DSTA Day on the Hill 2019 "BASICS and ASKS"

- **Promote regulatory pathway to market for hemp-derived CBD**
  - Exploring a legal path to market for food, beverages and dietary supplements containing hemp-derived CBD is consistent with FDA's strong public health goals. Recognizing CBD products as lawful foods, beverages or dietary supplements would allow the agency to impose a reasonable regulatory framework around the processing, manufacturing and marketing of hemp-derived CBD products not intended for use as drugs. It would also permit the agency to enforce existing regulations regarding registration of manufacturing facilities; observance of good manufacturing practice regulations; supply chain security; compliance with food additive and new dietary ingredient provisions for food and dietary supplements; and post-market surveillance of serious adverse events. If FDA fails to act, consumer interest in CBD will continue to grow along with a thriving but plainly unlawful array of CBD products. No one benefits from a "wild west" scenario in which companies willing to risk FDA enforcement distribute these products without appropriate FDA oversight and guidance.

- **Cosponsor the SNAP Vitamin & Mineral Improvement Act (HR 3142, S 1717), introduced by Sens. Tim Scott (R-SC), Kyrsten Sinema (D-AZ) and Reps. Tony Cardenas (D-CA), Mike Rogers (R-AL)**
  - Nutrient shortfalls are an immediate public health issue with a viable solution. Scientific studies have shown that taking a multivitamin/mineral (MVM) helps to fill nutrient gaps. Supplementation with a MVM is associated with a lower prevalence of inadequate nutrient intakes and decreased risk of nutrient deficiencies, with a more dramatic impact seen in those who take a MVM regularly. It is good public policy to encourage Americans to eat a healthy diet to ensure adequate dietary intake of micronutrients. However, the addition of a MVM to the diet can significantly help individuals—especially those at the greatest risk of insufficiency—to meet recommended intake levels. All Americans should have the ability to make daily choices that contribute to eating healthy and achieving optimal nutrient intake. A MVM provides a scientifically-supported way to increase nutrient intake and improve nutrient status, without increasing calories. Low-income Americans who are at increased risk for inadequate micronutrient intake and who cannot afford a MVM should be given equal opportunities as other Americans to fill nutrient gaps and thereby avoid the long-term consequences of vitamin/mineral insufficiency.

- **Encourage funding for FDA's Office of Dietary Supplement Programs**
  - After the passage of DSHEA, the dietary supplement industry was estimated at $4 billion in annual sales, but since that time, has grown to $43.2 billion. This robust growth of the industry reflects not only increased interest among consumers for these products, but also significant advancements in the science of health and nutrition. This growth also brings new regulatory responsibilities to appropriately monitor the overall marketplace. The Office of Dietary Supplement Programs (ODSP), within the Center for Food Safety and Applied Nutrition (CFSAN) at FDA, was elevated from a division in December 2015 to address the growth of the dietary supplement industry and underscore the important role that dietary supplement and functional foods play in public health and the economy. This elevation was widely supported by Congress and the dietary supplement industry. In early June 2019, the House Committee on Appropriations, Subcommittee Agriculture, et al. released a report outlining priorities for FY20 Agriculture-Rural Development-FDA appropriations. Included within: an additional $3 million dollars for FDA's Office of Dietary Supplement Programs, which would bring ODSP operating budget to $10.6M. Industry supports the same, plus an additional $2M.

- **Promote membership with bicameral, bipartisan Dietary Supplement Caucus (DSC)**
  - Founded in 2006, the DSC provides a forum for the exchange of ideas and information on dietary supplements—directing attention to the role of dietary supplements in health promotion and disease prevention. The caucus currently boasts 38 members, but efforts continue to build that number to 54 members (or 10% of Congress) by the end of 2020.

- **[HOUSE ONLY] Cosponsor the National Institute of Nutrition Act (HR 1887), introduced by Rep. Tim Ryan (D-OH)**
  - The purpose of the National Institute of Nutrition (NIN) would be to facilitate and help coordinate incisive research into nutrients, foods, and their relationships to better health. The establishment of the NIN would provide robust, independent, and much needed new evidence on health effects of foods as well as independence in translation of this evidence-based nutritional science into national dietary guidelines. Improving the nation's health through better nutrition will pay enormous dividends. As it stands today, direct and indirect costs of managing diet-related chronic conditions in the United States are estimated at over $1 trillion annually and growing. Poor eating also contributes to disparities: a vicious cycle of bad health, lost productivity, increased health costs, and poverty. Given the growing role of diet in human diseases, and the fact that one in four federal dollars is spent on health care, a National Institute of Nutrition becomes all the more imperative.

- **[SENATE ONLY] Cosponsor the Health Savings Act (S 12), introduced by Sen. Marco Rubio (R-FL)**
  - Tax-Free Health Accounts like Health Savings Accounts (HSAs) and Flexible Spending Accounts (FSAs) provide consumers with incentives to make smarter decisions and to take greater control over their healthcare. With the rising costs of healthcare, consumers should be encouraged to use products and services that are cost-effective and that focus on prevention and wellness. Tax policies should incentivize the use of dietary supplements containing such beneficial nutrients as calcium, vitamin D, omega-3 fatty acids, a multivitamin with folic acid and more. Consumers benefit when the government recognizes the substantial health benefits of dietary supplements products. Expanding the coverage of HSAs and FSAs to include those products will provide economic incentives for consumers to practice preventative healthcare.

- **[SENATE ONLY] Oppose Dietary Supplement-related AER Amendment Offered to Defense Authorization**
  - CRN has learned that a dietary supplement-related amendment to the National Defense Authorization Act (NDAA) for FY20 was accepted during a Senate Armed Services Committee mark-up. The amendment would direct the military to create a system to record "the use of dietary supplements and adverse events" by all members of the U.S. Armed Forces, and would require the Defense Department to document and communicate information of "adverse event report data regarding dietary supplement use" to FDA. This warrants the industry's opposition because it is both ineffective in what it purports to do, and actually discourages candor by military personnel about their supplement use. The Dietary Supplement and Non-prescription Drug Consumer Protection Act (2006) already requires reporting of serious adverse events to the FDA and permits voluntary reporting by healthcare practitioners. Further, the amendment omits the word "serious" with respect to serious adverse event reports. "Serious adverse events" is careful defined in law, which reduces the noise in the reporting system that would clutter it if every headache, incident of indigestion, and non-serious rash was reported into the records. The language also singles out dietary supplements to be reported, and does not require any other FDA-regulated product, like OTC products, cosmetics or medical devices to be subject to this mandatory reporting.