

CRN: The State of the Industry

Steve Mister, President & CEO, Council for Responsible Nutrition
The Conference: CRN's Annual Symposium for the Dietary Supplement Industry
October 23, 2009
The Terranea Resort – Rancho Palos Verdes, California

Change. Evolve. Erode. Improve. Create. Expand. Contract. Modify. Restore.
Mature. Transform. Change.

Good morning, I'm Steve Mister, President of the Council for Responsible Nutrition. Again I want to welcome everyone to CRN's Annual Conference and to Terranea. I hope you have a chance before the weekend is over to walk down to the beach, or at least walk out to the cliffs and see the waves. The views here are simply spectacular. And just the sound of the waves reminds us of both the lasting and repetitive motion of nature, and at the same time the fact that with each wave, the beach is changed. Because the only constant is change.

Whether we are victims or the masters of change is the theme of this year's conference, "Creating the Next Wave." It's a call to anticipate what's coming next and then to harness that power, just like the surfers do. When you can see the next wave coming, why not command and control it?

This weekend we're also celebrating an anniversary of sorts. As you heard yesterday Fifteen years ago this weekend, President Clinton signed into law the Dietary Supplement Health and Education Act of 1994 (DSHEA). That certainly was not the beginning of this industry, but it was a historic change that altered the direction of the industry and it certainly made possible much of the growth that we have enjoyed over the last fifteen years. It's worth pausing to reflect on how the industry influenced that law, and then in turn how that landmark event sent ripples throughout the industry.

But change can take many forms—positive and negative. And today, there is much talk within the industry of new winds of change. There is of course the potential for new legislation that would alter DSHEA. A new administration in Washington that has brought new leadership to the FDA and the FTC as you heard yesterday. And then we faced an economic downturn that is putting new stresses on our companies, even though the industry as a whole seems to be weathering the recession overall. And of course there's always the ever evolving science that doesn't always provide the answers that we want.

These are just a few of the waves of change to be confronted.

Through all these changes, some things endure, like this industry's commitment to providing quality products that help our customers stay healthy and cultivate their own wellness. The companies that comprise CRN have always maintained that core value.

So CRN's mission today is still essentially the same as it was in 1973 when we were founded. Now, we've tinkered with the words a little bit over time, but the mission is still: *To enhance and sustain a climate for our member companies to responsibly market dietary supplements and nutritional ingredients.*

Likewise, we never forget the guiding principles our membership has set for us. You expect CRN to shape the industry's operating environment through appropriate legislation and regulation; and to do that with the realization that it's the unquestioned commitment to science that's the true source of our influence and credibility.

Over the past five years, we've taken an even stronger role in building and sustaining consumer confidence to create a more favorable climate for the industry's products because, at the end of the day, if consumers aren't buying, then you're not selling. And throughout our work, we always find ways to strengthen the standing of the supplement industry by encouraging responsible behavior among all industry members. It's true what they say—one bad apple can spoil the whole bunch. If we can't get rid of the bad apples entirely, at least we can make it easier for consumers to tell which ones are the bad ones and which ones are not.

So today, I'd like to spend a few minutes examining what may lie ahead and how CRN is preparing for those changing times, particularly with regard to what's going on in Washington. And finally I'd like to offer some thoughts of how every company in this room can help to realize these aspirations. You see, the individuals, the companies, and the industries who really ride the waves of change, are those who anticipate it, prepare for it, and then master it.

As you heard yesterday, fifteen years ago, our biggest threat was an over-reaching FDA. More recently, the problem has been an FDA that's under funded and lacks the political will to do what it needs to do. And as a result today, many of the problems that burden the dietary supplement industry are ones that come from within the industry itself from that lack of oversight. As this industry has grown, not everyone who markets a product today and calls it a dietary supplement shares our commitment to our consumers, or our understanding of how nutrition works, or our dedication to the long-term growth of this industry. Today there are: Companies that intentionally – or inadvertently – put prescription drugs or anabolic steroids into their products and call them dietary supplements; products that just don't do what they claim, or over sell the benefits; companies that practice economically motivated adulteration, passing off shoddy products as something more than they are; and facilities that don't properly evaluate incoming ingredients and ignore the new GMP requirements in hopes that they will fall under the radar screen.

These are the kind of issues that attract attention of FDA, the consumer media, and even Congress. So it shouldn't surprise us when they want to respond, and how are we preparing for the coming storm?

Well, first of all, I want to make clear that I don't believe this is the time for alarmist rhetoric and hyperbole. The sky is not falling. Now we are under a "hurricane watch," but this is not the perfect storm. I am confident that this industry can weather these transitory times together and that we can emerge as a stronger industry, and CRN is poised to do that with plans in place that I'll be outlining in this speech.

But first we need to recognize that things are different than they were in 1994, and so the strategy today has to be different. First of all this industry is not the same one that it was in 1994 when DSHEA was passed.

There are many, many more players, which on the one hand tremendously increases our strength and our clout as an industry, but as I've already indicated the range of players is quite vast too, and there are good actors and bad actors.

Globalization has also created new challenges for this industry in the last 15 years. As we import more and more ingredients and even finished products from all over the world, it's harder to be assured that all the industry's upstream suppliers share that unflinching commitment to quality.

Our consumers are also different. Yes, we're now 150 million or more strong, and that's great, but as mentioned yesterday, I don't think our consumers today are not the same, hard-core, committed users of 30 years ago that rose up in protection of this industry. Our consumers today include: Young women thinking about getting pregnant and using folic acid and prenatal vitamins as they start that road; baby boomers looking to improve their joint health, or maybe lower control their cholesterol and protect themselves against heart disease; and high school and college athletes looking to improve their performance legitimately with product that help them reduce recovery time or lengthen their workouts.

This is the range of consumers we have today and the difference between these consumers and those that launched the massive grassroots campaign in 1994 that protected this industry is that these consumers will turn quickly on an industry if it lets them down. If we don't earn and maintain their confidence, a few negative, widely-reported events could easily drive these consumers from these products and a crisis in confidence could lead these customers to demand more regulation if they don't think existing law is sufficient and they perceive the industry is not capable of regulating itself.

And of course the American landscape is different than it was in 1994. We should not lose sight of the fact that DSHEA was enacted just two weeks before the 1994 election, and I would disagree from Patricia and Peter yesterday and say that I do think there was a link in these events because in 1994 just a couple of weeks after DSHEA was passed there was a Republican landslide in Congress that brought us the beginning of the Contract with America. It was a time when Americans were frightened after living

through the times to revise healthcare and Americans wanted government out of their lives and out of their medicine cabinets. Many of us will remember Mel Gibson.

Today, yes, there is another healthcare debate, but this time it's being overshadowed by the shenanigans of Wall Street and Main Street over the last couple years. Consumers who will shout out at a healthcare reform town hall meeting will also applaud new regulation if it also means their vitamins will be a little safer. So we have to remember that this is not 1994 and that the voters who brought President Obama into the White House wanted change in many aspects of their lives.

I'm spending so much time on this, because I want to stress that we have already carefully analyzed this landscape as we developed our response.

One of the things we did earlier this fall is when CRN convened a summit of our members to examine DSHEA, and we asked the question, "Did DSHEA get it right and are there things we would write differently if we were rewriting the law today?" It was a very productive conversation, but as a result of those discussions, CRN is more convinced than ever that DSHEA is still the appropriate regulatory framework for our products. CRN is committed to defending these fundamental tenets of that statute and we have committed anew to protect those basic pillars of that law.

But we do have an important role to making all of this work, and the first order of business is to expand our efforts to develop, support and encourage responsible, consumer-focused behavior within the industry. We have several projects that you know are already in place.

At the top of that is our program with the National Advertising Division (NAD) of the Better Business Bureaus. Since we initiated this program three years ago, the NAD has now examined over 75 cases, reviewed them, and issued their results. You heard the positive remarks from David Vladeck yesterday. I'm pleased to tell you that the Board of Directors of CRN and the NAD have signed an agreement to extend the program for another five years, until 2014. We will have a more official announcement in the coming weeks because we'll also be able to make some announcements about the scope and the funding of the program long term. But for now it's enough to ensure you that this program will continue. What we need though is more participation in the program. If you believe a competitor is making unsupportable claims for its products, then you owe it to your company and your consumers and the industry to step up and file a challenge.

A second area we need your help on is the SIDI program—the Standardized Information for Dietary Ingredients. It's another example of responsible behavior at work. This initiative has the potential to identify ingredient suppliers whose products aren't measuring up. If all industry members will commit to accept only the SIDI template or at least allow the SIDI template in lieu of individualized questionnaires, then buyers and sellers can really compare apples to apples, and herbs to herbs. Now here is the uncomfortable part—we're having trouble getting widespread adoption of the program. Inertia can be a hard thing to overcome, but only collective efforts my all of

industry are going to make this work. If your company hasn't adopted SIDI, I would ask you to take a second look at the program and see if you can incorporate it into your company.

A third example of companies collectively demonstrating responsible behavior is a new issue for us, which is the joint vendor qualification program to develop a set of standards that the manufacturers can use to qualify their new raw ingredient suppliers, as is required under the new GMPs. The immediate objective is to develop a prescriptive framework that includes key aspects of supplier qualification, and might even be used to help shape a future FDA guidance related to vendor qualification. The more long-term goal is to study and possibly create a "shared audit system" that lets companies pool their resources for independent audits of vendors that can be collectively utilized. It will make vendor qualification more consistent, and more efficient. And if you can envision a world without this program, imagine having to visit every single vendor that you deal with in order to qualify them, or if you're an ingredients supplier imagine the number of tour guides you're going to need to hire to accommodate all of your customers who want to see your plants.

Over the next year, CRN will also be reviewing its voluntary guidelines that we have on a number of issues for possible additions that will further demonstrate the commitment of this industry to the health and safety of our customers because our actions always speak louder than our words.

Over the past decade, CRN has established itself as the most trusted, the most recognized and the most influential voice to Congress and FDA representing dietary supplement manufacturers. Building on that reputation, we are already responding to the new political challenges in Washington, and as a demonstration of our ongoing willingness to come to the table, we have been intricately involved in the food safety legislation. And yesterday, as many of you know, we formally announced our support for the food safety efforts in the Senate. This is the same legislation that Dr. Hamburg testified on. Yes, this legislation does put some additional regulation on foods, including dietary supplements: annual registrations, mandatory recall authority for FDA, and a requirement that firms develop food safety programs for critical junctures in their manufacturing processes. But again, if we're going to be perceived as credible and helping our consumers assure a safe product, this is a necessary step.

We've also been working deliberately behind the scenes on the steroids issue. CRN made a conscious decision when this issue first arose not to be overly visible on this issue because we firmly believe our membership is not the problem, and so why get out front and own an issue that's not ours. At the same time we have been working deliberately and quietly, not only our friends in Congress, but also with Senator Spector's office and with the President of the U.S. Anti-Doping Agency to find common ground, and develop strategies that target the bad guys without putting burdens on legitimate products and legitimate manufacturers. These discussions may lead to industry support for additional authority for the DEA to schedule new designer chemicals, and may lead to more resources at FDA to help combat the problem from

their end. But these changes should not trouble legitimate manufacturers and marketers, and CRN will closely monitor these efforts to assure that whatever measures are developed will not impact legitimate products.

One of our real successes over the last year has been to reinvigorate the Dietary Supplement Caucus in the House of Representatives. We have hosted four lunchtime briefings to standing room only crowds of Congressional staff and sometimes members of Congress. This is important because the vast majority of Congressional staff today were not around when DSHEA was passed, and so without our positive influence they hear what our critics say which is that DSHEA deregulated the industry. These gatherings spread the positive message about supplements and their contributions to wellness, and we think that's an important first step. Our methods here are three-fold: first we need to introduce them to the industry, secondly, then educate them about the health benefits of supplements and the economic cost savings we have to the country through the use of our products. It's only then that we can persuade them of the correctness of our positions.

The goals of the coming year for the Dietary Supplement Caucus is to increase its visibility, its size and its influence on Capitol Hill. We'll be doing more briefings on a variety health-related topics, communicating to the Dietary Supplement Caucus members about issues that are relevant to the industry, and certainly encouraging more members of Congress to join. And we'll be talking to many of you about your local members of Congress so that you can urge them to join this group because they listen, as you know, more to their constituents than they do to the Washington lobbyists.

At the same time, we must use our credibility as "the science behind the supplements" to change the science landscape.

Our *Day of Science* earlier this week illustrates the work we are doing to help shape the research agenda is very important and we will continue to promote this alternative paradigm for dietary supplement and nutrition research—"evidence-based nutrition" as contrasted with "evidence based medicine"—that accounts for unique challenges of this area of research. But it's not enough as I said on Wednesday to criticize research models that we don't like; we have to engage academia and government institutions that fund this research to provide alternatives that do allow for rigorous examination of the benefits of dietary supplements.

We've also established a Medical Practitioners Subcommittee of the Senior Scientific Advisory Council that will develop specific projects to engage healthcare professionals to use dietary supplements and nutrition-based therapies in their practices. By creating partnerships with the healthcare community, we can counter some of the negative publicity that comes out and the misanalysis of the study du jour that you read in the consumer press. Another way to accomplish this is through a Research Exchange program, which will link researchers with companies that share their interest in a particular area of research.

I would also be remiss in talking about our Washington communications strategy if I didn't talk about our communications efforts in this area because critical to that has been "Life...supplemented." I'm delighted to tell you that we're not in the third year of "Life...supplemented" and that we have raised \$3 million for this effort, and it has not gone unnoticed. Through the "Life...supplemented" campaign we have been able to reach consumers with over 2,400 media articles and stories that have led to more than 957 million consumer impressions to date. But most importantly, are the messages that these impressions convey. They carry our key messages that supplements are an integral part of a healthy lifestyle, and that medical professionals whom consumers trust are using our products in great numbers.

Earlier this year, we launched the CRN Foundation to expand our ability to conduct consumer and practitioner education. As a 501c3 organization, it will be the new home for "Life...supplemented", as well as the NAD advertising program and our continuing education series for pharmacists and nurse practitioners.

We are also expanding our outreach to other organizations with health-related goals by developing communications that raise the importance of taking supplements and we do this through partnering with these groups through various campaigns. Recent examples include our work with the Healthy Mothers/Healthy Babies Foundation and the Better Sleep Council.

And lastly, we have stepped up our efforts in a vigorous rebuttal of the consumer media reports that dietary supplements are in an 'unregulated' or 'under-regulated' industry.

So what am I asking of our companies to do to accommodate this change?

Well I happen to have been having a change in my own life too because my oldest son, Matthew, is going to become a teenager on Monday. Can we talk change?

I've been contemplating recently about what advice I need to give him as he reaches the coming teen years, and what I realized is that the advice I would give him is not too different from the recommendations I would offer to CRN members.

First, take responsibility for what you do. And do good simply because it's the right thing to do. We can develop these programs, we can bring them to your table, but only you can take them into your companies and use them and integrate them into your systems.

We had a strategic planning consultant we worked with earlier this year who told our Board, "Culture eats strategy for lunch." Think about that. All the planning and strategy in the world goes to waste if the culture of the organization doesn't support that strategy. So we need you to take these programs back to your companies because when you do that, you're helping the larger picture of demonstrating a responsible industry at work.

Second, I'd advise my son to pick his friends carefully. Associate yourself with people who do what's right. You've already done that by coming to this conference, by being a CRN member, and yes, we love your dues, but we also want you to participate. We want you to take advantage our committee structure and get active in shaping the policies that run this organization. And, of course, we also need your help to bring in new members. Recruiting has never been more important for CRN. I'm very happy to say that in the four and a half years that I've been here we have brought new members in at every quarterly Board meeting that we've had. But we are still not the majority of industry by numbers of companies. There's a long way to go there with both big players and small players, and we really need your help because the industry will listen to their colleagues a lot more than they will listen to a sales pitch from me or one of the CRN staff.

And finally, I'd tell my son to live a life that you're not afraid will show up on a blog, or a gmail message, or a Facebook page. And that's true for us. We must always focus on our consumers. What would they do if they found out that you were receiving ingredients that didn't measure up because you could save a little money and it was too expensive to send them back? What would your consumers do if they knew you were pushing the envelope with your claims for things that you knew you couldn't support? We have to live every day as if what we do is going to end up on Facebook tomorrow.

As the industry matures, just like my son, I think we will earn the respect—of government, and the agencies, and Congress.

CRN is ready for the challenges that tomorrow holds and the changes that are on the horizon. We're poised to help our members be their best because when we join together to form a single voice, we are all stronger. When companies do that, the industry rises.

Long after we leave Terranea, the waves will still be crashing on the beach and change will keep coming to the shoreline, not only along this stretch of coastline, but the change will be coming to our world too. We are poised to help you address these waves of change, to capitalize on them and to emerge a stronger industry as a result. But we need your help, and we thank you for your confidence in CRN.