

INTEGRATIVE MEDICINE

An Update on the Legal Considerations of the Use of Cannabis in Veterinary Medicine

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Since the passing of the 2018 Farm Bill in the United States, which declassified hemp as a controlled substance at the federal level, questions about the legalities of cannabis use in animals and potential liability for veterinarians have arisen. Some veterinarians decline to discuss cannabis with their clients due to liability concerns, but many clients will use products marketed for pets. Veterinarians should understand the current regulatory landscape surrounding cannabis so they can have discussions with clients to promote patient safety without opening themselves to liability.

UNDERSTANDING THE CURRENT REGULATORY LANDSCAPE

In discussing cannabis, it is essential to understand and use appropriate terminology. Cannabis plants contain numerous cannabinoids that can bind to receptors in the endocannabinoid system in the human and animal body. Two of the most well-known cannabinoids include Δ -9 tetrahydrocannabinol (THC) and cannabidiol (CBD). The following definitions provide important distinctions based on the THC content of a product¹:

- **Cannabis** is sometimes used as an umbrella term that includes both hemp and marijuana. In some states, the term is used interchangeably with marijuana.

- **Marijuana** is a cannabis product containing more than 0.3% of THC by dry weight.

- **Hemp** is a cannabis product containing no more than 0.3% of THC by dry weight. Some states specify that the total THC cannot exceed 0.3%, though most states look at only the Δ -9 THC.

The 2018 Farm Bill removed hemp from the Controlled Substances Act, but marijuana remains a schedule I controlled substance regulated by the U.S. Drug Enforcement Administration. Laws related to medicinal and recreational use of marijuana and hemp in humans do not apply to veterinary species, and few states have specific laws regarding cannabis in animals.

In California, a bill (AB 2215) passed in 2018 provided protection for veterinarians who discuss cannabis; another bill (AB 1885) passed in 2022 prohibited the veterinary board from disciplining a veterinarian for recommending cannabis use in a patient.¹ Nevada has a law (AB 101) protecting veterinarians who recommend hemp-derived products for therapeutic purposes.

As of December 2023, there are 2 pending pieces of legislation that would legalize hemp CBD in food, which could have implications for animals based on the U.S. Food and Drug Administration's (FDA) current definition of food. Currently, there are no cannabis-

derived food ingredients in the Association of American Feed Control Officials Official Publication or that are generally recognized as safe for use in animals. There is pending legislation at the state level in Rhode Island (RI SB 810) regarding the use of cannabis in animals. A similar bill (State Assembly Bill 2023-A6435) was recently vetoed by the governor in New York.

“The American Veterinary Medical Association is actively monitoring cannabis legislation that would impact the veterinary profession,” said Rena Carlson, DVM, president of the AVMA.

As legislation continues to evolve, veterinarians should remain up to date on current federal and state regulations. State licensing boards, veterinary medical associations, and the AVMA are reliable sources of information for veterinarians (**BOX 1**).

THE ROLE OF THE FDA

The FDA has regulatory authority over any cannabis-derived products that are manufactured and marketed as drugs and food products under the Food, Drug, and Cosmetic Act (FDCA). The definitions of drugs and food are important to understand, especially when it comes to the regulation of cannabis:

- **Drugs** are defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or animals.”²
- **Food** is defined in the FDCA as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article for animals.” The FDA defines intended use as the “objective intent of the persons legally responsible for the labeling of drugs.”

The FDA indicates “the intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article.” Veterinarians, therefore, should consider both the label and the circumstances surrounding

“There are currently no FDA-approved cannabis-containing products for animals, and there are also no drugs derived from cannabis that are approved for animals.”

distribution of cannabis-derived products when making decisions regarding their use.³

There is currently only 1 FDA-approved cannabis-derived drug for humans, labeled for use in certain forms of epilepsy. Any other hemp-derived product that makes a claim on its label to treat, prevent, mitigate, or cure a disease is considered an unapproved drug. “There are currently no FDA-approved cannabis-containing products for animals, and there are also no drugs derived from cannabis that are approved for animals,” said Carlson. “Based on information published by the FDA, it appears that any products that currently include therapeutic claims for animals are being illegally marketed.”

However, there is a gray area when it comes to pet supplements. The term “dietary supplement” is defined in the Dietary Supplement Health and Education Act. This definition only applies to humans, according to the FDA.³ Because of this, hemp CBD products are not regulated by the FDA and are legal as long as no therapeutic claims are made, according to Stacey Evans, ElleVet Science’s vice president of general counsel, an expert on hemp CBD use in veterinary medicine, and past member of the U.S. Department of Agriculture Secretary’s Advisory Committee on Animal Health. Evans noted that “it is the companies who manufacture and sell [hemp CBD] products . . . that need to avoid particular language in their marketing materials to avoid their product being a drug.”

The FDA has sent numerous warning letters to manufacturers of hemp-derived products for both humans and animals that violate the FDCA. The FDA is most likely to enact enforcement against manufacturers, rather than individual veterinarians, for making claims that classify a product as a food or drug.

BOX 1 Additional Resource

- AVMA — Cannabis Use and Pets
go.navc.com/3Scjodp

VETORYL[®] CAPSULES

(trilostane)

5 mg, 10 mg, 30 mg, 60 mg and 120 mg strengths

Adrenocortical suppressant for oral use in dogs only.

BRIEF SUMMARY (For Full Prescribing Information, see package insert.)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: VETORYL Capsules are an orally active synthetic steroid analogue that blocks production of hormones produced in the adrenal cortex of dogs.

INDICATION: VETORYL Capsules are indicated for the treatment of pituitary and adrenal-dependent hyperadrenocorticism in dogs.

CONTRAINDICATIONS: The use of VETORYL Capsules is contraindicated in dogs that have demonstrated hypersensitivity to trilostane. Do not use VETORYL Capsules in animals with primary hepatic disease or renal insufficiency. Do not use in pregnant dogs. Studies conducted with trilostane in laboratory animals have shown teratogenic effects and early pregnancy loss.

WARNINGS: In case of overdosage, symptomatic treatment of hypoadrenocorticism with corticosteroids, mineralocorticoids and intravenous fluids may be required. Angiotensin converting enzyme (ACE) inhibitors should be used with caution with VETORYL Capsules, as both drugs have aldosterone-lowering effects which may be additive, impairing the patient's ability to maintain normal electrolytes, blood volume and renal perfusion. Potassium sparing diuretics (e.g. spironolactone) should not be used with VETORYL Capsules as both drugs have the potential to inhibit aldosterone, increasing the likelihood of hyperkalemia.

HUMAN WARNINGS: Keep out of reach of children. Not for human use. Wash hands after use. Do not empty capsule contents and do not attempt to divide the capsules. Do not handle the capsules if pregnant or if trying to conceive. Trilostane is associated with teratogenic effects and early pregnancy loss in laboratory animals. In the event of accidental ingestion/overdose, seek medical advice immediately and take the labeled container with you.

PRECAUTIONS: Hypoadrenocorticism can develop at any dose of VETORYL Capsules. A small percentage of dogs may develop corticosteroid withdrawal syndrome within 10 days of starting treatment. Mitotane (o,p'-DDD) treatment will reduce adrenal function. Experience in foreign markets suggests that when mitotane therapy is stopped, an interval of at least one month should elapse before the introduction of VETORYL Capsules. It is important to wait for both the recurrence of clinical signs consistent with hyperadrenocorticism, and a post-ACTH cortisol level of $> 9.1 \mu\text{g/dL}$ ($> 250 \text{ nmol/L}$) before treatment with VETORYL Capsules is initiated. Close monitoring of adrenal function is advised, as dogs previously treated with mitotane may be more responsive to the effects of VETORYL Capsules.

The use of VETORYL Capsules will not affect the adrenal tumor itself. The safe use of this drug has not been evaluated in lactating dogs and males intended for breeding.

ADVERSE REACTIONS: The most common adverse reactions reported are poor/reduced appetite, vomiting, lethargy/dullness, diarrhea, elevated liver enzymes, elevated potassium with or without decreased sodium, elevated BUN, decreased Na/K ratio, weakness, elevated creatinine, shaking and renal insufficiency. Occasionally, more serious reactions, including severe depression, hemorrhagic diarrhea, collapse, hypoadrenocortical crisis or adrenal necrosis/rupture may occur, and may result in death. **Owners should be advised to discontinue VETORYL Capsules and contact their veterinarian immediately in the event potential drug intolerance is observed.**

Approved by FDA under NADA # 141-291

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However, “liability concerns exist when recommending or using unapproved drugs,” said Carlson. This would be especially true if a board complaint was made due to an adverse event. Veterinarians should therefore be sure that any products they recommend comply with all federal and state regulations.

WHAT CAN VETERINARIANS DISCUSS IN PRACTICE?

Pet owners are exposed to marketing for CBD products that can be very persuasive, regardless of whether the products and their marketing are legal under current regulations. Many pet owners purchase CBD and hemp-derived products over the counter to administer to their pet, with or without the recommendation of a veterinarian—though most pet owners will tell their veterinary teams they are using such a product if asked.

Some pet owners want their veterinarian's advice before purchasing a product. In a 2018 survey of veterinarians by the Veterinary Information Network, 28.8% of respondents said they were asked about cannabis weekly and 26.4% said they were asked monthly.⁴ These questions were more common in states that have legalized recreational marijuana use for humans. This survey found that veterinarians who did not feel comfortable advising clients about CBD had concerns about their own knowledge base, the feeling of needing more data, and product legality.⁴

Though the regulatory landscape is complex, veterinarians should feel safe discussing hemp-derived CBD with clients. Most states do not have laws that explicitly prohibit the use of hemp CBD products in animals, though few states have legislation that protects veterinarians from board discipline for making such a recommendation, which leaves some veterinarians feeling uncomfortable doing so.

Carlson noted that the AVMA encourages veterinarians “to communicate with clients and respond to questions pertaining to potential treatment options.” These communications should include information on the range of treatment options available for a given condition, including FDA-approved animal drugs or off-label uses of FDA-approved human drugs.

LIABILITY REDUCTION

Discussing hemp creates no more legal liability “than answering any question about glucosamine or any other

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As with all drugs, side effects may occur. In field studies and post-approval experience, the most common side effects reported were: anorexia, lethargy/depression, vomiting, diarrhea, elevated liver enzymes, elevated potassium with or without decreased sodium, elevated BUN, decreased Na/K ratio, hypoadrenocorticism, weakness, elevated creatinine, shaking, and renal insufficiency. In some cases, death has been reported as an outcome of these adverse events. VETORYL Capsules are not for use in dogs with primary hepatic or renal disease, or in pregnant dogs. Refer to the prescribing information for complete details or visit dechra-us.com.

When answering client questions about hemp use in animals, it is important to document any discussions in the medical record.

animal supplement,” said Evans. “Veterinarians can reduce their liability risk by clearly communicating information or lack of information to clients so the clients can make informed decisions and by requesting a certificate of analysis to ensure the product is hemp and not marijuana.”

Word choice is important when having discussions on this topic with clients. Experts say to avoid using the term “cannabis” and instead use “hemp-derived CBD” products—even if medical marijuana is legal for humans in your state. It’s also important for veterinarians to avoid using the terms “prescribe” or “dispense” in relation to hemp-derived CBD products as these terms carry legal connotations that are regulated by state pharmacy laws.

When answering client questions about hemp use in animals, it is important to document any discussions in the medical record. This should include a discussion of potential drug interactions, monitoring for side effects, and the potential for toxicity or overdoses.

Another concern that veterinarians should be aware of is product quality. Carlson shared that “multiple assessments indicate that as many as 70% of hemp-based products available may not contain the concentration of chemical components indicated on

the label.” Veterinarians can contact the manufacturer “to inquire ... regarding which chemical constituents [the manufacturer] tests for and the analytical methods used to quantify them,” continued Carlson. “Alternatively, veterinarians can ask for a certificate of analysis of a company’s product from an independent third-party lab to determine THC, CBD, and other cannabinoids in a product,” said Evans.

FUTURE DIRECTIONS

On January 26, 2023, the FDA issued a statement that “concluded that a new regulatory pathway for CBD was needed that balanced individuals’ desire for access to CBD products with the regulatory oversight needed to manage risks,” shared Carlson. While this statement primarily addressed CBD in human food products, it stated “a new pathway could provide access and oversight for certain CBD-containing products for animals.”⁵ This suggests there may be more legal products available in the future though new regulations will be required.

Meanwhile, data around CBD use in animals continues to grow. Experts educate veterinary professionals on the current data around cannabis use in animals, which include numerous publications that include case reports and controlled clinical studies in multiple species.

Carlson noted that there remain many unknowns, but “there is definite veterinary interest in these products as potential therapeutic agents. Therefore, the AVMA will continue to encourage manufacturers of these products to demonstrate their efficacy and safety and seek FDA approval for any therapeutic claims.” **TVP**

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Dr. Boatright is a 2013 graduate of the University of Pennsylvania. She currently works as a small animal general practitioner in western Pennsylvania. As a freelance writer and speaker, Dr. Boatright enjoys educating students and colleagues about overcoming stressors in the profession, including spectrum of care medicine, mentorship, communication, and wellness.

