

CRN State of the Industry

~ The Conference ~

CRN Annual Conference on Dietary Supplements
Oct. 25, 2004, The Lansdowne Resort, Lansdowne, Virginia

Council for Responsible Nutrition (CRN) President Annette Dickinson, Ph.D., and Chairman of the CRN Board of Directors, Byron Johnson today gave the attached "State of the Industry" presentation in a members meeting during the association's annual conference on dietary supplements at Lansdowne Resort in Lansdowne, Va.

Byron Johnson:

Ten years ago, Congress passed the Dietary Supplement Health and Education Act (DSHEA), a landmark piece of legislation that created a new definition for dietary supplements within the category of food, and provided a better framework for the Food and Drug Administration to regulate our industry.

Ten years later, we are here today just outside our nation's capital to celebrate the ten year anniversary of the passage of DSHEA and to express our appreciation of the new determination at FDA, encouraged by former Commissioner Mark McClellan and Acting Commissioner Lester Crawford, our keynote speaker here today, to make DSHEA work.

I'm happy to report we see a new commitment at FDA to use the powers that DSHEA provided to create a level playing field among companies, to provide consumers with reasonable access to safe products, and to allow appropriate innovation by supplement companies who abide by the law.

If we as an industry do our part to ensure our products are of the highest quality and offer consumers a safe and beneficial supplement to their diets, then DSHEA IS HERE TO STAY.

FDA is committed to making it work and to enforcing the law. We need to be committed to supporting their full implementation of the law.

As I stand before you, our country is one week away from an election that will have a major impact on the next four years, and will serve to influence the future of this industry for many more years to come.

Today, right here, right now, I stand before you as Chairman of the dietary supplement industry's most influential trade association, the Council for Responsible Nutrition, or CRN, to say to you our industry will be better off in the next four years because of the actions this trade association has taken over the past two years.

As our country plans to go to the polls to vote for the next president, we, at CRN, will soon have our own new president. As you know, Annette Dickinson is planning to retire from CRN in the spring when the snow melts in Minnesota. Only then will she and her husband, Charlie, move there.

CRN State of the Industry

We all have had the great privilege of watching Annette work for CRN for 31 years. (Well, some of us were just children ... as I look out in this audience, some of you weren't even born when she first started.) We have all reaped the benefits of the credibility, the science, and the regulatory know-how she has brought to CRN and to this industry. As CRN Chairman for the past two years, I have enjoyed working closely with Annette, and it is my great honor to now introduce, a true leader of the dietary supplement industry, CRN's President the one and only Dr. Annette Dickinson.

Annette Dickinson:

Thank you Byron for that gracious introduction. I, too, have enjoyed our partnership for the past two years and have been honored to have worked in this industry for the past thirty-one years.

Thirty-one years.

Look how far our association and this industry have come in that time.

CRN has grown from a three company association to nearly 80 companies. The dietary supplement industry has grown from \$1 billion dollars in sales to a \$20 billion dollar industry in the U.S. We've gone from one industry trade show, to four industry trade shows plus three executive industry conferences. More than 150 million Americans take dietary supplements.

Our purpose today is to focus on the present and the future, not to dwell on the past. So, what, you ask, is the current state of the dietary supplement industry?

Byron Johnson:

Our industry has made progress this past year in five key areas that are absolutely vital to the health of our businesses.

We realize that in order to be able to move our industry forward, to strengthen consumer confidence, to earn the respect of regulators and law makers, to focus on the strong science that is supportive of so many of our products, we need to turn some lingering controversies into ancient history, and move some new programs into the forefront.

This year we stepped closer to that goal. Let's talk about ephedra, steroid hormone precursors, adverse event reporting, enforcement of DSHEA, and GMPs.

Annette Dickinson:

First, this past April, the FDA's ban on dietary supplements containing ephedra, a ban that CRN supported, went into effect. We can debate whether or not the ban was appropriate, we can debate whether or not the ban was legally sound, but one thing that

CRN State of the Industry

we cannot debate is the fact that ephedra – one product among thousands that this industry sold – was bringing the whole industry down. It was time for FDA to act, and the fact that the agency used new authority provided by DSHEA demonstrated that the law works.

Three lawsuits have been filed, challenging FDA's actions on ephedra. Our country's legal system allows for courtroom challenges, and there is a rightful expectation that when the government bans a product, that action is scientifically sound and legally solid in order to withstand a legal challenge.

We need to learn from this long and damaging controversy. If we ever again find ourselves under attack regarding the safety of a particular ingredient, and if we decide there is sufficient evidence to defend it, then we owe it to ourselves and our consumers to do everything necessary to demonstrate its value and its safety. This may include, for example, sponsoring clinical trials or supporting active postmarket surveillance to document the nature of consumers' experience with the product.

Byron Johnson:

Steroid hormone precursors.

A couple of weeks ago, the U.S. Congress passed a piece of legislation, actively supported by CRN and the other dietary supplement industry trade associations, as well as organizations such as the American Medical Association, the National Football League and the US Anti-Doping Agency, that effectively moves many steroid hormone precursor products, like "andro" out of our industry and puts them where they belong, on a list of controlled substances. This legislation, the Anabolic Steroid Control Act, was signed into law by the President on Friday and effectively prohibits the marketing of these substances as dietary supplements, thus removing another controversy that has served to undermine our industry's reputation.

Annette Dickinson:

The third issue this industry is facing is one for which we have an opportunity to proactively help steer our fate. Adverse event reporting. The time has come for adverse event reporting for serious incidents to become mandatory for our industry, and most likely also for the monographed OTC drug industry.

CRN is supporting Sens. Hatch, Harkin and Durbin's plan to work together to create a workable, reasonable, meaningful mandatory AER system for serious adverse events. It is critical for us to obtain Federal legislation on this issue and avoid having to deal with it state by state.

This is the right thing to do. As industry leaders, we must all agree, that the government must be made aware of any serious safety issue involving any product we make. This is common sense and good business practice, not just for our industry, but for all industries.

CRN State of the Industry

Byron Johnson:

We must have the safety of our consumers in our minds at all times. We must protect our consumers' safety and our consumers' trust, for consumers are the cornerstone of our industry.

Annette Dickinson:

As we face the reality of mandatory reporting of serious adverse events, we also need to ensure that the system includes some provision for realistically evaluating the significance of these events. Ideally, a credible third party needs to oversee the development of a database that will both identify problem areas and confirm the safety of dietary supplements used according to label directions.

The University of Minnesota is establishing a center for dietary supplement safety to undertake these types of activities. As an industry, we need to encourage a realistic evaluation of the safety of our products, and as an association CRN needs to be in the forefront of leading initiatives such as these.

Byron Johnson:

That brings us to the fourth key area. Enforcement of DSHEA.

Annette Dickinson:

In recent years, FDA has made it clear that implementation and enforcement are top priorities. New ingredient notifications are receiving careful review and safety provisions are being enforced. In the area of product claims, there has been a strong commitment to more cooperation between FDA and the Federal Trade Commission to go after bad actors. We share the agencies' commitment to seeing that consumers are provided with more accurate label and advertising information, scientifically-substantiated products and claims, and truth in communications, whether on the bottle or in the marketing materials. Through these initiatives, the agencies demonstrate the power and reach of their existing regulatory authority.

Byron Johnson:

CRN supports, and will continue to support, reasonable efforts to more fully implement the law. We know DSHEA provides a great framework for regulating our products. We know DSHEA can work - and with FDA's renewed commitment to make it work, we will make it work.

CRN State of the Industry

Annette Dickinson:

CRN will continue to use our legislative relationships to encourage, when possible, more appropriations to give the regulatory agencies sufficient staff and other resources to do the job.

Byron Johnson:

Good Manufacturing Practices. I think we're all familiar with those three words. But what we would really like is for consumers, for the media, and for others who criticize our industry to know is that our industry abides by Good Manufacturing Practices.

Annette Dickinson:

In the past year, CRN spent countless hours developing a joint submission with the other industry trade associations to present a coherent and specific set of comments. This is on top of all the work we've previously done.

Byron Johnson:

I know that FDA very much appreciated the extensive comments we provided on GMPs. I personally would like to thank Annette and also Paul Bolar of Pharmavite, who serves as chairman of CRN's Regulatory Affairs Committee, for the fine leadership they provided in working with the other trade associations to prepare the joint submission, which we all hope will form the basis for FDA's final GMP regulations. This was your association at work in one of its finest hours... and I predict... that work will pay big dividends for your business. No individual company could have done this kind of work alone. It's a benefit of being a member in a trade association like CRN.

Annette Dickinson:

The fact is, even though CRN member companies and other responsible companies are already abiding by GMPs which go beyond the scope of what's currently mandated by law, we need a final GMP rule and we need it soon. Consumers, the media, the industry renegades, and those who choose to denigrate our industry's products, need to hear that there is a mandatory, appropriate system in place that establishes Good Manufacturing Practices across the board – for all companies that manufacture dietary supplements that are sold in the U.S. We need this rule to bolster consumer confidence, and we need this rule to ensure competitive fairness. Once a final GMP rule is issued, we need to take an active role in educating the industry about that rule in order to help ensure proper implementation.

Byron Johnson:

As I come to the end of my two-year term as chairman of the Board of Directors for the Council for Responsible Nutrition, I want to remind every company that is a member in

CRN State of the Industry

this extraordinary association of the importance of membership. Spread the word: CRN is the full-service association that provides the kind of industry leadership needed. CRN is the full-service association that provides a voice for the credible science. CRN is the full-service association that legislators and regulators respect. CRN is the full-service association that is recognized on an international basis. CRN is the full-service association that the media turn to. CRN will continue to have a huge impact on the future of this industry. I want to thank my Board of Directors and my Executive Committee whose support these past two years was outstanding. Chuck Brice, Mike Doyle, Ted Ziemann, Bill Van Dyke, David Christensen, Joe LaPlaca, Andy Davis, Mark LeDoux, and John Venardos. And to the entire Board of Directors and CRN member companies...we couldn't have done it without your support – I salute you. As a team, we can be proud of the state of our industry and I'm proud to say that your CRN is prepared to meet the challenges of tomorrow.

As Chairman, I have had the great pleasure of working closely with Annette Dickinson. I can say from my personal travels and contacts in the industry and government, nationally and internationally, that without question Annette is a truly unique individual who is highly respected around the world. Annette, thank you for making the future of our industry brighter. We thank you and promise to protect the legacy that you have left for us.

Annette Dickinson:

Thank you Byron. I've told you personally, but I want to share with everyone here, what a pleasure it has been to work with you. Together we helped make a difference. And I stand with you in thanking our esteemed Board of Directors, Executive Committee, and member companies.

There's so much we have accomplished this year...publication of John Hathcock's much anticipated second edition of Vitamin and Mineral Safety; steps forward in Codex; legislative successes in turning away egregious legislation and passing positive bills; positioning CRN as the industry voice in the press; working with the other trade associations on regulatory and legislative issues; moving into a fiscally sound position for our association; pulling together this group for what we know will be another successful annual conference. But there's still so much more we can do.

One of the most important tasks before us today is to publicly and strongly position dietary supplement use as an integral component of a healthy lifestyle. We need to be convening stakeholder meetings and seminars to convey this message and to demonstrate how health-conscious consumers can best utilize our products to promote health and protect against disease, in the context of other healthy habits. CRN and our member companies need to pursue every opportunity to participate in professional meetings, trade shows, and consumer conferences where this positive message can be conveyed, and we need to support research to confirm the effectiveness of this combined approach to healthier living. The recently released Surgeon General's report on osteoporosis is an excellent springboard to get us started in this direction.

CRN State of the Industry

You can be sure you are not seeing the last of me. I intend to keep abreast of this industry because there's still so much more we can – and will -- accomplish. I hope to be affiliated in some capacity with the new Center for Dietary Supplement Safety at the University of Minnesota and I fully expect to consult for CRN and for companies in this industry.

What's my dream for the future of this industry? I envision as time moves forward and CRN continues its efforts to educate its various constituents about the scientifically supported benefits of dietary supplements, that our products will become an accepted core component of healthy lifestyle choices.

Just imagine it's June 12, 2008 and you turn on your local tv station and this is what you hear the anchors say:

Mike Greene: ... thank you for that report from Fed Ex stadium, Billy. I'll tell you coach Mike Doyle has turned the Washington Redskins around.

Judy Blatman: And it's amazing...he does it without paying those pumped up salaries for players. Well, there's good news on the health front for American families. Congress stood up for the poor people of this country today by passing a piece of legislation that will enable American families who use food stamps to purchase a multivitamin and other important dietary supplements with their food stamps. Senator Carolyn Sabatini, co-sponsor of the bill, told reporters that this is a bill that just makes good sense. According to the Senator, multivitamins are an essential part of a good nutrition program and everyone should have fair and affordable access to them. Supporters of this bill are now rallying round other healthcare initiatives that would allow tax deductible medical expenses for some dietary supplements. I'll tell you Mike, it's good to see Congress concerned about people's health.

Mike Greene: ... You're right about that Judy. And we'll be back.

Annette Dickinson:

And then it's April 17, 2014. Here's the television news report of the day.

Judy Blatman: ...well first lady Maria Shriver sure knows how to throw a State Dinner. Michael?

Mike Greene: Today, the department of Health and Human Services announced that 90 percent of Americans take one or more dietary supplements. Secretary Andy Davis noted that this may be one of the reasons we've seen such a dramatic reduction in the last 10 years in the population's incidences of certain cancers, upper respiratory infections in the elderly, age-related macular degenerations, and adult-onset of diabetes. The government, cautioned however, that Americans should be careful not to go overboard on efforts to get all of these important nutrients from foods, noting as a country, we're just eating too darn much.

CRN State of the Industry

Annette Dickinson:

Dreams can become realities – and will if we continue to work together towards these goals.

I am honored to have so many of our colleagues from D.C.'s regulatory agencies here. It shows that we've turned a page in our history. CRN considers these agencies to be partners, not foes; collaborators, not enemies. We – industry and government – both share the goals of consumer safety. We should look for ways to better understand the separate jobs we do. I understand there will be times when we stand on different sides of the fence. But we should also recognize that there are ways and times when we can work together to help benefit the public.

Thank you for your time today, and for the time you've allowed me to spend with you for 31 years.