



July 26, 2019

Dr. Kurt J. Matushek, Editor-in-Chief
Journal of the American Veterinary Medical Association
VIA E-MAIL: KMatushek@avma.org

Dear Dr. Matushek:

This letter and its enclosures concern a recent article authored by L.M. Freeman et al., which was published as a "Commentary" in the December 1, 2018 edition of *JAVMA*.¹ The article is entitled "Diet-Associated Dilated Cardiomyopathy in Dogs: What Do We Know?" For two distinct but equally important reasons, the article should be retracted immediately.

The first is that the article does not meet *JAVMA*'s high editorial standards. As the Committee for Publication Ethics (COPE) has explained, retraction is "a mechanism for correcting the literature and alerting readers to publications that contain such seriously flawed or erroneous data that their findings and conclusions cannot be relied upon."² As explained more fully in **Exhibit A** hereto, these are precisely the circumstances found here. The article grossly mischaracterizes the evidence surrounding its subject, it relies on anecdotes and conjectures instead of evidence for its most basic assumptions, it misrepresents studies that were unpublished at the time it went to print, it was written by authors with clear financial incentives to promote its main conclusions (regardless of their veracity), and those authors cleverly managed to avoid the peer-review process by improperly labeling their article a "Commentary," when in reality it is an evidence review (and is being treated as such by its readers), not an op-ed.

As explained more fully in **Exhibit B** hereto, retraction is also necessary because the article is defamatory to dozens of companies, including one of which I am the Chairman and CEO. The article's authors repeatedly assert that so-called "BEG" ("boutique," "exotic ingredient," and "grain-free") pet foods are "apparently associated" with canine DCM. This is a false statement of fact, because there is no peer-reviewed evidence suggesting any such association. In reality, no

¹ <https://avmajournals.avma.org/doi/full/10.2460/javma.253.11.1390>

² https://publicationethics.org/files/retraction%20guidelines_0.pdf

study has ever been performed suggesting that any of “boutique,” “exotic-ingredient,” or “grain-free” pet foods are correlated with higher rates of canine DCM than other pet food products. In the months since the popular article was published, my company has suffered significant financial damage as consumers have abandoned our products *en masse* due to concerns over their “apparent association” with canine DCM—an association for which there is zero evidentiary support. Accordingly, if the defamatory article is not retracted immediately, my company (and, in all likelihood, dozens of others that produce “BEG diets”) will have no choice but to seek other legal recourse.

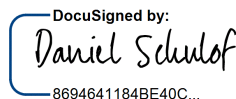
In addition to the two aforementioned exhibits, I have also included five additional enclosures that are relevant to this matter. **Exhibit C** and **Exhibit D** outline suspicious methodological irregularities present in each of two DCM studies recently published elsewhere by two of the subject article’s authors (DAA and JAS). **Exhibit E** is a list of veterinarians, animal scientists, and lay pet owners who endorse one or both of the grounds for retraction set forth here. **Exhibit F** is a copy of a federal lawsuit I filed today (acting in my personal capacity) against the Food and Drug Administration over its conduct in a related investigation into the dietary causes of canine DCM. And **Exhibit G** is a brief sampling of the many public websites where the article’s false and damaging statements are being regurgitated.

I wish to emphasize that expediency is of paramount importance in this matter. As you know, with more than 80,000 downloads in the past eight months, the subject article is by far the most popular piece of writing to be published in *JAVMA* over the past year. (It has been downloaded nearly ***four times*** as often as any other piece of writing to feature in the journal over the past twelve months.) The falsehoods it contains have been repeated time and again on websites and at veterinary clinics across the country (**Exhibit G** is a collection of just a few examples), with more coming into public view every day. To mitigate the ongoing damages being caused, it is imperative that retraction be affected immediately.

Finally, please note that I have also sent courtesy copies of this letter and its enclosures to the editors-in-chief of the journals where the studies discussed in Exhibits C and D were published, as well as the research ombudsmen at the FDA’s Center for Veterinary medicine and the five institutions where the authors of the subject article were employed at the time of publication (Tufts University, the University of California at Davis, the University of Illinois, and North Carolina State University).

Please do not hesitate to contact me if you have any questions.

Sincerely yours,

DocuSigned by:

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EXHIBIT A

LETTER DEMANDING RETRACTION DUE TO FAILURE TO COMPLY WITH EDITORIAL STANDARDS

Re: Retraction of Evidence Review Article Misabeled as a “Commentary” Due to Its Failure to Comply With JAVMA’s Editorial Standards

This letter concerns a recent article authored by L.M. Freeman et al., which was published as a “Commentary” in the December 1, 2018 edition of *JAVMA*.³ The article is entitled “Diet-Associated Dilated Cardiomyopathy in Dogs: What Do We Know?” For the reasons explained in this letter, the article should be retracted.

As the Committee for Publication Ethics (COPE) has explained, retraction is “a mechanism for correcting the literature and alerting readers to publications that contain such seriously flawed or erroneous data that their findings and conclusions cannot be relied upon.”⁴ According to COPE, retraction should be invoked in cases of clear evidence of unreliable findings. This is such a case.

I am moved to write this letter for three reasons. As the author of a recent book about bad science and conflicts of interest in the veterinary nutrition community,⁵ I am one of relatively few key opinion leaders positioned to recognize the various problems outlined below. Additionally, as the CEO of a company whose products are unfairly maligned by the false and disparaging statements of fact made by the article’s authors,⁶ I am obligated to pursue mitigation of the financial and reputational damages my business is suffering as a result of the article.

Most importantly, as a pet owner myself, I am compelled to do what I can to ensure that the leading veterinary science journal on the planet adheres to the very highest standards of credibility and integrity.

1. Despite Purporting to Review What is “Known” About Its Subject, the Article Was Allowed to Evade the Peer-Review Process Because It Was Improperly Presented to JAVMA as an Opinion-Based “Commentary”

As you know, per its editorial policies *JAVMA* typically limits so-called “Commentaries” to “opinion-based articles.” Because these articles primarily concern matters of opinion, and not fact, they are not usually sent for external peer-review.

But despite being presented to *JAVMA* as a Commentary, the subject article explicitly concerns itself with a factual matter: a review of “what is currently *known* about the possible association between certain diets and DCM in dogs” (emphasis mine). It is not a personal essay or professional perspective on a major news item; it is overview of the evidence (what is “known”) about a specific medical topic. Such an article should have been presented to *JAVMA* as a

³ <https://avmajournals.avma.org/doi/full/10.2460/javma.253.11.1390>

⁴ https://publicationethics.org/files/retraction%20guidelines_0.pdf

⁵ *Dogs, Dog Food, and Dogma: The Silent Epidemic Killing America’s Dogs and the New Science That Could Save Your Best Friend’s Life*. Present Tense Press, 2016.

⁶ KetoNatural Pet Foods, Inc. We produce so-called “BEG” diets. Although none of our customers has ever reported a dog developing DCM while eating one of our foods, our business has suffered and is continuing to suffer real financial and reputational harm as a result of the subject article.

“Viewpoint” article—as evidence review articles typically are—and therefore been subjected to external peer-review, per *JAVMA*’s editorial policies.⁷

But the article was not peer-reviewed and, as a result, it contains numerous factual errors, material omissions, and mischaracterizations of the evidentiary record surrounding its primary subject (i.e., what is “known” by the scientific community about the links between diet and dilated cardiomyopathy in dogs). Had the article been submitted for peer-review, these flaws likely would have been identified and the manuscript would either have been altered significantly or simply denied publication altogether. However, despite purporting to review what facts are “known” about potential links between canine DCM and diet, the article was presented to *JAVMA* as an opinion-based “Commentary” instead, and therefore allowed to avoid the peer-review process under *JAVMA*’s editorial guidelines.

Because the article so fundamentally misrepresents the actual evidentiary record surrounding its subject, the only appropriate course of action is to retract it.

2. There is No Evidence That DCM Cases Involving Dogs (Diet-Related or Otherwise) Are Increasing in Frequency

The subject article is purportedly justified by its authors’ observation that “over the past few years, an increasing number of DCM cases involving dogs appear to have been related to diet.” But no evidentiary support is cited for this factual proposition and my good-faith efforts to investigate the matter (which include interviews with several of the article’s authors, interviews with other board-certified veterinary nutritionists, interviews with authors of other scholarly papers concerning DCM, and an interview with a representative of the FDA-CVM), suggest that none presently exists. The assertion is based entirely on anecdotal observation and conjecture.

Of course, conjectures play an important role in the professional practice of science. But that role is limited to hypothesis development. Unless conjectures are subsequently tested and validated, they do not constitute an evidentiary basis for factual assertions.

This is of heightened importance in matters of nutritional science. As the authors of the subject article correctly note, “[t]he complexity of pet food manufacturing is often underestimated.” Casual reliance upon anecdotal reports is particularly risky when evaluating potential associations between complex nutritional formulations and specific health outcomes.

At present, the notion that DCM cases involving dogs (diet-related or otherwise) are increasing in frequency is nothing but a reasonable-sounding hypothesis. While studies testing the hypothesis would be timely and informative, they simply have not been performed. At the very least, the authors should have explicitly highlighted this lack of evidence in their article.

⁷ An article entitled “Special Topic: The Association Between Pulse Ingredients and Canine Dilated Cardiomyopathy: Addressing the Knowledge Gaps Before Establishing Causation,” was published earlier this year in the *Journal of Animal Science*. Like the subject article, it purports to review the relevant evidentiary record to determine what is known (and what isn’t) about dietary causes of canine DCM. But unlike the subject article, the *Journal of Animal Science* article **was** peer-reviewed. Surely it is no coincidence that this other article provides a far more accurate and fair representation of the evidence surrounding the link between DCM and diet than the subject article does.

But when an article is as high-profile as this one is (according to its own website, this is **by far** the most widely read article published in *JAVMA* over the last twelve months⁸), and it purports to review what is “currently known” about canine DCM, readers fairly assume that there is valid evidence suggesting that the disease has become more common in recent years. As this clearly is not the case, it would be more appropriate for the article to be retracted wholesale.

Interestingly, the subject article hardly mentions the evidence concerning actual DCM rates in dogs. Although the issue has received only limited attention, the best available evidence suggests that DCM currently impacts at most 1-2% of dogs.⁹ And, as the authors note, recent evidence suggests that diet appears to be a factor in only about 16% of those cases.

The relative rarity of canine DCM is underscored by the findings of the FDA-CVM, which received only 273 reports of canine DCM in the six months after issuing a highly-publicized public notification about the matter in July 2018 (the notification was amplified by national news coverage in outlets including the *New York Times*).¹⁰ Annualized, this represents perhaps 500 dogs per year, or less than 1 out of every 175,000 dogs in the United States. (According to *National Geographic Magazine*,¹¹ the odds of being struck by lightning during one’s lifetime—1 in 3,000—are about **sixty times greater**.)

In other words, here is “what we know” about rates of diet-associated DCM in dogs: (1) the best available evidence suggests that dogs have only a miniscule risk of developing diet-associated DCM and (2) there is no evidence that risk is increasing.

3. There Is No Evidence That DCM Is More Common in Dogs Fed So-Called “BEG” Diets

The central message of the subject article is that there is a suspicious correlation between so-called “BEG” diets and higher rates of canine DCM, but that a causal relationship between the two has not yet been established. This message is communicated throughout the article,¹² but is exemplified by the following excerpt:

“[T]he apparent link between BEG diets and DCM may be due to the grain-free nature of these diets ... possible nutritional imbalances, or inadvertent inclusion of toxic dietary components. Or, the apparent association may be spurious.”

This passage is typical of how the authors have chosen to portray the supposed link between BEG diets and DCM. In lay terms, “it looks like there’s a link, but we can’t be 100% sure just yet.”

⁸ <https://avmajournals.avma.org/action/showMostReadArticles?journalCode=javma>

⁹ See, e.g., Hogan and Green, “Dilated Cardiomyopathy in Dogs” in *Kirk’s Current Veterinary Therapy XIV*. Elsevier 2009 (dilated cardiomyopathy represents only 13.6% of all cardiac cases in domestic dogs).

¹⁰ <https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm630993.htm>

¹¹ <https://news.nationalgeographic.com/news/2004/06/flash-facts-about-lightning/>

¹² See, e.g., “Subjectively, it also appeared that these [DCM-diagnosed] dogs were frequently eating BEG diets...”; “... it appears that many dogs in both groups have been eating BEG diets...”; “... taurine deficiency should be considered as a possibility not just in dogs eating BEG ...”; etc.

There's just one problem: ***there isn't any evidence that BEG diets are associated with an increased risk of canine DCM.*** This is not to say that the studies suggesting a link are methodologically flawed or inconclusive; it is to say that there is literally ***no scientific evidence whatsoever.*** Not a single study has ever been conducted finding correlation between the two variables, let alone establishing some kind of causal relationship.

The entire basis for the “apparent link” between BEG diets and canine DCM are the subjective observations of unspecified practicing cardiologists. As explained above, it is wholly inappropriate to characterize such unsystematic observations as evidence of what is “known” about a phenomenon, particularly in the complex realm of nutritional science. As such, it is tremendously misleading for the authors to suggest that a “link” or “association” between BEG diets and canine DCM has been shown.

The limp qualification that this link is only “apparent” does not render these statements any less misleading. In total, the authors reference “BEG diets” ***seventeen times*** in their short article. The clear implication is that this entire category of products should be viewed as suspect but that an abundance of scientific prudence prevents the authors from making a more definitive statement.

Had the subject article been subjected to external peer-review, the lack of evidence suggesting a link between “BEG diets” and canine DCM would surely have been identified by reviewers. And given the centrality of this issue to the article as a whole, publication in anything resembling its current form would be highly unlikely. At this juncture, however, the only reasonable option is for the article to be retracted.

4. The Article's Unjustified Focus on “BEG Diets”

Despite being used seventeen times throughout the subject article, the expression “BEG diet” is not a commonly-used term of art in the pet food industry. Indeed, outside of work published by one or more of the authors of the article, I have not once seen it used elsewhere in the relevant scholarly literature. The term appears to have been coined by the authors themselves.

Collectively, the term “BEG Diets” refers to a massive group of products. Industry analyses¹³ suggest that 44% of the pet food products sold in America today are “grain-free.” But foods made by so-called “boutique” manufacturers and foods containing “exotic ingredients” (defined by the authors to include such commonplace foodstuffs as salmon, lamb, peas, and lentils) are not necessarily grain-free. As such, ***the majority of the pet foods sold in the country today likely fall into the category “BEG diets.”***

The popularity of these products demonstrates the risk inherent in relying on anecdotal observations as evidence in nutritional science matters. If more than half of the pet foods in the country are properly classified as “BEG diets,” ***one should fully expect most DCM-positive dogs to be eating them, even if there is no relationship whatsoever between the diets and the disease.*** As the article's authors surely know, commonality and correlation are not the same thing—correlation suggests a potential association, commonality does not.

Moreover, “BEG diets” represent a much larger group of products than the group identified by the FDA-CVM in connection with its ongoing investigation of potential links between diet and canine DCM. Thus far, the FDA's investigation is focused on “certain pet foods containing peas,

¹³ <https://www.nytimes.com/2018/07/24/health/grain-free-dog-food-heart-disease.html>

lentils, other legume seeds (pulses, and/or potatoes).” The authors make no attempt to explain why their article casts aspersions upon a far larger group of products than the FDA, when there is no scientific evidence justifying such a shift.

5. The Authors Mischaracterize Their Own Studies Concerning Diet-Associated DCM By Omitting Material Facts Concerning Those Studies

The subject article also references studies recently conducted by two of its authors (JAS and DAA) as evidence for the idea that “BEG diets” are associated with canine DCM. But a closer examination of these studies—neither of which was published prior to the subject article—reveals that the authors have mischaracterized their work by failing to disclose material facts that contradict the underlying message of the subject article.

These mischaracterizations-by-omission include the following:

- Dr. Stern’s recent paper¹⁴ did not include a finding of correlation between canine DCM and any of boutique diets, exotic-ingredient diets, grain-free diets, or “BEG diets” as a collective group. The authors of the Commentary failed to disclose this important fact in their article.
- Dr. Stern’s recent paper also did not include a finding of correlation between diet change and improved clinical status. In his study, all dogs that improved after switching diets **also received taurine supplementation**. Because taurine supplementation alone has commonly been shown to improve clinical status in dogs with DCM, Dr. Stern’s study design could not demonstrate that switching diets precipitated clinical improvement. The authors of the subject article also failed to disclose this important fact to readers.
- Despite evaluating a host of variables associated with the diets consumed by the DCM-positive dogs in their study, Dr. Stern and his colleagues curiously chose not to analyze the cyst(e)ine and methionine content of the various diets, despite the sizable body of existing evidence linking inadequate cyst(e)ine/methionine intake by dogs and both taurine deficiency and DCM. The authors of the subject article failed to disclose that Stern and his colleagues did not control for this common explanation for DCM in connection with their study. (Had they performed such an analysis, Stern and his colleagues likely would have found that the vast majority of the DCM-positive dogs in the study were indeed consuming less than the National Research Council’s recommended daily allowance for one or both of these DCM-linked amino acids.¹⁵)
- In a poster presentation also cited in the subject article,¹⁶ Dr. Adin and colleagues evaluated the dietary histories of 49 dogs diagnosed with DCM at North Carolina State University between 2015 and 2017. But the authors of the subject article failed to mention that only 22 of the DCM-positive dogs discussed in the presentation (~45%) were eating grain-free diets at the time of diagnosis, while 27 of them (~55%) **were eating grain-based diets**. This fact is all the more important—and its omission is all the

¹⁴ <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209112>

¹⁵ Unlike Dr. Stern and his colleagues, I have engaged an independent laboratory to determine the cyst(e)ine and methionine content of the various diets consumed by the DCM-positive dogs in their study. According to those results and the food intake data reported by Stern and his colleagues in their paper, the vast majority of the DCM-positive dogs in the study **do** indeed appear to have been consuming less than the National Research Council’s recommended daily allowance for one or both of these DCM-linked amino acids—a fact which might well explain their DCM diagnoses. A more detailed explanation of my work can be found in **Exhibit C**.

¹⁶ <https://eventscribe.com/2018/ACVIM/fsPopup.asp?Mode=PresInfo&PresentationID=393940>

more glaring—because the percentage of DCM-positive dogs eating grain-free diets aligned nearly perfectly with the percentage of the U.S. pet food market occupied by grain-free diets overall.¹⁷

- As with Dr. Stern's study, Dr. Adin's study was not designed to determine whether diet change alone was associated with improved clinical status because, like in Dr. Stern's study, all DCM-positive dogs that saw clinical improvement after a diet change (with a single exception) **also received taurine supplementation**.

6. Financial Conflicts of Interest

Notably, the authors of the subject article have benefited from financial support supplied by Hill's Pet Nutrition, Nestle-Purina Petcare, and Mars Petcare, three of the world's largest pet food companies. Some of these financial conflicts of interest were disclosed to the article's readers, while others were not.

This fact is relevant to the present inquiry because these "Big Three" pet food companies all have a direct financial interest in suppressing the popularity of "BEG" pet food products. Obviously, none of these large companies could be called a "boutique" producer. Less obviously, unlike most modern pet food producers, the vast majority of Hill's, Purina, and Mars products both (1) contain grains and (2) don't contain so-called "exotic" ingredients.¹⁸ In other words, if the market for "BEG" products were to suddenly disappear, Mars Petcare, Nestle-Purina Petcare, and Hill's Pet Nutrition would all benefit handsomely.

This is underscored by a shadowy website called "Taurine + DCM" (www.taurinedcm.org),¹⁹ which was anonymously created earlier this year, supposedly to provide dog owners with information about DCM. According to the website, there are only four pet food brands **anywhere in the world** that aren't implicated by the "apparent link" between BEG products and DCM: Hill's, Purina, Royal Canin, and Eukanuba (Royal Canine and Eukanuba are both owned by Mars Petcare).

In connection with the subject article, the primary author (LMF) disclosed financial conflicts of interest will **all** of Hill's, Purina, and Royal Canin. Another of the article's five authors (JER)

¹⁷ Interestingly, in the final version of this study, published this February in the *Journal of Veterinary Cardiology*, the number of DCM-positive dogs consuming grain-based diets at the time of diagnosis suddenly **dropped from 27 to 12**, increasing the relative prevalence of grain-free diets in the final study group from 45% of subjects to 75% of subjects. Dr. Adin told me that these 15 grain-consuming dogs were dropped from the final study due to not having "airtight diet histories." But, in comparison, **only one dog** consuming a grain-free diet at the time of diagnosis was dropped from the final study group for the same reason. This vast difference in exclusion rates cannot be explained by random chance, as I explain in detail in **Exhibit D**.

¹⁸ On its website, Hill's goes so far as to call grains "super foods." (<https://www.hillspet.com/dog-care/nutrition-feeding/grain-free-dog-food>).

¹⁹ It is not immediately clear from the site itself, its copyright notice, or the domain registration associated with the site exactly who created it. Interestingly, however, the site (1) uses the same "BEG diet" language echoed throughout the subject article, (2) links to the subject article and other studies and blog posts written by its authors (but not the aforementioned evidence review published in the *Journal of Animal Science*), (3) recommends only pet food products produced by Hill's, Purina, Royal Canin, and Eukanuba, and (4) features a host of "Myth or Fact?" marketing flyers created by Nestle-Purina Petcare.

disclosed financial conflicts of interest with Purina and Royal Canin. And another (DAA) disclosed financial conflicts of interest with only Purina.

But undisclosed financial conflicts of interest seem to exist here as well.

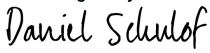
The Morris Animal Foundation is a 501(c)(3) organization created by Mark L. Morris, Sr., the founder of Hill's Pet Nutrition. As of 2017, Morris's grandson, David, was the vice-chair of the organization's board of trustees. Its chairman was a high-ranking Hill's executive for more than a decade. As of 2017, other Hill's-affiliated individuals were still sitting on the board of trustees as well.

In 2017, the Morris Animal Foundation provided substantial funding to research institutions where **four of the five authors** were employed at the time the subject article was written. That year alone, the organization gave \$231,479 to North Carolina State University (DAA), \$94,883 to Tufts University (LMF and JER), and \$150,299 to the University of California at Davis (JAS).²⁰

In addition, information made available to me pursuant to the California Public Records Act reveals that Royal Canin, Hill's Pet Nutrition, Nestle-Purina Petcare, and the Morris Animal Foundation have all donated money (collectively, more than \$1,000,000) to the veterinary school at the University of California Davis (JAS) since January 2017.

The subject article is premised almost entirely upon factual assertions for which there is no scientific evidence. It mischaracterizes studies performed by its authors that were not published until after the Commentary itself. It was not peer-reviewed and its authors have significant financial ties to organizations with a vested interest in spreading its message, regardless of whether that message is factually accurate. In order to preserve *JAVMA's* credibility, mitigate the financial and reputational damage caused to all manufacturers of "BEG diets" by the article, and foster truth and fairness in the professional practice of science, I urge you to retract the subject article immediately.

Sincerely yours,

DocuSigned by:

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Daniel G. Schulof

²⁰ <https://www.morrisanimalfoundation.org/sites/default/files/files/2019-02/6.30.18%20FORM%20990%20PUBLIC%20DISCLOSURE%20COPY.pdf>

EXHIBIT B

LETTER DEMANDING RETRACTION DUE TO UNLAWFUL DEFAMATION

Re: Retraction of Defamatory Article Causing Financial and Reputational Damage to Producers of So-Called “BEG Diets”

This letter concerns a recent article authored by L.M. Freeman et al., which was published as a “Commentary” in the December 1, 2018 edition of *JAVMA*.²¹ The article is entitled “Diet-Associated Dilated Cardiomyopathy in Dogs: What Do We Know?” For the reasons explained in this letter, the article should be retracted immediately.

1. The False Statement of Fact: There is an “Apparent Link” Between “BEG Diets” and an Increased Risk of Canine DCM

One of the central messages of the subject article is that there is evidence of a suspicious correlation between so-called “BEG diets” and higher rates of canine DCM. This message is communicated throughout the article (the authors reference “BEG diets” a total of **seventeen times**),²² but is exemplified by the following excerpt:

“[T]he apparent link between BEG diets and DCM may be due to the grain-free nature of these diets ... possible nutritional imbalances, or inadvertent inclusion of toxic dietary components. Or, the apparent association may be spurious.”

There is no scientific evidence that BEG diets are associated with an increased risk of canine DCM. This is not to say that the studies suggesting a link are methodologically flawed or inconclusive; it is to say that there is literally **no scientific evidence whatsoever**. Not a single study has ever been conducted finding correlation between the two variables, let alone establishing some kind of causal relationship.

This undeniable fact renders any reference to an “apparent link” between “BEG diets” and canine DCM demonstrably false, particularly when it comes in the pages of an esteemed scientific journal such as *JAVMA*. *JAVMA*’s readership reasonably expects statements of fact concerning what appear to be links, associations, or correlations between health outcomes and other variables to be grounded in valid scientific evidence of such associations—not mere anecdotes and conjectures. And, as the images compiled in **Exhibit G** hereto demonstrate, that is precisely how readers (even sophisticated ones) are interpreting the subject article’s references to an “apparent link” between “BEG diets” and DCM.

Ordinarily, the peer-review process functions to ensure that factual assertions contained in scholarly articles are supported by the relevant evidentiary record. In this way, the peer-review process functions as a safe harbor for academic publishers, insulating them against claims of defamation when their articles contain false statements.

In this case, however, **the subject article was not subjected to external peer-review**. Despite explicitly concerning itself with the factual question of what is “known” about the subject of diet-associated DCM, the article was, rather suspiciously, submitted to *JAVMA* as an opinion-based “Commentary” instead. As you know, under its editorial policies, *JAVMA* does not ordinarily

²¹ <https://avmajournals.avma.org/doi/full/10.2460/javma.253.11.1390>

²² See, e.g., “Subjectively, it also appeared that these [DCM-diagnosed] dogs were frequently eating BEG diets...”; “... it appears that many dogs in both groups have been eating BEG diets...”; “... taurine deficiency should be considered as a possibility not just in dogs eating BEG ...”; etc.

subject Commentaries to external peer-review. In most cases, this is a perfectly sensible policy, since matters of opinion reflect value judgments whose cogency does not depend upon evidentiary support. Unfortunately, in the present case this eminently reasonable policy appears to have been abused by the article's authors, who have shoe-horned false factual statements into what should have been exclusively an opinion-based article.

2. Evidence of the Authors' Reckless and Malicious Intent in Making Their False Statement of Fact

The term "BEG diet" is not a commonly-used term of art in the pet food industry. In fact, it appears that the authors of the subject article coined it themselves. And, because the term has never been used before in the peer-reviewed literature concerning canine DCM, it is clear that it was chosen by its authors for some other reason.

The evidence (circumstantial but abundant) suggests that reason was to negatively influence sales of "BEG diets."

With one exception (RCF), all of the authors of the subject article have financial ties to one or more of Hill's Pet Nutrition, Nestle-Purina Petcare, and Mars Petcare, three of the world's largest pet food companies. These conflicts of interest, discussed in greater detail in Section 6 of **Exhibit A** hereto, run into the millions of dollars.

These "Big Three" pet food companies have something else in common: the vast majority of their products do not qualify as "BEG diets." In fact, the only pet food companies in the world that make products other than "BEG diets" seem to be Hill's, Purina, and Mars. As such, the term "BEG diets" could accurately be defined as "pet food products made by companies other than Hill's, Purina, and Mars." It strains credulity to suggest that this is merely a coincidence.

There is also evidence of suspicious methodological irregularities in empirical studies which were conducted by the authors and cited in their article, but which were not published until *after* the subject article went to press. These irregularities, described in detail in **Exhibit C** and **Exhibit D** hereto, all served to make a "link" between BEG diets and canine DCM seem more "apparent." Again, it strains credulity to suggest that this too is a coincidence.

Last but not least, the authors' intent reveals itself when we consider their article against other recent scholarly work on the subject of diet-associated canine DCM. Just weeks after the subject article was published, the *Journal of Animal Science* published another evidence review on the relationship between diet and canine DCM, this one written by a collection of American and Canadian animal scientists. If you haven't done so already, I urge you to read it—you'll see that it provides an undeniably nuanced, rigorous, and serious look at the evidence surrounding its subject. And you'll surely notice that the term "BEG diet" is not used a single time in the article. Again, could it really be a coincidence that this group of earnest scientists evidently considered the conceptual lynchpin of the subject article totally irrelevant to their own analysis?

3. Financial and Reputational Damages Caused by the False Statement of Fact

The false statement that "BEG diets" are "apparently linked" to canine DCM has inflicted clear and easily-defined financial and reputational injuries upon a pet food company of which I am the founder and CEO, KetoNatural Pet Foods, Inc.

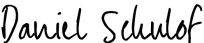
The subject article has already been downloaded more than 40,000 times, making it by far the most popular article to be published in *JAVMA* in the past year. Moreover, its false message has been disseminated even further by veterinary clinicians, mainstream media organizations, and popular social media accounts (see **Exhibit G** hereto).

Predictably, its message has trickled down to the pet-owning public, including our customers. KetoNatural is not mentioned by name in the subject article, but our products clearly qualify as “BEG diets”: we are a startup with less than two years of sales history (“boutique”), our recipes feature a limited amount of peas (an “exotic” ingredient), and our recipes don’t feature grains (“grain-free”). In the months since the subject article was published, we have received a litany of communications from customers concerned about the “apparent link” between our products and canine DCM. And many of these customers have decided to abandon our products altogether due to these innocently misguided concerns.

Based on the sheer number of such communications, my preliminary estimate is that these losses already amount to at least 10% of our annual sales. KetoNatural Pet Foods is a relatively small company, with annual sales under \$10 million. But if far larger makers of “BEG diets,” such as Blue Buffalo and Champion Pet Foods, are experiencing relative losses similar to ours, it is likely that their damages already run well into the ***hundreds of millions of dollars***.

I urge you to retract the subject article immediately.

Sincerely yours,

DocuSigned by:

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Daniel G. Schulof

EXHIBIT C

KAPLAN, JL, ET AL. (2018) "TAURINE DEFICIENCY AND DILATED CARDIOMYOPATHY IN GOLDEN RETREIVERS FED COMMERCIAL DIETS." *PLOS ONE* 13(12): E0210233

COMMENT CONCERNING METHODOLOGICAL IRREGULARITIES

In a popular article published in *JAVMA* last December, the above-referenced paper was held up by one of its authors (JAS) and other prominent veterinarians as evidence of an “apparent association” between canine DCM and so-called “BEG” (“boutique, exotic-ingredient, or grain-free”) pet foods. (Freeman, L.M., et al. (2018) “Diet-Associated Dilated Cardiomyopathy in Dogs: What Do We Know?” *J. Am. Vet. Assoc.* 253(11):1390-94.)

News of this “apparent association” has transcended the veterinary nutritional science community, receiving coverage in major media outlets, sparking alarm among pet owners, and even attracting the attentions of the US Food and Drug Administration.

This is surprising for numerous reasons. First of all, the authors of the present study did not actually find a correlation between BEG diets and an increased risk of DCM. Moreover, the authors did not propose any mechanism by which some quality shared by all “BEG diets” (a category likely including more than half of the pet foods sold in the United States today) might plausibly be said to be causing the condition. There is not even any peer-reviewed evidence that canine DCM has become more common in recent years, despite the authors’ assertion here that there has recently been “a surge in cases.”

But even if all of that is put aside, there is still another issue which the authors should be obligated to explain: why didn't they analyze their subjects’ diets for cyst(e)ine and methionine content?

There is already voluminous evidence linking inadequate cyst(e)ine and methionine intake with taurine deficiency and DCM in dogs. The mechanism through which the deficiency brings about the disease is well-understood and is highlighted in every leading veterinary nutrition textbook. Indeed, it is a key reason why cyst(e)ine and methionine are considered indispensable (“essential”) amino acids for dogs and the primary reason why both the AAFCO and NRC canine nutrient profiles include minimum daily intake requirements for both cyst(e)ine and methionine.

It is therefore surprising that the authors, several of whom work at the Amino Acid Laboratory at the University of California at Davis (one of the preeminent amino acid laboratories in the country), decided not to analyze the cyst(e)ine and methionine content of the diets being consumed by their DCM-positive subjects, particularly before proposing a novel theory about the “apparent association” between canine DCM and a diverse category of products that makes up at least half of the U.S. pet food market.

(The authors note in their paper that cyst(e)ine and methionine content were not considered because this information “was not made available by the diet manufacturers.” But this explanation seems at best incomplete, considering that the UC Davis Amino Acid Laboratory regularly performs this analysis for commercial customers at a rate of less than \$150/sample.)

Had they conducted such an analysis, the authors likely would have found that the significant majority of the DCM-positive dogs in their study were indeed consuming less than the NRC’s recommended daily allowance of methionine and/or cyst(e)ine/methionine.

I know this because I performed such an analysis myself. I commissioned an independent, third-party laboratory (Midwest Laboratories, Omaha, NE) to determine the cyst(e)ine and methionine content of the diets being fed to 20 of the 24 DCM-positive dogs in the study (I was not able to acquire samples of the others). The analytical method used was performic acid oxidation/acid hydrolysis (AOAC 994.12).

While testing revealed that all of the analyzed diets met AAFCO's minimum requirements for cyst(e)ine and methionine content, many did so only barely. This is notable because, in the present study, the authors also determined the extent to which their DCM-positive subjects were being overfed, underfed, or fed an appropriate amount by their owners. ***And they found that most dogs were not being fed nearly as much food as they ought to have been.***

Applying their data on this subject to the cyst(e)ine and methionine data produced by Midwest Laboratories, it becomes clear that 60-80% of the DCM-positive dogs in the study seem to have been consuming less than the NRC's recommended daily allowance of methionine or cyst(e)ine/methionine. A summary of these data, original test results from Midwest Laboratories, and other supporting documents can be found in a public document repository accessible via the following link:

www.veterinaryintegrity.org

These new data suggest that, if diet was in fact contributing to the development of DCM among the dogs in this study, then it was because the animals were being underfed, not because their diets were "grain-free," were produced by a so-called "boutique" producer, or contained a so-called "exotic" ingredient.

In the interests of promoting transparency and rigor in the practice of nutritional science, it is critical that the authors address these new findings and explain why cyst(e)ine and methionine content were not analyzed in the first place. Despite not finding any correlation between DCM and consumption of "BEG" diets, their study is nevertheless being held up as evidence of an "apparent association" between such diets and DCM. This "apparent association" was highlighted by one of the present paper's authors (JAS) in a prominent article he co-authored for *JAVMA*. The issue has also received major media attention and spawned a prominent FDA investigation, both of which seem to have been encouraged (if not precipitated) by one or more of the present study's authors.

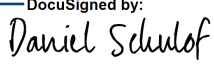
There is another reason why the authors should feel obligated to address the issues raised above. Although in the conflict of interest disclosure statement associated with the present study, its authors claim to have received "no specific funding" for their work, information disclosed to me pursuant to the California Public Records Act shows that the University of California at Davis itself has received more than \$1 million in funding from Hill's Pet Nutrition, Mars Petcare, Nestle-Purina Petcare, and the Morris Animal Foundation (a 501(c)(3) organization created by the founder of Hill's Pet Nutrition) since January 2017. Related documentation can be found in the document repository linked above.

This fact is relevant to the present inquiry because these "Big Three" pet food brands all have a direct financial interest in suppressing the popularity of "BEG" pet food products. Obviously, none of these large companies could be called a "boutique" producer. Less obviously, unlike most modern pet food producers, the vast majority of Hill's, Purina, and Mars products both (1) contain grains and (2) don't contain so-called "exotic" ingredients.

This is underscored by an anonymous public website called "Taurine + DCM" (www.taurinedcm.org), which was created earlier this year in order to provide dog owners with information about DCM. According to the website, there are only four pet food brands ***anywhere in the world*** that aren't implicated by the "apparent association" between BEG products and

canine DCM: Hill's, Purina, Royal Canin, and Eukanuba (Royal Canin and Eukanuba are both owned by Mars Petcare).

In other words, the authors have clearly benefited from the largesse of companies with a financial interest in publishing studies suggesting an “apparent association” exists between “BEG diets” and canine DCM. The public ought to understand whether the underlying data actually suggests an alternative explanation.

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Daniel G. Schulof

EXHIBIT D

ADIN, DAA, ET AL. (2019) "ECHOCARDIOGRAPHIC PHENOTYPE OF CANINE DILATED CARDIOMYOPATHY DIFFERS BASED ON DIET TYPE." *JOURNAL OF VETERINARY CARDIOLOGY* 21:1-9.

COMMENT CONCERNING DATA IRREGULARITIES

In a popular article published in *JAVMA* last December, the present study was held up by Dr. Adin and others as evidence of an “apparent association” between canine DCM and so-called “BEG” (“boutique, exotic-ingredient, or grain-free”) pet foods. (Freeman, L.M., et al. “Diet-Associated Dilated Cardiomyopathy in Dogs: What Do We Know?” *J. Am. Vet. Assoc.* 2018; 253(11):1390-94.)

News of this “apparent association” has transcended the veterinary nutritional science community, receiving coverage in major media outlets, sparking alarm among pet owners, and even attracting the attentions of the United States Food and Drug Administration.

This is surprising for numerous reasons. First of all, the authors of the present study did not actually find correlation between BEG diets and an increased risk of canine DCM (nor has anyone else). Moreover, the authors did not propose any mechanism by which some quality shared by all “BEG diets” (a category likely including ***more than half of the pet foods sold in the United States today***) might plausibly be said to be causing or exacerbating the condition. There is not even any peer-reviewed evidence that canine DCM has become more common in recent years, despite an assertion to the contrary in the present study.

However, even if all of that is temporarily put aside, the authors are still obligated to explain a troubling facet of their work: why were DCM-positive dogs fed grain-based (GB) diets excluded from their study group at a far higher rate than DCM-positive dogs fed grain-free (GF) diets?

The significance of this question can only be properly understood after a brief overview of the relevant timeline associated with the present study.

Preliminary data from the study were presented by Dr. Adin at the 2018 ACVIM Forum. At that time, the data set only included dogs diagnosed with DCM at North Carolina State University from 2015 to 2017. This amounted to 49 dogs. According to Dr. Adin, 22 of those DCM-positive dogs (~45%) were consuming GF diets, while 27 of the DCM-positive dogs (~55%) were consuming GB diets.

The final study includes dogs diagnosed with DCM at NCSU over a longer time period (January 1, 2015 to May 1, 2018). But it also excludes DCM-positive dogs that met any of a variety of exclusionary criteria. As a result, only 48 of the 91 dogs diagnosed with DCM at NCSU were included in the final manuscript. Of those, the authors report that 36 of them (75%) were consuming GF diets at the time of diagnosis, while only 12 of them (25%) were consuming GB diets.

In other words, while the number of DCM-positive dogs fed GF diets increased by 14 during the time between the abstract presentation and the final analysis, the number of DCM-positive dogs fed GB diets somehow ***decreased*** by 15.

I noticed this curious phenomenon and asked Dr. Adin for an explanation. She replied that the exclusionary criteria used for the final manuscript were more exacting than those used for the abstract. Specifically, dogs without an “airtight diet history” may have been included in the preliminary presentation but they were excluded from the final data set.

On its face, this appears to be a reasonable explanation for an otherwise-bizarre data point. But a closer look reveals a further anomaly that belies Dr. Adin’s explanation. Although 15 of the 27 GB dogs from the preliminary data set were excluded from the final data set due to incomplete

dietary history, Dr. Adin reported that far fewer GF dogs—**only 1 of the original 22**—were excluded for the same reason.

It appears that this vast difference in exclusion rates cannot be explained by random chance. Using commercially-available software, I tested the hypothesis that “completeness of dietary history” (yes or no) and “diet type” (GF or GB) are independent variables in this data set, using a Pearson’s X^2 test of independence. The results of that test follow.

Case Processing Summary						
	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Diet type * Completeness of dietary history	49	100.0%	0	0.0%	49	100.0%

Diet type * Completeness of dietary history Crosstabulation

			Completeness of dietary history		Total
			Complete	Incomplete	
Diet type	GB	Count	12	15	27
		Expected Count	18.2	8.8	27.0
		Standardized Residual	-1.5	2.1	
	GF	Count	21	1	22
		Expected Count	14.8	7.2	22.0
		Standardized Residual	1.6	-2.3	
Total	Count	33	16	49	
	Expected Count	33.0	16.0	49.0	

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	14.344 ^a	1	.000	.000	.000
Continuity Correction ^b	12.118	1	.000		
Likelihood Ratio	16.674	1	.000		
Fisher's Exact Test					
Linear-by-Linear Association	14.051	1	.000		
N of Valid Cases	49				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.18.

These results allow us to confidently reject the hypothesis that “completeness of dietary history” and “diet type” are independent variables in the present case. For some reason, GB dogs were far more likely than GF dogs to be excluded from the final study because of an “incomplete dietary history.” The authors need to explain what that reason is.

This need becomes more urgent when some broader context is considered.

The present paper is one of only two examples of recent peer-reviewed studies in which the rate of DCM diagnosis was reported among both GF-fed dogs and GB-fed dogs. Even though the

authors did not find any correlation between GF diets and increased incidence of DCM, their study is nevertheless being held up (by Dr. Adin and others) as evidence suggesting an “apparent association” between the two.

This is only possible because, at first glance, commonality often looks a lot like correlation. Even without an explicit finding of correlation, data suggesting that DCM-positive dogs are **often** fed GF diets might lead a layperson to conclude that a link exists between the two phenomena. Indeed, it appears that Dr. Adin and her *JAVMA* co-authors may have fallen victim to this very logical fallacy, since they repeatedly state that an “apparent association” exists between BEG diets and canine DCM, even though no data suggesting correlation between the two variables has ever been published.

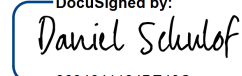
In the preliminary presentation of these study results, the **majority** of DCM-positive dogs were reported to be consuming GB diets. In the final manuscript, that number had dropped to **only 25%**. That feels very different.

The existence of relevant financial conflicts of interest and the potential for bias compounds the gravity of this issue. In the conflicts of interest statement associated with the present study, Dr. Adin disclosed that she has received research support from Nestle-Purina PetCare. Her co-authors on the popular *JAVMA* article also benefited from financial support (both disclosed and undisclosed) from Nestle-Purina, Hill’s Pet Nutrition, and Mars Petcare.

For a host of different reasons (many explained in detail in a letter I also sent to the editors of *JAVMA* today), these “Big Three” pet food companies all stand to benefit handsomely if consumers are led to believe that BEG pet foods pose unique health risks. As such, these companies, one of which funded Dr. Adin’s research, have a strong profit incentive to support research findings in which a comparatively large fraction of DCM-positive dogs are reported to be consuming GF diets.

These are precisely the results we find here. For reasons that cannot be explained by random chance, Dr. Adin and her colleagues excluded far more GB-fed dogs than GF-fed dogs due to concerns over completeness of dietary history. As a result, the relative prevalence of GF diets among the DCM-positive dogs in the study **nearly doubled**.

The authors should explain these unusual findings.

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Daniel G. Schulof

EXHIBIT E

CO-SIGNATORIES

(Approximately 250 copies of draft versions of these materials were disseminated to the attendees of the 2019 American Academy of Veterinary Nutrition Clinical Nutrition & Research Symposium, following a presentation about DCM delivered by Dr. Lisa Freeman, the corresponding author of the subject article. Since dissemination, the draft materials have been co-signed by approximately 200 veterinarians, research scientists, health care professionals, representatives of “BEG” pet food companies, and other interested parties. A brief sample of their comments follows. The complete list of co-signatories is available at the public website www.veterinaryintegrity.org.)

Nancy Anderson: "The reputation of the scientific community is suffering at a time when we need to be able to look to it as a beacon of integrity; instead shoddy methods and motivations such as Freeman's threaten it further. Please do the right thing."

Dr. Sarah Chapman, DVM: "I am disappointed in JAVMA. I expected to see research findings to back up their contentions, but there were none. I would like to know the cause of the DCM problem so that I can rationally advise clients. It is wrong to scare monger clients into feeding mass produced foods with ingredients of lower quality based on loose correlations."

Dr. Laurie Coger, DVM: "Enough is enough! It's time for all veterinarians to look at animal care from a biological viewpoint, rather than a "what we sell" viewpoint! We took an oath -- and advocating feeding animals contrary to their biology violates it."

Molly Garraway, Representative of "BEG" Pet Food Industry: "Our dogs deserve better."

Emily St. Clare: "I want real answers to the question of what is causing the increase in cases of DCM, not just industry-funded rhetoric."

Gayle Watkins: "As a PhD and scientist, I was chagrined at the factual errors and obvious bias in Lisa Freeman's JAVMA opinion piece. I can't imagine submitting such a poor quality article to any journal of significance. Nor can I imagine such a piece being published. The JAVMA's acceptance of this article significantly changed my opinion of its editorial quality and the present state of veterinary science. The damage Freeman's opinion piece and the JAVMA has done to dogs, their owners and dog food companies is substantial; repairing it will take a long time. The JAVMA's retraction needs to be immediate and widely publicized, not printed in fine print on the last page of the journal."

Ruthanne Lizotte: "The panic and fear caused by the misinformation spread throughout the internet by this article as well as DCM groups pushing big kibble companies is unethical and disheartening. It's time to be held accountable for damaging and incorrect finger pointing."

Dr. Nelson Mostow, MD: "It is important that veterinary journals adhere to the same ethical standards that medical journals do. As a physician I rely on the integrity of medical journals and rely on the journals I read to retract articles when the editors become aware of distortions of data or undisclosed biases. This includes retracting papers which contain skewed data and are influenced by corporations."

Tracey Rentcome: "I have been appalled at the so called 'science' of this whole debacle."

Cynthia Wyatt: "As the owner of a small pet supply shop, my staff and I have had innumerable conversations regarding this issue. While we repeatedly reassure our customers that the facts do not support the original article - which was full of conjecture and innuendo and void of any evidence or proof - we have definitely witnessed a significant change in our customers' buying habits. The pet food we sell in our shop has always been largely grain free, though we have offered grain-inclusive options as well. We are lucky that most of our customers will not buy from the Big 4 manufacturers under any circumstances, but we have had many switch to grain-inclusive and many more that have told us their Veterinarians (who should know better!) insist they switch their pets to one of the Big 4."

Kirsten Williams, Non-Veterinarian Medical Professional: "This and the other study published by Joshua Stern, DVM, are an insult to the academic and research communities. Additionally, the

widespread defamation and slander that has occurred as a result of these publications are appalling.”

Dr. Chris Ross, DVM: “The big panic created by the article in question pretty much smelled like something staged and I found it convenient that the dog food brands listed as safe were only the big names so I questioned it from the beginning. Watching and reading their studies that never had any blind neutral participants and a insufficient number of dog just supported that idea. I am glad they are finally being exposed for their false reports and hope that real studies and testing can be done for the benefit to the animals not anyone’s pockets.”

Brett Foreman: “I’m the owner of a holistic pet food store that carries several of the ‘BEG’ lines in question. We’ve questioned the validity of Dr. Freeman’s claims since the onset and have been waiting for more information while losing a percentage of our business to Big kibble as some customers bought the hype hook, line and sinker. From a retail and loving pet owner perspective, anything we can do to help, we’re willing to do. This hysteria is ridiculous and Dr. Freeman and her ilk should be ashamed of themselves for selling out to the bigs and furthering an agenda that is not only full of discrepancies and all out lies but is super damaging to the pet food industry outside of the Blg Kibble shelves.”

Julie McAlee: “As a veterinary consumer, I am dismayed to discover that information published in JAVMA and referred to by so many veterinarians is not peer-reviewed. On topics where consumers are likely to read, it’s not clear when a piece in JAVMA is not evidence-based. Please respect your broader audience better.”

Heather Grossman: “Science should be peer reviewed, in an era when the public already does not trust scientists, and people believe internet equals a PhDs, we need to make sure that real science gets published in high profile journals.”

Timothy Hagen: “As a vendor of so-called ‘boutique’ pet foods we have also been negatively affected by the publication of a speculative opinion article by a major respected veterinary medical journal. This needs to be retracted immediately, and that retraction must be publicized as widely as possible to mitigate the severe damage to the industry and harm to pets caused by incorrect advice.”

Dr. Albert Townshend, DVM: “I am a veterinarian. I have practiced for 50 years and consulted in both the pet food manufacturing industry and the independent pet retail industry. I agree wholeheartedly with your comments and concerns.”

Lindsay Gaudet: “I am a (human) epidemiologist. I both love dogs and sound health research. I was very dismayed when I read Freeman’s paper. Not only was the science being used to draw conclusions that I felt they couldn’t support, but the use of WSAVA Nutrition Guidelines as a proxy for diet quality is mind boggling to me, since as far as I can tell the guidelines only apply to the manufacturer and not the diet itself, were funded by Mars, Nestle, and Royal Canin, and some of the authors of the questionable papers sit on the committee that developed them. This issue is too serious and too complex to allow for slip-shod science. Not only is building “evidence” using poor methods unethical, in my opinion, but it will not serve to actually add clarity and will only further confound investigations into the truth behind what is happening. As health scientists, we need to demand better.”

Dr. Kathleen Fitzgerald, MD: “Not only as a physician for over 40 years, but as a breeder of internationally renowned Standard Schnauzers since 1981, I am appalled at how far ethics and

the scientific method have been betrayed by those who supposedly practice it in today's world. Why should anyone believe anything that a "scientist" believes when the proclamations are so obviously contaminated by prejudice and misrepresentation?"

Dr. Masuma Barrett, DVM: "This is an awful betrayal of the public's trust."

EXHIBIT F

SCHULOF V. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. DIST. COURT FOR THE DISTRICT OF UTAH

COMPLAINT

publishing science journalism and commentary on the pet food industry and the veterinary nutritional science community since 2011. *Kirkus Reviews* praised his 2016 book *Dogs, Dog Food, and Dogma: The Silent Epidemic Killing America's Dogs and the New Science That Could Save Your Best Friend's Life* as “a weighty scientific treatise” featuring “exhaustive research that ... uncovers the seemingly sinister influence of giants of the pet-food industry.” (See <https://www.kirkusreviews.com/book-reviews/daniel-schulof/dogs-dog-food-and-dogma/>.)

5. Defendant HHS is an agency within the meaning of 5 U.S.C. § 552(f) and is in possession or control of the records requested by Plaintiff that are the subject of this action. HHS controls the United States Food and Drug Administration (“FDA”) and is therefore the proper party defendant for this action.

The FDA's Investigation Into Diet-Linked Canine Dilated Cardiomyopathy

6. This FOIA lawsuit relates to records concerning the FDA's scientific inquiry into a “potential connection” between canine dilated cardiomyopathy (DCM) and certain pet food ingredients, including peas, lentils, other legume seeds, and potatoes.

7. Canine DCM is a rare disease of a dog's heart muscle. It results in an enlarged heart and it can be deadly. The etiology of the disease is not fully understood by the veterinary community, although there is peer-reviewed evidence that it can be caused by (1) insufficient consumption of the amino acids cyst(e)ine and/or methionine (the canine body uses these “building blocks” to produce the DCM-linked amino acid taurine) and (2) genetic factors, including some specific to certain breeds of dogs.

8. There are more than 70 million dogs in the United States and more than \$30 billion worth of pet food was sold in the United States in 2018. Peas, lentils, other legumes, and potatoes are common pet food ingredients, which have been used in pet food formulations for at least a

decade. These ingredients are commonly used as a source of starch in “grain-free” pet foods, which make up a large and popular subsector of the overall pet food market. According to the Dog and Cat Food Ingredient Center, approximately 44% of all dry dog foods sold in the United States in 2016 were grain-free and 66% of dry dog foods sold in the United States contained either peas, lentils, other legumes, or potatoes. (See <https://www.petfoodindustry.com/articles/7494-usage-rates-of-dog-food-ingredients-in-fda-dcm-warning>.)

9. On July 12, 2018, the FDA’s Center for Veterinary Medicine issued an online press release providing as follows:

The U.S. Food and Drug Administration is alerting pet owners and veterinary professionals about reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet foods containing peas, lentils, and other legume seeds, or potatoes as main ingredients. These reports are unusual because DCM is occurring in breeds not typically genetically prone to the disease. The FDA’s Center for Veterinary Medicine and the Veterinary Laboratory Investigation and Response Network, a collaboration of government and veterinary diagnostic laboratories, are investigating this potential association.

(See <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>.)

10. This announcement received widespread national media coverage, usually under alarming headlines. For instance, the *New York Times* published an article entitled “Popular Grain Free Pet Foods May Be Linked With Heart Disease” and *Slate.com* published another entitled “Please Stop Buying Your Pets Grain-Free Food.” (See <https://www.nytimes.com/2018/07/24/health/grain-free-dog-food-heart-disease.html>, <https://slate.com/technology/2019/01/stop-buying-grain-free-food-for-your-pets.html>.)

11. On February 19, 2019, the FDA issued a public update on the investigation, noting that only 273 cases of canine DCM had been reported nationwide since its original announcement. In its update, the FDA also highlighted the key role that a few specific veterinary researchers were playing in perpetuating the investigation:

FDA veterinarians have been working with the veterinary community to exchange information about existing cases and the type of clinical information that is most helpful to the investigation. We are also consulting with a cadre of board-certified veterinary cardiologists and nutritionists to learn more about the presentation of these cases and how they respond to treatment.

...

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.

(See <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm630991.htm>.)

12. Although they are all employees of research universities, these same three veterinary researchers have significant financial ties to one or more of three of the largest pet food companies in the world, Nestlé-Purina Petcare ("Purina"), Hill's Pet Nutrition ("Hill's"), and Mars Petcare ("Mars"). In recent academic publications, Dr. Freeman has had to disclose financial conflicts of interest with each of Hill's, Purina, and Mars and Dr. Adin has had to disclose financial conflicts of interest with Purina. (See <https://avmajournals.avma.org/doi/full/10.2460/javma.253.11.1390>.) Although Dr. Stern has not disclosed financial conflicts of interest in his recent publications, information produced to Plaintiff pursuant to the California Public Records Act shows that the research institution where he is employed (the veterinary school at the University of California at Davis) has received hundreds of thousands of dollars in funding from the three companies since January of 2017.

13. Collectively, these "Big Three" companies represent nearly *half* of the entire U.S. pet food market. (According to Euromonitor International, an industry analyst, the Big Three were responsible for more than 46% of the pet food sold in the United States in 2017.) The great majority of their products share a single quality in common: grain ingredients such as corn, rice, and wheat flour supply the starch content, instead of the peas, lentils, and potatoes that are more often used

in grain-free recipes. Indeed, according to “Taurine + DCM,” a website devoted to raising awareness about the FDA’s DCM investigation, pet-owners concerned about canine DCM should *only* choose foods produced by one of three companies: Hill’s, Purina, and Mars. (See <https://taurinedcm.org/taurine-dcm-faq/>.) In other words, *the Big Three have a massive profit motivation to drive pet food consumers away from grain-free pet foods featuring peas, lentils, other legumes, or potatoes.*

14. In the months since the FDA announced its investigation, Drs. Freeman, Stern, and Adin have all authored or co-authored articles about canine DCM. These articles have been published in both scholarly journals and online blogs. Most of these articles reference (1) a recent “spike” in canine DCM cases and (2) an “apparent association” between canine DCM and grain-free pet foods. But, critically, none of these articles cites any peer-reviewed evidence that canine DCM has become more common in recent years and none of them cites any peer-reviewed evidence showing grain-free pet foods present a higher risk of DCM than grain-containing ones. *To date, there is no published, peer-reviewed evidence of either of these phenomena.*

15. Nevertheless, the public has seized on these articles and the media attention generated by the FDA’s investigation as a reason to avoid or abandon grain-free pet foods. For instance, although *fewer than 300 cases* of canine DCM had been reported to the FDA as of February 19, 2019, a Facebook group called “Taurine-Deficient (Nutritional) Dilated Cardiomyopathy” presently has *more than 60,000 members*. (See <https://www.facebook.com/groups/TaurineDCM/>.)

Administrative History of Plaintiff’s FOIA Request

16. As the national media attention generated by the FDA’s investigation demonstrates, the pet-owning public has a keen interest in understanding whether certain pet foods carry a greater

risk of DCM than others. As such, the public has an interest in understanding the extent to which the FDA's investigation has been improperly influenced by profit-driven corporations. The mere existence of financial threads tying the FDA's DCM investigation to three of the world's largest and most influential pet food companies is not definitive evidence of wrongdoing. But, as documented in Plaintiff's 2016 book, *Dogs, Dog Food, and Dogma*, such influence-peddling would be consistent with a broader pattern of behavior that these companies have exhibited over the last few decades.

17. As a member of the news media covering the pet food industry, Plaintiff recognized the public's interest in understanding the nature of the Big Three's involvement in the FDA's DCM investigation. As part of an effort to research potential articles and/or books about the matter, he filed a FOIA request with the FDA's FOIA Officer on February 21, 2019, seeking access to and copies of a variety of records associated with the investigation.

18. On March 5, 2019, Defendant denied Plaintiff's FOIA request in full, citing 5 U.S.C. § 552 (b)(7)(A), the "law enforcement proceedings" exemption and designating Plaintiff's request as Request Number 2019-1704.

19. On March 19, 2019, Plaintiff lodged an administrative appeal of the denial with Defendant's Chief FOIA Officer, explaining that the denial was improper because the FDA's DCM investigation is an open scientific inquiry, not a "law enforcement proceeding" under § (b)(7)(A).

20. To date, Plaintiff has received no substantive response to his administrative appeal.

COUNT ONE

21. Plaintiff repeats and re-alleges paragraphs 6 through 20 above, including all exhibits referenced therein.

22. Plaintiff's FOIA Request No. 2019-1704 was improperly denied in full by the Defendant.

23. By letter dated March 19, 2019, Plaintiff submitted an administrative appeal of the improper denial, challenging Defendant's substantive response.

24. To date, Plaintiff has received no substantive response to his appeal. Plaintiff has therefore constructively exhausted all required administrative remedies.

WHEREFORE, Plaintiff prays that this Court:

- (1) Order Defendant to produce to Plaintiff all responsive, non-exempt agency records;
- (2) Award Plaintiff reasonable costs as provided in 5 U.S.C. § 552(a)(4)(E) and/or 28 U.S.C. § 2412(d);
- (3) Expedite this action in every way pursuant to 28 U.S.C. § 1657(a); and
- (4) Grant such other relief as the Court may deem just and proper.

Date: July 26, 2019

Respectfully submitted,

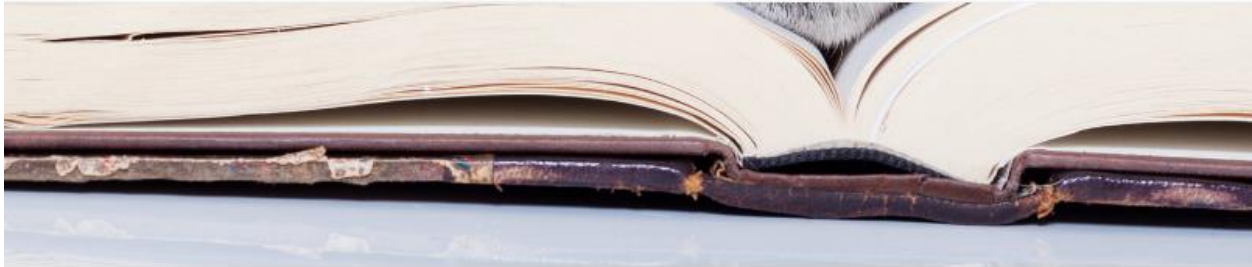
/s/ Daniel Schulof

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Pro se litigant

EXHIBIT G

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CAN YOUR DOG'S FOOD KILL THEM??

3/14/2019

[Comments](#)

There is a lot of hype right now about grain free foods and heart disease in pets. We reached out to Ann, our nutrition and internal medicine small animal VTS author, for her perspective and she gave us the low down.

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Grain-Free Diets and Dilated Cardiomyopathy

March 22, 2019 | by Danielle Smith Laughlin, DVM, DACVIM (Cardiology) BluePearl in Atlanta

Okaw Veterinary Clinic

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Grain-Free Causes Heart Failure

Grain-Free Diets can Kill

I know this title is harsh - but I want to grab your attention and have you keep reading. Grain-free diets have become very popular over the last 10 years. While grain can aggravate some allergies and intestinal diseases, the problem is that all foods are not created equally. The growth of boutique, small size who may not run post production nutritional ingredient testing and digestibility levels leave an impression of quality that may not be true. Veterinary cardiac specialists are finding dogs with life threatening heart disease who are low in taurine, an



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It's Not Just Grain-Free: An Update on Diet- Associated Dilated Cardiomyopathy

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HEART DISEASE AND YOUR PET

PET DIETS AND DILATED CARDIOMYOPATHY

Veterinary cardiologists have noticed an increase in a certain type of heart disease in dogs known as dilated cardiomyopathy or DCM. This increase in DCM cases seems to have an association with dogs fed diets that are considered boutique, exotic or grain-free.

In cats, a diet deficient of taurine, an amino acid important in the metabolism of fats, has been associated with this same type of heart disease. **Research linking taurine to heart disease in cats has been well-documented since the late 1980s, therefore it is now a required component of all cat foods and cat diets.**

Dogs can typically synthesize or make their own taurine. However, ingredient factors like fiber type, carbohydrate and protein sources, cooking methods and individual dog characteristics can affect how well their bodies make and use taurine.

Some of the newly diagnosed dog DCM cases were tested and had low levels of taurine. With taurine supplementation, their heart function returned close to normal. More commonly, DCM dog cases did not test low for taurine, but still responded to taurine supplementation and diet change. Some cases even responded with diet change alone.

The FDA, veterinary nutritionists, and veterinary cardiologists are working to tease out what specific



HELPFUL DEFINITIONS

Dilated Cardiomyopathy (DCM): A type of heart disease in which the heart becomes enlarged and does not beat or contract as effectively as it should. Symptoms can include increased sluggishness or sleepiness, coughing, decreased appetite, pale gums, and fainting.

Boutique: Small pet food producer without the resources or size to run their own research studies, employ a veterinary nutritionist, or manufacture their own food.

Exotic Ingredient Diets: Protein and plant sources in diets that are considered unstudied, unconventional and rare in the pet food market. Examples include kangaroo, lentils, peas, fava beans, buffalo, tapioca, barley, bison, venison and chickpeas.

Grain-Free: A diet that does not use grain-based products like wheat, oatmeal, corn or rice. Usually these diets substitute grains with other carbohydrate choices like