

Contact Us

If you would like to become a AONH Member, upgrade to the Elite Membership, or register for our Annual Natural Health Care Conference, please email:

info@aonh.org or call 202-505-AONH (2664)

Upcoming Events

· AONH Monthly Webinar, Wed., Sept. 12, 2012 at 8:00 pm EST. AONH Members will receive an email invitation to join us for the AONH Monthly Webinar. The Speaker is Osteopathic Physician, Dr. Rashid Buttar, speaking on the subject "Advance Cancer Intervention Protocol"



 AONH Monthly Webinar, Wed., Oct. 17th, 2012 at 8:00 pm EST. AONH Members will receive an email invitation to join us for the AONH Monthly Webinar. The Speaker is Chiropractor, Marty Monahan, and the subject he will be discussing is "Nitric Oxide-The Miracle Molecule"



• AONH Annual Natural Health Care Conference, Nov. 8-10, 2012 The AONH Annual Conference joins health care advocates and providers for an enlight ening program geared to the up-to-date natural health care practitioner. Registration for the event is normally \$299. Become a member and save up to \$100 off your registration! Event will be held in the Douglasville, Georgia.



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The Mission of Your Association

AONH is dedicated to public education and the professional development of natural health care around the world. Our aim is to unite our like minded members and speak as one voice and with one purpose.

Getting Involved

Associate. Select, and Elite Memberships are available.

For futher information on benefits you or your company can receive, please register for membership by visiting: www.aonh.org

Draft Guidance Still in the Balance

The European Union's ban, which went into effect May 1, 2011, appeared to foreshadow the direction American legislators were considering. A comparable draft guidance proposed by the FDA sparked a deep concern from the supplement industry and American citizens, as their right to choose their own health



care was in question. This collective outcry was heard as one voice, prompting

the FDA to draft a revised version of its guidance addressing the salient issue regarding new dietary ingredients (NDIs).

Senators Orrin Hatch (R-UT) and Tom Harkin (D-IL) played a pivotal role during this process and have raised the hopes of thousands by requesting greater clarity in definitions and parallel adherence to the original statute regarding herbal supplements. Steve Mister, president and CEO of the Council for Responsible Nutrition, said the FDA plans to address all five of the substantive issues raised by several associations including the Natural Product Association, the American Herbal Product Association, and the United Natural Products Association (4). The five issues are outlined as follows:

- Whether a synthetic version of a botanical ingredient can be a botanical ingredient.
- Grandfathered ingredients, and who has the burden to prove something is grandfathered.
- Whether an NDI has to be filed for each supplement or whether it can be filed with the ingredient itself.
- The breadth of the definition of chemical adulteration. As Mister explained, "The broader that is, the more ingredients that get caught up in the NDI issue and the fewer ingredients that are considered old.
- What is the appropriate standard of science to match the "reasonable standard of safety"?

Addressing these five issues could mark the beginning of a



How Can You Support these Issues?

As this issue clearly shows, the future of natural supplements is in the balance.

Perhaps the single most important thing a US citizen can do is write their state senator stating their support of natural health care. If you don't know who your representative is, or what his/her email is, go to: http://www.house.gov/representatives/find/

Let them know what's on your

You can make a difference by forwarding this newsletter and these links to all that you know. Be part of this most important of grass-roots movements.

mind and how they can help

you!

* Stop the present NDI Draft
Guidance: http://www.supplementcounsel.com/blog/fdarejects-senators%E2%80%99request-to-withdrawndi-draft-guidancewhat%E2%80%99s-next-forindustry-%E2%80%A6-andwhat-can-we-do



positive outcome, as desired by the various sectors of the supplement industry as well as the FDA. It underlines the power of a united voice in a ripple effect through which constituents and industry shape our legislation. This aforementioned power is not only heard as a voice advocating freedom of choice in health care and accessibility to herbal supplements, but also reveals the tremendous impact the supplement industry has on our country's economy.

The Industry Impact

A recent study funded by the Natural Products Foundation has found the total contribution of the supplement industry to the U.S. economy is 61 billion dollars per year. The study also showed that the supplement industry has enough activity throughout production and sales to support more than 450,000 jobs (2). These findings corroborate the industry's importance by quantifying its overall financial impact on the national economy by considering such contributing factors as supply, production, research, direct employment, manufacturing, taxes, and the extended financial effects these factors produce (2). The supplement industry represents an important component of the US economy, inevitably interconnected with many other industries.

USA TODAY headlines read "Supplement industry boosts Romney campaign by \$4.5M." The article stated "executives with companies selling everything from energy drinks to weight-loss pills made from African

mango-seed extracts are among the ranks of Republican Mitt Romney's top fundraisers (5)." The FDA's draft guidance does not exclusively affect Democrats or Republicans, but is rather an issue which challenges each American's rights. The article continued "unlike the pharmaceutical industry, supplement makers long have been exempted from federal review of their products for safety or effectiveness before being marketed (5)."

The term "exempt" is misleading and false, contrary even to recent reports published in the Chicago Tribune detailing widespread shortcomings of dietary supplement manufacturers inspected by the FDA. David Schardt, a senior nutritionist with the Center for Science in the Public Interest expressed "it [the supplement industry] is viewed as a Wild West arena, where virtually anything goes (5)." Interestingly enough, the article later describes, "The industry now is pushing the FDA to rescind what it claims are overly broad regulations proposed last year on new supplement ingredients. The proposal seeks to comply with a 1994 law that declared anything already sold as a supplement was considered safe, but said new ingredients introduced after that date would be subject to FDA scrutiny before being marketed (5)" – a far cry from the "exemption" mentioned previously.

Sweeping Claims

In response to a Chicago Tribune article which was critical, at best, of supplement manufacturing standards, Senators Dick Durbin, D-III., and Richard Blumenthal, D-Conn. sent letters to three major supplement organizations asking them to spell out their plans to improve conditions in the supplement industry (7). In a letter addressing Blumenthal, NPA executive director and CEO John Shaw wrote, "NPA believes the FDA's reckless comments in the Chicago Tribune article

distort the full picture of our membership's overall safety record. In fact, supplements have an excellent safety record, but we appreciate this opportunity to provide more information to you (6)." In a separate letter to Durbin, Steve Mister, CRN president and CEO cautioned the senators against making premature conclusions based on the FDA's report that 1-in-4 dietary supplement companies warranted a warning letter following an inspection. This is false, as the FDA concentrates its enforcement efforts on companies already suspected of being in violation of cGMPs, rather than a random sampling of the entire supplement industry and as such, not representative of firms in full GMP compliance.

Michael McGuffin, president of the American Herbal Products Association (AHPA), met with senator Durbin's staff members to discuss the senator's recently expressed concerns about the supplement industry's compliance with current good manufacturing practices (cGMPs). McGuffin restated a learning curve is expected when a manufacturing rule is revised, and drew an example from an FDA report that just 54 percent of seafood companies were in compliance with the new manufacturing rule issued for that industry five years after it was established in 1997 (1).

A Long Road Ahead

Even though the FDA has agreed to revise the draft guidance, there is still a lot of work ahead.

The media continues to publish unfounded sensationalism, which is perceived as fact by readers. We should expect to read more about the supplement industry in the coming months, as candidates continue their campaigns.



Now more than ever we are called to be informed, and inform others. Published statistics can be interpreted in different ways. Not knowing which method was used in conducting the study nor considering the specificity and the reliability of the study invalidates the extrapolation of results. In this case, a number of supplement firms failing to comply in manufacturing requirements does not represent the industry, but can influence the reader and evoke reactions akin to those of senators Durbin and Blumenthal.

Our voices have been heard, but we must continue on our mission as advocates of health, choice, and freedom.

Online Learning Hitting the Mark

AONH MEMBER VOICES HER APPRECIATION FOR THE ON-GOING MONTHLY EDUCATIONAL WEBINARS HOSTED BY AONH (see page 4)

"Thank you all so much for all the effort you have put into sharing all the great, informative material with us!!...I'm very appreciative because it helps me to be a much better technician which gives my clients more confidence. When I listen to their symptoms I can speak intelligibly about serious issues which gives them a lot more confidence in their health screening. Thank you again for all your hard work:)"

Jodi Krueger, Natural Health Care Professional and EDS Technician Winneconne, WI

HOW DO YOU JOIN?

Act today!

Email us at info@aonh.org or call 202-505-AONH (2664)

Your membership is yearly and entitles you to many benefits.

Cover Article References

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- 2. The Economic Contribution of the Dietary Supplement Industry Report, DaVanzo, J.E., Heath, S., El-Gamil, A. (2009)
- 3. "Dietary Supplements: Manufacturing Troubles Widespread, FDA Inspections Show." | Chicago Tribune. N.p., 30 June 2012. Web. 03 Aug. 2012.
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- 5. "Supplement Industry Boosts Romney Campaign by \$4.5M." | USA Today. Schouten, Web. 03 Aug. 2012.
- 6."Supplement Industry Responds to Senate Query on Alleged GMP Compliance Shortcomings | Drug Store News." Web. 03 Aug. 2012.
- 7. "U.S. Senators Call Supplement-makers to Account." | Chicago Tribune, 10 July 2012. Web. 03 Aug. 2012.