

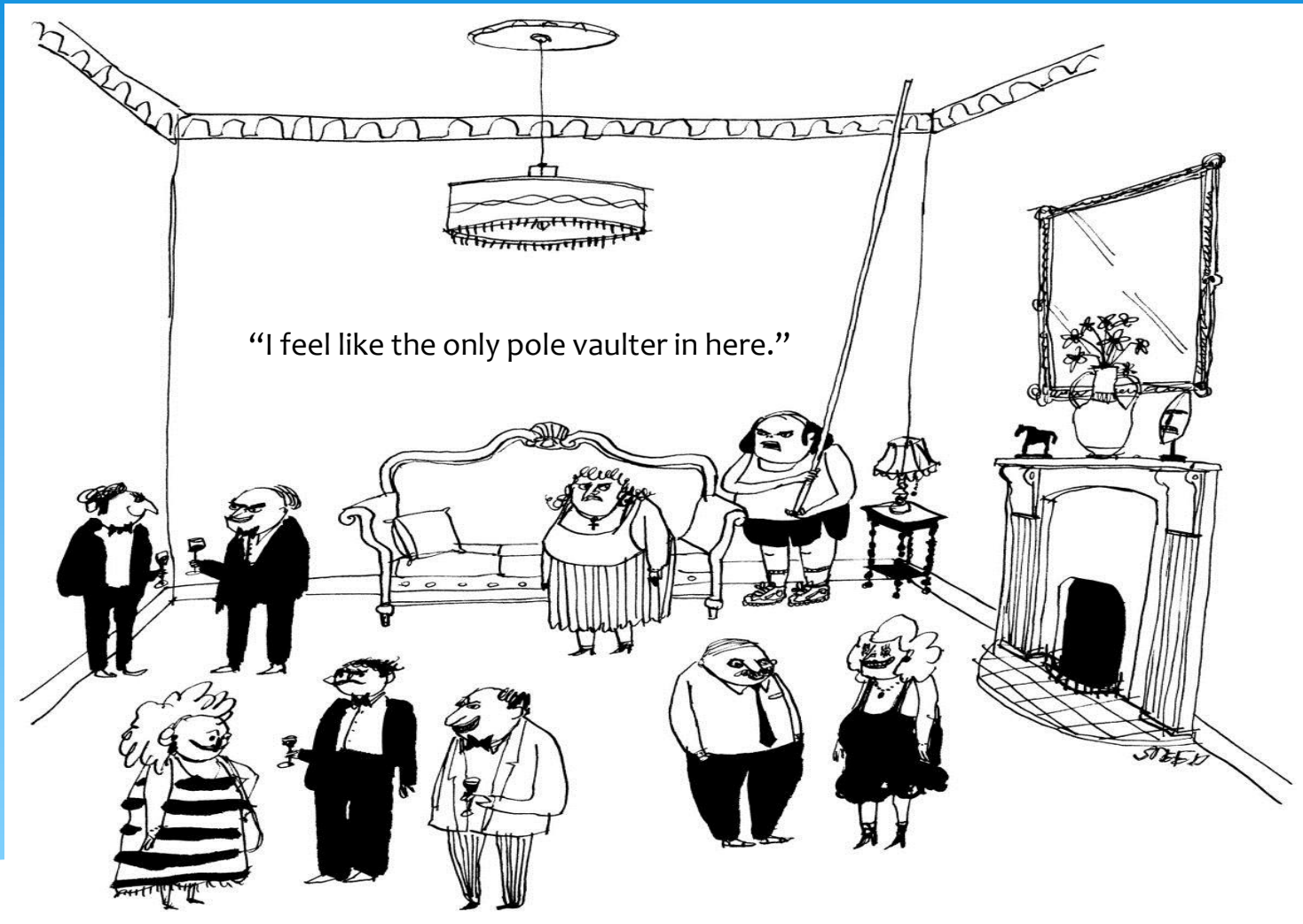
What *is* Real in Washington?*

2017 UNPA Retreat

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May 23, 2017

*Or, in the words of Sgt. Friday: “Just the Facts, Ma’am “

MY DISCLAIMER:



Who is this Government?

- * For the first time in history, we have a President with no government experience.
- * We have a deeply divided Congress:
 - Senate ratio:52-48
 - House ratio: 238-193

Overview

- * First, I'm going to bring you up to date on significant things that have happened since we last met.
- * I plan to talk about the composition and tenor of the current Congress, and touch on the key macro issues that Congress faces this year.
- * Feel free to gong me whenever you get bored.
- * And then Peter will drill down on some of the specific issues that will affect members more directly.

Who is this Government?

- * The implication is: it's all politics all the time.

Who is this Government?

- * We have a cabinet which seems to be largely comprised of former House members, or Wall Street executives.
- * Key for us: Tom Price, MD, HHS Secretary
- * Scott Gottlieb, MD, FDA Commissioner

Who is this Congress?

- * They're younger
- * Less experienced
- * More reactionary
- * And extremely partisan
- * Perhaps the most racially diverse, but still primarily white and male

Who is this Congress?

* Some House demographics:

88 Women (66D/22R)

53 Freshmen (25D/28R)

48 African-Americans (46D/2R)

DSHEA: 49 still there from 1994

Who is this Congress?

- * Some Senate demographics:

21 Women

7 Freshmen

3 African-Americans

DSHEA: 17 in Congress in 1994

Who is this Congress?

- * The House Chairman of Energy and Commerce, Greg Walden (OR), has a telecommunications background. His Democratic counterpart, Frank Pallone (NJ) is a co-chair of our DS caucus.
- * The Senate Chair, Lamar Alexander (TN) is an education and health care expert. The ranking Democrat, Patty Murray (WA) was in Congress for DSHEA.

Experience Levels Vary Dramatically

- * For example, on HELP (with FDA jurisdiction): Hatch has 40 years tenure; Hassan has 0
- * On Energy and Commerce, in 2009 there were 702 total years in Congress. Today: 601.
- * But on the House tax-writing Committee, in 2009 there were 498 total years, and now 508.

What a Difference a Year Makes

- * President Trump's election was a game-changer: Republican House, Republican Senate, Republican White House
- * And the possibility of changing the dynamics in the Supreme Court

What a Difference a Year Makes

* The Lions of 1994 are almost all gone:

-Dingell

-Kennedy

-Waxman

-Harkin

-Richardson

What a Difference a Year Makes

- * We've lost early, key DSHEA supporters
- * And even recent champions depart
 - Harry Reid (primary cosponsor)
 - Barbara Mikulski (key in Labor Cmte)
 - Jason Chaffetz's early retirement

What a Difference a Year Makes

- * We've picked up key advocates like Senator Tim Scott

What a Difference a Year Makes

- * Dietary Supplement Caucus membership down from 40 to 32;
- * Bolstering those numbers are a key priority.

What a Difference a Year Makes And What About 2018?

- * Entire House up for re-election
- * Senate: 8 GOP up for re-election
23 Democrats
+2 Independents
- * Mitch McConnell: “Don’t count your chickens before they’re hatched!”

Implications for UNPA Members

- * A populist Congress:

- The good news- grassroots can matter;

- The bad news- we can be one adverse event away from a bill.

Implications for UNPA Members

* A less experienced Congress:

The good news: more opportunities for education;

The bad news: no stable and knowledgeable leadership to influence opinion.

Implications for UNPA Members

* A younger Congress

The good news:
younger=healthier=more open to our
products and our message

The bad news: much re-
inventing of the wheel in Congress

Implications for UNPA Members

- * A less-experienced Congress
 - More reliance on leadership for key votes
 - Pallone is a key asset in the House (Ranking on E&C)

Key Issues Before the Congress

The White House

- * The recent furor about Flynn, Comey, Mueller, Russians etc. has sucked all the air out of the system;
- * The seriousness aside, it becomes interesting fodder for CNN, Twitter, and DC Parlor Games;
- * But, it will inevitably divert from other issues.

Key Issues Before the Congress

Health Care

- * The House recently passed The American Health Care Act – its repeal of the Affordable Care Act
- * Action now turns to the Senate, which has made it a top priority.
- * AHCA barely passed in the House 217-213
- * If anything the challenge is greater in the Senate where at least 3 Senators object to the House bill at each end of the spectrum. GOP can only lose 2 votes

Key Issues Before the Congress Tax Reform

- * The next GOP leadership priority is tax reform. Because of the parliamentary situation, health care must be done first.
- The shape and size of the effort are yet to be determined. So far, it looks totally partisan.
- Ryan issued a Blueprint for Reform last fall. No cards are on the Senate table.
- Issues we will be watching: corporate tax rates, whether there is a “BAT”

Key Issues Before the Congress

Government Funding

- * By September 30, all 12 appropriations bills must be done for FY 2018.
- * The good news: Congress recently passed the Omnibus Appropriations bill by a solid bipartisan margin
- * The bad news: now they have to do it all over again.

Key Issues Before the Congress

Government Funding

- * The atmospherics:

- Trump tweet: Our country needs a “good ‘shutdown’.”

- Politico: “Republicans on both ends of Pennsylvania Avenue are staring down a Fiscal 2018 budget calendar that is already the stuff of nightmares.”

Key Issues Before the Congress

Debt Ceiling

- * This fall, Congress must lift the statutory cap on the debt ceiling again or else the U.S. will default on its obligations;
- * This used to be *pro forma* – but now is an opportunity for conservatives to push for reduced government spending;
- * Politico: “The fiscal cliff to end all fiscal cliffs.”

Key Issues Before the Congress Trade

- * The tide has really turned in Congress on “free trade”.
- * Part of the support for Trump during the election came from Rust Belt states which lost jobs due to foreign competition.
- * Trump’s anti-free-trade message resonated there and with newer members of Congress.
- * Trump notified Congress 5/18 that he intends to “modernize” NAFTA and will start negotiations with Canada and Mexico. A 90-day clock started.

Key Issues Before the Congress

Other Deadlines

- * Other politically tough program extensions must pass this Fall:
 - National Flood Insurance Program
 - CHIP
 - Reauthorization of FAA
 - Reauthorization of Coast Guard
 - PDUFA
 - Community Health Center funding
 - Medicare extenders

Regulatory Reform

- * Finally, the new GOP “triumvirate” is undertaking a number of efforts to “deregulate” government.
- * Using the Congressional Review Act process, which allows regs to be overturned with a majority vote, Congress has nixed 14 Obama regulations.

Regulatory Reform

- * Trump has also issued Executive Orders:
 - 2:1 eliminate two rules for every new one
 - Comprehensive Plan to Reorganize the Executive Branch: task forces at each agency to search for rules to repeal or modify
- “We’re going to put the regulation industry out of work and out of business.” Donald Trump 2-24-17

The Facts:

"EVERY EXPERIENCE, NO MATTER HOW BAD
IT SEEMS, HOLDS WITHIN IT A BLESSING OF
SOME KIND. THE GOAL IS TO FIND IT."

- BUDDHA

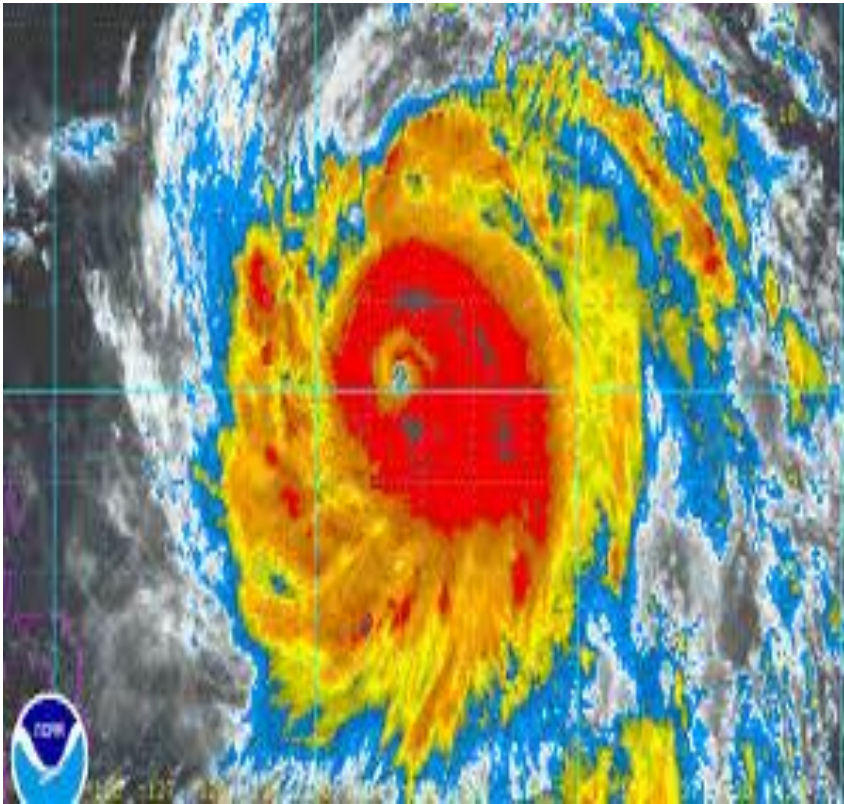


New RealPolitik in Washington

2017 UNPA Retreat

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Senior Political Advisor
May 23, 2017

Dietary Supplement Industry Threats and Opportunities



Threats

- **FDA Budget/Staffing Cuts**



- President asked for **\$40 million cut** in FY 2017
- Congress said “NO”; provided small increase
- President’s FY 18 Budget could call for **up to 37% cut**
- Congress will face increasing pressures to cut spending

Threats

* Cuts to FDA
Budget =



- * **FEWER** Inspections
- * **MORE** Bad Actors
- * **MORE** State AG Enforcement

Threats

- * The **Prescription Drug User Fee Act (PDUFA)** must also be reauthorized this year, which could be the vehicle for anti-DSHEA amendments on Senate and House floors.
- * **Department of Defense Authorization.** Last year was vehicle for attempt by Sen. Blumenthal and others to attach requirement for third party certification of all DS sold on military bases.

Threats

- **Dietary Supplement Labeling Act (DURBIN):**

Previous versions:

- * **HHS list of DIs and proprietary blends** that the Secretary determines “*could cause potentially serious adverse events, drug interactions, or contraindications, or potential risks to subgroups such as children and pregnant or breastfeeding women.*”
- * **Mandatory Warning Labels**
- * **Mandatory product registry**

No projected timeline for introduction

Opportunities

- * **Positive Signs from New FDA Leadership**

- * **Senator Hatch:** “Do you believe the FDA’s current regulatory framework under DSHEA provides for adequate enforcement tools to remove unsafe dietary supplements from the market?”

- * **Commissioner Gottlieb:** “As someone who uses dietary supplements everyday, I believe they serve an important role in health promotion for millions of Americans and I support consumer access to these products. I believe the regulatory framework under DSHEA is the right one, and if confirmed, I would commit to enforcing DSHEA, as intended by Congress.”

Opportunities

- * **Positive Signs from New FDA Leadership**



- * **IMPROVE** NDI Guidance
- * **INCREASE** Focus on Worst Offenders
- * **MORE** Open Dialogue with Industry

Opportunities

- * **Health/Flexible Savings Accounts (HSA/FSAs)**
 - * S. 403 (Hatch)/ H.R. 1175 (Paulson)
 - * *The term 'medical care' shall include amounts paid to purchase herbs, vitamins, minerals, homeopathic remedies, meal replacement products, and other dietary and nutritional supplements.*
 - * *\$1,000 per person per year limit*

Opportunities

* **Food Stamps/ “SNAP”**

- * Inclusion of MVM products as a **healthy choice option**
- * **No additional costs**, just optional choice
- * Vehicle is 2018 Farm Bill
- * Passed Senate in 2002 and 2006
- * No bills yet introduced



Opportunities

* **Medical Nutrition Equity Act**

- * New bill would require public and private insurance to cover costs of “**medically necessary foods and vitamins**”
- * **Bipartisan: Senators Casey (PA)/Grassley (IA)**
- * For those with **digestive and other inherited metabolic disorders, including celiac**
- * **Prescribed or recommended by health professional**
- * Outlook is uncertain; likely substantial price tag

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GMO Labeling Law

- * Signed into Law in July 2016
- * USDA has until July 2018 to adopt **mandatory disclosure standard**
- * USDA must first ID potential tech challenges for consumers thru electronic/digital disclosure
- * Deloitte will deliver report by July 2017
- * Seems to be on track, but **impact of new Administration is uncertain**



Allow Consumer Access to **CBD Oil**-

- S.1008 (**Gardner**) Therapeutic Hemp Medical Access Act - exempts CBD from Controlled Substances Act

-H.R. 715 (Griffith) Compassionate Access Act) –allows medical marijuana use and removes CBD from Controlled Substances Act.

-**FDA**: CBD oil is not a DS because cannot meet the grandfather;

--If not a DS or controlled substance, what is it?

Impact of new DOJ “**tough on crime**” agenda could create hurdles

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Single Food Safety Agency

- * HHS Sec. Price recently endorsed combining current USDA and FDA food safety into a single agency
- * Could include regulation of DS; **taking DS out of FDA and put in a new Agency**
- * **Positive:** Take out of Rx atmosphere/thinking
- * **Negative:** Become “riskier” part of new agency
- * Has been considered several times in years past but no action taken

CLOSING Points

BUCKLE UP!!!

