

WINNING by the
Rules
Our Commitment to Excellence

A Blueprint for the Future

The Council for Responsible Nutrition
State of the Industry Presentation

By

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Members of the Council for Responsible Nutrition (CRN), I welcome you to the 2002 CRN Annual Conference.

I also welcome soon-to-be CRN members. We are anxious to get better acquainted with you. We want to share CRN's unique values and our future plans, the foundation for building an even stronger industry. We can't spell success without "u." We want you to join CRN before you leave Savannah.

Invited guests, speakers and program participants...welcome and thank you for taking the time to participate in CRN's Annual Conference.

A special expression of appreciation to two sports legends and outstanding humanitarians: Tommy Lasorda, who spoke to us at lunch yesterday, and Bill Russell, whom you will hear from this morning.

Welcome, Board of Directors, CRN committee members, legislative counsel and legal counsel.

We thank you for your efforts on behalf of the dietary supplement industry. Your colleagues appreciate the time you spend on the activities of our industry.

Chairman Bill Van Dyke has led CRN through interesting times and through difficult, uncharted waters. Thank you Bill. Together, Bill and the CRN staff have faced numerous challenges.

A very special thanks to the entire CRN team for their tireless dedication, daily commitment, and phenomenal successes.

What is the state of the dietary supplement industry? Where have we been... and where are we going? What role does CRN play in today's industry and what role should CRN play? As importantly, what roles should you, our members, play?

As CRN approaches its 30th anniversary, it is appropriate to note that the middle years, (1990-1994), were marked by several major legislative successes. In each case CRN played a key role.

- In 1990, CRN was instrumental in attaining consideration for the inclusion of four health claims for dietary supplements in the Nutrition Labeling and Education Act (NLEA).
- In 1992, CRN almost single-handedly worked with Congress to ensure the passage of the Dietary Supplement Act to prevent FDA from lowering label reference values for vitamins and minerals.
- In 1993 and 1994, CRN worked closely with other associations to provide support for the passage of DSHEA.

Unfortunately, these legislative successes have not brought us continued, sustained marketplace success.

Today, we are facing tough times...dietary supplement sales are down in important product categories and channels of distribution; negative media stories are continuing; scientific study results are frequently negative; a growing number of outliers taint the industry; and the FDA is so resource-challenged that it cannot take enforcement actions quickly.

CRN's almost three decades of success and achievements have helped to create an environment for dramatic changes and growth in our industry. However, the promises and expectations of the not-too-distant past are seriously challenged today.

I have spent the past few months reviewing the state of the dietary supplement industry and what CRN can do to help reverse current negative trends.

Let's examine where we are.

First, the dietary supplement industry is on the cusp of failure. Unless immediate action is taken, we may not be able to maintain the components of DSHEA suitable for supporting a positive regulatory environment for responsible manufacturers.

Second, the current state of affairs is not someone else's fault. The roots of our problems start within our own industry, from the egregious practices of some to the lackadaisical attitudes of others.

Third, the industry has not invested sufficiently in its own future.

Fourth, the existence of several under-funded dietary supplement trade associations, all with overlapping mandates and activities, sometimes generate conflicting messages, and creates confusion for policy makers.

I am confident, however, that the dietary supplement industry can achieve success with a dedication and commitment to resolve today's problems and a willingness to seek the means to get the job done.

In fact, the Council for Responsible Nutrition is poised and uniquely qualified to accept this challenge to reshape the future direction of the dietary supplement industry.

To fully understand what we need to do, we must recall how we have arrived at our current position. Quite frankly, I believe the dietary supplement industry has squandered the legacy and the opportunities of the 1990's that NLEA, DSA, and DSHEA provided. NLEA and DSA, which passed Congress in 1990 and 1992, helped to set up the *UNANIMOUS* passage of DSHEA in 1994.

It is generally accepted that Congress passed DSHEA for three underlying reasons.

First, Congress had a high level of confidence in the safety and benefits of supplements, since the media, our best PR agency, frequently trumpeted the positive scientific evidence on the benefits of nutritional supplements released in the late 1980's into the mid 1990's.

Second, FDA mishandled and miscalculated the regulation of dietary supplements and gave real meaning to the expectation that they wanted to remove botanicals from the category, and limit the permissible amount of vitamins and minerals.

Third, under the leadership and guidance of Congressional champions, a fragmented industry was effectively harnessed to work together and to generate grassroots support for legislative action.

Unfortunately, since 1994, the terms of trade have changed drastically for the dietary supplement industry. The unique opportunity that the dietary supplement industry was given—to provide consumers access to safe products manufactured under GMP's and quality standards, and access to science-based information to ensure that informed marketplace decisions could be made—has not been fulfilled.

Some behave as though DSHEA was an endpoint. Actually, DSHEA was a new beginning. Our failure to recognize this has laid the foundation for the industry's current predicament.

Eroding strength of consumer confidence in dietary supplement products continues, especially regarding botanicals. This decline is based on safety concerns about some products, quality issues about other products, and egregious claims by some companies. Individually and collectively, these problems threaten the future growth and even the survival of our industry.

Over the years, recommendations for specific initiatives to address safety, quality, and claims, as well as to build our science base, have not received the level of commitment and support necessary to eliminate problems in these areas.

Now, more than ever, we must rid our industry of problems that impede our growth.

For too long, we have blamed everyone but ourselves.

We blame the media for writing negative stories and believe clever PR initiatives alone can restore consumer confidence. PR initiatives are more likely to be successful when the industry effectively resolves questions of safety, quality, and claims.

We blame FDA and FTC for not taking enforcement action and we believe that more appropriated money and a few more government officials will provide sufficient resources to take the "bad actors" out of the industry.

We blame a “handful of rogue manufacturers” and smugly say others are the problem without an honest assessment of what we should do better.

But let’s face it...we are the problem—either for what we do or for what we do not do.

It is time we accept the fact that we are the biggest threat to the future of our industry. We must stop pointing a finger outward and significantly increase our efforts to correct the solvable problems that are clear and present dangers to the dietary supplement industry.

We know that continuing with the status quo is not a path that will bring success.

We must blaze a new trail. The dietary supplement industry must change its way of doing business to survive and grow.

I want to share my vision for action, a vision that is clear and concise and one that can be translated into a realistic and achievable plan for success.

To prepare for this year’s unique State of the Industry, I followed Bill Van Dyke’s suggestion that I focus on the blueprint for CRN’s future that was favorably received in my recent presentation to the CRN Board.

The overall goal of the dietary supplement industry must be to promote growth in the dietary supplement industry by restoring consumer confidence in using dietary supplements.

I recommend that CRN expand its activities with a new blueprint for action to achieve this goal. This blueprint flows from earlier CRN initiatives presented at our 2000 Annual Conference, which were later incorporated into CRN’s Proactive Initiatives. These plans have formed the basis of CRN’s ongoing special activities for the past two years.

The actions I recommend build on CRN’s years of success, achievement, and credibility.

The tactical objectives of this plan should be designed to enhance the likelihood that consumers, media, decision-makers, and health care providers acknowledge that dietary supplements are safe, manufactured to quality standards, and supported by a steady flow of positive science-based information. This will be achieved by better defining an enforceable regulatory framework for companies to responsibly manufacture and market dietary supplements. The elements of the framework will require CRN to focus on Four Key Components:

- Developing a transparent system and process for assessing the safety of each ingredient used in dietary supplements and requiring that safety assessments be completed before the ingredient is marketed.
- Requiring a rational basis for product formulation, by demanding credible scientific evidence on each specific ingredient and combination of ingredients with sufficient

amounts of the ingredient to (1) achieve the benefit implied or claimed and (2) avoid the risk of adverse effects due to excessive intakes.

- Developing standards and guidelines for science-based substantiation for all information and claims about the benefits of dietary supplement products and supporting actions as required. CRN has established a committee that will develop substantiation guidelines for dietary supplement claims.
- Requiring all dietary ingredients and dietary supplement products be manufactured under rigorous GMP's and quality standards, with appropriate, useful certification to consumers.

Some elements relating to safety and GMP's were included in earlier CRN initiatives. However, this new undertaking needs to be broadened to provide the basis for a coherent, cohesive framework that will guide our industry. We have already made significant progress in several areas such as:

- stimulating third-party analytical methods for botanical ingredients;
- reviewing the safety and benefits of botanicals;
- using risk assessment to determine the safety of selected supplements;
- preparing a dietary ingredient safety review system and process and also updating the report on the safety of vitamins and minerals;
- disseminating more timely and useful positive information about the benefits of nutritional supplements;
- responding to unexpected crises; and,
- keeping Congress informed about our industry interests.

Today, the urgency to act is intense...CRN must assert a leadership role and implement these initiatives, which are essential to improve the environment for marketing dietary supplements and to restore consumer confidence in our products.

The recent Food and Nutrition Board draft document on a safety framework for supplements has underscored the urgency for an industry initiative. That report could be used by Congress or regulators to support pre-market approval for dietary supplement ingredients and/or products. We have two choices—strong self-regulation that we initiate or eventual pre-market approval by FDA. Which do you prefer?

CRN and its' members believe affirmative self-regulation is the proper way to complement aggressive regulatory enforcement. Two recent CRN initiatives will be highlighted at today's sessions—one involving sports nutrition supplements and one involving quality standards for the long chain omega-3 fatty acids, EPA and DHA.

In the sports nutrition supplements area, CRN has developed conservative, responsible guidelines for the use of sports nutrition supplements by young athletes. These guidelines, which were drafted for use at a unique CRN, NIH-ODS co-sponsored conference, will be available to attendees at today's general session on sports nutrition, following the keynote address by Bill Russell.

In the arena of quality standards, CRN's omega-3 working group has finalized a voluntary industry monograph incorporating stringent quality standards for EPA and DHA. These standards will help bolster consumer confidence in these ingredients, which offer such outstanding potential for reducing the risk of heart disease. This monograph enjoys the support of numerous suppliers and marketers of omega-3 fatty acids and exemplifies the substantive commitment to excellence that is needed to responsibly move the industry forward. This afternoon's session on omega-3 fatty acids will provide further insight into the monograph. This success demonstrates that the working group approach could be used as an effective tool for developing guidelines in other product areas.

CRN efforts should ultimately target all product categories—from vitamins and minerals to botanicals and other supplements. Our efforts will have a global impact on CRN's interests in regulatory activities around the world—from Codex, to the European Commission, TABD, and individual countries. CRN's International Trade and Market Development committee is overseeing a joint effort with CRN and several European associations on the implementation of the European Commission food supplements directive.

To effectively implement this blueprint, we will need to thoroughly examine the internal operation of CRN and fine-tune our day-to-day operations.

It will be necessary to update our bylaws, mission and objectives, and we must examine our internal processes and work flow to enhance management efficiencies.

We must acknowledge that our current governance structure was established for an industry that is quite different from today. Thus, we need to update our organizational and decision-making structures to be consistent with our industry interests and challenges.

We must not allow narrow, boutique interests of a few to distract the larger vision, concerns and interests of the industry.

We must focus on our vision and agenda and not get sidetracked by less important issues and concerns that can sap our resources.

As we fulfill this blueprint, we can revitalize CRN with additional members who are prepared to make the commitment to restore consumer confidence in dietary supplement products through a science-based focus on safety, quality, and information.

Yes, cost must be addressed before we launch these efforts.

Yes, dues increases and assessments will be necessary to get the job done. This plan will require serious funding. But before we decide whether we can afford this effort, we must first consider whether we can afford NOT to try. At the outset, we should agree on whether the job needs to be done, and if we agree, define and prioritize the necessary tasks. Clearly, we will have to bear the burden of investing in our own future and charting

our own course, but we can then also seek creative and alternative ways to supplement industry funds. It is possible that industry resources can be supplemented with foundation funding and government support for some initiatives.

This plan provides the basis for stimulating a major membership development drive to enlist broader support for CRN that would help to spread the burden from a few to many. For too long our industry has allowed unsupportive companies to act as "free riders." We can no longer tolerate "free riders" if we are to achieve our objectives.

How do we get from where we are today to where we want to be? The good news is that CRN has many of the components in place—beginning with the CRN staff. Also, we have some proactive initiatives underway that will allow us to hit the ground running in the right direction.

Although CRN's resources have been depleted over the past three years, our core institutional character remains intact. First, our very name—Council for Responsible Nutrition—is known globally as a Brand associated with credibility and success. Second, CRN's science staff are experts in their field and globally recognized. Third, CRN has evolved a focus of its activities that include regular day-to-day tasks that support our industry; crisis management including responses to the unexpected; and Board-approved proactive initiatives. Revitalizing CRN will be the first step towards effectively and rapidly moving towards success.

We must resolve to stay the course until the job is done.

What can you do?

Each CRN member would need to make a renewed commitment to support the framework to responsibly manufacture and market dietary supplements. Each member must step forward and accept the cost of doing business by paying more dues... while at the same time demanding value and success from your resources.

With increased resources, CRN can step up its initiatives to promote awareness of the industry's efforts to restore consumer confidence.

Additional resources would allow CRN to promote positive information about the safety, quality, and benefits of dietary supplements.

CRN should launch such efforts through alliances and partnerships with other associations, health care providers and professionals, and advocacy organizations.

CRN should promote and encourage expanded industry support for research and education. The future of our industry is dependent upon the development of a steady stream of new positive findings. We would encourage funds for research to fill gaps in our current knowledge base, leverage research dollars of federal and state governments, encourage private research, and disseminate information to various target audiences.

And, we would explore the roles the NIH-Office of Dietary Supplements and private foundations could play in helping achieve this objective of expanding the research base on dietary ingredients.

Special attention must be given to finding ways to ensure cooperation among dietary supplement trade associations. This is an area I have strongly supported and continue to support—as far back as the DSHEA period. Early this year, Bill Van Dyke, along with interested CRN members, took the initiative to seek to consolidate/merge several trade associations supporting the dietary supplement industry. Their objective was to build a strong unified voice through a consolidation/merger of all industry trade associations with four goals: 1) to present a single industry voice to the world; 2) to improve association financial efficiency by maximizing effectiveness of scarce industry resources; 3) to eliminate duplication and redundancy; and 4) to generate additional resources needed to implement initiatives in the communications, government relations, regulatory, education, and scientific areas.

Another idea is to encourage a federation of industry trade associations that could act as the impetus to consolidation. At a minimum it might offer an opportunity to share the costs of various overlapping expenditures from office space to public relations initiatives, lobbying teams, and other essential tools to support the dietary supplement industry.

Whether or not there is consolidation, we must agree on a new direction in association relations to maximize the value of industry efforts.

When our efforts are successful, we will see our vision for the future fulfilled:

- a credible industry that has raised the bar for every company to responsibly manufacture and market dietary supplements;
- a credible industry that has accepted the highest level of social responsibility and corporate accountability;
- a credible industry that promotes health and wellness for all consumers... an industry whose products help to reduce the risk of disease and lower health care costs;
- a credible industry that is working to sustain the future by supporting its research base;
- a credible industry that has a broad base of support from consumers, health care providers, and decision-makers; and finally,
- a credible industry of which each CRN staff member and every CRN member company can be proud... an industry that has made and continues to make real contributions to the public's search for health and wellness.

So what do we do next?

I propose the following action items and timeline of events.

First, assign the CRN staff the responsibility to develop the specific strategic details needed to achieve the four components of a new regulatory framework and seek Board review/approval at the December meeting.

Second, establish a fundraising group to identify potential non-industry sources of funds such as foundations, government, etc., and to report at the December Board meeting.

Finally, launch the effort by January 2003 with enthusiasm and commitment to success, and maintain vigorous management of its implementation.

The CRN staff is ready to move forward and work together with you to achieve our mission to help create an environment for responsible companies to grow by restoring consumer confidence in dietary supplements. Only in this way can we hope to return to our earlier days of golden opportunities—double-digit growth, positive scientific results supported by our industry, and a friendlier media.

I recommend CRN members endorse a comprehensive, well-coordinated fusion of science, communications, and government relations addressing both domestic and international activities.

I offer these principles to help guide such a fusion of values and activities:

1. Objectively assess problems and challenges.
2. Resist the urge to fragment association groups, while encouraging the association you support to provide the voice and services you need.
3. Increase legislative commitment.
4. Expand self-regulation and encourage responsible regulatory initiatives.
5. Nourish our science base since it is our lifeline—today and into the future.
6. Communicate credible information to key target groups.
7. Recognize the global arena to ensure that our domestic and international actions are compatible.
8. Pay your fair share. And,
9. Be optimistic... get prepared for the next wave of sustained success which will occur if you follow through with these industry team winning ways.

Speaking of winning, now we will have an opportunity to listen to one of the greatest team winners of our time—both on the court and in life.

Mark LeDoux, President of Natural Alternatives International, Inc., will introduce Mr. Bill Russell.

Thank you.