting veterinarians from making product and dosing recommendations is that the consumer is constrained to seek medical advice from pet store employees and bud tenders at the local dispensary whose primary motivation is not necessarily the health and safety of our animal patients.

Every day veterinarians dispense non-FDA approved supplements such as glucosamine and SAMe without any interference from veterinary state boards. Medical cannabis should be viewed no differently than other nutritional or herbal supplements. When we veterinarians dispense a supplement, we have more assurance our patient is receiving a high-quality product. Dispensing hemp-based CBD products from veterinary offices is a safety measure to protect animals.

More and more studies continue to demonstrate that hemp-based CBD products are both effective and have wide margins of safety. Within the last 3 years there have been over 20 veterinary cannabis specific publications on both pharmacokinetic/safety and clinical research.<sup>6</sup> Prior to legislation like CA AB 45, product labeling requirements have been woefully inadequate (see Vet Med: Research - Wakshlag et. al. paper).

The Veterinary Cannabis Society (VCS) is the first U.S. non-profit, 501(c)(3) organization focused on raising awareness of cannabis as a medicine for animals. It was established in 2020 with a team of dedicated veterinarians and cannabis industry leaders who identified a glaring gap in education around the safe and appropriate use of cannabis for treating animals. One of its primary goals is to provide veterinarians better guidance in their discussion and recommendations to consumers about cannabis products. Educational resources such as critically reviewed articles, a curated research library, podcasts, videos, and presentations are made available to VCS members. VCS has been working with the American Association of Veterinary State Boards (AAVSB) to provide guidance to the veterinary profession (see May 02, 2021, letter).

On behalf of VCS and practicing veterinarians in California and elsewhere, I request the California Veterinary Medical Board revisit and update its cannabis guidelines to specifically allow veterinarians to recommend and administer hemp-derived products (on par with NV veterinarians), considering the many advances in research and the current legislative landscape.

Sincerely,

A. Joy Perel, DVM

Jeff Pollard, DVM Diplomate, ABVP (Canine/Feline) Advocacy Committee, Veterinary Cannabis Society

PS See the following references attached: TVB - Cushing et. al. CA AB 45 NV AB 101 - VIN News article Plumbs - Cannabidiol (Epidiolex) AHVMA - Hazzah et. al. Vet Med: Research - Wakshlag et. al. AAVSB Policy Letter

<sup>1</sup>2018 Farm Bill provided a <u>carve-out for hemp</u>, defined as cannabis plants and plant parts containing no more than 0.3% THC.

#### <sup>2</sup>HR 841

Rep. Kurt Schrader on 02/04/2021 introduced a bill called H.R.841 – Hemp and Hemp Derived CBD Consumer Protection and Market Stabilization Act to make hemp, cannabidiol derived from hemp, and any other ingredient derived from hemp lawful for use under the Federal Food, Drug, and Cosmetic Act as a dietary ingredient in a dietary supplement, and for other purposes.

#### <sup>3</sup>S 1698

Sen. Ron Wyden on 05/19/2021 introduced a bill called S. 1698 - Hemp Access and Consumer Safety Act to allow for hemp-derived cannabidiol and hemp-derived cannabidiol containing substances in dietary supplements and food.

#### <sup>4</sup>"truth in advertising"

From CA AB 45: prohibit a manufacturer, distributor, or seller of an industrial hemp product from including on the label, or publishing or disseminating in advertising or marketing, a health-related statement, as defined, that is untrue...

<sup>5</sup>Control, Regulate and Tax Adult Use of Marijuana Act (AUMA), added by Proposition 64 at the November 8, 2016, statewide general election, regulates the cultivation,

distribution, transport, storage, manufacturing, testing, processing, sale, and use of marijuana for nonmedical purposes by people 21 years of age and older.

<sup>6</sup> List of Veterinary specific cannabis studies:

**Clinical Studies:** 

- 1. Gamble, L. et al. Pharmacokinetics, Safety, and Clinical Efficacy of Cannabidiol Treatment in Osteoarthritic Dogs. Frontiers in Veterinary Science. 2018
- 2. Kogan et al. The Use of Cannabidiol-Rich Hemp Oil Extract to Treat Canine Osteoarthritis-Related Pain: A Pilot Study. AHVMA. 2020
- 3. Verrico, et al. A randomized, double-blind, placebo-controlled study of daily cannabidiol for the treatment of canine osteoarthritis pain. PAIN. 2020
- 4. Wallace JE et al. Motivations and expectations for using cannabis products to treat pain in humans and dogs: a mixed methods study. J Cannabis Res. 2020 Oct 14;2(1):36.
- Mejia S et al. Evaluation of the Effect of Cannabidiol on Naturally Occurring Osteoarthritis-Associated Pain: A Pilot Study in Dogs. J Am Anim Hosp Assoc. 2021 Mar 1;57(2):81-90.
- McGrath S et al. 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. JAVMA. 2019
- Morris EM et al. The Impact of Feeding Cannabidiol (CBD) Containing Treats on Canine Response to a Noise-Induced Fear Response Test. Front Vet Sci. 2020; 7:569565.
- 8. Corsetti, S., et al. Cannabis sativa L. may reduce aggressive behaviour towards humans in shelter dogs. Sci Rep 11, 2773 (2021)
- Morris EM et al. Alteration of the Canine Metabolome After a 3-Week Supplementation of Cannabidiol (CBD) Containing Treats: An Exploratory Study of Healthy Animals. Front Vet Sci. 2021 Jul 16; 8:685606.

Safety and PK/PD Studies:

- Bartner LR et al. Pharmacokinetics of cannabidiol administered by 3 delivery methods at 2 different dosages to healthy dogs. Can J Vet Res. 2018;82(3):178-183.
- 2. McGrath S et al. A Report of Adverse Effects Associated with the Administration of Cannabidiol in Healthy Dogs, AHVMA J. 2018; 52, 34-38.
- 3. Deabold KA, et al. Single-Dose Pharmacokinetics and Preliminary Safety Assessment with Use of CBD-Rich Hemp Nutraceutical in Healthy Dogs and Cats. Animals (Basel). 2019;9(10):832.
- 4. Gamble LJ, et al. Pharmacokinetics, Safety, and Clinical Efficacy of Cannabidiol Treatment in Osteoarthritic Dogs. Front Vet Sci. 2018; 23; 5:165.

- 5. Vaughn D, et al. Preliminary Investigation of the Safety of Escalating Cannabinoid Doses in Healthy Dogs. Front Vet Sci. 2020; 7:51.
- Lebkowska-Wieruszewska B et al. Pharmacokinetics of Bedrocan®, a cannabis oil extract, in fasting and fed dogs: An explorative study. Res Vet Sci. 2019; 123:26-28.
- 7. Fernández-Trapero et al. Pharmacokinetics of Sativex® in Dogs: Towards a Potential Cannabinoid-Based Therapy for Canine Disorders. Biomolecules. 2020 Feb 11;10(2):279.
- Wakshlag JJ, et al. Pharmacokinetics of Cannabidiol, Cannabidiolic Acid, Δ9-Tetrahydrocannabinol, Tetrahydrocannabinolic Acid 50and Related Metabolites in Canine Serum After Dosing With Three Oral Forms of Hemp Extract. Front Vet Sci. 2020; 2020; 7:5.
- 9. Kulpa JE, et al. Safety and tolerability of escalating cannabinoid doses in healthy cats. J Feline Med Surg. 2021 Mar 26:1098612X211004215.
- 10. Wakshlag JJ et al. Pharmacokinetics of Cannabidiol, Cannabidiolic Acid, Δ9-Tetrahydrocannabinol, Tetrahydrocannabinolic Acid and Related Metabolites in Canine Serum After Dosing With Three Oral Forms of Hemp Extract. Front Vet Sci. 2020 Sep 4; 7:505.

Hannon et al. Serum cannabidiol, tetrahydrocannabinol (THC), and their native acid derivatives after transdermal application of a low-THC Cannabis sativa extract in beagles. Journal of Veterinary Pharmacology and Therapeutics. 2020. 43, 508-511.

11. Chicoine et al. Pharmacokinetic and Safety Evaluation of Various Oral Doses of a Novel 1:20 THC:CBD Cannabis Herbal Extract in Dogs. Front Vet Sci. 2020 Sep 29; 7:583404.