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THE DIETARY SUPPLEMENT  
INDUSTRY'S LEADING MAGAZINE

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**Honoring  
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# Back Talk



**Karen Howard, CEO,  
Executive Director Organic  
& Natural Health  
Association**

**Website:**

[www.organiednatural.com](http://www.organiednatural.com)

**VR:** What issues did you discuss during your meeting with the New York attorney general's office affecting the natural products industry?

**Howard:** We opened our discussion with an offer to collaborate and serve as an industry resource to the Attorneys General (AG). There is always room for improvement in any industry, and the supplement industry is no exception to that rule. Organic & Natural is committed to ensuring consumer access to quality products. We went to open a dialogue with the AG offices with the primary goal of making sure consumers have confidence in the authenticity and purity of the products they are purchasing. Did we disagree with the NY AG in certain areas? Yes. And, it was clear from our meeting the AG agrees with our position that this issue is not solely about testing. Supply chain integrity took center stage in our discussion.

**VR:** Why did you request this meeting and what were your goals?

## THIS MONTH:

Karen Howard has spent more than 30 years working with Congress, state legislatures and health care organizations to develop innovative health care policy and programs. She has worked to strategically advance the mission and vision of organizations through effective advocacy and strong collaboration. She has held a variety of executive positions, including serving as professional staff for a Congressional committee, and has policy expertise in the diverse areas of integrative and complementary medicine, managed care, health care technology and mental health.

Prior to joining Organic & Natural Health Association (O&N), she served as president of the National Animal Supplement Council (NASC), where she managed the NASC Quality Seal Program, a voluntary compliance program for manufacturers and distributors of pet supplements requiring adherence to the association's GMPs (good manufacturing practices), participation in a national adverse event reporting system, and a bi-annual audit.

Howard also served as executive director for both the American Association of Naturopathic Physicians (AANP) and the Association of Accredited Naturopathic Medical Schools.

Here she discusses a recent meeting with the New York attorney general's office and her thoughts on improving supplement safety and quality practices.



**Howard:** We went to New York to share our perspective on how best to keep bad products off the shelves, and demonstrate our willingness to improve the regulatory process in ways that benefit consumers. We represent the companies committed to the highest quality standards available, and the consumers' desire for products they can trust. Organic & Natural believes in transparency and honest relationships between consumers and corporations. Our members value business and marketing practices that are unambiguous, that requires traceability and accountability for all products, including herbal supplements. We discussed the entirety of the manufacturing process with the AG's office, and shared our perspective on how consumers who buy herbal supplements will be better served by requiring raw ingredient suppliers to adhere to the same GMP requirements as manufacturers. For us, testing is one of many tools that work to ensure ingredient identity, quality and safety. A tool that is only as good as the test itself, and the moment and the batch the test was applied. We wanted the AG to hear our perspective on the power of adhering to the dietary supplement GMPs, the standards quality companies are currently using, and how the quality suffers from not requiring consistent application of these rules.

**VR:** Organic & Natural is filing a petition with the FDA (U.S. Food and Drug Association). What is the purpose and goal of this petition?

**Howard:** The purpose of the petition is to apply the FDA's current cGMPs (code 21 CFR Part 111) to raw material manufacturers, thus ensuring supply chain integrity is managed at the earliest possible point. This will require manufacturers of raw ingredients to have a strong working relationship with farmers, and that appropriate cGMPs are instituted at the point where raw materials are manufactured. Doing so will provide flexibility welcomed by branded ingredient manufacturers that are already following cGMPs but are forced to compete with lower quality ingredient manufacturers that have minimal, if any, cGMPs.

**VR:** How important is supply chain integrity?

**Howard:** and we stand on the principle that FDA and FTC (Federal Trade Commission) have the authority to remove these substandard and often dangerous products off the shelves. True, they do already have that authority. The Organic & Natural Health Association is willing to take this one step further and petition FDA to impose existing cGMPs on raw ingredient suppliers. Without taking this step, the integrity of the supply chain will continue to result in poor products, poor health care outcomes, and worse attributions by industry critics. Will supply chain integrity eliminate all criticism and fix all our problems with DSHEA? No. And, it is essential to making dramatic strides in protecting consumers by improving the quality of products on the shelves.