2011 NAFFS CONVENTION PRESENTATION

UPDATE ON DIACETYL

By: Patrick J. McNamara on October 24, 2011

On August 12, 2011 the National Institute for Occupational Safety Health ("NIOSH") issued a detailed paper for external review which calls, for the first time, an occupational exposure limit for Diacetyl and 2,3-Pentanedione. This paper was issued by NIOSH as a result of extensive studies that were done following the development of various cases of severe obstructive lung disease, also known as bronchiolitis obliterans. This disease has been associated with Diacetyl where it was utilized in various facilities making butter flavor for microwave popcorn. A series of research papers began to establish a potential causative link between intense exposure to Diacetyl and the risk of developing bronchiolitis obliterans, which is incurable. NIOSH proceeded to use cross-sectional pulmonary function data from workers exposed to Diacetyl in conducting an analysis to determine to exposure and response relationship, and to identify the risk of pulmonary function decrease at various levels of Diacetyl exposure. NIOSH confirmed from its studies that a relationship did exist between Diacetyl exposure and lower pulmonary function.

Using this quantitative risk analysis, which is set forth in great detail in the external review draft, NIOSH is recommending that exposure to Diacetyl be kept below a concentration of 5 parts per billion at a time weighted average during a forty hour work week. NIOSH has determined that workers that are exposed to Diacetyl at this concentration should have no more than a 1 in 1,000 chance of suffering reduced lung function associated with Diacetyl exposure, and less chance for developing diseases such as bronchiolitis obliterans. Furthermore, to protect

against effects of short term exposure, NIOSH is also recommending a short term exposure limit for Diacetyl at 25 parts per billion for a fifteen minute period of time.

The report also goes on to note that there are other chemicals that are being used to substitute through Diacetyl. While acknowledging that there is little health effect data on these. NIOSH takes the position that it is appropriate to consider some of them as potentially as hazardous as Diacetyl, specifically, 2,3-Pentanedione. Published reports on the toxicity of it suggest that in lab rats it causes airway damage similar to that produced by Diacetyl. NIOSH also believes that the toxic potency of the two substances appears to be roughly the same. Accordingly, NIOSH is recommending that occupational exposure to 2,3-Pentanedione is at a level comparable to that for Diacetyl. NIOSH is recommending a 9.3 parts per billion work week exposure and a 31 parts per billion exposure during a fifteen minute time period.

NIOSH recommends that employers develop and implement comprehensive occupational safety and health programs to protect works with potential exposure to chemicals such as Diacetyl and other potentially hazardous chemicals. Such a program would include exposure and medical monitoring and implementation and assessment of exposure controls. NIOSH recommends that the exposure and control assessments should do the following: 1) determine worker exposure to Diacetyl and other flavoring chemicals used in the workplace; 2) evaluating the effectiveness of work practices and engineering controls; and 3) facilitating selection of appropriate protective equipment.

NIOSH is also recommending that medical monitoring and surveillance be implemented for workers with occupational exposure to Diacetyl and similar chemicals. NIOSH believes that this process should involve developing a medical monitoring program that includes spiromitry testing for pulmonary function, medical evaluation for workers found with abnormalities on

sporomitry tests, removal from exposure pending this evaluation of employees as needed, an analysis of medical surveillance and spiromitry data on a group basis to assess work related risk factors based upon a particular job, work task, conditions in the work place area, and other exposure indices. NIOSH's position is that the purpose of epidemiologic surveillance is to assist monitoring physicians and prioritizing and evaluating the effectiveness of interventions if necessary.

A copy of the actual report is included in the CD that is being distributed with my presentation today. The main text of the report, which covers these various items in far greater detail runs approximately 500 pages. There are a series of exhibits and appendices which follow which provide additional detail and scientific information.

OBESITY TAXES

On October 1, Demark announced it is imposing a surcharge on foods that are high in saturated fat. Items such as butter, common milk, cheese, pizza, meats, oil and processed foods are now subject to the tax if they contain more than 2.3% of saturated fats. Demark is the first European nation to implement such a tax. Various states, such as California and New York, have debated the possibility of imposing a tax on sugary drinks, sodas and other carbonated beverages and sports drinks, but none has yet to be enacted into law. England is also considering some type of obesity tax as well. It is estimated that in the United States approximately 10% of children between the ages of 2 and 5 are now categorized as being obese.

The University of Houston's Department of Health and Human Performance is now collaborating with the Centers for Disease Control to create an evaluation method to examine various childhood obesity programs. The project is going to evaluate a number of large scale childhood obesity demonstration programs already being implemented by the Centers for

Disease Controls and various research institutions in three large metropolitan regions. The program will be aimed at children between the ages of 2 and 12. Information on the programs will be disseminated not only among families and schools but also among health care providers, community and faith based organizations and other private sector institutions.

FOUR LOKO CHANGE LABELING AND PACKAGING

Manufacturers of the alcoholic drink Four Loko have resolved charges of deceptive advertising brought by the Federal Trade Commission. In so doing the company has agreed to change its label and packaging; the new labels will name the amount of alcohol in a can of Four Loko contains and compared to the amount found in regular beer. The manufacturer, Phusion Projects, will also change the packaging to put the drink in resealable containers.

FOOD SAFETY PROGRAMS STILL SUBJECT TO FUTURE BUDGET CUTS

At a Food Policy Conference conducted in Los Angeles on October 4th, USDA Secretary Tom Vilsack said that he was concerned about budgetary cuts in food safety program. He did state the nutrition assistance for poor families may be more vulnerable even as it helps reduce poverty. Currently in fiscal year 2012, based on a bill passed in the House of Representatives in June, the budget for the USDA's Food Safety and Inspection Service would be reduced by approximately 3.4% to a sum of approximately $972,700,000. effective October 1st. The Senate budget plan has no such reduction in it. In a speech recently given at the 34th Annual National Food Policy Conference in Washington, Food & Drug Administration Chief Margaret Hamburg reiterated her concerns for the need for sufficient funding to ensure food safety. Administrator Hamburg stated that "we need a world class science base to see over the horizon. We need to continue to work on preventative controls, importer accountability, compliance and inspection". She also went on to state that "we understand that these are times of fiscal constraints and we are

committed to doing our job by allocating our resources based on risks and priorities. We certainly cannot do everything we need to do – not without a significant infusion of financial resources". In current budget proposals the House of Representatives has proposed a cut in FDA funding of $285,000,000. in fiscal year 2012, which is a level of approximately 11% lower than funding for fiscal year 2011; in contrast, the Senate Appropriations Committee approved an extra $50,000,000. of funding for the FDA in fiscal year 2012.

ONGOING DEBATE ON USE OF BPA

As I reported to you last year the Canadian government declared BPA, a chemical widely used to create clear and hard plastics, as well as used in food container liners, to be a toxic substance. Despite these findings a recent study done by the FDA in conjunction with the National Center for Toxicological Research concluded that BPA is not harmful to infants, children or adults. However, this has not stopped several other industrial groups, associations and industries from removing them from their products. On October 10th the American Chemistry Council submitted a request to the Federal government to change the law to ban the use of BPA in baby bottles and children's sipping cups. The announcement from the American Chemistry Council that it issued the call to make clear to consumers that the substance is no longer used in the manufacture of these containers, although it remained convinced that inclusion of BPA in any food contact material was still safe. Earlier in this month, California became the tenth state to outlaw the use of BPA in baby bottles and sippy cups. It is also prohibited in Canada, the European Union, China, and Malaysia. The American Chemistry Council submitted its request to Dr. Francis Lin, Division Head at the FDA's Food Contact Substance Notification Review, to amend the food additive regulations that due to consumer preferences, all major product manufacturers have abandoned the use of polycarbonate resins containing BPA in baby

bottles and sippy cups. Back in 2009 six of the leading U.S. companies in the sector for manufacturing baby bottles and sippy cups, including Avent, Disney First Years, Gerber, Playtex, Evenflo and Dr. Brown announced that they will only use BPA free materials in the manufacture of their plastic products.

In France, the Health Minister announced on October 10th that he is giving his support to legislation that would outlaw the use BPA in all food packing starting in 2014, as well as proposing that it be banned in all packaging aimed at children starting in 2013. The measure is much broader than those I described previously and would prohibit the use of the substance in all food contact materials.

TOBACCO USE STUDY

On October 6th the FDA and the National Institute of Health announced a joint national study of tobacco users to monitor and assess the behavioral and health impacts of new government tobacco regulations. This is the first large scale collaboration between the two agencies on tobacco use research since Congress granted the FDA the authority to regulate tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009. The study is called the Tobacco Control Act National Longitudinal Study of Tobacco Users. Investigators will follow more than 40,000 users of tobacco products and those at risk for tobacco use from ages 12 and up. The study will examine what makes people susceptible to tobacco use, evaluate use patterns and resulting health problems, how often people relapse back into use or are able to cease using tobacco products, evaluate the effects of regulatory changes on consumers' attitude toward tobacco products, and assess differences in behaviors and key health outcomes in racial, ethnic, gender and age subgroups. It is the goal of the FDA to use the study findings to determine how best to use its regulatory power, such as making decisions regarding

marketing of products, setting product standards, and communicating the risks of tobacco use to protect the public health.

SODIUM CONSUMPTION POLICY MEETING BETWEEN FDA AND THE USDA FOOD SAFETY AND INSPECTION SERVICE

On October 11, 2011 the Food and Drug Administration and the Food Safety Inspection Service of the USDA announced that they will be jointly conducting a public meeting entitled "Approaches to Reducing Sodium Consumption" on November 10, 2011. The purpose of this meeting is to solicit comments, data and evidence relevant to the dietary intake of sodium, as well as current and emerging approaches designed to promote sodium reduction. The purpose of the public meeting is to provide interested persons with an opportunity to discuss the topics raised in the Federal Register notice that went out on September 15, 2011 to collect this information. Electronic comments can be submitted in advance of the meeting through the FDA website. You can also register through the FDA website if you wish to attend or make a presentation at this meeting. The meeting will also be available via webcast. The webcast will run all day from 9:00 a.m. to 5:30 p.m., running parallel with the date of the hearing, which is being conducted at the FDA White Oak Campus in Silver Springs, MD. The respective agencies are especially interested in hearing about sodium reduction related research results or ongoing research efforts. Electronic or written comments will be accepted through November 29, 2011.

FOOD SAFETY MODERNIZATION ACT

As you are probably aware, this law was signed by President Obama last January. It gives the FDA broad new authority to focus on preventing food safety problems and new enforcement authority designed to achieve higher rates of compliance with prevention and risk based food safety standards. The new law also gives the FDA new powers to hold imported foods to the same standards as domestic foods. It also directs FDA to develop an integrated

national food safety system working collaboratively with state and local authorities. Let me give you a brief rundown of the new mandates and authority that has been given to FDA:

- Prevention. A now has the authority to impose mandatory preventive controls for food facilities. For the first time, food facilities are required to implement a written preventative control plan that evaluates the hazards that could effect food safety; specifying the preventative steps and controls to be put in place to minimize and prevent those hazards; specifying how the facility will monitor these controls to ensure they are performing; maintaining routine records of monitoring; and specifying what actions a facility will take to correct problems that arise. Final regulations to establish this protocol are due out next summer.
- Mandatory produce safety standards. FDA has two years to issue regulations establishing science based minimum standards for the safe production and harvesting of fruits and vegetables. The regulations will address naturally occurring hazards, soil conditions, hygiene, packaging, temperature controls and water supply.
- Authority to prevent intentional contamination. FDA has 18 months to issue regulations to protect against the intentional adulteration of food, including the establishment of science based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points.
- Inspection and compliance. The new law provides FDA with several new mandates for inspection and compliance, including the following:
    - Mandated inspection frequency. Within one year of adoption of the law, FDA is supposed to inspect at least 600 foreign facilities and double those inspections

every year for the next five years. The obvious question will be whether there is sufficient funding and manpower to meet this mandate.

  - Records access. FDA will have access to records including industry food safety plans and the records that firms will be required to keep documenting implementation of these plans.
  - Testing by accredited laboratories. This program has to be established by January 2013 to establish a program for laboratory accreditation to ensure that US food testing laboratories meet appropriate standards.

- Enforcement Powers. The new law gives the FDA broad authority, including the following:
  - Mandatory recall power when a company fails to voluntarily recall unsafe food after being requested to do so by the agency.
  - Expanded administrative detention to hold products that are potentially in violation of the law.
  - Suspension of registration of a facility if FDA determines food poses a reasonable probability of serious adverse health consequences for enhanced product tracking ability.
  - Advanced recordkeeping for high risk foods. This will be done by rule making which is due in January of 2013.
- Imports. There are broad new powers given to FDA in this realm, including the following areas:

- Import or accountability where importers have explicit responsibility to verify their suppliers of adequate preventive controls in place to ensure the food they are producing is safe.
- Third party certification program, establishment of a system for FDA to recognize accreditation is due in January 2013.
- Certification for high risk foods. They must now be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the United States.
- Voluntary qualified importer program. FDA is to establish a voluntary program for importers to provide for expedited review and entry of foods from participating importers. It is expected implementation of this will be in the summer of 2012.
- Authority to deny entry. FDA can refuse entry into the US of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

Since adoption of the law, the FDA has already moved forward issuing draft guidance or taking other action to start implementation of this new law. In July, the FDA announced an anti smuggling program developed with the Dept. of Health and Human Services and the Dept. of Homeland Security to identify and prevent smuggled foods from entering into the United States, which poses a threat to national security or consumer safety. The FDA will be working with the US Customs and boarder protection to implement this program.

On July 3, 2011 the FDA issued draft guidance to the dietary supplement industry on assuring the safety of new dietary ingredients. Dietary supplement manufacturers are now

required to notify FDA in advance when they intend to add a new dietary ingredient to their products, except in situations where the ingredient has already been part of the food supply and has not been chemically altered for use in supplements. The notifications must identify the new dietary ingredient and be accompanied by evidence on its safety.

CAMPBELL SOUP SETTLES LITIGATION ALLEGING MISLEADING CLAIMS ON "LESS SODIUM" CONTENT IN TOMATO SOUP

A lawsuit filed in U.S. District Court in New Jersey was settled in September by the Campbell Soup Company. The lawsuit was brought by four women who claimed that the company's "less sodium" claim on cans of tomato soup was misleading. The plaintiffs accused Campbell Soup of selling its "25% less sodium" tomato soup at a premium price although it allegedly contained the same amount of sodium per serving as its regular tomato soup. Campbell's denied the allegations. In settling the matter, in a company statement, Campbell's stated that it has "agreed to a new process for labeling and advertising claims in California to avoid inconsistent comparisons between the same varieties of reduced sodium condensed and regular condensed soup". In April U.S. District Judge Jerome Simandle denied a motion by Campbell's to dismiss the case, ruling in part that consumers may be expected to find the less sodium claims misleading. In his ruling he stated that "it is a plausible inference from the facts alleged that it was reasonable for plaintiffs to expect that the soup they were receiving had 25% to 30% less sodium than the regular tomato soup, when the soups in fact had approximately the same amount of sodium". The settlement amount was $1.05 million.

NEW PATENT LAW SIGNED WHICH CHANGES THE SYSTEM FOR AWARDING PATENTS

Last month President Obama signed into law the America Invents Act. For the first time, the United States government will award patents to inventors on a first to file basis. Previously,

patents were issued on a first to invent basis, which some critics of the law thought created litigation over fights over who was truly the first party to invent the item being patented. The new law had bipartisan backing in Congress, which also provides that an applicant should have a decision within 12 months instead of the roughly 30 months that a current applicant has to wait. The law also allows the U.S. Patent and Trademark Office to keep the revenue it generates from fees in order to use it to higher additional staff. The Director of the Patent and Trademark Office has announced plans to hire between 1,500 and 2,000 new patent examiners to review applications for fiscal year 2012, which began on October 1st. The law also provides for up to 100 new administrative law judges to be hired to reduce the backlog of appeals. The U.S. Patent and Trademark Office issued nearly 250,000 patents in 2010.

The first to file system is used in numerous other countries, so it places the United States on the same playing field in determining priority of an invention based on the earliest date a patent application was filed with a patent office. The new law also creates a statute of limitations for a party wishing to challenge the filing of a petition to a period of nine months following the grant of the patent or issuance of a re-issued patent. Such a review may be granted if the petitioner can make a reasonable showing that at least one of the claims asserted in favor of the patent can be shown as being something that should not warrant issuance of a patent. The only other alternative is where the petitioner can show there is a novel or unsettled legal question important to the particular patent or application. Appeals of decisions by the Patent Trial and Appeal Board, which is replacing the Board of Patent Appeals and Interferences, would be taken to the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. The Act also amends the Federal Judicial Code to deny state courts jurisdiction over legal actions relating to patents, plant variety protection or copyrights. The new law grants the Court of Appeals for the Federal

Circuit exclusive jurisdiction of appeals relating to patents or plant variety protection. The new law also requires that at least three U.S. satellite offices for the U.S. Patent and Trademark Office be established, one of which will be located in Detroit, MI. The new law also requires that the Agency conduct a study and report to Congress on effective ways to provide independent and confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exists. The new law also expresses "the sense of the Congress that the patent system should protect small businesses and inventors from predatory behavior that could result in stifling innovation". The law will take full effect in September of 2012. It will apply to any patent issued on or after that effective date.

NEW STEPS BEING TAKEN BY U.S. DEPT. OF AGRICULTURE TO FIGHT E-COLI OUTBREAKS

On September 14, 2011 the USDA announced it was adding a series of six additional sero groups of e-coli bacteria which are now being declared as adulterants in non-intact raw beef. Raw ground beef, its components and tenderized steaks found to contain these bacteria will be prohibited from sale to consumers. The USDA's Food Safety and Inspection Service is launching a testing program to detect these dangerous pathogens and to prevent them from reaching the marketplace. The policy will go into effect on March 5, 2012.

FEDERAL TRADE COMMISSION PROPOSES NATIONAL STANDARDS FOR FOODS MARKETED TO CHILDREN

In May of this year the Federal Trade Commission set out a series of proposals prepared by an interagency working group designed to limit advertising to children of foods high in sugar, sodium or saturated fats, and also promote foods toward a healthier diet. The working group proposed that all food products in categories most heavily marketed directly to children ages 2 through 17 should meet these principles by 2016, and that the sodium guidelines should be

revised in 2021. The interagency working group combined resources from the Federal Trade Commission, Food and Drug Administration, Center for Disease Control and Prevention, and the USDA. The two guiding principles behind the proposal is to create a meaningful contribution to a healthful diet, as well as targeting nutrients that have negative impacts on health or weight. Those include saturated fats, trans fats, added sugars and sodium. The guidelines can be downloaded from the FTC website. However, various trade associations such as the Grocery Manufacturers Association and the American Bakers Association have submitted comments criticizing these proposals. On October 12th the Director of the FTC's Bureau of Consumer Protection, David Vladeck, testified on behalf of the FTC at a joint Congressional hearing held by the House Energy and Commerce Committee Subcommittee on Health and the Subcommittee on Commerce, Manufacturing and Trade. In his testimony, he noted that the Children's Food and Beverage Advertising Initiative, which had been established by companies in the food industries, proposed a uniform set of nutrition principles of its own, and that represented, in his testimony, "substantial progress". He noted in his testimony that the working group received numerous comments from various stakeholders such that the working group is considering making significant revisions to the initial proposed principles for crafting final recommendations to Congress.