BERNACKI, GAIL ATTACHMENTS TO SDL ATTACHMENT NO. 4

Mr. William Marler Marler Clark, LLP, PS 1301 Second Avenue, Suite 2800 Seattle, Washington 98101

RE: Case Review, E. coli O157:H7 Gail Bernacki

Dear Mr. Marler:

You asked me to review information regarding the 2012 illness of Gail Bernacki due to an *E. coli* O157:H7 infection.

I am a medical doctor, with substantial work and teaching experience in the areas of epidemiology and infectious diseases. Epidemiology is the branch of medicine that deals with the causes, distribution and control of disease in populations. I have significant experience with the epidemiology of foodborne disease, including *E. coli* O157:H7 outbreaks, both in the United States and abroad. I was State Epidemiologist for 15 of the 20 years that I worked for the Washington State Department of Health. From 2001 to March 31, 2008, I worked for the Field Epidemiology Training Program at the National Institute of Infectious Diseases in Japan. Since 1982, I have held a clinical faculty appointment at the University of Washington School of Public Health and Community Medicine. A true and correct copy of my curriculum vitae is attached.

A list of documents I reviewed to reach my conclusions is provided at the end of this letter. The significant facts found in the documents are summarized below:

- 1. Canadian Food Inspection Agency (CFIA) testing isolated *E. coli* O157:H7 from Tanimura and Antle romaine.
- 2. Pulsed Field Gel Electorphoresis (PFGE) testing of the isolate revealed an usual strain, which had not been reported since 2009.
- 3. Tanimura and Antle announced a recall of the affected romaine. Press releases regarding this recall were issued by the CFIA and the US Food and Drug Administration.
- 4. Gail Bernacki had a history of regularly consuming Tanimura and Antle romaine prior to her illness.
- 5. She subsequently became ill and was diagnosed with an E. coli O157:H7 infection.

6. PFGE showed that the isolate from her stool was indistinguishable from the isolate obtained from the Tanimura and Antle romaine.

Based on these facts, I can conclude, on a more likely than not basis, that:

- 1. Gail Bernacki was ill with an E. coli O157:H7 infection.
- 2. The source of her infection was Tanimura and Antle Romaine, which was contaminated with *E. coli* O157:H7.

Thank you for the opportunity to comment on this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,

John Kobayashi, MD, MPH

John M. Kobayashi

List of documents reviewed:

- 1. Canadian Food Inspection Agency, Report of Analysis 2012FFV-0000052649-4
- 2. Canadian Food Inspection Agency (CFIA) Health Hazard Alert, August 17, 2012
- 3. CFIA Expanded Health Hazard Alert, August 20, 2012
- 4. US Food and Drug Administration Recall Firm Press Release, Tanimura and Antle Voluntarily Recalls Single Lot of Romaine Lettuce Because of Possible Health Risk
- 5. Alberta Health Service, NDR Interview Form for Gail Bernacki
- 6. CFIA negative test result, Tanimura and Antle Romaine Lettuce Collected from Bernacki Home
- 7. email correspondence about collecting samples from Bernacki home