Written Testimony
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Submitted to the United States Senate Special Committee on Aging

on behalf of the American Herbal Products Association (AHPA), Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), Natural Products Association (NPA), and United Natural Products Alliance (UNPA)

"Dietary Supplements: What Seniors Need To Know"
May 26, 2010

The Council for Responsible Nutrition (CRN) appreciates this opportunity to provide testimony to the Senate Special Committee on Aging on behalf of the dietary supplement industry to reassure you and your colleagues, your constituents, and our customers that the dietary supplement industry is committed to manufacturing and marketing high quality, safe and beneficial products that have a valuable and appropriate role in a wellness regimen. This industry is likewise committed to ensuring that consumers receive truthful, accurate and non-misleading information on dietary supplements.

This testimony is submitted on behalf of the five trade associations who collectively represent all segments of the dietary supplement supply chain: ingredient growers, suppliers and processors, manufacturers and retailers. They are: the American Herbal Products Association (AHPA); the Consumer Healthcare Products Association (CHPA); the Council for Responsible Nutrition (CRN); the Natural Products Association (NPA); and the United Natural Products Alliance (UNPA).

These associations share the concerns of the Committee about any bad actors in the industry—those companies, whether they are manufacturers or retailers, that are either unaware of the extensive regulatory framework governing dietary supplements or are willfully breaking

the law. At the outset, we want to assure you that our industry condemns adulterated products and false, misleading or deceptive marketing practices—activities engaged in by a very small minority who have damaged the reputation of the responsible industry that comprises the vast majority of supplements sold in this country. The responsible supplement industry has a demonstrated track record of providing high-quality products to its consumers and of active lobbying for stronger regulatory guidelines, for broader implementation of the laws under which our industry operates, and for increased enforcement activity, as well as for adequate funding for the Food and Drug Administration (FDA). Our industry has gone even further—developing educational initiatives for consumers designed to make supplement shoppers more savvy and voluntary self-regulatory programs that address the issues that tarnish our industry and potentially hurt our consumers. The latter include a variety of training programs to inform manufacturers and retailers of the legal requirements and their compliance obligations.

Our industry, like all industries, has its outliers, and we applaud this committee's efforts to shine the spotlight on those activities that break the law. But we would be remiss if we did not put some perspective around these concerns. The great majority of American consumers who take dietary supplements are using safe, high-quality supplements to maintain and improve their healthy lifestyles. Adulterated dietary supplement products remain a small minority of supplement products sold in our country today.

More than 150 million Americans—including many who are extremely passionate about their right to purchase supplements—take dietary supplements each year. We know from market research that a high percentage of our consumers are highly proactive in managing their health, engaging by large measure in other healthy habits such as trying to eat a healthy diet, exercising regularly, visiting their doctors. The data defies the myth that supplement users will forsake other healthy behaviors and put their health solely in the hands of a supplement pill. To the contrary, dietary supplement users are more likely than nonusers to engage in the healthy habits noted above[1]. We also know that among the more than 150 million Americans who use dietary supplements are a high percentage of nine healthcare populations (including physician specialties such as orthopedists, cardiologists, dermatologists and OBGYNs, as well as nurses, nurse practitioners, pharmacists, and registered dietitians) who both personally take and professionally

[1] *See* Addendum #1.

recommend dietary supplements[2]. There are literally millions of shelf units of supplements sold in this country each year—and very few serious adverse events associated with their usage. In 2008 (the last year for which complete data is available), the agency received only 1,025 reports of serious adverse events associated with dietary supplements though it should be noted that these "signals" are not considered by FDA to be evidence that a dietary supplement actually caused the reported event. At the same time, the scientific support continues to grow for the important health benefits of many of our products—products like multivitamins, calcium, fish oil, vitamin D, and more—taken by our core consumers, including the aging and elderly populations.

Every regulated consumer products industry faces the kinds of challenges that the dietary supplement industry faces. By simply enforcing the current law, if the agencies devoted greater focus and had greater resources to fully implement it, these incidents could be further reduced. And when the pending Food Safety legislation (S. 510) is enacted (legislation which our industry supports), there will be additional laws in place—including mandatory recall authority for FDA—to continue to strengthen the regulation of this industry and conventional foods. No matter what the law requires, it is unrealistic to suggest that you would never find a retailer giving bad or illegal advice, or that you could never discover a manufacturing error.

Pharmaceuticals, conventional foods, medical devices and cosmetics—all regulated by FDA—likewise have accidents and rogue players. But our industry has made great strides in the past decade, and we pledge to continue to support reasonable regulation that makes sense for our industry, is not duplicative or contradictory to laws already in place, and that benefits our consumers. However, we will also continue to fight against unnecessarily burdensome regulation that drives up consumer prices, adds unnecessary paperwork and bureaucratic obstacles to market, or restricts truthful information about supplements from reaching consumers—all of which provide no real return or protection for health conscious consumers.

Since the passage of the Dietary Supplement Health & Education Act (DSHEA) in 1994, our industry has come of age, and as we mature, like all industries with growing consumer interest, there are some growing pains. Through the work of the five trade associations, we have fostered an understanding and acceptance, even a desire, among supplement ingredient suppliers, manufacturers and retailers, for strong and enforced regulation—separating those companies

[2] *See* Addendum #2.

who cannot or will not follow the law from those companies who go above and beyond what is legally required. The passage of the 2004 anabolic steroids law, the removal of ephedra, the adverse event reporting law, and the issuance of GMP regulations were all accomplished with the support of the industry associations. As your hearing today points out, clearly, there is more work to be done. As an industry, we are willing to work cooperatively with government, regulators, suppliers, manufacturers, and retailers, as well as consumers, and consumer groups who are willing to partner with us to make certain that the American public has access to the most safe, high-quality dietary supplements the marketplace can offer.

Let us also deal directly with a myth that has been fostered by our critics, perpetuated by the media since 1994, and is widely circulated in the halls of Congress. Many charge that DSHEA de-regulated the industry, stripped FDA of its power over dietary supplements, and rolled back the previous regulation of vitamins. That is simply false. The passage of DSHEA provided FDA with new enforcement authority not previously available:

- It gave FDA the ability to remove from the market supplements that pose a significant or unreasonable risk of injury or illness—a power the agency has used on several occasions since 2000;
- It authorized the creation of GMP regulations distinct for supplements and separate from food GMP regulations;
- It created the imminent hazard to public health standard which allows FDA to remove unsafe products from the marketplace immediately;
- It required notification to FDA for all new dietary ingredients, along with the submission of evidence of reasonable expectation of safety of the ingredient; and,
- It even prescribes that labeling statements about how a dietary supplement will affect the structure or function of the body, so-called “structure/function claims,” must be submitted to FDA within 30 days of first use and must be truthful and not misleading with adequate substantiation.

DSHEA made certain that dietary supplements were to be regulated as a category of foods, not drugs. Prior to 1994, on some occasions, FDA regulated supplements as foods; on others, it tried to regulate them as drugs or food additives. But to be clear, FDA never had legal pre-market approval authority for dietary supplements—DSHEA did not change that fact.

The industry would like to address the three areas of highest concern to the Special Committee on Aging. For each area, we will summarize the current legal requirements, demonstrating that the existing law already addresses the concerns that have been raised. Then we will provide information on specific industry programs and voluntary efforts that are also in place to foster compliance, and in many cases, encourage responsible behavior even beyond the requirements of the law. And finally, Senators Harkin and Hatch recently introduced the Dietary Supplement Full Implementation and Enforcement Act of 2010, and we urge this committee to add its support for this legislation as it will propose increased funding for FDA. This legislation will help to ensure that the agency has sufficient focus and resources at its disposal to implement a law—DSHEA—which already provides FDA with ample authority to ensure consumer safety, while still providing consumers access to the products they seek.

Product Quality

Questions have been raised about the quality, purity and potency of dietary supplements and the commitment of supplement manufacturers to produce safe and beneficial products. Three things should be considered here. First, DSHEA requires all dietary supplements to be produced under strict manufacturing conditions to ensure product quality; second, that regulation is being enforced; third, the trade associations are aggressively educating industry of its obligations to ensure product quality.

After years of prodding, pleading and urging from industry, and indeed by some in Congress, FDA issued the final GMP regulations in 2007. Next month, the three-year phase-in of these regulations will be completed and all companies finally will be subject to supplement-specific GMPs, nearly 16 years after the passage of DSHEA. Even before the supplement GMPs went into effect for the supplement industry, manufacturers were subject to the requirements of conventional food GMP regulation.

Now, under the GMPs specific to dietary supplements, all manufacturers are required to test every lot of incoming material to confirm the identity of the ingredients. They are required to qualify their vendors so that other aspects of quality—like the purity of the ingredient from contaminants, and the consistency of the material—are assured. These rules mandate training of personnel, master batch records and production logs, calibration of equipment and measuring

devices, cleanliness of the work environment to prevent cross contamination, and testing of finished products against label claim, just to name a few. While no law can provide complete assurance against mishaps, these regulations, when fully implemented will give consumers more confidence than ever in the quality of supplements.

To its credit, after issuance of the GMPs and in the face of competing resource needs, FDA has pursued an aggressive industry education effort to be sure supplement companies understand their obligations under the new regulations. The agency has already conducted numerous inspections under the new GMPs, and the industry is encouraged that FDA has announced a robust agenda of inspections in the coming year. And while the discovery of violations is not a positive development, the issuance within the last month of a warning letter on GMP compliance issues that resulted from an inspection signals that FDA has the tools available to insist that industry members comply with the rules. What the agency needs is more resources to put sufficient, well-trained inspectors in the field.

The collective efforts of all five industry trade associations further demonstrate the commitment of this industry to full implementation of the GMPs. Over the past three years, our organizations have hosted over 25 well-attended educational events for industry to acquaint manufacturers with the new GMP rule and explore the specific requirements it imposes. Our efforts range from webinars and conference calls with industry and FDA representatives, to trade show conferences and all-day symposia, as well as creating manuals, chapters and by-lined articles on the GMPs to companies offering personalized seminars.

The trade associations have also developed the Standardized Information for Dietary Ingredients protocol, or "SIDI," for short. This collective effort, across all five associations, has helped to standardize the communications between ingredient suppliers and manufacturers so that manufacturers can compare competing ingredients, obtain all relevant information documentation about the quality of ingredients, and make smarter purchasing decisions. That effort has expanded to produce another voluntary guideline that prescribes best practices for developing the Certificate of Analysis that accompanies each lot of raw material shipped to a manufacturer—and even more industry-endorsed, voluntary guidelines are planned.

The Natural Products Association has developed the GMP Certification program, one of several opportunities for manufacturers to undergo rigorous inspection and receive certification of their products. Manufacturers voluntarily permit third party auditors to inspect their facilities

and test their products in hopes of receiving a seal of approval for their labels. Over 60 companies have participated in this program. NPA's TruLabel program randomly selects products from retail shelves and tests their contents for conformance with the label. If a product is determined to be out of conformance, the company is notified and asked to take corrective action.

The United Natural Products Alliance has offered numerous GMP and quality management seminars for industry executives in conjunction with FDA, the University of Mississippi, the United States Pharmacopeia, AOAC International and NSF International. Such training programs provide state of the art instruction on analytical methods, vendor qualification, certificates of analysis, botanical identification and other important technical subjects. (See www.unpa.com for all seminar programs.)

Do all these efforts assure with 100% certainty that a laboratory will never find a product on a store shelf that doesn't meet the GMPs? Of course not. But more than ever, dietary supplement manufacturers have every incentive to produce the best quality products, and real sanctions in place if they don't.

Related to the issue of quality, are persistent questions about the safety of some dietary ingredients. Under DSHEA, dietary supplement ingredients already on the market in the United States as of October 1994 were "grandfathered," in the same way the 1958 food additive amendments to the FDCA "grandfathered" as safe hundreds of substances already being used in foods at the time. DSHEA also established a premarket notification procedure that requires manufacturers who use new ingredients in dietary supplements after 1994 to provide a notification to FDA that sets forth the basis for considering the ingredient to be "reasonably expected to be safe," and there is clear authority in DSHEA for FDA to declare a supplement adulterated if it contains a new dietary ingredient for which an NDI notification was not filed. FDA has been receiving these notifications on a regular basis since the passage of DSHEA and has been giving them serious attention. But the agency has objected to about 70% of the more than 500 notifications it has received.

To assist industry members in filing NDI notices, the American Herbal Products Association created an NDI Database designed to ease access to and understanding of the notifications submitted to FDA. The searchable database allows companies to easily locate individual notifications by searching for key terms that include the generic and brand name of

the NDI itself and the Latin name (genus) of herbal NDIs, as well as the name of the submitting firm or the report number assigned by FDA.

What is needed, though, to increase success in filing NDI notifications, is a formal guidance from FDA that explains clearly the agency's views on what constitutes a new dietary ingredient versus a grandfathered one and provides instruction on how firms can establish the reasonable expectation of safety from the evidence they provide. Industry has been asking for this guidance for years and FDA has been promising it, but to date, it has not been issued.

Product Advertising and Labeling Claims

This Committee has also raised questions about the advertising and marketing of dietary supplements, inquiring whether there is adequate protection for consumers from false or misleading advertising. As with the product quality issue, the answers begin in the plain language of the statute. DSHEA expressly requires that all labeling claims must be truthful, not misleading, and substantiated with adequate evidence. In addition, DSHEA sets clear boundaries on permissible claims for supplements. Any claim to treat, prevent, mitigate or cure a disease is not permitted, and the statute provides that such claims render the product an unapproved new drug, subject to various civil and criminal penalties. Health claims—those that make an association between a dietary ingredient and the reduction of risk of a disease, such as calcium's ability to reduce the risk of osteoporosis—require the approval of FDA based on significant scientific agreement. Even structure/function claims that do not require the approval of FDA, nevertheless are required by the statute to be submitted to FDA within 30 days of the first use, giving the agency oversight for the kinds of claims that are made.

The Federal Trade Commission (FTC), not FDA, has jurisdiction over dietary supplement advertising. The general standards for consumer advertising apply to supplement claims, but FTC has stated that it "gives great deference to an FDA determination of whether there is adequate support for a health claim. Furthermore, FTC and FDA will generally arrive at the same conclusion when evaluating unqualified health claims."[3] Although FDA's enforcement of supplement labeling claims has been sporadic, that has not been the case for FTC. Aggressive enforcement against false or misleading advertising has led to large civil fines and disgorgement

[3] http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

of unjust profits. In particular, FTC has collected fines and mounted aggressive enforcement of such things as bogus cures, weight loss claims and claims to prevent colds and flu—actions the five trade associations have publicly supported.

In the area of advertising, the industry associations have also pro-actively worked to remind manufacturers and marketers of the restrictions on their advertising and even developed voluntary programs to help police these ads. Four of the five associations have conducted educational programs for their members and the larger industry, to underscore the limits of permissible claims. Three years ago, CRN launched a program with the National Advertising Division (NAD) of the Council of Better Business Bureaus to raise the level of scrutiny of supplement advertising. Through a series of unrestricted grants that total almost $1.5 million funded by CRN, the NAD has been able to add a staff attorney who reviews dietary supplement claims full-time. Challenges can be brought by competitors, consumers, the trade associations or the NAD itself. Claims are evaluated by examining the data submitted by the advertiser itself and written decisions are issued and made public for each case. Since its inception three years ago, the NAD program has issued over 85 opinions that collectively form precedent that guides marketers for future ads. Advertisers who ignore the NAD process or refuse to comply with those decisions do so at their peril: the NAD routinely refers those ads to FTC for follow up and we have been assured those cases get high priority attention for federal investigation.

The Natural Products Foundation (NPF) also maintains a Truth in Advertising program, giving manufacturers the opportunity to pledge to follow FTC's advertising parameters, and notifies manufacturers that it judges to be in violation of the law. If the company does not respond or modify its ads, the NPF notifies FTC and FDA asking that they investigate the charge.

The major media operations that run annual tradeshows for suppliers, manufacturers and retailers also have advertising review programs that screen ads whose claims do not seem to be supported by the evidence. Perhaps more consumer publications should take a cue from these trade journals and institute similar policies not to accept ads containing unsubstantiated or impermissible claims.

So does this mean you will never see a late-night infomercial or a newspaper ad that makes unsupported claims for a dietary supplement? All industries are held hostage to overzealous advertisers. We acknowledge the supplement industry has companies that will push

the envelope and even flout the law. Once again, we call upon Congress to provide additional resources to support enforcement activity by both FDA and FTC, along with continued cooperation between these two agencies, to further the critical mission of assuring consumers get accurate information about the dietary supplements they use. New laws that would restrict legitimate commercial speech are neither needed nor appropriate; but rather efforts should be focused on more robust enforcement against the most outlandish of these claims without favoritism against those companies with the deepest pockets.

Product Claims at Retail

Third, the Committee has exposed some retail salespeople making misguided and impermissible statements for dietary supplements directly to their customers. This is the first time we have heard the audio recordings and we do not know their full extent, or even whether the retailers in the GAO's investigation are aware that they are breaking the law. But as with the previous topics, the Committee should be assured that this kind of behavior is patently illegal and unacceptable. Retailers who make inaccurate or impermissible claims for a dietary supplement have, by their oral comments, misbranded the product at the point of sale under section 403 or the FD&CA, and if the claim is to treat, prevent, cure or mitigate a disease, they have converted the product to an unapproved new drug. These actions also run afoul of the FTC, which has stated that supplement marketers should ensure that ***anyone*** involved in promoting products is familiar with basic FTC advertising principles. The FTC itself has stated that it "…has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. Therefore, all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims."[4] Furthermore, making a false or misleading statement about a dietary supplement in a consumer transaction violates many states' consumer protection, anti-fraud and unfair competition statutes. In addition, in many states, the licensing requirements for healthcare professionals would make statements about the ability to treat or cure a disease illegal as the unlicensed practice of a medical

[4] http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm.

professional. So there is no question that the legal authority is available to address these marketing practices.

Retailer Education

Whether it is attributable to turnover in the retail sector, new retailers entering the market, or over-enthusiastic testimonials from clerks who are supplement users themselves, the industry recognizes that it is not acceptable for salespeople to make illegal claims to consumers. Here are some of the things we are already doing about it:

- The Natural Products Association has developed a handbook for retailers to assist their retail members with determining their rights and responsibilities under the law. The handbook is clear: You may not diagnose a customer's ailments—that is the practice of medicine. You may not prescribe—suggesting a dietary supplement as an effective treatment or cure of a disease is illegal without a license.
- All the trade associations regularly engage in webinars and symposia to remind their members about what can and cannot be said about supplements. Most of these programs engage officials from FDA and FTC to remind participants of the law, and we are grateful to both agencies for their generous and enthusiastic participation in these industry events. NPA also provides an online quiz for its members "What You Can Tell About the Products You Sell."
- All three major retail vitamin/supplement chains require initial training for all their entry-level employees and provide ongoing continuing education for their retail staff. Other resources include online training, tests for proficiency, monthly newsletters to employees and offsite training sessions that repeatedly remind these employees about the limits on what they can say to consumers.
- Separately, the major direct selling companies who market dietary supplements maintain extensive compliance materials and hold training sessions with their independent distributors to instruct them and reinforce the directive that they may not promote supplement products for diseases or oversell the products' benefits.

However, based on the testimony today, the industry associations recognize that there is more we need to do to give consumers confidence in their supplement purchases. So today, the five associations pledge to the Committee that, either collectively or individually, we will increase

our efforts to educate and train retailers who sell dietary supplements and their staffs about what can and cannot legally be said to customers. These efforts may take the form of breakroom posters, brochures that are shipped along with the product, heightened visibility of training events at trade shows or individual follow-up from manufacturers' representatives, but be assured that we take this revelation seriously. We also ask the assistance of FDA and FTC to provide compliance assistance, particularly to small retailers

Consumer education

But the matter of creating more savvy, more educated consumers is not solely the responsibility of retailers. We also have some simple advice for consumers: the only medical advice consumers should take when it comes to buying supplements is from their healthcare professional—a doctor, a nurse practitioner, a pharmacist, a nurse, a registered dietitian, or a naturopath, for example. Retail professionals—sales clerks, direct sellers, customer service representatives, are there to help customers navigate the retail landscape, to distinguish products, to explain what the products do—but also what the products don't do. Dietary supplements are not intended to treat, prevent or cure disease—and unless a person is working under the guidance of a healthcare professional who is specifically prescribing their care, consumers should not purchase a dietary supplement with that expectation—and a retailer should not sell a dietary supplement with that promise.

Our industry has a responsibility to protect consumers—particularly those who may be more vulnerable to sales pitches—for informing consumers about what supplements reasonably can and cannot do. We echo the well-known adage: if something sounds too good to be true, chances are it is. If, for example, a sales person advises that just by taking a supplement, a person will lose 40 pounds in four weeks, or look 20 years younger, ask for a different salesperson. If a retail clerk tells customers that a supplement product will cure cancer, they should report it to the store's management and walk out of the store immediately. CRN's "Life…supplemented"[5] consumer wellness initiative educates consumers that dietary supplements are an important part of overall wellness, but that they are just one piece of the wellness equation. Consumers shouldn't expect to pop a pill as a magic bullet that will solve their health concerns, but rather

[5] www.lifesupplemented.org.

should consider incorporating supplements as one of the smart choices they make for healthy living.

Our government has a responsibility too—a responsibility to enforce the law, and a responsibility to educate the public. One of the mandates from DSHEA was to ensure consumers have more information about dietary supplements and FDA and the then newly-formed Office of Dietary Supplements were tasked with this mandate. We would like to see more done in this area and urge the government to find ways to increase public/private partnerships to further educate consumers in this area, so consumers are better able to protect themselves from overzealous or misinformed retailers.

Lastly, despite the issues that have been raised today, we ask the Committee not to lose sight of the important health benefits dietary supplements provide to consumers, specifically to the aging and elderly populations. From the importance of a multivitamin in filling nutritional gaps and helping promote overall good health, to calcium and vitamin D for strong bones; from specialty supplements like omega-3s for supporting heart health to glucosamine and chondroitin for supporting joint health; from botanicals like lutein and bilberry for eye health to saw palmetto for prostate support and to soy and garlic for heart health—dietary supplements are mainstream, affordable options for healthy lifestyles.

The positive health effects of dietary supplements can mean not only a better quality of life for individuals, but also potential positive effects on healthcare cost savings for our country. Studies commissioned by industry and performed by the Lewin Group published between 2003 and 2008 demonstrate significant cost savings in the billions from supplements including calcium, vitamin D, omega-3 fatty acids, lutein, and the multivitamin with folic acid.[6]

Conclusion

Dietary supplements offer American consumers, and especially elderly Americans, an effective way to maintain their healthy lifestyles. The vast majority of dietary supplements are safe and beneficial. Those who say all we need to do to protect senior citizens is to change the law, are unfamiliar with the scope of existing law. The framework of the law is substantial—but

[6] http://www.lewin.com/content/publications/3393.pdf
http://www.lewin.com/content/publications/2833.pdf

we need more cops on the beat to make sure it is fully implemented. Give FDA the resources, the support and the clear directive to flex its regulatory muscle.

We also respectfully urge this committee to join Senator Harkin and Senator Hatch in support of their recently introduced bill, the Dietary Supplement Full Implementation and Enforcement Act of 2010; legislation that will provide increased funding for FDA to help ensure the agency has additional resources to implement the current law. This legislation directs the agency to provide annual reports to Congress making itself accountable for enforcing key provisions of the law, just as the industry is responsible for complying with them. Having more laws, without enforcement, only disadvantages the responsible members of industry who do comply with the law because it is the law and because it's the right thing to do for their consumers, and rogue companies will just have more laws to violate. As previous FDA Commissioners have testified to Congress, DSHEA provides more than adequate authority for government while still allowing consumers appropriate access to the products and health information they demand.

Thank you for the opportunity to share our views with the Committee.

This Testimony has been submitted on behalf of the following trade associations:

American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products, including foods, dietary supplements, cosmetics, and nonprescription drugs. Founded in 1982, AHPA's mission is to promote the responsible commerce of herbal products. Website: www.ahpa.org

Consumer Healthcare Products Association (CHPA) is the 129-year-old, not-for-profit association representing the makers of over-the-counter medicines and dietary supplements, and the consumers who rely on these healthcare products. Website: www.chpa-info.org.

Council for Responsible Nutrition (CRN) represents dietary supplement manufacturers and ingredient suppliers. Its members manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains as well as products marketed through natural food stores and direct selling companies. CRN's 70+ manufacturer and supplier members also agree to adhere to voluntary guidelines for formulation, manufacturing, and labeling as well as CRN's Code of Ethics. Website: www.crnusa.org

Natural Products Association (NPA), founded in 1936, is the nation's largest and oldest non-profit organization dedicated to the natural products industry. The Natural Products Association represents more than 10,000 retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Website: www.npainfo.org

United Natural Products Alliance (UNPA), founded in 1991, is an association of dietary supplement and functional food companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability. Website: www.unpa.com.

ADDENDUM #1

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Healthy Lifestyle Habits of Supplement Users & Non-Users

Below are findings from the 2009 CRN Consumer Survey on Dietary Supplements that examines the healthy habits of supplement users and non-users. The annual survey, which assesses U.S. adults' attitudes and usage of dietary supplements, has been conducted by Ipsos Public Affairs for nearly ten years.

Summary:

A larger percentage of supplement users are more likely than non-users to be engaged in the following behaviors: trying to eat a healthy diet, exercising regularly, visiting their doctor regularly, regularly getting a good night's sleep, and maintaining a healthy weight.

Survey question: "I…"	**% Agree – Supplement Users**	**% Agree - Don't take supplements**
Try to eat a balanced diet	88%	76%
Exercise regularly	64%	52%
Visit my doctor regularly	72%	57%
Regularly get a good night's sleep	69%	65%
Maintain a healthy weight	62%	60%

2009 CRN Consumer Survey on Dietary Supplements Methodology*: The 2009 CRN Consumer Survey on Dietary Supplements was conducted August 26 through September 1, 2009 by Ipsos Public Affairs and funded by CRN. The survey was conducted on-line and included a national sample of 2,043 adults aged 18 and older from Ipsos' U.S. on-line panel. The survey has been conducted annually since 2000. Weighting was employed to balance demographics and ensure that the sample's composition reflects that of the U.S. adult population according to Census data and to provide results intended to approximate the sample universe. A survey with an unweighted probability sample of this size would have an estimated margin of error of +/- 2.2 percentage points.*

ADDENDUM #2

Life...supplemented™

These are findings from nine healthcare populations surveyed for the 2007-2009 Healthcare Professionals (HCP) Impact Studies, conducted by the "Life…supplemented" consumer wellness initiative to assess healthcare professionals' personal usage of and recommendations for supplements.

	Population	Use Dietary Supplements (%)	Regular Users (%)	Recommend Dietary Supplements (%)
2007 Oct 2-11	Physicians (PCP, Ob/Gyn, Other Specialists)	72%	51%	79%
	Ob/Gyn (Also included in the results for "Physicians")	80%	56%	91%
	Registered Nurses	89%	59%	82%
2008 Aug 28-Sep 12	Cardiologists	57%	37%	72%
	Dermatologists	75%	59%	66%
	Orthopedists	73%	50%	91%
2009 Oct 3-11	Nurse Practitioners	95%	71%	96%
	Registered Dietitians	96%	74%	97%
	Pharmacists	86%	62%	93%

Survey methodologies for all populations can be found at:
http://lifesupplemented.org/supplements/healthcare_professionals_impact_study/methodology.htm.