
Did Industry Funding Influence an FDA Investigation into Canine Heart Disease and Grain-Free Dog Food?

By **Helen Santoro**

In 2018, the U.S. Food and Drug Administration, acting on input from a group of veterinary researchers, began investigating whether the increasing popularity of grain-free dog foods had led to a sudden rise in a potentially fatal heart disease in dogs, dilated cardiomyopathy.

Four years later, the FDA has found no firm link between diet and dilated cardiomyopathy. Nor has it rejected such a link, and the research is ongoing. Publicity surrounding the suspected diet-driven dog market for

Furthermore, the pet food industry may have collected data for a study, and of interest, extensive reporting.

A six-month investigation by 100Reporters has found that veterinarians who prompted the FDA to consider diet have financial and other ties to the leading sellers of grain-inclusive pet foods. Additionally, agency records show that for the initial study, some vets were instructed to submit only dilated cardiomyopathy (DCM) cases



that implicated grain-free, “exotic” or “boutique” pet foods. Suppliers of ingredients used in grain-free dog foods have also exerted pressure on the FDA to protect their market.

DCM Reports to FDA - By Year (Dogs & Cats)

Data from the US Foods and Drug Administration

Consequently, some say the conversation around DCM and grain-free food is deeply divided, with each side claiming the other is serving competing agendas and prioritizing industry relationships over scientific integrity and the lives of pets.



“This became such an emotional issue,” said Dana Brooks, CEO of the Pet Food Institute, whose members produce most of the pet foods and treats in the US. “We’re scrambling to try to even determine what’s going on.”

*Dana Brooks. Photo courtesy of the
Pet Food Institute.*

CAUSE FOR CONCERN

Grain-free diets started to become popular for pets in the early 2000s, in response to a desire among owners to move away from grains that were thought to provoke allergies in pets. This period also saw a wave of gluten-free foods in humans, which spilled over into the pet food market. "Pet foods reflect the interests and the

tastes of their owners,” said Marion Nestle, a professor emerita of nutrition, food studies and public health at New York University. “You make foods that are designed to appeal to owners.”

Grain-free diets are more expensive than grain-inclusive ones, said Gregory Aldrich, an animal nutritionist and associate professor at Kansas State University and president of Pet Food Ingredient and Technology, Inc., which offers nutrition and technical services to pet food manufacturers and ingredient suppliers. Pulses — seeds from legume plants including peas, beans and lentils that are commonly used to replace grains in grain-free food — have more protein and less starch than grains, making them more costly for manufacturers and consumers, Aldrich said.



Marion Nestle. Photo by Bill Hayes.

DCM Cases: Breeds Most Frequently Reported to the FDA

Source: US Food and Drug Administration, January 2014- April 2019.

In 2016, pulses became particularly popular in pet foods, with 124 new pet food products containing them introduced in the US that year. By 2019, approximately 43 percent of dry foods sold were grain-free, **reaching \$5.4 billion in sales**. Total pet food and treat sales **hit almost \$37 billion** that same year.

During this period in 2017 and 2018, veterinarians started seeing an influx of dogs with DCM, the second most

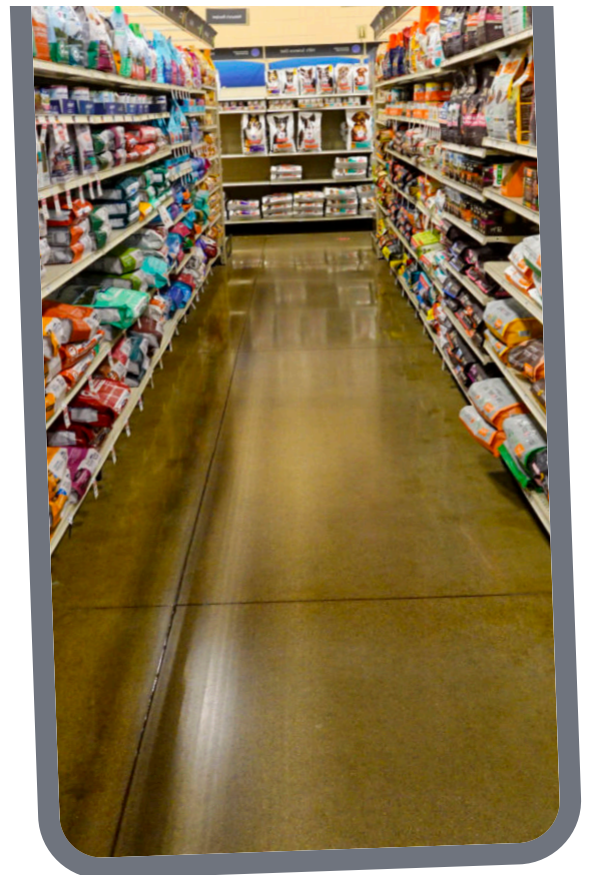


common heart disease in canines. In larger breeds like the Doberman Pinscher, the disease has a prevalence of over 50 percent, while in smaller breeds, it's very rare. Overall, **less than one percent of dogs** are estimated to have this disease. Once heart failure from DCM begins, the survival time is **typically less than one year**. In some cases, the dog dies suddenly before any symptoms appear.

Some of these DCM cases were reported to the FDA, which typically sees one to three reports of the disease annually. However, between January 1 and July 10, 2018, they received 25 case reports.

Seven of these cases were submitted by a single source: professor, veterinarian and animal nutritionist Lisa Freeman from Tufts University's Cummings School of Veterinary Medicine.

FDA records obtained under the Freedom of Information Act, however, indicate that those reports may not have been fully representative of cases seen at the Tufts clinic.



AP Photo/Michael Conroy.

SHAPING THE INQUIRY

In a June 2018 email to Jones, Freeman attached a document showing that her center had instructed vets to report cases to the FDA, "If patient is eating any diet besides those made by well-known, reputable companies or if eating a boutique, exotic ingredient, or grain-free (BEG) diet." Exotic ingredients include kangaroo, duck, buffalo, tapioca, salmon, lamb, bison, venison, barley and pulses.

When asked if this request could be perceived as cherry-picking the data at a seminal stage of the investigation, Freeman responded through Tufts University's media relations, stating: "The protocol in that email was developed for and intended to help veterinary cardiologists in the early stages of the investigation into potential associations between diet and dilated cardiomyopathy."



According to the FDA, the document shared by Freeman was generated by Tufts veterinary staff for use by Tufts veterinarians.

“The FDA has never requested that DCM cases reported to the agency be limited to certain diet types,” an FDA spokesperson wrote in an email. “We welcome all DCM reports with a suspected link to food, regardless of the type of diet.”

Freeman has a long history of receiving funding from pet food companies including Nestlé Purina Petcare, Hill’s Pet Nutrition, and Mars Petcare. This is common within the field of animal nutrition, as a large portion of funding for studies on pet food and nutrition come from big pet food companies.

According to PubMed.gov, Freeman has produced scientific work funded by Hill’s and Mars since 2002 and Purina since 2004. Over the past 20 years, she has been an author on studies funded by these pet food companies around 30 times. In recent years, Freeman has included a **more detailed conflict of interest declaration** than those seen in her past studies, which states: “In the last 3 years, Dr. Freeman has received research funding from, given sponsored lectures for, and/or provided professional services to Aratana Therapeutics, Elanco, Hill’s Pet Nutrition, Nestlé Purina PetCare, P&G Pet Care (now Mars), and Royal Canin.”

In response to questions about payments from Mars, Hills and Purina and the DCM cases she presented to the FDA early on in the investigation, Freeman stated the following through Tufts University’s media relations: “I stand behind the research that my co-authors and I have contributed to this body of work, and I have transparently disclosed the sources of funding for the work I conduct on this topic. I respect the scientific process and am hopeful that continued advances in research will help clarify the association between diet and DCM.”

Two other veterinary cardiologists — Darcy Adin from the University

of Florida College of Veterinary Medicine and Joshua Stern from the University of California, Davis School of Veterinary Medicine — also collaborated with the FDA. In an FDA update on the investigation, the agency named the three, saying that “FDA veterinarians have been working with Drs. Lisa Freeman of Tufts University, Joshua Stern of UC Davis and Darcy Adin of the University of Florida to learn more about their research findings and the cases they’ve encountered.”

Emails obtained from a public records request indicate that the connection between DCM and grain-free dog food was first suggested in 2017. In March 2018, Jennifer Jones, a veterinary medical officer at the FDA assigned to the investigation, received an email from a vet asking to “discuss our findings on dilated cardiomyopathy and dietary relationships in our clinic over the past year.”

The emails show that the following month, Freeman, Adin and Stern discussed their clinical observations surrounding grain-free dog foods and DCM in a call with the FDA, after which Jones asked them to email her spreadsheets of their case data.

Adin has been involved in studies that received funding from Purina since 2018 and, since 2017, from the Morris Animal Foundation, a nonprofit animal health charity founded by Mark Morris, Sr., who created the first line of dog foods produced by the company that would become Hill’s Pet Nutrition.

Adin commented through University of Florida public relations that she has never directly received funding from the Morris Animal Foundation or Purina, but was a primary and co-author on studies into an unrelated heart condition, degenerative mitral valve disease, funded by the Morris Animal Foundation.

Animal numbers in DCM Reports received between January 1, 2014 and April 30, 2019

	Number of reports	Number of animals affected	Number of deaths
Dogs	515	560	119
Cats*	9	14	5

*Cats are generally more likely to develop hypertrophic cardiomyopathy (a heart disease)

Source: US Food and Drug Administration

Stern has been an author on studies funded by the Morris Animal Foundation since 2011, and he currently receives funding from the foundation.

“I completely understand conflict of interest concerns with people being funded by the pet food industry and I acknowledge that that is something that we are up against,” Stern said in an interview, noting that this also applies to researchers and veterinarians who don’t believe there is a connection between DCM and grain-free food. “It’s hard to find a veterinary nutritionist that hasn’t done research for pet food companies.”

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All three veterinary schools also have close ties to the pet food industry — another common issue in this field. For example, UC Davis has a [Hill’s VIP Market program](#) where faculty, residents and students get discounts on Hill’s food, and Purina has [donated \\$50,000 annually](#) to the veterinary school’s Center for Food Animal Health since 2006. Purina has also [funded scholarships for students](#) at the University of Florida. In the early 2000’s, Tufts had a Hill’s Resident Research Fund, and Purina has [offered resident research grants](#) and scholarships for student representatives.

Purina, Hill’s and Mars produce some of the most popular grain-inclusive dog foods, including Purina Pro Plan and Purina ONE, Hill’s Science Diet and IAMS Proactive Health (IAMS is owned by Mars). They all also sell grain-free diets. However, grain-inclusive foods are key drivers of dry dog food sales across the industry.

Purina, Hill’s and Mars did not respond to multiple requests for comment.

I completely understand conflict of interest concerns . . . It’s hard to find a veterinary nutritionist that hasn’t done research for pet food companies.

Joshua Stern, University of California at Davis, School of Veterinary Medicine

RISING CASES

On July 12, 2018, the FDA publicly **announced its investigation**. Many of the 25 dogs with DCM that spurred the investigation did not have a genetic predisposition for the disease, causing concern among vets. The common thread, the FDA reported, appeared to be a grain-free diet.

“Early reports from the veterinary cardiology community indicate that the dogs consistently ate these foods as their primary source of nutrition for time periods ranging from months to years,” the FDA wrote.

In a June 2019 update, the FDA went further, naming **16 dog food brands** that appeared most frequently in their DCM case reports. This was shocking, said Brooks. “We’ve never seen anything like that before without a certainty of the cause.” Over 90 percent of the listed brands were grain-free.

Joseph Bartges, a professor of animal medicine and nutrition from the University of Georgia’s College of Veterinary Medicine,

Following the announcement of the investigation in July 2018, reports of DCM cases skyrocketed. By July 2020, the FDA **had received over 1,100 reports of DCM in dogs**.

This drastic increase is likely because the FDA encouraged veterinarians to report the disease, said Brooks. **In a November 2020 statement**, the Pet Food Institute, Brooks’ organization, wrote that current research suggests “that a variety of factors may influence the development of DCM.”

The investigation was also **covered extensively by the media**, likely influencing the public’s purchasing decisions.

In subsequent research, Adin reported that dogs with DCM that are eating grain-free food may get better when they change their diet. Adin and colleagues examined the medical records of dogs diagnosed with DCM or congestive heart failure that were in one of two dietary groups — those who were only on a grain-inclusive diet, or those who were on a grain-free diet and then switched to a

was not surprised that the dog food brands named most frequently in the DCM reports were grain-free. He noted at the American Feed Industry Association's 2020 conference that the FDA announcement and updates on the investigation seemed to urge pet owners to report dogs with DCM who were eating grain-free food.

"When you only look for what you want to see, you only see what you look for," Bartges said during an interview.

grain-inclusive diet. Both groups also received standard medical treatment.

They discovered that dogs that switched from a grain-free to a grain-inclusive diet lived an average of 465 days compared to 263 days for dogs only on a grain-inclusive diet.

Additionally, researchers found that dogs on a grain-free diet developed DCM, on average, at around six years old, compared with dogs on a grain-inclusive diet who developed the disease at around nine years old, suggesting that **diet may be a risk factor**.



Dollar sales trend of Grain Free Dry Dog Food is flat , 0.2%, for the first time in four years

Across xAOC+Pet GF Unnamed Brands are a key driver being up/flat +0.6% L26W, and +2.5% historical CAGR

xAOC+Pet Grain Free Dry Dog Food \$ Vol

(4-Year Trends by Half-Year Periods)

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Jan June 2021	Total GF	Named Brands	Unnamed Brands
\$% Chg vs YAG	(0.2%)	(-1.0%)	+0.6%
\$% Chg vs 2YAG	(-11.6%)	(-14.1%)	(-8.5%)
CAGR	(-4.0%)	(-8.5%)	+2.5%

Source: NielsenIQ RMS AOD, Half Years W/E 07/03/21 vs YAG, 2YAG, and 3YAG, xAOC + Pet, Dry Dog Food by Grain Free Char

Throughout its investigation, the
FDA has repeatedly stated that
DCM is a complicated issue



involving multiple factors, and the link to diet is suspected but not proven. They also noted that there are an estimated 77 million pet dogs in the US, and most have been consuming pet food of all types without developing DCM.

Steven Solomon, director of the FDA's Center for Veterinary Medicine (CVM), emphasized this point during a **September 2020 symposium** at Kansas State University, in what some described as a bid to "walk back" the tie between diet and DCM, implied when the FDA associated the 16 brands of dog food with heart disease in dogs.

In a speech, Solomon said that "DCM is a scientifically complex, multifaceted issue," adding that "we at CVM currently do not view this as a regulatory issue," meaning they are not requesting any food recalls, though they welcome new scientific research.

Yet since Solomon's appearance, the investigation has gone silent. So silent, in fact, that at least one veterinarian in the field thought the investigation was closed. However, it is still ongoing, according to an FDA spokesperson asked to comment.

Some believe this silence is because the FDA is trying to distance itself from the investigation **due to lack of evidence linking DCM to grain-free food**. Others say it's because of pressure the agency received from the pulse industry, which has profited significantly from the grain-free pet food trend.



In fact, the USA Dry Pea & Lentil Council's 2019 annual report stated the organization "convinced the FDA to clarify their language about their concerns and **minimize the damage to the industry.**" A **newsletter by the US Pulse Industry** also noted that BSM Partners — a pet care research and consulting firm that works with Zignature, one of the 16 pet food brands listed in the FDA update — aimed to raise \$5 million for three research projects to "determine the real cause(s) of DCM in dogs." As of 2018, pet food companies pledged to donate \$3 million to this effort, and the pulse crop industry set a goal of \$1 million. After a request for comment, the newsletter was removed from the Northern Pulse Growers Association website.

"With the FDA investigation still ongoing and new research emerging each year, we trust that the FDA will continue to analyze the research available to them, and provide us all with guidance if and when a cause is determined," the USA Dry Pea & Lentil Council and American Pulse Association wrote in an email.

Sen. Jon Tester from Montana — a principal growing region for pulses — also **sent a letter to the FDA** in 2019 complaining that the agency "issued an unsubstantiated warning that was taken as fact by many pet owners," dealing a "sharp blow" to pulse farmers. The following year, seven senators signed **another letter** to FDA officials ahead of the Kansas State conference, urging that "the best available science is made available and examined, so as to prevent any bias about causation of this disease." Furthermore, on Feb. 2, 2020, Solomon, director of the FDA's Center for Veterinary Medicine, **met with the USA Dry Pea & Lentil Council.**

"The FDA has heard and has met with many different stakeholders on the issue over the last four years, including the pulse industry," an FDA spokesperson wrote in an email, "but ultimately, all FDA decisions and work are guided by science, data, and our public health mission."

The fact that people from the pulse industry and their advocates in Congress are speaking with the FDA about this investigation is not at all surprising to Nestle, whose book examined the secretive

companies and politics behind pet food.

Laura Schmidt, a professor of health policy at the University of California, San Francisco, has seen human food companies use similar strategies to protect their product. It takes an incredible amount of time and money to formulate, test and market a new product to the public, Schmidt said. “They don’t want anybody publishing findings that go against their storyline.”

AN IMPACTED MARKET

Meanwhile, research into DCM has continued. This March, Freeman published another study funded in part by Purina concluding that dogs with DCM or heart defects that precede cardiac failure who were eating grain-free diets had **small but significant improvements in their hearts** after switching to grain-inclusive diets.

Anna Kate Shoveller, professor of animal nutrition at the University of Guelph in Canada, and her team also presented findings at the 2021 American Feed Industry Association conference on the impact of pulses in grain-free diets on Siberian Huskies' cardiac health. They fed the huskies one of four diets with varying amounts of pulses over a 20-week period and found that their cardiac health did not change based on the quantity of pulses consumed.

Regardless of how much more time and money goes into this research, the FDA investigation has already had a substantial impact on the pet food market. Since June 2018, the market for grain-free dry dog food **has been on a decline**, with the brands named in the FDA investigation seeing a particularly steep decrease in sales up until the last half of 2020, according to NielsenIQ, a data analytics company.

The reason that this steep decrease in sales stopped may be due in part to the pandemic, which brought about a surge in pet industry sales. In fact, these sales in the U.S **exceeded \$100 billion for the first time ever** in 2020 and a survey by the American Pet Association found that **owners spent 11 percent more on pet food** that year as well. However, overall grain-free sales continued to decrease by \$60 million in 2021.



From the beginning of the investigation to 2020, there was a 19 percent shift in volume from grain-free dry dog food to grain-inclusive food, according to former NielsenIQ retail client director, Brad Boldrige.

Veterinarians like Aldrich and Bartges don't think there will be a clear answer to the DCM question anytime soon. This is in part, they say, because nutritional studies on dogs with DCM are expensive and difficult to conduct. It's also likely there are multiple factors contributing to this disease, including a dog's breed, their individual physiology and even other environmental factors, said Brooks.

The powerful influence of the pet food and pulse industry over animal nutrition science is also going to make getting a clear answer about the disease difficult, said Nestle. "They're all trying to protect their market share," she said.

Correction: An earlier version of this story mistakenly described the founder of the Morris Animal Foundation, Mark Morris, Sr., as the founder of Hill's Pet Nutrition, and said that a Hill's employee chaired the foundation's board. Additional information that was inadvertently omitted from the original story has since been restored.

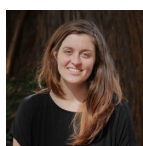
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Helen Santoro is a science and investigative journalist who writes about health, medicine and LGBTQ+ communities. Her stories often focus on health disparities faced by disadvantaged populations and health care discrimination against transgender and queer people. This is her first piece for 100Reporters.

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