ETHICAL ADVICE ON DIETARY RECOMMENDATIONS IN THE SHADOW OF DCM

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INTRODUCTION

Canine dilated cardiomyopathy (DCM) has been a hot topic in the pet food industry, the veterinary community, the press and among pet owners. Although there may be a potential association, there is no proven direct link (i.e. cause and effect) to grain-free foods (both over the counter or therapeutic) to cause DCM in dogs. In fact, the update provided by the FDA June 27, 2019 stated that they did not identify a direct link of BEG foods to DCM. The FDA is continuing to investigate and gather more information to identify if there is truly a specific dietary link to development of DCM and will provide updates to the public as information develops. In the meantime, we need to understand how the grain-free market has gained traction with consumers over the years and how commercial bias (whether known or unknown) can impact veterinary knowledge and ethics.

THE HISTORY OF BEG: HOW DID WE GET HERE? The rise of the term "BEG"

In early June 2018, Lisa M. Freeman, DVM, Ph.D., D.A.C.V.N., a veterinarian and professor with the Cummings Veterinary Medical Center at Tufts University, wrote an article titled, "A broken heart: Risk of heart disease in boutique or grain-free and exotic ingredients." She stated, "that cardiologists had noticed higher rates of DCM in Golden Retrievers and some atypical dog breeds." Additionally, she furthers writes, "the dogs were consuming boutique or grain-free diets, and diets with exotic ingredients - kangaroo, lentils, duck, pea, fava bean, buffalo, tapioca, salmon, lamb, barley, bison, venison and chickpeas. Even some vegan diets have been associated. It has even been seen in dogs eating raw or home-prepared diets." Although these statements were made as if they are fact and backed by science, the statements were actually anecdotal. In fact, she notes that Dr. Joshua Stern from the University of California Davis was conducting research on taurine deficiency and DCM in Golden Retrievers (i.e. no conclusion or clinical evidence when she wrote the article).

FDA's request for DCM and Diet Cases

In July 2018, the Food and Drug Administration (FDA) announced they were investigating a potential connection between diet and cases of canine heart disease. In their statement they wanted to alert pet owners and veterinary professionals about reports of DCM in dogs eating certain pet foods containing peas, lentils, other legume seeds, or

potatoes as main ingredients. At the time, the only reported information was 4 atypical DCM cases (three Golden Retrievers and one Labrador Retriever) and the FDA encouraged pet owners and veterinary professionals to report cases of DCM in dogs suspected of having a link to diet.

The JAVMA article

On December 1, 2018, Freeman et al. (2018) published a non-peer reviewed commentary in JAVMA titled, Dietassociated dilated cardiomyopathy in dogs: what do we know? In the commentary, the authors wanted to raise awareness based on a non-published and non-peer reviewed survey of veterinary cardiologists about cases of possible diet associated DCM in dogs examined in the past 2 years. Information for > 240 cases was obtained, with responses received from the United States, United Kingdom, Canada, Israel, and Austria. Additionally, the authors wanted to reiterate the July 2018 FDA announcement alerting pet owners and veterinarians about reports of DCM in dogs eating pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients has raised concerns among the pet-owning public. Additionally, the article reiterated to look for signs in dogs only being fed BEG foods. Similar to the Dr Lisa Freeman article mentioned above, this article made sweeping claims and conclusions about "good" and "bad" pet food with unscientific opinions and without scientific data.

THE SCIENTIFIC PROOF OR LACK THEREOF? The Golden Retriever DCM and Diet Study

The study referenced above by Dr Lisa Freeman was published by Kaplan et al. on December 13, 2018. In their study, they identified 40 golden retrievers to participate in the study. Sixteen were excluded because of inadequate imaging, had no evidence of DCM/cardiac disease or normal taurine status. In the remaining 24 golden retrievers, 23/24 dogs diagnosed with taurine deficiency and dilated cardiomyopathy were fed diets that were either grain-free, legume-rich, or a combination of these factors.

In the table below, Kaplan et al. (2018) identifies the foods that were associated with DCM in Golden Retrievers (n=24). From the data collected we can clearly see that Acana represented 57.7% of the foods fed to the dogs with diagnosed low taurine and DCM (with pork and squash representing 2/3 of the Acana foods). It is important to note that the author(s) noted the limitations (i.e. lack of control group) in their study. Kaplan et al. (2018) concludes, "the need for controlled, prospective studies of larger sample size are needed to determine if the clear associations identified in this manuscript represent a cause-and-effect relationship between DCM, taurine-deficiency, specific ingredients, and grain-free food varieties in general. Without such studies we cannot conclusively define which dietary characteristics are

List of pet food brands with their diet varieties and characteristics fed to dogs diagnosed with DCM

Diet Brand	Diet Variety	No. of dogs with DCM	No. of dogs with low Taurine	Feeding Trial Tested	Formulated to Meet AAFCO Guidelines	Meets WSAVA Guidelines	G	L
1	a	10	10	No	✓	No	1	1
	ь	4	4	No	✓	No	1	1
	с	1	1	No	✓	No	1	
2	d	1	1	No	✓	No	1	1
3	e	1	1	No	✓	No	1	1
	f	1	1	No	✓	No	1	1
4	g	1	1	No	✓	No	1	1
5	h	2	2	No	✓	No	1	1
6	i	1	1	No	✓.	No	1	1
7	j	1	1	No	✓	No	1	1
8	k	1	1	No	✓	No	1	1
	1	1	1	No	✓	No	1	1
9	m	1	1	No	✓	No	1	

1a = ACANA Singles Limited Ingredient Diet Pork & Squash Formula (dry); Manufactured

by Champion Petfoods USA Inc., Auburn, KY 42206.

1b = ACANA Singles Limited Ingredient Diet Lamb & Apple Formula (dry); Manufactured by Champion Petfoods USA Inc., Auburn, KY 42206.

Ic = ACANA, unknown variety; Manufactured by Champion Petfoods USA Inc., Auburn, KY 42206.

2d = Taste of the Wild Pet Food Pine Forest Canine Recipe with Venison & Legumes (dry); Schell & Kampeter, Inc. Manufactured by Diamond Pet Foods.

3e = 4health Grain Free Beef & Potato Formula (dry); Tractor Supply Co.; Manufactured by Ainsworth Pet Nutrition, Meadville PA 16335.

3f = 4health Grain Free Chicken & Vegetable Formula (dry); Tractor Supply Co.; Manufactured by Diamond Pet Foods.

4g = Zignature Lamb Formula Limited Ingredient (dry); Pets Global, Inc.; Manufactured by Tuffy's Pet Foods, Perham, MN 56573.

5h = Instinct Limited Ingredient Diet Grain-Free Recipe with Real Lamb (dry); Nature's Variety, Saint Louis, MO 63146. Manufactured by CJ Foods, Inc, Bern, KS, 66408.

6i = NutriSource Grain Free Chicken and Peas Formula (dry); Manufactured by KLM Family Brands, Tuffy's Pet Foods, Perham, MN 56573.

7j = Kirkland Signature Nature's Domain, Turkey Meal & Sweet Potato Formula for Dogs (dry); Manufactured by Diamond Pet Foods.

8k = Fromm Lamb & Lentil Recipe Dog Food (dry); Manufactured by Fromm Family Foods LLC, Mequon WI 53092

81 = Fromm Salmon a La Veg (dry); Manufactured by Fromm Family Foods LLC, Mequon WI 53092

9m = Orijen Regional Red (freeze-dried medallions); Manufactured by Champion Petfoods USA Inc., Auburn, KY 42206.

(✓) Diet meets criteria under the specific category

involved with the pathogenesis of this condition." Based on the data they observed, one could only draw the conclusion that DCM could be associated with grain-free dry kibble since only 9 out of 26 reported number of dogs (34.6%) consuming the foods were consuming "exotic" proteins.

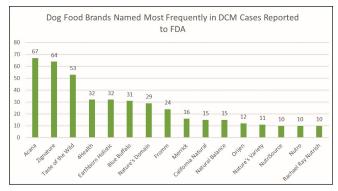
FDA investigation update: more data

After almost a year of investigating the link of "BEG" diets to DCM, the FDA provided an update on their investigation into the potential link between certain diets and DCM. The update provided information on all the animals in reported cases, including breed, age, sex, foods consumed, diagnosis, etc. FDA also provided bar charts for protein sources involved in the cases that were tied to the investigation.

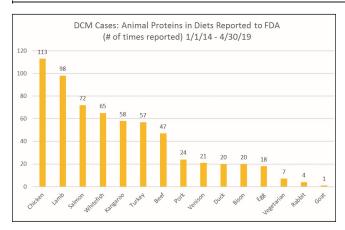
In addition, FDA reported all pet food brands named in DCM reports submitted to the agency. Unfortunately, they only graphed the top 16 brands, and this is what took over the headlines in the press. If the press and others took the time to actually review all the cases reported to FDA (submitted through April 30, 2019), they would have seen other brands like Purina ONE, Hill's Pet Nutrition, Halo, V-Dog, Lotus and others. What is more important is that the majority of brands named in the report were not boutique brands

and can be found in large pet specialty, grocery and mass market stores. Thus, the "B" in BEG is inaccurate and a misnomer.

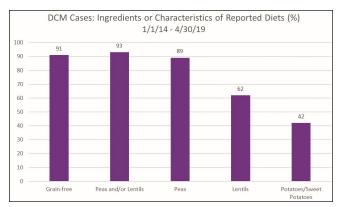
Additionally, veterinarians need to keep in mind the bigger companies that own the actual brands. If readers looked at the actual cases reported to FDA, they will see that major industry giants actually had multiple brands in the report. For example, Mars Petcare had numerous cases reported



Date Accessed August 31, 2019: https://www.fda.gov/animal-vet-erinary/news-events/fda-investigation-potential-link-between-certain-diets-and-canine-dilated-cardiomyopathy



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under their brands California Natural, Nutro, Evo and Royal Canin. While Nestlé Purina had cases reported under their brands Merrick, Purina, Purina ONE, Purina Pro Plan, Whole Earth Farms and Castor Pollux. The J.M. Smucker company also had case reported under their brands Rachael Ray Nutrish, Natural Balance and Nature's Recipe. Lastly, you have companies like Schell & Kampter, LLC (Diamond Pet Foods) that produce Taste of the Wild, Diamond Professional Plus, Diamond Naturals and co-manufacture Kirkland Nature's Domain (Costco) and 4Health.

For proteins, the FDA noted "that animal protein sources in the reported diets varied widely, and many diets contained more than one protein source. The most common proteins in the reported diets were chicken, lamb and fish; however, some diets contain atypical protein sources such as kangaroo, bison or duck. No one animal protein source was predominant." Said differently: Of the cases investigated, 75% were common protein sources (chicken being No. 1), 24% were novel protein sources and 1% were vegetarian foods. In case you were wondering, kangaroo was only 9.3% of the total cases. Thus, the "E" for exotic in the acronym BEG is also inaccurate and a misnomer.

In regard to grain-free, a majority of foods implicated did

contain peas and lentils (93% of total cases) and were grain-free (91% of total cases); however, that is what the original request from the FDA and JAVMA article requested. It is important to note, that almost 10% of the report cases were actually grain based even though grain-free was requested.

Additionally, 88% of the foods implicated were dry foods and a negligible amount are wet (canned), raw, home cooked or freeze dried.

FDA investigation: More than pretty graphs!

In addition to the pretty FDA bar graphs, there was additional information that did not make the press or the top headlines in veterinary journals. For example, the FDA recognized that past publications and research suggest that Golden Retrievers may be genetically predisposed to taurine deficiency, which is well-documented as potentially leading to DCM. Keep in mind all the information provided up to this point never looked at genetics.

The FDA also acknowledged that they are still gathering information to better understand if (and how) taurine metabolism (both absorption and excretion) may have a role in these reports of canine dilated cardiomyopathy. Also, the FDA had tested multiple products for minerals and metals (calcium, magnesium, phosphorus, iron, cobalt, copper, zinc, selenium, iodine) and amino acids including taurine, cysteine, and methionine. That product testing did not reveal any abnormalities. The FDA even found average percent protein, fat, total taurine, total cystine, total methionine, total methionine-cystine, and resistant starch content on a dry matter basis were similar for both grain-free labeled and grain-containing products. Thus, the FDA has not found any nutrient deficiencies to date. With that being said, they have not looked at digestibility and/or bioavailability of these nutrients in dogs. Nor do we know taurine synthesis efficiencies in all breeds.

In their update, the FDA reviewed 340 dog's medical records, only 202 dogs (59.4%) were confirmed DCM cases with heart changes characteristic of DCM on cardiac ultrasound - including decreased ventricular systolic function and dilation. Of the pets with confirmed DCM, approximately 15% (n=32) also had evidence of valvular degeneration and 12% (n=24) had atrial fibrillation. Approximately 38% (n=77) of dogs with DCM had a history of confirmed or suspected allergies or sensitivities to an environmental and/or food allergen that was manifested as dermatitis, otitis, or gastrointestinal disease. Approximately 9% (n=18) and 8% (n=17) of dogs with DCM had a history of hypothyroidism and one or more tick-borne diseases (e.g. Lyme, Anaplasmosis), respectively. Why are these numbers important? First, veterinarians may be too quick to come to a solution. Second, there could be other underlying factors like primary or secondary illnesses. For example, in humans when gastrointestinal disease exists there is an increased risk of DCM which is linked to carnitine deficiency. Thus, it becomes important to know the case history in addition to

diet history. In the day and age of Dr. Google clients could be self-diagnosing gastrointestinal issues by switching them to grain-free foods and veterinarians may not knowing there is another underlying issue. Also, the taurine values have been all over the board (low, medium and high). Thus, taurine is not necessarily the root cause.

Lastly, the FDA has not found a link of BEG food causing DCM. Contrary to how the popular press may spin the graphs.

BEG DOES NOT EQUAL DCM!

Based on the data we have today, there is no cause and effect relationship of BEG foods causing DCM. We know that the "B" and the "E" in BEG has been disproven. We also see there is grain foods being fed to dogs with DCM. Thus, having veterinarians focus on grain-free foods only will likely miss cases of dogs consuming grain-based foods made by other companies. In other words, if you don't look for it in all food types, you will not likely find the root cause. For example, we know that beet pulp decreases taurine status (due to increased excretion of bile acids containing taurine) and decreases protein digestibility (taurine precursors) in dogs. For those of you not familiar with beet pulp, it is a good source of both soluble and insoluble fiber and is commonly used in grain-based dog foods. Also, it raises the question if grain free (the G) is truly the issue, especially when the issue does not exist in the other food forms (wet, raw, home cooked or freeze dried).

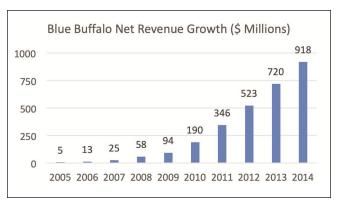
GRAIN-FREE FOODS: WHERE DID THEY COME FROM?

Grain-free foods have been in the marketplace for decades; however, their popularity was minimal at best with foods only being sold as "therapeutic" foods or as super-premium foods in neighborhood pet stores. Most top selling foods in the marketplace contained grains and many did not even contain "natural" claims. All of that would begin to change in 2007.

On March 15, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. FDA found contaminants in vegetable proteins imported into the United States from China and used as ingredients in pet food. In particular, the ingredients were wheat gluten and rice protein concentrate tainted with melamine.

Since both ingredients were grain-based this led to certain companies launching big consumer facing advertising campaigns that focused primarily on "free of" claims like no corn, wheat or soy and grain-free. As a result, foods that contained alternative grains (barley, oats and sorghum), grain-free or non-Chinese sourced ingredients began to flourish. Additionally, the 2007 pet food recalls made many consumers aware of how pet food is made, where the products were produced and the consumer quickly realized that premium and grocery pet foods contained many of the same ingredients and/or manufacturers of finished goods.

For example, companies like Blue Buffalo capitalized on



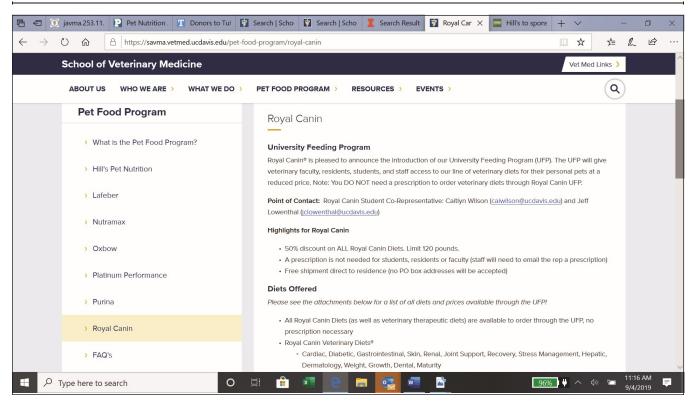
Date Accessed September 4, 2019: https://sec.report/ Document/0001193125-15-235199/

this and grew their companies from \$25 million in net revenues in 2007 to \$918 million in 2014 (see table below) by focusing on advertising and customer education. As companies like Blue and other smaller companies flourished it was at the detriment of the larger companies. Shortly thereafter, the mainstream brands (Purina, Mars Petcare and Hill's Pet Nutrition) caught up to the trend-setters, and then you had grain free and gluten free flooding the market as you see today in all marketplaces.

VETERINARY BIAS

As a board-certified nutritionist I will be the first to tell you that grain-free foods are no better than grain foods (based on current research). In fact in 2017, I wrote an article titled, "Why grain-free pet food isn't better and carbs are good", which focused on the benefits of carbohydrates in foods (both nutritionally and from a food science standpoint) and how both were highly digestible. Most will acknowledge the only benefit exists for animals with food sensitivities; however, given the past recall in 2007 consumers see grain-free as a more premium product today. What does this mean for veterinarians? If veterinarians recognize there is no difference if the food contain grains or are grain-free then veterinarians need to take into account any perceived bias or conflicts of interest before they engage their client. Veterinarians need to recognize that consumers may be feeding the dogs certain foods because of the client's lifestyle choices without detriment to the pet (i.e. organic, grainfree, gluten free, no beef, etc.).

Thus far, we have covered how there is no direct link of "BEG" foods to DCM. Additionally, we focused on the rise of the grain-free pet food industry; however, there may be many veterinarians that are still fearful of or down rate despise grain-free foods. Well it must make you wonder why? Is it because of the article you read in JAVMA (mentioned above) and you took it as fact-based paper vs an opinion commentary, is it based on what you were taught in school, the food you carry in your clinic or the clinical studies you read throughout your career? If you answered yes to any those you may have an unknown bias that could inadvertently being impacting your ethics and decision making.



Date Accessed September 4, 2019: https://savma.vetmed.ucdavis.edu/pet-food-program/royal-canin

How so?

First, let's focus on articles and clinical studies. Now they may appear to be fact based and may have reputable people authoring the study or article. With that being said, does their school receive any funding that could persuade them to think in a certain way when designing the studies or writing the article? For example, the authors of "Diet-associated dilated cardiomyopathy in dogs: what do we know?" all work for universities that have nutrition services and nutritionists who have received funding for research by Purina, Hill's Pet Nutrition and/or Royal Canin. If you read the fine print or understood all the other funding going into the university besides research would you think differently?

Second, let's focus on how corporate sponsors impact a veterinarian through their education. The companies I mentioned above also funded nutrition centers and feeding programs for their veterinary students (picture below). Could this lead to a potential bias later in a veterinarian's career? If a Blue Buffalo, Champion or another top selling grain-free food company sponsored and continuously funded the universities would the Freeman et al. (2018) article be different? Only time will tell since they have sponsored Clinical

Trials Office at The Ohio State University College of Veterinary Medicine.

Lastly, is there other potential bias's that veterinarians may not be aware of that can unknowingly impact their ethics?

WHAT'S MY ETHICAL ADVICE?

Veterinarians should stay true to their core values of openness, objectivity and truthfulness whenever interacting with a client. Before giving nutritional guidance on anything including topics in the news, new food trends or even therapeutic food guidance veterinarians need to consider their source of information (peer-reviewed vs. commentary), the potential impact of any bias whether it be unknown or from leading "experts". In the case of BEG foods, when veterinarians ask their clients what do you feed your dog? The veterinarian should not be quick to respond with, "change the food if they are on a grain-free food because it causes heart disease or DCM". Especially, when there is no data to support the change. Nor would there be a reason to change a food in an otherwise healthy dog. Nor if it is simply a client's lifestyle choice.