

State Attorneys General

A Communication from the Chief Legal Officers
of the Following States and Territories:

Connecticut * District of Columbia * Hawaii * Idaho
Indiana * Iowa * Kentucky * Massachusetts * Mississippi
New Hampshire * New York * Northern Mariana Islands
Pennsylvania * Rhode Island

April 2, 2015

The Honorable Jerry Moran
Chairman
Committee on Commerce, Science, &
Transportation, Subcommittee on Consumer
Protection, Product Safety, Insurance, &
Data Security

The Honorable Richard Blumenthal
Ranking Member
Committee on Commerce, Science, &
Transportation, Subcommittee on Consumer
Protection, Product Safety, Insurance, &
Data Security

The Honorable Joe Pitts
Chairman
Committee on Energy and Commerce,
Subcommittee on Health

The Honorable Gene Green
Ranking Member
Committee on Energy and Commerce,
Subcommittee on Health

Dear Chairmen Moran and Pitts and Ranking Members Blumenthal and Green:

We write to urge you to launch a comprehensive congressional inquiry into the herbal supplements industry, and to weigh a more robust oversight role for the Food and Drug Administration.

The multibillion dollar herbal supplements industry is built on the promise that its products will improve the health and well-being of those who use them. Yet, a current state investigation has raised serious concerns about the marketing and safety of the herbal supplements regularly consumed by millions of Americans.

As you know, for purposes of federal law, herbal supplements are a subcategory of dietary supplements, a category encompassing vitamins, minerals, amino acids, and certain other substances. Under the Dietary Supplement Health and Education Act, herbal and other dietary supplements are subject to a much less rigorous oversight process than pharmaceutical products.

Recently, the New York State Office of the Attorney General examined popular herbal supplements sold by four major retailers.¹ Many of the products tested were contaminated with allergens, plant species left off the label, or other potentially dangerous substances, or so

¹ See, <http://well.blogs.nytimes.com/2015/02/03/new-york-attorney-general-targets-supplements-at-major-retailers/>.

thoroughly “processed” that the genetic material of the original “natural” plant source was unrecognizable or not present at all. As a result, several members of Congress, including leadership from these subcommittees, called on the FDA to investigate the findings.

The current investigation in New York and subsequent interest by other states, and the outstanding request to FDA, represent only the most recent indication of serious problems in the herbal supplements industry. The scientific community and the media have issued a series of troubling reports that suggest broader problems. Researchers, for example, measured high levels of heavy metals like lead, mercury, and arsenic in certain supplements.² Products falsely identified as black cohosh—an herb commonly taken to reduce menopause symptoms—may have caused severe liver damage in certain women.³ And media reports have uncovered over-the-counter supplements, including those purporting to build muscle, aid weight loss, and reduce anxiety, that were secretly laced with dangerous prescription medications.⁴

Additionally, if the producers of herbal supplements fail to identify all the ingredients on a product’s label, a consumer with food allergies, or who is taking medication for an unrelated illness, is taking a potentially serious health risk every time a contaminated herbal supplement is ingested.

The FDA has long been aware of problems in the dietary and herbal supplement supply chain, from dubious ingredient sourcing to a failure to carry out proper testing on finished products. In FY 2013, FDA inspectors cited two out of every three supplement manufacturers for allegedly violating current good manufacturing practices or “cGMPs.” More than one in five of those citations—called Form 483s—observed that the manufacturer failed to verify that a finished supplements batch met product specifications as to identity, purity, strength, or composition. A similar proportion was cited for failing to employ an appropriate test or examination to verify the identity of a dietary ingredient before incorporating it in the final product.⁵

Pharmaceutical manufacturing abroad has a record of serious lapses in quality control and sanitation, as revealed in a number of FDA investigations.⁶ The dietary and herbal supplements industry likewise relies on a web of overseas suppliers and manufacturers, and there is ample reason to believe that the FDA would observe similar deficiencies if its jurisdiction expanded. Indeed, given the warning signs observed to date, and the limited oversight, we believe the quality control and sanitation lapses in the supplements industry could be considerably worse.

The states will continue to vigorously pursue supplement manufacturers and retailers who break public health and consumer protections laws and endanger the health and well-being of the

² See, “Contamination and Adulteration of Herbal Medicinal Products (HMPs): An Overview of Systematic Reviews,” *European Journal of Clinical Pharmacology* (2012).

³ See, “Black cohosh: Insights into adulteration and hepatotoxicity” *Planta Medica* (2014).

⁴ See, e.g., <http://www.usatoday.com/story/news/nation/2013/12/19/dietary-supplements-executives-criminal-records-spiked/4114451/>.

⁵ <http://www.naturalproductsinsider.com/news/2014/02/fda-data-supplement-cgmp-compliance-rates-show-mo.aspx>.

⁶ http://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries.html?_r=0.

residents of our states. Congress and the FDA, however, are ideally positioned to hasten a broad-based solution that guarantees the safety, efficacy, and reliability of the herbal supplements sold nationwide. In particular, we strongly believe that your subcommittees should act in concert with the FDA to explore and address the following issues:

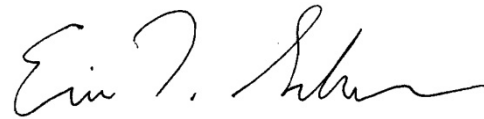
1. The adequacy and effectiveness of existing quality assurance measures for verifying the source, identity, purity, potency, and quality of ingredients and fillers;
2. The adequacy and effectiveness of existing regimes for verifying the identity, composition, purity, potency, and quality of the finished products sold by domestic manufacturers and retailers;
3. The degree to which product labels and marketing, including use of the terms “natural,” “herbal,” and “extract,” mislead consumers about the contents of herbal and dietary supplements and whether the FDA should develop standards and restrictions governing their use;
4. The extent to which Congress should mandate, or direct the FDA to develop, enhanced, uniform, industry-wide quality assurance and verification regimes to guarantee the source, identity, purity, and potency of materials incorporated into herbal and dietary supplements; and,
5. The extent to which Congress should mandate, or direct, the FDA to develop enhanced manufacturing and supply chain management requirements for the industry to guarantee the safety and efficacy of the finished herbal and dietary supplements.

We believe the safety and efficacy of these supplements is a matter of deep public concern across the country. We therefore urge you to take swift action—and stand ready to assist in any way we can.

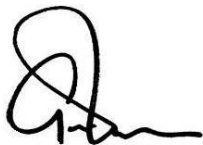
Respectfully submitted,



Greg Zoeller
Indiana Attorney General



Eric T. Schneiderman
New York Attorney General



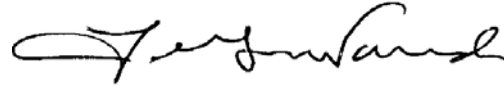
George Jepsen
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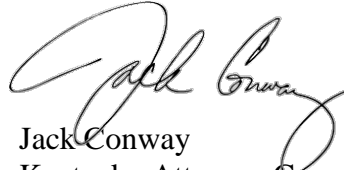
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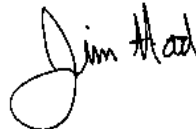
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