

## Industry Needs To Re-Think DSHEA

30 April 2003

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***Industry leaders must address the realities of a post-DSHEA world by looking in the mirror.***

The Dietary Supplement Health and Education Act (DSHEA) became law nearly 10 years ago amid high hopes that barriers to growth and FDA's overreaching were behind us. Prospects for long-term expansion and sustainable markets seemed assured.

Fast-forward a decade, and the reality is far less rosy: DSHEA is under attack and its future uncertain, as is the future of the industry. Due to lack of self-regulation, greater business risks, self-destructive behavior and most importantly erosion of consumer trust, the supplement industry is in crisis.

The crisis is captured in a recent press release issued by a well-known dietary supplement company as part of its forward looking statement disclaimers. In addition to the standard risks and liabilities the disclaimer referred to new risks and costs illustrative of virtually the entire dietary supplement industry.

These new risks included:

- Slow-to-negative growth in the industry;
- Adverse publicity;
- Adequacy and availability of insurance coverage (particularly for products containing ephedra);
- Exposure to and expense of resolving product liability claims and other litigation; and
- Limitations on future financing (increases in the cost of borrowing and unavailability of capital).

Like certain other manufacturers, the company that published these disclaimers recently said it would discontinue ephedra products. Spiraling insurance costs, plus the risk of product liability claims (risks that could do more to change our industry than even regulatory change) likely contributed to the decisions.

Unfortunately, merely defending DSHEA will not save the supplement industry. In a December 19 issue of the *New England Journal of Medicine*, two articles were published with familiar titles and related themes: "Herbal Medicines—What's in the Bottle?" and "Botanical Medicines, the Need for New Regulations."

The latter article, authored by two MDs, called for six changes to the regulatory system:

1. mandatory registration with the FDA;
2. following GMPs and allowing FDA to inspect records;
3. pre-market approval of evidence showing that products "present no substantial/unreasonable risk of injury";
4. reporting all adverse events to FDA;
5. unambiguous labeling of ingredients and interactions; and
6. convening HHS expert panels to review the safety of all dietary supplements except essential nutrients and single/multivitamins.

The industry responded appropriately, saying that DSHEA has adequate authority to deal with most of these issues; however, this response must also include action from the industry.

## **Facing Up to Reality**

How did we go from boundless potential to besieged industry, and what can we do to secure our future? We believe that five key realities must be addressed: 1) Defending DSHEA will not save the supplement industry; 2) Discipline, not regulation, will create a sustainable marketplace; 3) Popular political support has eroded; 4) Too many companies are competing for too few customers; 5) Negative media is a symptom, but not necessarily the problem.

### ***Reality # 1: Defending DSHEA Will Not Save the Supplement Industry***

There is growing discussion that the next great challenge will be defending DSHEA in the next Congress. However, defense of DSHEA should not be a defense of our misdeeds, but it should recognize our failure to abide by the principles laid down by DSHEA. The task is to build on the foundation of DSHEA, which means accepting the need for modifications to our treasured law in the interest of all parties. A zealous, unthinking defense will likely fail and only sharpen critics' resolve to force an even greater overhaul or possibly a repeal.

The fact is we already live in a post-DSHEA world. Passage of the Public Health, Security and Bioterrorism Preparedness and Response Act of 2002 (Title 3—Protecting Safety and Security of Food and Drug Supply) grants FDA broad new powers to stop "suspicious" goods from entering the country, inspection of food facilities and access to company records. This law specifically includes our industry and when implemented by late-2003 could have profound implications for products that may have possible contamination issues, such as herbal/botanical ingredients. In addition, the January 2000 Final Regulation on Structure Function Claims stripped away our ability to promote the benefits of key categories like allergy, cold & flu, blood pressure and cholesterol management. In short, the world that we thought we created through DSHEA no longer exists.

### ***Reality # 2: Discipline, Not Regulation, Will Sustain the Market***

It is truly a myth that we are unregulated. In fact, many industry observers believe that there are plenty of regulations that have, for one reason or another, not been enforced by the FDA. Congressman Frank Pallone (D-NJ) pointed this out again in a strongly worded letter to the new FDA Commissioner Dr. Mark McClellan on Dec. 20, 2002 in response to recent statements. Pallone wrote, "The agency's actions and omissions to act (in spite of industry's repeated requests for guidance and cooperation), contribute to the myth that the industry is unregulated, add fuel to the recent controversy regarding the use of certain dietary supplements and do a disservice to the American consumer."

We believe that FDA's failure to enforce should be addressed by the new Commissioner before he throws too many stones. However, it is also self-deception to believe that more regulation alone will restore order and public confidence. With the rules already on the books widely regarded as adequate, what is urgently needed is the will to self-regulate. We do not have the time or luxury to believe that new GMPs alone will solve quality problems.

DSHEA cannot bring order to the industry; it was never intended to do so. The purpose of DSHEA was to correct the behavior and excesses of FDA, which it did with alacrity and astonishing force. Just as we demanded that FDA be held accountable, so we are now being held to account. Self-regulation is the short-term answer to the barrage of public criticisms and sinking consumer confidence—and if we don't show a willingness to do it, the FDA and others will do it for us.

### ***Reality # 3: Popular Political Support Has Eroded***

Historically we have been economically insignificant but politically powerful. The consumer base upon which we relied as a political buffer was ideologically driven by a belief in natural self-care and a desire for self-reliance. This is why consumers shop at health food stores and why they react to any threat to free choice or access to supplements. The supplement industry of 2002 looks very different. Ownership has shifted from private to public, and management from entrepreneur/founders to professional executives. As a result, the industry has replaced activism with profit goals and risk aversion.

### ***Reality # 4: Too Many Companies Compete for Too Few Customers***

DSHEA was the "big bang" for the dietary supplements industry. The sudden confirmation of our existence (and legitimacy) caused a chain reaction of capital investment, distributor and retailer expansion, positive news coverage and above all a supreme sense of self-confidence.

In all of this, we like other industries (e.g., telecom and dot-com) forgot the big issue: Don't lose your consumer on the way to the bank. The industry made its move to the mass market but did not truly capture the mainstream. We have far fewer committed consumers than we need, and we have fallen into the unfortunate habit of driving away those that remain with quality and safety embarrassments, herb/drug interaction concerns, and unsubstantiated claims. Since the beginning of the year, the authors have each received hundreds of unsolicited email offers to reduce our weight by 20%, reverse the aging process by 50%, or expand the size of our male organs by 100%.

Fueled by low barriers to entry, the industry is quite simply too big for its consumer base. We operate in a maturing industry knocked off kilter by consumer confusion and lack of confidence in product efficacy and quality. Until a state of equilibrium is regained, we must attract new customers or contract.

DSHEA dissipated most of its energy early on and can no longer provide enough momentum to sustain growth. Except for GMPs, all operative provisions of DSHEA have been implemented. We are now in the regulatory phase of establishing order by clarifying operational and marketing practices rather than reordering the statutory framework.

### ***Reality # 5: Negative Media Is a Symptom, Not the Problem***

The media has increased its negative-to-positive ratio on supplement stories from 2-to-1 in 1998 to 7-to-1 in 2002. The press must be managed more proactively. For better or worse, the media does drive sales. The best thing companies can do is fix some of the fundamental problems articulated here so the media has fewer negative stories to report.

## **A Solution**

DSHEA is not a shrine but a legacy. It should be viewed as a living instrument, both flexible and adaptable enough for changing times. We must change too. One opportunity is to support the expansion of functional foods and traditional medicines, where many dietary ingredients still have great potential. Our task is to approach the future not fearing the demise of DSHEA but rather seeking to address and solve our immediate problems while we reassess DSHEA, its guiding principles and how they can best serve our consumers and therefore ourselves.

The industry must also demonstrate that it can indeed self-police. In the realm of advertising, steps are being taken to create our own version of the National Advertising Division (NAD) of the Better Business Bureau (BBB), a highly successful model used by advertising agencies to self police unsubstantiated and false advertising copy. FTC has indicated a strong interest in working with companies on this initiative.

Another proactive model is being tested by Omega-3 manufacturers, the Council for Responsible Nutrition, and legal counsel, which have formed a task force to address quality standards. This culminated in a voluntary monograph for labeling and quality for marine-based Omega-3 products. The program goes into effect January 1, 2003 (see [www.crnusa.org](http://www.crnusa.org)).

Quality testing company ConsumerLab.com recently awarded 12 supplements an average passing rate of 73%, with a low of 41% for ginseng and a high of 96% for Co-Q10. Although its methodology has been challenged by some, it has filled a self-policing niche in the industry. We predict that the next round of ConsumerLab results for Omega-3 will rise from 70% to a greater than 90% pass rate. We challenge the rest of the industry to reach a minimum of 90% on this index by next year, closing in on 100% by the time the winner of the 2004 election for President is inaugurated.

Whether DSHEA survives rests entirely in our hands. If history is any guide, we can expect even more dramatic change if we prove incapable of managing ourselves under the rules we created.

## Sources

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