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What's Up in Washington?!

American Spice Trade Association Annual Meeting

Maile Gradison Hermida, Partner

April 24, 2017



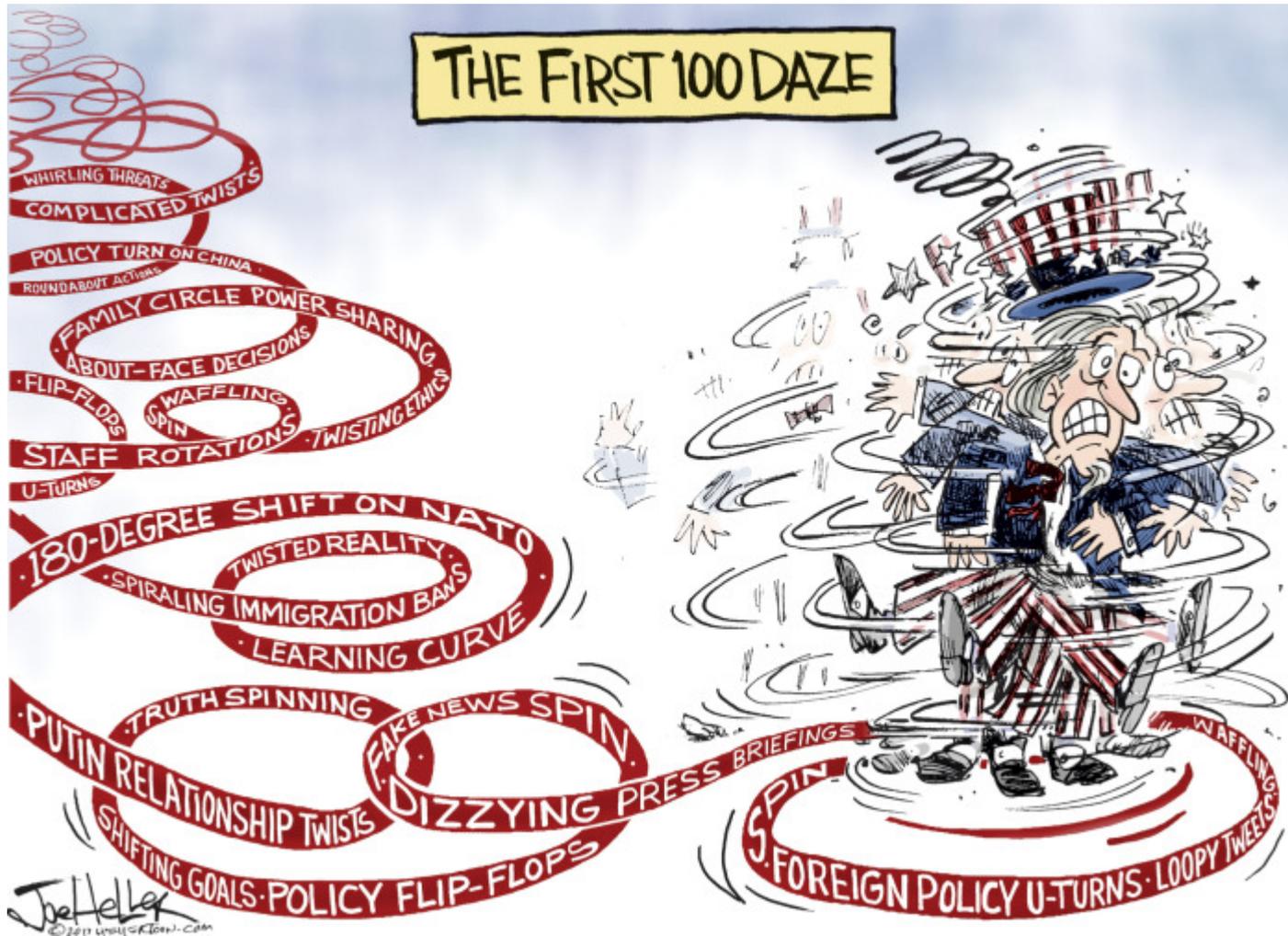
Agenda



Agenda



THE FIRST 100 DAZE



Joe Heller
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Areas of Focus

- Trump Administration Activities and Initiatives
- In Focus:
 - Food Regulation
 - Trade
 - Tax Reform

Administration Activities and Initiatives



Actions so Far

- Regulatory Freeze
- 2-for-1 Rule
- Regulatory Reform Agenda
- Executive Branch Reorganization
- Hiring Freeze (and Thaw)
- Budget Proposal



Regulatory Freeze (January 20, 2017)

- AKA “Priebus Memo”
- Delays further action on:
 - (1) regulations that have not yet been sent to the *Federal Register*;
 - (2) regulations that have been sent to *Federal Register* but had not yet been published; and
 - (3) regulations that had been published but had not yet reached their effective dates
- Regulations not yet published (items 1 and 2) are delayed until an agency head appointed by President Trump can review and approve them



Executive Order 13771 (Jan. 30, 2017)

- AKA, “One In, Two Out” (or 2-for-1) Rule
- For FY 2017, must be no net increase in costs for the regulations promulgated and repealed
- For FY 2018 and subsequent years:
 - OMB will set a cap for each agency on total net increase in costs for new and repealed regulations
 - Agencies must identify two or more offsetting regulations to be repealed for each regulation that increases incremental costs
- Limited to “significant regulatory actions” (e.g., regulations or guidance costing more than \$100 million or raising novel legal or policy issues)



Executive Order 13777 (Feb. 24, 2017)

- Orders each agency to identify a Regulatory Reform Officer (RRO) who will oversee the agency's implementation of the regulatory reform agenda and chair a Regulatory Reform Task Force for the agency
- Task Forces will evaluate existing regulations and make recommendations on whether a regulation should be repealed, replaced, or modified
- When repealing existing regulations to comply with EO 13771 (2-for-1), agencies must consider the regulations identified by the Task Forces as outdated, unnecessary, or ineffective



Executive Order 13781 (March 13, 2017)

- Directs Office of Management and Budget (OMB) to develop a plan for reorganizing the executive branch and eliminating unnecessary agencies, components of agencies, or agency programs
- Within 180 days, heads of agencies must submit a plan to OMB to reorganize each agency to improve efficiency, effectiveness, and accountability
- OMB also must solicit public comments
- OMB's plan for reorganizing the executive branch must include:
 - Recommendations to eliminate unnecessary agencies/components/programs;
 - Recommendations to merge existing agency functions; and
 - Identification of any legislation or administrative measures needed to execute the reorganization



Executive Order 13781, cont'd

- In drafting the proposed plan, OMB must consider:
 - Whether some functions would be better left to state/local governments or the private sector;
 - Whether some functions are redundant;
 - Whether administrative capabilities for operating an agency/component/program are redundant with other agencies/components/programs;
 - Whether the cost of continuing to operate the agency/component/program are justified by the public benefits it provides; and
 - The cost of shutting down or merging agencies

Federal Hiring Freeze (January 23, 2017)



- Presidential Memorandum Implementing Hiring Freeze
- No vacant positions may be filled and no new positions may be created
 - Exception for national security or public safety responsibilities, internal advancements
- OMB guidance suggested exemption could be interpreted to include activities performed by FDA/USDA inspectors and potentially other food safety personnel
- OMB ordered to recommend long-term plan for reducing federal work force within 90 days

Federal Hiring Freeze Lifted (April 12, 2017)

- OMB issued its *Comprehensive Plan for Reforming the Federal Government and Reducing the Federal Civilian Workforce*
- This officially ended the federal hiring freeze
- However, in the words of OMB Director Mulvaney, “it does not mean that agencies will be free to hire willy-nilly”
- Instead, each agency has been directed to complete a series of actions as a part of a comprehensive government-wide Reform Plan for publication in the President’s FY 2019 budget.



OMB Memo – Goals of the Government-Wide Reform Plan

When implemented, these reform efforts should accomplish the following objectives:

- Create a lean, accountable, more efficient government that works for the American people;
- Focus the Federal government on effectively and efficiently delivering those programs that are the highest needs to citizens and where there is a unique Federal role rather than assuming current programs are optimally designed or even needed;
- Align the Federal workforce to meet the needs of today and the future rather than the requirements of the past; and
- Strengthen agencies by removing barriers that hinder front-line employees from delivering results.

OMB Memo – Goals of the Government-Wide Reform Plan



When implementing

- Create a...
- Focus on... are the... assuming...
- Align the requirements...
- Strengthen results.

objectives:

the American people;... those programs that... role rather than

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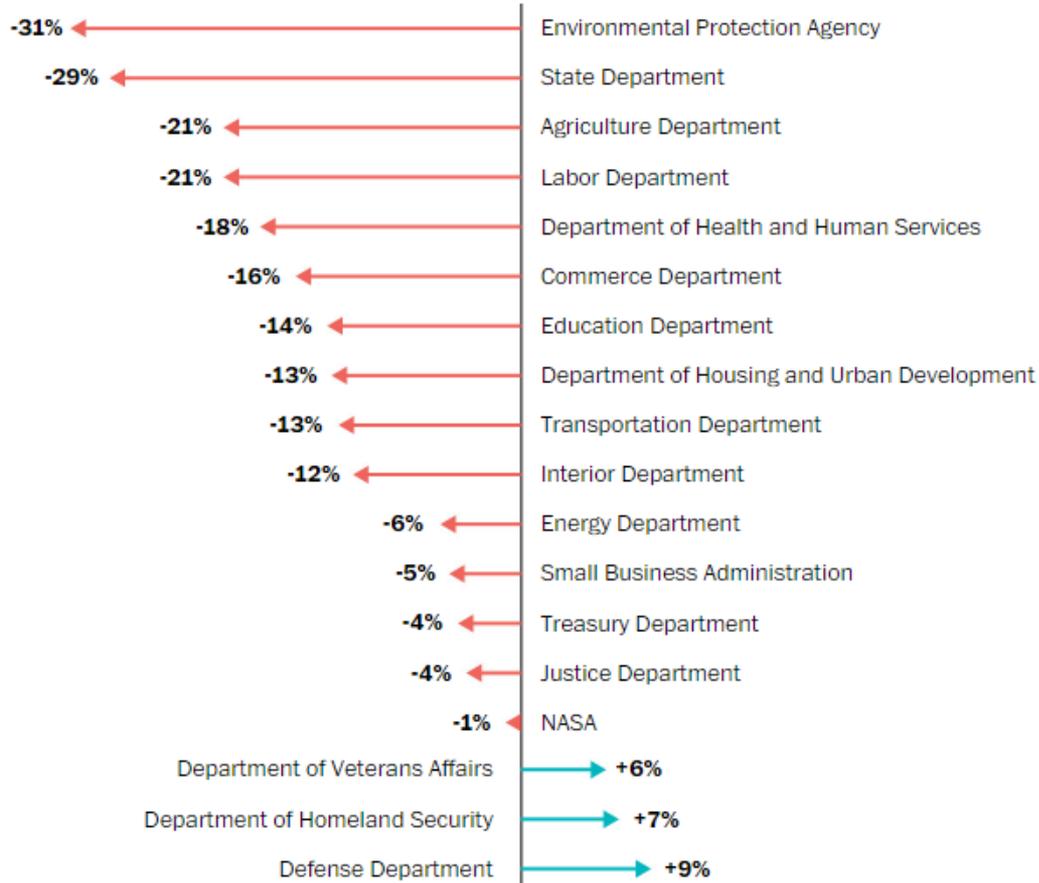
employees from delivering

First Steps in Agency Reform: FTC

- The Federal Trade Commission recently outlined some of the actions it has taken to implement the Trump Administration's reform directives:
 - Working to **streamline demands for information** in investigations to **eliminate unnecessary costs to companies and individuals** that receive them
 - Reviewing dockets and **closing older investigations** where appropriate
 - Identifying **unnecessary regulations** that are no longer in the public interest
 - Working to **integrate economic expertise** earlier in FTC investigations to better inform agency decisions about the consumer welfare effects of enforcement actions
 - Establish a process for the Acting Commissioner to collect and review ideas on **process streamlining and operational efficiency opportunities** from across the agency



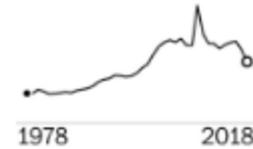
Proposed Budget Cuts



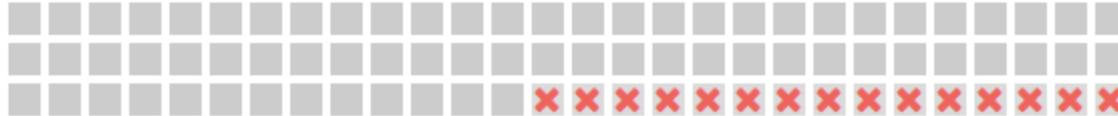
Proposed Budget Cuts

DEPARTMENT OF HEALTH AND HUMAN SERVICES

2017 BUDGET	2018 PROPOSAL
\$84.1B	\$69.0B



Decreased \$15.1B (-18% change)

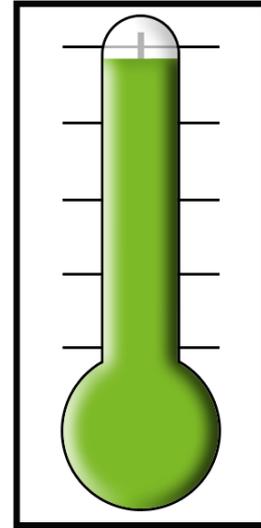


Food Regulation Impacts



Status of FSMA Implementation

- **FDA has issued 7 final rules:**
 - Preventive Controls for Human Food
 - Preventive Controls for Animal Food
 - Produce Safety
 - Foreign Supplier Verification Program (FSVP)
 - Accreditation of Third-Party Auditors
 - Sanitary Transportation of Food
 - Food Defense/Intentional Adulteration
- **Next Up: Guidance**
 - Several draft guidance documents have been issued; more to come



Compliance Timeline—Key Dates

- **September 19, 2016**
 - Preventive controls (PCs) and updated cGMPs for human food (facilities over 500 employees)
- **March 17, 2017**
 - PC supplier verification for larger suppliers (500+ employees)
- **April 6, 2017**
 - Sanitary food transportation
- **May 30, 2017**
 - FSVP for larger suppliers
- **September 18, 2017**
 - PC's for human food (<500 employees)
 - PCs for animal food
- **March 19, 2018**
 - FSVP and PC supplier verification for smaller suppliers (<500 employees)
- **July 26, 2019**
 - Intentional adulteration

FDA's FSMA Inspection Plans

- Preventive Controls inspections started in January 2017, but PC supplier verification inspections have not started yet
 - 750 “FSMA” (PC/GMP) inspections the first year
 - 300 PC inspections (240 domestic / 60 foreign)
 - 450 modernized GMP inspections
- FDA is still working on its strategy for FSVP inspections
 - Inspections will not occur at the border
- Expect a very regulatory approach
 - Where there is a requirement for something to be written, FDA will inspect for adequacy and then assess implementation
 - Anticipate that inspectors will seek to determine compliance with each and every applicable regulation and sub-regulation

Nutrition Facts Panel Updates

Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

Calories 230 Calories from Fat 72

Total Fat 8g **% Daily Value*** **12%**

Saturated Fat 1g **5%**

Trans Fat 0g

Cholesterol 0mg **0%**

Sodium 160mg **7%**

Total Carbohydrate 37g **12%**

Dietary Fiber 4g **16%**

Sugars 1g

Protein 3g

Vitamin A 10%

Vitamin C 8%

Calcium 20%

Iron 45%

* Percent Daily Values are based on a 2,000 calorie diet.
Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Nutrition Facts

8 servings per container
Serving size 2/3 cup (55g)

Amount per serving

Calories **230**

% Daily Value*

Total Fat 8g **10%**

Saturated Fat 1g **5%**

Trans Fat 0g

Cholesterol 0mg **0%**

Sodium 160mg **7%**

Total Carbohydrate 37g **13%**

Dietary Fiber 4g **14%**

Total Sugars 12g

Includes 10g Added Sugars **20%**

Protein 3g

Vitamin D 2mcg 10%

Calcium 260mg 20%

Iron 8mg 45%

Potassium 235mg 6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

- NFP revisions have been finalized
- Awaiting on guidance on added sugars and dietary fiber
- Compliance Date: July 2018
 - But, industry is seeking an extension so there can be harmonization with GMO labeling rules

Leadership Changes

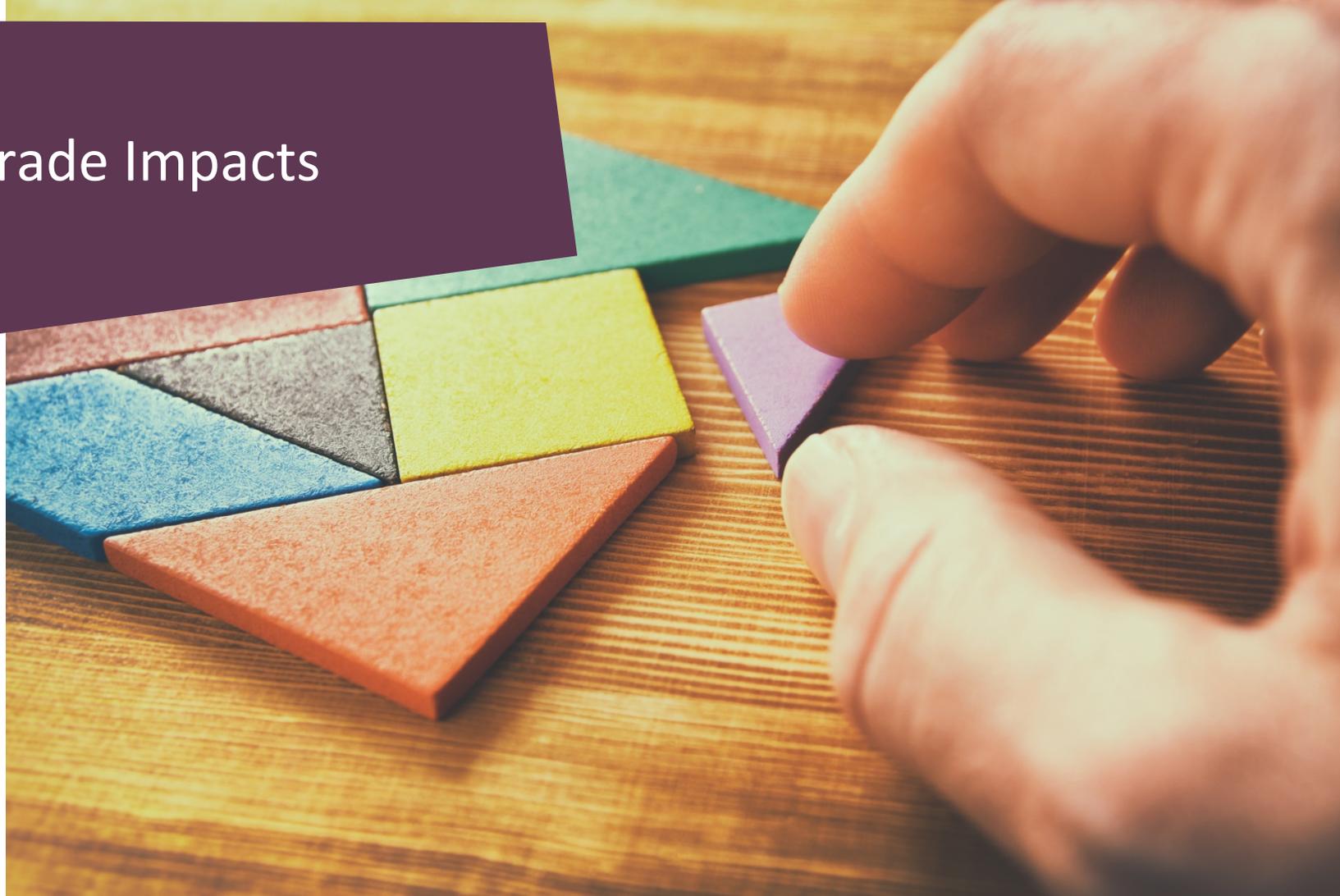
- Secretary of HHS: Tom Price
- FDA Commissioner:
 - Acting: Dr. Stephen Ostroff
 - Nominated: Dr. Scott Gottlieb
- Deputy Commissioner for Foods and Veterinary Medicine:
 - Prior: Dr. Stephen Ostroff
 - Current: Erik Mettler
 - Future: TBD
- CFSAN Director:
 - Current: Dr. Susan Mayne
 - Future: TBD



What to Expect in the Next Year?

- Trump Administration unlikely to focus on food and agriculture issues
- FDA inaction for the foreseeable future – awaiting new leadership
 - Slow trickle of FSMA guidance releases
- Smaller federal government – how far will budget reductions extend?
- FDA food safety agenda likely to remain vibrant in the near-term
 - FSMA/food safety implementation is well on its way
 - Rise in enforcement action over past two years evident
 - Food safety typically not political
- Industry might seek some refinements to FSMA – but not a repeal
- Industry also is seeking an extension of the NFP compliance date – but not a repeal

Trade Impacts



Trump's Campaign Promises

7 Point Plan to Rebuild the American Economy by Fighting for Free Trade

1. Renegotiate or terminate NAFTA
2. Withdraw from TPP
3. Designate China as a “currency manipulator”
4. Direct Commerce and USTR to identify and end foreign trade abuses
5. Impose 45% tariffs on China
6. Pursue “bilateral trade deals”
7. Impose 35% tariffs on U.S. companies that move U.S. factories to Mexico



Key Trade Actions to Date

1. Announced on Day 1 US withdrawal from the Trans-Pacific Partnership (TPP)
2. Seeking to renegotiate NAFTA (Commerce Department and Office of the United States Trade Representative (USTR))
 - High stakes! Big changes may require Congressional approval
 - Economic and political costs of termination, so ultimately Trump may just get political credit from supporters just for trying to renegotiate
3. Executive Order to Commerce Department and OMB on “Buy American and Hire American” for US Government procurement
4. Executive Order to Commerce Department requiring an examination of the trade practices in countries with which the United States runs a “trade deficit” (China, Japan, Germany, Mexico, Ireland, Vietnam, Italy, South Korea, Malaysia, India, Thailand, France, Switzerland, Taiwan, Indonesia and Canada)

U.S. trade law vests broad authority in the president

- Termination and Withdrawal Authority for Trade Agreements
 - Section 125 of Trade Act of 1974
- Authority to Designate Currency Manipulators
 - 1988 Trade Act
- Authority to Raise U.S. Duties
 - Section 301(b) – Unfair Trade Practices
 - Section 232 – National Security
 - Balance-of-Payments
 - International Emergency Economic Powers Act (IEEPA)
 - Section 125 – Authority to Raise Tariffs to 1975 Levels
- Import Relief
 - Section 201, AD/CVD, Section 421 (China)
- Authority to Enter Into Bilateral Trade Negotiations
 - Bipartisan Congressional Trade Priorities Act of 2015



Political challenges to trump's trade agenda?

- Congressional Republicans – Mostly Free Traders
- U.S. Multinationals and Agriculture – Big Exporters
- Mexico – 2nd Largest U.S. Export Market = 1.1 Million Jobs
 - Machinery (\$82 billion); Motor Vehicles (\$22 billion); Corn, Soybeans, Dairy, Beef, and Pork (\$7.4 billion)
 - Ending NAFTA – Boosts Illegal Immigration; Benefits China
- China – 3rd Largest Export Market = 950,000 Jobs
 - Aircraft (\$8 billion); Farm Products (\$6 billion); Motor Vehicles (\$5 billion); Semiconductors (\$2 billion)

Tax Reform



US Tax Reform – Timing

- Republican Budget, Health, Tax Agenda Discussed at Philadelphia Retreat
 - April 7 - Conclude Obamacare Repeal/Replace.
 - Memorial Day - Pass the FY18 Budget (this is the legislative vehicle for tax reform.)
 - August Recess - House passes tax reform.
 - Thanksgiving - Tax reform passage and becomes law.
- More realistically –
 - Obamacare replacement may be pushed to next year
 - Senate not likely to complete tax reform until the Fall or later
 - Ultimate tax reform bill enacted – if at all – very late in 2017 or in 2018

US Tax Reform – Key Proposals

- House Republican (Ryan/Brady) Blueprint
 - Corporate rate to 20% (eliminate AMT)
 - Full expensing of capital expenditures
 - No deductibility of interest expense (except to extent of interest income)
 - Border adjustable – “destination based cash flow tax,” i.e., cost of goods sold that are imports are non-deductible, and export sales are not taxable
 - One-time tax on accumulated foreign subsidiary earnings and profits, and shift to territorial tax system
 - Eliminate all “special interest” tax incentives, except R&D and LIFO tax accounting
- Bottom Line: Would effectively tax imports by at least 20%

US Tax Reform – Key Proposals

- Trump Tax Reform Plan
 - New tax “plan” proposing “massive” tax cuts expected as early as the end of this week
 - Corporate rate to 15% (eliminate AMT)
 - Choose between full expensing of capital expenditures or deductibility of interest expense
 - One-time (“deemed repatriation”) tax on accumulated foreign subsidiary earnings and profits; then impose global minimum tax on US company earnings abroad
 - Eliminate all “special interest” tax incentives except R&D credit
- Senate Republican Plan
 - ? Reportedly being drafted

The Bottom Line

IF WALTER CRONKITE WERE STILL REPORTING TODAY...



Final Thoughts

- We are in a deregulatory environment now
 - But, we're all still trying to figure out exactly what that means in practice
- For FDA, no new rules may be issued, but we weren't expecting anything new after the whirlwind of activity during the Obama Administration
 - FSMA and the NFP rules are not going away, but industry may seek some refinements
 - Inspection and enforcement efforts will expand over time, but FDA funding will be key
- Trade + Tax = Big issues to watch
- Stay tuned!
- Stay engaged!

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