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Interviews

"Dietary supplement quality is a question of commitment."

An interview with Loren D. Israelsen
30 July 2001

Background

Perhaps no individual represents the dietary supplement industry more effectively than **Loren D. Israelsen**. As an attorney, policy maker and corporate leader, Israelsen has served as president of Nature's Way, Issues manager for dietary supplements to the Trans-Atlantic Business Dialogue (TABD), and advisor to the federal Office of Dietary Supplements. His work as executive director of the Utah Natural Products Alliance was instrumental in the introduction and passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994.

Israelsen is a frequent lecturer on policy and commercial issues affecting dietary supplements and has published numerous articles in the field. He currently serves as president of the LDI Group, a strategic consulting firm with clients in the functional food, pharmaceutical and dietary supplement industries.

In response to a request by *SupplementQuality.com* editor Wyn Snow for his thinking on the major issues facing the supplement industry today, Israelsen commented via phone and email. In this important interview, he focuses on efficacy research, health claims, safety, product quality, and global harmonization of government regulation.

Efficacy

SQ: One important challenge facing the supplement industry is proving the effectiveness of products. What do you see as

Privacy policy

Sponsorship

the best means of conducting further research?

Israelsen: Proving efficacy for dietary supplements is complicated by the fact that they are made up of a variety of differing chemical compounds. The gold standard in research, of course, is the placebo-controlled, crossover double-blind study, which was principally designed to test single chemical entities against placebo.

However, many of our most important supplement products do not behave in the body like single chemical entities, which is one of the virtues of supplements. The diverse nature of plant extracts, even within the same species, makes it considerably more difficult to assess their effectiveness in controlled studies.

This diverse biochemistry is also one of the criticisms of supplements. How, for example, would one test the anti-cancer effects of antioxidants or the energizing effects of Siberian ginseng using placebo controls in a study population of 200 people? This is obviously difficult to do and historically has not been done for both economic and common sense reasons.

This is why bibliographic, open studies and traditional wisdom are widely relied on by sellers and users of dietary supplements. It is also the basis of a different approach to regulating and approving botanicals as drugs in Western Europe, Asia and elsewhere. The US is singularly unreceptive to accepting non-double-blind evidence as the basis of efficacy for botanicals and other dietary ingredients.

There will be little important privately funded research on dietary supplements until there are financial rewards -- such as drug exclusivity, patents or reimbursement. It appears the most effective way to conduct significant new research is to get the government to pay for it, as we now see at the National Institutes for Health (NIH) with St. John's wort and several other botanicals. If these studies are positive, it will be a major boost for the industry and the studied dietary ingredient. If they are negative or inconclusive, there will be the sound of air escaping from the tires of the industry.

While I am enticed by these pivotal NIH studies, this approach is really risky. Typically, it takes several studies to reach consensus on the true utility and

safety of any substance, especially in the natural products arena.

I see a great need to create research incentives for dietary supplements. Until this happens, there will be very little new news on the efficacy of this class of products.

SQ: Much research about supplements is characterized as "flawed" by the medical community. Is this just smoke or is much of the extensive research truly inadequate? (There are upwards of 400,000 titles in the IBIDS database (International Bibliographic Information on Dietary Supplements), created and maintained by the federal Office of Dietary Supplements.)

Israelsen: To most doctors, any study is flawed if it is not a placebo-controlled, crossover, double-blind study. Current medical science discounts bibliographic, personal case reports or observational studies as nothing more than anecdotal.

I don't question the statistical power of the double-blind study, but I do question its relevance when such studies are used as the basis for approving drugs that will be used by millions of men, women and children of all ages, races and with broad genetic differentiation. This is partly why a number of drugs are withdrawn from the market, because they have proven to be very dangerous when placed in a broader genetic population.

This is why many consumers take comfort in using supplements that have long human experience even though double-blind studies are absent. Doctors have been sold on a specific style of research as the only credible one, while most lay persons are sold on what they sense, feel and gain from shared experience with others.

SQ: What about communicating the results of existing research?

Israelsen: The best way to communicate the results of existing research is to put it in front of people's faces -- on the label. Of course, we are now talking about drug claims, not nutrient or structure/function claims. We have reached a plateau on label claims. Structure/function claims were a rising tide phenomenon. The public is now much more aware of the general use of many botanicals and other supplements. but generically so. Few consumers can

tell which product is a useful one and which one is a phony. There is a lot of room to improve the present situation with respect to claims and research incentives for supplements.

Health claims

SQ: What about the ruling by the federal Food and Drug Administration (FDA) on the health claim for saw palmetto?

(A petitioner sought to use a claim supported by approximately two dozen research studies that saw palmetto is effective for easing symptoms of benign prostatic hyperplasia or hypertrophy (BPH) disease, which is a non-cancerous growth in the prostate gland. Roughly 80% of men over the age of 40 have urination problems caused by BPH.)

Israelsen: The FDA's denial of the saw palmetto/BPH health claim petition is no surprise. There are lots of reasons for this. Saw palmetto is not a nutrient -- which is a critical precondition for a health claim. The proposed claim is a chronic treatment and not a prevention claim, which is also a novel aspect and which the FDA is resisting. Nobody eats saw palmetto as a food or food ingredient, so it is not eligible for the *generally recognized as safe* (GRAS) food ingredient category.

Should saw palmetto be approved as drug? In my opinion, the answer is yes. Will the FDA do this? I hope so, as it is probably the best product we have with respect to the risk/benefit equation for a condition that is non-malignant, self treatable and chronic. It fills a therapeutic gap for many men who don't need to rely on a prescription drug for early stage BPH. If the FDA refuses to accept saw palmetto as a legitimate treatment for BPH, it will be time to go see the Congress again.

SQ: What about the herbal new-drug guidelines published by the FDA? Do you see this having any effect on the marketing of herbal products? (Only products approved as drugs by the FDA are allowed to make health claims.)

Israelsen: The FDA published a guidance for botanical new drugs to clarify what it expects of a plant drug. There is nothing really new or different in this document except to formalize a heretofore unwritten set of views and policies within the FDA.

There will be no immediate effect on the present herbal market because of this new guidance. but if a

botanical new drug application is approved by the FDA for an important product (such as ginkgo or St. John's wort), this would be big news and would likely give the whole herbal category a big boost due to the halo effect.

Safety

SQ: Another big challenge facing the supplement industry is supplement safety. We keep seeing headlines whose underlying message is: "Supplements are dangerous and unregulated."

Israelsen: Proof of safety is really an equation:

$$\text{Safety} = \text{Benefits} - \text{Risks}$$

Critics of our industry accept the risks and deny the benefits, which equals *unsafe* in their minds. The Dietary Supplement Health and Education Act (DSHEA) of 1994 defines a safety standard for supplements, which assumes a higher benefits factor and relatively low risk factor. This is why our critics don't like DSHEA. It is the risk factor!

SQ: How best can the industry address issues like the controversy over identifying the specific risks of using ephedra products? (For the most part, industry spokespersons state that ephedra is safe when used as directed. The FDA and some people in the medical community believe that ephedra is dangerous and has caused severe side effects, even several deaths.)

Israelsen: Naturally, the risk-to-benefit ratio among various supplements is different. Ephedra is chemically and pharmacologically active and has a higher risk factor, but to many users, it also has a very high benefit factor (energy gain and weight loss).

High risk-to-benefit ratios always mean controversy. Americans are disserved when we treat all supplements as having the same levels of risks and benefits, because they do not. Clearly, some supplements require special labeling, controlled potencies, limits on how long they are used, etc. DSHEA allows for all of this.

SQ: Similar controversies have occurred with chaparral and comfrey; kava is looming on the horizon. Are questions about high risk factor supplements best addressed on a

product-by-product basis? Would it be better to create a new category for "potentially hazardous botanicals"? Or would this undermine the status of all botanicals?

Israelsen: Creating a separate category for potentially hazardous botanicals isn't necessary. Such products have been and will be dealt with on a case-by-case basis with existing law and regulations (comfrey, chaparral, aristolochic acid, and GBL are good examples).

Product quality

SQ: Another big challenge facing the supplement industry is a perception on the part of both the public and media of serious gaps in the quality of dietary supplements. ConsumerLab's testing program addresses one corner of the "do the contents match the label" issue. What more needs to be done industrywide?

Israelsen: Dietary supplement quality is a question of commitment. We know what it takes to make a properly sourced, tested and manufactured supplement. The problem lies in our apparent inability to hold ourselves, as an industry, to a high common standard.

This is a matter of resolve and self-governance. To the extent that bad products (defined as failure to meet label claims) are available to consumers, we are all diminished as an industry. As we have seen in ongoing exposés focused on quality failures, tragically DSHEA is blamed for this. As a result, we are in danger of losing our most important success, because we apparently cannot behave ourselves.

The FDA has failed to inspect facilities or bring appropriate enforcement cases when and where they should. Most of the industry's trade associations have urged the FDA to do so. The FDA claims they don't have the money to do it. In response, the industry's trade associations have urged Congress to allocate monies for specific enforcement activities to address this problem. The industry has also urged speedy publication of proposed good manufacturing practice (GMP) regulations. So far, we wait in vain.

Personally, I am at a loss to explain why the industry has been so tolerant of shoddy products. As always, this appears to be an 80/20 (perhaps 90/10) rule. Most companies make a real effort to sell a quality

product and for the most part do so. Those that can't or don't meet basic standards of quality should be drummed out of the industry as fast as possible.

The global economy and harmonization of supplement regulations

SQ: The global economy is bringing new challenges to the dietary supplement industry. The various nations of the international community maintain separate regulatory environments for supplements. In particular, DSHEA has allowed Americans a higher degree of health freedom than our European counterparts.

Efforts to harmonize regulations internationally focus on the Codex Alimentarius (of the World Health Organization), as well as other organizations, such as the Trans-Atlantic Business Dialogue (TABD). You are involved in some of the ongoing harmonization discussions. What do you see approaching on this horizon?

Israelsen: Globalization is a fact, and it is going on as we speak. Harmonization is a result of globalization, and so the question is, what countries and what organizations will set the agenda for the rest of the world?

Codex has become the battle cry for those opposing both globalization and harmonization, fearing that DSHEA will be displaced by international treaties to which the US is a party. The supplement industry as a whole opposes a "Codex-style" framework for dietary supplements. Collective efforts to oppose the present Codex initiatives are working. The Transatlantic Business Dialogue (TABD) is a useful effort in this respect, as is the work of the International Alliance of Dietary Supplement Associations (IADSA).

As always, international initiatives require a lot of time and patience. Fortunately, there are a lot of skilled and committed people in the US and Europe working to identify and resolve threats created by Codex and other initiatives that would move us in the direction of unnecessary and unwanted regulation.

SQ: The TABD is encouraging US and European regulatory bodies to develop standards for "safe upper dosage limits", which it intends to promote as maximum dosage levels for supplements. However, a fair amount of scientific controversy surrounds the question of how to determine

what these safe upper limits and maximum dosage levels should be. (For further details, see SQ's [interview with Robert Reynolds](#) and story on [RDAs and Safe Upper Levels](#).)

Israelsen: Safe upper limits is a big issue. Both the US and European dietary supplement groups are very conscious of finding the right upper limits, meaning maximum potencies that are safe. The key issue is not to approach this from a minimum-nutritional-needs perspective. That is the thinking we are opposed to.

SQ: The World Trade Organization (WTO) is another potential influence on the harmonization of supplement regulations. The WTO has international jurisdiction in resolving regulatory disputes between countries that have signed various free-trade treaties. Is this a threat to DSHEA?

Israelsen: This issue involves treaty obligations that flow from the fact that the US is a signator country to WTO agreements. I have asked a lot of people about the commitments of the US with respect to domestic laws (like DSHEA) and national commitment to the WTO -- which may be inconsistent with DSHEA. I have not yet gotten a good answer, and so I remain concerned about this specific issue.

Afterword

Israelsen's remarks shine a spotlight on ways that industrywide quality standards might solve several problems that have undermined consumer confidence in supplements and flattened industry growth. More directly, his comments bear on key issues relating to safety, efficacy and overall product integrity.

The most reliable method of drumming shoddy products out of the industry under a self-regulation model is to create a clear means for consumers to distinguish good from bad. Underwriters Laboratories (the familiar UL symbol) have done this for a host of electrical and other products. ConsumerLab and others are doing something similar for supplements by putting a quality seal on the label of approved products. Other industries have established self-regulatory bodies that debate quality issues and establish quality standards. Why not supplements?

As Israelsen points out, the industry's failure to govern itself puts DSHEA at risk. If new legislation were to be passed into law that authorizes the FDA to pre-screen new supplement products, it well might create gridlock for product development, drive prices of new products through the roof, and make it more difficult for consumers to get full, accurate information about supplement health benefits.

Supplement companies, trade organizations, and the FDA have come together to develop rigorous test methods for botanical materials at the Institute for Nutraceutical Advancement. Surely a similar umbrella organization can be formed to hammer out ongoing consensus on standards for product quality, efficacy research, safety issues and appropriate label warnings for individual supplements.

What's needed is leadership -- for individual consumers, industry leaders and health care providers to come forward and say, "Let's get this done now." ■