



**Steve Mister, President & CEO, CRN
State of the Industry Address
September 19, 2013
“A Tale of Two Industries”**

“It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness...it was the season of Light, it was the season of Darkness, it was the spring of hope, it was the winter of despair...”

For those of you who may have read Charles Dickens’ *A Tale of Two Cities*, these words might sound familiar. But for the rest of us, I might just as easily have been assessing the current state of the dietary supplement industry.

In many ways, we are living through a tale of two industries—the best of times *and* the worst of times. Depending on which camp you fall into, the dietary supplement industry is either a bunch of snake oil salesmen with shoddily-made potions praying on the misplaced aspirations of an unsuspecting public—or the quality-focused providers of well-made health products with well-documented evidence that these supplements promote good health and wellness, and in some cases, lower the incidence of chronic and costly disease.

It’s important to take a few minutes and consider that both camps have reasons for their viewpoint.

The best of times? We find ourselves here in Utah with CRN celebrating 40 years of successes.

- The Nutrition Business Journal touts annual growth of the dietary supplement industry for 2012 at seven-and-a-half percent (7½%). Over the past ten years, the industry has
- gone from 20 billion to 32-and-a-half billion dollars. During that period, the growth of dietary supplements has been the envy of other sectors of the economy.
- Our own consumer survey, which you will hear more about tomorrow, continues to demonstrate that consumer attitudes toward our products are positive and relatively stable. Despite the bad press, eighty-five percent (85%) of Americans—including those who don't take supplements—say they are somewhat or very confident in dietary supplements.
- The dietary supplement industry continues to attract outside investment: Equity capital is flowing into the industry. Large consumer products companies and even pharmaceutical giants are taking notice and some are even doubling down on their investments.
- For most CRN members, the transition to dietary supplement GMPs, although certainly not inexpensive or without adjustment, has been a relatively smooth one. And by working to understand and comply with these requirements, these firms now have external validation that they are producing well-made, thoroughly tested products that deliver in the bottle what is on the label, consistently made to high quality standards.
- CRN's program with the National Advertising Division, now seven years old, has reviewed over 150 cases and has been responsible for ending many misleading, in some cases, downright false, claims. It continues to be applauded by Members of Congress, the

media, and even some of our critics, as well-conceived and well-executed and helping to rid the marketplace of untruthful advertising.

- *Life...supplemented*, our consumer wellness education campaign, originally intended to be a three-year program, ran for five years, raised almost five million dollars and changed the conversation about dietary supplements. By positioning supplement use as one of the three pillars of health, along with good diet and regular exercise, the program assured consumer media covering the industry that dietary supplement users were not just seeking a magic bullet in lieu of other healthy behaviors. *Life...supplemented's* healthcare professionals survey was well received and well covered by the press, documenting that healthcare practitioners are both using supplements and recommending them to their patients.
- Turning to Washington, we seem to be keeping our Congressional critics at bay. Since the passage of DSHEA nineteen years ago, it has only been amended twice, both times with the industry's blessing and support. The adverse event reporting law in 2006 happened only because of strong lobbying by CRN and others in the industry; and the Food Safety Modernization Act in 2011 included several provisions that impact dietary supplements only because we agreed to be part of that sweeping effort to ensure the quality of the food supply. Conversely, Senator Durbin's Dietary Supplement Labeling Act has not attracted much support among his colleagues and was soundly voted down when he tried to insert it into the drug user fee legislation last year—although we have to remain constantly vigilant against such threats.

So for many reasons, it's a great time to celebrate CRN's 40 years of representing the industry.

But it's also the worst of times:

- In the past five years, FDA has issued warning letters, recalls and seizures for over 400 products that were marketed as dietary supplements, but according to FDA, contain undisclosed prescription medicines, anabolic steroids, and in some cases, illegal drugs.
- Now we know these are not products marketed by CRN members, but the reality is that many consumers don't know the difference. And when the consumer media report on these incidents, they don't distinguish between the fringe and the mainstream industries. In fact, some of these illegal products may end up sitting next to ours on a store shelf or a click or two away on a retail internet site. To the rest of the world, they are the face of dietary supplements.
- According to FDA, the compliance rate for much of the industry for GMPs is abysmal. FDA says that over a third of its inspections have led to a call for Voluntary Actions on the part of the manufacturer, and another 34% have led to notices of Official Action Indicated. So according to FDA, less than one in three inspections gets its stamp of approval. And further, the agency has issued over 25 warning letters since January related to GMP problems that weren't adequately addressed—even months after the first inspection.
- Now again, we can question those numbers. Many of the companies issued those warning letters are not ones that the mainstream industry has even heard of. And we did predict when the GMP rules were issued that it would inevitably lead to a winnowing of the industry. But one can't help but wonder if the inspection rates are truly a representative cross-section of the industry, or if FDA is targeting—as it should—those companies that it suspects are most likely to have their heads in the sand. But if that's the case, then the

story in the press is not truly reflective of the industry. But in either case, the perception is what matters.

- On another front, we continue to see negative press reporting that dietary supplements don't work, or even worse, that they may hurt you, generated from research studies that, at best, have limitations and weaknesses that don't get discussed—or at worst, the researchers have their own agenda for generating sensational headlines to advance their own careers.
- Take, for example, the recent prostate cancer study on omega-3s. The study didn't even ask where the omega-3 came from: whole fish or supplements? By design it could not demonstrate a causal relationship anyway. It failed to consider that many of the subjects may have increased their omega-3 intake *because* they were at risk of prostate cancer, rather than the other way around. And it ignored the fact that populations around the world with the greatest omega-3 intakes have the lowest prostate cancer risks. But that didn't stop the researchers, or the headlines that followed. And so we have spent a lot of time playing defense and reassuring wary consumers.
- Indeed, if you listen to our critics, they paint a picture of a rogue industry promoting dangerous mega-dosages of supplements, consumers popping untested treatments, and a wild west, unregulated environment where you can pretty much do and say what you want.

That's not the industry I know. But each one of these problems puts our consumers at risk – either by exposing people to unsafe drugs and poorly manufactured supplements or by deterring them from using proven beneficial supplements because of overblown fears and the sins of outlier companies.

The best of times...the worst of times.

When I had my own 40th birthday, I remember it was a time for some introspection. Momentous events like this are a good opportunity to take stock and make some changes. So I want to offer some thoughts on what I believe CRN and the industry need to do as we move into the next 40 years.

Unlike Dickens' novel, however, the situation we find ourselves in is not a division between the "haves" and the "have nots." Some of the smallest companies in the industry, some of whom are CRN members, are doing remarkable things in quality and research of their products. Conversely, some large firms that boast enviable short-term growth, are failing to make the GMP investment and are buying and selling ingredients on nothing more than price, without asking the critical questions about identity, purity and sourcing. The division lies in whether a company is choosing to invest in its products and its customers for the long-term health of the industry.

So we, the responsible, mainstream industry, must demonstrate more clearly the differences between "us" and "them." There are some who sit in the middle, and hopefully they will move our way, and responsible companies have a role in helping those firms move in our direction. But it's time for companies in the industry to decide where they stand...who they stand with...and then take a stand.

So, we need to recommit ourselves to research. Rigorous, thoughtful, well-executed research must be the core of every new product we introduce, every claim that we make, and every safety question we answer. Supposition and testimonials are no substitute for research, and as the FTC likes to remind us, "the plural of anecdote is not data."

I know many of your companies are already expanding your research budgets. That's great. But if not, I'd invite you to ask yourself:

What portion of your profits is going into research to justify your existing claims and to explore new claims?

How much of your substantiation file uses research on your own product, not just the ingredients that may go into it?

How do you know your proprietary combination of ingredients in the particular amounts that are unique to your brand actually works? Could there be synergistic or antagonistic actions at play? Is it really being absorbed and getting to the tissue and cells where it's needed?

To answer these questions means research, research, research. That's what will set us apart.

In the past few years, CRN has, with your help, increased our research investment too. We've made some great strides:

- The Health Care Cost Savings Study that will be unveiled tomorrow by the CRN Foundation is the most comprehensive examination to date of how dietary supplement usage can help reduce medical costs. I'm very proud of the foresight and the funding from our members to produce this work.
- Over the past year, CRN has been producing for the peer-reviewed literature a series of research studies examining dietary intake. These studies illuminate how the eating habits of most Americans are failing to achieve the levels of nutrient sufficiency we recognize to be adequate.
- Our benchmarking of consumer usage and attitudes is making its way into a peer-reviewed journal, defying with data the misconception that dietary supplement users are less apt to engage in other healthy behaviors.

- You've already heard from John Blair about our original research examining the state of the evidence for calcium safety.
- And we have just begun to release a new edition of CRN's well-received *Vitamin and Mineral Safety*.

But that's not enough. We've got to do a lot more that can only be accomplished with more funding and a greater commitment of the industry. And the CRN Foundation can be an ideal partner for companies who want to come together to fund research.

Second, responsible companies must help consumers Differentiate the Good from the Bad. If we can't eliminate the tainted products and the shoddy manufacturers, we can at least make it easier to tell who they are. Maybe that means increasing the investments in third party certification programs like USP or NSF or other programs. Maybe it means helping our retail partners appreciate what's behind these programs and why they matter. Maybe it's more consumer education about third-party seals so our customers will understand how to navigate the supplement aisle. CRN's Board of Directors convened a Third-Party Certification Task Force this year to explore the various certification programs in the market. The task force did not select any one program over another, but everyone involved agreed we need to devote more attention to these programs. And we'll hear more about two of them tomorrow.

Another way we can distinguish ourselves is through an expansion of CRN's Recommendations for Industry, our Voluntary Programs and our Best Practices Guidelines. Our caffeine labeling guidelines created this past year is just one example. And I want to applaud CRN's companies who spent several months developing our guidelines. We asked a lot—putting the interests of consumers ahead of the temptation to resist label changes. Some wanted

more than we agreed to; some wanted less; and somehow we arrived at a program that will give consumers the relevant information they need to select the products that are right for them.

Over the next year, CRN will be reviewing and reissuing all of our current voluntary programs. We are also working on new voluntary programs. CRN has a task force underway to examine one of the hottest growing areas—“whole food supplements” with the goal of developing a common definition for what that term means—so consumers will know what they are getting under that banner.

This weekend, our Board will be considering the product of several months of work by the Enzymes Task Group—a white paper on best practices for the handling and labeling of enzymes.

Each of these programs can set responsible firms and quality products apart so consumers can make educated choices about products that will affect their health.

Third, and perhaps most controversial, I believe CRN and its members need to work more closely with our regulators and **Begin a Dialogue** on addressing these problems. Many of you have heard me say “FDA is the one with guns and badges; they just need to enforce the law.” But we can help them. If you know a competitor is spiking a product, tell FDA. If you discover incoming materials that are adulterated to fool your tests, tell FDA. If your contract manufacturer has never heard of a batch record, find a new manufacturer, and then tell FDA. If we expect FDA to clean up the problems, we can at least give the agency a road map.

But even beyond that, a mature, robust industry understands that a dialogue with regulators about how to address problems leads to a stronger marketplace. Now let me be clear, I am not calling for an overhaul of DSHEA. The law provides ample authority to FDA, some of which the Agency has only just begun to explore. But within the regulatory framework that

DSHEA envisions, we may be able to help FDA better identify the players, the products, and the problems. It is certainly worth having the conversation.

Finally, we have to grow the ranks of the good guys. That means urging others to join us. It's not CRN against the rest of the industry—there are many companies that are not yet CRN members who share our priorities and commitment. So nothing we do should suggest that only CRN members have a monopoly on quality and consumer-centric decision making. We need those companies that are not yet members to want to join us. We need to give them more reasons to be part of our community, to demonstrate the value of membership.

So CRN changed its dues and membership structure this year and those changes go into effect on January 1st. For ingredient suppliers, contract manufacturers without brands of their own, and ingredient representatives, their dues rates will go down and CRN will hopefully be more financially attractive.

For our largest members, we are asking for more. The cap on our dues will increase over the next three years, with our largest members paying \$200,000 a year. We will ask that members who market functional foods—those products that are marketed under a Nutrition Facts label, but contain dietary ingredients and make structure function claims for their products—that they include those sales in their dues calculation.

I know these are big requests. They require shifting resources and going to investors or top brass to ask for more funds. But these changes are necessary to fuel the kind of robust representation and advancement of the industry that CRN has demonstrated its ability to do—and that you have come to expect from your association.

Recruiting is everyone's job, so I'm calling on each of our members to identify and target at least two companies you do business with and help bring them into CRN. We could triple our membership and our capacity!

We are at a momentous time, and not just because CRN happens to have an anniversary to celebrate. I believe that the decisions we make over the next three years will determine the long-term direction of this industry.

Will we rise to these challenges? Or will we hope that someone else will do the research? Will we hope that FDA will identify the bad actors on its own? Will we hope that consumers will know how to buy the right products without becoming distrustful of all our products when other fail them?

Years from now, we will look back at this moment and either applaud the vision and determination of the players of this time, or we will shake our heads and lament the wasted opportunities. I believe the consequences are that grave.

And so returning to my friend Charles Dickens, where we started this speech, I have to ask will this be the best of times or the worst of times? Will this be a time of Bleak House or Great Expectations?

I know which path we are capable of taking. Let's make the next 40 years of this industry as robust as the past 40. And when people look back at this moment, let's give them a Dickens of a time trying to see how we could have pursued any other path than the one we chose.

Thanks for listening.