NATURAL PRODUCTS INSIDER®

SupplySide®

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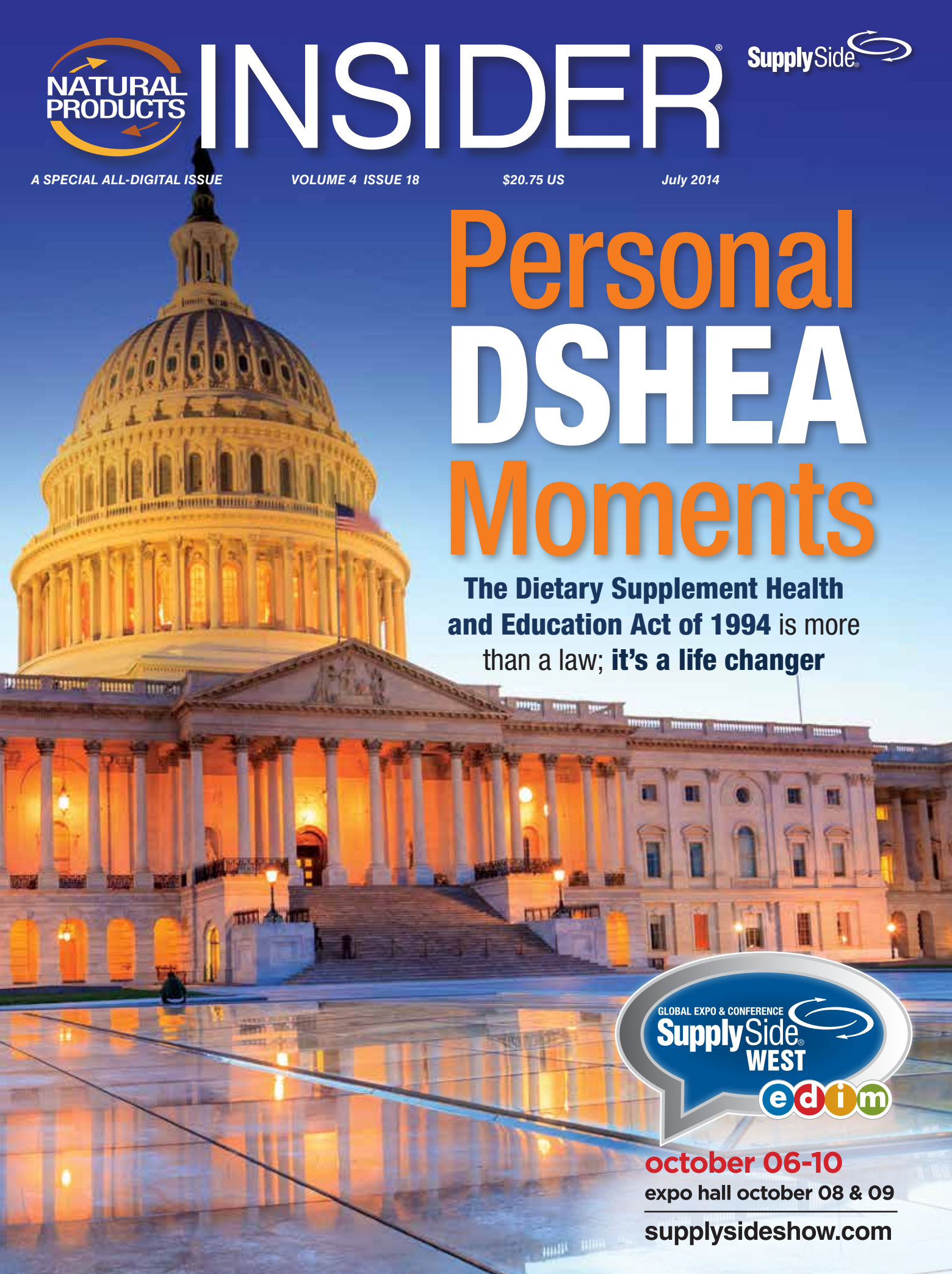
Personal DSHEA Moments

The Dietary Supplement Health and Education Act of 1994 is more than a law; **it's a life changer**



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A DSHEA Cliché?

As **INSIDER** has covered the 20th anniversary of the Dietary Supplement Health and Education Act of 1994 (DSHEA) this year with an Immersion Center, Digital Issues, Reports and print articles, I've heard from industry stalwarts that the younger generation needs to be more interested in the politics and politicians that govern the industry.

The younger people, they say, have been privileged to flourish under the landmark legislation that gave "dietary supplement" a definition, a place in the law and a credibility in the market. Sure, those who weren't in the industry 20 years ago still know the importance of the law's implications, such as good manufacturing practices (GMPs), new dietary ingredient (NDI) notifications and the Office of Dietary Supplements (ODS), but they are lax on political involvement—the kind of involvement that was necessary when FDA wanted to regulate supplements as drugs or food additives.

Twenty years ago, I was not in the industry. In October 1994, I was not interested in politics. I was interested in tetherball. I didn't know what DHSEA was until I started working at VIRGO five years ago, when we were celebrating the 15th anniversary of the law.

Under Jon Benninger, vice president of VIRGO's Health & Nutrition Network, and Heather Granato, vice president of content of VIRGO's Health & Nutrition Network, I learned not only how to pronounce "DSHEA," but how important the law is to the supplement industry. It didn't take long before I Googled Mel Gibson's famous pro-DSHEA commercial.

While I know a lot about DSHEA, I am still learning from those who were around when it passed, such as Loren Israelsen, president, United Natural Products Alliance, who offers insight to the tenure of the industry back then (on page 6); those who use DSHEA every day at work (and thank the law for creating their jobs), such as Elan Sudberg, who explains on page 4; and those such as C. Leigh Broadhurst, who say the industry still faces threats (page 18), despite winning with DSHEA.

As we take this time to look at the personal moments these industry stalwarts have with DSHEA, we should reflect on how the law affects us, our jobs and the supplements we take. But we also need to take this time to plan our current involvement. If the industry needed us to unite like it did back then, would we, the younger generation, be able to live up to the legacy left by DSHEA? I hope so.

Sandy Almendarez
Editor in Chief
(480) 281-6745
salmendarez@vpico.com
@SandyAlmendarez

DSHEA From a Lab Perspective

by Elan Sudberg

If Alkemist Labs had a grandfather, his name would be DSHEA. He would be 20 years old and have already fathered a son, cGMPs (current good manufacturing practices), who would have fathered a handful of testing labs. Without either, there would simply be no lab perspective.

In 1992, spearheaded by Loren Israelsen, president, the United Natural Products Alliance (UNPA), and a small group of other legal warriors, the Health Freedom Act was born. Over the course of the next two years, it matured and became what we now know as the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Prior to DSHEA, the dietary supplement industry was all but a nameless sore point for FDA. Perceived as a bunch of hippie snake-oil salesmen, FDA made it clear its mission was to prevent such trade. While good companies did exist back then—many matured into the banner companies of today—the industry was void of relevant regulation, definitions and guidance. Food GMPs (21CFR 110) did exist, but to apply them to the industry meant making sure no birds lived in your manufacturing facility and other important, but not fully relevant, rules.

From the perspective of quantum mechanics, the numbers we associate with fundamental observable properties do not exist independent of observation. In other words, the numbers for a given particle do not attain a specific value unless it has an interaction with another particle. Even the physical world does not exist unless it is "perceived" in this sense.

DSHEA made it possible to establish definitions for ingredients and combinations of such, giving rise to vocabulary used to describe the dietary supplement industry. From that point on, DSHEA established safeguards such as cGMPs (21CFR 111) and new dietary ingredients (NDIs). DSHEA helped to create the lab perspective—the reality—we know, love and thrive from. It not only put Alkemist Labs and our competitors on the map, it created the map. ■

Élan M. Sudberg is CEO of Alkemist Labs, an analytical testing lab. He holds a degree in chemistry from California State University Long Beach, and has authored numerous journal articles on phytochemistry and analytical techniques for the natural products and nutraceutical industry.

*This article originally ran on **INSIDER**'s Supplement Perspectives blog.*

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DSHEA, 20 Years Later: Loren Israelsen Looks Back—and Ahead

by Pete Croatto

"There is no comparable law in any other country," said Loren Israelsen, president of the United Natural Products Alliance (UNPA). "Seriously, DSHEA (the Dietary Supplement Health and Education Act of 1994) stands unique on the global scene." He would know. Israelsen worked on getting DSHEA passed in 1994, and he has seen the law evolve.

INSIDER's Supplement Perspective blog talked with Israelsen about the time DSHEA passed and what's to come. The interview has been edited for clarity.

Supplement Perspectives: What's striking about DSHEA is that it really was, at its heart, a grassroots movement. Could the same type of change have occurred if the movement came just from big companies?

Loren Israelsen: No. A couple of reasons: Big companies would seldom have ever sought this kind of change. The ideas in DSHEA typically don't come from big industry. This really was predicated on revolutionary ideas and really big change. The normal Washington legislative procedure is to quietly shop some ideas around, see if you can build it into something, and then get it dropped in as an amendment to some other bill. That's the most convenient and efficient way to do these things. You don't need a populist uprising to do that. Hence, you would not use the DSHEA approach as we did.

SP: Is there another issue now that warrants such an approach?

Israelsen: In fact, we do have one; it's called the GMO (genetically modified organism) labeling issue. It's DSHEA's first cousin, if not little sister.

SP: So, without DSHEA this wouldn't be happening?

Israelsen: That's a good question. I suspect it would be going on. The efforts around organic labeling and legislation, which have been going on for as many years as DSHEA itself, really came out of the heart of the food industry and the food culture. DSHEA really, truly came out of the heart of the supplement culture and industry centers. Twenty years ago, they were at different places. The only times we would truly cross over would be at [Natural Products] Expo West and in a health food store. The individuals involved and the members of Congress who were the leaders on

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DSHEA 20TH ANNIVERSARY
Immersion Center

For the past 20 years, the supplement industry has thrived under the Dietary Supplement Health and Education Act of 1994 (DSHEA), but that doesn't mean everyone agrees on the law's implementation. This **INSIDER** Immersion Center explains how DSHEA has been enforced through its various sections, such as NDIs, GMPs, ODS and more, while celebrating those whose work has kept the law strong during the past two decades.

Explore Today.

those issues were different. What we find intriguing, and a very important signal, [is] for the first time in 20-plus years, these two sides are merging together around the GMO labeling issue. You will have people who are truly from the organic food clan, marching shoulder-to-shoulder with someone carrying a gun in defense of DSHEA. I think they will recognize each other as brothers- and sisters-in-arms. I'm trying not to get militaristic about this. We have a convergence going on, and that is one of the news stories of 2014.

SP: It must be nice to have that co-mingling, because you have support in place for the next issue after GMOs.

Israelsen: This is one of my mantras: Our industry operates on roughly a 20-year cycle. We will go through something great—DSHEA, organic legislation, Proxmire amendment, etc.—and then we really have this tremendous moment of coming together, joint action, and a period of active, selfless work in support of an idea and a principle. We've had a great track record. We tend to win.

[We] enjoy the fruits of that effort. Then, we tend to forget. The original combatants retire, move on and do something else. Now, 20 years later, we've got to really rebuild it all. Something has to be done. If not us, who? How do we do it? Let's organize this thing and move on. What we're seeing now is organization of meetings, a great deal of coverage in the media, consumers who are literally pounding their fists on check-out counters asking retailers, "How come you don't know if this non-GMO or not? Why do I have such difficulty figuring out if I'm buying something I really regard as bad for my family? Why are you carrying this product at all? What's wrong with you?" That rise of emotion is a really good sign that we're getting ready for the work ahead.

> "There's just a lack of appreciation for what DSHEA did to create a different marketplace, especially for those younger people in the industry."
>
> — Loren Israelsen, United Natural Products Association (UNPA) president

SP: What would the industry look like today if FDA had achieved its goal to approve claims?

Israelsen: [Without DSHEA] it would look a hell of a lot smaller. It would largely be confined to health foods stores. The assortment of products would be far narrower, meaning lot of well-known botanicals, amino acids, minerals, high-potency vitamins/minerals, probiotics, possibly even fish oils, may or may not even be on the shelf.

The working documents that were FDA's go-forward plan identified most of what I just described as unapproved food additives, drugs or otherwise, not

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candidates to be dietary supplements. So, if FDA had acted on its working plans, I think you could say realistically that is what the industry would have looked like. A lot of the innovation, a lot of the creativity and the good ideas wouldn't be there. Products in larger juice formats would not be there. A lot of the creative ideas and people would not have moved into this space because it would have looked quite dry and barren to a lot of people.

SP: As time goes by, do you think DSHEA's effects are forgotten?

Israelsen: I do. I think there's a lack of gratitude. No, first, it's appreciation. There's just a lack of appreciation for what DSHEA did to create a different marketplace, especially for those younger people in the industry. The analogy, just based on age, would be a young teenager today who has an iPhone who is texting and lives in a digital world. If they see a fax machine, [they ask] "What is that? How did anybody use that thing?" Even a typewriter. They'd say, "You actually did business on that?" and they're astonished. The understanding of how daily life was conducted and what tools and mechanisms were available for communication, transportation and all these things blows their minds. That is our problem: The context in which DSHEA was crafted and passed, and the tools used to do that and the attitude and role of government at that time—the young members of our industry have no software to understand that.

Part of our work in the 20-year recognition of DSHEA is to try to bring some of that to life. There are stories, people, ephemera and case studies to be used where we need to teach the next generation that this is an ongoing duty. And the non-GMO issue is an extension of that continuing duty, and it will keep going. There are all kinds of things beyond non-GMO that are the work of this industry.

SP: How do you get that younger generation to carry that flame?

Israelsen: We have the good fortune of being a kind of a lighthouse to a genotype of people who are drawn and called to the natural health and organic world and all it represents. A lot of them come to us wanting to be a part of this. Our job is to receive them, embrace them, hand them a shovel, say, "start digging," and put them to work. That's really the best thing to do—have a very keen recognition that they come to us wanting to be a part of this. Interestingly, we have a lot of older execs come to this industry, people who have had long careers in other industries—big food, big pharma, academics—and have stayed here because they [see] a sense of community unfelt and unseen from the worlds they came from. That's part of who we are. We need to invite people to join with us, then give them something to do.

When I showed up on the scene that's kind of what happened to me. Somebody said, "Hey, you're standing around loitering, get over here and start doing this." I said, "Who, me?" He said, "Yeah, you." I now know looking back

that it was one of the greatest times of my life. I was allowed to be part of something that I didn't appreciate then as much as I do now. Here I am 33 years later, and I'm still doing it. There must be something to it, at least for me, as to why I keep doing this along with so many others…We are called to this. Many of us feel that way. We stay because this is the life we live. We really do live what we preach and, consequently, it's really important.

SP: How long do you expect DSHEA to stay relevant? Will it be replaced by something that incorporates the Internet or have better definitions and timetables? Or will it be amended as time goes on?

Israelsen: We don't know. DSHEA remains relevant as the operating framework for this industry. Having said that, after 20 years, so much has changed. We have other laws that have been passed that are essentially additions to DSHEA, designed to add structural strength, widen the roads, put up the radio tower on top of the building. [They] take into account what happens now: things like adverse event reporting, allergen labeling, the Food Safety Modernization Act (FSMA) and steroid control legislation.

So, DSHEA used to be the sole skyscraper on the horizon. If you look at it now, you see other structures, buildings and communities that are the realization of how the world has changed. So, the big debate is: will DSHEA be repealed? I doubt it, seriously doubt it. Could it be amended? Possibly, if there was a really good reason that would strengthen DSHEA in terms of its mandates, all right, let's listen to an idea. More than likely, the best ideas will be as we've seen in the past. That is, take a specific issue, and if we need a tune-up, let's brace that onto or next to DSHEA. That seems to work really well. Those that want to repeal or deeply amend DSHEA don't seem to appreciate that you mess with a great deal of software and operating systems, which are working day in, day out. So, it's not a little, simple thing to do.

> "We all look at the finished product and think, 'Yeah, that was great,' and forget just how difficult [passing the law] was."
>
> — Loren Israelsen, UNPA president

You change one thing and there's a great deal of downstream effect, and then you have a lot of uncertainty—usually rulemaking and policymaking—that goes on for years. We know this. DSHEA was passed 20 years ago, and the rulemaking process for DSHEA is still not done. So, what you end up with an "under construction" sign always on the roads. That is not an efficient way to run laws. Ideally, it's, "here's the law, and here are the hard deadlines" to have the regulatory components put into place.

If there's any observation about DSHEA, [it] is we should have built in some hard deadlines for the completion of GMPs (good manufacturing practices), new dietary ingredients (NDIs), policy and practice, that kind of thing. It would have helped a lot.

SP: Yeah, but hindsight is 20/20.

Israelsen: This is the hardest part, I guess, of DSHEA. We all look at the finished product and think, 'Yeah, that was great,' and forget just how difficult it was. You had such deeply opposed sides in Congress. You had multiple interests within the industry itself who wanted and needed different things; the constant barrage of media dumping on this thing—pro and con—just as we see right now. In the midst of the revolutionary 1994 political elections, and wow. It's hard to imagine with all of that tumult and all the game playing that this bill passed. You could fill pages with the details of how that happened. It's an extraordinary story, and most people after they hear about it say, "I can't believe DSHEA ever became a law." Just from the timing, the process and the intrigue. It really is a John le Carre novel.

SP: Was there one obstacle or moment where you and your allies thought, "Oh geez, we're toast?"

Israelsen: There were many of those, but one really does stand out. It was May 1994. There was a critically important Senate mark-up. So, in the Senate HELP (Health, Education, Labor and Pensions) Committee, chaired by Sen. Ted Kennedy (D-Massachusetts), not a friend of the bill, this was the do-or-die moment. Complicating the fact was that it was Nelson Mandela's inauguration day. Three members of the committee had flown to South Africa to be part of that. We didn't know how they were going to vote. Two of the three were Democrats; one was Republican.

Normally, you would give your proxy vote to the ranking member of your party, in other words, to Sen. Kennedy. Which means, we assumed, that he would vote "no" on DSHEA. We were frantically doing the head count trying to figure out if we've got the votes. It was a very intense mark-up. Chairman Kennedy called for a vote. We were urging Sen. Orrin Hatch's (R-Utah) staff to ask for a postponement to get these people back from South Africa. We ran the numbers, and were convinced we were going to lose. If we lost this vote, that was the end of DSHEA. Well, Sen. Kennedy insisted on proceeding, and long story short, we won.

Something that's quite extraordinary and unusual is that one of the Democrats—I won't name names at this point—in South Africa gave their proxy vote to Sen. Hatch. And when that senator's name was called, all eyes were on Sen. Kennedy, expecting "nay." All of a sudden, over on the right side,

here is Sen. Hatch saying, "yea," and we thought, "What the hell is going on here?" It appeared that Kennedy didn't know that was coming, which was a substantial breach of protocol. One more thing of that sort happened, and that gave us the two votes we were missing. We won it by one at the end of the day. The gallery erupted into huge applause, screaming and standing on chairs. And Chairman Kennedy was so annoyed—he pounded his gavel so hard on the table that the head broke off and flew into the crowd.

That's one of, man, I don't know, 50 events of that kind, that you go through and think, "Yeah, that really happened. Yeah, we got on the edge and somehow survived it." It was a bill like that. Every other week there was a drama of some sort.

SP: Twenty years later, would you be willing to do it all over again?

Israelsen: [Laughs] Would I be willing to do that again? I don't have the physical strength to do that again. My wife would never give me permission to do it. And I would be looking for the smartest kids in the room and say, "You want to do something fun that will never be forgotten?" and send them off and be their guide and mentor. And that's what we need. We need that younger generation of folks who are willing and able to do exactly that. We want and need others to do that. They need to go prove themselves, learn the lessons and become the leaders of the future for this industry. ■

*This article originally ran on **INSIDER**'s Supplement Perspectives blog.*

We Made an Impact

by Al Powers

I will never forget the extraordinary industry efforts that went into the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) 20 years ago. Manufacturers, distributors, retailers and consumers all worked together for the common cause of defending health freedom. I remember the entire industry gathered at a fund-raising event at the National Nutritional Foods Association (NNFA, now known as the Natural Products Association [NPA]) show in Las Vegas, and it was standing room only in a crowded ballroom.

To this day, I have never seen the industry united around a common cause like we were then. In my 40-year career in the health food industry, I have never seen more passion for fighting for our industry since the industry was literally facing obliteration by Congress. Retailers were actively getting their customers to write letters or send faxes to members of Congress. This effort led to the second-largest letter writing campaign that Congress has ever experienced next to the Vietnam War.

Talk about making an impact!

The industry also organized a "supplement black out day" where health food stores draped black sheets over vitamin sections and explained to customers that they would not be able to purchase vitamins unless they took action to write members of Congress. At that time, I was managing health food stores, and I can tell you this had a big impact on my customers.

The passage of DSHEA was the major milestone that shaped the course of the health food industry.

NOW Foods provided bus transportation for hundreds of members of the industry and health food customers to protest at the Daley Center in downtown Chicago. This campaign brought much awareness to the problem our industry was

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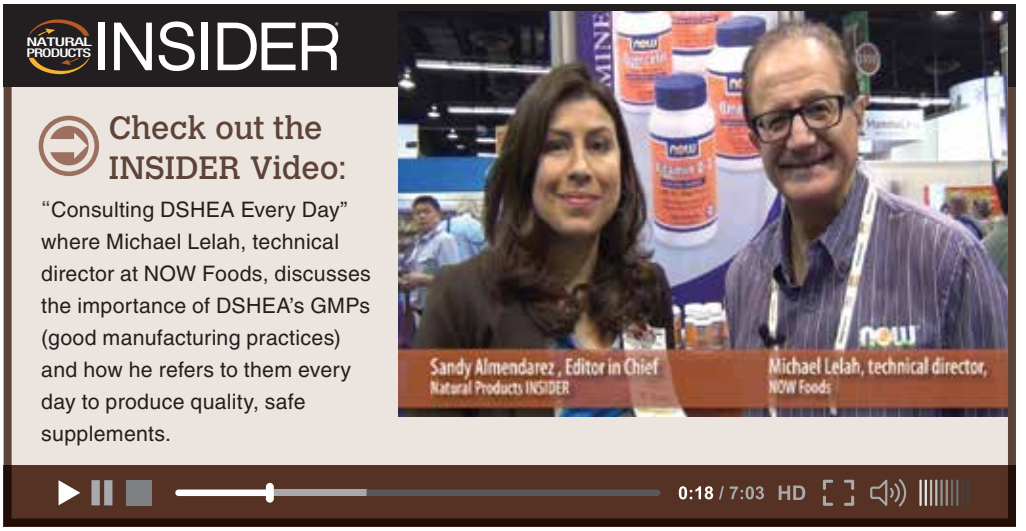

facing—plus coverage in the Chicago press—and it showed how much consumers wanted to continue purchasing safe supplements.

The passage of DSHEA was the major milestone that shaped the course of the health food industry and the framework of regulatory compliance to this day.

As I look back, it was the most exciting time to be in our industry; we achieved such incredible unity. It also serves as an example of what we can achieve if we work together and join forces to advocate for our industry and consumer health freedom.

In the light of the ongoing media war on vitamins, I urge industry members to get involved and join our trade associations in defending our industry. ■

Al Powers is the CEO of NOW Health Group. Under his leadership, NOW Foods became a top brand in the natural products channel, is one of the 101 Best and Brightest companies to work for in the Chicagoland area and has been named Manufacturer of the Year twice. Powers has many years of health food retailing experience and is on the board of the Natural Products Association (NPA).

*This article originally ran on **INSIDER**'s Supplement Perspectives blog.*

A Piece of Legislation Comes of Age

by George Pontiakos

Twenty years ago, the dietary supplement market was not only born, it avoided death. With the passing of the Dietary Supplement Health and Education Act of 1994 (DSHEA), the term "dietary supplement" was formally defined; there were to be no more arguments about whether supplements were foods or drugs, and no more attempts to regulate them out of business as an unapproved food additive.

A set of regulations specifically tailored toward this new category was made possible, allowing DSHEA to establish the foundation of the current dietary supplement market.

With industry experts drafting it and full support from ingredient suppliers, this great piece of legislation had potential to be effective immediately. It was not. Whether it was FDA's lack of resources or not, the implementation and enforcement of DSHEA was not present. Only now, 20 years later, is it starting to reach its full potential.

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However, it took more than a decade to establish GMPs (good manufacturing practices), providing the industry clear, concise requirements that detail both process and responsibility across our industry. Yes, we are seeing injunctions, seizures and what seems like countless warning letters, but this only means the legislation is doing its original intended function. The United Natural Products Alliance (UNPA) has stated that FDA's increased GMP enforcement has had a positive impact with DSHEA compliance. Although it may have not come as soon as we wanted, we are going to witness the removal of companies uncommitted to quality, as well as increased consumer confidence in an industry that was lacking it.

We are going to witness the removal of companies uncommitted to quality.

Since DSHEA's implementation, I have seen the dietary supplement industry evolve and mature rapidly, scaling from an entrepreneurial marketing culture to a mature, disciplined and customer-focused industry that cares deeply about the quality, efficacy and method of action of our products. I have worked across six separate industries during my career, and I can honestly say none of them would have been able to embrace, recalibrate and implement a regulation as far reaching as the GMPs in the timeframe we have.

We are finally seeing immense progress in DSHEA, and I see the future as a positive one for the dietary supplement marketplace. ■

As president and CEO of BI Nutraceuticals, George Pontiakos oversees all aspects of operations for BI Nutraceuticals, as well as the Zuellig Group Nutrition and Ingredients division in China. Pontiakos has held senior leadership positions at several consulting, medical services and technology companies.

*This article originally ran on **INSIDER**'s Supplement Perspectives blog.*

DSHEA: Our Safe Harbor in a Sea of Never-Ending Tumult

by C. Leigh Broadhurst

While we may crab about the strained language and euphemism overload created by the Dietary Supplement Health and Education Act of 1994 (DSHEA), these have been halcyon days for the natural products industry. Indeed, this digital issue wouldn't exist today without the freedom we've had to develop, allowing us to market products and reinvest capital rather than paying for clinical trials and overbearing regulatory/safety compliance.

FDA doesn't like the natural products industry. In the past five years, FDA regulatory authority has escalated. The pharmaceutical industry, despite massive campaign contributions, is experiencing an all-time high of government fines and litigation—and the new medical devices tax. Last year, Sens. Dick Durbin (D-Illinois) and Richard Blumenthal (D-Connecticut) reintroduced the Dietary Supplement Labeling Act, which grants numerous government agencies regulatory power over the industry, virtually assuring that products such as extracted phytochemicals from non-food plants will be off the market.

Increasing FDA regulatory authority is part of a comprehensive plan for government control of health care.

With this proposed act, further industry expansion is nearly impossible. Increasing FDA regulatory authority is part of a comprehensive plan for government control of health care.

Late last year, I read in the *Wall Street Journal* and *The New York Times* that another medical study found multivitamins are useless and recommended they be avoided. This is just the latest of many such pronouncements that produce a few weeks of kerfuffle for our industry, but ultimately anger and confound the authors and their elitist cronies. Why? Because the desired effect—the public abandoning supplements in droves—never seems to happen.

I've seen polls claiming that 50 percent of U.S. adults use dietary supplements; typically a few hundred per year experience serious side effects and nobody dies. (In contrast,

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prescription and OTC (over the counter) drugs kill thousands yearly and cause many more serious side effects.) Economics 101 shows 150 million people in a free market will not pay for something that's "useless." Even if some of them are, Psychology 101 tells us that up to 30 percent of people in any clinical trial respond to placebo.

Put simply, people taking supplements believe they are doing something healthy that reduces their risk for illness. They gain happiness, self-empowerment and peace of mind, which always correlates with better health outcomes.

It's no secret that unscrupulous vendors, substandard products and nonscientific approaches exist and (even proliferate) in our industry. You know who you are, and I would appeal to you to clean up your act or at least lie low. We must ensure that DSHEA remains status quo, because our industry hangs in the balance. ■

C. Leigh Broadhurst, Ph.D, is a research geochemist and geobotanist at a government agricultural research facility and a leading state university in Maryland, as well as a consultant for Ark Naturals, a science-based natural pet products company. Her research publications span scientific fields from high temperature magmatic simulations to the origin of type-2 diabetes. In addition, she participates in a cross-disciplinary scientific collaboration that investigates the impact of brain-specific nutrition on the origin of modern human intelligence. The author of "Prevent, Treat, and Reverse Diabetes," Broadhurst has been a lecturer and consultant in the natural products industry for almost 20 years.

*This article originally ran on **INSIDER**'s Supplement Perspectives blog.*

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Vice President, Sales, Health & Nutrition
Danica Cullins dcullins@vpico.com
(480) 990-1101, ext. 1200

Strategic Account Director **Amy Thorlin**

Senior Account Executives **Ioana Neacsu**
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