A PERSONAL HISTORY OF
THE COUNCIL FOR RESPONSIBLE NUTRITION (CRN),
1973 TO 2007

Compiled by Annette Dickinson, Ph.D.,
Current Consultant, Past President, and Original Staff Member
November 2007

DEDICATION AND NOTES

I would like to dedicate this history, with respect and affection, to all of the CRN member company representatives, Board members, and staff who have been my colleagues and friends and who helped make my three-plus decades of service a real pleasure and a constantly changing adventure.

In the preparation of this document, I have relied on written records where those are available and on personal memory when necessary. I apologize in advance for any errors of recall, including omission of any names or events that should have been covered.

NOTE: Following the timelines in this document may be somewhat confusing. Discussions are organized by topic, and timelines may overlap or go back and forth from one topic to another.

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TABLE OF ABBREVIATIONS

ABC	American Botanical Council
ADA	American Dietetic Association
AI	Adequate intake
AHPA	American Herbal Products Association
ANPR	Advance notice of proposed rulemaking
ASEAN	Alliance of SouthEast Asian Nations
ASTHO	Assoc. of State and Territorial Health Officials
BSE	Bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention
CHPA	Consumer Healthcare Products Association
CPSC	Consumer Product Safety Commission
CRN	Council for Responsible Nutrition
DSA	Direct Selling Association
DHA	Docosahexaenoic acid (an omega-3 fatty acid)
DRI	Dietary reference intakes (EAR, RDA, AI, UL)
DSEA	Dietary Supplement Education Alliance
DSHEA	Dietary Supplement Health and Education Act
EAR	Estimated Average Requirement
EMS	Eosinophilia myalgia syndrome
EPA	Eicosapentaenoic acid (an omega-3 fatty acid)
FTC	Federal Trade Commission
FDA	Food and Drug Administration
FDAs	Flexible spending accounts
GMPs	Good manufacturing practices
HSAs	Health savings accounts
IADSA	International Alliance of Dietary Supplement Assns.
IPEC	International Pharmaceutical Excipient Council
IOM	Institute of Medicine

NAD	National Advertising Division of the Council of Better Business Bureaus
NCI	National Cancer Institute
NTD	Neural tube defects
NGO	Non-governmental organization
NHF	National Health Federation
NIH	National Institutes of Health
NNFA	National Nutritional Foods Association (now NPA)
NLEA	Nutrition Labeling and Education Act
NPA	Natural Products Association (formerly NNFA)
NSF	Formerly National Sanitation Foundation
ODS	Office of Dietary Supplements (at NIH)
OTC	Over-the-counter (drugs)
PAC	Political action committee
PR	Public relations
RDA	Recommended Dietary Allowance
SIDI	Standardized Information on Dietary Ingredients
SIIP	Standardized Ingredient Information Protocol (task group)
TABD	Trans Atlantic Business Dialogue
UK	United Kingdom
UL	Upper level of tolerable intake
USDA	U.S. Department of Agriculture
USP	U.S. Pharmacopeia

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The Council for Responsible Nutrition (CRN) has been representing a growing segment of the dietary supplement industry since 1973. Throughout that time, CRN has consistently sought to emphasize the scientific basis of supplementation, to provide member companies with up-to-date information about emerging scientific and regulatory issues, to work cooperatively with key regulatory agencies to develop reasonable approaches to this product category, to educate legislators about the safety and benefits of dietary supplements, and when necessary to develop and pursue changes in the law in order to preserve consumer access to a wide range of dietary supplements and to full information about the composition, safety and benefits of dietary supplements.

These goals are reflected in the current statement of CRN's Mission, which is "to enhance and sustain a climate for our member companies to responsibly market dietary supplements and their ingredients by maintaining and improving confidence among consumers, media, government leaders, regulators, healthcare professionals and other decision makers with respect to our members' products."

FOUNDING OF CRN, 1973

The Council for Responsible Nutrition was incorporated in the District of Columbia in 1973 by three companies that were key players in the dietary supplement industry at that time, although none of the three founding companies currently exist as corporate entities. Philosophically, CRN's goal was to establish a moderate, rational, scientifically-based voice on dietary supplement issues at a time when most of the organizations speaking on the subject tended to be somewhat extreme. Practically, its

goal was to bring some high-caliber legal and public relations talent into the effort to prevent FDA from limiting the amounts and combinations of vitamins and minerals that could be marketed as dietary supplements.

The founders of CRN were:

- William T. Thompson, II, President of the W.T. Thompson Company;
- George Crawford, Vice President of Archon Pure Products Corporation; and
- Nolan Draney, Executive Vice President of Plus Products Corporation.

Archon Pure Products Corporation was a newly-formed publicly-held conglomerate that proposed to introduce some well-established natural products brands into supermarkets – a novel idea, at the time. Under the leadership of founder Dan Ritchie and the company's Vice President George Crawford, Archon had acquired Radiance Vitamins, El Molino Mills, Hain Oil, and other natural products companies in preparation for this move. (Although Archon was later dissolved and its assets acquired by Iroquois Brands, Radiance Vitamins today exists as a separate company, and Hain is now part of the Hain/Celestial Group, a major player in the natural products industry.) At the time of its formation, Archon Pure Products Corporation wanted a Washington presence and had retained the public relations firm of Burson Marsteller and the law firm of Wilmer, Cutler and Pickering. Burson Marsteller interviewed candidates to open and run Archon's Washington office and hired Annette Dickinson to do the job beginning in October 1972. She had been working for consumer advocate Robert B. Choate, dealing with food and nutrition issues. Her first assignment for Archon was to become familiar with the history of the Food and Drug Administration's (FDA's) proposed vitamin and mineral regulations, including the extensive administrative hearings held from 1970 to 1972, since final FDA regulations on this subject were expected to be published at any moment. The regulations would establish a standard of identity for vitamin and mineral supplements, severely limiting the amounts and combinations of nutrients they could contain.

Bill Thompson was an English major and something of a philosopher, who became a businessman when, upon his father's death, he was called upon to help his

mother ("Mrs. T") run the family's nutritional supplement company, the **W. T. Thompson Company.** (The company was in business for more than 50 years but no longer exists as a separate entity. The Thompson brand was acquired in the 1990s by Rexall/Sundown and in 2000 by Nutraceutical Corporation.) Bill Thompson was deeply interested in the philosophy as well as the practice of nutritional supplementation, and he had long been interested in establishing a nonprofit association of some type that would champion the concept of supplementation. He was also impatient with some of the existing voices that spoke for the industry, which he found to be unnecessarily strident. The existing trade associations and advocacy organizations tended to view the FDA as an enemy conspiring with the medical community to beat down the concept of nutritional supplementation, whereas Thompson took the view that reasonable people could disagree about approaches to product regulation and that such people could also sit down together and work out solutions. He wanted to create a new voice for the industry that would adopt a cooperative approach to dealing with the regulatory agencies and with Congress and that would rely on science to inform its judgments about policy issues.

Plus Products Corporation was a manufacturer of nutritional supplements and other products (including Tiger's Milk protein powders and bars), well known for its historic association with nutritionist and author Adelle Davis, who served as a consultant to the company. Its President was Nolan Draney, who at a later time became President of the W.T. Thompson Company. (The Tiger's Milk brand is currently owned by Schiff Nutrition International, formerly Weider Nutrition International.)

In June of 1973, Bill Thompson and George Crawford and Nolan Draney formally founded a nonprofit association to be called the Council for Responsible Nutrition. At the time, the W.T. Thompson Company and Plus Products Corporation were members of the National Nutritional Food Association (NNFA), of which they continued to be active members, although their establishment of a new organization created considerable controversy.

The initial Articles of Incorporation described CRN as a tax-exempt Civic League established under 501(c)(4) of the Tax Code, with companies as voting members and consumers as non-voting supporting members. Within a month, however, this initial concept had evolved, and the Articles were amended to provide that the Council would

instead be formed as a tax exempt Business League or Trade Association under 501(c)(6) of the Tax Code, and this continues to be its status today. Its members would be companies that manufacture, distribute or sell high-potency vitamin or mineral products. The scope of membership was later expanded to include companies marketing the full range of dietary supplements. The proposed activities of the Council, however, remained unchanged from the initial concept, being focused on scientific, regulatory and legislative concerns. See **ATTACHMENT A** for the full text of the Articles of Incorporation. The Council was established to:

- educate and inform the public about scientific discoveries in human nutrition and the governmental regulation of nutritional practices;
- inform its members about relevant legislative and administrative developments at the national, state or local level;
- provide a forum for its members to examine and review governmental actions;
- represent the interests of its members on the subject of vitamin and mineral regulations; and
- develop legislative and administrative proposals for submission to appropriate branches and agencies of government concerning responsible nutritional regulation.

CRN took over the Washington resources that had already been assembled by Archon, including the K Street office and the sole employee Annette Dickinson, and retained the public relations firm and the law firm. See **ATTACHMENT B** for a list of the initial and subsequent locations of the CRN offices. Bill Thompson was designated as President, and Peter J. Semper, a talented and experienced practitioner of public relations and Bill Thompson's right-hand-man, agreed to serve as Executive Director. Larry Zoeller was CRN's account executive at Burson Marsteller, and Daniel Marcus was CRN's legal counsel at Wilmer, Cutler, and Pickering. Annette Dickinson became Director of Washington Affairs, and she began arranging meetings with various regulators and legislators, to introduce CRN and to express the Council's willingness to explore reasonable solutions to the issues at hand.

REGULATION, LEGISLATION AND LITIGATION, 1970s

FDA's tentative final rule establishing a Standard of Identity for vitamin and mineral supplements was published in January 1973. Publication of the final rule followed in August 1973, and within 24 hours fifteen petitions for judicial review had been filed, including CRN's. In a race to the courthouse, the first petition was filed by the National Nutritional Food Association, and the case became known as NNFA vs FDA. The rule was stayed pending judicial review, and FDA officially withdrew it in 1979 after a series of legal and legislative setbacks, as described below.

While the courts reviewed the legal challenges to the FDA rule, advocates of health foods and nutritional supplements continued their efforts to obtain legislation to prevent FDA from limiting the formulations of vitamin and mineral supplements. The primary advocate of the legislation was the National Health Federation (NHF), a health-rights organization that represented consumers but was also funded by industry donations skillfully solicited by the NHF's man in Washington, Clinton Miller. The legislation, popularly known as the "vitamin bill," had been introduced in one Congress after another for many years and attracted numerous cosponsors, but was never given a hearing by the House Health Subcommittee. CRN had no particular ties to the existing legislation, and CRN's legal counsel questioned whether the bill as written would even accomplish the intended result of preventing FDA from unreasonably restricting formulations. Thus, CRN was open to considering other alternatives that might be viewed favorably by the powerful Chairman of the House Health Subcommittee, Paul G. Rogers (D-FL).

Chairman Rogers turned out to be open to reasonable alternative approaches, and a hearing on the whole issue was held by the House Health Subcommittee in October 1973. For daring to depart from the original language and concept of the existing "vitamin bill," both CRN and Congressman Rogers became objects of vilification by NHF and by industry supporters of the original legislative approach. By attacking Congressman Rogers in his own district during an election, the NHF guaranteed that Rogers would pursue his effort to pass an alternative version, even after Senator Proxmire entered the fray as the Senate champion for the original language.

The original "vitamin bill" would have written a definition of "special dietary uses" into the Food, Drug and Cosmetic Act and would have forbidden FDA from

limiting the amount of any ingredient unless it was "ordinarily injurious to health." The approach favored by Congressman Rogers and his health subcommittee would avoid any sweeping restriction of FDA's authority over product safety but instead would specifically prohibit FDA from limiting the formulation of dietary supplements by means of a standard of identity and prevent the agency from classifying dietary supplements as drugs solely because their potency exceeded recommended amounts. It also would expand FDA's authority over dietary supplement advertising.

CRN remained committed to Congressman Rogers' approach, despite severe NHF pressure on the member companies to renounce it. Eventually, modified and supported by Senator Proxmire as well as by Rogers' Health Subcommittee, it became law in 1976. The law added a new Section 411, "Vitamins and Minerals," to the Food, Drug and Cosmetic Act. It prohibited FDA from establishing maximum limits on the levels or combinations of vitamins or minerals in nutritional supplements by the use of its authority to establish a standard of identity or to declare a product to be misbranded. The law did not change FDA's authority to use the food additive provisions to regulate the safety of ingredients in such products, but did forbid classifying a supplement as a drug solely on the grounds that its potency exceeds the level considered to be "nutritionally rational or useful." It also codified FDA's regulatory definition of "special dietary use," and another section gave FDA authority (shared with FTC) over the advertising of nutritional supplements.

In the meantime, the Second Circuit Court of Appeals in 1974 found that FDA's standard of identity was unreasonably restrictive and overturned it in part, ordering FDA to revisit the rule and broaden its provisions. FDA proposed revisions in 1975, but the 1976 Vitamin Bill was passed before the revisions were finalized. FDA made further revisions in response to the legislation, but these were again overturned in part by the courts in 1978. In 1979, FDA threw up its hands and revoked the entire vitamin and mineral regulation – the basic labeling provisions as well as the standard of identity that had been the source of such controversy -- leaving nutritional supplements without any rule specifically governing their labeling. Companies voluntarily adopted the nutrition labeling format that FDA had created for conventional foods in 1974, and this remained the unofficial but generally accepted labeling format for over two decades. Regulations

establishing the current official nutrition labeling format for dietary supplements were not finalized until 1997.

Meanwhile nutritional supplements were being evaluated in another set of FDA proceedings, namely the massive OTC Drug Review – the brainchild of Peter Barton Hutt, FDA's chief counsel at the time (now with the firm of Covington & Burling and counsel to CRN). FDA's 1973 regulation establishing a standard of identity would not only have limited the levels and combinations of vitamins and minerals in nutritional supplements – it also provided that higher potencies and different combinations could be marketed only as OTC drugs, provided these were endorsed by an expert review panel. Even while FDA's 1973 regulation was being challenged in court and in Congress, the OTC review process was continuing apace. FDA initially formed seventeen OTC review panels, each dealing with a particular category of products (e.g., antacids, laxatives, cough/cold preparations). The expert panel on OTC vitamins and minerals was chaired by Irwin Rosenberg, a gastroenterologist with nutritional expertise, now at Tufts University. In addition to their expert members, the OTC Review panels generally had a consumer liaison member appointed by consumer groups and an industry liaison member appointed by the Proprietary Association (now the Consumer Healthcare Products Association). Pursuant to its intent to be actively involved in any regulatory proceedings affecting its members' products, CRN asked FDA for permission to appoint its own additional industry liaison member of the OTC panel on vitamins and minerals, and permission was granted. CRN's representatives over the several years of the panel's deliberations included Dr. William Marshall of Archon Pure Products Corporation and Dr. Harry Wax of Radiance Vitamins, followed by CRN's Annette Dickinson. Dickinson had been a consumer liaison member of the first OTC panel (on antacids), when she worked for consumer advocate Robert B. Choate, and thus is probably unique in having served both as a consumer liaison and an industry liaison on the OTC review panels. The vitamin panel's OTC monograph, with incredibly bad timing, was published in the *Federal Register* on March 16, 1979 -- the very same day as FDA's wholesale withdrawal of the standard of identity and labeling regulations for vitamin and mineral supplements. The NHF leaped to the conclusion that this was yet another diabolical conspiracy on the part of FDA to withdraw the vitamin regulations on one hand while

declaring the products to be OTC drugs on the other hand. In fact, it would have been possible for a general class of OTC vitamin and mineral formulations to exist quite independently of other formulations marketed as nutritional supplements, and this might have been of some use to the industry – but Senator Proxmire immediately demanded that FDA kill the OTC panel's monograph on vitamins and minerals, so it never progressed any further.

CHANGING OF THE GUARD

In 1979, Bill Thompson stepped down as President of CRN and nominated J. Robert Brouse of the Shaklee Corporation for the position of Board President, to which he was elected unanimously, while Thompson was given the newly-created title of Chairman. See **ATTACHMENT C** for a list of CRN Board members during its first decade and for a list of the current (2007) Board members.

Robert Brouse, who had played a leadership role in the Direct Selling Association (DSA) before joining Shaklee, embarked on an effort to professionalize the CRN staff and to expand the membership. (Brouse unfortunately did not remain with Shaklee very long, but returned to Washington and later served on the executive staff of the Consumer Healthcare Products Association.)

Peter Semper had served (somewhat informally) as the Executive Director of CRN since its founding, but in 1979 CRN conducted a search for a fulltime professional Executive Director, and A. Beth Coleman was hired to fill the position. She had previously served in leadership roles with the New York Port Authority and with the Girl Scouts of America. Annette Dickinson preferred to remain focused on the scientific and technical aspects of CRN's work and had the title of Technical Director, even though she was not at that time a full-time employee of CRN. (She had established a separate organization, the Basic and Traditional Food Association, whose initial product was a nutrient density chart intended to serve as a guide to food choices. She also published a monthly review of the nutrition literature called *The Scherer Survey* as a consultant to the R. P. Scherer Corporation.) Brouse and Coleman initiated a major membership recruitment campaign and made considerable progress over a short period of time, but the

Board let Coleman go in 1981. Dickinson served a brief stint as Executive Director while assisting the Board in the search for a new executive officer.

In addition to establishing a procedure for soliciting and reviewing numerous applications for the position, Dickinson decided to approach John B. Cordaro, who according to the trade press was just completing his service as Executive Director of the Food Safety Council, which had fulfilled its mission of developing a conceptual process for making better decisions about food safety and was therefore being disbanded. Cordaro had a strong background on food issues and policy management, having served with the Agency for International Development, the office of Senator Hubert Humphrey, and the Office of Technology Assessment prior to his tenure with the Food Safety Council. Although he had planned to take a break before launching into another position, he was intrigued by the CRN opportunity and was interviewed by the Board of Directors during its meeting at the 1982 Annual Conference at the L'Enfant Plaza Hotel in Washington, D.C. An offer was made and accepted, and John Cordaro began what would prove to be a 20-year career at CRN. He initially had the title of Executive Director, but this was shortly changed to President. Accordingly, the head of the CRN Board of Directors after this time was designated as Chairman. See **ATTACHMENT D** for a list of Board Presidents or Chairmen and staff executive officers from 1973 to 2007.

Cordaro and the Board continued the work begun by Brouse and Coleman and substantially expanded CRN's membership base. Key to this accomplishment were the efforts of Robert K. Fredericks of the R. P. Scherer Corporation and Kenneth M. Rosenberg of the Pharmavite Corporation, both of whom were leaders within the Board at the time Cordaro was hired. Fredericks and Rosenberg were active in urging their colleagues as well as their suppliers and customers to join the association, and they encouraged other Board members also to actively recruit members. Cordaro took the lead in arranging regional meetings and other opportunities for membership recruitment, drawing from the full spectrum of the dietary supplement industry – manufacturers marketing products through the natural products sector, the mass market, and the direct sales segment of the industry, as well as many major suppliers of dietary supplement ingredients. See **ATTACHMENT E** for a table showing CRN membership in 1983 (the ten-year anniversary), 1990 (the year of NLEA), 1994 (the year of DSHEA), and 2007.

MAJOR CRN INITIATIVES PRIOR TO DSHEA

John Cordaro led CRN to establish a Code of Ethics and to undertake some broad initiatives in the area of health claims for all foods (including dietary supplements), and also urged legislation that would permit Food Stamp recipients to use their food stamps for nutritional supplements. He also pursued numerous other programs, as described in other sections of this document, below.

Code of Ethics: In 1985, CRN established a comprehensive Code of Ethics for member companies, emphasizing the commitment of responsible companies to fair trade practices, truthful labeling and advertising, and serving consumer needs for safe and beneficial dietary supplements.

Health claims: The concept of health claims for foods was just emerging in the mid-1980s, following the joint campaign on fiber and cancer risk that had been launched by the Kellogg Company and the National Cancer Institute (NCI), which brought the concept of health claims to national attention. Cordaro systematically positioned CRN as a leader in policy forums debating the pros and cons of various approaches to health claims, and took the opportunity to argue that any health claims policy developed for the conventional food industry should also apply to dietary supplements. At the time, this was highly controversial, since FDA's initial guidelines for health claims would have specifically excluded dietary supplements. CRN submitted comments to FDA on the issue and participated actively in the lobbying that surrounded the passage of the Nutrition Labeling and Education Act of 1990 (NLEA).

NLEA made nutrition labeling mandatory, changed its emphasis from vitamins and minerals to macronutrients, and for the first time permitted health claims in the labeling of foods, including dietary supplements. The legislation initially included a list of six specific priority health claims that FDA was instructed to evaluate first, and it was Cordaro who suggested to Senate staff that the list be expanded to include another four claims especially appropriate to dietary supplements. Dickinson and other members of the CRN staff reviewed the state of the evidence on several nutrient/disease relationships and recommended the four to be added, including folic acid for reducing the risk of neural tube birth defects, antioxidants for reducing the risk of cancer, omega-3 fatty acids for reducing the risk of heart disease, and zinc for improving immune function in the

elderly. Thus, NLEA as enacted included a list of ten priority health claims for FDA review.

CRN was active throughout the period of FDA's rulemaking on the ten priority health claims in the early 1990s, submitting extensive comments and encouraging the involvement of scientific experts on each topic. NLEA clearly established the policy that health claims should be available for dietary supplements as well as conventional foods, and 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.

Food stamps: John Cordaro also saw the public policy implications of the government's refusal to permit food stamp recipients to use their stamps to purchase vitamin or mineral supplements, and he sought on several occasions to make a change in this policy. Congressman Mickey Leland (D-TX) addressed the 1987 CRN Annual Conference and urged the industry to support initiatives to improve nutrition. Congressman Bill Emerson (R-MO) introduced legislation to permit the purchase of multivitamins with food stamps, and hearings were held in the House and Senate in 1994 and 1995, at which CRN's Annette Dickinson testified. CRN also worked with academics who were in favor of the legislation, and encouraged them to testify. Dan Shaughnessy worked with CRN in efforts to pass the food stamp bill, as did the Washington firm of Olson, Frank and Weeda. The legislation did not pass, although a Senate bill required the U.S. Department of Agriculture (USDA) to prepare a report on the potential impact of permitting people to use their food stamps to purchase dietary supplements. The Senate version of the 2007 Farm Bill, which is under consideration as this history is being written, includes a provision permitting food stamps to be used to purchase some vitamin/mineral supplements.

CRN also responded actively and effectively, in the period between its formation in 1973 and the passage of DSHEA in 1994, to a wide variety of other challenging issues, always making every effort to base its positions on good science and rational policy considerations. These activities included combating a proposed FTC protein rule, obtaining modification of an FDA rule on protein products intended for weight loss, adopting voluntary dosage limits for vitamin A and other nutrients, developing guidelines for claims and analytical methods for fish oils, dealing responsibly

with the tryptophan recall and providing funding for research and a registry of cases, supporting proactive public policy on folic acid and neural tube defects, and pursuing a settlement agreement with the State of California regarding minimum feasible levels of lead in calcium supplements. See **ATTACHMENT F** for a summary of these and other major CRN activities undertaken on behalf of the industry in the period from 1973 to 1994.

DOCUMENTING SAFETY AND BENEFITS OF SUPPLEMENTS

CRN has consistently sought to educate various audiences about the safety and benefits of nutritional supplements, as well as other types of supplements, emphasizing the fact that most supplement users are ordinary people making rational decisions to add nutritional insurance to other elements of a healthy lifestyle.

In 1988 and 1989, John Cordaro was successful in raising funds from CRN members for a major PR effort to support the concept of supplementation, and a Nutrition Education Coalition was established. The *Vitamin Gap* campaign developed by Avrett, Free & Ginsberg featured the concept of a "vitamin gap" caused by common nutritional shortfalls. Ads included a "National Vitamin Gap Test" about food habits, suggesting that many people have vitamin gaps, and concluding that "Vitamins fill the gap." The print ad ran in a number of women's magazines and was promptly challenged in a complaint to the National Advertising Division (NAD) of the Council of Better Business Bureaus, filed by Dr. Victor Herbert and Dr. Stephen Barrett. Ultimately, the ad was fully vindicated by NAD.

In 1987, CRN published the first edition of *Benefits of Nutritional Supplements*, authored by Annette Dickinson. This was an effort to systematically compile the scientific evidence supporting the likely benefits of various nutritional supplements, in an easy-to-read format. Updated versions were published in 1993, 1997 and 2002. CRN arranged press conferences and satellite media tours surrounding the release of the 1997 and 2002 editions of the *Benefits* paper.

In 2003, Judy Blatman and Mike Greene, with the assistance of Gretchen Powers, designed and executed a highly effective Congressional education campaign around the theme "DSHEA: It makes sense; let's make it work." Full-page ads featuring the

benefits of various dietary supplement products were placed in Congressional newspapers and distributed to individual Congressional offices in information kits, along with a copy of the 2002 updated edition of CRN's publication *Benefits of Nutritional Supplements.*

Over the years, CRN took note of negative statements about dietary supplements that appeared in various editions of the *Dietary Guidelines for Americans.* CRN repeatedly objected to these statements and periodically met with USDA and HHS officials to explore alternatives. Gradually the statements became somewhat less negative, and the most recent edition (2005) identifies several nutrient shortfalls that exist in the U.S. population and recognizes that some people may benefit from some nutritional supplements.

In 2006, the NIH Office of Dietary Supplements persuaded NIH to convene a state-of-the-art conference on multivitamins and disease prevention. Annette Dickinson, retired from CRN, and Andrew Shao, CRN's VP, Scientific and Regulatory Affairs, prepared a comprehensive position paper on the benefits of nutritional supplements. The conference unfortunately concluded that there was not sufficient information to recommend for or against routine use of a multivitamin for the purpose of preventing chronic disease, for the general healthy population. However, CRN's Judy Blatman, VP Communications, mobilized a network of PR resources focused on this conference, and CRN's more positive perspective was liberally covered in the media reports.

In 2007, CRN launched a major PR initiative, "Life…supplemented," with special funding provided by CRN member companies, above and beyond membership dues. CRT/tanaka is the agency selected to execute the initiative. "Life…supplemented" is a consumer wellness campaign dedicated to driving awareness about the mainstream use of dietary supplements as an integral part of a proactive personal wellness regimen that combines healthy eating, dietary supplements and physical activity along with other smart lifestyle choices, such as not smoking and getting enough sleep. The program is intended to span a multi-year period and includes a variety of tactics including a consumer-oriented website, a "cool tool" interactive wellness scorecard, an on-line advertising campaign, a survey of health professionals' dietary supplement usage and attitudes, press releases and other forms of outreach to media.

CRN has not neglected telling the safety side of the supplement story. In 1995, CRN was fortunate in adding John Hathcock to the staff specifically to deal with nutrient safety issues. He is a nutritional toxicologist who had been at FDA for a decade, following a decade in academia, and he had already written extensively on the topic of the safety of vitamins and minerals. His current title at CRN is VP, Scientific and International Affairs. In 1997, CRN published the first edition of John Hathcock's work, *Vitamin and Mineral Safety,* which applied classic techniques of nutritional toxicology to the evaluation of vitamin and mineral safety, calculating an upper safe level of intake for each nutrient based on accepted principles of quantitative risk assessment. The paper is valued not only in the U.S. but internationally, and it has been translated into Japanese and Spanish by interested organizations. In addition to preparation of the CRN publication, John Hathcock also prepared a shorter version that was published as an article in the *American Journal of Clinical Nutrition*. Hathcock also obtained member company funding for various U.S. and international workshops and seminars on nutrient safety. CRN published an updated version of the vitamin and mineral safety document in 2004.

Beginning in 2005, Hathcock and Andrew Shao, VP, Scientific and Regulatory Affairs, began preparing risk assessments for nutrients other than vitamins and minerals. In 2006, Drs. Hathcock and Shao coauthored and published five peer-reviewed risk assessments on substances including creatine, lutein, lycopene, glucosamine, chondroitin, carnitine, and coenzyme Q-10. In 2007 the two published a risk assessment on vitamin D that appeared in the *American Journal of Clinical Nutrition* and called for a 5-fold increased in the UL for vitamin D. Risk assessments for the important amino acids taurine, glutamine, and arginine have been submitted for publication. The methodology used in these risk assessments is similar to that used by CRN for essential nutrients with no known toxicity. This was first proposed by CRN in 2004 as the Observed Safe Level (OSL), defined as the highest intake level used in a well-designed clinical trial with no adverse effects, in which there is sufficient confidence to base an upper limit. The concept was later adopted by FAO/WHO in 2006 as the Highest Observed Intake (HOI) and has been included as one element of an overall approach to risk assessment by scientific and regulatory authorities around the world.

INTERNATIONAL ACTIVITIES

In the 1990s, Codex Alimentarius, an international organization under the World Health Organization and the Food and Agriculture Organization that establishes guidelines and standards for foods and food ingredients in global commerce, began to involve itself in matters relating to vitamin and mineral supplements. In 1998, CRN sought and obtained official designation as a Non-Governmental Organization (NGO) eligible to participate actively in Codex Alimentarius meetings and working groups, thus becoming the first (and for many years the only) NGO representing dietary supplement interests in this critical international arena. Because the focus has generally been on safety issues and related proposals to establish maximum levels for nutrients and other compounds marketed as dietary supplements, John Hathcock has been CRN's key representative to Codex.

Hathcock has also worked with CRN member companies to modify proposals in various individual countries that would have placed severe and unwarranted dosage restrictions on specific vitamins and minerals or other key ingredients of dietary supplements. In a broader context, he has also played a key role in discussions with the European Commission regarding its separate directive on vitamin and mineral policy, which has been finalized and is now being implemented.

CRN is a member of the International Alliance of Dietary Supplement Associations (IADSA), which monitors global regulatory activities and provides advice and information to countries seeking to improve or modernize their regulatory approaches relating to dietary supplements. John Hathcock serves as an advisor to IADSA and is often called upon to advise individual countries or regional coalitions (such as the Alliance of SouthEast Asian Nations, ASEAN) on possible approaches to evaluating dietary supplement safety. Hathcock has been supported and assisted in all these activities by CRN's very active International Trade and Market Development Committee, under the recent leadership of Mark LeDoux of Natural Alternatives International and the current leadership of John Venardos of Herbalife.

RESPONDING TO EMERGING SCIENCE

In the 1980s and early 1990s, the science in favor of the benefits of generous intakes of vitamins and minerals was golden. Academic and government scientists alike predicted magnificent advances in public health that could be attained if only people got more beta-carotene, vitamin C, and vitamin E. In 1992, the Public Health Service recommended that all women of childbearing age should be sure to get 400 mcg of folic acid daily to help protect against having a baby with a neural tube defect. In 1993, two articles from Harvard were published in the New England Journal of Medicine, suggesting that women and men who took at least 200 IU of vitamin E daily had about a 40% decreased risk of getting heart disease. NIH consensus conferences on calcium and osteoporosis affirmed the role of supplements in providing the additional calcium needed by many adults, especially postmenopausal women. DSHEA was enacted in part on the strength of this longstanding wave of good news about nutrients and supplements.

CRN helped to proclaim the good news – but when the news is good, research scientists are eager to tell the tale themselves and there is no overwhelming need for others (including trade associations) to exert themselves to provide perspective. This situation changes dramatically when bad news strikes, as it did in 1994 with publication of the results of the Finnish Alpha-Tocopherol Beta-Carotene trial. In almost 30,000 Finnish smokers who continued to smoke and were given vitamin E and beta-carotene to see whether these nutrients would reduce their risk of lung cancer, the researchers and the public were stunned when the results were negative rather than positive. In those given beta-carotene, the risk of lung cancer was actually increased. CRN provided comments for the media, on behalf of the industry, and the NCI researchers at their press conference mercifully said that in their hearts, they did not believe there was harm in beta-carotene.

The Finnish study marked the beginning of a period of mixed results from major clinical trials, many of which raised questions about potential benefits and even about longterm safety. Nutrients involved included notably beta-carotene and vitamin E, but also the B vitamins that affect homocysteine levels (folic acid, B-6, and B-12). CRN has remained the strongest voice of the industry on scientific issues and has consistently sought to put new studies in perspective, emphasizing the positive where possible and seeking balance when some authors overstated the conclusiveness of their negative

findings. In these efforts, CRN was and is guided by the views of scientific experts who are specialists in particular nutrients or in the concept of preventive nutrition and who remain convinced that the totality of the evidence will ultimately confirm benefits. A basic question that is always relevant is whether a given clinical trial is truly a test of the hypothesis of prevention, and CRN hones in on this issue when the study has been done in people with disease and is therefore more nearly a trial of treatment effects than preventive effects.

In 2004, researchers at Johns Hopkins University published a meta-analysis purporting to show an increased risk of total mortality in subjects given high levels of vitamin E in clinical trials, compared to subjects in the control group. With special funding from 9 member companies, CRN went into overdrive to prepare a prompt but comprehensive response, including running a full-page ad in the *New York Times*, *Los Angeles Times* and *USA Today* with quotes from key scientists affirming the safety of vitamin E. CRN's John Hathcock already had a major scientific paper on the safety of vitamins C and E, co-authored with 13 other scientists, about to be published in the *American Journal of Clinical Nutrition*, which was valuable but not enough to turn the tide. The statistics used in the meta-analysis were questionable, and a later analysis by other experts at Johns Hopkins University, prepared for the NIH state-of-the-science conference on vitamins in 2006, concluded that there was no credible evidence that vitamin E increased mortality – but the damage was done (as always) in the first wave of media reports and could not be undone by mere fact and reason.

CRN sponsored a well-attended seminar in New York in 2005 on the safety and benefits of vitamin E, for media health and nutrition writers, in an effort to put the evidence on vitamin E into perspective. The Office of Dietary Supplements in cooperation with some of the Institutes at NIH sponsored a workshop on vitamin E in the spring of 2005, at which scientists were invited to address the safety of vitamin E in order to determine whether there was any need based on safety concerns to consider discontinuing a major clinical trial on vitamin E and selenium for reducing the risk of prostate cancer in over 30,000 men. The trial was not discontinued.

As some nutrients have come under attack in the past decade, others have risen to increased public awareness due to continuing good news, including marine omega-3 fatty

acids (EPA and DHA) and vitamin D. As always, CRN can be counted upon to be on the spot with an analysis and relevant comments, whether the results are positive or negative and whether the subject is vitamins or botanicals or other supplements like glucosamine. Hardly a week goes by without its share of good news as well as bad news, and CRN's constant presence as a source of accurate information for the industry and for the media has become a given. CRN's communications team has done an excellent job of making the media aware of the fact that the Council can be counted on for a quick reaction, and CRN's scientists have done an excellent job of seeking always to be up to speed on the latest findings and ready to respond with an analysis of the newest study for the member companies and a quotable quote for the media. Accomplishing these goals means being under constant pressure to deal with breaking news at the drop of a hat, regardless of other commitments. This requires a level of cooperative interaction among staff members that is quite remarkable, and CRN's ability to sustain such a high level of performance over the long haul may be its greatest achievement.

CRN's scientific capability has recently been enhanced further by the formation of a Senior Scientific Advisory Council (SSAC), made up of the most senior scientists in participating member companies. The group was formed at the urging of Shao and Hathcock, to advise CRN scientific staff on particular projects, but also to addess the longterm objective of influencing the scientific research agenda. Leveraging the group's networking capability and utilizing the members' combined expertise in order to raise the awareness and credibility of CRN in the eyes of the academic community has been one of the main goals. By 2007 SSAC had established its own webpage on CRN's members-only website, developed a database of 400+ government and privately funded clinical trials involving dietary supplements and established several annual research awards through the American Society of Nutrition (ASN) to be given out in conjunction with the annual Experimental Biology conference.

NEW RDAs AND POSSIBLE NEW LABELING REGULATIONS

The Food and Nutrition Board of the Institute of Medicine (IOM), within the National Academy of Sciences, has since 1941 been responsible for establishing the Recommended Dietary Allowances and for periodically revising and updating them. In

1993, the IOM announced that it would undertake a comprehensive new review of its recommendations, and for the first time would take into consideration the potential benefits of certain nutrients in protecting against chronic disease, as well as their role in meeting basic nutritional needs. Where previous RDA publications had been produced by the Food and Nutrition Board acting as a single unit, the new recommendations were created by a number of different expert committees on specific classes of nutrients: bone-related nutrients, antioxidants, B vitamins, other micronutrients, macronutrients, and electrolytes. The recommendations made for each nutrient included not only RDAs but also Estimated Average Requirements (EARs) and Upper Levels of Tolerable Intake (ULs). Where information was inadequate to permit establishment of an EAR and an RDA, an Adequate Intake (AI) was set instead. These recommendations, collectively known as Dietary Reference Intakes (DRIs) were published in six large separate volumes beginning in 1997 and ending in 2004.

In response to questions about when the new DRIs would be incorporated into nutrition labeling, FDA has consistently indicated that it plans to propose updates to nutrition labeling regulations after completion of the DRI process. As a first step, the agency published an Advance Notice of Proposed Rulemaking on November 2, 2007, requesting comments on the best approach to updating the reference intakes used in calculating the Percent Daily Values (%DV) for vitamins and minerals. This has proven to be a contentious subject in the past. In 1990 and 1991, CRN strongly objected to an FDA effort to base label reference values on a population-weighted mean of the RDAs for each nutrient, instead of using the highest RDA as the label reference value. CRN hotly opposed this proposal, which would have resulted in values that under-estimated desirable target nutrient intakes for many people. CRN established a working group that encouraged scientists to speak out on this issue, and worked with legislators to secure passage of the Dietary Supplement Act of 1992 which put a moratorium on FDA's ability to change the label reference values for a period of one year.

FDA later contracted with IOM to prepare a report on how the new DRIs should be used in nutrition labeling, and the report issued in 2003 recommended not only the use of a population-weighted mean, but also recommended basing the calculation on the Estimated Average Requirement instead of the Recommended Dietary Allowance. This

would result in even lower reference values. Some nutrition experts, including the former Executive Director of the Food and Nutrition Board Allison Yates and two chairs of the IOM Committee on Uses of the DRIs have strongly objected to this recommendation in articles and letters published in the *American Journal of Clinical Nutrition*. CRN has said in public statements that it recognizes the need to update the basis for nutrition labeling, but that it will oppose FDA adoption of any approach to calculating label reference values that would underestimate desirable target nutrient intakes for many population groups.

IMPLEMENTATION OF NLEA AND PASSAGE OF DSHEA

Some aspects of FDA's implementation of the Nutrition Labeling and Education Act helped set the stage for additional legislation, and the controversial recommendations of an FDA task force on dietary supplements provided the final impetus for the passage of the Dietary Supplement Health and Education Act (DSHEA).

NLEA required FDA to evaluate ten priority health claims within a year, and the FDA proposals published in late 1991 appeared to be designed in most cases to avoid permitting health claims for dietary supplements. Only the proposed rule on calcium and a reduced risk of osteoporosis would permit a health claim for conventional foods and dietary supplements equally. The proposed rules on fiber and cancer, soluble fiber and heart disease, and antioxidants and cancer would permit a claim only for foods that naturally contained the relevant nutrients, and denied the claims for supplements containing those same nutrients. The dietary supplement industry, convinced FDA intended to deny it the benefit of NLEA health claims, supported a Health Freedom Act introduced by Senators Hatch and Harkin that would permit such claims. It did not pass in 1992, but was a precursor to the 1994 Dietary Supplement Health and Education Act.

Then FDA added fuel to the fire. Twenty years after FDA's 1973 effort to severely limit the formulation of nutritional supplements, the agency appeared to forget the lessons learned at that time and once again went on the attack against dietary supplements. FDA Commissioner David Kessler had appointed an internal agency task force to provide advice about how dietary supplements should be regulated, and in June 1993 an Advance Notice of Proposed Rulemaking (ANPR) was published, based on the

task force's advice. It suggested that the levels of vitamins and minerals permitted in supplements should be limited, that amino acids were unapproved food additives and could not be sold as supplements, and that many botanical ingredients were either unsafe or inherently used for therapeutic purposes. The publication of the ANPR created a furor that led to the relatively swift passage in October 1994 of the Dietary Supplement Health and Education Act (DSHEA). CRN played a key role, along with the other industry trade associations, in obtaining widespread support for this legislation in both the House and the Senate – to the extent that ultimately 2/3 of the Senators and over half the Representatives had signed on as cosponsors to the bills. The key sponsors in the Senate were Senator Orrin Hatch (R-UT) and Senator Tom Harkin (D-IA), and the key sponsor in the House was Representative Bill Richardson (D-NM). Their staff members, especially Patricia Knight in Senator Hatch's office, managed the entire process of getting the bills passed and also managed the Herculean task of keeping all the industry players in line, despite organizational competition among the groups. Some of the associations specialized in grassroots organizing. CRN specialized in negotiating legal and technical issues with the key legislative players, whenever the need or the opportunity arose. In the final midnight hours of tough negotiations among key staffers in the House, CRN's legal counsel Daniel Marcus of the firm of Wilmer, Cutler and Pickering was the only industry representative allowed by the Congressional staff to participate directly in the process. Congressman Henry Waxman (D-CA) was Chairman of the House Health Subcommittee, and Congressman Dingell (D-MI) was Chairman of the parent Commerce Committee, and their staffers played a major role in determining the final shape of DSHEA. The legislation that emerged from that midnight meeting included numerous new provisions, such as the requirement for the now-ubiquitous "disclaimer" that appears on dietary supplement labels bearing structure/function claims. The next day, CRN's Board of Directors came within a hair of deciding to oppose the bill with these amendments, but Marcus persuaded them there was no option, unless they were prepared to give up the legislation altogether. In the end, the disclaimer has proven not to be a problem.

DSHEA passed, and it was signed into law on October 25, 1994. It had the immediate impact of permitting a vast array of structure/function claims, and letters of

notification about those claims started pouring into FDA; the agency issued major regulations defining the scope of structure/function claims in January 2000. The law required FDA to modify the nutrition labeling regulations applicable to dietary supplements that had been developed following NLEA, and the amended regulations were finalized in 1997. It grandfathered dietary supplement ingredients already on the market but required New Dietary Ingredient notifications for new ingredients; FDA is reviewing NDI notifications but has yet to issue a guidance document or regulations regarding the process. DSHEA retained FDA's traditional authority over the safety of foods and food ingredients, and added an additional provision declaring dietary ingredients to be adulterated if they posed a "significant or unreasonable risk" of illness or injury.

EPHEDRA, ANDRO, AND ADVERSE EVENT REPORTING

The passage of DSHEA outraged the critics of dietary supplements, who generally exaggerated its impact and misrepresented or misunderstood the laws and regulations that applied to dietary supplements before the existence of DSHEA. This outrage, plus a series of controversies over specific ingredients in the decade after DSHEA, triggered potentially damaging legislative proposals at the Federal and State levels.

Ephedra: When FDA first began hearing of adverse events related to ephedra in 1992 and 1993, the cases appeared to be related to products marketed by a single direct selling company in Texas. Ephedra/caffeine combinations marketed specifically as alternatives to street drugs also came on the market, and CRN publicly denounced them and urged FDA to take enforcement action against these types of products "masquerading as dietary supplements." However, little enforcement action was undertaken and gradually more companies got into the ephedra business, marketing the products to enhance sports performance and also as diet aids. FDA received more widespread reports of adverse events and convened special meetings of the Food Advisory Committee in 1995 and again in 1996 to try to determine what action should be taken. On both occasions, there was a diversity of opinion among members of the committee; but on both occasions a substantial core group of experts on botanicals recommended dosage

limits. In 1997, FDA issued a proposed rule that would have imposed a dosage limit and other restrictions -- based not on the advice of the Food Advisory Committee but based instead on an extrapolation of dosages involved in the adverse event reports. The GAO later found FDA's reasoning to provide an inadequate scientific basis for the proposed rule, and the proposal was withdrawn. In 2000, CRN contracted with Cantox, a scientific research firm, to prepare a quantitative risk assessment on ephedra, as a possible tool for identifying a scientifically sound dosage limit. The report recommended a dosage limit of 90 mg daily (30 mg per dose) of ephedrine alkaloids, for people with no contraindications, and a limited duration of use (maximum of 6 months). Under the leadership of Commissioner Mark McClellan, FDA contracted with the Rand Corporation for a comprehensive analysis of the ephedra situation. In 2002, FDA proposed a ban on ephedra-containing dietary supplements, concluding that they presented a "significant or unreasonable risk" to consumers because their potential risks outweighed their potential benefits. The rule became effective in January 2003 and survived subsequent judicial challenges filed by individual companies. CRN shared industry concerns about the appropriateness and implications of FDA's risk/benefit analysis but did not file a legal challenge to the rule.

Congressional concern over the ephedra issue created a push for legislation that would amend some aspects of DSHEA and require the reporting of serious adverse events to FDA by companies marketing dietary supplements. Congressmen Waxman and Dingell were the centers of action in the House, and Senator Durbin became the key proponent of action in the Senate after the ephedra-related death of a young man in Illinois. CRN and the other industry trade associations successfully opposed the sweeping legislation put forward by Senator Durbin, but supported separate legislation that would require the reporting of serious adverse events.

Andro, other steroid hormones, and precursors: Controversy surrounding athletes' use of steroids and other illegal substances (including androstenedione or "andro") spilled over to include dietary supplements. Athletes that tested positive for illegal substances sometimes claimed the substance must have come from their dietary supplements, and some dietary supplements were found upon analysis to contain illegal substances. Supplements containing androstenedione ("andro") and related compounds

were readily available over the internet and elsewhere. Senator Hatch and Senator Biden cooperated to pass the Anabolic Steroid Control Act of 2005, adding anabolic steroid hormones and some precursors to the Drug Enforcement Agency list of controlled substances, with support from the dietary supplement industry, including CRN. DHEA was deliberately omitted from this list, as it is not considered anabolic and does not otherwise meet the criteria for controlled substances, but its omission continues to be the subject of some controversy.

Adverse Event Reporting: For many years, there were calls from legislators and academics and consumer advocates for a law to require mandatory reporting of adverse events associated with dietary supplements. Such reporting was already mandatory for prescription drugs, medical devices, and OTC drugs approved through New Drug Applications, but not for OTC drugs covered by monographs and not for dietary supplements or conventional foods. During the long ephedra controversy, it was revealed that one of the major marketers of ephedra had received thousands of reports of adverse events (some of them serious), which apparently had not been evaluated by the company, let alone reported to FDA. California was also considering its own legislation on mandatory reporting of adverse events. Senator Durbin had introduced sweeping legislation that would modify many provisions of DSHEA and also require the reporting of adverse events. After Senator Hatch's staff requested that the associations come to agreement on adverse event reporting language they could support, CRN took the initiative in 2004 to convene a small working group to develop legislative language focusing just on the issue of adverse event reporting for dietary supplements and for OTC drugs. The key industry trade associations representing dietary supplements and OTC drugs all participated, and CRN counsels Peter Hutt and Eugene Lambert of Covington & Burling provided legal guidance and advice. Senate staffers invited industry participants to a series of meetings during which the language of potential legislation was hammered out. The Dietary Supplement and Nonprescription Drug Consumer Protection Act was ultimately introduced and endorsed by a broad spectrum of Congressional advocates and critics of dietary supplements, including Senators Hatch, Harkin, Enzi, Durbin, and Kennedy on the Senate side, as well as Representatives Dingell and Waxman on the House side. It became law in December 2006, as a result of the last substantive vote of

the 109th Congress, and the requirement for mandatory reporting of serious adverse events will become effective for manufacturers of dietary supplements and OTC drugs in December 2007.

EXPANDING CRN'S LEGISLATIVE CAPABILITIES

Outside legislative counsel: For a number of years CRN relied on the firm of McGuiness and Holch for outside legislative counsel. Kevin McGuiness and Markham Erickson provided excellent support, despite the fact that CRN's budget did not permit full utilization of their resources. In 2004, because of Congressional activities that were considered a threat to DSHEA, CRN decided it was necessary to invest additional resources in legislative counsel, and a number of firms were invited to make presentations to the Government Relations Committee. CRN selected Jay Hawkins, who was initially with the firm of Bergner, Bockorny, Castagnetti & Hawkins but later joined The Alpine Group. The outside legislative counsel and Mike Greene, CRN's Senior Director of Government Relations, worked effectively to ward off negative legislation and to support positive legislation. A longtime goal of Mike Greene's was realized when CRN initiated an annual Lobby Day involving Congressional visits by members of the Board of Directors and other CRN members, scheduled in conjunction with one of the Washington Board meetings.

Establishing an effective PAC: After periodic but unsuccessful attempts to establish an effective Political Action Committee (PAC) in earlier years, Mike Greene led CRN to succeed in this effort in 2004.

State legislative initiatives: CRN members have periodically requested CRN involvement in lobbying for or against specific initiatives undertaken in a State legislature. In 2003, the State of California considered legislation that would have required mandatory reporting of all adverse events to the State. The potential impact of this was so broad that CRN mobilized resources to an unusual degree, under the leadership of Mike Greene. CRN believed any requirement for AER reporting should be mandated at the Federal level and not at the state level, and that the requirement should apply to *serious* adverse events and not to minor events such as headaches and upset stomachs. Ultimately a California lobbyist (Randy Pollock) was retained to provide

assistance on this and other issues, and ultimately the California AER legislation was defeated in 2004. This California experience marked the beginning of ongoing CRN activities in the state, including an annual Lobby Day in Sacramento, during which groups of CRN members visit numerous California legislative offices to discuss particular issues.

GOOD MANUFACTURING PRACTICES, SIIP, AND SIDI

DSHEA authorized FDA to establish new Good Manufacturing Practice regulations for dietary supplements, provided these were "modeled after" food GMP regulations. CRN approached FDA officials shortly after the passage of DSHEA and offered assistance in drafting GMPs. CRN convened a GMP working group and invited representatives of other associations to join in the effort, which resulted in a comprehensive draft that was submitted to FDA in November 1995. The draft was published by FDA as an Advance Notice of Proposed Rulemaking in February 1997. Extensive comments were received, and FDA published a proposed rule in March 2003. The proposed rule was a severe disappointment, failing to incorporate recognized principles of quality assurance and instead requiring exhaustive finished-product testing. CRN again convened a GMP working group to assist in the preparation of extensive comments, in an effort to put FDA on the right track. CRN also retained an economic analysis firm and a recognized GMP expert (Carl Reynolds, retired from FDA) to add to the value of the comments, and obtained meetings with FDA officials to emphasize the importance of major modifications in the proposal. CRN also invited other associations to participate in preparing joint industry comments submitted to FDA in January 2004, following the close of the official comment period, in order to further emphasize the need for modifications and to illustrate the degree of industry agreement on the nature of the necessary changes. The final rule on dietary supplement GMPs, published by FDA in June 2007, shows that the agency accepted many of these comments to an almost unprecedented degree, and the final rule is greatly improved. CRN sponsored a 3-hour webinar in July 2007 in cooperation with Virgo Publishing to provide an in-depth review of the final rule, and sponsored a full-day members-only in-person workshop in Washington, D.C., in August 2007 in cooperation with CHPA, to permit members to

further probe the rule's provisions. FDA's Vasilios Frankos participated in both meetings. Large companies must comply with the GMP rule by June 2008, while small and very small companies must comply by June 2009 and 2010, respectively. The phased compliance dates are intended to ease the burden on smaller companies. However, companies of all sizes have been busy preparing to comply fully as soon as possible, and it is expected that the new GMPs will raise product quality and enhance consumer confidence in dietary supplements across the board. Of course, adequate enforcement by FDA and by state regulatory agencies will be key to realizing the full benefits of the new GMP rule.

In a related effort, with the goal of assisting member companies in ensuring product quality, CRN took the lead in 2006 in establishing the Joint Standardized Ingredient Information Protocol (SIIP) working group, with the cooperation of three other trade associations. CRN's Andrew Shao worked closely with the International Pharmaceutical Excipients Council (IPEC), CRN members, and other industry trade associations to design the Standardized Information on Dietary Ingredients (SIDI) protocol, to help streamline communications between ingredient suppliers and manufacturers regarding the quality of ingredients and also to ease the burden on suppliers of responding to individual customer inquiries in various formats.

BOTANICAL ISSUES

During its first two decades, CRN had historically been focused on nutritional products, while the American Herbal Products Association and the Utah Natural Products Alliance had dealt primarily with botanical products. In the mid-1990s a number of CRN member companies, including those involved in the mass market, expanded into the field of botanical products and requested that CRN develop expertise in this arena. After a long search, in 1998 CRN added John Cardellina to the staff to fulfill this role as VP, Botanical Science and Regulatory Affairs. He is a natural products chemist who had been working in drug discovery research at the National Cancer Institute. He developed a strategic overview of problems facing the botanical industry in a paper calling for "seed to shelf" controls, and in 2000 he convened an expert committee to prepare a review of botanical safety. He also managed numerous crises related to botanical issues that

erupted during his tenure. These included putting a clinical trial on St. John's Wort in perspective, helping to resolve controversies over permissible levels of a fungicide (quintozene) in ginseng products, safety issues associated with kava, and working with AOAC and other stakeholders to begin the systematic development of methods of analysis for botanical ingredients in dietary supplements. A summary of these activities is included in **ATTACHMENT G**. At the end of 2002, Cardellina returned to the National Cancer Institute to pursue his career in natural products research. CRN currently relies on its member companies with botanical expertise and on outside experts for guidance in this area, pending recruitment of another pharmacognosist or natural products chemist on staff to direct the association's activities relating to botanical issues.

MULTIPLICITY OF OTHER INITIATIVES

CRN undertook a multiplicity of other activities on behalf of the industry, following the passage of DSHEA and up to the time of this writing (2007). These were pursued under the leadership of CRN Presidents John Cordaro through 2002, Annette Dickinson from 2003 to 2005, and Steven Mister beginning in the spring of 2005. Mister was recruited as CRN President by a search committee of the Board, following Dickinson's announcement of her intention to retire. Key activities not discussed elsewhere in this history have included: participation in the Commission on Dietary Supplement Labels, continued involvement with FDA on issues relating to health claims and qualified health claims, sponsoring a workshop on structure/function claims, working with FTC to obtain guidance on dietary supplement claims in advertising, helping the industry comply with agency policy on BSE, evaluating data on vitamin A and hip fracture, cosponsoring a PEP Conference with ODS, sponsoring scientific workshops on melatonin and DHEA, supporting legislation that would permit the use of Health Savings Accounts and Flexible Spending Accounts for some dietary supplements, supporting a CRN working group that developed a quality monograph for omega-3 fatty acids, serving on the FDA Food Advisory Committee, exploring a possible product stewardship initiative, petitioning FTC for action relating to the business practices of ConsumerLab.com, and entering into an unprecedented partnership with NAD to increase

oversight of advertising claims for dietary supplements. See **ATTACHMENT G** for a summary of these and other initiatives undertaken by CRN in recent years.

CRN ANNUAL CONFERENCES AND "DAY OF SCIENCE"

From the beginning, CRN planned for its annual conferences to be modeled after professional association meetings, with substantive speakers discussing scientific and regulatory issues of interest to the member companies. This was in contrast to most industry conferences, which at the time were primarily trade shows, although virtually all now include a substantive program as well. Also, CRN established a policy of alternating the locations of the annual conferences between the East and West coasts, for the convenience of member companies.

CRN's science focus has been further emphasized by the recent establishment of a separate "day of science" workshop. At the 2004 Annual Conference, John Hathcock, CRN's VP, Scientific and International Affairs, organized a full day of scientific presentations immediately following the conference, to focus on key research areas of interest to the membership. In 2006 and 2007, CRN's Andrew Shao, VP, Scientific and Regulatory Affairs, institutionalized this concept by establishing an annual day of science (called "The Workshop: A Day of Science") in the spring of the year, separate from the Annual Conference. This annual event further highlights CRN's unique commitment to a focus on the science underlying the use of dietary supplements.

Two of CRN's earliest annual conferences established the precedent of featuring speakers and events relating directly to CRN's most vital legislative and scientific concerns. At the first formal Annual Conference at the Madison Hotel in Washington, D.C., in 1975, the guest of honor was Congressman Paul G. Rogers, Chairman of the House Health Subcommittee and ultimate arbiter of pending vitamin legislation. During the 1977 conference, CRN hosted a Congressional reception honoring the Senate Select Committee on Nutrition and Human Needs for its controversial work in establishing Nutrition Goals. Several key Senators put in an appearance, along with their staff members, and a surprise guest, Dr. Linus Pauling, came to the reception, rode with Bill Thompson on CRN's rented double-decker bus back to the L'Enfant Plaza, and then stayed for dinner with CRN members.

Key FDA and FTC officials have been featured at numerous conferences, illustrating CRN's commitment to working cooperatively with regulators to improve the environment in which the member companies do business. Officials from other U.S. government agencies have also appeared, including Peter Greenwald, Godfrey Oakley, Paul Coates, and Bernadine Healy.

International officials have often been featured, including officials of the European Commission, Codex Alimentarius, and Health Canada.

Legislators have been frequent speakers, including not only Paul G. Rogers but also Orrin Hatch, Claude Pepper, William Proxmire, Henry Waxman, and Mickey Leland.

Many research scientists have appeared to discuss their findings and their views about supplements, including Irwin Rosenberg, Charles Hennekens, Kedar Prasad, David Heber, Michael Davidson, Mark Levine, Bill Pryor, Jeffrey Blumberg, William Connor, Julie Buring, Alexander Leaf, Meir Stampfer, Eric Rimm, Allen Taylor, Paul Jacques, Walter Willett, Norman Farnsworth, Larry Clark, Varro Tyler, Gilbert Omenn, Robert Russell, Gerald Combs, Ishwarlal Jailal, Tieraona LowDog, Barbara Timmerman, Bruce Ames, Balz Frei, Richard Kreider, Carol Johnston, Larry Walker, Richard Anderson, Maret Traber, and Reinhold Vieth.

Marketing is always a favorite topic, with speakers from well-known groups such as *Nutrition Business Journal*, the Natural Marketing Institute, Gallup, and A.C. Nielsen.

Authors and media personalities have also been featured at CRN annual conferences, including Robert Atkins, Ken Cooper, Bob Arnott, Jean Carper, Nancy Snyderman, Phil Lempert, Dan Pink, Dan O'Connor, Holly Atkinson, Norman Ornstein, and David Katz.

Other notable speakers have included Eric Dezenhall, James Carville, Charlie Cook, Mark Blumenthal, and Michael Jacobson. And few will forget the 2002 Annual Conference featuring motivational talks by baseball hall-of-famer Tommy Lasorda and basketball hall-of-famer Bill Russell.

CRN annual conferences have been held every year since the first one in 1975, with only one exception. In 2001, the planned October conference was cancelled following the tragedy of 9/11, due to widespread anxiety regarding air travel and widely

varying corporate travel policies regarding employee travel in the wake of that event. **ATTACHMENT H** provides a listing of locations and a partial list of key speakers at CRN Annual Conferences.

Beginning in about 1983, CRN has presented one or more Steuben apple awards during the Annual Conference, honoring member company representatives (and sometimes CRN staff members or legal counsel) for outstanding service to the organization. **ATTACHMENT I** provides a partial listing of recipients of the CRN Steuben apple awards for outstanding service.

EXPANDING CRN STAFF

Of course, CRN is defined to a large extent by the capability of its staff and also by the Board's willingness to provide sound advice and guidance while allowing the staff the flexibility to do its job effectively and efficiently – which often involves the need to take action and express opinions about emerging issues on very short notice. CRN has been blessed overall with excellent staff, capable Board leadership, and outstanding legal counsel. See **ATTACHMENT J** for a list of key CRN staff and counsel from 1973 to the present writing (2007).

CRN COMMITTEES AND TASK GROUPS

CRN has always relied heavily not only on CRN staff but also on capable and involved committees and task groups to accomplish its many objectives. Standing committees have ongoing responsibility for the oversight of key policies and initiatives in many areas, including finances and compensation, media relations, government relations, international activities, membership development, regulatory affairs, and scientific initiatives. Task groups are formed from time to time as circumstances require, to permit affected member companies to join forces in dealing with particular issues as they arise. Recent task groups have included those focused on vitamin E, multivitamins, glucosamine and chondroitin, B vitamins, and omega-3 fatty acids. Other task groups have a broader focus, including outreach to health professionals, conducting an annual Consumer confidence survey, and establishing a Standardized Ingredient Information Protocol (SIIP) to streamline the necessary exchange of information between ingredient

suppliers and finished product manufacturers. Without the generous contribution of time and effort to these activities, on the part of CRN member company representatives, the organization's numerous meaningful accomplishments would not have been possible. See **ATTACHMENT K** for a list of current CRN committees and task groups.

RELATIONSHIP WITH OTHER INDUSTRY ASSOCIATIONS

CRN has always considered itself a leader among the associations in the dietary supplement industry, because of its unique emphasis and capability in the scientific arena and because of its commitment to responsible industry practices. At the same time, CRN has always sought partnerships with other associations when they would strengthen the industry's leverage on key issues. This was particularly the case in the long effort to develop GMP regulations and to help FDA get them right. Cooperation among the associations has also been critical in helping the industry deal with other issues including helping members understand and evaluated FDA regulations such as those governing structure/function claims, responding to challenges involving California's Proposition 65, and supporting Congressional efforts to craft and pass legislation requiring reports to FDA of serious adverse events. CRN staff members have always had good working arrangements with the staff of other industry trade associations, and this ability to work together as needed has benefited all the member companies.

On other issues, CRN has found strength in having the courage to depart from the path taken by other groups. This was the case in the very founding of CRN and in its early willingness to develop and support legislative language that differed from that historically favored by other industry and advocacy groups, in order to enable the 1976 Vitamin Bill to move forward to successful passage with the necessary support of the then-Chairman of the House Health Subcommittee.

Of course, each of the industry associations necessarily competes with the others for membership, funding, and media attention, and there have been periodic efforts to merge two or more of the various associations. These efforts have not so far been successful, largely because there are very real reasons why certain companies identify with particular associations, and the associations do not all serve exactly the same needs.

The **Consumer Healthcare Products Association (CHPA)** represents manufacturers of over-the-counter drugs, many of whom also make and market dietary supplements. Some of CHPA's members also belong to CRN, where they find a sharper focus on the dietary supplement aspect of their business, but where they are still associated with a number of large consumer products companies that take a highly professional and responsible approach to the issues that confront them.

The **Direct Selling Association (DSA)** represents companies whose method of distribution is through direct selling, including multilevel marketing. DSA represents these companies on issues relating to their business practices and generally not on issues relating to the nature of the products they sell. A number of DSA members are also members of CRN, where they are able to focus on the legal and scientific and marketing issues that relate specifically to the dietary supplement category.

The **Natural Products Association (NPA)**, historically the National Nutritional Food Association (NNFA), represents natural products retailers and also the manufacturers that specialize in the natural products segment of the industry. Their interest is not limited to dietary supplements, but includes the full spectrum of natural products. Some of NPA's manufacturer members also belong to CRN, where they can focus strictly on the manufacturer's perspective on regulatory and legislative issues affecting just the dietary supplement category.

The **American Herbal Products Association (AHPA)** represents companies and practitioners that operate in the botanical arena. They deal not only with the uses of botanicals as dietary supplements, but with all uses of botanicals, including their use as medicinal agents. AHPA's staff and members have unique expertise in botanicals, and CRN has worked closely with AHPA in dealing with a number of issues, particularly those relating to the safety of particular ingredients. Some of AHPA's member companies also belong to CRN, which pays attention solely to the dietary supplement aspects of their business.

The **American Botanical Council (ABC)** is not a trade association, but is a private nonprofit organization dedicated to educating the public about botanicals. It is headed by Mark Blumenthal and publishes a monthly journal called *HerbalGram.* ABC has published English translations of the German Commission E monographs and more

recently *The ABC Clinical Guide to Herbs,* a reference work that grew out of a course Blumenthal developed for the University of Texas. Blumenthal is a tireless resource and an excellent spokesperson, and CRN, like many others inside and outside the industry, has frequently relied upon him for information and advice on specific issues.

The **United Natural Products Alliance (UNPA)**, originally the Utah Natural Products Alliance, represents primarily but not solely companies that are based in Utah and engaged in the manufacture of dietary supplements and other natural products. Its membership is comprised of companies that are basically clients of Loren Israelsen, a talented legal and legislative expert with close professional ties to Senator Orrin Hatch.

The **Dietary Supplement Education Alliance (DSEA)** is an advocacy and educational group and not a trade association. It was established in order to educate the public about dietary supplements, and like the trade associations it seeks its funding from companies that market dietary supplements and other natural products. Some of CRN's members are also supporters of DSEA.

The **Coalition to Preserve DSHEA** is not a trade association but is a nonprofit advocacy organization. It was formed by a handful of companies to support political action and other legislative outreach efforts in addition to those already launched by the various industry trade associations. CRN and other trade associations sit as nonvoting members of the Board of the Coalition, but funding and policy direction come from the supporting companies.

All of the industry trade associations provide great value to their member companies, and CRN has a special place in the business plans and initiatives undertaken by its participating members. It will be up to CRN to continue to make itself indispensable to the companies that support it and that direct its activities through their service on the Board of Directors. If history is a reliable guide, it can be predicted that CRN will continue to succeed in this undertaking.

ATTACHMENT A: CRN ARTICLES OF INCORPORATION

Articles of Incorporation,

Council for Responsible Nutrition

Incorporated June 1973

Articles amended July 1973, October 1973, May 1981

Text below is June 1973 unless otherwise noted; emphasis added to show changes.

Text in *italics* was replaced by later revision.

FIRST: The name of the corporation is the Council for Responsible Nutrition and it is hereinafter called "the Council."
SECOND: The period of duration of the Council is perpetual.
THIRD (June 1973): The purpose for which the Council is organized and is to be operated is to be a civic league exclusively to promote the social welfare and specifically to seek to insure the continued availability to individuals of the range and quantities of naturally available foods and nutrients necessary for meeting and sustaining the individually determined requirements of their bodies at an optimum level of nutrition, and any other lawful purpose, and in furtherance of such purpose, the Council's activities shall be, inter alia, to
THIRD (July 1973): The purpose for which the Council is organized and is to be operated is to be a business league or trade association to promote the common business interests of members of the high potency vitamin or mineral industry who manufacture, distribute, or sell high potency vitamin or mineral products; and more particularly and in furtherance of such purpose, the Council's activities shall be, inter alia, to
(a) educate and inform the public, by direct communication or otherwise, with regard to scientific discoveries in human nutrition and the governmental regulation of nutritional practices;
(b) inform its members of the relevant legislative and administrative developments on the national, state and local levels;
(c) provide a forum for its members to examine and review governmental actions and activities;
(d) represent the interests of its members with respect to federal, state and local legislation and administrative developments concerning vitamin and mineral regulations;
(e) develop legislative and administrative proposals for submission to appropriate branches and agencies of government concerning responsible nutritional regulation.

FOURTH: The Council shall have members.
FIFTH (June 1973): The members of the Council shall be companies engaged in the manufacture, distribution, or sale of high potency vitamin or mineral food or food supplements in the United States and the consumers of such products. There shall be one class of voting members. There shall be an additional class of non-voting supporting members. The manner of election, the qualifications, the rights and dues of each class of members shall be set forth in the By-Laws.
FIFTH (July 1973): The members of the Council shall be persons engaged in the manufacture, distribution or sale of high potency vitamin and mineral products. There shall be one class of members. The manner of election, the qualifications, and the rights and duties of members shall be set forth in the By-Laws.
FIFTH (May 1981): The members of the Council shall be corporations and persons engaged in the manufacture or distribution of nutrient supplements or of the principal ingredients in nutritional products, and corporations or persons who supply services or other support for such companies. The manner of election, the qualifications, and the rights and duties of members shall be set forth in the By-Laws.
SIXTH: The manner of election or appointment of Directors of the Council shall be provided for in the By-Laws.
SEVENTH: The internal affairs of the Council shall be regulated by the By-Laws, and the business and affairs of the Council shall be managed and conducted by the Directors in accordance with the By-Laws. The power to adopt, alter, amend or repeal the By-Laws shall be vested in the directors. The provisions of the By-Laws and the management of the Council in accordance therewith shall be subject to the following:
(a) the Council shall not be conducted for profit;
(b) (June 1973) the Council shall not carry on a business with the general public in a manner similar to organizations which are operated for profit;
(b) (July 1973) the Council shall not engage in a regular business of the kind ordinarily carried on for profit;
(c) no part of the net earnings of the Council shall inure to the benefit of or be distributed or distributable to its members, Directors, officers or other private persons, provided that nothing herein shall preclude the Council from paying reasonable compensation for services rendered and making payments and distributions in furtherance of the purposes set forth in Article THIRD hereof;
(d) the Council shall not perform particular services for individual members;

(e) (June 1973) the Council shall not exercise any power nor engage in any activity that would prevent it from obtaining exemption from federal income taxation as a corporation described in Section 501(c)(4) of the Internal Revenue Code of 1954, as amended (or the corresponding provision of any future United States Internal Revenue law) or cause it to lose its exempt status under such Section;
(e) (July 1973) the Council shall not exercise any power nor engage in any activity that would prevent it from obtaining exemption from federal income taxation as a corporation described in Section 501(c)(6) of the Internal Revenue Code of 1954, as amended (or the corresponding provision of any future United States Internal Revenue law) or cause it to lose its exempt status under such Section;
(f) in the event of dissolution or final liquidation of the Council, the Board of Directors hall, after paying or making provision for the payment of all the liabilities of the Council, apply and distribute the assets of the Council as follows: *(details omitted from this text)*
EIGHTH: *(initial address was that of C.T. Corporation System in Washington, D.C.)*
NINTH: The number of Directors constituting the initial Board of Directors of the Council is three (3) and the name and address, including the street and number, of each person who is to serve as an initial Director until the first annual meeting are as follows:
William T. Thompson, Jr. President, W.T. Thompson Co. 23529 S. Figueroa Street Carson, California 90744
George Crawford Vice President, Archon Pure Products Co. 9595 Wilshire Boulevard Beverly Hills, California 90212
Nolan Draney Executive Vice President, Plus Products 2425 E. 38th Street Los Angeles, California 90058
TENTH: The incorporators of the Council are Marshall Hornblower, Daniel Marcus, and Daniel Polsby of 900 – 17th Street, N.W., Washington, D.C. 2006 *(attorneys at CRN's law firm of Wilmer, Cutler and Pickering)*

ATTACHMENT B: LOCATION OF CRN OFFICES, 1973-2007

1973 - 1974	1776 K Street, Washington, D.C. 20006 (sublet from Burson Marsteller)
1975 - 1977	1225 Connecticut Avenue, N.W., Washington, D.C. 20036 (sublet from Washington Service Bureau)
1978 – 1981	1707 N Street, N.W., Washington, D.C. 20036 (top floor of a townhouse office building)
1982 - 1984	1725 I Street, N.W., Washington, D.C. 20006
1985 – 1989	2100 M Street, N.W., Washington, D.C. 20009
1990 - 1999	1300 – 19th Street, N.W., Washington, D.C. 20036
1999 – 2002	1875 I Street, N.W., Washington, D.C. 20006
2003 - 2007	1828 L Street, N.W., Washington, D.C. 20036

ATTACHMENT C: CRN Boards of Directors in the first decade and in 2007

1973:	President: Bill Thompson, W.T. Thompson Co. George Crawford, Archon Pure Products Corporation Nolan Draney, Plus Products Corporation
1974:	President: Bill Thompson, W.T. Thompson Co. George Crawford, Archon Pure Products Corporation Nolan Draney, Plus Products Corporation Marshall Ackerman, Rodale Press
1975:	President: Bill Thompson, W.T. Thompson Co. George Crawford, Archon Pure Products Corporation Nolan Draney, Plus Products Corporation Raleigh Shaklee, Shaklee Corporation
1976:	President: Bill Thompson, W.T. Thompson Co. E.D. Schilling, Shaklee Corporation Edward Isett, Plus Products Corporation Don Winn, Archon Pure Products Corporation

Board expanded from 4 to 5 members

1977 -78:	President: Bill Thompson, W.T. Thompson Co. E.D. Schilling, Shaklee Corporation Edward Isett, Plus Products Corporation Don Winn, Archon Pure Products Corporation Annette Dickinson, Basic & Traditional Food Association
1979:	President: J. Robert Brouse, Shaklee Corporation Chairman: Bill Thompson, W.T. Thompson Co. Edward Isett, Plus Products Corporation James F. Pomroy, Iroquois Brands, Ltd. Annette Dickinson, Basic & Traditional Food Association
1980:	President: Robert K. Fredericks, R. P. Scherer North America Chairman: Bill Thompson, W.T. Thompson Co. Larry A. Weber, Rexall Corporation James F. Pomroy, Iroquois Brands, Ltd. Lawrence G. Farren, Shaklee Corporation

Board expanded from 5 to 9 members:

1981:	President: Robert K. Fredericks, R. P. Scherer North America Chairman: Bill Thompson, W.T. Thompson Co. Jim Pomroy, Iroquois Brands, Ltd. Larry Weber, Rexall Corporation Don Aberg, Naturite Health Products Larry Farren, Shaklee Corporation Tom Egan, Hoffman-LaRoche, Inc. Ken Rosenberg, Pharmavite Corporation Gerry Wilson, Henkel Corporation
1982:	Chairman: Larry Weber, Rexall Corporation Frank Rawding, Hoffmann-La Roche Inc. Kenneth Rosenberg, Pharmavite Corporation Bill Thompson, W.T. Thompson Co. Larry Farren, Shaklee Corporation Brian Dobson, Iroquois Brands, Ltd. Donlan Aberg, Moxie Industries (Nutrition Products of America) Robert K. Fredericks, R. P. Scherer Corporation James Martin, Vita Fresh Vitamin Co.
1983:	Chairman: Larry Farren, Shaklee Corporation Don Aberg, Nutrition Products of America Brian Dobson, Iroquois Brands, Ltd. Robert K. Fredericks, R. P. Scherer North America Gordon Freshman, Banner Gelatin Products Jim Martin, Vita-Fresh Vitamin Company Frank Rawding, Hoffmann-La Roche Inc. Kenneth M. Rosenberg, Pharmavite Corporation Bill Thompson, W.T. Thompson Co.

The CRN Board expanded steadily in size during the 1980s and especially in the 1990s, when the Bylaws were amended to provide permanent Board seats for members paying high dues levels. By 1995, the CRN Board had reached its current size of 25 to 28 members. The dues threshold that qualifies a company for a permanent Board seat is raised periodically. Other Board members are elected by the membership. There are special provisions to ensure that smaller companies have significant representation on the Board and that both ingredient suppliers and finished product manufacturers are equitably represented.

See the following page or the CRN website at www.crnusa.org for a list of current members of the CRN Board of Directors. There are currently (in 2007) twenty-eight members of the Board.

CRN BOARD OF DIRECTORS, 2007

OFFICERS:

Marjorie Fine, Chair
Mark LeDoux, Chair Elect
David Christensen, Treasurer
Joseph LaPlaca, Secretary
Steven M. Mister, Esq., President

MANUFACTURER BOARD MEMBERS

Kristen Blanchard, Nutramax Laboratories, Inc.
Paul Bolar, Pharmavite LLC
Mike Bradley, Perrigo Company
Dwight Brown, Wyeth Consumer Health
Samuel Caster, Mannatech, Inc.
David Christensen, Bayer Healthcare LLC
Marjorie Fine, Shaklee Corporation
Richard Godfrey, Swiss Caps USA, Inc.
Jeff Hinrichs, Nutraceutical Corporation
Byron Johnson, Access Business Group/Nutrilite
Harvey Kamil, NBTY, Inc.
Mark LeDoux, Natural Alternatives International
Tom Mooy, Leiner Health Products
David Morrison, Vitamin Shoppe
Mark LeDoux, Natural Alternatives International
David Sullivan, GNC, Inc.
Dan Thomson, Schiff Nutrition International, Inc.
John Venardos, Herbalife International of America
Tyler Whitehead, Nu Skin International Inc./Pharmanex LLC

SUPPLIER BOARD MEMBERS

Chuck Brice, Kemin Foods, L.C.
David Eckert, Cognis Nutrition & Health
Larry Esposito, Innophos, Inc.
Janice Binger, Archer Daniels Midland Company
Joseph LaPlaca, DSM Nutritional Products, Inc.
Folker Ruchatz, BASF Corporation
Don Stanek, Linnea, Inc.
Steve Snyder, Cargill Health & Food Technologies
William Van Dyke, B&D Nutritional Ingredients, Inc.

ATTACHMENT D: CRN Board Presidents, Board Chairs, and staff executive officers, 1973 to 2007

1973 - 1978:	Bill Thompson, W. T. Thompson Co., President Peter J. Semper, Executive Director
1979:	J. Robert Brouse, Shaklee Corporation, President Bill Thompson, W. T. Thompson Co., Chair A. Beth Coleman, Executive Director
1980 - 1981:	Robert K. Fredericks, R. P. Scherer Corporation, President Bill Thompson, W.T. Thompson Co., Chair A. Beth Coleman, Executive Director
1982:	Larry Weber, Rexall Corporation, Chair John (J.B.) Cordaro, President
1983 - 1987	Larry Farren, Shaklee Corporation, Chair John (J.B.) Cordaro, President
1988 - 1991	Kenneth M. Rosenberg, Pharmavite Corporation, Chair John Cordaro, President
1992	Larry Haverkost, Warner-Lambert, Chair John Cordaro, President
1993 - 1994	Manfred Dunker, Henkel Corporation, Chair John Cordaro, President
1995 – 1996	John Hale, Eastman Chemical, Chair John Cordaro, President
1997 - 1998	Stephen Fischer, Pharmacaps, Chair John Cordaro, President
1999 – 2000	Sal Palladino, BASF, Chair John Cordaro, President
2001-2002	Bill Van Dyke, B & D Nutritionals, Chair John Cordaro, President
2003-2004	Byron Johnson, Access Business Group, Chair Annette Dickinson, President

2005 – 2006	Chuck Brice, Kemin Foods, Chair Steven Mister, President
2007 – 2008	Marjorie Fine, Shaklee Corporation, Chair Steven Mister, President

ATTACHMENT E: CRN Membership

CRN Member companies in 1983 (the ten-year anniversary), 1990 (the year of NLEA), 1994 (the year of DSHEA), and 2007 (the current year)

1983: Thirty-three voting members	**1990: Fifty Voting members**	**1994: Sixty-five voting members**	**2007: Sixty-four voting members**
If a company's name has changed over time due to acquisitions, etc., the company is listed in alphabetical order according to its name in 2007.			
		Nutrilite (later part of Access Business Group)	Access Business Group (Amway, Nutrilite, Quixtar)
		Accucaps	
		ADM	ADM
			Ajinomoto
			Albion Laboratories
	Amcon	Amcon	
American Health			
	American Laboratories	American Laboratories	
	Anabolic Labs	Anabolic Labs	
			Azko Nobel
		B & D	B & D
			Balchem
Banner Gelatin	Banner Gelatin; Pharmacaps (two separate members)	Banner Pharmacaps	
BASF	BASF	BASF	BASF
		Miles Laboratories (later acquired by Bayer)	Bayer
Bell Pharmacal			
			Beijing Gingko Group, North America
			Bioiberica
	BioSan	BioSan	BioSan
			Biosyntrx
			Biotron
	Warner-Lambert (later part of Pfizer)	Pfizer Food Science Group	Cadbury Schweppes (part of Pfizer)

1983: Thirty-three voting members	1990: Fifty Voting members	1994: Sixty-five voting members	2007: Sixty-four voting members
		Capsugel	
			Cargill Health & Food Technologies
	Central Soya		
	Chase Laboratories	Chase Pharmaceutical	
			Chemi Nutra
	Chugai Boyeki	Chugai Boyeki	
Henkel Corporation	Henkel Corporation	Henkel Corporation (later Cognis)	Cognis Nutrition and Health
	Colorcon	Colorcon	Colorcon
	Coors BioTech		
		Creative Business Strategies	
		Crompton & Knowles	
		Daiichi	
	Degussa		
DeLavau	DeLavau		
D&F			
	Diamite	Diamite	
			Douglas Laboratories
Hoffman LaRoche	Hoffman LaRoche	Roche Vitamins	DSM (purchased Roche Vitamins)
Eastman	Eastman	Eastman	
	Edward Mendell	Edward Mendell	
	Eisai	Eisai	
			Embria Health Services
			EPAX AS
		E.T. Horn	E. T. Horn
		FMC Corp	
	Fairhill Foods		
		Fortitech	
			Fuji Health Science
		Gail Becker Associates	GBA Health Communications
	Gallard Schlesinger	Gallard Schlesinger	
	Garden State Nutritionals		
	General Nutrition Corporation	General Nutrition Corporation	General Nutrition Centers

1983: Thirty-three voting members	**1990: Fifty Voting members**	**1994: Sixty-five voting members**	**2007: Sixty-four voting members**
			Generichem
	Gillco Products		
Gillespie & Assoc.	Gillespie & Assoc.		
			GNLD
Grain Processing			
			Gumlink A/S
Hall Labs	Hall Labs	Hall Labs	
	HealthComm	HealthComm	
		Health for Life	
			Herbalife International
		Indena	Indena USA
			Innophos
		Inter-Cal	
			Iovate Health Sciences Research
Iroquois (acquired Archon Pure Products Corp.)			
			Kalsec
			Kaneka Nutrient, L.P.
		Kelco Div. of Merck	
			Kemin Health
			Kyowa Hakko USA
Leiner	Leiner	Leiner	Leiner Health Products
			Linnea
Linwilco			
	Lonza	Lonza	Lonza
Makers of Kal			
			Mannatech
			Merical
Moxie			
		MW International	
MWM Chemical			
			Natural Alternatives International
Natural Organics			
Naturite			

1983: Thirty-three voting members	**1990: Fifty Voting members**	**1994: Sixty-five voting members**	**2007: Sixty-four voting members**
Rexall Corporation	Nature's Bounty; Sundown Vitamins/Rexall Group (separate members)	Nature's Bounty (later NBTY); Rexall/Sundown (separate members)	NBTY
	NeoLife	NeoLife	
	Nepera		
	Nitta Corp		
			Nutraceutical Corp.
			Nutramax Laboratories
Nutrition 21		Nutrition 21	Nutrition 21
		Nutro Laboratories	
			OmegaPure
		Omega Tech	
			Omya
Perrigo	Perrigo	Perrigo	Perrigo
	Pharmachem	Pharmachem	
			Pharmanex
Pharmavite	Pharmavite	Pharmavite	Pharmavite
		Pharmline	
Phoenix Labs			
Plus Products Corporation			
		Pronova Biocare	
		Pure-Gar	
			Rainbow Light
			Reliv International
			Rhodia
	Rhone Poulenc	Rhone Poulenc	
			Ross Products
R.P. Scherer	R. P. Scherer	R. P. Scherer	
			Schiff Nutrition International
	Seltzer Chemicals		
		Seven Seas, Ltd.	Seven Seas, Ltd.
Shaklee	Shaklee	Shaklee	Shaklee
			Sierra Mountain Minerals
	Solaray		
		Specialty Minerals	
	Stauber Chemical	Stauber	
			Swiss Caps USA

1983: Thirty-three voting members	1990: Fifty Voting members	1994: Sixty-five voting members	2007: Sixty-four voting members
Takeda-Fallek	Takeda USA	Takeda USA	
Tanabe			
	Tishcon	Tishcon	
	Twin Laboratories		
Vita-Fresh			
	Vitaline	Vitaline	
		Vitamin Health Centers/Obtibal	
			Vitamin Shoppe
	VitaTech	VitaTech	
W.T. Thompson Co. (brand later purchased by Rexall Sundown, then Nutraceutical)			
		Wakunaga	
Winning Labs			
		Lederle Laboratories (later acquired by Wyeth)	Wyeth Consumer Healthcare

ASSOCIATE MEMBERS, 1983, 1990, 1994, 2007

1983: Eleven associate members	1990: Ten associate members	1994: Eight associate members	2007: Ten associate members
Adpak Marketing			
Bestways			
	Calpac Container Company		
			Covance Laboratories
	Creative Business Strategies		
		Dobson Communications	

1983: **Eleven associate members**	**1990:** **Ten associate members**	**1994:** **Eight associate members**	**2007:** **Ten associate members**
			Eurofins Scientific
Falcone & Assoc.			
Gail Becker Associates	Gail Becker Associates (later upgraded to voting member)		
	Garrison Consulting Group		
	Glamour Magazine		
		Loren Israelsen	
			Joy's Quality Management Systems
		Mahon Securities	
Wm. Douglas McAdams	Wm. Douglas McAdams	Wm. Douglas McAdams	
Modern Foods			
			NSF International
Natural Foods Merchandiser	New Hope Communications (parent of NFM)	Natural Foods Merchandiser	
	Prevention Magazine		
			PROSAR
			SafetyCall International
Self Magazine			
Semper-Moser			
Setco	Setco	Setco	
		Herbert V. Shuster	Shuster Labs
	Top Seal Corp	Top Seal Corp	
			U.S. Pharmacopeia
			Venable LLP
Vinyard & Lee			
			Virgo Publishing

INTERNATIONAL CORRESPONDENT MEMBERS, 1990, 1994, 2007

1983: No international category	**1990: Five international correspondent members**	**1994: Four international correspondent members**	**2007: One international correspondent member**
		Sue Akeroyd & Associates	
	BASF AG	BASF Germany	
	Booker Health Products		
	Efamol		
	Hermes GMBH		
			Jamieson Laboratories
		Otsuka Japan	
	Seven Seas Ltd.		
		Vitamex America	

ATTACHMENT F: SOME ACTIVITIES ON BEHALF OF THE INDUSTRY, 1973 TO 1994

TOPICS COVERED IN THIS ATTACHMENT AND NOT IN THE MAIN TEXT:

Donation of Vitamin A for Blindness Prevention

FTC protein rule

FDA rule on protein products for very low calorie diets

Responding to rules pertaining to accidental pediatric iron poisoning

Encouraging voluntary compliance with tamper-resistant packaging

Dosage limits for vitamin A and other nutrients

State dietetics licensure laws

Compiling industry sales data

USP initiative to establish monographs for dietary supplements

Fish oil claims and analytical methodology

Scientific seminar in England on fish oils and bleeding time

Tryptophan recall and EMS outbreak

Public policy on folic acid and neural tube defects

Lead in calcium, Prop 65 settlement agreement

Donation of Vitamin A for Blindness Prevention: Vitamin A deficiency is the leading cause of childhood blindness in the developing world. One of CRN's first initiatives was to donate a million capsules of vitamin A to an international blindness prevention program, in the early 1970s.

Opposing the FTC protein rule: In the late 1970s, the staff of the Federal Trade Commission proposed a rulemaking that would have required a "crepe label" on protein supplements, telling people there was no need for such products. CRN strongly opposed this effort, submitted extensive comments, and appeared at public hearings to testify against it, on the grounds that many consumers valued such products and had a right to

make their own choices regarding the selection of protein foods. The FTC Commissioners ultimately voted against issuing the rule.

Modifying the FDA rule on protein products used in very low calorie diets: In the late 70s, "liquid protein diets" became popular and about 60 deaths were reported involving people who lost large amounts of weight in short periods of time on such diets, many of them under physician supervision. In most cases, the product used was a liquid protein hydrolysate providing poor quality protein, but in a few cases people were using other protein sources including egg whites, chicken breast, or whole protein powders. FDA proposed to require a severe warning, not only on the liquid protein products that were primarily involved in the cases, but also on whole protein powders. CRN strongly opposed extension of the rule to cover whole protein powders. Ultimately FDA modified the rule to apply primarily to protein products offered for use in very low calorie diets (under 400 calories per day).

Responding to rules pertaining to accidental pediatric iron poisoning: Due to reports of accidental iron poisoning in children who gained access to their mothers' prenatal iron supplements and other products containing iron, the Consumer Product Safety Commission in the late 1970s required virtually all dietary supplements and pharmaceuticals containing iron to be packaged with child-resistant closures. CRN assisted its members in complying with this requirement by obtaining a brief extension of the effective date to provide the companies with adequate time to obtain the closures. In 1997, FDA finalized an additional rule requiring a black-box label warning on virtually all dietary supplements containing iron and also requiring that products providing more than 30 mg per dosage unit should be available to consumers only in some form of unit-dose packaging (such as blister packs). CRN submitted comments on the rule. Another organization filed a legal challenge to the unit-dose packaging requirement, arguing that poison prevention packaging was the purview of CPSC and not FDA. The court agreed and invalidated that portion of the FDA rule.

Encouraging voluntary compliance with tamper-resistant packaging: Following the Tylenol tampering incident, FDA issued regulations requiring tamper-resistant packaging for OTC drug products. CRN encouraged dietary supplements manufacturers to comply with those requirements, as a matter of good product

stewardship and also because of liability concerns. Because of widespread voluntary compliance, FDA did not find it necessary to issue a separate rule covering dietary supplements.

Dosage limits for vitamin A and other nutrients: It has long been recognized that both vitamin A deficiency and excessive vitamin A are teratogenic. In the 1980s there were a number of scientific articles urging pregnant women to avoid high intakes of vitamin A, but there was controversy about the threshold level of concern. CDC issued a notice cautioning against the use of high levels. CRN adopted a voluntary dosage limit of 10,000 IU. At a later date, the State of California required a Prop 65 warning for dosages above 10,000 IU. After other reports of adverse events, CRN adopted voluntary dosage limits for vitamin B-6 and for nicotinic acid.

Opposing some state dietetics licensure laws: In the 1980s there were numerous efforts by dietitians at the state level to obtain licensure laws that would have interfered with the ability of other persons, including product marketers, to educate consumers about dietary supplements or preventive nutrition. CRN opposed laws that were overbroad in their provisions, but did not object to licensure laws that simply established the necessary training and appropriate scope of practice for dietitians.

Compiling industry sales data: In the 1970s and 80s, data pertaining to industry sales were difficult to find. For a period of time, a CRN industry data committee compiled estimates of sales and prepared an annual report. As other sources of good information about industry sales became available, notably from the *Nutrition Business Journal* and the Natural Marketing Institute, CRN discontinued this separate activity.

Participating in the USP initiative to establish quality monographs for dietary supplement ingredients and products: The U.S. Pharmacopeia (USP) is the official standard-setting body for pharmaceuticals in the U.S. In 1988, under the leadership of Dr. Ralph Shangraw, USP established an expert committee with a mandate to establish quality monographs for dietary supplement ingredients and products. Despite serious concerns that USP would apply drug standards to dietary supplements, CRN decided to work with the USP committee to ensure that appropriate standards were set. The USP activity continues to the present day, and some CRN member company representatives serve as members and even chairs of USP expert committees carrying on

this work. There are currently five USP expert committees relating to dietary supplements. These include two standards committees, the Dietary Supplement Botanical Committee and the Dietary Supplement Non-Botanical Committee; the Dietary Supplement Information Committee; the Dietary Supplement Performance Standards Committee (dealing with issues such as disintegration and dissolution); and the Dietary Supplement General Chapters Committee (dealing with issues such as GMPs).

Fish oil analytical methodology and claims: In the late 1980s, there was an explosion of scientific evidence regarding the health benefits of fish oils (omega-3 fatty acids) and a consequent increase in the number and variety of such products on the market. There was controversy regarding appropriate methods of analysis and increasing regulatory concern about the claims of health benefits that were being made. CRN established a fish oil working group to address these issues and worked with FDA to consolidate industry responses to a large number of warning letters that were sent out in 1988, at a time when the debate about FDA policy on health claims was still ongoing. A decade later, CRN had occasion to form a second omega-3 working group, as described in Attachment G.

Scientific seminar in England on fish oils and bleeding time: In evaluating the safety of fish oil products, FDA had raised concerns about the potential for increased bleeding times. (Bleeding time is measured by the number of seconds required for bleeding to stop following a standardized pinprick test; increased bleeding time as shown by this test may or may not suggest an increased risk of clinically meaningful bleeding following angioplasty or other surgery, for example.) Scientists involved in research with fish oils appeared to believe that an increase in the actual risk of bleeding was unlikely. CRN cosponsored a scientific seminar on fish oils and bleeding times in Chester, England, in 1990 on this topic, which resulted in a position paper indicating that increased bleeding was not likely to occur in people using fish oil products.

Outbreak of EMS related to L-Tryptophan: In late 1989, there was an outbreak of eosinophilia myalgia syndrome (EMS) related to the consumption of L-tryptophan. The syndrome was marked by high eosinophil levels in the blood and severe muscle pain, sometimes reaching such severity as to restrict mobility and even interfere with breathing. The Centers for Disease Control (CDC) mounted an international effort

to identify cases and to trace the source of the L-tryptophan used by the patients. Soon after the initial recognition of the possible involvement of L-tryptophan, CRN supported a nationwide recall of the product and offered assistance in tracing "hot lots." A tryptophan working group was formed to provide funding for special initiatives. CRN helped fund a consumer hotline and case registry provided by ASTHO (Association of State and Territorial Health Officials) and participated in several scientific conferences convened on an emergency basis to probe the cause of the syndrome and to explore possible treatments. Ultimately over 1500 cases were identified by CDC, internationally, including numerous deaths. Most cases were traced to L-tryptophan supplied by a single Japanese manufacturer and containing a characteristic "peak" identified as a tryptophan dimer (a compound formed by the bonding of two molecules of tryptophan). FDA has not permitted L-tryptophan to be returned to the market as a dietary supplement, although it is used as an ingredient in infant formula and in enteral foods.

Public policy on folic acid and neural tube defects: Scientists at CDC led the way in developing an advisory from the Public Health Service, issued in 1992, encouraging women of childbearing age to obtain 400 mcg of folic acid daily to reduce their risk of having a baby with a neural tube defect (NTD) such as spina bifida. CRN participated in workshops sponsored by CDC in preparation for this policy statement and actively encouraged FDA to follow suit by approving a health claim allowing products with folic acid to make label statements about the importance of this B vitamin in reducing the incidence of these birth defects. FDA delayed action while developing a policy requiring folic acid to be a component in the enrichment of grain products, and final rules permitting the health claim and requiring folic acid to be included in enriched grain products were issued in 1996.

Lead in calcium: In 1986, the State of California enacted a ballot initiative known as Proposition 65 (Prop 65) that required the state to establish a list of chemicals known to be carcinogens or reproductive toxins and that required label disclosures regarding the presence of such substances in consumer products. Lead is a listed chemical under Prop 65, so all products containing lead above a very stringent threshold should be required to bear the Prop 65 warning. In the early 1990s the Natural Resources Defense Council (NRDC) tested various calcium supplements and calcium-containing

antacids for lead and found many of them to contain levels that would trigger the Prop 65 warning, so NRDC brought suit to force the State to take action against them. Since lead and calcium occur naturally together in the environment, ingredients that contain calcium virtually always also contain some lead. There are methods available that will reduce lead levels, but it may not always be feasible to achieve levels as low as the Prop 65 limit for lead. Since a number of CRN member companies had products that would be affected, CRN obtained expert counsel from an attorney and a scientist experienced in Prop 65 issues and approached the California Attorney General's office about seeking a settlement agreement that would recognize the benefits of obtaining adequate calcium and at the same time require calcium products to reduce lead levels to the lowest feasible levels. CRN and the member companies submitted extensive information regarding the lowest feasible lead levels in various source materials. Ultimately the companies involved organized themselves as a Joint Defense Group and took over the negotiations, which resulted in a settlement agreement defining minimum feasible levels of lead in calcium products (supplements and antacids) and in multivitamins. These lead levels are stringent but not as low as the general threshold for lead under Prop 65.

ATTACHMENT G: MULTIPLICITY OF INITIATIVES, 1994 TO 2007

TOPICS COVERED IN THIS ATTACHMENT AND NOT IN THE MAIN TEXT:

Participation in the Commission on Dietary Supplement Labels

Preparing list of ingredients "grandfathered" under DSHEA

Attempting to stem the tide of DSHEA-bashing

Input to FDA policy on qualified health claims

Donations of multivitamins to birth defect prevention programs

Workshop on structure/function claims

FTC guidance on dietary supplement claims

Quintozene in ginseng products

Safety of Kava

Benefits of St. John's Wort

Developing methods of analysis for botanical ingredients

Helping industry comply with agency policy on BSE

Evaluating data on vitamin A and hip fracture

Cosponsorship of PEP Conference with ODS

Scientific workshops on melatonin and on DHEA

Supporting Health Savings Accounts and Flexible Spending Accounts

Omega-3 quality monograph developed by CRN working group

Joint CRN/CHPA/NFI petition to FDA for omega-3 health claim

Serving on FDA Food Advisory Committee

Product stewardship initiative

Petition for FTC action on ConsumerLab.com business practices

NAD oversight of advertising claims

The Commission on Dietary Supplement Labels: DSHEA required the establishment of a Commission on Dietary Supplement Labels, to prepare a report and make recommendations regarding the labeling and regulation of dietary supplements. John Cordaro successfully lobbied officials in the White House and at HHS to appoint

CRN's Annette Dickinson as a member of the Commission. She served on the Commission for its 2-year existence, under the leadership of Ken Fisher as executive director and Mal Nesheim of Cornell University as Chairman. The Commission's report was published by HHS in 1997 and referenced by FDA in proposing later regulations, including those outlining the permissible scope of structure/function claims.

Grandfather list: DSHEA provides that dietary ingredients already in use in October 1994 are "grandfathered" and may be used without the need for further notification, whereas companies must notify FDA and provide safety information before using "new dietary ingredients." CRN and other associations compiled lists of ingredients known to be in the marketplace at the time DSHEA was passed. The lists are not intended to be definitive, but serve as an information resource for companies.

Attempting to stem the tide of DSHEA-bashing: After the passage of DSHEA, there was a veritable tsumani of DSHEA-bashing launched by the media, academics, physicians, pharmacy associations, and consumer groups who viewed the law, not as a mandate to continue the previous policy of treating dietary supplements as foods, but as a whole new innovation overturning the presumed inevitability that dietary supplements ought to be drugs. FDA has long since accepted DSHEA as a simple fact, but the rabid critics will not be mollified. CRN attempts to respond to unwarranted attacks on DSHEA, and the need for such response will undoubtedly continue.

CRN consumer confidence surveys: Since 2000, CRN has sponsored an annual consumer confidence survey conducted by IPSOS, a major marketing research firm. The CRN survey is supported by contributions from member companies, in return for which they receive detailed results from the survey. Highlights are presented at CRN annual conferences by Randi Neiner of Shaklee, who chairs the Consumer Confidence Survey Subcommittee.

Qualified health claims: CRN has continued to be deeply involved in commenting on FDA actions regarding NLEA health claims. In 1999, the courts ruled in *Pearson v Shalala* that, while FDA could ban health claims that were "false or misleading", the agency could not necessarily ban health claims that failed to meet the NLEA standard of "significant scientific agreement." Instead, the court said FDA was required to consider whether it was feasible to develop qualifying language that would be

nonmisleading and that would convey to consumers the level of scientific support for the claim. CRN participated actively in the public meetings held by FDA to determine how to proceed on the issue of qualified health claims.

Joint CRN/CHPA/NFI petition to FDA for omega-3 health claim: CHPA invited CRN and the National Fisheries Institute to join in petitioning FDA for an omega-3 health claim following the 1999 Pearson decision requiring FDA to consider claims with qualifying language. This petition was filed in April 2000 in support of Jonathan Emord's petition for such a qualified health claim. The literature review was prepared by ENVIRON, a research firm, and an extensive petition was prepared by CHPA's Patrice Wright, supported by a specially-convened omega-3 working group. In October 2000, FDA exercised its enforcement discretion to permit a qualified health claim for dietary supplements containing omega-3 fatty acids EPA and DHA, allowing product labels to state that the scientific evidence that these fatty acids reduce the risk of coronary heart disease is "suggestive, but not conclusive." In 2003, CRN submitted additional comments in support of other petitions to extend the qualified health claim to conventional foods. In November 2004, FDA granted the petitions for a qualified health claim for omega-3 EPA and DHA in dietary supplements and in conventional foods, stating that "supportive but not conclusive research" shows that consumption of products containing these substances "may reduce the risk of coronary heart disease."

Organizing donations of multivitamins to CDC and various State birth defect prevention programs: CRN was approached by some State birth defect prevention programs, funded by CDC, for donations of multivitamins containing folic acid to be distributed to low income women of childbearing age. CRN's Annette Dickinson contacted several member companies, who agreed to donate the products. Currently, CRN and its member companies are among those supporting other organizations such as Vitamin Angels and Nourish America (formerly Vitamin Relief) that provide nutritional support to needy populations and to those stricken by disaster.

Structure/function claims: DSHEA permitted dietary supplement labels to bear claims describing the effect of a product on the structure or function of the body, provided the company notified FDA of the claim within 30 days, had substantiation for the claim, and used a label disclaimer specified by DSHEA. This provision of DSHEA

was self-implementing, and companies began to make use of it immediately following the passage of the Act. CRN submitted extensive comments on FDA's 1998 proposed rule on structure/function claims, which was finalized in January 2000. Soon after publication of the rule, CRN and CHPA cooperated in sponsoring a workshop for members to discuss the provisions of the rule.

FTC guidance on dietary supplement claims: While companies were quick to employ structure/function statements in dietary supplement labeling and in advertising, there were numerous questions regarding the level of substantiation the Federal Trade Commission would expect companies to have for advertising claims. CRN relayed these questions to FTC staff and urged that guidance be issued. In 1998, the FTC published *Dietary Supplements: An Advertising Guide for Industry* (popularly known as the "green book" because of its distinctive cover). CRN sponsored a workshop to permit member company representatives to discuss it and ask questions of FTC officials.

Quintozene in Ginseng: Early in John Cardellina's tenure at CRN, he was instrumental in working with member companies, other trade associations, and FDA to respond to problems involving the presence of quintozene (a fungicide) in ginseng products.

Safety of Kava: In 2001, there were reports of potential liver damage from the use of kava in Europe and Canada, and FDA ultimately issued a consumer alert regarding these concerns. John Cardellina worked with CRN members, other trade associations, and FDA to evaluate the reports and recommend appropriate labeling for kava products.

Benefits of St. John's Wort: In 2001, NIH researchers published a study finding that St. John's Wort was not effective in alleviating serious depression. Since the weight of the evidence supported the benefits of St. John's Wort for mild to moderate depression and not for serious depression, CRN's John Cardellina worked with Mike Greene and a CRN member company's PR firm to convey the message that the study was focused on an inappropriate target. Experts in botanical science participated with Cardellina in a press conference, and the message was effectively delivered.

Development of Methods of Analysis for Botanical Ingredients: Historically, USP has been the primary source of methods of analysis for pharmaceutical ingredients, and AOAC and the Food Chemicals Codex (FCC) have been the key sources for official

methods of analysis for food ingredients. Also, individual companies often have methods of their own that are utilized to determine the identity and quantity of various ingredients. Both USP and AOAC have been involved in developing methods of analysis for ingredients used in dietary supplements, and the American Herbal Pharmacopeia also published a number of monographs on herbals. In the late 1990s there was a coordinated effort to expand and expedite method development activities, particularly for botanical components. John Cardellina represented CRN in those efforts, and many dietary supplement companies participated actively. Currently the various methods development initiatives are being promoted, coordinated, and to some extent funded by the NIH Office of Dietary Supplements, with Joe Betz as the person primarily responsible for the activity.

BSE: In the late 1990s, there was an international scare regarding the potential for Bovine Spongiform Encephalopathy (BSE) to be transmitted to humans from animal-derived products, especially beef-derived products. USDA tightened import controls, and FDA issued guidance for pharmaceutical and biological product manufacturers, which were relevant also to manufacturers of foods and dietary supplements. CRN convened a working group, with the cooperation with all the dietary supplement industry trade associations, to clarify the expectations of USDA and FDA regarding necessary documentation of the sourcing of animal-derived ingredients and surveyed members to confirm compliance with agency guidance.

Vitamin A: In 2002, Harvard's Walter Willett and others published an article suggesting that in the Nurses' Health Study there was an increased risk of hip fracture in women who habitually consumed amounts of vitamin A (as retinol) equal to 100% of the Daily Value established for nutrition labeling, namely 5000 IU per day. CRN sought expert consultation and convened conference calls among members to consider this issue, but decided against revising its voluntary vitamin A dosage limit of 10,000 IU. However, many companies as a result of these discussions made the decision to lower the levels of retinol in multivitamins, sometimes absolutely lowering the vitamin A level in the product and sometimes making up the difference with beta-carotene. This is another example of voluntary industry self-regulation in response to a potential safety issue, in the absence of direct regulatory action on the matter.

Performance-Enhancing Products (PEP): In the midst of strong debate about the use of performance-enhancing products by athletes, CRN worked with the NIH Office of Dietary Supplements to co-sponsor a conference on performance-enhancing products in January 2002. CRN also developed guidelines on the responsible use of dietary supplements by young athletes, and these were released at the conference.

Melatonin and DHEA: CRN's John Hathcock organized workshops at the request of the membership to explore the safety of melatonin (1995 workshop) and of DHEA (1997 workshop), featuring recognized experts on these topics. In 2005 Andrew Shao authored the position paper "DHEA: The Basic Facts," which pointed out that while there is scant evidence for DHEA as a performance-enhancing product, there is a large body of data regarding its safety and benefit in supporting the health of seniors.

Supporting Health Savings Accounts and Flexible Spending Accounts: As a means of permitting people to set aside pretax funds to use for medical expenses, Congress has created Health Savings Accounts (HSAs) and Flexible Spending Accounts (FSAs). Funds in these accounts can be used by individuals to cover the cost of medical expenses and prescription drugs. CRN and other industry groups are supporting amendments that would permit such accounts also to be used for the purchase of dietary supplements and meal replacement products with FDA-approved health claims.

Omega-3 quality monograph developed by CRN working group: In response to concerns about the quality of some omega-3 EPA and DHA products on the market, a number of manufacturers of fish oils requested that CRN form a working group of companies that wished to establish a monograph prescribing analytical methods and standards of quality. The working group was established, with Annette Dickinson as CRN staff liaison, and in 2002 it published a quality monograph which is widely recognized as an industry standard for self-regulation. In 2006, the working group expanded its activities further and established itself as an independent entity, now known as the Global Organization for EPA/DHA Omega 3 (GOED).

Serving on FDA Food Advisory Committee: In 2002, CRN's Annette Dickinson was appointed to serve a three-year term as an industry liaison member of FDA's Food Advisory Committee.

Product stewardship initiative: From 2003 through 2004, CRN worked on a product stewardship initiative, modeled on programs successfully implemented in other industries. Bob Hamilton of Access Business Group, who had been instrumental in developing such a program for the household products industry, worked closely with CRN staff and a large Product Stewardship Committee to create the framework for an extensive program. At the end, however, there remained serious questions about the practical scope and implementation of such a program, and it was not launched.

ConsumerLab.com: In 2005, CRN petitioned the Federal Trade Commission to investigate the business practices of ConsumerLab.com and to take enforcement action to prevent unfair business practices and consumer deception. CRN charged that ConsumerLab induced companies to pay to have their products tested in return for assurance that failing results would not be revealed. CRN alleged that the published test results misled consumers by purporting to reveal all results but actually withholding information about some failures. The FTC declined to take the case, and ConsumerLab subsequently sued CRN for defamation. After a New York court dismissed seven of the eight charges, a settlement was reached between the parties. No payments were required by the settlement.

NAD oversight of advertising claims: CRN's member companies have for many years discussed various approaches to strengthening industry self-regulatory activities, especially in the area of advertising claims. In 2007, under the leadership of CRN President Steven Mister, CRN reached agreement on a new initiative with the National Advertising Division (NAD) of the Council of Better Business Bureaus, under which CRN will provide funding for expanded activities in monitoring dietary supplement advertising and challenging ads believed to be false or misleading. As of this writing, numerous cases have already been reviewed by NAD under this new initiative.

ATTACHMENT H: CRN ANNUAL CONFERENCES

Listed below are the dates and locations of CRN Annual Conferences, plus a sampling of selected speakers at each one.

1974: Torrance, California

Members' meeting at the W. T. Thompson Company

1975: Madison Hotel, Washington, D.C.

Paul G. Rogers, Chairman of the House Health Subcommittee

1976: Silverado Hotel, Silverado, California

Stephen H. McNamara and Taylor Quinn of FDA

1977: L'Enfant Plaza Hotel, Washington, D.C.

Congressional Reception in honor of the Dietary Goals, attended by several Senators and their staffers, plus surprise guest Linus Pauling, who accompanied CRN members back to the hotel for dinner.

1978: No information available

1979: Biltmore Hotel, Santa Barbara, California

Sanford Miller, Director of FDA Bureau of Foods
Ewan Cameron of the Linus Pauling Institute
Harrison Sheppard and Judith Neibrief of FTC
William Haskell of Stanford University
Elaine Monsen of the University of Washington
Richard Keelor, President's Council on Physical Fitness and Sports

1980: Capital Hilton Hotel, Washington, D.C.

1981: Arizona Biltmore, Phoenix, Arizona

Harold Sandstead, USDA Human Nutrition Research Center
Irwin Rosenberg, University of Chicago
T. Colin Campbell, Cornell University
Robert Atkins, author

1982: L'Enfant Plaza Hotel, Washington, D.C.

1983: Biltmore Hotel, Phoenix, Arizona

Paul G. Rogers on "a decade of progress"
Paul Saltman, U.C. San Diego
Alfred E. Harper, University of Wisconsin
John Erdman, University of Illinois
Helen Guthrie, Penn State University
Hamish Munro, Tufts University

1984: Hyatt Regency on Capitol Hill, Washington, D.C.

Senator Orrin Hatch
Representative Henry Waxman
Peter Greenwald, NCI
Charles Hennekens, Harvard University
Michael Jacobson, CSPI

1985: La Costa, California

Congressman Claude Pepper
Kedar Prasad, University of Colorado
Sushma Palmer, Food and Nutrition Board
William DeWys, National Cancer Institute
T. George Harris, American Health magazine

1986: J. W. Marriott, Washington, D.C.

Model hearing on health claims
Sanford Miller, FDA
David Heber, UCLA
Oliver Alabaster, George Washington University
William A. Peck, Washington University
Joseph Califano, former HEW Secretary

1987: Camelback Inn, Scottsdale, Arizona

Congressman Mickey Leland
Louis Avioli, Washington University
Ronald Ross Watson, University of Arizona
Michael Davidson, St. Luke's Medical Center
Howard Jacobson, University of North Carolina
Mark Levine, NIH

1988: Hotel Intercontinental, Hilton Head, South Carolina

Richard K. Manoff
Ronald Smithies, NAD
William A. Pryor, LSU
Kedar N. Prasad, University of Colorado
Ranjit K. Chandra, Memorial University of Newfoundland
Ralph Shangraw, University of Maryland

1989: Mayflower Hotel, Washington, D.C.

1990: Westin La Paloma, Tucson, Arizona

Jeffrey Blumberg, Tufts University
Aubry Milunsky, Boston University
Herbert Pierson, NCI
Fred Shank, FDA

1991: Buena Vista Palace Hotel, Orlando, Florida

Senator William Proxmire (retired)
David Eisenberg, former CEO, People's Drug Stores
Gary Dykstra, FDA Task Force on Dietary Supplements

1992: Rancho Bernardo Inn, San Diego, California

Michael Taylor, FDA
Elizabeth Yetley, FDA
Donna Porter, Library of Congress
Matthias Rath, substituting for Linus Pauling
James Enstrom, UCLA
William Connor, Oregon Health Sciences University
Carl Keen, UC Davis
D.M. Hegsted, Harvard Medical School (emeritus)

1993: L'Enfant Plaza Hotel, Washington, D.C.

James Carville, Political Strategist
Jeffrey Blumberg, Tufts University
Julie Buring, Harvard Medical School
Peter Greenwald, NCI
Alexander Leaf, Harvard Medical School
Eric Rimm, Harvard School of Public Health
Meir Stampfer, Harvard School of Public Health
Allen Taylor, Tufts University
Bob Lake, Alan Rulis, Beth Yetley, all of FDA

1994: Ritz-Carlton Laguna Niguel, Dana Point, California

Kenneth Cooper, The Cooper Aerobics Center
Julie Buring, Harvard Medical School
William Pryor, LSU
K. Michael Hambidge, University of Colorado
Paul Jacques, Tufts University
Joe Mulinare, CDC
Alan Levy, Mitch Zeller, and Beth Yetley, all of FDA

1995: Resort at Squaw Creek, Lake Tahoe, California

Bob Arnott, Health correspondent, CBS News
Jean Carper, author
Ed Scarbrough, FDA
Ken Fisher, Commission on Dietary Supplement Labels
Norman Farnsworth, University of Illinois
Anne Maher, FTC

1996: Ritz-Carlton, Amelia Island, Florida

Bernadine Healy, former Director of NIH
Godfrey Oakley, CDC
Bernadette Marriott, Office of Dietary Supplements, NIH
Malden Nesheim, Cornell University, Chair of Commission
Beth Yetley, FDA
William Pryor, LSU
Charles Hennekens, Harvard Medical School
Larry Clark, Arizona Cancer Center
Stephen Sinatra, New England Heart Center
Varro Tyler, Purdue University
Edward Croom, University of Mississippi
Mark Blumenthal, American Botanical Council

1997: Ritz Carlton Laguna Niguel, Dana Point, California

Charles Cook, political analyst
Kenneth Cooper, The Cooper Aerobics Center
Gilbert Omenn, University of Washington
William Pryor, LSU
Stephen Sinatra, New England Heart Center
Robert Russell, Tufts University
Panel on Prop 65
Anne Maher and Michelle Rusk, FTC
Gerald Combs, Cornell University

Ishwarlal Jialal, University of Texas
M. Rene Malinow, Oregon Health Sciences University

1998: Charleston Place, Charleston, South Carolina

Nancy Snyderman, medical correspondent for ABC News
Tieraona Low Dog
Simon Pettman, EAS
Basil Mathioudakis, European Commission
Allison Yates, Food and Nutrition Board
Cutberto Garza, Food and Nutrition Board
Tom Aarts, Nutrition Business Journal
Stephen H. McNamara
CRN 25th Anniversary Celebration

1999: Westin Mission Hills Resort, Palm Springs, California

Oren Harari, Management Expert
Charlie Cook, political analyst
Bruce Ames, UC Berkeley
John Cardellina, CRN (Seed to Shelf)
Beth Yetley and Margaret Porter of FDA
Ann Grandjean, University of Kansas
Prosy Delacruz and Susan Loscuttoff, California regulators

2000: Doral Golf Resort & Spa in Miami, Florida

Joe Levitt, Director, CFSAN, FDA
Tom Aarts, Nutrition Business Journal
Karen Bundy, Gallup Organization
Maryellen Molyneaux, Natural Marketing Institute
Balz Frei, Oregon State UKniversity
Ishwarlal Jialal, University of Texas Southwestern Medical Center
Paul Coates, NIH Office of Dietary Supplements
Norman Farnsworth, University of Illinois at Chicago
David Heber, UCLA

2001: Cancelled in the wake of 9/11

2002: Westin Savannah Harbor Resort in Savannah, Georgia

Tommy Lasorda, baseball Hall-of-Famer
Bill Russell, basketball Hall-of-Famer
Eric Dezenhall, crisis management expert
Tieraona LowDog, Integrative Medicine Associates
Rick Kingston, PROSAR, Inc.

2003: Westin La Paloma in Tuscon, Arizona

Mark Blumenthal, American Botanical Council
Joseph Baca, Office of Compliance, CFSAN, FDA
C. Lee Peeler, FTC Bureau of Consumer Protection
Christopher Whitehouse, The Whitehouse Consultancy
Richard Kreider, Baylor University
Dan O'Connor, Management Ventures
Ishwarlal Jialal, University of California, Davis
Carol Johnston, Arizona State University
Barbara Timmermann, University of Arizona
Larry Walker, University of Mississippi
Gerald Combs, USDA Human Nutrition Research Center
Richard Anderson, USDA Human Nutrition Research Center

2004: Lansdowne Resort in Lansdowne, Virginia (near Dulles Airport)

Lester Crawford, FDA Acting Commissioner
Robert Brackett, CFSAN, FDA
Susan Walker, CFSAN, FDA
Paul Coates and staff, NIH Office of Dietary Supplements
Philip Waddington, Canada Natural Health Products Directorate
Michelle Rusk and Richard Cleland, FTC
Mary Ann Johnson, University of Georgia
Marilyn Speedie, University of Minnesota
David Schardt, Center for Science in the Public Interest
F. Edward Scarbrough, USDA U.S. Manager for Codex

2005: Renaissance Esmeralda, Indian Wells, California

Phil Lempert, expert in consumer trends
Barbara Schneeman, Director, ONPLDS, FDA
Reinhold Vieth, vitamin D expert, Toronto
Maret Traber, Linus Pauling Institute, Oregon
James Joseph, Tufts University, Boston
Holly Atkinson, journalist and author
Dan Beck, A.C. Nielsen
Steve French, Natural Marketing Institute

2006: Royal Sonesta Boston, in Cambridge, Massachusetts

Dan Pink, author and expert on innovation and competition
Margaret O'K. Glavin, Associate Commissioner, FDA
Lydia Parnes, Director, Bureau of Consumer Protection, FTC
Andrea Levine, Director, National Advertising Division, CBBB

Norman Ornstein, election analyst, CBS News
Margaret A. Chesney, NCCAM, NIH
Walter Willett, Harvard School of Public Health
Patrick G. O'Malley, Archives of Internal Medicine
Jefrey Blumberg, Tufts University

2007: Westin Kierland Resort in Scottsdale, Arizona

Robert Brackett, CFSAN, FDA
Michael Morton, Vitamin Relief
Scott Gottlieb, American Enterprise Institute
Stephen Barnes, University of Alabama, Birmingham
Paul Stoltz, The Adversity Advantage
Basil Mathioudakis, European Commission
David Katz, Medical Contributor, ABC-TV

ATTACHMENT I: Recipients of CRN Steuben Apple Award (partial list)

2007: Mark Blumenthal, American Botanical Council
Randi Neiner, Shaklee Corporation
Carolyn Sabatini, Pharmavite

2006: Gail Becker, GBA Health Communications
Patricia Knight, Chief of Staff to Senator Orrin Hatch
Eugene Lambert, Covington & Burling

2005: Ed Croom, Indena USA
Joy Joseph, Pharmavite
John Hathcock, CRN

2004: Marjorie Fine, Shaklee Corporation
Peter Barton Hutt, Covington & Burling

2003: Paul Bolar, Pharmavite
Joe LaPlaca, DSM Nutritional Products

2002: Bill Van Dyke, B&D Nutritional Products
Harvey Kamil, NBTY
Verna Breland, CRN

2000: Evelyn Jarvis-Ferris, Shaklee Corporation
Salvatore Palladino, BASF Corporation

1999: Michael Leiner, Leiner Health Products

1998: Stephen E. Fisher, Banner Pharmacaps
Jacqueline Leffyear, CRN
Nada L. Seide, annual conference consultant for CRN

1995: Anthony Iannarone, Roche Vitamins
Barry Kaufman, BASF

ATTACHMENT J: CRN staff and counsel, 1973 to 2007

CRN Executive Directors and Presidents: CRN's current President is Steven M. Mister, Esq., who was recruited by a search committee of the Board in 2005, following Dickinson's announcement of her intention to retire. CRN's first Executive Director (1973 to 1979) was Peter Semper. Beth Coleman was recruited as CRN's first full-time paid Executive Director (1979 to 1981). John (J.B.) Cordaro was recruited in 1982 and served two decades as CRN's President, until the end of 2002. Annette Dickinson, who was CRN's initial staff member and who handled scientific and regulatory affairs from 1979 to 2002, served as President from 2003 to 2005.

Legal counsel: CRN's current legal counsel is the firm of Covington & Burling, and in particular Peter Barton Hutt and Eugene Lambert. CRN's legal counsel at the time of its formation and for more than two decades after that was the firm of Wilmer, Cutler and Pickering. Daniel Marcus and William J. (Bill) Kolasky were the two mainstays for CRN. Ultimately Marcus and Kolasky chose to focus their expertise in legal specialties other than food and drug law, and in 2000 CRN turned to the firm of Covington & Burling as its outside counsel.

CRN scientific and regulatory staff: CRN's current scientific and regulatory staff includes John Hathcock, Vice President, Scientific and International Affairs, and Andrew Shao, Vice President, Scientific and Regulatory Affairs. John Hathcock was recruited from FDA in 1995 and is in charge of CRN's policy development relating to the safety of vitamins, minerals, and other substances marketed as dietary supplements. He also has been active and highly influential in international affairs, especially where safety issues are involved. Andrew Shao was recruited in 2005, as Annette Dickinson was retiring and Steven Mister was coming on board as President. He earned his Ph.D. from Tufts University, had solid industry experience at Kemin and at GNC, and has proven to be highly skilled in evaluating scientific issues, formulating policies, organizing effective action, and being a spokesman for CRN. John Cardellina was recruited from a research position at the National Cancer Institute in 1998 to serve as CRN's VP, Botanical Science and Regulatory Affairs; he left CRN at the end of 2002 to return to NCI. Annette Dickinson was successively technical director, Director of

Scientific and Regulatory Affairs, and VP, Scientific and Regulatory Affairs from 1979 to 2002. For a few years, CRN's scientific staff had the luxury of a senior science writer, Cathy Fomous.

Legislative Affairs: CRN's current Senior Director of Government Relations is Mike Greene, capably assisted by Ingrid Lebert and also supported by the Washington, D.C. lobbying firm The Alpine Group (in particular Jay Hawkins and Courtney Johnson), and California lobbyist Randy Pollock. During John Cordaro's Presidency, CRN had a succession of capable personnel in government affairs, including Phyllis Balan, Susan Fitzgerald, Cathy Badami (now Schuhart), Katherine Meshkin, and Mike Greene. Cordaro also made use of outside legislative consultants, notably David Jenkins, Kevin McGuiness and Markham Erickson

Communications: CRN's current VP, Communications is Judy Blatman, who was recruited by John Cordaro in 2001. CRN's communications department also includes two director positions – Season Solorio, Director, Public Relations and an open postion for a Director, Media Relations – as well as Communications Coordinator Kate Murphy. Gretchen Powers, former Director, Communcations, recently chose not to return to her full-time position following the birth of her first child, but will continue to consult with CRN on specific projects including graphic design, website maintenance, and the web-based biweekly "members only" newsletter. Ms. Blatman's previous communications coordinators included Lisa Hadesman, Patrick Landin, and Carly Gerkin. Throughout its history, CRN has periodically launched special projects utilizing outside PR firms including Ketchum Communications, CooperKatz & Company, Wyatt Communications, Dezenhall Resources, Fleishman Hillard, and Porter-Novelli. Ms. Blatman has recently launched CRN's newest PR campaign with CRT/tanaka. Prior to Ms. Blatman, John Cordaro recruited a series of communications directors during his tenure at CRN, including Bruce Brown, Katherine Smith, Mary Burnette, and Moira Saucer. Cordaro also utilized Washington writer Jeff Cohn on frequent occasions for special writing projects.

Executive management: CRN's current Director of Finance & Administration is Michael Ahearn. For many years during John Cordaro's presidency, Phyllis Balan served as CRN's Director of Administration and also provided expertise in

legislative affairs. Verna Breland subsequently served as Director of Administration for many years before her departure in 2005. In 2000, John recruited Dan Shaughnessy, who had earlier provided expert consultation to CRN on issues relating to food stamp legislation, to serve as VP for operations.

ATTACHMENT K: CURRENT CRN COMMITTEES AND TASK GROUPS

Standing committees of CRN have ongoing responsibility for the oversight of key policies and initiatives. Task groups are formed from time to time as circumstances require, to deal with particular issues as they arise. Special initiatives that may be undertaken by task groups are funded by members of the group and not through the CRN operating budget.

Standing Committees:

Audit Committee
Compensation Committee
Government Relations Committee
International Trade and Market Development Committee
Media Relations Committee
Membership Development Committee
Regulatory Affairs Committee
Senior Scientific Advisory Council

Examples of Recent CRN Task Groups:

Vitamin E Task Group (2005-2007)
NIH Multivitamin Conference Task Group (2006)
GAIT Trial and GAIT II (glucosamine and chondroitin) Task Group, (2006-2007)
NORVIT (Vitamin B) Task Group (2003-2006)
Omega-3 Fatty Acid Task Group (2000-2006)
Dietitian Outreach Task Group (2005-2006)
Consumer Confidence Survey Subcommittee (2001-2007)
Standardized Ingredient Information Protocol Task Group (2005-2007)