Jerky Pet Treat Adverse Events: Descriptive Epidemiology
AAVLD 2014

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What are Jerky Pet Treats?

- Dried chicken, dried duck, dried sweet potato or yams, and variations, such as jerky wrapped yams, sweet potatoes, rawhides

- Ingredients usually consist of meat, often contain glycerin and +/- seasonings, usually without preservatives, shelf stable for months at room temperature. Most product is irradiated

- Most is imported, due to cheaper source materials (white meat chicken), preference for dark meat for human consumption
History

- The jerky pet treat (JPT) issue came to the attention of FDA CVM in the summer of 2007 after the melamine incident was coming to a close
- Blog reports appeared after a major retailer withdrew a brand of chicken JPT from shelves
  - Trace melamine was detected, but not confirmed by FDA
- 9/13/2007: the AVMA issued an alert regarding illness and consumption of JPT (specifically chicken)
- 9/14/2007 ACVIM issued an alert:
  - ACVIM Diplomates were reporting primarily small breed dogs presenting with acquired Fanconi syndrome following consumption of JPT from China
History, continued

• By early September 2007, FDA had received approximately 70 complaints (reports) of illness involving 95 dogs
• FDA issued a caution to consumers on 9/26/2007, after which report numbers increased further
• In total, during 2007, FDA received approximately 180 complaints of canine illness with a reported history of consumption of JPT (~21 were reports of acquired Fanconi syndrome)
Australian Experience with Chicken Jerky

- Acquired Fanconi “outbreak” starting September 2007
- 108 cases of acquired Fanconi were reported in Australia associated with consumption of the same brand of chicken jerky treats imported from China (Kramar Supa Naturals)
  - MF Thompson, LM Fleeman, AE Kessell, LA Steenhard, AVJ 91(9): 368-373, 2013
  - Introduced to the market two weeks prior to first reports
  - Median onset 12 weeks
- Product was withdrawn from the market about 16 months later, reporting declined
- Introduction of a “budget version”: Kramar Supa Naturals Chicken Breast Bites in 2009; cases appeared again (product withdrawn quickly)
Canadian Veterinary Medical Association notice to members: June 2011

- “Recently, several veterinarians in Ontario have reported cases of dogs that have been showing signs similar to Fanconi syndrome. All dogs in the reported cases had been fed chicken jerky treats that were manufactured in China.

- Signs of Fanconi syndrome can include decreased appetite, decreased activity, vomiting, and increased water consumption and/or increased urination. Blood tests may show increased urea nitrogen and creatinine. Urine tests may indicate Fanconi syndrome (increased glucose). The problem is that this can be confused with diabetes.”
Reports – 2007 to July, 2014

Approximate number of JPT reports received by year since 2007
Methods of Reporting: Pet Food related Adverse Events

Pet Food AE

Voluntary Reporting (veterinarian/pet owner)

- Safety Reporting Portal:
  - Pet Food Reports (PFRs)
  - Livestock Food Reports (LFRs)

- Small % received other ways, including Medwatch forms.

- Consumer Complaint Coordinators (District Offices): Consumer Complaints in FACTS

http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm
The Safety Reporting Portal

The Safety Reporting Portal streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food Manufacturers, Processors, Distributors, and Holders
- Researchers
- Drug Manufacturers

Others, including concerned citizens, health professionals, and public health officials, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

Learn more about mandatory and voluntary reporting.

Reports You Can Submit Through this Portal

FDA safety issues involving:

- Human or animal reportable foods
- Animal drugs
- Pet foods

NIH safety issues involving:

- NIH gene-transfer research

For other issues, find out where to submit your report.
Consumer Complaints

- Complaints are taken by FDA Consumer Complaint Coordinators (CCC)
- CCC are located in district offices
- CCC may alert CVM or request guidance
- CVM monitors consumer complaints collected by CCC
  - www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators
CVM Information Processing

For pet food/animal feed

- Consumer Complaint Coordinator
- Safety Reporting Portal (PFR reports)
- Consumer Complaints in FACTS
- Emergency Operations Network (EON)
- Access Database (Trending/Analysis)
Case definitions

- **Gastrointestinal:**
  - Cases limited to signs such as vomiting, diarrhea, which may be hemorrhagic, anorexia, pancreatitis, combinations of these.

- **Hepatic:**
  - Blood work that indicates liver enzyme elevation(s), veterinary diagnosis of hepatic failure. Usually also have gastrointestinal signs.

- **Renal:**
  - Blood work indicates renal failure, BUN, creatinine and urine results; or veterinarian diagnosed renal failure.

- **Urinary:**
  - Marked polyuria, polydipsia. May not have done labwork.
  - Also owner reported renal failure.

- **Fanconi-like syndrome (FLS):**
  - Glycosuria with normoglycemia or hypoglycemia +/- PennGen. Cases often display PD/PU, anorexia, lethargy, may have azotemia, often have gastrointestinal signs. Often hypokalemic, may have low or high phosphorus, metabolic acidosis.

- **Neurologic:**
  - Reports seizures, ataxia, tremors, neurologic signs, but no other major system.

- **Hematic:**
  - Severe bleeding, hemolytic anemia as the main signs reported.
What is Fanconi syndrome?

- **Proximal renal tubular dysfunction:**
  - glucose, amino acids and electrolytes fail to be reabsorbed and pass into the urine leading to clinical signs of increased thirst and urination, metabolic acidosis and eventually renal failure

- **Genetic:**
  - Basenji-usually affected between the ages of one and five years. In the US, 10% of Basenjis are found to have glycosuria

- Labrador Retriever?
Acquired Fanconi Syndrome/acquired proximal renal tubulopathy

- any age, may resolve with treatment (genetic forms don’t resolve)
- Glycosuria, aminoaciduria, +/- azotemia (all may resolve)
- Considered uncommon in dogs
- Potential causes:
  - heavy metals (lead, mercury, cadmium), Lysol, nitrobenzene, maleic acid, ethylene glycol
  - Medications:
    - outdated tetracyclines, gentamycin, azathioprine, valproic acid, salicylates
  - Disease states:
    - Leptospirosis, hepatic copper storage hepatopathy
<table>
<thead>
<tr>
<th></th>
<th>% of solute reabsorbed in unaffected dogs</th>
<th>% of solute reabsorbed in affected dogs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>100%</td>
<td>39 – 65%</td>
</tr>
<tr>
<td>Amino Acids</td>
<td>97-100%</td>
<td>50 – 99%</td>
</tr>
<tr>
<td>Phosphate</td>
<td>90%</td>
<td>47 – 79%</td>
</tr>
</tbody>
</table>

Our metabolic screening test results reveal severe amino aciduria, mild glucosuria and moderate lactic aciduria which are consistent with Fanconi Syndrome. Fanconi Syndrome may be primary (inherited) or secondary (acquired). We have associated the presence of Fanconi Syndrome with the ingestion of Chinese chicken jerky treats particularly in small breed dogs. We suggest to withdraw any supplements, provide supportive care and resubmit in a couple of months. Also, toxicological analysis of supplements may be recommended. You may consider treating this dog with the Gonto protocol. Please keep us informed.
Reports by System (all years)

- GI: 55.7%
- Renal: 22.4%
- Other systems: 17.4%

Reports for GI/hepatic and Renal/urinary systems

- GI/hepatic: 60.3%
- Renal: 9.3%
- Other system: 8%
Case Example

- A 10 year old Pug mix developed polyuria, weight loss, vomiting, diarrhea after consuming treats. Vet diagnosed pet with renal failure. Treated, but worsened, euthanized
- Got a new puppy soon afterwards, and fed puppy from the leftover bag of treats. Two weeks later, puppy developed lethargy & vomiting. At vet: BUN 137, creatinine 4.8, USG 1.013, 2+ glycosuria, trace proteinuria. Treated, survived
## Age by System (years)

<table>
<thead>
<tr>
<th>AGE (yrs)</th>
<th>Overall</th>
<th>GI</th>
<th>Hepatic</th>
<th>FLS</th>
<th>Non-FLS</th>
<th>Renal</th>
<th>Urinary</th>
<th>Neuro</th>
<th>Hematic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>6.44</td>
<td>5.8</td>
<td>7.1</td>
<td>5.5</td>
<td>7.51</td>
<td>7.41</td>
<td>6.6</td>
<td>7.57</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>6</td>
<td>5</td>
<td>7</td>
<td>5.5</td>
<td>8</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>8</td>
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<tr>
<td>Max</td>
<td>18</td>
<td>18</td>
<td>15</td>
<td>12</td>
<td>18</td>
<td>16</td>
<td>16</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>0.15</td>
<td>0.15</td>
<td>0.25</td>
<td>0.23</td>
<td>0.21</td>
<td>0.19</td>
<td>0.25</td>
<td>0.83</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>4654</td>
<td>2434</td>
<td>210</td>
<td>231</td>
<td>794</td>
<td>360</td>
<td>222</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

### AGE INDEX compared to GI mean/median age

![AGE INDEX compared to GI mean/median age](chart.png)
## Weight (lbs.) by System

<table>
<thead>
<tr>
<th>Weight (lbs.)</th>
<th>Overall</th>
<th>GI</th>
<th>Hepatic</th>
<th>FLS</th>
<th>Non-FLS Renal</th>
<th>Urinary</th>
<th>Neuro</th>
<th>Hematic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>40</td>
<td>41.58</td>
<td>37.2</td>
<td>20.8</td>
<td>39.6</td>
<td>36.8</td>
<td>43.9</td>
<td>42.3</td>
</tr>
<tr>
<td>Median</td>
<td>28</td>
<td>30</td>
<td>28</td>
<td>13</td>
<td>30</td>
<td>25</td>
<td>33</td>
<td>27</td>
</tr>
<tr>
<td>Max</td>
<td>203</td>
<td>203</td>
<td>114</td>
<td>155</td>
<td>195</td>
<td>185</td>
<td>180</td>
<td>120</td>
</tr>
<tr>
<td>Min</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>N</td>
<td>4335</td>
<td>2304</td>
<td>197</td>
<td>202</td>
<td>713</td>
<td>337</td>
<td>204</td>
<td>56</td>
</tr>
</tbody>
</table>

### Weight INDEX by compared to GI mean/median weight

- **Gi**: 1.00
- **Hepatic**: 0.86
- **FLS**: 1.00
- **Non-FLS Renal**: 1.00
- **Urinary**: 1.00
- **Neuro**: 1.00
- **Hematic**: 1.00

- **Mean**
- **Median**
Gender (2007 – 7/2/2014)

Gender by System (% female)

- GI: 51.7%
- Hepatic: 51%
- FLS: 64.5%
- Non-FLS Renal: 55.3%
- Urinary: 58.8%
- Neuro: 50%
- Hematic: 41.7%
## Top 10 breeds by case type

<table>
<thead>
<tr>
<th>GI</th>
<th>HEPATIC</th>
<th>FANCONI</th>
<th>Non-FLS Renal</th>
<th>URINARY</th>
<th>NEUROLOGICAL</th>
<th>HEMATIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labrador Retriever</td>
<td>Labrador Retriever</td>
<td>Maltese</td>
<td>Mixed - LG</td>
<td>Mixed - LG</td>
<td>Labrador Retriever</td>
<td>Dachshund</td>
</tr>
<tr>
<td>Mixed - LG</td>
<td>Chihuahua</td>
<td>Chihuahua</td>
<td>Labrador Retriever</td>
<td>Yorkshire Terrier</td>
<td>Mixed - LG</td>
<td>Labrador Retriever</td>
</tr>
<tr>
<td>Chihuahua</td>
<td>Mixed - LG</td>
<td>Yorkshire Terrier</td>
<td>Yorkshire Terrier</td>
<td>Chihuahua</td>
<td>Chihuahua</td>
<td>Mixed - LG</td>
</tr>
<tr>
<td>Shih Tzu</td>
<td>Beagle</td>
<td>Shih Tzu</td>
<td>Chihuahua</td>
<td>Labrador Retriever</td>
<td>Dachshund</td>
<td>Australian Shepherd</td>
</tr>
<tr>
<td>Yorkshire Terrier</td>
<td>Jack Russell Terrier</td>
<td>Mixed - SM</td>
<td>Shih Tzu</td>
<td>Dachshund</td>
<td>Yorkshire Terrier</td>
<td>Chihuahua</td>
</tr>
<tr>
<td>Poodle</td>
<td>Dachshund</td>
<td>Poodle</td>
<td>Beagle</td>
<td>Shih Tzu</td>
<td>Boston Terrier</td>
<td>Cocker Spaniel</td>
</tr>
<tr>
<td>Dachshund</td>
<td>Maltese</td>
<td>Dachshund</td>
<td>Mixed - SM</td>
<td>Mixed - SM</td>
<td>Mixed - SM</td>
<td>Miniature Pinscher</td>
</tr>
<tr>
<td>German Shepherd</td>
<td>Shih Tzu</td>
<td>Cavalier KC Spaniel</td>
<td>Dachshund</td>
<td>Poodle</td>
<td>Shih Tzu</td>
<td>Pomeranian</td>
</tr>
<tr>
<td>Golden Retriever</td>
<td>Poodle</td>
<td>Jack Russell Terrier</td>
<td>Poodle</td>
<td>Beagle</td>
<td>Poodle</td>
<td>Pug</td>
</tr>
<tr>
<td>Mixed - SM</td>
<td>Schnauzer</td>
<td>Pomeranian</td>
<td>Schnauzer</td>
<td>Jack Russell Terrier</td>
<td>Jack Russell Terrier</td>
<td>Shetland Sheepdog</td>
</tr>
</tbody>
</table>

24
Death rates (2007 to July 2014)

Death rate (%) by system

<table>
<thead>
<tr>
<th>Category</th>
<th>Death Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>18.1</td>
</tr>
<tr>
<td>Hematic</td>
<td>53</td>
</tr>
<tr>
<td>Non-FLS Renal</td>
<td>46</td>
</tr>
<tr>
<td>Hepatic</td>
<td>25</td>
</tr>
<tr>
<td>Neurologic</td>
<td>18.6</td>
</tr>
<tr>
<td>Urinary</td>
<td>18</td>
</tr>
<tr>
<td>FLS</td>
<td>7.5</td>
</tr>
<tr>
<td>GI</td>
<td>7.2</td>
</tr>
</tbody>
</table>

Deaths by system (# died)

- GI: 234
- Urinary: 78
- Non-FLS Renal: 410
- Hepatic: 48
- Hematic: 38

Legend:
- GI
- HEPATIC
- FLS
- NON-FLS RENAL
- URINARY
- NEURO
- HEMATIC
Geographic Locations

• Reports received from all 50 states, 5 Canadian provinces
• Besides the large number of reports from Florida, California and Texas, there does not seem to be a geographic distribution pattern that lends clues to etiology
• Reports tend to coincide with the distribution of US population
  – Greater proportion of FLS reports from Florida may be due to interest and awareness among specialists
# Top 10 states by case type (2007 – 7/2014)

<table>
<thead>
<tr>
<th>GI</th>
<th>HEPATIC</th>
<th>FANCONI</th>
<th>Non-FLS Renal</th>
<th>URINARY</th>
<th>NEURO</th>
<th>HEMATIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>CA</td>
<td>FL</td>
<td>CA</td>
<td>CA</td>
<td>CA</td>
<td>TX</td>
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<tr>
<td>FL</td>
<td>FL</td>
<td>CA</td>
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<td>FL</td>
<td>FL</td>
<td>CA</td>
</tr>
<tr>
<td>TX</td>
<td>TX</td>
<td>NJ</td>
<td>TX</td>
<td>TX</td>
<td>PA</td>
<td>WA</td>
</tr>
<tr>
<td>NY</td>
<td>WA</td>
<td>OH</td>
<td>WA</td>
<td>PA</td>
<td>MI</td>
<td>MD</td>
</tr>
<tr>
<td>NJ</td>
<td>PA</td>
<td>NY</td>
<td>NY</td>
<td>MI</td>
<td>NY</td>
<td>GA</td>
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<td>PA</td>
<td>NY</td>
<td>MI</td>
<td>PA</td>
<td>OH</td>
<td>OH</td>
<td>MI</td>
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<td>WA</td>
<td>IN</td>
<td>WA</td>
<td>VA</td>
<td>IL</td>
<td>WA</td>
<td>NJ</td>
</tr>
<tr>
<td>MI</td>
<td>OH</td>
<td>IL</td>
<td>NJ</td>
<td>NY</td>
<td>MN</td>
<td>PA</td>
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<tr>
<td>OH</td>
<td>GA</td>
<td>NC</td>
<td>IL</td>
<td>MA</td>
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<tr>
<td>NC</td>
<td>IL</td>
<td>PA</td>
<td>NC</td>
<td>NC</td>
<td>NJ</td>
<td>NY</td>
</tr>
</tbody>
</table>
Case Control Study with CDC

- In May 2014, FDA & CDC collaborated on a study of cases reported to FDA of sick dogs compared with “controls”
- Goal is to compare foods eaten by both groups and determine if sick dogs are eating more jerky
- “Sick dogs” included diagnosis of Fanconi (or FLS) and dogs ≤5 yrs. with renal failure.
- Study is still ongoing
2012 Inspections

- In April 2012, FDA inspected 5 jerky pet treat facilities in China. Firms were selected based on number and severity of illness reports.
- Valuable information was obtained regarding manufacturing operations, ingredients & raw materials used, processing, packaging, quality control, sanitation, and product testing.
- FDA identified concerns on record keeping practices of several inspected firms.
- Resulted in AQSIQ seizing products and suspended exports to the U.S.
Take Home Points

• Pets can be sentinels for broader food issues
  – More limited diet generally (less variety)

• Acquired Fanconi
  – Urine samples – treat eaters
  – Small breed dogs, but not limited to those
  – Withdrawal of treats and support therapy
  – May resolve!
  – Report cases to FDA
Questions?