

**BUILDING INFORMED TRUST**  
*THE WHITE HOUSE, THE CONGRESS... AND YOU*

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**BUILDING INFORMED TRUST**

**KNOW YOUR AUDIENCE**



## BUILDING INFORMED TRUST

## KNOW YOUR AUDIENCE

### Factors:

- No record on many specific issues, including DS.
- Would bring in new team: HHS Secretary, FDA Commissioner.
- Chance to bring a new way of thinking to FDA.
- Opportunity to revisit NDI and other regulations.



## BUILDING INFORMED TRUST

## KNOW YOUR AUDIENCE

### FACTORS:

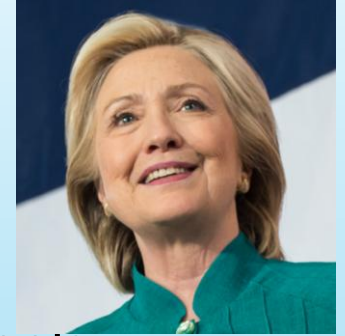
- Was a cosponsor of the House DSHEA (HR 1709) in 1994.
- Supportive of CAM, opposes GMOs.
- Seen as anti-business.
- Member of the Senate HELP Committee – hasn't shown recent interest in DS.

**NB:** Could be HELP Chair next year!



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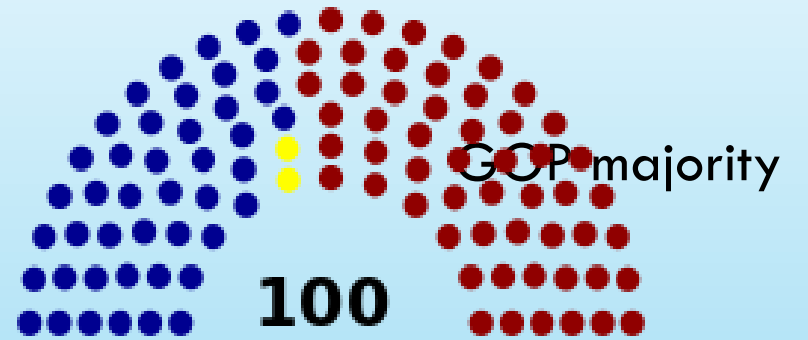


### FACTORS:

- Considerable Executive Branch, Senate, [and White House] experience— she gets how government works.
- Appreciates value of grassroots, consensus building.
- May be more sympathetic to regulatory rather than free-market solutions to problems.
- Some of current HHS team could stay on (Califf? Burwell?).
- Policies/team very developed. Could hit the ground running.

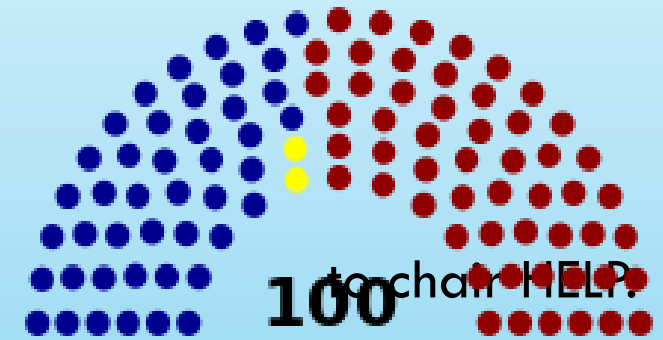
## UNITED STATES SENATE

- Hard to overestimate political volatility where hangs in balance. (Currently 54:46)
- 24 GOP seats to 10 Democrat seats are up for re-election. Of the 34 seats, 5 are open due to retirements - (GOP: Vitter, Coats, Rubio/ Dem: Boxer, Reid, Mikulski).
- Only 9 of the 66 original Senate DSHEA cosponsors remain; and four are retiring this year (Mikulski, Reid, Coats, Boxer). But four House cosponsors (Crapo, Reed, Portman, Inhofe) since elected to Senate.



## UNITED STATES SENATE-IMPORTANCE

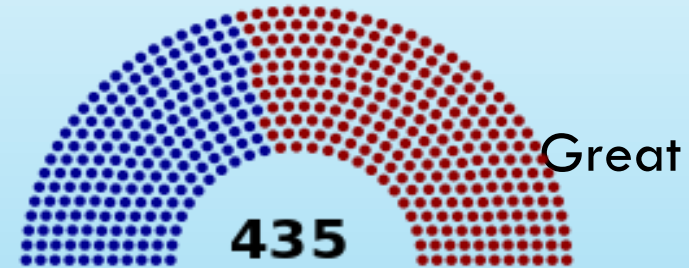
- Will confirm new HHS Secretary, FDA Commissioner.
- If turns Democrat, Sanders could be chair of HELP.
- If remains GOP, Alexander (R-TN) would continue
- Our most senior advocate, Orrin Hatch (R-UT)'s term is up in 2018.
- Senate co-chair of Dietary Supplement Caucus, Martin Heinrich, becoming more active in DS issues.
- Industry critics, Dick Durbin (D-IL) and Richard Blumenthal (D-CT) continuing to be active.





## HOUSE OF REPRESENTATIVES

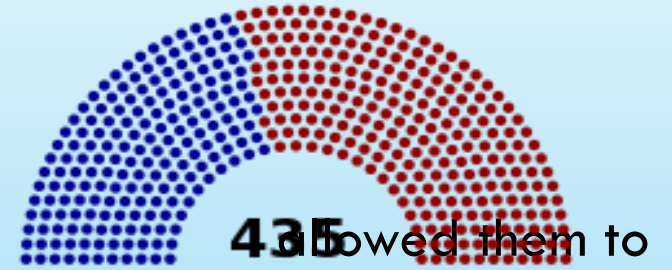
- Republicans have largest majority since Depression (246:188).
- Every seat is up for re-election.
- Pollsters believe it is unlikely Democrats can regain 30 seats to win majority – but are not ruling it out.
- Only 18 of the original 261 cosponsors remain in the House (plus four went to the Senate).
- Effect of Presidential race on downstream candidates is the big wildcard.





## HOUSE OF REPRESENTATIVES-IMPORTANCE

- Their larger GOP majority plus differing rules has react more quickly to unwise agency proposals.
- Due to Committee chair term limits, E&C Chair Fred Upton (R-MI) an original DSHEA supporter, will step down. He is expected to be succeeded by next-in-line Ed Whitfield (R-KY) or John Shimkus (R-IL). Shimkus has been supportive of DS industry.



*“The Senate has a seniority system...we have a meritocracy”* -Speaker Paul Ryan

- With their changing numbers, keeping House members abreast of DS issues is a continual education job on which the trades collaborate jointly.

**CONGRESS**

- Congress is in the midst of a major generational shift. It is increasingly:
  - Younger
  - Less experienced
  - More eager for change



ience

	<u>1994</u>	<u>2015</u>
GI Generation (b. 1900-1927)	12%	0%
Silent Generation (b. 1928-45)	58%	14%
Baby Boomers (b. 1946-64)	30%	63%
Gen X (b. 1965-1979)	0	21%
Millennials (b. 1980- )	0	2%

## BUILDING INFORMED TRUST

## WHAT WE SAY:



Dietary Supplements are regulated under a 1994 law....

The FDA has abundant power to take problem supplements off the market....

There are very few problem products compared to the literally thousands of supplements which are helping more than 150 million Americans lead healthier lives...

- **New York Times: Study Warns of Diet Supplement Dangers Kept Quiet by F.D.A.** 4-7-15
- **Science: Feature: Revealing the hidden dangers of dietary supplements...** 8-20-15
- **PBS FRONTLINE: The New York Times and Canadian Broadcasting Corporation examine the hidden dangers of vitamins and supplements, a multi-billion industry with limited FDA oversight...** 1/19/26
- **VOX Science and Health: Stop Wasting your money on dietary supplements...** 3-10-16
- **WSGBH News: The Unregulated Truth Behind Dietary Supplements. “For the most part, they are totally unregulated. It’s a bit shocking and I must say that it’s one of the things that shocked us as well as we sort of launched into this investigation.” Frontline correspondent Gillian Findlay said on Boston Public Radio.** 1-19-16

## BUILDING INFORMED TRUST

## WHAT YOUR AUDIENCE HEARS

- Super Herbs Supplement Recalled for Undeclared Drug 4-12-16
- LGD-Xtreme Dietary Supplement Recalled for Unapproved Drug 4-5-16
- Pink Bikini Dietary Supplement Recalled for Unapproved Drug 12-13-15
- Natureal Dietary supplement Recalled for Unapproved Drugs 11-11-15
- Mayhem Dietary Supplement Recalled for Unapproved Drug 11-17-14
- Black Ant Dietary Supplement Recalled Again 5-19-14

- **Even things we've advocated, can get spun wrong:**

### **FDA Creates Office of Dietary Supplement Programs**

The FDA announced yesterday that they have created Dietary Supplement Programs (ODSP), which will be a new division under the Office of Nutrition Labeling and Dietary Supplements. This change will “enhance the effectiveness of dietary supplement regulation by allowing ODSP to better compete for government resources and capabilities to regulate this rapidly expanding industry.”

The FDA does not regulate dietary supplements until there is a problem reported. The government takes action to remove supplements from the market that may be dangerous to consumers, and removes those that are falsely labeled or contain undeclared drugs. Other actions the government can take is enforcing good manufacturing practices regulation, especially when violating those practices can compromise product safety or can result in consumer deception. The dietary supplement industry has grown from \$6 billion in sales 20 years ago to more than \$35 billion today. December 22,

2015 by Linda Larsen



- The media drum beat is increasingly louder, and we must work harder to counter that.
- Industry has been very united and proactive in:
  - building ties to FDA (e.g. joint letter to new Commissioner)
  - urging the FDA and Justice to make enforcement a priority, both from an organizational standpoint (new elevated office) and with respect to their actions (Hatch and Heinrich letters to DoJ)
  - building the Congressional Dietary Supplement Caucus (at a record high of 39 members, both House and Senate) and conducting briefings for congressional staff
  - visiting all new members to brief them on industry



## BUILDING INFORMED TRUST

## WHAT WE ARE DOING TO BUILD TRUST

- working with our allies in Congress to foster legislation beneficial to the industry
- Sen. Hatch and Rep. Paulsen bills to allow HSAs and FSAs to be used for DS expenditures)
- DS Caucus Chair Jason Chaffetz' (R-UT) efforts to foster greater information to be shared with consumers (“Free Speech About Science Act” rewrite)
- We’ve also been united in fighting efforts that would harm industry, such as Sen. Blumenthal’s (D-CT) efforts to require third-party certification outside FDA for all supplements sold on military bases

- We've also been working to educate Senator Claire McCaskill (D-MO) who is investigating DS through her position as the top Democrat on the Senate Aging Committee. Recently, she has focused on DS and cancer drugs interactions. Focusing congressional efforts on problem players is a benefit to the industry.
- AHPA and UNPA have retained an advisor to help us get our message through to State Attorneys General, who increasingly have been active in the DS space. "Settlements" like that in NY which resulted in a parallel and differing regulatory scheme for certain products and certain manufacturers in isolated geographic locales can only undermine the national system administered by the FDA.

- Sen. Durbin's Dietary Supplement Labeling Act:
  - no projected timeline for introduction;
  - industry working hard to develop voluntary alternative.
- Sen. Blumenthal: amendment to Defense Authorization to require third party certification of all DS sold on military bases.
  - Industry opposition resulted in withdrawal in Committee.
  - May be offered on floor this week.
  - UNPA is working with other trades; sent letter in opposition to all Senators.

■ **CBD Oil**- Two differing approaches allow consumer access to CBD oil:

- **Gardner bill** – Therapeutic Hemp Medical Access Act – S 1333 - exempts CBD from Controlled Substances Act (5/13/15)

-Bipartisan cosponsors: Orrin Hatch(R-UT); Ron Wyden (D-OR); Johnny Isakson (R-GA); Jeff Merkley (D-OR); Michael Bennet (D-CO); Alexander (R-TN); Johnson (R-WI); Baldwin (D-WI); Tillis (R-NC); Blunt (R-MO); Lee (R-UT); Graham (R-SC); and Warner (D-VA)

-**Chaffetz bill** – The CBD Oil Act of 2016 (HR 4779) – bars prosecution if use of CBD oil is legal under state law.

-Bipartisan cosponsors: Raul Labrador (R-ID); Steve Cohen (D-TN); William Clay (D-MO); James Sensenbrenner (R-WI); Glenn Grothman (R-WI); Walter Jones (R-NC); Gerald Connolly (D-VA); David Loebsack (D-IA).

-**Griffith bill:** Compassionate Access Act (HR 1774 (5/15/15) –allows medical marijuana use and removes CBD from Controlled Substances Act.

Four cosponsors: Earl Blumenauer (D-OR); Barbara Lee (R-CA); John Conyers (D-MI); and Robert Hurt (R-VA).

- Extremely complicated issue:

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

- GW Pharma has an IND which could also block it from being sold as a DS;

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

■ **GMO Legislation:**

-**HOUSE:** Safe and Accurate Food Labeling Act: (Mike Pompeo, R-KS)  
(HR 1599)

-Passed July 2015

-Allows voluntary labeling but FDA may require labeling if necessary to protect public health or if otherwise is misleading. Requires FDA to define “natural” with Federal pre-emption.

**SENATE:** S. 2609 (Pat Roberts R-KS) – Requires Sec. of Agriculture to establish a voluntary national labeling standard for bioengineered foods. Approved by Agriculture Committee in March.

-Unclear if can be passed by Senate this year. Cloture failed 48-49 in March.

-Almost daily negotiations continue between Agriculture Committee Chair Pat Roberts (R-KS) and Ranking Democrat Debbie Stabenow (D-MI).

-Race against the clock: Vermont law in effect 7/1/16



- We've been working hard in DC with our trade partners, a non-stop effort.
- This year the schedule is attenuated because of the elections. Congress will adjourn for seven weeks in the summer and come back after Labor Day only until September 30.
- A lame duck session is expected.
- Next year we will face a number of uncertainties because of the new membership in Congress, potential musical chairs of Committee leadership, and the agenda and staffing of a new President.
- The Prescription Drug User Fee Act (PDUFA) must also be reauthorized next year, which is certain to provide an open vehicle for FDA amendments.

## BUILDING INFORMED TRUST

## CONCLUSION

- It is helpful to Loren and us if you keep an open dialog about your company's priorities, your local priorities and your interactions with members of Congress.
- If you need help in getting started on this, we are always there to help you.
- We hope we have conveyed to you the necessity of amping up our interactions with the changing face of this Congress.

WITH APOLOGIES TO GARY LARSON- A LOBBYIST'S NIGHTMARE!

