

CRN: The State of the Industry

Steve Mister, President & CEO, Council for Responsible Nutrition
The Conference: CRN's Symposium on Dietary Supplements
October 4, 2008

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

Good morning, I'm Steve Mister. Welcome to *The Conference*. Thank you Marjorie for that terrific address. You so eloquently described the rich heritage that CRN has. What an impressive list of accomplishments over the past 35 years. And you know, that kind of legacy brings with it a tremendous mantle of obligation to build on and refine that mission even as we face the challenges ahead of us.

During the past 35 years, something has happened to this industry. We've matured from being viewed as "fringe" or "alternative" to being mainstream healthcare with over \$23 billion in sales in the U.S. alone—world class companies turning out quality supplements that make a positive difference in the lives of over 150 million Americans. This industry has grown up. No longer an adolescent, resistant to any regulation and responsibility, but a mature industry ready to promote on a world stage the safety and many health benefits of our products. And the Council for Responsible Nutrition has been growing with you.

It's so exciting to be here in New Mexico for Balloon Fiesta. In some ways this event reminds me of CRN. Any one hot air balloon is in itself an amazing combination of art and technology, but when you put a whole bunch of them together, well then you have a Fiesta.

The dietary supplement industry is like that. Our industry is varied and diverse – many ingredients, many sources, many different sized players and methods of getting our products into customers' hands. But our real beauty and strength is when we come together, united with a common mission and a single voice. As we have shown again and again, it is our collectiveness that makes us rise to new heights. CRN is honored and humbled to be a facilitator and agent for that unity.

Being here during the Balloon Fiesta got me thinking about what else we can learn from hot air ballooning—talk about an activity that is dependent upon which way the wind blows. So as I recap our program of work and suggest CRN's strategic direction for the coming year, I thought I'd return to hot air ballooning.

Strong winds can wreck a balloon—so can lightning.

Unexpected climate changes are inevitable, but navigating through them is the trick. CRN helps you stay vigilant and there will be no shortage of dangers for the supplement industry in the coming year.

- Food safety legislation will most certainly be high on the agenda for the new Congress in 2009—with that will be debates about country of origin labeling, border inspections, third party certification, and fees— inspection fees, import fees, and facilities fees. We'll represent your interests in those discussions.
- On top of that we are anticipating a report by the Government Accountability Office (GAO) on dietary supplements early in the New Year. That will heighten Congressional attention on industry.
- At FDA, the widely anticipated guidance on new dietary ingredient notifications and further implementation of GMPs are just two items on the agenda.

CRN will be your eyes and ears in Washington to see what's on the horizon, and your voice when an industry response is called for. Some would say that's what we do best – responding quickly to these threats. In many cases, CRN is the only association to tackle the tough issues.

Which brings me to another truth about balloons: It takes awhile after blasting the burners to see the change in lift that results. The pilot must anticipate a needed change in altitude long before the passengers actually feel it. And that's true of the supplement environment: Will you see what's coming? Can you afford to wait to do something until the next media crisis? Or the next full assault on this industry?

Over the past three years, CRN has become more pro-active—anticipating challenges and opportunities before they arise and positioning our members for advantage.

Our public relations initiative, “Life ...supplemented”, is a great example of that kind of pro-active thinking. It started with a brainstorming session, which led to a thorough research period and a commitment that we would not launch the program until we reached our goal of \$1 million for the first year. And by the spring of 2007 we had pledges for \$1,030,000 from 24 companies and we launched.

You'll hear later today about the details of Year One, but let's look at some of the top-line results:

- Almost 250 stories placed in the consumer media
- Over 170 million consumer impressions

- An award-winning website that has attracted more than 70,000 visitors and over 10,000 consumers have taken the *My Wellness Scorecard*. If you don't know yet whether you are an Alphawell or an OhWell, or somewhere in between, you need to find out.

The second year promises even more. We'll announce this week that we've raised the second million for Year Two—this time from 29 companies.

While many in the industry have talked about changing the public perception of supplements, we are actually doing it. Without a lot of fanfare, but with a well researched, well planned and well executed campaign that's producing results.

But "Life...supplemented" is a three-year undertaking, and it's not too early to start thinking about Year Three of this program. We need the financial support of every company in this room. Consider whether you can afford a donation of any amount—and then consider whether you can afford to sit on the sidelines.

And "Life...supplemented" is not the only proactive initiative at CRN.

We recognized that healthcare professionals hold enormous potential for growing this industry. The more confident doctors, nurses, pharmacists and dietitians are in our products, the more likely they will be to integrate them into their practices and their recommendations to consumers. So we're executing a series of projects to heighten awareness and understanding of supplements among these healthcare professionals.

This year we partnered with *Drug Store News* to produce two separate continuing educational webinars for pharmacists. The first on dietary supplement regulation attracted over 1,000 pharmacists and the second on interpreting supplement research attracted over 750.

Last month, we launched our Commitment Project in partnership with Healthy Mothers, Healthy Babies to encourage use of folic acid by all new brides-to-be of childbearing age.

Then there's our *Open a Dialogue* initiative. Next year we will expect to put over 10,000 brochures into the hands of consumers that encourage them to talk openly and honestly with their healthcare providers about the supplements they use and why.

Did you know that in a balloon, the propane is heated through a coil of tubes that surround the flame? By heating the propane first, it makes it burn more efficiently—demonstrating that sometimes exposing something to a little heat actually makes it better.

In this industry sometimes the heat of the spotlight can be a good thing too. Of course I'm referring to our joint self-regulatory program for advertising with the NAD. To date, the NAD has reviewed over 40 dietary supplement ads under our program and has issued detailed decisions on whether the claims are truthful and well substantiated, the same standard used by the Federal Trade Commission. Several companies have ignored these challenges against their advertising at their peril and have faced FTC enforcement instead. CRN has brought 12 of these challenges. And with every case, the word spreads as to what constitutes appropriate advertising and that there is a new sheriff in town and that sheriff is the industry itself.

This program has not gone unnoticed. Members of Congress have praised this program for marshalling the resources and attention of industry to regulate itself. And just last week, FTC Commissioner Thomas Roush lauded our efforts in a speech calling them an "excellent example of self-regulation" and calling the program a "wonderful campaign that empowers companies who are tired of having the dietary supplement industry referred to as the wild west."

There are other areas in which CRN is shining the heat of a spotlight on ourselves too.

Earlier this year, our Board of Directors adopted sweeping changes to our Code of Ethics. Rather than adding more specific behaviors to the long list of prescribed and prohibited actions, this new Code describes 6 general areas of activity and calls on our members to strive for the highest conduct to develop safe and beneficial quality products, to advertise truthfully with well-grounded support for their claims, and in their business practices with suppliers, customers and even competitors. All our members will be asked to pledge their support for these aspirational practices when they renew their membership in January.

Our voluntary marketing program for DHEA is the latest example of how we help companies do the right thing, because it's the right thing for our consumers, and helps level the industry playing field at the same time. This program calls on CRN members who market DHEA to refrain from targeting their marketing to teenagers – who are unlikely to see benefits from use of the products anyway and to avoid claims that would unrealistically imply the products have an anabolic effect on otherwise healthy teens.

To steer a balloon you don't move left or right, you move up or down into the wind currents; sometimes that means confronting the headwinds.

And CRN is not afraid to tackle issues head on when it's called for. This year we have begun efforts to expand and strengthen the Congressional Dietary Supplement Caucus— on the theory that the best defense is a strong offense. So far, we've conducted two Congressional briefings: the first attracted over 70 people to hear about sports nutrition and get assurance that anabolic steroids

and banned substances have no place in dietary supplements. The second, held in September, focused on consumer usage and cost savings to healthcare from supplement usage.

We'll continue to strengthen the Dietary Supplement Caucus in Congress next year so that our allies are well-armed with the truth about the safety of our products and their contributions to wellness and prevention.

We have also launched Dietary Supplement Information Updates—a series of regular communications to Congressional staff on the latest research, regulatory activities and self-regulation by the industry.

And of course we'll continue to engage FDA head on—whether it's Adverse Event reporting forms, labeling requirements, GMP implementation, adequate evidence for health claims.

But our activities are not limited to Congress. In November, CRN will conduct a media briefing in New York City with journalists from major print, broadcast and on-line media to educate them about the emerging science, our healthcare professionals study, and the use of sports supplements by athletes—engaging some of our harshest critics: the media.

Sometimes, confronting the problems calls for a global response. It may be possible for a balloon to go around the world in 80 days, but in today's global economy, good ideas and bad ones can encircle the world instantaneously.

For instance, in the absence of a scientifically based method for setting upper levels, countries pursue politically derived limits—sometimes setting the upper level as low as one times the Recommended Daily Allowance. Anything more simply cannot be imported.

This year, we have been focusing a lot of attention on ASEAN – an alliance of 10 Southeast Asian nations that are harmonizing their food and supplement laws to make them more attractive trading partners with the rest of the world. ASEAN is something of a tipping point because what comes out of these revisions will influence the rest of Asia, and then Latin America, and perhaps even Europe. Not to mention, as we form blocks of countries that adopt a science based approach, it makes it more likely that CODEX itself will follow suit.

Finally we announced earlier this year a new collaboration with NNFA-Japan. This effort will facilitate the sharing of regulatory and legislative information between officials in the U.S. and Japan and with the goal of making all dietary/food supplements—whether produced in Japan or the rest of the world—more accessible to Japanese consumers.

It's a fact of physics: larger balloons can fly higher than smaller ones.

The work we do at CRN requires critical mass—everyone pulling together for the good of the industry. And I don't mean an acquiescent nod, but active engagement of our members. Let me give you a couple of examples:

The Standardized Information on Dietary Ingredients Program or SIDI. It started as a program to bring efficiencies to the communication between ingredient suppliers and manufacturers. Now it's much more than that. Recognized by FDA as a way to ensure quality throughout the supply chain, it fosters compliance with the new GMPs and helps product manufacturers compare apples to apples when making vendor decisions. But we need everyone to buy in, especially product manufacturers – you are in the position to drive this initiative by requiring the SIDI template from your ingredient suppliers. Some might ask why? I've got my own program in place and it works very nicely, thank you. Well here's why. Unless we move toward a standard template, fringe players and competitors willing to cut corners will be able to get by with less. If we move toward an industry standard, then we level the playing field. We need every company to join in so that those who refuse to employ SIDI become the outsiders.

Similar is the move toward analytical methods to assure the quality of ingredients and finished products, the new GMPs require use of scientifically valid methods of identifying incoming ingredients—what if none exist or are not widely agreed upon? Again, some companies are further along than others and what we are asking of you is that you come to the table and share your methods with the rest of the industry. Why share your assays and give away your proprietary information? Because until we develop widely agreed upon methods, fringe players will be able to pass off substandard products as comparable to yours because there is no common measuring stick by which to hold them accountable.

There are other ways to get involved too: Does your company have representation on all our standing committees and task groups? If not join them and get full value for your membership. It's a law of physics that bigger balloons fly higher—So how high do you want to fly?

Just a thought: Being a great airplane pilot does not prepare you to fly a balloon—the two inventions just work differently. The same problem exists with the way we study dietary supplements when we treat them as if they were drugs.

When researchers insist that nutrients perform like pharmaceuticals, insist that studies intended to show prevention should produce treatment outcomes, or create meta-analyses that creatively exclude relevant studies while including less meaningful ones, you've got an airplane pilot in the balloon.

When FDA demands randomized clinical trials to support a health claims when to do so is impractical, unethical or just impossible—that's an airplane pilot in the balloon.

So CRN will continue to advocate to recognize the differences between evidence-based medicine and evidence-based nutrition. That doesn't mean we eschew rigorous research, but we will keep being critical when studies on supplements miss the mark.

We'll keep calling for proper recognition of the wealth of research that goes beyond the RCT, and we'll continue to incentive-ize promising research in the field as examples of studies done right.

We launched three new programs this year: the Mary Schwartz Rose awards given by the American Society of Nutrition to recognize researchers that are getting it right, Research Watch and the Clinical Trial Database to keep our own members informed about not only recently published research, but even clinicals that are still in progress, that may be wrapping up and preparing for publication, and ones that are published online, but not available through PubMed. It's another way to keep the industry on top of emerging science.

Speaking of science, did you know that there are fewer air particles inside a balloon that outside—they are just moving faster.

This gives me an opportunity to recognize some of the fastest and best movers I know: the CRN staff. These are the people who are really responsible for CRN's successes, who live and breathe this industry everyday. I couldn't be more proud of the work we are doing.

Our latest addition to our staff is Dr. Duffy MacKay—whom I hope you will get to meet at this conference – further strengthening the best science team in the industry of Doctors John Hathcock, Andrew Shao, and our part-time consultant Annette Dickinson.

I also want to acknowledge the leadership we have from CRN's Board of Directors who provide invaluable strategic guidance, steer the direction of this organization and generously give their time and resources to support our work. In particular, I want to say thanks to our current Chair, Marjorie Fine who has brought tremendous energy and passion to her term as Chair and has provided incredible counsel to CRN and to me over the past two years.

Great balloon rides require a lot more than just hot air—and you've heard too much of my mine already.

So I as close, I hope you leave this session with undeniable confirmation that at CRN, we don't just talk about the problems—we deliver solutions.

From our “Life Supplemented” program, to our regular interactions with Congress and the FDA. We see the challenges, and we also see the potential. We are dedicated to establishing and executing programming to achieve it.

This industry is rising, it’s poised to soar. Won’t you join us and be part of that ride?

Thank you.