

# EXHIBIT C

## MINUTES TASK FORCE ON ALPHA GAL FRIDAY, JANUARY 29, 2016

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The Task Force on Alpha Gal met on Friday, January 29, 2016, at 10:00 a.m., in Room 149 of the State Capitol in Little Rock, Arkansas.

Committee members present: **Representatives** Julie Mayberry, Chair and Dwight Tosh, Dr. James Bledsoe, Ms. Zane Chrisman, Dr. Curtis Hedberg, Dr. Kelly Loftin, Dr. Michael Looper, Ms. Karen McCumpsey, Ms. Montine McNulty, Dr. Tina Merritt, and Dr. Susan Weinstein.

The meeting was called to order by Representative Mayberry.

### **Consideration to Approve the November 20, 2015 Minutes** [EXHIBIT C]

Dr. Merritt made a motion to approve November 20, 2015 minutes, Ms. McNulty seconded the motion. Without any objection the minutes were approved.

### **Presentation on the Brief History of Food Allergen Labeling in the United States, Dr. Steven Gendel, Vice President, Food Allergen Division, IEH Laboratories and Consulting Group** [EXHIBIT D1 – D2]

Representative Mayberry introduced, via conference call, Dr. Steven Gendel, Ms. Jenny Kleinman, Southwest Regional Education and Advocates Senior Associate, Food Allergy Research Education (FARE) and Linda Temple. She shared a short bio on Dr. Gendel and his many years of experience addressing the issues of food safety, science and policies. His presentation provided an overview of food allergen regulation and labeling regulation in the United States and other countries, to gain a better understanding of how things have progressed in recent years. The importance of allergen labeling is something that people had not been aware of until the 1990's. Awareness of this issue was pushed by advocacy of patients and their families who felt this problem was not being addressed enough by the medical community. As part of the labeling process, the Food and Drug Administration (FDA) developed guidelines and policies. Shortly afterwards, on an international level, the United Nation Food and Agricultural Organization brought together a group of experts through the Codex Alimentarius Commission to gain their knowledge on the importance of food allergens and to suggest their point of views.

The next major thing that occurred, in the mid 2000's, was the Food Allergen Labeling and Consumer Protection Act (FALCPA). This legislation defines, in legal terminology, the "Major Food Allergens". This bill also mandated labeling for the presence of those allergens and the specific format that was available. Finally, it is important to recognize that the purpose of the law and labeling regulations was to provide "plain language" information for consumers. In the 2010's, the most important thing to take place was the "Food Safety Modernization Act", which was signed by the President in early 2011. This created major changes in the way the food safety systems work in this country. One of the major components of this act is that it explicitly designated food allergens as hazardous. This law was

important because it extends the regulatory umbrella for allergens to processing as well as labeling. The “Proposed Food Labeling Modernization Act” was introduced to both the House and the Senate. This bill is a very complex bill, which will add sesame to the list of Major Food Allergens. Congress recognizes what the laboratories and consulting groups calls the “Big 8”: milk, eggs, fish, tree nuts, wheat, peanuts, soybeans and crustacean shellfish and any ingredients that contain proteins from one of these food groups. Compared on an International level, the “Big 8”, which was originally derived from the Codex Alimentarius Commission, has since been implemented in Canada and the European Union which includes (*sesame, mustard, celery and lupine*). Japan has a more complicated set of regulations with a mandatory set of labeling and requirements. Asian countries include buckwheat as an allergen as a reflection on the consumption pattern, due to buckwheat noodles being a popular food in the country. There have been well over 200 to 300 other foods that has been recognized to cause food allergies, however you can’t compose the entire list of every food item in the law, but the allergens that were chosen cause the vast majority of problems relating to food allergies.

How was significant food allergies identified? They were identified through expert clinical opinion and later “Multiple” criteria through expert opinion. Key factors include prevalence and severity. It was later discovered that “milk and egg” are much more prevalent in children than in adults; these of course are considered major problems considering that children are less likely to have a healthy diet. An additional factor considered is the public health impact of “hidden allergens”, things that people may not recognize in food.

Lastly, Mr. Gendel pointed out the legal issues of food allergens stating that FALCPA (and Proposed FLMA) amended the Federal Food Drug and Cosmetic Act (FD&C Act). These Acts were part of the FD&C Act enacted in the past. Unfortunately, FD&C Act applies only to FDA regulated foods under the FD&C Act. There are a lot of agencies involved in food regulation in particularly the USDA, Food Safety and Inspection Service (FSIS) and Treasury/TTB. They have issued regulations for consistency of labeling in addition to the organization in the Treasury Department of the Alcohol and Tax Trade Bureau which regulates labeling of alcoholic beverages. This creates consistent labeling. Major food allergens must be amended by Congress, due to FDA limited options. FDA has a wide range of responsibilities for the food supply industry; thus regulating all matters within the USDA. The FDA has many stakeholders who are all interested in enforcing their policies; they have limited resources. The FDA also has to consider their prioritization (in no particular order); legal mandates and limitations, external influences, public health and practicality.

In closing, Mr. Gendel asked that the committee continue to raise awareness of this issue because the more people know about this in government and in other areas the better off we are. He also mentioned that the committee should take action by submitting a citizen’s petition to the FDA; which was done by other groups in terms of the sesame situation with the labeling issues before the law was proposed. A formal petition requires a response from the FDA; however, there is no timeline in receiving the response. Lastly, he stated that the committee should consider engaging this issue on an International level due to other countries addressing similar issues and learning how they are addressing it in comparison.

Representative Mayberry pointed out some of the hidden ingredients that she discovered in certain food items and stressed the importance of food labeling. She asked Mr. Gendel if he would describe what is needed to put together a citizen's petition to present to the FDA. Mr. Gendel stated that citizen's petitions range all over the board being specific as: approval of a fruit additive (being there is a very detailed process for a fruit additive petition). He added that the petition needs to be presented in the form of an essay explaining "what the problem is" and provide some scientific data on how widespread it is. Mr. Gendel also suggested adding, the nature of the difficulties in "plain language" in the labeling process along with a list of suggestions changes you would like to see within the limits of authority that they currently have.

Representative Tosh shared his personal experiences with Alpha-Gal. He stated he doesn't think a lot of people understand this issue or the restrictions of not consuming certain foods such as mammalian meat. He expressed concern about what direction should the committee proceed in dealing with the awareness of Alpha Gal. Representative Mayberry expressed concern regarding the point of contact for addressing the issue in "awareness" for Alpha Gal and asked if Ms. Montine McNulty had any suggestions on bringing awareness to the issue. Ms. McNulty stated that there is a big difference in the manufactures and food producers and everyone has noticed the shift in removing certain ingredients from foods. She continued by stating that what is driving these changes are the health issues that are associated due to these ingredients that are found in certain foods.

Representative Mayberry stated that she would like to move forward in putting together the "citizen's petition". She asked for the support of Dr. Merritt in gathering whatever scientific information is needed in preparing the petition. Representative Mayberry provided the FDA website for the (Safety MedWatch) that was provided by FDA government personnel. This website allows you to make any report of Alpha Gal reactions that you may experience.

**Dr. Merritt made a motion to move forward in drafting the "citizen petition". Dr. Susan Weinstein seconded the motion, without any objections the motion passed. Representative Mayberry asked that staff be engaged in drafting the petition.**

**Presentation on Arkansas Poison Control Howell Foster, Director, UAMS College of Pharmacy, Arkansas Poison Control Center and Drug Information [EXHIBIT F]**

Mr. Foster presented his presentation on Arkansas Poison Control Center and provided resources that are available to the public for free. Arkansas Poison Control Center offers confidential helpline that is available 24 hours a day, 365 days a year. Health care professionals are available to the general public along with treatment advice and follow up. Arkansas Poison Control Center houses a staff of six (6) Nurses, six (6) Pharmacists, Certified poison specialist (CSPI), 2-DABAT, Medical Director (MD, Ph.D, ABMT) and Support staff (Supervised Pharmacy or Medical students). Gluten is the most similar type of call received. The center has a lot more data on gluten than on Alpha Gal.

Dr. Merritt asked if the manufacturers are testing the new biological for Alpha Gal. Mr. Foster stated he has not seen anything on that.

Representative Mayberry asked if Mr. Foster could provide data on how many phone calls the center receives on Alpha Gal. Mr. Foster replied that he could track that information through the center and try to push the American Association of Poison Control Center to enter a code that would allow him to specifically track Alpha Gal.

**Presentation on Minimizing Tick Bite Exposure, Dr. Kelly Loftin, Associate Professor/Extension Entomologist, Division of Agriculture, University of Arkansas at Fayetteville** [EXHIBIT E]

Dr. Loftin presented his presentation on Minimizing Tick Bite Exposure. Arkansas has two main types of ticks:

(1) Hard Ticks (Ixodidae) “*often associated with Alpha Gal*” (review handout)

- Lone Star Tick – *Amblyomma Americanum*
- Gulf Coast Tick – *Amblyomma Maculatum*
- American Dog Tick – *Dermacentor Variabilis*
- Winter Tick – *Dermacentor Albipictus*
- Black-Legged Tick – *Ixodes Scapularis*
- Brown Dog Tick – *Rhipicephalus Sanguineus*

(2) Soft Ticks (Argasidae)

- Fowl Tick – *Argus Persicus*
- Spinose Ear Tick – *Otobius Megnini*

Dr. Loftin listed preventative measures to minimize tick bite exposures: avoid tick infested areas, wear proper clothing, use tick repellents, routine self-checking, controlling ticks in the environment, and controlling ticks on hosts. Dr. Loftin will email a link to the committee on the YouTube tutorial on “tick removal”.

Representative Mayberry recognized guests to provide personal testimony on their experiences with Alpha Gal.

With no further business, the meeting adjourned at 11:56 a.m.