

# Annual Legal, Regulatory and Compliance Forum on Dietary Supplements

June 27 - 28, 2016

## Dietary Supplements: The State of the Union

Steve Mister, President & CEO  
Council for Responsible Nutrition



Tweeting about this conference?

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# Last year at this time.....

- New York AG investigation



## The New York Times

### New York Attorney General Targets Supplements at Major Retailers

By ANAHAD O'CONNOR  
FEBRUARY 3, 2015 12:00 AM

The New York State attorney general's office accused four major retailers on Monday of selling fraudulent and potentially dangerous herbal supplements and demanded that they remove the products from their shelves.

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# In 2016...

- Industry engaged in substantive conversations about quality, transparency and accountability
- Several industry initiatives are in progress
- Both mfrs and retailers focused on improving category reputation



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# Meanwhile, on Capitol Hill



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# Blumenthal's Military Amendments

- National Defense Authorization Act

- Amendment would have prohibited sales of dietary supplements on military bases without third party certification; floor amendment limited to high risk categories
- Industry opposed as a “back door” effort to impose third party certification to all products; encourages on-line and off base purchases; no standard for third parties



- Amendments offered but not voted on

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# Dietary Supplement Labeling Act of 2016???



Previous versions included:

- Mandatory product registration
- Mandatory label database
- Label warnings for “possible adverse effects” (to be developed by IOM; enforced by FDA)
- Pre-market submission of claim substantiation

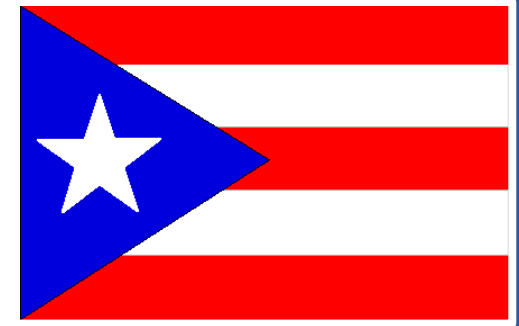
No introduction yet...

# Senator McCaskill's Letters

- Senate Select Committee on Aging
- Letters to 15 supplement retailers on products marketed for Alzheimer's and “healthy aging” claims
- Letters urging retailers to stop selling picamillon
- Letters to HCPs asking about supplement interactions with cancer meds



# Puerto Rico Debt Relief



- PR Administrative Order 346 issued in Feb. 2016
- Requires registration of products, mfrs, wholesales & retailers
- Not authorized under 2004 drug registration law
- Effort to pass PR legislation failed
- Can Congress stop it?



# GMO legislation



- Vermont law effective July 1
- Boxer/DeFazio bill – mandatory warnings for the *presence* of GMOs
- Pompeo/Butterfield bill – voluntary labeling for the *absence* of GMOs
- Roberts/Stabenow bill seeks compromise
  - Pre-empts state laws on GMO labeling
  - Creates a single nationwide, mandatory label for GMO products

# 21<sup>st</sup> Century Cures

- Occupying the House Energy & Commerce Committee
- Focuses on drug and device development and approval
- Possible vehicle for DSHEA changes?



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# Safe Food Act of 2015

- Would reorganize FDA and USDA to create a single food agency
- Would dietary supplements stay as foods or become part of a “drug” agency?



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# Flex Spending for Supplements

- FSAs/HSAs allow consumers to set aside pre-tax money to reimburse their qualified medical expenses
- Affordable Care Act revoked the ability to use FSAs for OTC expenditures; dietary supplements were never included
- Family & Retirement Health Investment Act expands use of FSAs and HSAs for a variety of health-related expenses; restores OTC coverage and adds dietary supplements along with other preventive expenses.



# Flex Spending for Supplements

## Calcium & Vitamin D Dietary Supplements and Osteoporosis

A new economic report shows that taking specific dietary supplements can provide significant individual and societal healthcare savings, by reducing the number of hospitalizations and other costly medical events associated with chronic diseases. This infographic demonstrates the cost savings that can be realized through the utilization of calcium and vitamin D supplements among all U.S. women over the age 55.

**Relative risk reduction**

18.6%

Using calcium and vitamin D supplements at preventive intake levels can reduce the risk of having an osteoporosis-related event.

**1,208,000 Events avoided**

between 2013 and 2020 among the targeted population of U.S. women over 55 with osteoporosis.

On average, 151,053 osteoporosis-related medical events can be avoided each year through the use of calcium and vitamin D at preventive intake levels.

**How calcium and vitamin D work**

Calcium is essential to bone health, and vitamin D promotes calcium absorption and is needed for bone growth. As we age, we naturally experience some bone loss; however, supplementing with calcium and vitamin D can prevent this and increase bone mass to decrease risk of fracture.

**Potential savings**

Between 2013 and 2020, medical event costs related to osteoporosis will average nearly \$17 billion annually. The use of calcium and vitamin D supplements at preventive intake levels by the targeted population of U.S. women 55+ who have osteoporosis can reduce those costs.

	AVERAGE ANNUAL (2013-2020)	CUMULATIVE (2013-2020)
<b>Avoided expenditures with supplementation</b>	\$1.9 billion	\$15.0 billion
<b>Net savings after cost of supplements</b>	\$1.5 billion	\$12.2 billion
<b>Savings yet to be realized if targeted population takes calcium and vitamin D at preventive intake levels</b>	\$1.4 billion	\$8.6 billion

**Osteoporosis human toll**

The number of U.S. women over 55 with osteoporosis is expected to rise 13% between 2013 and 2020.

Women over 55 with Osteoporosis

9.4 MIL.
8.3 MIL.
1.4 MIL.
1.3 MIL.

Portion who will be hospitalized

**The opportunity**

Calcium and vitamin D supplements are used by 29% of U.S. women 55+ which means that 71% of U.S. women 55+ are not taking calcium and vitamin D supplements. There are still cost savings yet to be realized through the increased use among the target population.

29% Take calcium and vitamin D supplements

71% Yet to benefit

**16¢ Daily cost**

Median cost at preventive intake levels, 2013

**15% Event rate**

% of targeted population that will experience a medical event

**Preventive Intake Level**

Frost & Sullivan identified a preventive level based on their meta-analysis of scientific studies included in this economic report. Consumers who are interested in the findings of this economic report should talk about smart prevention with their health care practitioners to determine which dietary supplements at which intake levels may be appropriate for them.

**Calcium & Vitamin D**

1,000 mg. 800 IU

Preventive intake level for women 55 and over

Notes: Numbers have been rounded. Exact numbers can be found in the full report.  
Sources: Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements—Frost & Sullivan, www.frost.com; Event rate data from the Centers for Disease Control and Prevention, www.cdc.gov.

**FROST & SULLIVAN**

**Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements**

An Economic Case for Promoting Increased Intake of Key Dietary Supplements as a Means to Combat Unsustainable Health Care Cost Growth in the United States

Christopher Shanahan, M.S.  
Robert de Lorimier, Ph.D.

www.frost.com



# WIC & SNAP benefits



- Reauthorization in 2018
- Industry seeking to include multivitamin (and possibly other supps with FDA-approved health claims) in allowable benefits
- Does not increase costs of programs; gives participants more options for nutrition

# Free Speech About Science



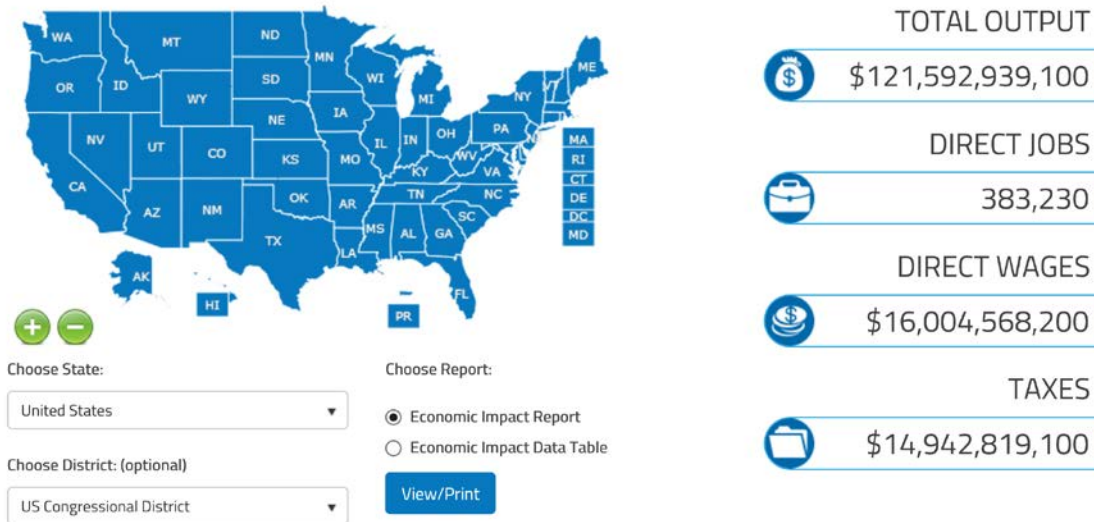
- FDA does not allow dissemination of science about food
  - Disease research makes product misbranded
  - Disease endpoints used as evidence of intent to market as a drug
- Industry seeking a way to permit posting of research online
- Focus on “third party literature” provisions of DSHEA

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# Economic Impact of the Industry

- New study commissioned by CRN
- Examines direct, indirect & induced effects
- \$122 billion; 750,000 jobs, \$38 billion in wages
- Available at [www.crnusa.org/economicimpact](http://www.crnusa.org/economicimpact)



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# Regulatory Climate for Dietary Supplements

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# FDA – Is this a new day?

- New **Office** of Dietary Supplement Programs
- Numerous vacancies
- NDIs – any time soon?
- GMP inspections—but what happens next?
- Sluggish response to steroids, synthetic stimulants and pure caffeine



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# FDA – Other open items



- Nutrition Facts & Supplement Facts labeling changes – final rule effective 2018
- Implementation of FSMA for ingredients
- Investigational New Drug (IND) applications – the impact on supplements
- Medical foods – dietary management of a disease that cannot be achieved by the modification of the normal diet alone?

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# When FTC goes to court...



Recent cases & investigations offer mixed directions to industry:

- POM Wonderful
- Basic Research
- Hi-Tech Pharmaceuticals
- Bayer/Phillips Colon Health

# FTC issues of interest

- Native advertising
- Endorsements & testimonials
- Upcoming workshop on disclosure
- Negative payment options
- Substantive issues: brain health, kids' products, weight-loss



# State Activity for Dietary Supplements

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# State Attorneys General



- DNA testing has lost its luster
- NY investigation brought new attention to the industry
- Several ongoing investigations
  - Oregon AG focused on NDIs
- Ongoing questions and conversations
  - NAAG presentation in Oct. 2015
  - CWAG presentation in July 2016

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# State Legislative Activity

- Pure caffeine restrictions
  - Illinois, Ohio, New York
- New York
  - Restricts sexual enhancement products
- Massachusetts
  - Weight management and muscle enhancement
- California Prop 65
  - Reform efforts, new website and warning verbiage
- Nutritionist licensing



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# So what does it all mean?

- A tumultuous time for the dietary supplement industry
- New scrutiny & unwanted attention
- Multiple challenges & opportunities
- Requires careful monitoring, proactive initiatives and quick-trigger responses



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# Thanks for listening!

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