

## FDA Statement

# Statement by FDA Commissioner Scott Gottlieb, M.D., on the FDA's new resource guide to support responsible opioid prescribing for pain management in animals

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## For Immediate Release

August 15, 2018

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## Statement

This statement was updated on August 20, 2018 to reflect the current available products for use in animals.

As FDA Commissioner, addressing the opioid epidemic and the misuse and abuse of these drugs remains one of my highest priorities. As we look at tackling the opioid crisis, it's important that we take a close look at all the access points where these powerful medications can be obtained. We must also ensure that all health care professionals understand their role and responsibility in prescribing these products, and lend our support in appropriately managing them.

One such important care group is veterinarians who may prescribe them to manage pain in animals.

The FDA remains committed to addressing the epidemic on all fronts, with a significant focus on decreasing exposure to opioids and preventing new addiction by taking steps to encourage more appropriate prescribing. One of the key ways we offer support to health care providers who have a nexus to prescription opioids is encouraging them to take advantage of any available opportunity to educate themselves about the safe use of opioids. When it comes to the prescribing of these drugs in humans, we have worked carefully on developing a framework for the content for these trainings made available through the Risk Evaluation and Mitigation Strategy (REMS) program for opioid analgesics. Our training "[blueprint \(/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm\)](/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm)" provides information on acute and chronic pain management; safe use of opioid analgesics or other non-opioid or non-drug treatments; as well as material on addiction medicine and opioid use disorders.

While any health care provider can take advantage of these trainings, we recognize there hasn't been a lot of information tailored specifically for veterinary medicine. That's why we have developed a [new resource \(/AnimalVeterinary/ResourcesforYou/ucm616944.htm\)](#) containing information and recommendations specifically for veterinarians who stock and administer opioids. Today we're issuing important information for veterinarians to ensure they have additional context regarding the potential for people to misuse the products that they are prescribing to their animal patients.

We recognize that opioids and other pain medications have a legitimate and important role in treating pain in animals – just as they do for people. But just like the opioid medications used in humans, these drugs have potentially serious risks, not just for the animal patients, but also because of their potential to lead to addiction, abuse and overdose in humans who may divert them for their own use.

While opioids are just one part of the veterinarian's medical arsenal for treating pain in animals, it's important to understand the role veterinarians, who stock and administer these drugs, play in combatting the abuse and misuse of pain medications. This is especially important because there are few opioids specifically approved for use in animals, and only two are currently being marketed (buprenorphine for use in cats and butorphanol for use in cats, dogs and horses). Recuvyra, a fentanyl product, is not currently marketed by the manufacturer. Carfentanil, which is 100 times more potent than fentanyl, is no longer FDA-approved for use in animals after Wildlife Laboratories withdrew the application for Wildnil this past spring. Companies are making business decisions about discontinuing the marketing of these products in the context of the current epidemic and with the goal of wanting to avoid the possibility of products being obtained or used illegally. The result is a lack of products that are FDA-approved specifically for use in animals, leaving veterinarians to prescribe products originally approved for use in humans when they determine a need for opioid pain medications for pets.

Among the recommendations we're announcing today for veterinarians is a reminder about the importance of following all state and federal regulations on prescribing opioids to animals for pain management and how to properly safeguard and store these medications to ensure they remain in the legal supply chain.

While each state creates its own regulations for the practice of veterinary medicine within its borders, including regulations about secure storage of controlled substances like opioids, veterinarians should also follow professional standards set by the American Veterinary Medical Association (AVMA) in prescribing these products to ensure those who are working with these powerful medications understand the risks and their role in combatting this epidemic. Veterinarians are also required to be licensed by the Drug Enforcement Agency to prescribe opioids to animal patients, as are all health care providers when prescribing for use in humans. These measures are in place to help ensure the critical balance between making sure animals can be humanely treated for their pain, while also addressing the realities of the epidemic of misuse, abuse and overdose when these drugs are diverted and used illegally by humans.

The FDA is also recommending veterinarians use alternatives to opioids for pain management when appropriate; we're educating pet owners on the safe storage and disposal of opioids; we're advising veterinarians to develop a safety plan in the event they encounter a situation involving opioid diversion or clients seeking opioids under the guise of treating their pets; and taking steps to help veterinarians spot the signs of opioid abuse.

We've also provided a list of additional resources on opioid abuse; proper disposal of unused medications; advice on how to keep opioids and other medications safe in a veterinary clinic or other veterinary facility; and access to federal opioid training, among other resources.

We know that licensed veterinarians share our concerns and are committed to doing their part to ensure the appropriate use of prescription opioids. We hope the resources we're providing today, coupled with the existing guidelines from AVMA, will assist the veterinary medical community about steps they can take when prescription opioids are part of their care plan for their animal patients.

As medical professionals, veterinarians have an opportunity to partner with the FDA and others to take on this public health crisis. We encourage them to continue to work with their clients and both local and national organizations, such as their state board of veterinary medicine and AVMA, to join in the fight against this tragic epidemic. In turn, we're committed to continuing to support these professionals in their efforts to curb the diversion of opioids that are meant to manage animal pain.

We're also committed to continuing our support of other health care professionals who utilize opioids while providing care for those in their communities, including making sure they have the information they need to appropriately manage and prescribe these products. Our efforts today build on the work we continue to advance on the appropriate prescribing for human patients, including our recent updates to the content included in training programs made available to all health care professionals involved in pain management.

And we remain steadfast in continuing to identify opportunities to bolster our support for the health care community. We're continuing our work to educate all providers on appropriate prescribing practices, including significant updates to our REMS program. For the first time, our REMS add approved immediate-release opioid analgesics intended for use in an outpatient setting, in addition to the extended-release and long-acting formulations of these drugs that have been subject to a REMS since 2012. These are just some of the efforts we are undertaking. We'll have more to announce in the coming weeks.

Working together, I believe that we can make progress in preventing new cases of addiction while ensuring appropriate and rational prescribing of opioids for human and animal patients with medical need.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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