



DSHEA 10 Years Later: How Did We Get Here?

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NFM Reader Opinion

The stars are aligned for an assault on the Dietary Supplements Health and Education Act intended to result in its amendment, or possibly, its repeal. Congressional insiders agree that if DSHEA is to be changed, it will happen in 2004—the groundwork has been laid. Hearings have been held, zeroing in on the industry's failures and abuses (ephedra, andro, Internet claims). Food and Drug Association press releases are coordinated with media exposés to affect opinion about DSHEA. A powerful congressional veteran, John Dingell, D-Mich., said, "I would like to repeal the whole sorry mess."

Learning from history

Contrary to industry mythology, in 1994 DSHEA did not pass by a unanimous vote of the House and Senate. No House floor vote on DSHEA was ever held. In fact, the House version of DSHEA never made it out of committee. DSHEA became law because of a confluence of political forces. The Gingrich New Deal Republicans were about to sweep out the House Democrats who were holding up DSHEA, which caused the Democrats to unload the DSHEA issue at the last minute to save their jobs. In the Senate, Sen. Orrin Hatch, R-Utah, held off a last-minute attempt to derail DSHEA as it was coming up for unanimous consent vote in the closing minutes of the 1994 Senate session. DSHEA was a political Hail Mary of unprecedented proportions.

It's important to note that 10 years later, the core enemies of DSHEA remain in Congress. Just as DSHEA was created by last-minute deals, this same process could change it again.

Although there are numerous initiatives under way to protect DSHEA, we believe there are three core strategies to defend this legislation: proactively resolve the four signature issues within the DSHEA debate; identify and protect the most important provisions of DSHEA; and restore consumer confidence.

Resolve signature issues

The "Unregulated Industry" Issue, as illustrated by ephedra. We must have a satisfactory political and regulatory solution to ephedra by April 2004. The

industry should not oppose the Food and Drug Administration's action of Dec. 30, 2003 to ban ephedra. If, however, the FDA overreaches in its plan to define "unreasonable risk," the industry may feel compelled to challenge the FDA on procedural grounds. Congressional sentiment against ephedra could prompt many members to vote in favor of anti-DSHEA legislation. The controversy surrounding ephedra has become a lightning rod that has galvanized concern about other herbs and dietary supplements.

The "Drugs as Dietary Supplements" Issue, as illustrated by andro. The Anabolic Steroid Control Act of 2003 (S.1780, the Biden/Hatch bill) should be an industry priority, with a goal to remove the steroid precursor issue before the 2004 Olympic games begin in September. A supplement doping scandal this year could ignite an anti-DSHEA debate in Congress.

The Quality Issue, as illustrated by good manufacturing practices. The industry must make progress in responding to the FDA's unacceptable GMP proposal. We should prioritize a small-business economic analysis that demonstrates that the FDA's failure to correctly assess the economic impact of the GMP rule will result in soaring production costs for small-lot and specialty supplements. The Safety Issue, as illustrated by adverse event reports. The industry must recognize that for supplements to become more fully accepted, there must be ways to ensure confidence in their safety. This means developing a process of monitoring cases of adverse responses and providing a proactive way of dealing with this issue.

Identify and manage DSHEA's most important provisions

We believe there are three fundamental and critical provisions of DSHEA that must be managed:

1. The definition of dietary supplements.
2. The provision that dietary supplements are not food additives.
3. The decision that the FDA has the burden of proof to prove a product is unsafe before it can remove it from the market.

The first issue defines what can be sold as a dietary supplement. The second removes one of the strategies used by the FDA to overregulate our industry. The third provision is at the heart of the DSHEA debate and will become the most contentious single DSHEA issue.

Most of the attacks on DSHEA have specifically targeted these provisions. The supplements industry should bear this in mind during the coming DSHEA debates.

Restore public confidence

After progress has been made with the first two strategies, the industry needs to restore consumers', health professionals', congressional members' and regulators' confidence in the safety and benefits of dietary supplements via GMPs, quality standards and truthful claims management.

Efforts to adopt certification standards should be fully supported, including USP and NSF programs. The American Botanical Council's new Safety Labeling Program provides safety information for manufacturers to use in product labeling to reduce the incidence of adverse events. In addition, industry leaders should continue to do everything possible to share information about Internet marketers of supplements with the FDA and the Federal Trade Commission, and identify rogue marketers to the FTC to draw a line between responsible and fringe players.

The industry needs to restore confidence in the safety and benefits of dietary supplements.

On the retail front, store owners/managers are some of the most effective gatekeepers. They decide what goes on their shelves and hold the greatest buying power in the value chain. We anticipate a renewed cooperation between retailers, trade associations and industry leaders, including adherence to labeling practices, ingredient safety and dosage limits when deciding product acceptance and placement. A retailer peer group is being formed to explore ways to realize this gatekeeper function. Clearly, it should not be the ongoing task of retailers to pass judgment on product safety or legitimacy. However, as an interim step, this should be an effective tool to turn the corner on the current malaise in sales and industry growth.

Another key gatekeeper is the media. New Hope Natural Media (*The Natural Foods Merchandiser's* parent company) has an extensive standards policy and practices program for the industry's two largest trade shows, as well as publications. Other industry trade and consumer publications have expressed interest in adopting similar standards and practices. This should be fully supported by everyone in our industry.

Politically, it is not helpful or productive to scare consumers through "the government is trying to take away your vitamins" campaigns or to support extremist calls to abolish the FDA. It is also extraordinarily destructive to personalize regulatory issues. In 1994, personal attacks made against members of Congress and their families by overzealous members of our industry nearly derailed DSHEA, and we are still paying politically.

In conclusion, our best defense to the anticipated attack on DSHEA this year must be a clear and focused offense to address issues that have become symbolic of the debate about whether DSHEA is bad law. Industry executives must be prepared to spend time and money on DSHEA defense and industry self-regulation. Failure to do so could be the most expensive decision the industry ever makes.

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