CRN Chairman's Remarks

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Good morning.

I'm thrilled to be up here, welcoming all of you to the 2019 CRN Annual Conference Destination: Vitality. It is a great honor to lead CRN at such a moment in history – for our industry and for our organization. It is fair to say that our industry is having a **pivotal** moment.

More Americans use our products in search of better health and – yes, there's that word again, vitality – than ever before. We are a central pillar of the self-care movement. And emerging science promises even bigger breakthroughs around the corner.

I used the word "pivotal" deliberately. In engineering, a pivot is a central shaft on which a mechanism turns. Without it, the mechanism is a piece of junk, unable to perform the work it was designed to do. In business, we often speak of a pivot as a key change from one phase to another, often from a startup to a mature operation. Even the pivot tables on my Excel spreadsheets help me manipulate data to see it more clearly and draw conclusions.

And since we partied like it was 1994 last night**,** I can't help but remember the Friends scene where they are trying to hoist a couch around a bend in some stairs, and Ross keeps yelling at them to PIVOT! (If you remember the scene – you know exactly what I mean. If you are too young, or maybe missed that one, it's readily available on YouTube.)

This pivotal moment – this inflection point that we are living in – is our chance to change the future. Certainly every moment, in some sense, provides the opportunity for change; we always have a chance to shape our futures – personally, professionally, and even as an industry. But only certain moments are pivotal. These are the moments when the stakes are high, when circumstances and actors collide, when opportunities converge, and significant change is possible. It's times like these when the right move – or the wrong one – can have magnified effects for good or ill that will resonate for many years.

I believe we are called to get this moment right, to be bold and act decisively. And that if we do not outline the shape of this industry for the future now, in this moment – then it will be shaped for us.

My CRN chairmanship so far has been about several of these pivotal initiatives. Some are well underway – and some are just getting started. I'd like to briefly take you through a few of them, and ask for your help to deliver the change we still need to see.

I inherited Board leadership in January from Jim Hyde. Jim is a strong industry leader and he is a good friend—and he certainly left big ski boots, …er…, shoes to fill. And is it just me, or did everything really start moving into overdrive right about the time my term began? Jim's tenure seems really calm compared to what we've been dealing with so far this year and I can assure you that I've let him know it.

In February, Dr. Gottlieb announced a series of new efforts to "strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight." That statement was notable for a number of reasons.

First, he acknowledged being a user of dietary supplements and as a physician that he recognizes the benefits that they can play as a part of a comprehensive care plan. This is groundbreaking stuff, given the strained relationship our industry has often had with FDA.

Second, he recognized, as we always have, the significant balance that DSHEA struck between consumer access to dietary supplements and ensuring their safety, and how that law set the cornerstone for the thriving industry we have today.

He then looked to the future, and suggested that more still needs to be done. And yes, he called this a pivotal time.

Dr. Gottlieb called for a public dialogue on whether steps could be taken to further strengthen DSHEA – to bring it into the modern era when dietary supplements have become a mainstream product taken by 77% of Americans. One of those items he called for dialogue on was the prospect of a mandatory listing for dietary supplements.

In his words, such an initiative could "provide significant benefits by improving transparency in the marketplace and promoting risk-based regulation." Continuing, he said, "it could also help facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors who put the public at risk and undermine consumer confidence in the entire industry."

Of course, discussions of a possible mandatory listing requirement aren't new to us. In fact, a key session of last year's CRN conference was the very engaging debate on stage on just that issue – pro and con. Strong arguments were made on both sides, and I think, based on audience polling at the time, that our membership was fairly split.

CRN's board took up this issue and continued the discussion in each successive board meeting. Over time, it became more and more clear that a new era calls for new thinking. Much of the animosity and distrust we had with our regulator is really a thing of the past. When someone complains about the FDA these days, it is more likely to be about a lack of enforcement directed at a recalcitrant competitor, or a frustration about the lack of decisiveness at FDA,

rather than comparing them to “jack booted thugs” as we remember the attitude that prevailed in the pre-DSHEA days.

I’m proud to have facilitated and promoted that open dialogue at our board meetings, and that it ultimately led to the adoption of a strong statement of support for a mandatory product listing. For responsible companies, I feel that this is truly a no-brainer. We’re the ones endeavoring to do everything by the book – and the ones who get hurt when a company cuts corners and ignores the law to create lower quality products that don’t compete on a level playing field. And we are the ones who have the most to lose if some less than responsible actor creates a true public health crisis through carelessness that impacts sales and confidence across the entire industry.

Some have said – Doesn’t a mandatory listing paint targets on our backs for the FDA to come get us? But, resoundingly, the answer to that is “No”— those of us who observe the high standards to meet CRN’s membership criteria and the will to do things right – are not the sort of actors the FDA will be pursuing. A product registry will allow FDA to see for the first time the breadth and extent of the supplement marketplace. It allows FDA to determine who is using a particular ingredient, what claims are being made on the label, and whether the contact information for reporting an adverse event is properly provided. Responsible actors have nothing to fear from mandatory listing. Now, of course, some disreputable actors will ignore the mandatory listing requirements, but this law would make it easier to identify their failure to file and to prosecute them.

Others opposing a mandatory registry contend that it is too burdensome, particularly for small business. But again, CRN members know from experience that isn’t the case. Our own Supplement OWL registry has demonstrated that companies of all sizes can submit their labels and product information without it disrupting their companies and create a transparent database for regulators.

Since CRN’s board made this decision on mandatory listing, we’ve been out advocating for it. Our staff has begun lobbying Congress and working to build support for a mandatory listing with other stakeholders. It’s been discussed at our legal and regulatory conferences, and a topic for meetings with retailers. Steve has been on panels at our industry trade shows, most recently at Supply Side West, laying out the case and debating other industry players.

It is clear that there is not consensus across the industry just yet – but we will keep at it. And that’s where you can help. Many of you are also members of other associations who have taken positions against mandatory listing. You need to use your company’s influence to move them toward support. We believe this is the right way to go – and that now is the time to pivot in that direction.

We have led in this area of transparency in another regard too, by creating the Online Wellness Library, our beloved Supplement OWL. Three years ago at this conference, CRN committed to create a voluntary product listing for the whole industry to use. Every member company with finished products in the market is represented in the Supplement OWL, as well as a lot of companies who aren't CRN members. This has been a rousing success, showing that companies that enter their labels can achieve greater transparency and trust and that it does not result in painting a target on your back. Importantly, this initiative could provide a template for FDA for a mandatory listing, and we've offered to share both the structure of the Supplement OWL and the data with FDA.

As you know, we've recently changed vendors for this project and there is a new look and feel to the database, so it's easier than ever to use. If you haven't visited the Supplement OWL website recently, it's worth taking a peek. And if you have labels in the registry, it's a good time to double check that everything is in there and it is up to date. For the ingredient suppliers and contract manufacturers in the audience, you can help too. Help us spread the word, particularly with your customers whose products are not in the OWL yet. Could you encourage them to participate? Even as we are supporting the move to a mandatory listing requirement, the interim best step is to make sure we are all fully participating in our voluntary listing program.

Also, I'm proud to announce that other user-friendly changes will be rolling out to the OWL in 2020, including a self-service portal that should make entering labels and checking them even easier than the current process. Stay tuned for the timing on that, but our coders are already hard at work on delivering this improvement.

And – I hope you noticed that I did not lead with CBD – but no talk from the chairman would be complete without talking about it. In any other year, our advocacy for a mandatory product listing would be the screaming large headline coming out of our work. And once we are successful in that effort, I believe that will be the legacy of this era we'll look back to with considerable pride as a true pivot point toward an even more safe, more responsible future.

But CBD is a noisy ingredient. It has a tendency to shout everything else down – to grab all the oxygen in the room. It demands that you pay attention. You certainly can't go to a trade show without seeing it everywhere. And because it is such a potentially revolutionary ingredient, with many possible benefits, plus long-pent up demand combined with a bit of allure brought on by the prior illegal status of hemp, I don't have to tell you CBD has spread faster than kudzu.

The market has clearly gotten out ahead of the regulation. It's a complicated subject, but, to put it plainly, we've been calling on FDA to take a very simple step. Simply use the discretion that Congress gave the agency in DSHEA to open both the pharma lane and the dietary supplement lane. The regulatory roadblock isn't safety – it's about whether there can be a legal dietary supplement lane at all. The discretion Congress has already given FDA would allow it to

do that, and that would immediately clarify the regulatory picture, establish a fully developed regulatory framework for the oversight of these products, and incentivize companies to invest in the expensive safety data that a new dietary ingredient requires.

The current regulatory framework is more than sufficient to handle the CBD market. But FDA needs to enforce existing laws and regulations it has on what it means to be a responsible dietary supplement. That includes adhering to good manufacturing practices, registering your facilities with FDA, setting up a serious adverse event reporting system, accurately listing all ingredients on the label, making only appropriate and well-supported claims, and all of the other strictures of our industry.

We know that this market has created a bit of a gold-rush mentality, and that many non-supplement companies have gotten into the market. As an association, we believe the status quo creates risk for our whole industry. Without appropriate regulation and oversight, combined with huge consumer demand, I fear it is just a matter of time before something happens that could have long-lasting repercussions. Will someone take a badly made product and have a terrible or even tragic outcome? And how would such a tragedy reverberate through the whole dietary supplement industry? Would consumers' confidence in the category as a whole be totally shaken? Would sales of completely unrelated products plummet? Probably. The possible loss of a promising botanical ingredient will truly be the least of our worries if something like this happens.

At CRN, we moved early in the year to welcome companies that market hemp-derived CBD. This was a move we had debated for some time, and we ultimately concluded that as we seek to clarify the regulatory picture, those companies most directly involved – and those who most stand to benefit – should be providing both insight and resources to the effort.

We are proud of all of our members – including our new CBD members and legacy members who are moving into the space – because they are doing it right. They know the proper way to source, manufacture, and market a dietary supplement, whether they are a new entrant or a company who has been in the industry since the beginning. And for consumers looking to sort out the wheat from the chaff in a very confusing and inadequately policed marketplace, CRN membership can be an important signal that the company knows and takes its responsibilities seriously.

We will continue to advocate for a lawful pathway to market, to engage with the FDA and Congress, to collaborate (and when necessary, disagree) with our fellow trade organizations, and to provide education and resources for diverse audiences including industry, consumers and retailers. We hope that we are nearing a solution to the regulatory quagmire, but we won't quit until we have.

Helping to create more educated consumers has taken shape in another initiative this year too—our Be LabelWise campaign. You are all well aware that new Supplement Facts requirements will kick in early next year, and into 2021 for smaller manufacturers. We've had a campaign all year to let consumers know about these changes and what they mean, and we've gotten very good traction in the media and with many of your consumers when you've helped us spread the word. Some nutrients will no longer be required to appear in the Supplement Facts box, and other ingredients, like added sugar, will make their first appearance. Units of measure are changing which can be confusing if you are used to selecting a product based on international units of the ingredient. And the Daily Values for other nutrients have changed to reflect contemporary diets and newer science about our nutritional needs. Our campaign helps our consumers navigate all these changes.

But more than anything else, this consumer education program underscores why the label is changing: because this industry cares about its consumers and wants to provide useful information, and secondly because our labels ARE regulated by FDA. The underlying message reminds consumers that supplements are indeed regulated and that responsible industry complies with those regulations—despite what some misinformed news outlets and so-called experts might say.

If you haven't had a chance to see all of the great content we've developed, check it out at www.belabelwise.org.

Again, this is an initiative designed to benefit the whole industry, so if you want to learn more, CRN's communications team would be delighted to help you find out how to get involved.

And speaking of a more informed consumer, this goal is also driving our efforts in the area of probiotics. After CBD, probiotics continues to be one of the fastest growing areas for dietary supplements. With the emerging science, the potential health benefits from these products continues to grow. So the regulation of these products needs to keep pace. Let's start with the FDA, who continues to insist that probiotics be labeled in terms of their metric weight simply because that's the way they've always done it for supplements generally. This makes no sense because live probiotics and dead probiotics have the same weight. What consumers should care about is receiving live organisms that are viable through their shelf life. So CRN continues to advocate for FDA to require probiotics be identified on labels down to the strain level; to mandate the labeling of probiotic quantities in terms of live organism count, for instance, by colony forming units—or CFUs—instead of metric units (mg); and to insist that label measures reflect the full shelf life of the products, not just at the time of manufacture. We are still waiting final guidance from the agency, but I can assure you we are keeping the heat on

At the Codex Alimentarius Nutrition Committee, we continue to oppose new proposals that would harm the international trade of these products. Later this month, our staff will be in

Germany to stop proposed guidelines that could mandate stringent clinical testing for effectiveness of probiotics that are not uniformly recognized and run counter to the general guidelines for health claims for supplements. And then at the state level, we succeeded in stopping new legislation on probiotics labeling in California that was inconsistent with federal regulations. As the leader in effective advocacy for this industry, CRN has been representing your probiotics interest on all stages.

There are so many other initiatives we are working on – that you need to know about and engage in – but time doesn't permit a thorough highlight of them. I will name just four of them right now:

- our work against new tariffs,
- strengthening industry relations with retailers,
- streamlining certificates of free sale, and
- protecting the sports nutrition sector from illegal ingredients

Each and every one of those initiatives is really important.

You know that many of our companies source from China – and that means we are keenly impacted by new Chinese tariffs. We have been advocating directly with the administration on this issue, to make sure that they are aware of and can seek to mitigate these impacts, which hurt American jobs and American consumers.

We are proud of a collaboration with the U.S Chamber of Commerce to create an industry spotlight piece that they have been using with stakeholders to help us tell our story. They've also shared CRN consumer usage data, figures from our economic impact report and information on the direct and indirect impacts these tariffs can have on industry costs and consumer prices.

Because we know how vital it is, we are working continuously to improve industry relations with retailers. This summer, we launched the Retailer Relations Forum to educate and enable CRN member companies to protect and grow their business with retailers. We've already had one in-person event at the NACDS Total Store Expo in August, and more are on the calendar.

We also continue to sponsor and attend Shopping for Health, a conference for registered dieticians, nutritionists, and consumer advisors at supermarket and retail chains.

This year, we presented on the dangers of adulterated products in the marketplace and how to avoid them. We also regularly provide content to these audiences, including a webinar to educate retail dieticians about the current state of CBD.

On streamlining certificates of free sale, we continue to submit comments and have dialogue with the FDA to request that the agency adopt a new template for issuing Certificates of Free

Sale. This is a critical issue, especially at a time when US imports are being affected on a number of international trade fronts, which is not getting any attention from the agency. CRN has continued to present reasonable, straightforward solutions to make the FDA's Certificates of Free Sales more usable and reduce the need for time-consuming "work arounds." In 2020 we plan to start working to implement these changes ourselves if the FDA continues to ignore our requests.

In sports nutrition, we are working to foster the growth of this sometimes controversial sector. CRN's survey reveals that these products continue to gain in popularity, so we must stay vigilant and protect this area through combatting harmful legislation and by promoting the health and wellness benefits of these products through education programs. Last year, CRN launched the consumer education initiative, #SARMsCanHarm to raise awareness of Selective Androgen Receptor Modulators, a dangerous class of ingredients that pose a threat to consumer safety, especially in the bodybuilding and fitness communities. We continue to advocate for legislation to protect consumers from SARMs and are anticipating legislation to be introduced in Congress soon.

So, while CBD may make the headlines, and may be the thing you get asked about the most from friends outside the industry, you can see that it is actually just a very small part of what we are doing. We will work to bring a resolution to the confusion on CBD – but as we do, we'll continue on all of these other initiatives, with no less vigor or enthusiasm.

As I draw my remarks to a close, I'd like to thank Jim Hyde and all of our former board chairs for the leadership and vision they've provided us. We wouldn't be where we are today without your sacrifices and investment of yourselves in our industry's well-being.

I want to thank the terrific CRN staff who have not missed a beat as we've asked them to respond to a wide array of complicated and demanding issues.

And also to acknowledge that in the past two years, we've now had a complete turnover in leadership in three key departments – communications, science and regulatory and government relations.

I'd like to recognize and thank Judy Blatman, Duffy MacKay and Mike Greene who led us so well in those areas. And to commend the leadership who will lead us into the future and move our industry forward. Brian Wommack has now been leading comms for more than a year and a half; Andrea Wong has been promoted from within to take over science and regulatory from Duffy; and Julia Gustafson joined us just last month to lead our government relations department. We are proud both of being able recruit bold leaders from outside the industry in Brian and Julia, and to recognize and reward excellence from within through the promotion of Andrea.

I also want to acknowledge the key contributions of Andrew Shao, who so ably led our science and regulatory department as we sought a new leader for the department. Thank you, Andrew, for such excellent service.

And of course, I'd like to thank and acknowledge Steve Mister and his whole team. Steve's leadership is always on display, but in a year of profound staff change where he's needed to create the right team to move us into the future, it really shines. Thank you, Steve, for all you do for the association and for the industry, and to the whole staff for their diligence and effectiveness.

This is a pivotal time – and you are a pivotal part of building the new future. There are many unresolved issues and challenges. But because of all we have accomplished, and the trust of the American public, we have innumerable opportunities.

Thank you for being here and for engaging with us this week. We expect you will leave here with more knowledge, more connections, and more resilience to meet the challenges – and the opportunities -- that lie ahead.

I look forward to working with you in the coming year to continue to deliver for our industry. We are the stewards of our industry and what we do will determine our future. Thank you for your confidence in me and for all you do to support our efforts.
