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## ***The Workshop Addresses Questions of Dietary Supplement Research***

WASHINGTON, D.C. October 22, 2009 – An October 21 scientific symposium, *The Workshop: A Day of Science*, presented by the Council for Responsible Nutrition (CRN), brought together renowned scientists and academics, including Paul Coates, Ph.D. and Joseph Betz, Ph.D., both from the Office of Dietary Supplements (ODS) National Institutes of Health (NIH), for a robust discussion on dietary supplement scientific research, addressing questions such as “Do dietary supplements work?” and “Are we studying dietary supplements the right way?”

Steve Mister, president and CEO, CRN, began the morning by setting the stage for a full-day of scientific presentations. “The one question I get asked most when I tell neighbors, friends or new acquaintances that I work in the dietary supplement industry is, ‘Do they work?’” said Mr. Mister during his [opening remarks](#). “At the end of the day, that is why we are here—to be able to assure our customers that when they invest their money—and their faith—in our products that they are getting something that really will improve their health, help to keep them well, maybe even reduce their risk of a chronic disease, or in some cases, actually treat or reverse the disease itself.”

Mr. Mister went on to discuss one of the major challenges facing dietary supplement research—what kinds of scientific research, whether it be observational trials, randomized-controlled trials or case-reports or anecdotal evidence from healthcare practitioners, are the best way to study dietary supplements. However, Mr. Mister noted that criticizing research is useless if the dietary supplement industry doesn’t suggest an alternative for how to better study nutrients.

“As CRN continues our initiative to define a new paradigm of supplement research, today’s sessions will help identify methods and approaches that explore wellness as more than the absence of disease, and prevention as more than the abatement of symptoms. It will lead us closer to establishing a

new framework for evidence-based nutrition, a paradigm for integrating dietary supplements into healthcare, that is just as authoritative and as scrupulous and as defensible as evidence-based medicine, but unique in recognizing the differences between drugs and nutrients,” said Mr. Mister.

Throughout the rest of the day, invited expert speakers continued to build upon Mr. Mister’s remarks. Keynote speaker, David Heber, M.D., Ph.D., director, UCLA Center for Human Nutrition, went on to discuss the enigma of botanical dietary supplements and whether or not “botanical synergy” can be studied. “Botanical synergy” or “herbal synergy” refers to the idea that an extract containing a combination of agents works better than one isolated and purified active ingredient. Dr. Heber’s presentation went on to question whether the reductionist approach of isolating a single compound—which is how drug-based randomized controlled trials (RCTs) are typically designed—is the best way to study dietary supplements.

Following Dr. Heber’s presentation, Dr. Coates, chair of the first session, introduced the session topic of different perspectives on nutritional supplement research. Jeffrey Blumberg, Ph.D., director, Antioxidants Research Laboratory Jean Mayer USDA Human Nutrition Research Center on Aging, and professor, Friedman School of Nutrition Science and Policy, Tufts University, began the first session by interpreting the results of some recent high-profile RCTs and asking the question of whether or not nutrient supplementation is justified by the science. Citing high-profile RCTs which claimed to find “no benefit” of supplements, Dr. Blumberg noted that though he personally conducts RCTs and believes they are an important research approach, while it may be appropriate for investigational new drugs, they may not be the best way to study dietary supplements.

Alan Kristal, Dr.P.H., associate head, Fred Hutchinson Cancer Research Center, followed Dr. Blumberg’s presentation, speaking about randomized trials of nutrient supplementation and where to go from here. Dr. Kristal cited a greater need for smaller scale RCTs to help form more solid hypotheses that would better inform the design of large-scale RCTs to ensure that the right questions are being asked.

Speaking after lunch, during the second session of the day, Dr. Betz discussed unique challenges and possible solutions for the scientific evaluation of botanicals and specialty dietary supplements,

pointing out that many studies in the scientific literature look at the ability of an agent to treat, cure and mitigate disease—yet many of the studies in the scientific literature are studying dietary supplements, which cannot make claims to do these things and noted that this is a major disconnect in studying dietary supplements. “Dietary supplement endpoints are hard,” Dr. Betz noted. “I challenge a clinical trial designer to come up with a design that answers the question of, ‘Are we maintaining wellness?’”

Catherine M. Meyers, M.D., Office of Clinical & Regulatory Affairs, National Center for Complementary and Alternative Medicine (NCCAM), NIH, who spoke following Dr. Betz, agreed that it’s necessary to define what constitutes “wellness” in order for government institutions, who frequently conduct research, to begin developing studies to show the benefit of dietary supplement products. “People are motivated to use dietary supplement products for reasons of wellness—but there needs to be an effort to more specifically define what these wellness reasons are and how we measure them.”

The final presenters of the day, Dennis Bier, M.D., director, Children’s Nutrition Research Center, Professor of Pediatrics, Baylor College of Medicine and David S. Jones, M.D., president and chief medical officer, Institute for Functional Medicine, engaged each other and the audience in a robust discussion on how practicing physicians can or cannot interpret research on dietary supplements into practice with their patients. Drs. Bier and Jones gave divergent viewpoints, but each brought equally fascinating perspectives to the table.

CRN’s scientists, Andrew Shao, Ph.D. and Douglas MacKay, N.D., both vice presidents, scientific and regulatory affairs, were responsible for creating the agenda. Drs. Shao and MacKay ended the day by thanking the speakers for such interesting discussion. Mr. Mister also extended a special thank you to Drs. Coates and Betz from ODS NIH and Dr. Meyers from NCCAM, citing their involvement in *The Workshop* as a demonstration of openness of government agencies to consider that dietary supplement research has unique challenges that must be addressed as these agencies develop their funding priorities for future research.

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The **Council for Responsible Nutrition (CRN)**, founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 70+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN’s Code of Ethics. Visit [www.crnusa.org](http://www.crnusa.org).