

What's New in Washington

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Congress has continued its focus on appropriations, nominations and investigations as the Memorial Day recess approaches. The administration continues to focus on trade as the President's top policy priority.

The main legislative agenda item continues to be the budget and appropriations for Fiscal Year (FY) 2020. Legislators are grappling with how to handle the discretionary spending caps and prevent the impending \$126 billion in automatic, across-the-board spending cuts, known as sequestration, that will be triggered in January 2020, if Congress fails to reach a deal. Budget Committee leaders in both chambers have spent weeks negotiating, but a compromise has yet to materialize. Consequently, House Speaker Nancy Pelosi (D-CA) and Senate Majority Leader Mitch McConnell (R-KY) have begun discussions over a two-year budget deal at the leadership level. Any deal is likely to come together no earlier than late summer or early fall.

While the constructs of a budget caps deal remain up for debate, lawmakers are beginning to markup the FY 20 appropriations bill in an attempt to keep the process somewhat on track. In the House, several Appropriations Subcommittees have already begun marking up appropriations legislation, including the Labor-HHS-Education and Legislative Branch bills. The Senate is continuing to negotiate on spending levels and has yet to release or markup any spending measures. The Senate is continuing to negotiate on spending levels and has yet to release or markup any spending measures.

Closely connected to the budget caps debate are negotiations surrounding the debt ceiling. The temporary suspension of the debt limit expired in early March. However, the Treasury continues to use "extraordinary measures" to prevent a default on U.S. debt. Those measures are expected to run out as soon as September, putting pressure on Congress to suspend or raise the debt ceiling by the fall. It's possible that a debt ceiling increase could be attached to another "must pass" item, including any budget deal that may come together.

In the House, the new Democratic majority continues to press forward on a number of bills central to the Democratic agenda during this work period, including bills to reaffirm U.S. commitment to the Paris Agreement on climate change, prohibit discrimination based on sexual orientation or identity, provide disaster relief funding and rollback Administration guidance on the state innovation waiver provision of the Affordable Care Act.

In the Senate, Republican leadership is expected to continue to push forward on judicial and executive nominations, and is trying to pass a disaster aid package by Memorial Day.

Drug pricing, privacy and trade are expected to continue to dominate the policy discussions in both chambers over the course of the summer.

Developing Story

On Thursday afternoon, the President announced an immigration plan to address border security, interior enforcement, asylum policy, modernization of ports of entry, and the current immigrant visa or "green card" system. The stated goal of the plan is to 1) secure our borders; 2) protect American wages; 3) attract and retain the best talent; 4) unify families; 5) provide labor for critical industries; and 6) preserve humanitarian values. The plan does not address "Dreamers," individuals who were brought to the U.S. illegally as

minors, nor does it address recipients of Temporary Protected Status. Further, the plan makes no changes to non-immigrant visa programs (known as “guestworker” programs) and does not mandate the use of E-Verify for employers.

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COMMITTEES ADVANCE DRUG PRICING LEGISLATION

Committees Advance Drug Pricing Legislation

House committees continue to advance legislation on drug pricing issues, though the more sweeping proposals have so far been avoided. On April 4, the House Energy and Commerce Committee marked up six bills aimed at promoting generic and biosimilar competition. The bills advanced with bipartisan support following the adoption of several amendments intended to address Republican concerns with the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 965) and the Protecting Consumer Access to Generic Drugs Act (H.R. 1499). Two of the bills – the Orange Book Transparency Act (H.R. 1503) and the Purple Book Continuity Act (H.R. 1520) – passed the full House on May 8 by votes of 422-0 and 421-0, respectively. The House Ways and Means Committee, meanwhile, advanced a package of drug pricing transparency bills on April 9. The legislation, known as the Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act, contains several proposals related to price disclosures, rebate transparency and inpatient hospital drug costs. The House Energy & Commerce Committee is slated to consider similar transparency proposals in a legislative hearing scheduled for May 21.

On April 30, the House Judiciary Committee advanced several drug pricing bills with bipartisan support, including the CREATES Act, legislation to prohibit “pay-for-delay” settlements, a bill to prevent abuse of the Food and Drug Administration citizen petition process and a measure to require that the Federal Trade Commission study the role of pharmacy benefit managers (PBMs) in the drug supply chain.

On the Senate side, five PBMs testified before the Finance Committee on April 9. Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) sent a letter to several PBMs the week prior, questioning whether they “are appropriately leveraging their power for the benefit of taxpayers and patients, especially patients who take multiple or high-cost medications.” Additional legislative action on drug pricing legislation is expected in the coming months in the Finance Committee and the Health, Education, Labor and Pensions (HELP) Committee. HELP Committee Chairman Lamar Alexander (R-TN) has indicated that drug pricing reforms could move as part of a broader Senate package focused on consumer health care costs.

Meanwhile, the Department of Health and Human Services (HHS) on May 8 finalized a rule that will require direct-to-consumer television advertisements for prescription drugs and biologicals covered by Medicare or Medicaid to include the list price if the price is \$35 or more for a month’s supply or the usual course of therapy. The administration also has several other regulations in the works that could impact the pharmaceutical industry. A forthcoming rule from the Centers for Medicare and Medicaid Services (CMS) would effectively ban drug manufacturers from providing rebates under Medicare Part D plans unless they are offered directly to patients at the pharmacy counter. CMS recently released guidance indicating that the final regulation, which is still under development, will not take effect until the 2021 plan year. Members of Congress have expressed concern about the rule and its effect on premiums and federal spending. Projections from the Congressional Budget Office (CBO) indicate about \$177 billion in savings could be

achieved if Congress were to repeal the regulation once it is finalized.

It is uncertain when the administration will formally release its proposal for the International Pricing Index model. It could be included in a forthcoming rule to provide Part D plans with additional flexibility in managing the six “protected classes” of drugs.

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SENATE INCHES CLOSER TO PRIVACY DRAFT

Senate Inches Closer to Privacy Draft

The Senate Commerce Committee continues to push forward on privacy, holding a hearing on April 1 titled, “Consumer Perspectives: Policy Principles for a Federal Data Privacy Framework.” Senate Commerce Chairman Roger Wicker (R-MS) recently stated that he hopes to mark up a data privacy bill before the August recess. He also confirmed that the bipartisan Senate Commerce privacy working group still does not have bill text drafted and has only discussed baseline concepts. Sen. John Thune (R-SD) and Sen. Maria Cantwell (D-WA) recently joined the Senate Commerce privacy working group with Senators Wicker (R-MS), Jerry Moran (R-KS), Brian Schatz (D-HI) and Richard Blumenthal (D-CT).

Sen. Chris Coons (D-DE) also confirmed that he and Sen. Marsha Blackburn (R-TN) are taking the lead in forming a Senate Judiciary privacy working group, but members have noted that who will participate is still being determined. While Senate Judiciary Chairman Lindsay Graham (R-SC) has stated that the Senate Commerce Committee will take the lead in drafting privacy legislation, he also intends to clarify jurisdictional questions related to privacy in the coming weeks.

The House Energy and Commerce Committee recently held a hearing on oversight of the Federal Trade Commission (FTC) and privacy-related issues. Commissioners urged Congress to enact privacy legislation that is enforceable by the FTC, grants the FTC civil penalty authority and targeted APA rulemaking authority, as well as jurisdiction over nonprofits and common carriers. Chairman Simons notably warned against giving the FTC broad rulemaking authority. The Commissioners has split viewpoints on the issue of preemption, while Commissioner Chopra discussed the need to hold executives accountable for privacy violations. Following the hearing, subcommittee Chairwoman Jan Schakowsky (D-IL) stated that she hopes to have a privacy bill by the end of the year.

While the Committees with jurisdiction over privacy remain active on the issue, Democratic leaders have also weighed in on the issue. In a recent interview, Senate Minority Leader Schumer (D-NY) expressed optimism about achieving bipartisan support for federal privacy legislation in the 116th Congress, but he also pointed to the need for the proposal to have support from the White House.

Speaker Nancy Pelosi (D-CA) has also raised concern about preemptive legislation, but she has noted that she may be open to a federal standard that would serve as a baseline for other privacy-related state laws.

April featured the introduction of the following privacy-related bills:

- Sen. Blackburn (R-TN) introduced the Senate version of her BROWSER Act, which requires opt-in consent for the collection of sensitive information and opt-out consent for non-sensitive information.
- Senators Mark Warner (D-VA) and Deb Fischer (R-NE) introduced the Deceptive Experiences to Online Users Reduction (DETOUR) Act, which would prohibit large online platforms from using deceptive user interfaces, or “dark patterns,” in order to facilitate consumer data collection.
- Senators Ron Wyden (D-OR), Cory Booker (D-NJ), and Rep. Clarke (D-NY) also introduced the Algorithmic Accountability Act, which would authorize the FTC to create rules requiring that companies perform studies evaluating the accuracy, fairness, bias, discrimination, privacy and security in their software.
- Sen. Ed Markey (D-MA) introduced the Privacy Bill of Rights Act, which would prevent companies from using consumers’ personal information in discriminatory ways, create a

FTC website informing consumers about their privacy rights, enable state attorneys general to bring action against companies with privacy violations and establish a private right of action for individuals.

- Sen. Elizabeth Warren (D-MA) introduced the Corporate Executive Accountability Act in early April. The bill notably proposes up to one year of jail time for corporate executives found liable for a data breach or other privacy violations.

The push from industry groups to address discrimination has also continued into the month, with over 20 public interest groups, including Color of Change, Demand Progress, National Urban League and Public Citizen, recently sending a letter to Senate Commerce and House Energy & Commerce leadership on the need to address data-driven discrimination and equal opportunity in privacy talks.

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TRADE DEVELOPMENTS

Trade Developments

President Trump Declares National Emergency to Secure the Information and Communications Technology and Services Supply Chain

On May 15, 2019, the President issued an Executive Order (EO) on Securing the Information and Communications Technology and Services Supply Chain, pursuant to the authority described in the International Emergency Economic Powers Act (IEEPA). This statute allows the President to exercise certain actions to deal with any unusual and extraordinary foreign threat to the national security, foreign policy, or economy of the United States upon the President's declaration of a national emergency with respect to that threat. In the EO, the President declared a national emergency with respect to the ability of "foreign adversaries" to create and exploit vulnerabilities in information and communications technology and services in order to commit malicious, cyber-enabled acts. Read more [here](#).

USMCA Progresses, Still More to Go

This month, the effort to complete the renegotiation of the North American Free Trade Agreement (NAFTA) fulfilled its latest requirement under the rules of Trade Promotion Authority (TPA), but the political road still has many twists ahead.

On April 18, the U.S. International Trade Commission (ITC) released its report assessing the likely economic impact of the United States-Mexico-Canada Agreement (USMCA). The ITC found the USMCA would boost economic growth by a moderate 0.35 percent and create 176,000 jobs over the next six years. The report surprised most observers, who expected a smaller—and potentially even negative—impact on growth because tariffs are already eliminated under NAFTA and the new agreement includes more restrictive rules of origin and less stringent investor protections. However, the ITC adopted new modeling techniques estimating the impact of reduced policy uncertainty that had not been used in assessments of previous free trade agreements. Publishing the report is among the last requirements under TPA before the debate shifts completely to Congress.

Under TPA, the next key step is for President Trump to submit to Congress a draft Statement of Administrative Action (SAA) detailing the administration's plans to implement the agreement. Then, at least 30 days after submitting the SAA, the administration may submit the text of the bill that will make the necessary changes to law required by the agreement. This submission will trigger a series of congressional actions culminating in up-or-down votes in the House and Senate over the course of 90 legislative session days. To ensure a smooth process, administration officials have pledged to work with Congressional leaders, especially Speaker Pelosi, on the timing of this submission.

Over the past month, Ways and Means Committee Democrats have sent a series of letters to U.S. Trade Representative Robert Lighthizer staking out positions on outstanding issues that they believe still need to be addressed before the agreement can earn their support. To date, the letters have addressed labor, the environment and enforcement. A fourth letter covering concerns with access to medicines and biologics is expected in the

coming weeks. In addition, many Republicans, including Senate Finance Committee Chairman Charles Grassley, continue to insist that the President lift tariffs on imports of steel and aluminum from Canada and Mexico so that these countries will lift their retaliatory tariffs on U.S. exports. While these concerns remain, it is unlikely that there will be a swift passage of the deal.

U.S.-EU Trade Tensions Rise

Earlier this month, both the United States and the European Union proposed retaliatory tariffs on tens of billions of dollars of imports from each other that stem from a 15-year-old dispute at the World Trade Organization (WTO) regarding subsidies for their respective airline manufacturers. The United States challenged alleged subsidies granted by the European Union to European aircraft manufacturer Airbus, and the European Union challenged alleged subsidies granted by the United States to American aircraft manufacturer Boeing.

In the initial disputes, the Dispute Settlement Body in both cases found that the responding country had violated WTO obligations by providing subsidies to the aircraft manufacturers. The United States and European Union both sought retaliation after the issuance of the respective decisions, but had also both taken measures intended to address the violations. In the last year, the WTO Appellate Body found in both cases that neither party had successfully brought its measures into full compliance.

As a result, on April 12, 2019, the office of the U.S. Trade Representative (USTR) published in the Federal Register a preliminary list of European Union imports valued at approximately \$11 billion targeted for retaliatory tariffs and solicited comments on the list from the public. According to the Federal Register notice, a hearing was held on May 15 and written comments are due by May 28.

The United States has indicated that it would not impose tariffs until a final decision is made by the arbitrator approving the retaliation. Once the arbitrator issues its decision, the United States can immediately request authorization to retaliate in the amount determined by the arbitrator.

Five days after the USTR released its preliminary list, the European Union proposed its own list of U.S. products targeted for retaliation and requested comments from the public. The European Union's preliminary list covers approximately \$23 billion in U.S. imports.

As with the United States, the European Union has stated that it would not retaliate until authorized by the WTO. If the arbitral decision is issued in May 2020, then the European Union might receive authorization to retaliate in June 2020.

U.S.-Japan Meetings

On April 25, Japanese Economy Minister Toshimitsu Motegi and Amb. Lighthizer met to begin working towards a bilateral deal. The two discussed autos, agriculture, and digital trade. The following day, President Trump met with Japanese Prime Minister Shinzo Abe to continue the discussion. According to press reports, the President expressed hopes that Japan will purchase large amounts of military equipment from the U.S. and that Japan will lower its tariffs on U.S. agriculture exports. American farmers are especially interested in striking a quick deal with Japan for more market access. International competitors in Australia, Canada, Mexico and New Zealand are increasing their market share in Japan following the implementation of the revised Trans-Pacific Partnership, which no longer includes the United States.

Following his meeting with Prime Minister Abe in April, President Trump will travel to Japan twice in the next two months. First, he will meet the new Emperor in Tokyo at the end of May, and then he will attend the next G20 meeting in Osaka at the end of June. These regular bilateral meetings between the two leaders will ensure more activity on trade issues between Japan and the United States.

China Tariffs on the Rise

On Sunday, May 5, President Trump surprised trade observers by threatening to further raise tariffs on imports from China in a pair of tweets. At the time of his tweet, the President had imposed an additional duty of 25 percent on \$50 billion of imports from China and an additional duty of 10 percent on a separate list of \$200 billion worth of Chinese imports.

Following through with his threat, the President is increasing the duty rate from 10 percent to 25 percent as well as imposing a new 25 percent duty on the roughly \$300 billion of Chinese imports that face no additional duty under his Section 301 investigation into China's unfair trading practices.

The following day, Ambassador Lighthizer and Treasury Secretary Steven Mnuchin told reporters that the President's decision stems from China "reneging" on commitments made earlier in the negotiation. In the midst of continuing talks with Chinese Vice Premier Liu He in Washington, on Thursday, May 9, USTR published a [Federal Register Notice](#) triggering the tariff increase of 10 percent to 25 percent on List 3. USTR also published an ["implementing modification"](#) regarding products already exported from China to clarify:

- For goods imported before 12:01 AM (Eastern) on Friday May 10, the duty rate continues to be 10 percent.
- For goods that were exported from China before 12:01 AM (Eastern) on Friday May 10 and imported before Saturday June 1, the duty rate is 10 percent.
- For goods imported on or after Saturday June 1, regardless of when they were exported, the duty rate is 25 percent.
- For goods exported from China on or after Friday May 10, regardless of when they were imported, the duty rate is 25 percent.

In addition, on Monday May 13, USTR [published](#), its plans to add tariffs on nearly all remaining products that are not yet subject to additional tariffs (i.e. List 4). The proposed product list excludes pharmaceuticals, certain pharmaceutical inputs, select medical goods, rare earth materials, and critical minerals. Requests to appear at the public hearing and the expected testimony are due by June 10. The deadline for written comments and the public hearing date are both set for June 17. Rebuttal comments are due seven days after the public hearing. The proposed tariffs may take effect soon after the rebuttal comment period closes on June 25th.

Ambassador Lighthizer has pledged since mid-February that if the duty rate increased to 25 percent from 10 percent then USTR would create an exclusion process for companies affected by those tariffs in certain circumstances. For instance, a company could argue that if they were not excluded from the tariff then it would result in severe economic harm or that the product at issue is unrelated to China's Made in 2025 industrial policy. This pledge was reiterated in a written response to a Congressional "Question for the Record" from a February 27 hearing, where USTR [stated](#) its intentions to create an exclusion process for those products if duties are raised to 25 percent. On Tuesday, May 14, the USTR released a [Federal Register Notice](#) announcing additional tariff exclusions covering approximately 515 separate exclusion requests.

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ARTIFICIAL INTELLIGENCE UPDATES

Artificial Intelligence Updates

Reps. Daniel Lipinski (D-IL) and Tom Reed (R-NY) introduced bipartisan artificial intelligence legislation titled, Growing Artificial Intelligence Through Research Act, or the GrAITR Act ([H.R.2202](#)). This legislation seeks to establish a coordinated federal initiative aimed at accelerating AI research and development for U.S. economic and national security. The legislation would provide a guide map for harnessing U.S. research into Artificial Intelligence (AI) technology. The GrAITR Act would create a strategic plan to invest \$1.6 billion over 10 years in U.S. research, development and application of artificial intelligence across the private sector, academia and government agencies. The National Institute of Standards and Technology, the National Science Foundation, and the Department of Energy stand to benefit from a strategic AI roadmap going forward.

The House Financial Services Committee established and named members to two new task forces focused on financial technology (FinTech) and artificial intelligence. Congressman Stephen Lynch (D-MA) will lead the FinTech Task Force and Congressman Bill Foster (D-IL) will chair the AI Task Force. Congressman French Hill (R-AR) will serve

as the top Republican on each task force.

The Center for Medicare and Medicaid Services' (CMS) AI Health Outcomes Challenge is officially underway and encouraging innovators from all sectors, not solely health care, to submit an application. The program challenges innovators to harness AI solutions to predict unplanned hospital visits, skilled nursing facility admissions and adverse health events. CMS is in need of solutions that empower clinicians to provide appropriate resources to the highest risk patients at the right time to predict and drive quality health improvements. Solutions with explainable output data that build transparency and trust between clinicians and patients are also needed. Learn more about the competition [here](#).

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NEW OMB POLICY WILL LIKELY REDUCE INFORMAL AGENCY GUIDANCE

New OMB Policy Will Likely Reduce Informal Agency Guidance

On April 11, 2019, acting director of the Office of Management and Budget (OMB) Russell Vought announced a new policy for review of federal agency rules and guidance that represents a significant change of process for issuance of informal guidance materials and can be expected to decrease the volume of informal agency guidance. The directive, in the form of a memorandum to all heads of executive departments and agencies, requires agencies to submit to OMB's Office of Information and Regulatory Affairs (OIRA) a summary of any proposed guidance document or rule and, in most cases, a detailed analysis of the expected impact of the proposed guidance or rule. Following OIRA's review, Congress will have the option of review pursuant to the Congressional Review Act. While Congress typically does not exercise the option, it may invalidate any rule through a joint resolution of disapproval, which is subject to presidential veto. Click [here](#) to read more.

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