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Cannabis status 'constantly, rapidly changing'

Prospects improve for legal veterinary involvement

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For The VIN News Service

The legal and medical landscape of cannabis is in upheaval. During the past five weeks:

- The U.S. Food and Drug Administration approved, for the first time, a drug derived from the plant *Cannabis sativa*, commonly known as marijuana.
- Canada passed a law allowing recreational use of marijuana by adults across the country, effective Oct. 17.
- Two U.S. senators, a Republican and a Democrat, teamed up on legislation that would resolve conflicting state and federal laws on marijuana by establishing the primacy of state laws. President Trump said he'd "probably



Photo courtesy of GW Pharmaceuticals

For the first time, the U.S. Food and Drug Administration has approved a drug derived from the marijuana plant. The manufacturer is a British company, GW Pharmaceuticals, which grows the plants in England.

(<https://www.nytimes.com/2018/06/08/us/politics/trump-marijuana-bill-states.html>)” support the bill.

- A bipartisan committee of the California Legislature unanimously voted in favor of a bill that would, for the first time in any U.S. state, allow veterinarians to discuss the use of cannabis products with pet owners.

As Tanya Frye, a spokesperson for the Canadian Veterinary Medical Association (CVMA), said last week on the eve of her group's annual meeting, where cannabis was prominent on the agenda, things are "constantly, rapidly changing ... everywhere."

First marijuana-derived drug approved

On June 25, the FDA took the unprecedented step of approving a drug comprised of an active ingredient in marijuana (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm>) — cannabidiol, typically called CBD. One of many biologically active compounds in marijuana, CBD is distinct from tetrahydrocannabinol, or THC, the compound that produces a high. CBD does not cause intoxication or euphoria.

The new prescription drug, named Epidiolex, is labeled for use in human patients to treat either of two forms of rare, severe epilepsy: Dravet syndrome and Lennox-Gastaut syndrome. Epidiolex also may be used as an extra-label drug in veterinary patients.

The federal Animal Medicinal Drug Use Clarification Act (AMDUCA) (<https://www.fda.gov/animalveterinary/guidancecomplianceenforcement/actsrulesregulations/ucm611046.htm>) authorizes extra-label use of human drugs in veterinary medicine. The FDA may restrict extra-label use (sometimes called off-label use) in animals of specific drugs, but it has not restricted Epidiolex, an agency spokesperson said.

The only proviso given by the agency is that "Veterinarians must follow the principles discussed in AMDUCA, as well as any state and federal regulations for the handling of the drug." Spokesperson Siobhan DeLancey explained that the proviso applies to any extra-label use of a drug in veterinary patients; it isn't particular to Epidiolex.

Before Epidiolex is cleared for sale in the country, the U.S. Drug Enforcement Agency must review and classify it. For the moment, the drug technically is illegal because the DEA considers CBD a Schedule I drug, which by definition (<https://www.deadiversion.usdoj.gov/schedules/#define>), "ha[s] no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse."

The DEA has 90 days from the date of FDA approval to decide how to classify Epidiolex, according to Wade Sparks, a DEA spokesperson. "It's approved as medicine, so it can't be Schedule I," he said.

He emphasized that the rescheduling will apply only to Epidiolex and not to other CBD products.

With a decision due from the DEA by late September, GW Pharmaceuticals PLC, the company that makes Epidiolex, plans to start selling the drug this fall, according to Steve Schultz, vice president of investor relations. While a price hasn't been set yet, Schultz said, "We want to make sure that we price this in a way that makes it available to patients that need it."

Schultz also said the company would make ample supplies. "We have an internal forecast of expected demand and we manufacture well above that expected forecast," he said. "It's hard, because we don't really know what the actual demand will be for the drug. There's clearly a very high level of awareness about the use of CBD as an anti-convulsant. There's

even more of a high level of awareness of Epidiolex after two weeks of very, very extensive and broad-based reporting on the approval. We think that there's going to be substantial demand for this medicine, but we're not really giving any public guidance at this point."

Dravet syndrome affects between 5,000 to 10,000 people in the U.S., and Lennox-Gastaut affects 30,000 to 35,000, he said.

Despite the DEA position that CBD is illegal, multiple companies, usually operating out of states where recreational marijuana is legal, sell CBD products for people and pets alike. Veterinary researchers (<http://news.vin.com/VINNews.aspx?articleId=48152>) have begun exploring the potential of CBD to treat dogs for conditions such as epilepsy and osteoarthritis.

Schultz said he can't comment about the possible applications of CBD in veterinary patients. "I want to be crystal clear with your readership that we haven't studied Epidiolex for veterinary applications," he said. "Our focus is on rare diseases in humans where there are significant unmet needs."

Marijuana to be legal throughout Canada

On June 21, Canada became the second country in the world, after Uruguay, to legalize marijuana. The law takes effect Oct. 17. Canada has allowed the nationwide use of marijuana for medical purposes since 2001, but legalization for adult recreational use (<http://www.parl.ca/DocumentViewer/en/42-1/bill/C-45/royal-assent>) will profoundly widen the availability of cannabis and products derived from cannabis.

"It will permit every adult to purchase, possess and share between friends up to 30 grams or the equivalent," said Dr. Sarah Silcox, president of the Canadian Association of Veterinary Cannabinoid Medicine (CAVCM). "From a veterinary standpoint, our clients now have legal access to the product."

As in the United States (<http://news.vin.com/VINNews.aspx?articleId=42622>), pet owners in Canada who have experienced or witnessed medicinal benefits of cannabis wonder whether it might help their animals with ailments, as well, Silcox said.

A veterinarian in Ontario with a house-call practice focused on hospice and palliative care, Silcox said she has several clients who give their pets cannabis. "Most are using medical cannabis they've obtained legally through their own prescription, and they're diverting to their pet," she said.

Figuring out dosing is a matter of cautious experimentation. "We follow a mantra in cannabinoid medicine: Start low, go slow," Silcox said.

None of Canada's laws addresses veterinary use of cannabis. The CAVCM, along with groups including the CVMA, are pressing for inclusion (<https://www.canadianveterinarians.net/news-events/news/cvma-submits-comments-to-hc-on-proposed-approach-to-regulation-cannabis>).

Silcox said attention to veterinary use is relatively new. Human patients, she said, "fought long and hard for that right [to use cannabis]. I just don't think our profession [has been] fighting for the same rights for our patients until this past year."

Founded last year, the CAVCM's stated purpose (<https://www.cavcm.com>) is to advocate for fair access and species-specific research of medical cannabis, and to promote education related to veterinary cannabinoid medicine.

Silcox said the group has about 100 members to date. While that's a small subset of the estimated 14,345 veterinarians in Canada, the issue of veterinary cannabis is now mainstream. At the CVMA annual convention last week in Vancouver, the National Issues Forum topic was "Therapeutic Use of Cannabinoids in Veterinary Medicine."

Legislative activity south of the border

In the United States, liberalization of marijuana laws has occurred incrementally — state by state — while the federal government continues to prohibit marijuana and its derivatives. That creates a legal morass.

The conflict could be resolved under a bill introduced on June 7 by Democratic Sen. Elizabeth Warren of Massachusetts and Republican Sen. Cory Gardner of Colorado. Dubbed the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act (<https://www.congress.gov/bill/115th-congress/senate-bill/3032>), the legislation would amend the Controlled Substances Act so that its provisions on marijuana would not apply to anyone who follows their state or tribal marijuana laws.

Meanwhile, California is poised to become the first state to recognize veterinary medicine in its marijuana statutes. AB 2215 (https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB2215) would allow veterinarians to discuss the use of medical cannabis for their patients; authorize adults to use cannabis for medical purposes on animals they own; and require the state Veterinary Medical Board to adopt guidelines by Jan. 1, 2020, for practitioners to follow when discussing cannabis with clients.

Endorsed by the California Veterinary Medical Association, the bill passed the Assembly with a large majority in late May, and received unanimous support from the Senate Business, Professions and Economic Development Committee on June 25. The Senate Appropriations Committee is scheduled to consider the bill on Aug. 6.

The bill sponsor, Assembly Member Ash Kalra, a Democrat from San Jose, said he learned from veterinarians that they're not allowed to talk about cannabis use in their practices despite the potential medical benefits, especially of CBD.

"The vet board has recommended [that they] don't talk about it because you could lose your license," Kalra said. "I don't blame them. If the law is silent on it, why take a chance?"

He decided to try to remedy the situation. "We want to get rid of the liability and let veterinarians do their job. They know more about pets and how to take care of them than anyone else," Kalra said.

He added: "We don't want people to guess [at usage and dosing]. That's why allowing them to go to their vet and talk about it is critical; and ultimately, setting up guidelines and best practices."

California isn't the first state to try to address cannabis in veterinary medicine. An attempt in Nevada (<http://news.vin.com/VINNews.aspx?articleId=42622>) in 2015 to authorize veterinary use fell flat when no one took the idea seriously.

Kalra said the topic draws giggles in California, too, but it's not dismissed as a joke. Speaking of the unanimous Senate Business, Professions and Economic Development Committee vote in favor, Kalra said, "I'm excited. Even pretty conservative Republicans voted for it. When they get beyond the laugh factor, [they realize that] it's not about getting pets high. ... Caring for our pets is a bipartisan issue."

The California legislation inspired a lawmaker in New York to introduce a similar bill. However, that bill, [A10104 \(https://www.nysenate.gov/legislation/bills/2017/a10104\)](https://www.nysenate.gov/legislation/bills/2017/a10104) didn't make it out of committee before the legislative session ended in June.

The sponsor, Assembly Member Amy Paulin, a Democrat from Scarsdale, is up for re-election this fall. If re-elected, Paulin said she "absolutely, 100 percent" will reintroduce the bill next year.

"I read about what was happening in California and I thought, 'Wow,' " Paulin said. "I actually have an older pet, and I thought if this was something that could help alleviate pain, it would be a tremendous blessing to animal owners who love their pets."

Paulin has an 18-year-old, 10-pound poodle named Hercules. "I want all options for him," she said.

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