



## **Opening Remarks**

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**Scientific Forum Exploring Causes of Dilated Cardiomyopathy in Dogs**  
**Kansas State University**  
**Virtual**

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Good morning, everyone. It is an honor to kick off this scientific forum to explore the causes of dilated cardiomyopathy (DCM) in dogs. First, let me give a big thank you to Dr. Ensley and Kansas State University's (KSU) College of Veterinary Medicine and Veterinary Diagnostic Laboratory for putting this forum together in the face of all the uncertainty that exists in our world. I know that most of you, including me, would have preferred that we could come together in person. In my experience, the networking that takes place among colleagues during breaks and over lunch is an important opportunity to exchange knowledge. But as we have all had to do since the pandemic started, we will do the very best we can do to exchange as much information as possible using our virtual tools.

For those of you who are not aware, KSU is a participant in the Center for Veterinary Medicine's (CVM) Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Vet-LIRN promotes human and animal health by collaborating with veterinary diagnostic laboratories to provide scientific information, build laboratory capacity for routine and emergency response, and train scientists, and Vet-LIRN laboratories help investigate potential problems with CVM-regulated products, including animal food and animal drugs. CVM supports this network and its efforts through funded cooperative agreements.

One of my guiding principles is that decisions need to be based on the best evidence and scientific data available to ensure timely public health actions. This could not be more true than when we look back on what brought us to this forum. For those of you who have not heard me speak on this issue, I would like to reiterate some points I make each time I speak on this topic.

Without a Centers for Disease Control and Prevention (CDC) for animals, there is no entity other than CVM who takes and reports adverse events for animal drugs and food, much like CDC does with their morbidity and mortality weekly reports for human illness. This sometimes places FDA in a complicated position. We are a public health agency that receives adverse events and publicly reports them when we see significant trends and signals. But, we are also a regulatory agency that is compelled to take compliance or enforcement action on our regulated products when necessary. So, when there is a signal and an association that could impact human or

animal health with a product we oversee, we have a public health obligation to share that information transparently.

Let me get us started today with a quick recap of how CVM saw the DCM scientific issue unfold. Since our forum today is focused on dogs, I am also going to focus on dogs, but I just want to remind you that we have received a small number of reports of DCM occurring in cats.

We received the first report of DCM in a dog in 2014, then a handful of sporadic reports coming in through 2017. In those four years, we received reports involving 13 dogs. In early 2018 we received a notable increase in adverse event reports that got our attention, specifically the unique signal found by veterinary cardiologists who reported seeing DCM occurring in breeds not typically genetically prone to this disease. They were in a wide variety of breeds, including small- to medium-sized dogs not typically understood to have genetic forms of DCM. Many of the adverse event reports we received contained medical records and other documentation from veterinarians.

The DCM signal was strong enough, and the initial reports were compelling enough, that we determined we had an obligation to alert pet owners and veterinarians about this animal health concern, while recognizing that we did not have an understanding of why the reporting was elevated. We issued the first of three advisories in July 2018, with follow-ups in February 2019 and June 2019.<sup>1</sup> The June 2019 advisory included us posting case information.<sup>2</sup> We subsequently received multiple requests under the Freedom of Information Act for this adverse event data that we are obligated to release upon request. And while I acknowledge that this generated angst, it is in keeping with another one of my guiding principles, that we should act openly and transparently with all parties. It is typical that whenever we raise awareness of an issue as we did with these advisories, we get more reports coming in to us.

To help separate out general cardiac cases from DCM, our CVM scientists – including epidemiologists, nutritionists, and veterinarians – used a multidisciplinary investigational approach to evaluate these adverse events. They created a case definition of a dog diagnosed

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<sup>1</sup> U.S. Food and Drug Administration, Center for Veterinary Medicine, “FDA Investigating Potential Connection between Diet and Cases of Canine Heart Disease,” July 12, 2018, available at <https://www.fda.gov/animal-veterinary/cvm-updates/fda-investigating-potential-connection-between-diet-and-cases-canine-heart-disease> (accessed September 22, 2020); “FDA Provides Update on Investigation into Potential Connection between Certain Diets and Cases of Canine Heart Disease,” February 19, 2019, available at <https://www.fda.gov/animal-veterinary/cvm-updates/fda-provides-update-investigation-potential-connection-between-certain-diets-and-cases-canine-heart> (accessed September 22, 2020); and “FDA Provides Third Status Report on Investigation into Potential Connection between Certain Diets and Cases of Canine Heart Disease,” June 27, 2019, available at <https://www.fda.gov/animal-veterinary/cvm-updates/fda-provides-third-status-report-investigation-potential-connection-between-certain-diets-and-cases> (accessed September 22, 2020).

<sup>2</sup> U.S. Food and Drug Administration, Center for Veterinary Medicine, “Dilated Cardiomyopathy in Dogs and Cats: Complaints Submitted to FDA-CVM: January 1, 2014 – April 30, 2019,” June 2019, available at <https://www.fda.gov/media/128303/download> (accessed September 22, 2020).

with dilated cardiomyopathy, rather than hypertrophic cardiomyopathy or other types of cardiac disease. To date, we have received more than 1100 reports for dogs that meet this case definition. To put these reports in perspective, during the same period, we have received approximately 2000 cardiac-related reports for dogs overall, which means that more than half of the cardiac-related reports we received were about DCM.

Now let me turn to the actions FDA scientists took with respect to these reports. We analyzed multiple sources of information, including medical records – which I already mentioned – environmental exposure, animal diagnostic samples, and diets. When possible, we obtained case information on the dogs’ dietary history. For the diets in the reports, we examined the ingredient panel and looked for trends in the types of protein reported in the dogs’ diets. We found a wide variety of proteins, including chicken, lamb, salmon, whitefish, kangaroo, turkey, and beef, but the data did not show any correlations related to protein. When we had food samples available, our scientists considered a wide variety of nutritional components, including protein, fat, moisture, fiber, starch, vitamins and minerals, and metals.

Then we looked for trends related to grains, or rather, the lack of grains. More than 90 percent of products, according to their labels or label ingredients, were “grain-free.” These products did not contain corn, soy, wheat, rice, barley, or other grains. Ninety-three percent of reported products had what appeared from the ingredient panel to be high proportions of peas or lentils or both. A small percent of reported products contained potatoes, including sweet potatoes, in the ingredient list.

A pattern emerged. Dogs in cases submitted to FDA were reported to have consumed diets containing high proportions of pulse ingredients, which are dried legume seeds, including peas, chickpeas, and lentils. We knew the proportions were high because of how these ingredients were listed or ordered on the product label, in descending order by quantity. Again, many of these diets were labeled as “grain-free,” and they didn’t contain corn, wheat, or other traditional pet food grain ingredients. Our scientists took note of this pattern with the ingredients without a determined cause and effect.

It is important to note that pulse ingredients have been used in pet food for a long time, and we have no evidence to indicate that they are inherently dangerous. However, CVM’s data show that they are used in these “grain-free” diets in greater proportion than in grain-containing formulas, which means there is an area to investigate further. We have asked pet food manufacturers to share diet formulation information, which could substantially benefit the investigation.

What we at CVM have learned since these cases first started coming to our attention is that DCM is a scientifically complex, multifaceted issue. It is rewarding to see how the issue has brought together many people with various expertise to discuss the issue and try to figure out

this scientific puzzle. The CVM team has been pleased by the cooperation, responsiveness, and scientific exchanges that have occurred. The veterinary cardiology and veterinary nutrition communities, the Pet Food Institute's nutrition subcommittee members, and individual companies have all lent their time and expertise to aid us in our investigation.

And I want to be clear: we at CVM currently do not view this as a regulatory issue. We have not requested any recalls. We have not taken any compliance or enforcement activity. This is a matter of science, and my hope and the hope of all the CVM staff working on this issue is that all the scientific expertise that is assembled here today will be able to put some more of the scientific puzzle pieces together. And I also hope that the dialogue and information exchange that begins today will continue. Pet owners and the animals they care deeply about are depending on all of us.

I recognize that discussions on DCM have been sensitive for many, and CVM acknowledges the impact of the information we have released. Even terminology is difficult because of the impact of word choices when discussing this phenomenon. In today's discussion, CVM is going to use the term "grain free," which most closely describes what we are seeing in the data. We do not mean to be pejorative. This is one of our ongoing struggles – choosing terminology that is scientifically accurate, understandable to pet owners, and that does not cast a shadow over products that are otherwise known to be healthful and safe. I appreciate the fact that FDA's voice is the voice veterinarians and pet owners listen to, yet too often our messages have been repeated inaccurately by third parties. The result is that in the internet age of phenomenally fast sound bites, complex scientific messaging is often lost in translation. We have tried to be careful in our messaging, and we recognize going forward not to speak on this topic publicly unless we are clarifying information or have something substantive to share.

As I have said on numerous occasions, we are not looking to put out any additional information until we have more scientific certainty. CVM does not review or declare any particular type of pet food as "safe" the way we do with animal drugs. I believe that our approach to date speaks to the fact that, based off the adverse event reports we have received, we have observed an association between certain diets and DCM. However, it has been nothing that would trigger a recall or market withdrawal, because the DCM issue seems to involve more factors than the food itself.

Although CVM's investigation must be driven by science and our public health mission, we are acutely aware that promoting transparency and public awareness may not be kind to everyone's bottom line. I empathize with those of you who have experienced adverse consequences in your businesses, and with those of you in the veterinary community who have

had your own challenges in sharing your scientific findings and trying to determine what type of diets to recommend to your clients and their pets.

Before I conclude my remarks, I would like to say a special thank you to those of you who have been willing to come here today to share your scientific work. As I said earlier, this has not been easy. And I would especially like to thank those industry and veterinary leaders, who, despite facing economic loss and other pressures, have put their resources into helping to solve this issue. I personally commend all of your efforts to advance our scientific understanding and the collaboration among us.

Today provides us an opportunity to combine the findings from each of our independent research perspectives to describe what we are seeing and identify any possible causes. Ideally, I think we all would really like to emerge from today's meeting with a full understanding of what causes DCM and with a pathway forward. That would be fantastic, but realistically speaking, here are what I envision as next steps:

- First, the scientific work and exchanges among this community will hopefully continue and expand, especially identifying any scientific gaps and collaborating to fill those gaps.
- Second, to the extent that there is new information that helps clarify any previous misunderstanding or interpretation, we at FDA will work to find a way to communicate that information.
- Third, FDA will continue to collaborate with ongoing scientific endeavors.
- And finally, KSU will be distributing the proceedings shortly after the symposium. These will include the abstracts and slides from those of you who have agreed to release them, and they will include FDA's materials.

I am very much looking forward to hearing each one of your presentations and having them available in the proceedings.

Thank you, and now let me turn it back to Dr. Ensley.