

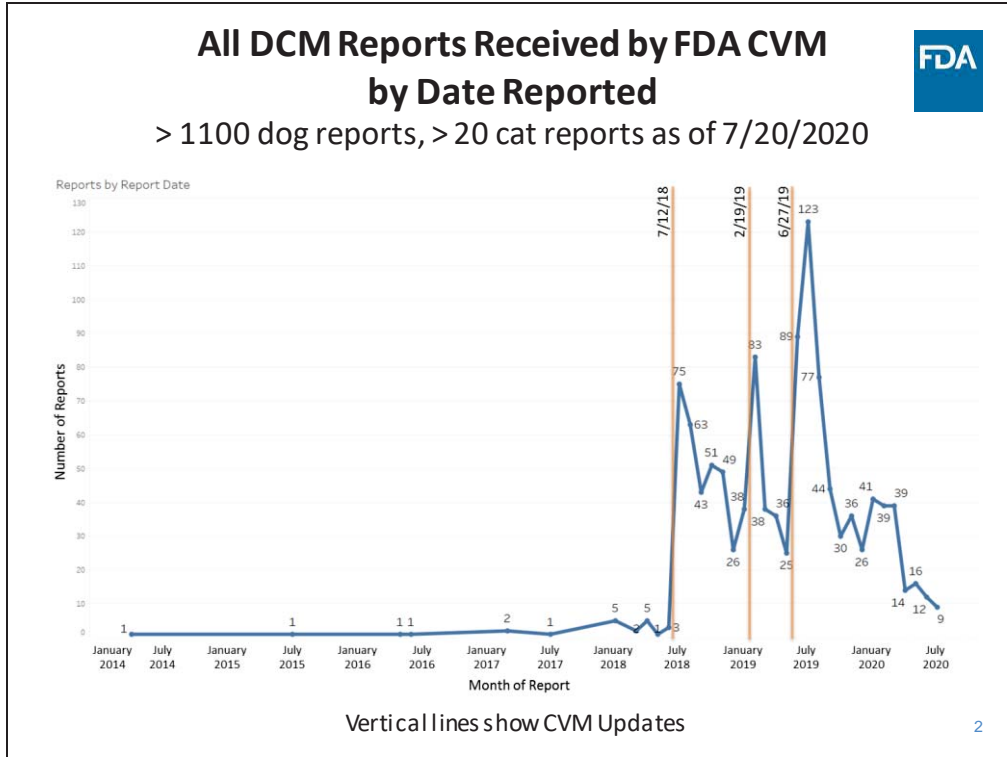


# **FDA UPDATE ON DILATED CARDIOMYOPATHY: FULLY AND PARTIALLY RECOVERED CASES**

Kansas State University's Scientific Forum Exploring Causes of Dilated  
Cardiomyopathy in Dogs

September 29, 2020

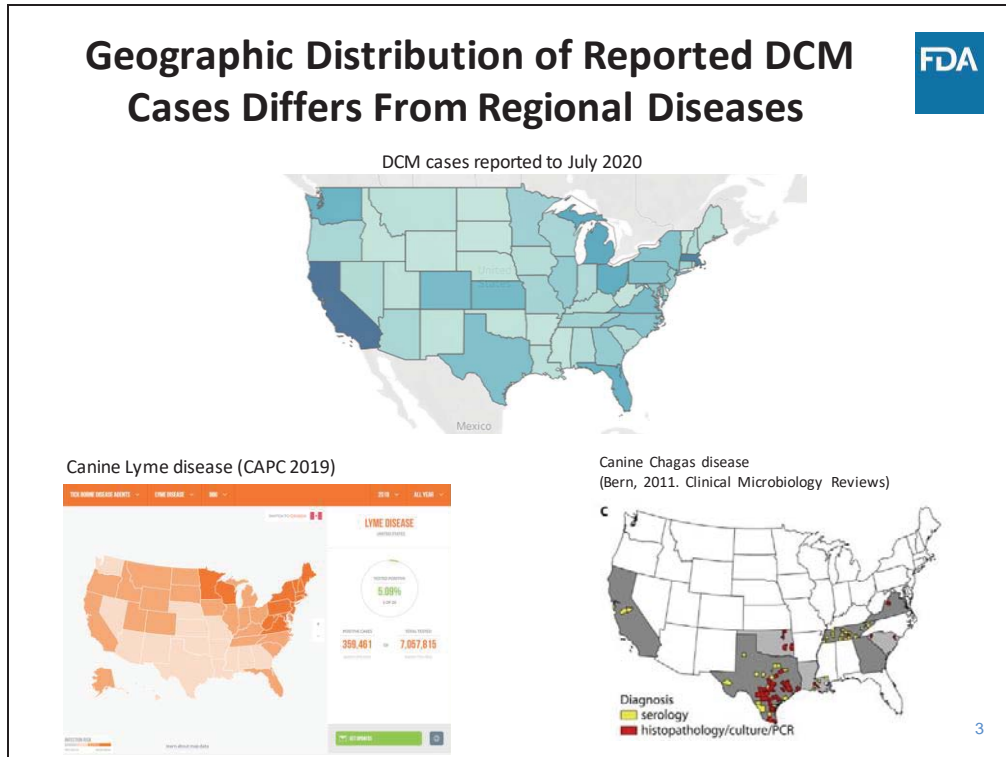
FDA Center for Veterinary Medicine



Here you'll see a timeline of dilated cardiomyopathy (DCM) reports received by the U.S. Food and Drug Administration (FDA). In early 2015, the FDA began to receive reports of DCM suspected to be related to diet (with one additional report in early 2014 that was a little different compared to the rest). We saw an uptick in 2018, with an increase in the number of well-documented cases. We released our first Center for Veterinary Medicine (CVM) Update on July 12, 2018, to make the public aware. Follow-ups were released on February 19, 2019, and June 27, 2019. Following each Update, FDA tends to get a surge in reporting; however, reporting continues in between updates. You'll see a drop in reporting in 2020 – all adverse event reporting to FDA CVM has declined in the past 6 months – likely related to COVID-19.

As of July 2020, we have received more than 1100 reports of DCM in dogs and more than 20 in cats.

## Geographic Distribution of Reported DCM Cases Differs From Regional Diseases



FDA has received reports of DCM from all 50 U.S. states as well as many Canadian provinces and a case from Europe. The geographic distribution of our DCM cases appears to reflect the U.S. population/population centers.

We show the geographic distributions of Lyme and Chagas disease here, as they've been mentioned as possible differential diagnoses for our dog DCM cases. By comparison, the geographic distribution of canine Lyme disease (reflected by >350,000 positive tests recorded by the Companion Animal Parasite Council in 2019) is very heavily distributed towards the northeastern United States and Minnesota and Wisconsin. The distribution of canine Chagas disease is very much focused in the southern United States, especially Texas.



## Vet-LIRN Case Investigations

- FDA CVM reviews all adverse event reports received
- Vet-LIRN investigates a **subset** of these reports
  - Investigations help FDA identify a cause for animal illness
  - Similar to CDC outbreak investigations

> 1100 DCM cases reported to FDA



> 150 DCM cases investigated by FDA Vet-LIRN

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FDA CVM reviews all adverse pet food events received. The Veterinary Laboratory Investigation and Response Network (Vet-LIRN) investigates a **subset** of these reports. These investigations help FDA identify a cause for animal illness, similar to a Centers for Disease Control and Prevention (CDC) outbreak investigation. Imagine a funnel. At the top are the more than 1100 DCM cases that have been reported to FDA. But, at the bottom of the funnel is a small subset of approximately 150 DCM cases that Vet-LIRN investigated for today's presentation. The data we're sharing with you today represents only a subset of all DCM reports submitted to FDA.



## Vet-LIRN Case Investigations

### Group One

- DCM reports received January 2018 to April 2019
- 121 dogs with DCM
  - 107 of them had full or partial recovery

### Group Two

- DCM reports received November 2019 to July 2020
- 40 dogs with DCM
  - *Preliminary data*

### Goals for each Group:

- Identify factors that may affect recovery
- Document echocardiogram changes over time

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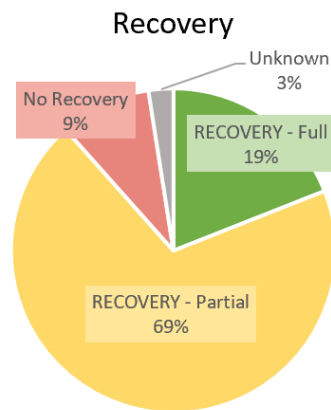
The 150 investigated DCM reports were divided into two groups. Group One includes 121 dogs with DCM whose reports were received by FDA between January 2018 and April 2019 – an earlier group of reports. One hundred and seven of the 121 Group One dogs with DCM had either full or partial recovery.

Group Two includes preliminary data from 40 dogs with DCM whose reports were received by FDA between November 2019 and July 2020 – a more recent group of reports. Our goal for both groups is to identify factors that may affect recovery in the dogs and to document the echocardiogram changes over time.

## Group One Dogs with DCM



- 19% fully recovered
- Data are fluid and changing
- Continue to follow dogs
- More dogs expected to reach full recovery



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Of the 121 Group One dogs followed over time, 107 dogs had various stages of recovery. Nineteen percent of dogs fully recovered (n=23), and approximately 70 percent of dogs had partial recovery (n=84, improved left ventricular size and/or systolic function). Nine percent of dogs had no left ventricular size or function improvement. For the dogs with no recovery (11 dogs), 7 had died. This data is fluid and changing. We continue to follow these dogs, and more are expected to reach full recovery.

## Group One Fully (n = 23) and Partially (n = 84) Recovered Dogs: Signalment



- Partially Recovered Signalment:

Dogs	Age (yrs)	Weight (lbs)		Sex	# of Reports	%
Mean	6.4	62		F	44	52.4%
Range	1 - 13	14 - 105		M	40	47.6%
n	84	84		n	84	

- Fully Recovered Signalment:

Dogs	Age (yrs)	Weight (lbs)		Sex	# of Reports	%
Mean	6.6	54.2		F	7	30.4%
Range	0.8 - 13	5 - 88		M	16	69.6%
n	23	23		n	23	

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Looking at the signalment for the two groups, in the partially recovered group of 84 dogs, average age was 6.4 years and average weight was 62 pounds, with sex being slightly more female at approximately 52% female and approximately 48% male. Age and weight were similar in the 23 fully recovered dogs, with average age 6.6 years and a slightly lower average weight at 54.2 pounds. This group was more male, with approximately 70% male and 30% female.

## Group One Fully and Partially Recovered Dogs by Breed (n = 107)



- Partially Recovered (n = 84)
- Fully Recovered (n = 23)

Breed	# of Reports
Golden Retriever*	21
Mixed	21
Labrador Retriever*	5
Australian Shepherd	3
Doberman Pinscher	3
American Bulldog*	2
French Bulldog*	2
German Short-haired Pointer*	2

There were an additional 25 breeds reported only once in the Partially Recovered Group.

Breed	# of Reports
Golden Retriever*	6
Mixed	6
American Cocker Spaniel	1
Australian Cattle Dog	1
Basset Hound	1
Beagle	1
Bluetick Coonhound	1
German Shepherd	1
Maltese	1
Pit Bull	1
Pomeranian	1
Whippet	1
Yorkshire Terrier	1

\* AKC top 10 breeds in 2019

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Breeds among the 107 fully or partially recovered dogs were diverse, with Golden Retrievers most common, tying with a variety of mixed-breed dogs. Other breeds included both large and small breeds, such as Labrador Retrievers, Doberman Pinschers, a Basset Hound, French Bulldogs, and a Pomeranian. All breeds with an asterisk next to them are breeds listed in the American Kennel Club's top 10 breeds of 2019.





### Group One Fully Recovered Dogs: Comorbidities

	Comorbidity	Number of Dogs
Less severe, clinically	Congestive heart failure	6
	Arrhythmia	7
	Valvular changes	8
	Low Taurine	10

Note: Minimal overlap in the # of dogs with CHF or Arrhythmia. Only 1 dog had both.

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The most commonly reported comorbidity was low blood taurine, seen in 10 of the 16 dogs tested (n=10/16 tested), followed by Degenerative Valve Disease (n=8). Overall, the dogs that have fully recovered were not some of the most severe clinically, and they had less congestive heart failure (CHF) and arrhythmias. Only one dog had both CHF and an arrhythmia.

## Group One Fully Recovered Dogs: Historical Findings

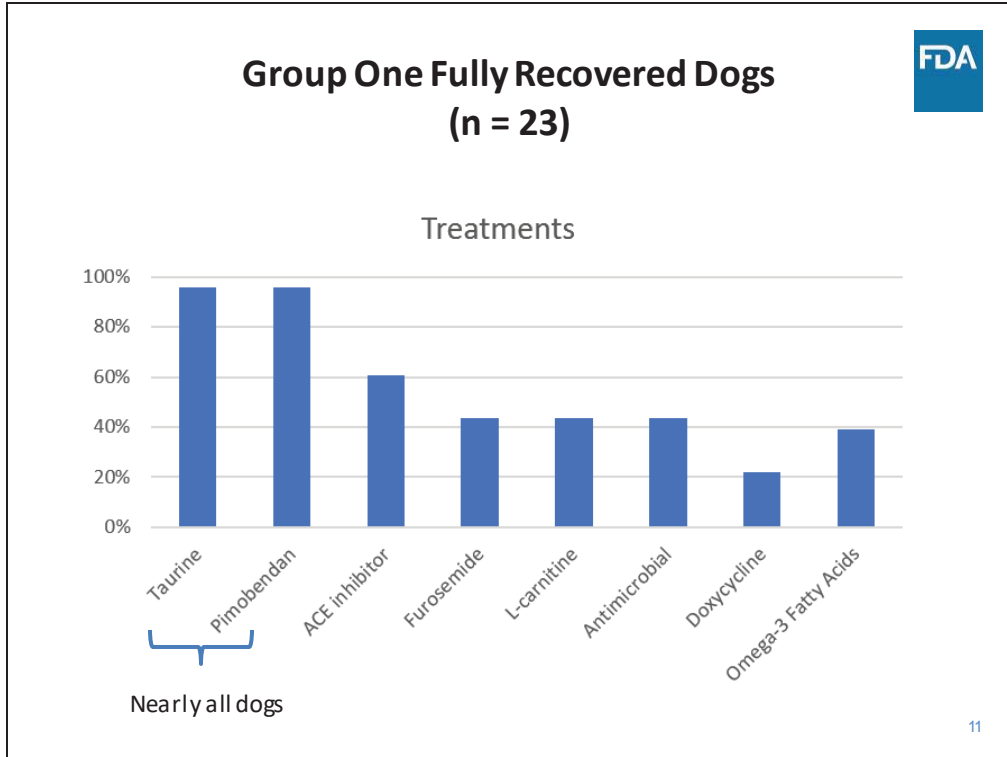


Historical Findings	Number of Dogs
Crystalluria	2
Proteinuria	2
Polyuria	2
Lyme positive	2
Gastrointestinal disease	3
Allergy or Atopy	13

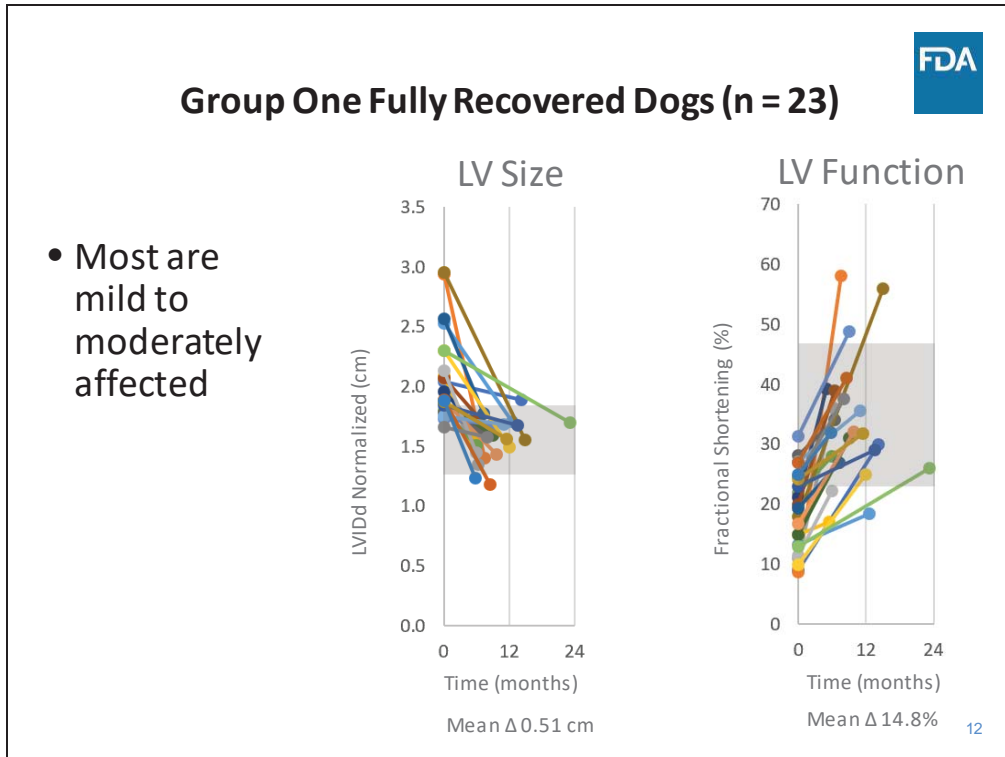
Often why  
the reported  
diets are fed

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Allergy or atopy followed by gastrointestinal disease (i.e., sensitive stomach/irritable bowel disease) was the most frequently reported historical comorbidity. The diets reported to us for these dogs contain novel and/or limited ingredients and are likely fed to the dogs to help nutritionally manage allergies, atopy, and gastrointestinal diseases. There were only two dogs in each of the other categories.



All dogs that fully recovered received a diet change. Nearly all dogs were also treated with taurine and pimobendan. Over half of the dogs also received an ACE inhibitor, whereas additional treatments and supplements varied.



Here we show the left ventricular size and functional recovery in the 23 dogs. The “normal” ranges are represented by the gray boxes (Cornell, et al. 2008). Looking at each y-axis, most dogs were not severely dilated or hypokinetic at diagnosis. However, some dogs were more severely affected. The severity of DCM at diagnosis, however, did not preclude a dog from recovering.

The mean recovery is shown below each graph (i.e., normalized centimeters and percentage points).

Citation: Cornell, Craig & Kittleson, Mark & Torre, Paul & Haggstrom, Jens & Lombard, Christophe & Pedersen, Henrik & Vollmar, Andrea & Wey, Aaron. (2004). Allometric Scaling of M-Mode Cardiac Measurements in Normal Adult Dogs. Journal of veterinary internal medicine / American College of Veterinary Internal Medicine. 18. 311-21. 10.1111/j.1939-1676.2004.tb02551.x.



## Group One Fully Recovered Dogs (n = 23)

### Recovery Time

- ~6 to 12 months
  - A few up to 2 years
- Recovery time did not correlate with:
  - Age, Weight
  - Initial LV size or function
  - Decreased taurine
  - Congestive heart failure

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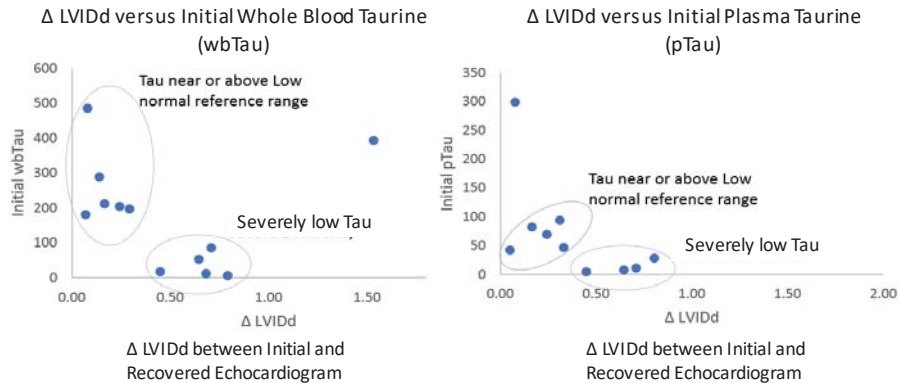
Most dogs recovered between 7 to 13 months after their initial diagnosis. Some dogs recovered more quickly (5 months) and some more slowly (23 months). These estimates are based on how frequently an echocardiogram was performed, often at 3- to 6-month intervals. It is possible, but unknown, if dogs would show recovery sooner had they gotten an earlier echocardiogram.

Importantly, the recovery time did not correlate with the dog's age, weight, initial left ventricular size or function, low taurine status, or the presence of congestive heart failure.

## Group One Fully Recovered Dogs (n = 23)



- 10 of 16 dogs tested had low taurine
- Initial LV size did not correlate with initial taurine levels
- Dogs with severely low taurine = **GREATER** LV **size** improvement
- Amount of LV **functional** improvement unrelated to taurine



We looked for factors that might correlate with how much the hearts were physically recovering. In other words, under what conditions do some hearts shrink more than others during recovery?

This slide shows that dogs with severely low taurine values had left ventricles that shrank more than dogs with taurine values near, within, or above reference range.

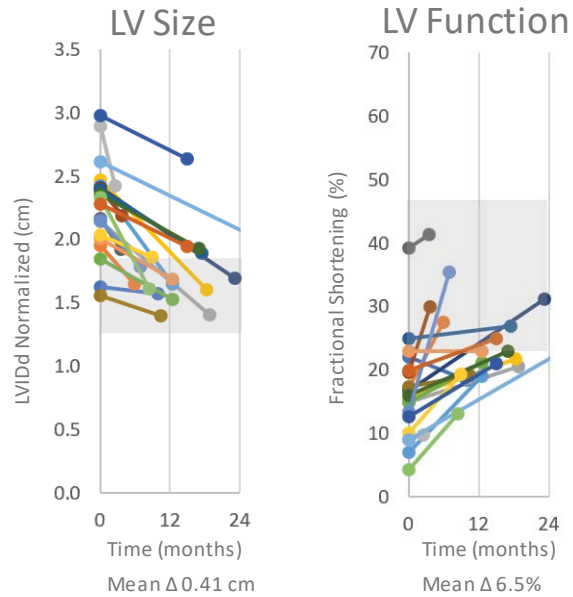
On the x-axis we have the total centimeter heart change between diagnosis and recovery. The y-axis shows either the whole blood or plasma taurine values taken near the time of diagnosis. You can see that two groups emerge. The group with a taurine near or above the lowest normal reference value recover less on the x-axis, i.e., their hearts shrank less. The group with a taurine more severely below the reference range had hearts that recovered, or shrank, more.

One might argue that dogs with lower taurine had more severely dilated hearts and therefore had to shrink the most to reach normal size. However, blood taurine values did not correlate to how large the left ventricle was at diagnosis.

## Group One Partially Recovered Dogs



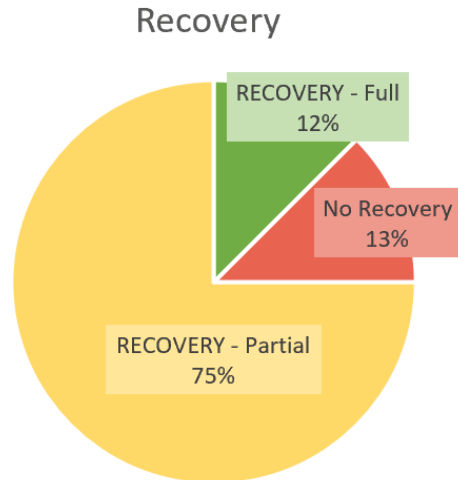
- DCM is more severe than in the fully recovered dogs
- 51 dogs had congestive heart failure
- 50% of dogs tested had low taurine



Here are some general characteristics of the 84 dogs with partial recovery. These dogs had more severe DCM, meaning greater dilation and lower function at diagnosis. Fifty-one dogs were in congestive heart failure, and half of the dogs that were tested for taurine had low values (n= 27/54 tested). These graphs show how left ventricular size and function are improving over time after diet change and cardiac treatments.

## Group Two Dogs with DCM

- Reported to FDA between 11/2019 and 7/2020
- All had a diet change
- ~75% partially recovered
- Data are fluid and changing
- Continue to follow dogs



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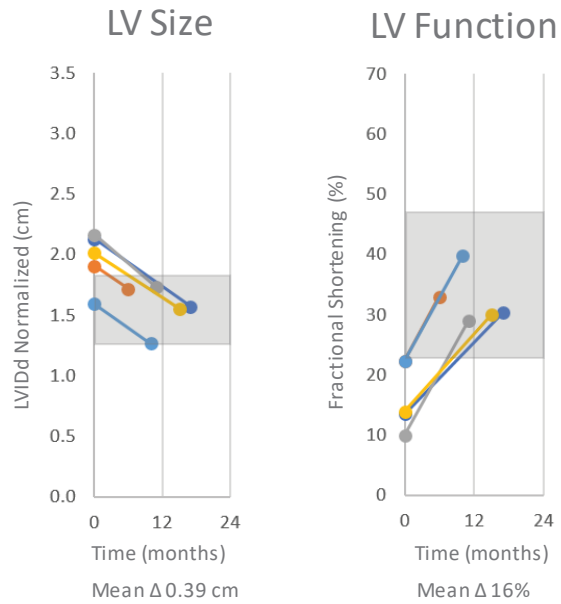
Here is Group Two, which includes 40 recent cases of DCM. All of the dogs have had a diet change, and approximately 75 percent have partially recovered (5 had full recovery, 30 partial, 5 no recovery). Please note, similar to Group One, these data are fluid and changing. We will add more dogs to this group as they get recheck echocardiograms (i.e., we need at least two echocardiograms to determine recovery status), and more dogs will likely fully recover.



## Group Two Fully Recovered Dogs



- 5 full recovery
- Mild to moderate DCM
- Comparable to Group One fully recovered dogs



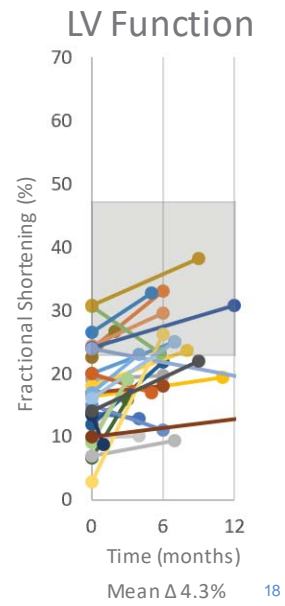
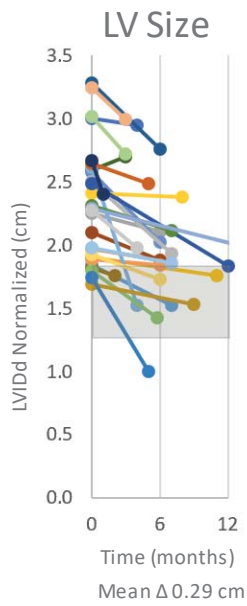
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Five dogs had full recovery, with mild to moderate DCM. They appear comparable to the Group One dogs that fully recovered from DCM.

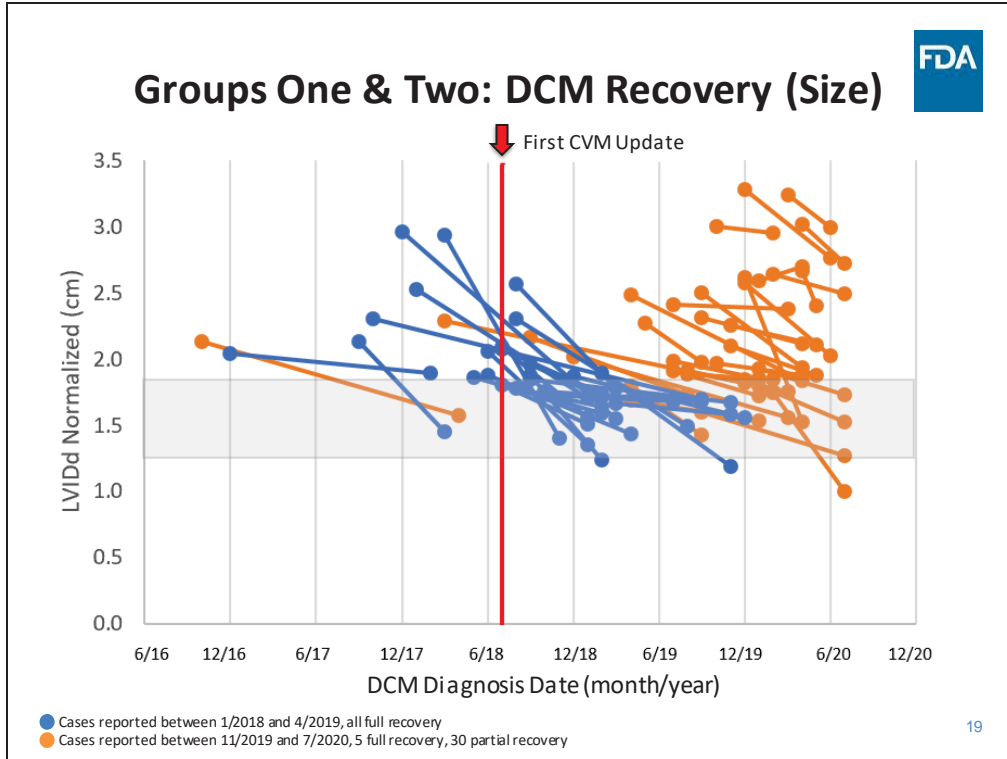
## Group Two Dogs Partially Recovered Dogs



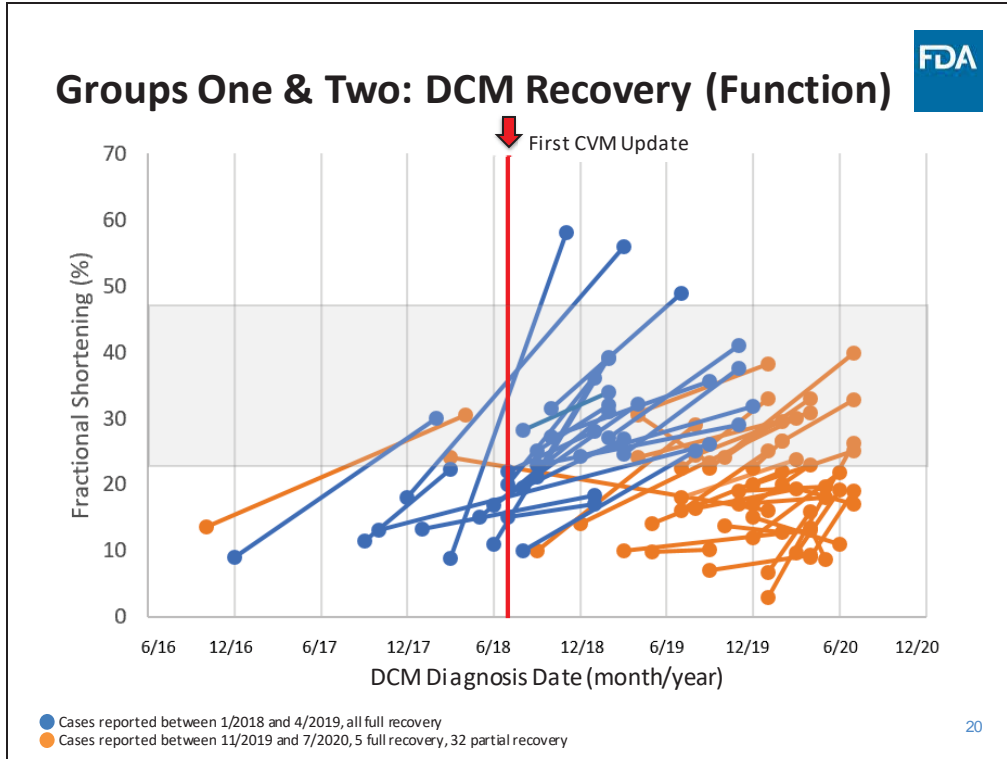
- 30 partial recovery
- Moderate to severe DCM
- Comparable to Group One partially recovered dogs



Thirty dogs had partial recovery, with mild to severe DCM. They appear comparable to the Group One dogs that are partially recovering from DCM.



All dogs had a diet change on this graph, which shows left ventricular size changes over time. The date of DCM diagnosis is on the x-axis, and the left ventricular size is on the y-axis. The blue points are dogs that fully recovered from Group One. The orange points are dogs that either fully or partially recovered from Group Two. The date of FDA first public update is shown by the red line. As you can see, we have been and continue to get cases of dogs that begin to recover left ventricular size after discontinuing the reported diets and getting medical treatment.

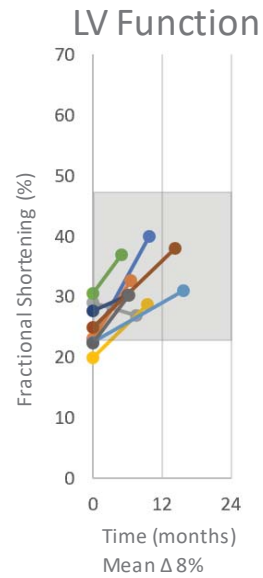
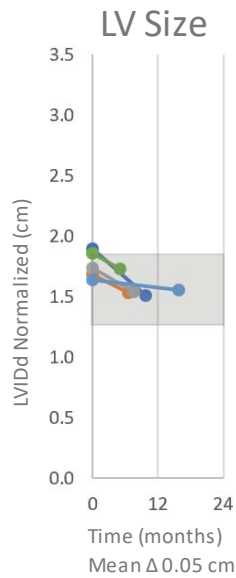


The same graph is shown here but shows the left ventricular function on the y-axis. Again, we have been and continue to get cases of dogs that begin to recover left ventricular systolic function after discontinuing the reported diets and getting medical treatment.

## Dogs with LV Hypokinesia (not DCM)




- 14 dogs
- Reports received 7/2018 – 12/2019
- 10 fully recovered LV function
  - All had a diet change
  - 5 also improved LVIDd



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I want to end my portion of the talk by switching gears a bit. Historically, dogs with DCM present to clinicians when their disease is severe enough to cause clinical signs, such as cough, shortness of breath, or exercise intolerance. However, it is most likely that there are gradual changes to the heart that occur before the onset of clinical signs, such as left ventricular (LV) hypokinesia. Therefore, I wanted to briefly talk about a few cases of LV hypokinesia, not DCM. Similar to dogs with DCM who recovered after diet change, 10 of the 14 dogs with LV hypokinesia, a presumable condition that occurs prior to development of DCM, fully recovered after diet change. Notably, although they did not have left ventricular dilation, their LV size improved in five cases.

# Reported Product Label Evaluations



**Definitions\* used in this analysis:**

- **Grain-free:** A food that does not have wheat, corn, ancient grains (i.e., spelt, quinoa), barley, rice, rice bran, or soy\*\* ingredients on the label
- **Peas “top”:** Means peas in the top 3 to 4 ingredients after the animal protein/meats (same for lentils)
- **Pea fractions:** includes pea protein, pea fiber, pea starch, pea flour, etc. (same for lentils)

\* Definitions are not intended to imply causality  
\*\* Soy is technically a legume

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Over the next few slides, we’ll be looking at the characteristics of the products reported to FDA to have been fed to the 107 fully and partially recovered cases. For the 23 fully recovered cases, we’ll also look at the characteristics of the products reported to have been fed in the recovery period. If there’s time, we’ll also look at the hypokinesia cases.

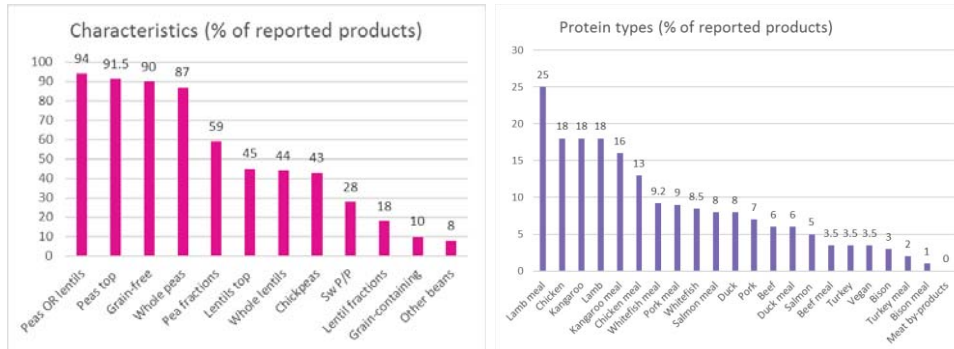
We characterized the reported products by examining ingredient lists that were obtained by online searches for product labels or by using submitted photographs (when available) for reported diets. Given that these cases are from 2018 to 2019, archived label information was checked as needed.

Any information we obtained from owner interviews was incorporated, although owner interviews couldn’t be done in all the cases. We do owner interviews to confirm what was fed and to add anything that was missing. We considered diets fed to the dogs in the two to three years prior to diagnosis; however, new diets in the month prior to diagnosis were not considered.

- Definitions used for the purposes of this analysis include:
  - **Grain-free:** A food that does not have wheat, corn, ancient grains (i.e., spelt, quinoa), barley, rice, rice bran, or soy\*\* ingredients on the label
    - \*\*Soy is a legume but grouped with grains for this analysis
  - **Peas “top”:** Means peas in the top three to four ingredients after the animal protein/meats (same for lentils)
  - **Pea fractions:** Includes pea protein, pea fiber, pea starch, pea flour, etc. (same for lentils)

Because some dogs were fed more than one diet, the results are shown on both a product basis and a case basis. Some products were missing information, and if so, the product was excluded from that analysis and the numbers are the proportions of those with data. Sufficient data were available for >92 percent of products for most of the characteristics, and >96 percent for others.

## Before-diagnosis Diet Characteristics for Group One Fully and Partially Recovered Cases (n = 107): % of Reported Products



\* “By weight, whole grains (1,869,087 tons) are the most used ingredients in dog and cat foods. This is followed by chicken (854,988 tons), meat and bone meal (635,652 tons), corn gluten meal (476,599 tons) and soybean meal (437,251 tons).”

\*Pet Food Production and Ingredient Analysis– March, 2020 prepared for PFI and NARA by Decision Innovation Solutions; <http://feeder.org/wp-content/uploads/200218-Pet-Food-Report.pdf>.

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Before-diagnosis diet characteristics for Group One fully and partially recovered cases. This slide shows the characteristics of reported before-diagnosis diets on percent of reported products basis.

- 90% of the reported products met our exposure definition for “grain-free” (no corn, wheat, soy, or rice). This is consistent with patterns we’ve seen when looking at all our DCM cases.
- 94% of reported products contained peas and/or lentils in their top ingredients.
- 91.5% of the products had peas in the top ingredients.
- 87% of the products had whole peas (versus fractions) on their ingredient lists.
- 59% of the products had pea fractions.
- Lentils (45%) and lentil fractions (18%) were less common.
- Sweet potatoes or potatoes were only listed ingredients in 28% of reported products.
- Animal source proteins – No single animal protein type predominated, and this has been consistent over time. Lamb meal is the most common of the animal proteins, but chicken, kangaroo, lamb, and kangaroo meal are also common among reported products. None of the product labels had meat by-products, chicken by-products, or poultry by-products.

Looking at the Pet Food Production and Ingredient Analysis published online in March 2020 we see that “By weight, whole grains...are the most used ingredients in dog and cat foods. This is followed by chicken..., meat and bone meal..., corn gluten meal... and soybean meal...” The reported products in our 107 cases show a different pattern.



## Group One Fully and Partially Recovered Cases (n = 107): Case-based Evaluations of Diets Fed Prior to Diagnosis

% cases exposed to:	Before diagnosis diet
Grain-free (GF)	<ul style="list-style-type: none"><li>• 98 of 105* (93%) ate GF</li><li>• 95 of 105* (90%) only ate GF</li></ul>
Grain-containing**	<ul style="list-style-type: none"><li>• 7 of 105* (7%)</li></ul>
Diet with whole pulses	<ul style="list-style-type: none"><li>• 100 of 103*** (97%)</li></ul>
Diet with meat/poultry by-products	<ul style="list-style-type: none"><li>• 0 cases (0%)</li></ul>

\* In 2 cases, not enough product information was available to determine GF exposure status.

\*\* Of 7 cases consuming grain-containing without consuming a grain-free diet:

- 4 of 7 ate a vegan diet with whole peas as first ingredient
- 2 of 7 ate chicken or lamb and rice diets with split peas
- 1 of 7 ate lamb meal & rice diet

\*\*\* In 4 cases, the flavor variety was missing limiting label evaluation.

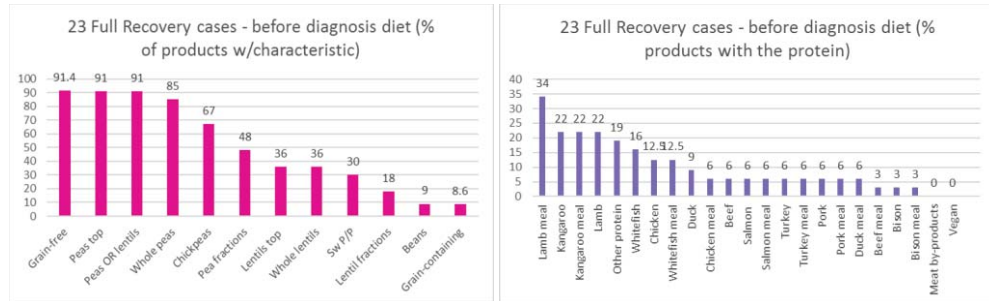
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For fully and partially recovered cases on a case-based evaluation, of the 107 fully and partially recovered cases:

- 2 of the 107 cases did not have enough information to determine grain or grain-free exposure status, and 4 of the 107 did not have enough information to determine pulse exposure status.
- 98 of 105 (93% of cases) ate grain-free foods.
- 90% (95 of the 105 cases) only ate grain-free foods.
- Of the 7 that ate grain-containing foods without eating grain-free foods:
  - 4 of the 7 ate a vegan diet with whole peas as the first ingredient.
  - 2 of 7 ate chicken or lamb and rice diets containing split peas.
  - 1 of 7 ate lamb meal and rice.
- 97% of cases (100/103) were exposed to whole pulse ingredients in their diets.
- 0% of cases were exposed to diets with meat by-products or poultry by-products.



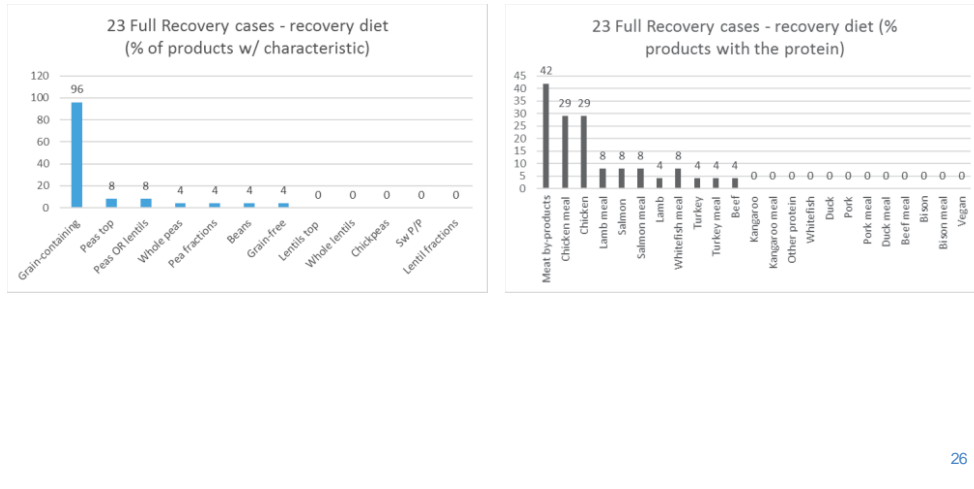
## Group One Fully Recovered Cases (n = 23) Before-diagnosis Diets: Characteristics of Reported Products



For Group One fully recovered cases – the *BEFORE diagnosis diets*, on a PRODUCT basis:

- 91.4% of reported products fed to fully recovered cases before diagnosis met our definition used here of grain-free.
- 91% of reported products had peas or lentils.
- 91% of reported products had peas in the top ingredients. 85% of products had whole peas, and 48% had pea fractions.
- 67% had chickpeas, 36% had lentils, and 18% had lentil fractions.
- Animal-source proteins: Although a wide variety is seen, the most frequent ones are lamb meal, kangaroo, kangaroo meal, and lamb.
- None had by-products.
- According to the Pet Food Ingredient Analysis (March 2020): “Chicken and chicken-related food ingredients, such as ‘chicken meal’, chicken fat, and chicken by-product meal are present most often for both cat and dog food products.”
  - The animal source proteins in the products reported before diagnosis in our 23 fully recovered cases show a different pattern.

## Group One Fully Recovered Cases (n = 23) Recovery Diets: Characteristics of Reported Products



For Group One fully recovered cases – *Recovery diets*, on a PRODUCT basis:

- 96% of the reported diets fed in the recovery period are grain-containing, although 3 were “hydrolyzed protein” diets – 2 with corn starch, 1 with brewer’s rice. For this analysis, I considered corn starch a grain (or grain derivative), although it was harder to categorize. Brewer’s rice is a grain.
- Only 8% of reported recovery diets had peas in the top ingredients, 4% had whole peas, and none had lentils.
- Animal-source proteins: 42% of the recovery diets contained meat by-products or poultry by-products (primarily poultry by-products).
- 8% of the recovery diets had lamb meal, whereas 34% had lamb meal in the before-diagnosis phase.



## Group One Fully Recovery Cases (n = 23) Case-based Evaluations

% cases exposed to:	Before diagnosis diet	Recovery diet
Grain-free (GF)	22 cases (96%) only ate GF	1 of 22* cases (4.5%)
Grain-containing	1 case (4%)**	21 of 22* cases (95.5%)
Diet with whole pulses	22 cases (96%)	1 of 21* cases (5%)
Diet with meat/poultry by-products	0 cases (0%)	8 of 21* cases (38%)

\* Recovery diet information was not available for one case, and flavor variety information for a second case.

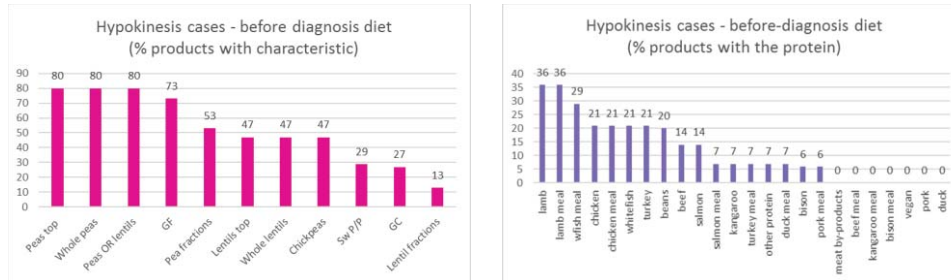
\*\* One case ate a lamb meal/brown rice diet prior to diagnosis.

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For Group One fully recovered cases – Case-based Evaluations (*before and after diagnosis*):

- We were unable to get recovery diet information in one case, so recovery diet information is shown for 22 of the 23 cases, and one additional case did not have recovery diet flavor variety information.
- 96% of the 23 fully recovered cases ate grain-free *before diagnosis*, and 1 of 22 (or 4.5% of cases) ate grain-free in the recovery phase. This was a commercial raw grain-containing diet without pulse ingredients, and the dogs was also fed some homecooked foods. Three of the cases consumed hydrolyzed protein diets in recovery: 1 had brewer's rice, and 2 had corn starch.
- 1 of the 23 cases ate a grain-containing lamb meal and brown rice diet before diagnosis.
- 96% of cases ate diets with whole pulse ingredients before diagnosis; only 1 of 21 (or 5% of cases) did in the recovery phase.
- No cases ate product with by-products before diagnosis; 38% did after, during the recovery phase.

## LV Hypokineses Cases (n = 10): Before-diagnosis Diets

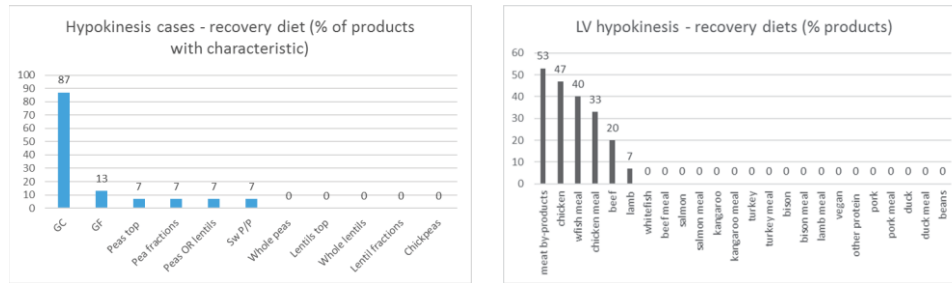


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### LV Hypokineses Cases – Before diagnosis diets:

- The trends look similar to previous slides; however with only 10 cases, and one case that ate multiple canned foods in addition to a lamb and rice diet, the percentages of each were a bit lower.
- 73% of the reported products fed before diagnosis were grain-free.
- 80% of the reported products had peas, whole peas, or peas or lentils in the top ingredients.
- Animal-source proteins: Again, there was lots of lamb and lamb meal in addition to many other types of proteins, and no by-products.

## LV Hypokinesia Cases (n = 10): Recovery Diets



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### LV Hypokinesia cases – *Recovery diets*:

- 87% of products were grain-containing.
- 7% had peas, pea fractions, peas or lentils, and of those, none were whole peas or lentils. Seven percent had sweet potato/potato ingredients.
- 53% contained by-products, and chicken and chicken meal were common. None had lamb meal.



## LV Hypokinesia Cases (n = 10): Case-based Evaluations

% cases exposed to:	Before diagnosis diet	Recovery diet
Grain-free (GF)	8 cases (80%) only ate GF	1 of 9* cases (11%)**
Grain-containing	2 cases (20%)***	8 of 9* cases (89%)
Diet with whole pulses	10 cases (100%)	0 of 9* cases (0%)
Diet with meat/poultry by-products	0 cases (0%)	7 of 9* cases (78%)

\* Recovery diet information was not available for one case.

\*\* One case ate a grain-free commercial diet with no pulse ingredients as well as a home-cooked diet in the recovery period.

\*\*\* Two cases ate lamb/lamb meal/chicken meal/rice diets with whole pulse/split pea ingredients prior to diagnosis (one of these also ate variety of canned foods).

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### LV Hypokinesia cases – Case-based evaluations:

- One of the 10 cases did not have recovery diet information available, so the recovery diet information is based on 9 hypokinesia cases.
- 80% of hypokinesia cases ate *grain-free foods before diagnosis*; only 1 of 9 ate *grain-free foods in the recovery period*.
  - That one case ate a grain-free commercial diet with no pulse ingredients as well as a home-cooked diet in the recovery period.
- Of the 2 cases that ate *grain-containing food before diagnosis*, both ate lamb or chicken meal and rice diets with whole pulse/split pea ingredients (one also ate a variety of canned foods).
- 100% of the LV hypokinesia cases ate diets with *whole pulses prior to diagnosis*, and none (0%) did during recovery.
- 0% of these cases ate *by-products* prior to diagnosis, and 78% of cases were exposed to by-products in the recovery period.

