

## **CRN: Promoting Responsibility With A Revolutionary Passion**

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Good morning and welcome to CRN's Annual Conference.

### **[Welcome to The Conference]**

As Chuck has illustrated, it has been a very busy year for CRN. Our strategic capacity process has helped us focus on what we do best; articulate why our members belong to this organization; and prioritize what we need to do to deliver on that value proposition.

The challenge before us in the coming year is to build on that momentum to continue to deliver on the goals we have set. I'm going to focus my remarks today on CRN's major strategic initiatives.

### **[Self-regulation = Responsibility.]**

The first is *Responsible Self-regulation*. The staff at CRN takes very seriously the mandate that our members have given us to encourage manufacturers and marketers of dietary supplements to act responsibly, always putting their customers first. I had an opportunity to write a guest column this year on the adverse event bill and I pondered in print the question, *What makes an industry responsible?*

### **[What makes an industry responsible?]**

My grandfather used to say that integrity is what you do when no one is watching. Well, you could characterize responsibility as "how you act when no one forces you to behave that way." What are we doing to assure and improve the quality of our products and the confidence of our customers?

As another year wanes, it appears less likely that FDA and OMB will meet their self-imposed deadline of December for publication of the final rules for good manufacturing practices. Now I want to assure you that it's not for CRN's lack of trying.

### **[A responsible industry tirelessly calls for a level playing field.]**

CRN has continued its campaign to call for GMPs:

- We've asked the Administration to make this happen.
- We've communicated with FDA at all levels of the agency, including Mike Leavitt, the Secretary of HHS, and with OMB, in meetings, in letters, and in speeches.
- We've called on Congress to pressure the agencies and were instrumental in getting ten members of Congress to send a letter to Secretary Leavitt demanding GMPs this year.
- In a public event celebrating the 100<sup>th</sup> anniversary of the Pure Food & Drug Act, with our acting FDA commissioner in the audience, CRN used its podium time to outline the case for GMPs, reminding Dr. von Eschenbach that while some companies already abide by these standards, final rules will level the playing field and demand all manufacturers play by these rules.

### **[A responsible industry lives by GMPs, even if they aren't required.]**

I have also had the opportunity to tour many of our members' facilities this year—both large and small companies—and I never stop being amazed at the commitment to quality that I see in testing of raw ingredients, the manufacturing lines, the packaging operations, the quality control laboratories, and the R&D facilities. As I said, *responsibility* is how you act when no one forces you to behave that way. What I see is responsibility—and I want to commend all the companies who share that commitment and encourage the rest of the industry to step up and self-impose these high standards on themselves. *It's what a responsible industry does.*

### **[It's what a responsible industry does.]**

Another way we exhibit responsibility is through concern for our customers. What if, despite all the steps we take to assure the safest, purest, highest quality products, something goes wrong? Don't we want to know about a product that potentially could harm our customers? And shouldn't we tell the agency that's charged with regulating us? Isn't that what a responsible industry would do?

**[A responsible industry takes care of its customers.]**

And so we'll continue our fight in the coming days and weeks, or for as long as it takes, to pass mandatory reporting of serious adverse events for this industry. We've made a lot of progress this year. We've negotiated the bill itself, built consensus across the industry, reached out to garner support from consumer representatives; and conducted countless meetings on Capitol Hill to shore up support. We believe this legislation can be enacted in this Congress and we will continue that push.

Once enacted, the adverse event reporting law will demonstrate to our critics that we are a regulated industry; it will give our consumers faith that FDA will know whatever we know about the safety of products in the marketplace; and CRN believes, several years from now, it will provide a track record demonstrating the wide margins of safety consumers receive when they purchase a dietary supplement. *It's what a responsible industry does.*

We must be responsible marketers too.

**[Responsible companies exercise restraint in advertising.]**

Being responsible means conducting our own marketing in ways that consumers can rely on. We can be creative in touting the benefits, but we won't mislead or deceive our consumers. It also means having the courage and conviction to call out our competitors when we see egregious advertising that exceeds the bounds of what is truthful and can be substantiated with science.

**[Responsible companies look out for the good of the industry.]**

Tomorrow CRN will announce a new initiative with the National Advertising Division that will increase scrutiny of dietary supplement advertising. But for this new initiative to work, it will call on manufacturers to shine the light of scrutiny on those who push the envelope too far. Industry will be called on to police itself knowing that competitors are watching. And companies will need to step forward with the appreciation that when consumers are misled, hoodwinked, bamboozled or deceived about any supplement, it affects their faith in the reasonable, well-documented and legitimate claims of all supplements. *What would a responsible industry do?*

**[Responsible companies invest in improving the climate so they can thrive.]**

Our work continues in other ways too. CRN will continue to work with AOAC and others to establish widely accepted analytical methods for the evaluation of dietary ingredients—so we can all agree on what a finished product should look like, and how to measure if it has the right ingredients, in the right quantities to deliver the benefits intended.

We'll continue our joint effort to establish a standardized format for the communications between suppliers and manufacturers that will streamline data flow about ingredients and expand the information finished goods makers have about the quality and pedigree of the ingredients they use.

And we'll continue to work for more resources at FDA and FTC to address dietary supplement issues. It may seem paradoxical to give your regulator more ammunition to regulate you, but responsible companies know that reasonable regulation provides assurance that products are safe and well-made. *That's what a responsible industry does.*

**[Communicating with healthcare professionals is responsible.]**

Moving on to CRN's second initiative for the coming year—to develop and implement targeted communications to healthcare professionals that demonstrate the safety and benefits of our products. While it may seem intuitive that supplement manufacturers can and should be in dialogue with healthcare practitioners, selecting the targets for our communication is actually the result of asking a more fundamental question . . .

**[What business are we in?]**

As dietary supplement manufacturers, exactly *what business are we in?* Knowing who we are is fundamental to establish who we should be talking to.

So, I'll ask, Is this a *commodities* industry?

### **[Commodities?]**

Although it may seem like this is a commodities market from time to time, as margins are squeezed and competition is fierce, the answer is no. Savvy product manufacturers and innovative ingredient suppliers are demonstrating everyday the value of unique and proprietary combinations of ingredients, inventive processes to deliver the ingredients, and novel ways to attract consumer attention. And the variety of price points, channels of distribution, and the strength of brands all prove that this is no commodity business.

### **[Blind Faith?]**

Is this a business built on “blind faith?” . . . Take this pill and hope for the best. No, we’ll leave that to the pixie dust salesmen. We are about demonstrable results. New science is re-enforcing everyday the undeniable link between good nutrition and supplementation and good health. In just the last year alone, newly published research has demonstrated the ability of glucosamine and chondroitin to reduce pain in those with osteoarthritis; the heart healthy benefits of omega 3 fatty acids plus a whole lot more, new protections offered by an old standby vitamin D, benefits of green tea, and the list goes on.

We’ve got a lot more work to do in this area, but make no mistake, if this industry is going to continue to grow, it will be because companies are committed to the science and mainstream consumers are assured of demonstrated health benefits that surround these products—not unattainable promises. Our newly-formed Senior Scientific Advisory Council will help us refine our commitment to scientific research. If we were based only on blind faith, there wouldn’t be much room for CRN’s mantra, “the science behind the supplements.”

### **[Just another food business?]**

Is this a just another *traditional food* business? You know, discretionary or impulsive purchases or indulgences, the way consumers buy high end chocolates or reward themselves with a decadent slice of cake? If one doughnut is good, how much better would two be? Although some of our critics might mischaracterize our products that way, again, the answer is no. We’re a consumer good, yes, but this industry is not about impulses and “wants,” it’s about offering consumers a chance to make smart choices about their health everyday. Regulated like foods? Yes, but marketed like food, of course not.

### **[Pharmaceuticals?]**

So, is this a pharmaceutical business? No, no, no. Let me say that again. No, this is not a pharmaceutical business. And to our industry colleagues who voice anxiety that accepting any form of regulation will transform us into drugs, let me assure you that won’t happen under our watch. The legal environment that we operate in does not reward innovation with exclusivity and patent protection in the ways it awards monopolies to drugs; the regulatory limitations do not permit us to label products with curative and treatment claims; our margins do not produce the profits to invest in R&D the way pharmaceuticals do; and the ways our products work do not typically provide instant relief and gratification as many pharmaceuticals do. We are not drugs; we don’t want to be treated like drugs; and this industry will not succeed if we create the expectation that we are just like drugs.

### **[“Alternative” Healthcare?]**

Are we an “*alternative*” industry? One that appeals only to those on the fringe; desperate patients unrealistically seeking miracles in a bottle. Are our consumers so outside mainstream medicine in this country that we do better to position ourselves as an alternative to western medicine? As anti-doctor? or as a substitute for pharmaceuticals? Of course, the answer is once again a resounding NO. Over 150 million Americans use dietary supplements. That’s hardly an alternative or fringe movement. People who use dietary supplements are also more apt to visit their doctors, and to integrate their supplement regimens into other healthcare practices. We are not “alternative.”

### **[Dietary supplements are mainstream healthcare.]**

All of this leads to the inescapable conclusion that dietary supplements are a mainstream healthcare business. For almost two-thirds of American adults, we are part of a culture of wellness. And so the choice to focus some of our public messages on mainstream healthcare practitioners is inescapable as well.

**[Let's talk to healthcare practitioners.]**

Now, coming to terms with the fact that we are a mainstream healthcare industry has some implications. For one thing, it opens up opportunities to be recognized by government agencies as contributing to better health. It presents the opportunity to have supplements included in flexible spending accounts and healthcare savings accounts. It opens the door to inclusion in the Older Americans Act so seniors can get a multivitamin along with a hot meal at a senior center. It challenges the past practices of allowing food stamp recipients to buy junk food with their subsidies but not a supplement that provides crucial nutrition or has an approved health claim to help prevent disease. It opens doors to talk to insurance carriers and HMOs about promoting supplements to reduce healthcare costs and keep people well.

**[Open a dialogue.]**

So we must start talking to health care practitioners about the culture of wellness to which supplements contribute. In the coming year, we will *open a dialogue*. Pharmacists, dietitians, nurses and nurse practitioners, and yes, doctors. Now don't expect success overnight, but CRN will initiate the conversation. We will talk about the science behind our products; communicate the safety of our products; provide education on regulations and the quality assurance that goes into our manufacturing. And we'll counter the misinformation in the healthcare community as well with an eye toward informing them what their patients already know . . . dietary supplements are mainstream healthcare.

Then we need to urge these practitioners to open a dialogue with their own patients. Ask patients what they take; learn from their patients why they do, and discover for themselves how supplements contribute to better health. Now, there are no supplements that can cure a closed mind, but starting a dialogue with our partners in healthcare will help position us for even more widespread acceptance.

**[A strategic rapid response is responsible.]**

CRN's third initiative is our strategic rapid response. It's our proven ability to speak credibly to the media in the face of negative science or misinterpretation of science. A recent evaluation of CRN's media presence counted almost 700 media stories quoting or referring to CRN in the past 24 months. Whether its promoting the positive side of the GAIT trials or combating misinterpretation of the Women's Health Initiative, CRN has a strong track record of evaluating the science with credibility and serving as the spokesperson for industry. We will continue to do this as the media coverage unfolds because there needs to be a credible authoritative science-based voice and CRN is that voice.

**[How do you study prevention?]**

But to be strategic about this approach, we have to do more than respond. Clinical research that studies supplements as if they were drugs can be like forcing a square peg into a round hole. After all, FDA doesn't let us market our products as cures or treatments—so why only give credence to studies that test them that way? Clinical trials that are of short duration, involve only a limited population of subjects and neatly control for all other variables except the molecule being administered may not be the most appropriate way to study whether nutrients reduce the risk of disease.

We need to start reframing the way researchers, academics, and government agencies think about prevention—how they define it; the way they study it; and how they measure it. Is there a better way to study cancer prevention, heart attack reductions and long-term joint health than a placebo controlled clinical trial that isolates a single compound? Can a study in a disease population tell us something about how those nutrients work in healthy individuals? And vice versa? Our strategic approach must include a paradigm shift that values the use of observational studies, cohort studies, intervention studies and survey research as well as the traditional clinical trial. Let's study prevention by recognizing all the factors that contribute to health.

**[Let's talk with consumers.]**

And finally there's been a late change to the program for the coming year. Just as we were wrapping up our three strategic capacity endeavors, the consumer press took a series of jabs at dietary supplements starting this past spring. Even the mainstay of the industry, the multi-vitamin has come under attack. It became apparent that a fourth strategic initiative was called for—a public relations outreach that restores pride in the industry, balances negative media and increases our ability to retain and attract customers.

We cannot combat the drumbeat of negative publicity if we are merely responsive and allow our critics to set the agenda. We need to tell our own story. Based on all we've learned about this industry, we need messages that position our products as mainstream, rather than alternatives.

**[Let's tell our own story.]**

After briefings with CRN's Board of Directors and a brainstorming session with several potential funders, CRN is moving forward with the planning of a public relations initiative that will be announced in more detail very soon. The program will embrace a platform approach that provides opportunities for news media publicity, paid media and consumer outreach. So stay tuned. Some have asked "why CRN?" So I want to use this opportunity to clarify this will be an industry-wide campaign, embracing the range of vitamins, minerals, botanicals and herbals, sports nutrition and specialty products. On the theory that a rising tide floats all boats, we will address the category for the common good.

**[CRN will lead for the common good.]**

This is not a program about branding CRN, or promoting this association. However, it will be a program managed by CRN. Our Board has examined the landscape of the industry and made several observations: CRN is uniquely positioned with the media—we are a trusted and reliable voice of industry with a portfolio of being quoted. We are well-positioned with an experienced communications and media relations staff that is deep enough to manage an account of this size on a day-to-day basis. Because of our science focus, we have the credibility with the media without being dismissed as simply a pro-industry mouthpiece. Because it is an industry campaign, we will be seeking funders from CRN's members and from non-members. We are extending an open hand to all companies in the industry—whether they belong to CRN or not—to join the steering committee and to pledge funding to this project. This industry is at a critical juncture—we must focus on our consumer and embrace this opportunity to change the discourse.

**[Responsible companies can inspire revolutions.]**

And so we find ourselves today in Boston, a city known for fanning the flames of a revolution once before. The power of revolutionary thinking leads to revolutionary change. Whenever change is deliberate and radical, it's revolutionary. We hope the next few days will inspire you to embrace the future with our vision for this industry, a future that offers new potential for dietary supplements. With all this on the horizon, our industry is headed for a future that may be nothing less than revolutionary.

Thank you.