# September 2013 Issue | Loren Israelsen, Esq. United Natural Products Alliance

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Welcome to *Functional Medicine Update* for September 2013. You're in for a real pleasure, and a surprise, and an "ah-ha" moment this month. Let me set the context as to why I would be so bullish about the content of this issue. As you recognize, over the last 25 years there have been some very substantial changes in the way that health is viewed in our country--the dominant disease patterns, the changing dynamics within the industry that we call the health and disease industries, changing in agriculture, changing in commerce as it relates to foods and nutrition products, rapidly continued rise in the prevalence of obesity, increased use of various medications to manage lifestyle disease symptoms and signs. I mean this is a pretty panoramic cultural transformation and transition that's been occurring that surrounds health. In fact, it is interesting to note that some individuals have defined this era of our go-forward history as being the age of health—that this will be the biggest singular issue as we have aging baby boomers, as we have more burden of chronic illness, as we start to see disorders that were at one time relegated to older age now being seen in younger people, like we're starting to see diabetes in teenagers that was called adult-onset diabetes 20 years ago, but now we have to call it type 2 because it is being seen in children. All of these trends are pointing us in the direction that new solutions to problems need to be developed, and this is one of the reasons that we felt that functional medicine, as an operating system for the new healthcare challenges, new healthcare advocacy, could be so important.

### To Understand Our Future, It Is Important to First Understand Our Past

But in order to understand our future sometimes it is important to understand our past. Where did we come from? How did we get here? We've tried very hard in the three-plus decades of Functional Medicine Update to give a historical perspective to what's going on in the now and how that might influence what is going to happen in the future. I'm very proud when I go back and think of the topics that we've discussed over the years in *Functional Medicine Update*, many of which at the time seemed to be maybe at the bleeding edge were actually found to be at the leading edge and became dominant new concepts. Five to seven years later people were talking about this as if it were a great new discovery and was changing our view of certain aspects of health and medicine, and yet if we go back to root origins we were talking about these concepts in Functional Medicine Update almost a decade previously.

So it's important, I think, sometimes to understand where we have come from to understand where we are going. That's really what you're going to be enriched by in this issue of *Functional Medicine Update*. We have the privilege of talking with an architect of one of great transformations in health care that has

occurred within the last 50 years, and that's the transformation that occurred with the outcome of things like organic agriculture, things like the range of botanical medicine products that are now available to the healthcare consumer. Things that relate to the wider array of what Linus Pauling called orthomolecular substances—things that were natural to the human body that would correct certain kinds of metabolic disturbances that were previously not allowed for commerce, and then under the new law of the land passed in 1994 called the Dietary Supplement Health Education Act became available.

Think back, if you would to the rising tide of general understanding of the role that omega-3 fatty acids have in promoting appropriate health, and go back, if you have been in this field for a few decades, and remember the era of the Pritikin regime that said all fats were bad and that the best approach was to cut all fat out of our diet, and now we've come to where we recognize there are certain fats that are good, and in fact we haven't been getting enough of them. Witness the literally thousands of scientific studies that have been published on the clinical benefit of omega-3 fatty acid intake and supplementation. Research and science that has actually transformed the industry, leading to a small sidebar in nutritional supplement family that started off as MaxEPA, an RP Shearer product first sold in the United States as a fish oil supplement in the early 1980s, to where now it is Lovasa sold by GlaxoSmithKline, that has sales of greater than 1.5 billion dollars annually for that product, meaning it is a blockbuster drug in the parlance of traditional pharma.

So these are major transition conceptual things that are occurring, not to mention the sweeping change in the view of medicine, personalized lifestyle medicine, functional medicine, integrative medicine, which are now finding their ways into the curricula of medical schools, and into advanced training and fellowships, and ultimately into new reimbursable programs for intervention, as seen with the Ornish program through Medicare for individuals that have cardiovascular disease. So I think we're in an extraordinarily robust and rich time of transition, and to understand where this transition might take us and the responsibilities we have for stewarding it in the right direction so it really will produce societal benefit and reduce the burden of reducible disease and enhance quality of life for hopefully hundreds of millions of people over the years to come, we have to know a little bit about where this concept was born in the culture of today, and what some of its strengths and limitations are based upon this history.

I went back and said, "Who in my nearly 40 years of involvement in this field would I think would be the best chronicler of this history? A person who has really been at the moments of great change, both an architect and an historian and communicator that relates to these major epic transitions that occurred?" And of course, the name that comes immediately to my mind is a friend and colleague, Loren Israelsen, who is an attorney and is the executive director and founder of the United Natural Products Association.

Loren and I have had the privilege (for me, at least) of spending many, many hours together over the last nearly 30 years, both talking about where the future of this industry and this field might be going, and also talking about responsibilities, and conduct, and standards of identity, and professionality, and what defines excellence so that this will stick and really become a significant contributor to reducing the burden of disease. I'd have to say that Loren has made extraordinary contributions across this wide-ranging platform of both industries and consumer activism and delivery systems that is seen in many different areas of impact. So we're very privileged this month, in our September issue of Functional Medicine Update, to do something we've never done in the history of FMU, and that's to have a discussion—I would call it a fireside chat, an intimate conversation—with an architect of this great social change who has been a principal player in manifesting this change in our culture, and kind of

understanding, from his perspective, how we got to where we are today, what are some of the things that we are very proud of that open the door for future opportunities for improvement, and what are some of the things that we still have work to do, that are still areas that require our vigilance, our diligence, and our commitment to honor these traditions, and to hold them sacred, and to make sure that they are properly applied so that they really will deliver the benefit to society that they have the opportunity to do.

With that in mind, let's move into our extraordinary verbal journey, conducted tour, with Loren Israelsen

## INTERVIEW TRANSCRIPT

Guest of the Month

Loren Israelsen, Esq.
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Here we are once again at that portion of our Functional Medicine Update series that I think is, for each one of us, kind of a discovery process, because we've had the chance to talk with some of the world's great luminaries as it pertains to the way that health care is emerging and evolving, and how personalized lifestyle medicine and functional medicine are playing roles in this emergent global healthcare system. One of the things that I noted as I went back and reviewed the luminaries that we've had the privilege of interviewing is that there was a notable absence of one of the individuals that has had the most significant impact on my understanding and my asking the right questions—or hopefully asking the right questions—about the landscape under which all of this form of health care is delivered, which is the regulatory and legislative landscape. Of course I'm speaking about my friendship and my professional relationship with Loren Israelsen that goes back now more than two-plus decades.

Loren, as probably you know, is an iconic figure in our industry. He's a lawyer by background, working with Senator Orrin Hatch. Later he was very, very important in the guidance of the development of the nutritional supplement and dietary supplement industry first as a senior leader in companies that played significant roles in carving out a legitimacy in this space, and then later as a very important figure, and probably in my estimation the most important figure in working with Senator Hatch, and then later Senator Kennedy and Senator Harkin, in what became the passage of a bill that I think most of us felt, in the 1990s, was very unlikely to be passed, called the Dietary Supplement and Health Education Act. Loren worked with a number of his colleagues and associates tirelessly through the midnight hours, drafting and redrafting, and discussing and modifying the language in the bill that eventually led it to be the law of the land, which has an international global implication as it relates to the use of nutritional supplements, claims that can be made for them, and how it impacts ultimately the healthcare system and individuals' ability to get these products and to use them as part of their health programs.

Through all of this Loren has maintained an extraordinary high-level professional relationship with leaders in congress, with leaders within the industry, with raw materials suppliers, and breeding suppliers, finished product suppliers, and the myriad of different hoops that have to be jumped through, including relationships with the Food and Drug Administration as they started to better understand what their future might look like as it relates to the regulation of this category.

We know that the United States becomes a lightning rod for much of the rest of the world as it relates to its regulatory standards and procedures, and therefore Loren certainly has had a global impact in Europe, Asia, and even in our discussions with our colleagues in Australia as to how things work their way through the regulatory framework as it pertains to nutritional products.

So with that fairly lengthy introduction, I guess the last thing I should I should say is that Loren Israelsen is also one of the great human beings. He's a humanist. He's a broad-ranging thinker, and brings perspectives to our discussions, always, that cause me to have to stop and learn new things. Loren, thank you for being part of Functional Medicine Update, and welcome as a key opinion leader to help us understand a little bit more about this complexity of the regulatory environment of nutritional supplements.

LI: Thank you, Jeff. It's my pleasure.

JB: For those who are not maybe as familiar as you and I are with the history of how we've gotten to where we are today, could you take us back to how Loren Israelsen started down this path as an extraordinarily talented law school graduate—a guy that had spent some time in Japan and learned Japanese who comes back and is on this path now for 30 years. How did this all begin and what were some of the critical steps along your path?

The Nutritional Supplement Industry Had No Roadmap or Guidebook

LI: Like so many things, it was serendipitous. I was finishing law school. I had no idea what I wanted to do, and went to a birthday party. I was living with nine guys in kind of an Animal House set up. We were always ranging around for a meal, and ended up at somebody's birthday party, and the birthday boy was the general manager of Nature's Way Products. We were introduced. He said, "Listen, I could use some help down here," and offered me a part-time job, which I took. That became a summer job, and in turn that became a full-time offer of employment. In 1981, I dove off that cliff and took the position as general counsel of Nature's Way at a time when, to the best of my knowledge, this was the first time a lawyer had gone inside the health food industry to work for a company selling supplements or natural products. The beauty was there was no roadmap, there was no guidebook, we pretty much made the whole thing up as we went, and that was the beginning of what is now a 34-year career in this industry.

JB: Well it's to our advantage, obviously that that transition occurred because I recall meeting you for the first time at the Nature's Way facility in Utah and was very, very impressed with the way that you were thinking on a much more broad base about the future of the industry, and as I recall, were already in discussions as it relates to some of the things that were going on in Europe as it relates to botanical medicines, Schwabbe and Medhaus companies, and kind of thinking about how one could lift the professionalism of the industry and the reproducible quality assurance of products to make sure that what people were buying and using was delivering the goods. Tell us a little bit about how that ultimately evolved for you.

LI: Good questions, Jeff. Yes, as I was involved with the company, I was new to the industry. My family, we had no history or experience using botanicals, dietary supplements, really nothing in the natural products arena at all, so this was all new to me. I was fascinated by everything. As I got to know the culture and the traditions of the industry I was really struck by what a powerful belief system this is, and

that consumers of our products hold a really strong and centered view about how we as humans coexist with plants, animals, biosystems—that this underlying belief was very attractive to me. Today I would consider myself among the believers that have been for decades. But I was as impressed by…I guess coming out of law school, there was a lack of scientific rigor of investigation of research. That is understandable because of the belief system the industry really was nurtured in for so many decades.

As I looked at our company, there were several things that I thought we needed to do: go find the world's best researched products, bring them into our portfolio, and introduce those, such as from Germany, Italy, France. So I spent about two-and-a-half years combing Europe, traveling high and low and side to side, trying to figure out best-of-class products, introducing myself, our company, and went from the early days when I was not taken seriously because everybody in Europe knew that you couldn't take a scientifically researched product to the United States and make a success of it. Two reasons: a very hostile FDA, and an uninformed consumer that didn't have an appreciation for science. So we made a deal that if I could help solve the FDA problem, will you help us solve the science problem? That was a handshake deal. A number of companies in Europe agreed to come over under the Nature's Way banner, and that was so successful that those companies today are the owners of Nature's Way.

At the same time, we were very interested in organic agriculture. I believe it was in 1985 I made a trip to Trout Lake Farms in Washington state, and we developed the first major company program with an organic grower—in this case Trout Lake Farms—to supply against an annual contract requirement—to bring stability to the farmer a strong commercial relationship, and an advertising campaign to begin teaching the rest of the industry that you could grow and produce beautiful, high quality, organic botanicals, which was a new thing. We were also interested in quality systems, and this is where you and I, Jeff, got together along the way as we were fighting the battles of DSHEA, was the need to quantify and qualify the various quality standards that existed for the various categories of dietary supplements, which turned out to be a monumental task that was really the beginning of beginning to sort out in a coherent way, how can consumers understand something about the quality of the products they are buying? It was through that project that a number of wonderful people that who have remained good friends and colleagues I would say now for 22 to 23 years, so those were some of the projects that we were really interested in that I was particularly hopeful that we could develop and make a difference with.

JB: I think you are, as always, understated in your advocacy of the past, because that role that you played in introducing these European pharmaceutical botanical medicine providers to what was going on in the states and then reciprocally understanding what might be needed in the United States to bring these higher quality materials with a different standard of evidentiary support to the states, and then working as an advocate to form the regulatory framework to allow that to occur is no small undertaking; it's huge. Of course, eventually then things like the commission e-monographs being translated and becoming available in the United States, and all sorts of things then happened after that in the concept of organic agriculture, of which there were, many, many other participants and players, but it always takes a few people to lead the division and I think that you did an extraordinary job in kind of having a vision as to what a legitimate industry that was really providing high quality service and products might look like, which then leads me to the next question. Now, how did you first meet or get involved with Senator Hatch and later with Senator Harkin?

Early 1990s: Darkening Skies and Growing Rhetoric from the FDA

LI: I first met Senator Hatch in 1978 when I worked in his office for a short time and was introduced to the unique world of Capitol Hill, Washington DC, and from that beginning, built and maintained great relationships with him and with his office. He always said, from the very beginning: "I am an advocate for Utah." He is a personal believer in natural health and wellness—a very deep believer. After my tenure at Nature's Way—this is rolling forward now to 1990, 1991—I had seen Senator Hatch at an event, told him that we were gravely concerned about the darkening skies and the growing rhetoric coming from FDA that there confrontations that were very explicit indicators that FDA was going to essentially scope down the range of claims, ingredients, and motion that the supplement industry could operate in to the point that after my tenure at Nature's Way, I contacted a number of my colleagues in Utah. We began sit-down meetings and for probably six months we would get together at least once a month and literally on a white board try and figure out what could we do as an industry to protect ourselves against what felt like a certain attack from FDA. We concluded that nothing short of legislation would really solve the problem. We were not naïve, in that we understood that the chances of that happening were so remote that it was unlikely we could interest anyone in Congress to introduce a bill that would rectify the problems we had identified, nor did we think the industry would be supportive of that sort of effort. We were not organized politically to do it. We were certainly not funded to do it. But we thought, "You know what, there is really no other option." We put together a draft of ideas. I flew to Washington, DC and sat down with Senator Hatch, and the meeting was remarkably short. I basically said, "Senator, we've got some deep concerns. We've got some ideas." At about that point he said, "Count me in." He said, "I'll need details and I'll need to get my staff involved, and you will need to go get yourself a good democrat in the House of Representatives to co-sponsor the bill in the house, but if you'll take it that far, let's get this thing going." So in June of 1992, Senator Hatch and Congressman Bill Richardson from New Mexico jointly introduced the bill called The Health Freedom Act, which was the original name of the bill that finally passed in 1994 as the Dietary Supplement Health and Education Act. So literally, it was a simple start—beginning with Senator Hatch—simply saying, "I'm in. I understand the problem, and I will do all I can to help create an environment that provides stability, opportunity, consumer access, to products and information, and where we need to reel back FDA, we'll do it." And sure enough, that's what happened.

The Dietary Supplement and Health Education Act: So Much More than Labeling

JB: You know, these are easy stories to be told in retrospect, but very complicated stories in the real time of the moment. I'd like to take a couple of steps again with you through this process to give our listeners a sense of the spar and parry and the dynamics that occur in these kind of cultural transitions, because this is fairly big impact on society, on commerce, on decision-making, on even health care and even in the broad sense with the passage of DSHEA. I think it is very interesting when I just hear you rename the Dietary Supplement and Health Education Act to remind myself that it was not just dietary supplements, it was health education, the combination of those. It's a very important, I think, positioning, and often I believe that people, when they say DSHEA, just think of it as somehow regulating dietary supplements with a structure/function claim opportunity, but there is much more below the surface that has significant spreading implication coming out of the McGovern Committee reports on diet and health in the country that preceded this, and talking more and more about people aspiring to take charge of their health through implementation of different strategic approaches toward diet, exercise, lifestyle, environment. This was a movement that had broad spreading implications, not just pills in a bottle or powder in a can, that you were spearheading and I think the concept of dietary supplement and health education is much broader in its implications than probably some people, upon reflection, thinking. Who did you go after on the democratic side to be your advocate? I know the answer to this, but some of our listeners may not.

LI: It was an interesting battle that required bipartisan support in the Senate, in particular. We had heard—there were rumors—that Senator Tom Harkin from Iowa was a very interested senior member, and that if we could gain his support it would make all the difference. Indeed we met with him a number of times. In one of the great stories of DSHEA, he said, "I will be there when you need me." Curiously, he did not come on and cosign the bill early on. There was a strategic wisdom in doing that—that at the critical moment when there a big Senate hearing about DSHEA, and if the bill had not been as it is called "marked up" out of that committee, this would have been the end of the bill. The vote was going to be very, very close. Senator Harkin had not yet publicly declared his support. We believed that he would do that. What we did not know was that he would reveal himself not just as a supporter, but as an extraordinary champion, and he gave a statement during that committee hearing that is still one of the great statements of all time with respect to this industry. He made it abundantly clear that he not only supported the bill, he would provide any necessary means of support he could. He told his personal story of being a lifetime allergy sufferer, who had been cured, literally overnight, by using a natural product recommended by a very curious little old man that sought out Senator Harkin, almost as if he intended to appear before Senator Harkin to give him this news personally. It's really quite a mystical story in many ways. But the Senator was indeed cured for life of these allergies, and his support from that moment in 1993 to this moment in 2013 has been unabated, unqualified support for natural health and for dietary supplements. It was a wonder to behold to see him play his cards so carefully, and by his skill was able to save that hearing from defeat, bring two other democrats on to join the bill, and, by a very narrow vote, we survived that critical Senate committee hearing to live another day, and ultimately to win the battle of DSHEA.

JB: So, personalities, people, improbable events…somehow the universe has a warp and weft to it that creates the unexpected, all of which was happening during this interesting period. One of the things that I recall you were confronting was, as you mentioned earlier, could the industry police itself? Would it have the intention of quality that would justify these remarkable steps to redefine legislatively, in the regulatory framework, the scope of practice of the industry. It was that, then, that led you and I to form the Natural Product Quality Assurance Alliance, which I thought was quite an interesting chapter in the industry's evolution. Can you kind of reflect back to that period in the early 90s?

The Political Landscape Has Changed and DSHEA is Under Review

LI: Indeed. What we learned very quickly as we were advocating on Capitol Hill for the right of consumers to have access to supplements and information about supplements, we were being asked the same question over and again: You're asking for a lot. Can you demonstrate to us your worthiness to have these liberties and freedoms, which are unusual in a regulated market environment? In other words, are you capable of self-policing and assuring us that product quality claims substantiation will be adequately respected? We honestly did not have any convincing materials to answer the question, which was the moment of creation of the Natural Products Quality Assurance Alliance, that you and I and others were involved in, to create a compendium of standards, but that required us to scour the industry, have numerous and robust discussions about how do we do these things? We did develop a compendium, which we did present to most members of Congress. It was a critical tool in helping us assure the membership that we understood the concern and that we would address it. However, one thing you learn with great victories is that there tends to be a great period of relaxation and the adoption of triumphant behavior, which means that the hard work of governance often goes neglected. It's my greatest regret, with the victory of DSHEA, that the dual responsibility to continue the hard work of administration of

that law, of developing quality standards, of self-policing our practices and behaviors within the industry, did not match the promise of the bill itself. We continue to struggle with that today. To speak freely, it is the greatest threat to the continued existence of DSHEA. If consumers lose confidence in the quality and integrity of our products, if health professionals are uncertain of their therapeutic and medical benefit, or of their safety, that the erosion of that confidence will ultimately lead to a review on Capitol Hill. As we know, Senator Hatch is in his final term. Senator Harkin is retiring next year. Our historic political leadership is in transition, and this is the critical moment now where we will see whether the industry can bring together a clear and focused agenda to maintain quality, close ranks, protect standards and practices, otherwise that we will be back on Capitol Hill, revisiting the very issues that we thought we had resolved in 1994.

JB: I want to proceed a little bit with that in more detail, but I'd like to go back and pick up a couple of very important things that you mentioned and emphasize them. The importance of single individuals can never be, I think, diminished as it relates to these great cultural changes, and of course your contributions stand very high. And Senator Harkin, who you mentioned, also, along with Senator Hatch, have made remarkable contributions to changing the landscape for health care, so when I think of this period, I'm thinking not only about what Senator Harkin and Hatch did as it relates to the advocacy of the ultimate passage of the DSHEA, but also of the pressure put on the National Institutes of Health to change research and medical training in the area of these products and concepts that was found through the funding of the Office of Complementary and Alternative Medicine, a new division of NIH that didn't exist before, kind of a step-child division at first, but it's gotten a little bit more muscle over the last 15 to 20 years, and that was born, really, out of this whole zeitgeist—this whole similar intellectual endeavor that was being spearheaded had broad-ranging, sweeping effects on not just consumer understanding and availability of these products, but health education and later even medical understanding of these products and how they play a role in health care. It sometimes may be difficult for people to see how these points of the curve are all interconnected to form a new functional status, but I think as you look back you must take great pleasure in seeing the spreading effect of these concepts in terms of cultural transitions and recognition of the viability of this model for disease prevention and health promotion.

LI: Oh, there is great pride and a sense of "We really did something useful and important with DSHEA." We went into that very narrowly focused battle around what we now call dietary supplements, but have to remember that until this law passed, we didn't even have a legal definition of what it is we were fighting for. That was one of our problems. We just had no framework to deal with. Perhaps the most striking lesson is the enormous power of the grass roots that rose up to support DSHEA from 92 to 94. It was far greater than anything we realized existed. And for me it was a revelation in understanding that within the American cultural tradition there is a very deeply held sense of health populism, that consumers here, unlike any other country that I'm familiar with—and I've done a lot of traveling—have a sense of a right and entitlement to knowledge, to access to products, unlike any other country. That creates a populism when these issues end up being politicized, and this has happened in the 1950s, the 1970s, in the mid 80s, and again in the mid 90s; the same thing has happened over and again. And in fact, the roots of this goes back to the 1830s and 40s with a guy named Samuel Thompson that was going door to door selling small, medicinal herb seed packets and little booklets to housewives, encouraging them to grow medicinal herb gardens. His books provided medical advice and so on. He was routinely hounded by physicians and doctors of the day, told that he was a quack and practicing medicine, and that this was their exclusive domain. Samuel Thompson was to a large degree protected by a cadre of housewives that were thrilled at the prospect of growing their own plants, having their own medicine, which they made with their hands.

That tradition is unchanged to this day. This is what we have learned. So that other industries—the pharmaceutical industry, the packaged foods industry, the information industry, practitioners of all sorts—sat up and paid attention in 1994, realizing that something big had happened here, that there was a tremendous consumer base for these products. And the post-DSHEA world was immediately all about, how can we get into this? And that was Big Food, Big Pharma, Big Medicine all trying to figure out, what the magic here? There is lightning in this bottle and we don't understand what it is, but it's big, it's powerful, and they spent a great deal of time and money—and still do—trying to figure out how can they create legitimacy with natural health shoppers. So we had no idea, Jeff, going into the post-DSHEA period, that we would change not just the regulation of dietary supplements, but entire categories of other products and classes of service that are fundamentally changed because of what happened with this one category of dietary supplements.

JB: That was beautifully stated and I was reminded, I think it was 2010 when I attended, as did you, the meeting on complementary and alternative medicine sponsored by the Institute of Medicine. I think this was the first time ever that the National Academy of Sciences, with its outreach to the IOM, sponsored, in their Washington, DC, headquarters, a cooperative meeting among different representatives of this field called complementary and alternative medicine that was really born out of that same period as we're discussing of DHSEA. This all kind of came together, and Tom Harkin (Senator Harkin) played a role in the formation of the CAM division, or the Office of Complementary and Alternative Medicine within NIH, so one can see the spreading effect ultimately rising up to what might be arguably considered the high standard of scientific evidence, which is the National Academy of Sciences and the Institute of Medicine, where these topics were seriously discussed, and as I recall Senator Harkin, who gave a keynote speech at that meeting, became one of the great advocates for broadening our perspective of health care, broadening our perspective of medical services to include these concepts that were born out many of the discussions that happened in the early 90s that led to the passage of DSHEA. It's a remarkable example of cultural transformation, I think, that occurred during that period.

LI: It was very formative, and only now—with the benefit of 20 years of look back—can we begin to piece together the real effect that this has had, just as you have described. That the concepts of health and wellness, the emerging understanding of personalized medicine and personalized health care in many respects find their roots that were manifested through DSHEA, but we also could look at DSHEA at those beginning points and look back again in time and realize that the foundations on which that success in the mid-90s was based on was truly predicated on other foundational transitions and transformations, but it's the same pattern; it's a repetition of the same theme. But generationally it's all new to us, and no doubt there will be another generation following us that will rediscover the very same powerful current of populism, self-determination that Americans specifically, based from the political point of view, profoundly want to understand how to hold and retain the ability with knowledge and products to stay healthy and well, and are far less interested in institutionalized answers. Our task going forward is to meet that new challenge. As information now flows so quickly, as the power of individualized knowledge about our personal genetic history will become so accessible, is to understand once again, how do we understand this new science? Not be afraid of it. Not reject it. Flow with it, so that we can be a part of the DNA of this evolutionary process going on right now.

JB: That's really, really beautifully insightful, and I think it codifies so much of what we've been trying to do in Functional Medicine Update over these 30-plus years in continually raising the bar of understanding and allowing people to get what I call this virus of knowledge in their nervous system that

becomes infective, so that they can see that there is substance, and value, and reproducibility/authenticity to these concepts that deliver improved patient outcome and improved health outcomes. There is one little vignette I'd like you to share, which is just an anecdote, but you tell the story so well and I think people that are not familiar with it will enjoy hearing it, and that is the seminal moment in the passage of DSHEA and the interrelationship with Senator Ted Kennedy. I think that that might be an interesting little part of how sometimes the magic that occurs in the moment is totally unexpected.

Tense Moments as the Clock Ticked Down: How Last-Minute Negotiations Passed DSHEA

LI: There were a couple of moments of truth. There were three that I'll do very quickly. The first was another hearing in the Senate, that Senator Kennedy was chairing, and he and Senator Hatch had an extremely close personal relationship, but on this issue they profoundly disagreed. This was another critical hearing, and it was our understanding that Senator Kennedy wanted to postpone the hearing to collect a few more votes to vote down the bill going through committee. Senator Hatch insisted on the vote. We were in the gallery and we were terrified that a big mistake was about to be made, that the bill was going to be lost right before our eyes. What we did not know is that Senator Hatch had rounded up enough votes to win, and Senator Kennedy looked directly at Senator Hatch and said, "Orrin are you sure you want to do this?" And he said, "Yes, Mr. Chairman. Let's count the votes." The room was electric with energy. Sure enough, we won by, I believe it was, two votes. The room erupted into cheering, and that is bad protocol in the Senate. Senator Kennedy took his gavel and hit it so hard on the table calling for order the head of the gavel broke off and flew off into the middle of the room. It was a fantastic moment.

There was a second meeting at the very end, which was an intense negotiation between all of the principals. It was Waxman, Dingell, Kennedy, Hatch, Harkin, Richardson, all gathered in a little closet room on Capitol Hill, trying to come up with a very last minute agreement. At one point Senator Kennedy pulled Senator Harkin aside. They had a private chat and he said, "I will support this, but I need your personal promise that you will help see this thing through and that the industry, who I really don't trust, will behave itself, and that you, my fellow democrat, need to make sure that happens. Do I have your assurance?" And Senator Harkin said, "You have it." The final moment was literally probably five or four minutes before the end of the 1994 congressional session, and our bill was up for unanimous consent, which was the only way it could pass. We were told the bill should come up at about 9 pm. Nine came and went, 9:30, 10, 10:30 came and went, and our bill was nowhere to be seen. We were very concerned about foul play at this point, and sure enough had found that another senator had put a hold on our bill, and all they had to do was wait it out, the bill would die, and would never be seen again. We thought that Senator Kennedy had done this, but couldn't believe it because he was really a man of his word. Senator Hatch found Senator Kennedy on the floor of the Senate with about four minutes to go. This was about 11:23 pm. The clock is literally counting down below five minutes, and there was a very heated exchange between these two old friends on the Senate floor. Senator Kennedy said to Senator Hatch, "I promise you it's not me. It's not me." And we found out, within about 30 seconds, who it was, and one of the great standoffs in congressional history occurred. The other senator, who was retiring that night, had secretly put a hold on our bill, but he had federal judges that required senate confirmation. So I won't finish the story because you can fill in the blanks, but at the very last minute there was both the passage of DSHEA and the confirmation of federal judges from one state.

JB: It's so rich. I so appreciate your sharing this. This is a legacy that—on so many levels—is a teaching

moment for all of us, about perseverance, about serendipity, about, you know, sometimes things are right even against what appears all odds and they happen against all probability, so very remarkable. And it also reminds us how important and sacred this bill became in changing the architecture of health care in the country, but also the responsibility that it places on all of our shoulders to preserve its integrity and to stand up to that commitment that Senator Harkin made to Senator Kennedy to guard the implementation of this in ways that would maintain the proper intention of it. Which then relates to you and your professional evolution because you turned around and formed this organization that has become a standard bearer for quality, and integrity, and kind of a watchdog of the industry (a participatory watchdog, I would say), which is really engaged in a form of information, self-regulation, and that's the United Natural Products Alliance, which is just celebrating its 20th anniversary. Congratulations. I can't believe it's been 20 years. Tell us a little bit now, as the UNPA—your organization that you founded and are executive director of—has come to the 2013 threshold and we've got this new emboldened FDA that is relooking at DSHEA and looking at the provision under what is called new dietary ingredients, which is a look-back now as to what's been going on in the industry, and what's good news and what's not-so-good news. What's your view of where we are and how this interrelates to some of the opportunities going forward?

Work on Refining and Enforcing DSHEA Continues in a World that has Changed Since 1994

LI: Yes, UNPA was formed in 1992 with the express purpose of advancing what became DSHEA. When the bill passed, we saw a mandate to work towards a full implementation of the bill. We're here nineteen-and-a-half years later still working on it. Much has yet to be done, as it turns out. A major bill very often takes roughly a generation—20 years—to see whether it will be truly and fully implemented. It's surprising to me that here we are still working on some fundamentals, unfortunately. Organizationally we're really focused on safety, science, and quality. Within that, we're looking at DSHEA implementation. That really focuses on good manufacturing practices. The industry has not yet fully adopted the common standard of GMPs that is adequate. There is too much variability in quality. That's a great concern to us. That the world has changed since '94, that we live in a highly globalized supply chain. It is extremely difficult to track and trace the source of your ingredients in that global supply chain. We're doing a lot of work trying to create systems and mechanisms so that companies will have a much better idea of their ingredient pedigree, so that we really have confidence in the global supply chain, which is not going to go away; it will just become more so. FDA has proposed a guidance regarding new versus old dietary ingredients. That's important because DSHEA created a grandfather date of October 1994, that old ingredients that were on the market at that time would not need to undergo additional or new safety reviews unless there was some evidence of a problem. However, going forward, new ingredients—and this is the question: what is a new ingredient?—need to go through an FDA review process. We agreed to this and think that's appropriate. The problem is that FDA's definition of that process is at odds with ours as an industry, so we are trying to work out a compromise to be able to move forward. I anticipate some problems and some disagreements yet on that.

Another area of great interest is adverse event reporting. This was created by a separate law from DSHEA, but is bolted onto DSHEA in so far as dietary supplement companies have to surveil and report to FDA if there was a serious adverse event. That helps us understand if there is a trend either that is cause by ingredients, where the safety in the broader population tends to be unpredictably unsure, or if there is a blip in the supply chain with an unsafe ingredient that gets into the supply chain. This is an important measure. It's critical that companies have good systems to implement it. We're big supporters

of trying to make sure that that is being done correctly. We're also very interested—you and I have talked about this a lot, frequently—the role of information as it flows to consumers. What we have to always remember is, when we look at important moments in history it is to try and remember what was life was like at that time, and in 1994 this was just the beginning of the internet and the worldwide web, and for many email was still new. Cell phones were very crude and not particularly useful. As we look back on how people were able or not able to get information, we had no way of imagining that the problem would be too much information that is undifferentiated, and the source and origin of that information would be so plentiful that the trick was not how to be able to protect people's access to information, but now it is how do we filter and qualify high-quality sources of information. That's what consumers really need. We're still, like everyone else, trying to figure out how to do that. Our law was built around the idea that the government would try and prevent the flow of information, but the government didn't understand either that they would not be able to stop what has become a globalized information network. So that's a real point of interesting concern to us, is how do we manage information, because was a very critical part of DSHEA (protecting the ride and flow of information).

Those are among the things that we're really focused on right now. We have other issues of great interest that we're working on, but DSHEA-related, those continue to be our high-activity focus points.

JB: Loren, I think what you just provided us in these last minutes is truly epic; it's seminal. I'm sure you've told the story many, many times to many different groups, but I think this may be the first time that this has been codified for a medical audience globally that are functional medicine devotees. I think it gives every one of these listeners a much clearer perspective as to the landscape of this extraordinary changing environment that was really borne and germinated out of the early 90s and the response that ultimately became DSHEA and how that affected NIH with the formation of the Complementary and Alternative Medicine office there, and how that led to increased funding and now a well-over 150 million dollars annual budget of the NIH for funding of research into this area with raising the bar for science-based information, and how that led to the formation of the GMPs for dietary supplements that are changing manufacturing policies and procedures, and how that led, then, to changing communications through the support of structure/function claims. All of this has a global impact on health care. I think that a lot of this goes back to the advocacy, the vision, and the tireless work that you've put into this field over these many 30 years. I want to thank you for this narrative, but more thank you for what you've done. Anyone that is not familiar with UNPA should go to the website UNPA.com. It's interesting that you've still got on your team Peter Rieneke and Patricia Knight, who were working with you through Senator Hatch in DSHEA way back when. This is a body politic of knowledge that is second to none in the universe. I think that this next step forward for not just the industry, but the interrelationship with health care at large is going to be of critical importance in this time of rising burden of chronic disease globally and the fact that drugs don't seem to solve these problems and that we have to find new solutions and have to draw from a legacy of experience that a lot is rooted in—historical healing methods and a healing environment—which is in this industry and the things that you've advocated. The test is upon all of our shoulders as we go forward to make this really stand up and be meaningful in reducing the burden of illness and improving people's capability to live long healthy lives. Thank you so, so much for all that you've done and for sharing this with us. This will be an epic discussion.

LI: Jeff, it's my pleasure. A real honor to spend the last hour with you, and I salute you for everything you did in the critical moments of DSHEA. I think without your steady hand and deep insights I don't know if we would be having this conversation today.

JB: Thank you and we'll keep in close touch with you and UNPA. More yet to be seen. Thanks so much.

LI: Thank you, Jeff.

## Bibliography

No articles were cited in this issuep>