

Chairman's Address:

Marjorie Fine, Chairman, Board of Directors, Council for Responsible Nutrition
The Conference: CRN's Annual Symposium on Dietary Supplements

October 4, 2008

The Hyatt Regency Tamaya Resort & Spa – Santa Ana Pueblo, New Mexico

Thank you Bill.

Thirty-five years ago, in 1973, three visionary men from three forward thinking dietary supplement companies founded a trade association with the goal of establishing a moderate, rational, scientifically-based voice for the supplement industry. Some of these leaders have passed on, but their legacy remains intact. They were Bill Thompson of the W.T. Thompson Company, George Crawford of Archon Pure Products Corporation, and Nolan Draney of Plus Products Corporation.

Today, in 2008, after thirty-five years of accomplishment, CRN has grown from three member companies to 83. And CRN is still recognized, now internationally, as the mainstream, rational, scientifically-based voice for the supplement industry. CRN's mission—to enhance and sustain a climate for our member companies to responsibly market dietary supplements and their ingredients—reflects the philosophy of the founders. Although the players and the programs have changed over the years, CRN has maintained and strengthened its position at the forefront of industry issues, at the center of industry power, and at the helm of industry leadership.

The first challenge addressed by CRN in 1973 was FDA's attempt to establish a restrictive Standard of Identity for vitamin and mineral supplements. The industry and some health-rights organizations launched a massive legal and legislative campaign to overturn FDA's effort to restrict consumer choice by imposing a rigid and conservative view of nutritional rationality. CRN was one of more than a dozen parties who immediately filed a legal challenge to the FDA rule, which the courts overturned not once but twice—once in 1974 and again in 1978 after FDA attempted a grudging and inadequate re-write. CRN also jumped into the legislative fray and initially drew strong industry criticism for not automatically supporting the bill favored by the National Health Federation. Instead, CRN supported development of an alternative legislative approach that could gain the favor of Congressman Paul Rogers, the powerful chairman of the House Health Subcommittee, whose backing CRN believed to be essential to ultimate success. The CRN approach won the day, and the "Vitamin Bill" was passed in 1976 through the efforts of Congressman Rogers, ultimately joined by Senator Proxmire, who had initially championed a different bill. The legislation avoided any sweeping restriction of FDA's authority over product safety, but still prevented the agency from establishing maximum limits on the levels or

combinations of vitamins or minerals in nutritional supplements, or from classifying a supplement as a drug solely on the grounds that its potency exceeded the level considered to be “nutritionally rational or useful.”

CRN’s activities gained immediate attention within the industry, and seven years after the “Vitamin Bill” passed, CRN’s membership had increased to 33 voting companies.

In 1990, with fifty voting members, CRN participated actively in the lobbying efforts surrounding the passage of the Nutrition Labeling and Education Act of 1990. NLEA made nutrition labeling mandatory, and for the first time permitted health claims in the labeling of foods, including dietary supplements. The whole issue of health claims was highly controversial at the time, and the notion of extending health claims to dietary supplements as well as conventional foods was especially contentious, since FDA had already made clear its desire to specifically exclude dietary supplements. Thanks to the efforts of our longstanding champion Senator Hatch and other allies, NLEA clearly established the policy that health claims should be available for dietary supplements as well as conventional foods. In implementing the Act, FDA determined that the substantiation standard for health claims for dietary supplements should be the same as that for conventional foods. This still holds today, and CRN played a role both in ensuring that health claims would be available to dietary supplements and in developing a specific list of dietary supplement health claims that FDA was required to review as a top priority. That list included the health claim relating to folic acid and neural tube birth defects, which FDA eventually approved. It also included claims relating to vitamin C and cancer, as well as omega-3 fatty acids and heart disease. It was FDA’s denial of these latter two claims that led to the 1999 judicial decision in the Pearson case that created qualified health claims.

In the early 1990s, FDA Commissioner David Kessler convened a task force to reconsider the overall question of how dietary supplements should be regulated. Astonishingly, the task force issued a report that appeared to hark back to the 1970’s notion of imposing broad restrictions. In 1993, FDA published an Advance Notice of Proposed Rulemaking that suggested that the levels of vitamins and minerals permitted in supplements should be limited, that amino acids were unapproved food additives and therefore could not be sold as supplements, and that many botanical ingredients were either unsafe or inherently used for therapeutic purposes. FDA’s action created a furor in the supplement industry, and CRN and other industry associations and companies rallied once more to defend the consumer’s right to have access to a wide variety of dietary supplements, and to have more information about the potential benefits of such products.

In 1994, with CRN boasting 65 voting members, the association joined forces with other industry groups and, working with our good friends and industry

champions, Senators Orrin Hatch and Tom Harkin, and then-Congressman (now New Mexico governor) Bill Richardson, garnered massive Congressional support for the landmark legislation that still guides the supplement industry today—the Dietary Supplement Health and Education Act of 1994. DSHEA was passed by unanimous consent and, among other things, it reaffirmed the status of dietary supplements as a category of food and created a specific definition for dietary supplements. DSHEA also provided FDA with additional enforcement authority including the ability to remove from the market products the agency deems unsafe through an “imminent hazard” clause and/or “a significant or unreasonable risk” clause. DSHEA further called for the establishment of good manufacturing practices—and after the passage of DSHEA, CRN worked tirelessly for 13 years to get a final GMP rule, which finally came about in 2007. I couldn’t be more pleased by the fact that that strong and comprehensive supplement-specific GMPs now exist. The first of 3 compliance dates has already passed, so large companies are now operating under the new GMPs, and smaller companies will follow suit over the next two years.

From its beginnings, CRN has recognized the need to explore constructive alternatives when faced with challenging issues, in order to gain support from powerful potential allies while still aggressively pursuing an agenda that best serves our members. As we’ve matured as an industry, we’ve learned to embrace regulation that helps protect our consumers, but still allows our companies the flexibility and pathways necessary to use science to improve current products... and to develop and bring new products to market. We’ve learned to support self-regulation that helps assure responsible marketing, while enabling us to communicate with our customers and potential customers. We’ve learned to fight *for* legislation that is meaningful and science-based, and fight *against* legislation that is nothing more than window dressing and bureaucratic red tape. And we’ve learned that while one company can be influential, can be forward-thinking, can be appropriately aggressive...it is, in fact, the *combined* voices and actions of a coalition of companies that can move mountains, build bridges, and best ensure an industry’s bright future.

During my two-year tenure as CRN chair, I am proud of the many accomplishments that have taken place...from the release of the final GMPs from their bureaucratic prison, to the enactment of a law that rightly makes it mandatory for companies to report serious adverse events to the government agency that regulates the supplement industry. From the partnership, driven by CRN, of four trade associations on the SIDI initiative that places focus on a protocol that creates efficiency and quality control for supplier and manufacturers doing business together...to the strategic, creative and innovative lifestyle public relations campaign, “Life...supplemented” that celebrates the more than 150 million Americans who take supplements each year. From the thought-provoking concept that we may not be studying the effects of nutrients the right way... to the brave and bold leadership demonstrated by this association and its members

in providing a financial grant to the National Advertising Division to increase scrutiny of dietary supplement advertising.

The fact is this: the Council for Responsible Nutrition consistently shows fearless leadership, pursues aggressive action, and implements tangible programs that support our mission to enhance and sustain a climate that permits our member companies to responsibly market dietary supplements and their ingredients.

One thing that is particularly striking to me is that so many of us have been on this road together for such a long time. It says something to me about this industry—that there is dedication, that there is a belief in the products we sell and in the work we're doing. I commend all of you who have brought your companies into CRN, and those of you who are actively involved in CRN leadership activities, whether at the Board level, or through committee participation. This association exists to serve you...but without your service, would cease to exist.

CRN, however, is not a private club. And we recognize the need to broaden our membership ranks. It's gratifying to see so many new faces here this year, and we are very pleased to welcome companies who are not currently members of CRN. I hope that our members will take special care to meet those company representatives that are attending this conference for the first time.

The Board made a tough, but I believe ultimately wise, decision this year. In an effort to make membership in CRN more accessible across all sectors of the responsible industry, CRN has revised its dues structure, thereby lowering annual dues for those small and mid-size companies with more than \$5 million but less than \$150 million in annual U.S. sales. This showed true leadership from the largest companies, who will see dues increase, in order to expand CRN's breadth of company representation. Our goal is to create a more equitable dues structure across the board, but still allow us to maintain the high level of membership benefits and service, while attracting new companies.

We are facing some challenging times ahead for our industry, based in part on the challenges faced by our country. We cannot become complacent about the accomplishments we have already achieved. We must continue our advocacy and education work, our communications efforts, our legislative agenda, and our support of the science. In short, we must plan for the future.

I'd be remiss if I didn't thank Steve Mister and the CRN staff—not only for the work they've done to make this conference the best executive conference in the industry, but also for their on-going commitment to all our members and to the dietary supplement industry at large. It's been a pleasure and an honor to work with them these past two years.

At the end of this year, I will relinquish my CRN chair—but I will not relinquish my involvement with, my dedication to, and my confidence in, CRN. I urge you to

join me as we all reaffirm our commitment to CRN, the leading association representing our industry. Let us continue to take responsibility for the future of this industry and take ownership of the mission we have set for ourselves. By playing an active role in our association and urging others to join us, we can constantly improve the outlook for the industry by expanding and strengthening CRN.