

May 10, 2019

Washington Update

This Week in Congress

House – The House passed [H.R. 1520](#), “The Purple Book Continuity Act,” [H.R. 1503](#), “The Orange Book Continuity Act,” [H.R. 986](#), the “Protecting Americans with Preexisting Conditions Act,” and [H.R. 2157](#), the “Supplemental Appropriations Act.”

Senate – The Senate confirmed the nominations of Kimberly Reed to be President of the Export-Import Bank and Spencer Bachus and Judith DelZoppo Pryor to be Members of the Board of Directors of the Export-Import Bank.

Next Week in Congress

House – The House is expected to consider [H.R. 5](#), “The Equality Act,” which would prohibit discrimination based on sex, sexual orientation, and gender identity.

Senate – The Senate is expected to consider the nomination of Brian Bulatao to be an Under Secretary of State, as well as several judicial nominations.

TAX

House Ways and Means Committee Holds Hearing on Tax Gap

Key Points:

- *Democrats in the hearing argued that cuts to the IRS budget have made it harder to reduce the tax gap via tax collections.*
- *Republicans stressed the importance of smarter audits, improved customer service, and a simpler tax code.*

On Thursday, the House Ways and Means Committee held a hearing on the tax gap. During the hearing, Democrats suggested that significant cuts to the Internal Revenue Service’s budget over the past decade have impacted its ability to reduce the tax gap via collections. Department of Treasury Inspector General for Tax Administration J. Russell George, a witness in the hearing, said the IRS

has eliminated 1,600 revenue officers over seven years.

Republicans on the Committee argued that hiring more revenue officers would not bridge the tax gap. Ranking Member Kevin Brady (R-TX) stressed the importance of smarter audits, improved customer service, and a simpler tax code. Representative David Schweikert (R-AZ) urged the Committee to think creatively and consider ideas such as adding third-party information reporting.

Table of Contents

Tax	1
Financial Services	3
Health	10
Trade	13

Congressional Democrats to Decide Next Steps in Fight for President Trump's Tax Returns

Key Points:

- *House Ways and Means Chairman Neal (D-MA) said he will decide by today whether to turn to the courts to obtain President Trump's tax returns.*
- *Treasury Secretary Steven Mnuchin denied Neal's request on May 6, saying the request presents serious constitutional questions.*
- *The New York State Senate recently passed a bill that would allow the state Department of Taxation and Finance to release any tax returns requested by the House Ways and Means Committee, the Senate Finance Committee, or the Joint Committee on Taxation for any legitimate legislative purpose.*

House Ways and Means Committee Chairman Richard Neal (D-MA) said he will decide by today whether to go to court to obtain President Trump's tax returns after the Administration rejected the request. Treasury Secretary Steven Mnuchin, on May 6, denied Chairman Neal's request saying it was "unprecedented and it presents serious constitutional questions."

A recent article by the *New York Times* on the President's tax returns led to Senate Finance Committee Ranking Member Ron Wyden (D-OR) adding additional pressure on the White House to release the tax returns. Ranking Member Wyden has already introduced legislation, the Presidential Tax Transparency Act ([S. 20](#)) that would require presidents to release their tax returns. Ranking Member Wyden stated: "[r]eleasing one's tax returns is the lowest ethical bar for presidential candidates and this blockbuster from the *Times* further shows why it should be required by law." He added: "[i]t also shows one of the reasons why Secretary Mnuchin has chosen to

break the law, rather than comply with Chairman Neal's request under section 6103 of the tax code for President Trump's returns."

The New York State Senate passed a bill on May 8 that would allow the state Department of Taxation and Finance to release any tax returns requested by the House Ways and Means Committee, the Senate Finance Committee, or the Joint Committee on Taxation for any legitimate legislative purpose. The bill is set to go next before the state Assembly, where 106 of the 150 seats are held by Democrats. The bill would then go to Governor Andrew Cuomo (D-NY).

SECURE Act Faces Obstacles before Reaching House Floor

Key Point:

- *The provision in the SECURE Act that would allow section 529 educational savings plans to pay for homeschooling expenses has caused controversy and delayed a vote on the House Floor.*

The Setting Every Community Up for Retirement Enhancement (SECURE) Act was set to be considered this past week but House Majority Leader Hoyer (D-MD) delayed the timeline and said he hopes to reach an agreement to bring the bill to the floor before the Memorial Day recess. The delay mainly comes from controversy surrounding a provision that would allow section 529 educational savings plans to pay for homeschooling expenses. Critics say the provision should not have been included in a retirement bill.

The House may make changes to the bill that was unanimously reported out of the Ways and Means Committee. Meanwhile, the Senate is waiting for the House to approve the SECURE Act and plans to quickly pass its version of the

legislation (RESA) on the Senate floor by voice vote.

Upcoming Hearings and Meetings

May 14

Retirement: On May 14, the Senate Finance Committee will hold a hearing entitled: “Challenges in the Retirement System.” Witnesses in the hearing will include Joni Tibbetts, Vice President, Retirement, The Principal Financial Group, Des Moines, IA; The Honorable Tobias Read, Treasurer, State of Oregon, Salem, OR; Joan Ruff, Board Chair, AARP, Washington, DC; Lynn D. Dudley, Senior Vice President, Global Retirement and Compensation Policy, American Benefits Council, Washington, DC. The hearing will take place at 10:15am in 215 Dirksen Senate Office Building.

May 15

Climate Change On May 15, the House Ways and Means Committee will hold a hearing entitled: “The Economic and Health Consequences of Climate Change.” The hearing will take place at 10:00am in 1100 Longworth House Office Building.

For more information about tax issues you may [email](#) or call Christopher Hatcher at 202-659-8201. Henry Homans contributed to this section.

FINANCIAL SERVICES

SEC Holds Small Business Capital Formation Advisory Committee Meeting and Roundtable

Key Point:

- *The SEC hosted the first meeting of its Small Business Capital Formation Advisory Committee.*

On May 6, the Securities and Exchange Commission (SEC) convened a pair of events focused on small business capital formation. In the morning, the SEC Office of the Advocate for Small Business Capital Formation hosted a [roundtable](#) to hear from small businesses and their investors. In the afternoon, the SEC convened the first [meeting](#) of its Small Business Capital Formation Advisory Committee.

Martha Miller (Advocate for Small Business Capital Formation, SEC) said that small businesses are the lifeblood of the American economy. She said that her office’s mission is to improve small businesses’ access to capital. She said that a small percentage of small business investment goes to companies in the American heartland. She expressed concern that there is lack of funding for important companies across the country. She said that it is important to examine regulatory frameworks to make sure that there are no structural barriers to the flow of capital.

SEC Chairman Jay Clayton said that small business investors play a critical role in the economy. He said that he hopes that the SEC can help foster collaboration between businesses and funders. He noted that the SEC’s rules and regulations pertaining to capital raising need to reflect the fact that companies of different sizes have different needs. He added that it would be helpful for the SEC to “cut out intermediaries” so that capital can flow where it is most needed. He said he looks forward to hearing “actionable suggestions” from the Advisory Committee.

Commissioner Hester Peirce said ensuring a thorough understanding of the industries being regulated is one of the biggest challenges regulators face. She argued that it is essential to solicit feedback from companies of all sizes.

She added that she appreciates the efforts to assemble a geographically diverse group and looks forward to working with committee members from around the country.

Commissioner Elad Roisman said capital formation is a priority for him and he called on the Advisory Committee to advise the Commission on how capital formation can be expanded to smaller markets.

Senate Banking Committee Holds Hearing on Privacy Rights and Data Collection

Key Point:

- *The Committee discussed the issues surrounding the collection and use of consumer data by financial institutions, credit bureaus, and social media companies.*

On May 7, the Senate Banking Committee held a [hearing](#) entitled “Privacy Rights and Data Collection in a Digital Economy.” Chairman Mike Crapo (R-ID) stated the hearing’s purpose was for the Committee to evaluate the following: the European Union’s (EU) 2016 General Data Protection Regulation (GDPR); how companies and financial institutions use sensitive information; and how individuals can have more control over their personal data. He said it is important to understand how data is used, is transferred for advertising, and impacts decision making. He stated his concerns with data collection go back to creation of the Consumer Financial Protection Bureau (CFPB). He said a consumer’s knowledge into what information is being collected, what it is used for, and how it shared is vital to individual’s exercising their rights. He noted the data collection ecosystem is more expansive than ever before as financial regulators and private companies are collecting and sharing data, and the internet is used to carry out everyday life functions. He said the way data is used matters immensely and noted that

consumers should have control over their data. He highlighted how the EU took steps in 2016 by giving their users more control through the implementation of the GDPR.

Senator Sherrod Brown (D-OH) stated because technology has evolved rapidly, it is important to recognize the knowledge about its full use and potential has not been discovered. He highlighted the Equifax breach and how sensitive financial information of 170 million Americans remains vulnerable to criminals and bad actors. He stated the Equifax incident should prove that just warning people not to share personal on the internet is not the best solution. He suggested that because data is not limited to bank accounts and credit scores, most consumers do not realize data is being monetized. He said telling people to look out for themselves when it comes to data is counterproductive since consumers cannot opt out of internet services and banking services. He said if data collection is not taken seriously, big companies and financial institutions will continue sharing consumers’ most intimate details. He emphasized the need to include a discussion about where the government needs to step in to regulate the collection, use, and storage of personal data.

There was some bipartisan agreement from those present at the hearing on the principle that consumers should have to give consent in order for their data to be collected and used. Senator Jack Reed (D-RI) suggested that people should own their data and should have to opt-in to have it collected. Senator John Kennedy (R-LA) contended that Congress should pass a law asserting: (1) users have a property right to their data; (2) they can knowingly and willfully license that data; (3) the user agreement must be written in plain English; (4) users can change their minds about licensing data; (5) users have the right to know what data has been collected and what analysis

has been done using it; (6) users can know what social media companies are doing with their data; (7) users can transfer their data; and (8) users must be notified immediately if their data is breached.

Senate Appropriations Committee Holds Hearing on the SEC and CFTC Budgets

Key Point:

- *Members questioned SEC Chairman Clayton and CFTC Chairman Giancarlo about a range of issues, including cybersecurity, cryptocurrency, Regulation Best Interest, swaps regulation, and CFTC user fee proposals.*

On May 8, the Senate Appropriations Committee's Subcommittee on Financial Services and General Government held a [hearing](#) to discuss the Fiscal Year (FY) 2020 budget requests for the Securities and Exchange Commission (SEC) and the Commodity Futures Trading Commission (CFTC).

SEC Chairman Jay Clayton said additional funding has allowed the SEC to make targeted hires in areas such as cybersecurity and enforcement. He stated that they have been able to lift their hiring freeze and enhance their cybersecurity capabilities. He said for FY2020 the SEC is requesting \$1.746 billion, which is a 4 percent increase. He emphasized that their request is deficit neutral and will be offset by transaction fees. Clayton said the budget request focuses on continued investment in human capital. He stated that information technology, including cybersecurity, makes up an increasing portion of the SEC budget.

CFTC Chairman J. Christopher Giancarlo said there is strong partnership between the SEC and the CFTC, noting that they work together on enforcement, cryptocurrency regulation, Dodd-Frank Act (DFA) harmonization,

clearinghouse oversight, and disaster recovery testing and planning. He noted that while most Americans do not trade in derivatives, they rely on them for stable prices. He stressed the importance of having a dedicated, independent regulator to the strength of the American derivatives markets. He emphasized the need to ensure that the CFTC has adequate resources. He said the CFTC is requesting \$315 million for FY2020, which is made up of \$284 million for operations and \$31 million for the relocation of three regional offices.

Chairman John Kennedy (R-LA) and Senator Chris Van Hollen (D-MD) questioned whether the CFTC should be funded through a user fee. Van Hollen said the CFTC's FY2020 budget request includes \$16 million generated through a fee on transactions. He said the SEC is funded through a similar provision. He suggested that a CFTC user fee is a good idea, stressing the need for the CFTC to have additional resources. Giancarlo said many previous CFTC budget requests also included "some sort of fee arrangement." He said some previous proposals were transaction-based, which he was not supportive of "as a markets person." He stated that it is up to Congress to determine how the CFTC is funded. He said if Congress decides to implement a fee, then the CFTC would act on that.

Ranking Member Chris Coons (D-DE) said the SEC is working on regulations to implement a new standard of care for financial professionals. He said the regulations would not impose the same standards on broker-dealers as investment advisers. He stated that this differs from the regulation previously put forward by the Department of Labor. He asked about the differences between the roles of broker-dealers and investment advisers. Clayton stressed the need to preserve competition and choice. He stated that for many investors the fee for service model is

cheaper than the investment adviser model. He stressed the need to allow investors to choose the right model for them. He stated that the level of conduct required on brokers side should be enhanced.

Chairman John Kennedy (R-LA) asked about the CFTC's swaps reforms. Giancarlo said he was a supporter of the core reforms in Title VII of the DFA, including clearing and swaps reporting. He stated that the CFTC erred in implementing the swaps execution requirements, which has made the U.S. less competitive and prevented innovation. He stated that he has proposed a more flexible approach, which more closely follows Congressional intent and will lead to innovation and new market participants entering the market. He suggested that he will likely not be able to complete this regulation during his term, but he encouraged the future chairman to take it up.

House Financial Services Committee Approves Five Bills

Key Points:

- *The Committee approved bills related to veterans' mortgages, rural job creation, the Bank Secrecy Act, whistleblowers, and insider trading.*
- *The Committee postponed consideration of legislation related to beneficial ownership.*
- *The Committee also approved resolutions to create task forces related to financial technology and artificial intelligence.*

On May 8-9, the House Financial Services Committee held a [markup](#) and approved five financial services bills and two resolutions:

- The Protect Affordable Mortgages for Veterans Act of 2019 ([H.R. 1988](#)), introduced by Representative David Scott (D-GA), which would clarify seasoning requirements for certain

refinanced mortgage loans under the Economic Growth, Regulatory Relief, and Consumer Protection Act. The Committee favorably reported H.R. 1988, as amended, by voice vote.

- The Expanding Access to Capital for Rural Job Creators Act ([H.R. 2409](#)), introduced by Representative Cindy Axne (D-IA), which would require the Securities and Exchange Commission's (SEC) Advocate for Small Business Capital Formation to identify unique challenges facing rural-area small businesses in securing access to capital, and in its annual report to Congress, to identify the most serious issues encountered by rural-area small businesses and their investors. The Committee favorably reported H.R. 2409 by voice vote.
- The Coordinating Oversight, Upgrading and Innovating Technology, and Examiner Reform Act of 2019 ([H.R. 2514](#)), introduced by Representative Emanuel Cleaver (D-MO), which would amend the Bank Secrecy Act (BSA), including by authorizing financial institutions to share BSA data with certain affiliates, and codifying financial regulators' guidance enabling community financial institutions to share training and technology resources. The Committee favorably reported H.R. 2514, as amended, by a vote of 55-0.
- A bill to amend the Securities and Exchange Act of 1934 to amend the definition of whistleblower ([H.R. 2515](#)). The bill, introduced by Representative Al Green (D-TX), would amend section 922 of the Dodd-Frank Act (DFA) to clarify that whistleblowers who report alleged misconduct to their employers, and not to the SEC, are also protected by the anti-retaliation

provisions in section 922. The Committee favorably reported H.R. 2515, as amended, by voice vote.

- The Insider Trading Prohibition Act of 2019 ([H.R. 2534](#)), introduced by Representative James Himes (D-CT), which would codify the definition of illegal insider trading under securities laws. The Committee favorably reported H.R. 2534, as amended, by voice vote.
- A [resolution](#) to establish the House Committee on Financial Services Task Force on Financial Technology. Representative Stephen Lynch (D-LA) will serve as Chairman of the Task Force and Representative French Hill (R-AR) will serve as Ranking Member. The resolution was adopted without objection.
- A [resolution](#) to establish the House Committee on Financial Services Task Force on Artificial Intelligence. Representative Bill Foster (D-IL) will serve as Chairman of the Task Force and Representative French Hill (R-AR) will serve as Ranking Member. The resolution was adopted without objection.

The Committee postponed consideration of the Corporate Transparency Act of 2019 ([H.R. 2513](#)) until a later date. The bill, introduced by Representative Carolyn Maloney (D-NY), would require corporations and limited liability corporations (LLCs) to disclose their true “beneficial owners” to the Financial Crime Enforcement Network (FinCEN) at the time the company is formed.

Ranking Member Patrick McHenry (R-NC) agreed to support the Insider Trading Prohibition Act, with the understanding that Representative James Himes (D-CT) and Chairwoman Maxine Waters (D-CA) would

work to address his concerns as the bill goes to the House Floor. Himes responded that he would do so.

SEC Approves Proposed Rules on Large Accelerated Filers and Cross-Border Swaps

Key Point:

- *The proposed rules would modify the definitions of accelerated filers and large accelerated filers, and address the cross-border application of certain security-based swap regulations.*

On May 9, the SEC held an open meeting and approved proposed amendments to the accelerated filer and large accelerated filer definitions. As described in an SEC [press release](#), the proposed amendments would:

- Exclude from the accelerated and large accelerated filer definitions an issuer that is eligible to be an SRC and had no revenues or annual revenues of less than \$100 million in the most recent fiscal year for which audited financial statements are available.
- Increase the transition thresholds for accelerated and large accelerated filers becoming a non-accelerated filer from \$50 million to \$60 million and for exiting large accelerated filer status from \$500 million to \$560 million.
- Add a revenue test to the transition thresholds for exiting both accelerated and large accelerated filer status.

On May 10, the SEC issued [proposed rules](#) related to the cross-border application of certain security-based swaps regulations. As noted in an SEC [press release](#), the proposal addresses four issues:

- the use of transactions that have been “arranged, negotiated, or executed” by personnel located in the United States

as a trigger for regulating security-based swaps and market participants;

- the requirement that non-U.S. resident security-based swap dealers and major security-based swap participants certify and provide an opinion of counsel that the Commission can access their books and records and conduct onsite inspections and examinations;
- the cross-border application of statutory disqualification provisions; and
- the questionnaires or employment applications that security-based swap dealers and major security-based swap participants must maintain with regard to their foreign associated persons.

Senate Confirms Export-Import Bank Nominees

Key Points:

- *The Senate confirmed three nominees to the Board of the Export-Import Bank. The Board will have a quorum for the first time since 2015.*
- *The Export-Import Bank's authorization is set to expire at the end of the fiscal year.*

On May 8, the Senate confirmed the following nominations:

- Kimberly Reed, to be President of the Export-Import Bank of the United States, for a term expiring January 20, 2021. Reed was confirmed by a vote of 79-17.
- Spencer Bachus III, to be a Member of the Board of Directors of the Export-Import Bank of the United States, for a term expiring January 20, 2023. Bachus was confirmed by a vote of 72-22.
- Judith DelZoppo Pryor, to be a Member of the Board of Directors of the Export-Import Bank of the United States, for a term expiring January 20,

2021. Delzoppo Pryor was confirmed by a vote of 77-19.

With the confirmation of Reed, Bachus, and Delzoppo Pryor, the Export-Import Bank has a quorum for the first time since 2015. The Bank is prohibited from approving loans exceeding \$10 million without a quorum. The authorization for the Export-Import Bank is scheduled to expire at the end of Fiscal Year 2019.

Waters and McHenry Introduce NFIP Extension Bill

Key Point:

- *The bill would extend the authorization for the NFIP to September 30, 2019. The authorization is currently set to expire on May 31.*

On May 9, House Financial Services Committee Chairwoman Maxine Waters (D-CA) and Ranking Member Patrick McHenry (R-NC) announced that they had introduced the National Flood Insurance Program Extension Act ([H.R. 2578](#)), which would extend the authorization for the National Flood Insurance Program (NFIP) to September 30, 2019. The NFIP's authorization is currently set to expire on May 31. Waters and McHenry issued a [press release](#), which stated:

We have introduced legislation to extend the NFIP's authorization to September 30, 2019. It is important that Congress does not allow the National Flood Insurance Program to lapse. This extension prevents harm to homeowners and the housing market while also providing time to reach bipartisan consensus on much-needed reforms to the program. We remain committed to a long-term bipartisan flood insurance reauthorization bill and

will continue to work together toward that goal.

Upcoming Hearings and Meetings

May 14

Retirement: The Senate Finance Committee will hold a hearing entitled “Challenges in the Retirement System.”

May 15

Worker Rights: The House Financial Services Committee’s Subcommittee on Investor Protection, Entrepreneurship and Capital Markets will hold a hearing entitled “Promoting Economic Growth: A Review of Proposals to Strengthen the Rights and Protections for Workers.”

Sanctions: The House Financial Services Committee’s Subcommittee on National Security, International Development and Monetary Policy will hold a hearing entitled “Assessing the Use of Sanctions in Addressing National Security and Foreign Policy Challenges.”

Financial Regulators: The Senate Banking Committee will hold a hearing entitled “Oversight of Financial Regulators.” The witnesses at the hearing will be: The Honorable Joseph M. Otting, Comptroller, Office of the Comptroller of the Currency; The Honorable Randal K. Quarles, Vice Chairman for Supervision, Board of Governors of the Federal Reserve System; The Honorable Jelena McWilliams, Chairman, Federal Deposit Insurance Corporation; and The Honorable Rodney E. Hood, Chairman, National Credit Union Administration.

Treasury Budget: The Senate Appropriations Committee’s Subcommittee on Financial Services and General Government will hold a hearing to discuss the Fiscal Year 2020 budget

request for the Treasury Department. Treasury Secretary Steven Mnuchin and IRS Commissioner Charles Rettig are expected to testify at the hearing.

Retirement Security: The House Budget Committee will hold a hearing entitled “Keeping Our Promise to America’s Seniors: Retirement Security in the 21st Century.”

May 16

Prudential Regulators: The House Financial Services Committee will hold a hearing entitled “Oversight of Prudential Regulators: Ensuring the Safety, Soundness and Accountability of Megabanks and Other Depository Institutions.”

Payday Lending: The House Oversight and Reform Committee’s Subcommittee on Economic and Consumer Policy is expected to hold a hearing entitled “CFPB’s Role in Empowering Predatory Lenders: Examining the Proposed Repeal of the Payday Lending Rule.”

May 21

HUD: The House Financial Services Committee will hold a hearing entitled “Housing in America: Oversight of the U.S. Department of Housing and Urban Development.”

May 31

Financial Technology: The Securities and Exchange Commission’s (SEC) Strategic Hub for Innovation and Financial Technology (FinHub) will hold its 2019 FinTech Forum to discuss distributed ledger technology and digital assets. The event will include panels on: (1) Capital Formation Considerations; (2) Trading and Markets Considerations; (3) Investment Management Considerations; and (4) Distributed Ledger Technology Innovations:

Industry Trends and Specific Use Cases for Financial Markets.

For more information about financial services issues you may email [Joel Oswald](#) or [Alex Barcham](#).

HEALTH

Energy and Commerce Continues to Examine Prescription Drug Pricing

Key Points:

- *The House Energy and Commerce Committee's Health Subcommittee held a hearing examining prescription drug prices with witnesses from representatives of the drug supply chain.*
- *Discussion focused on negotiations between members of the supply chain, use of value-based contracts, utilization management, and transparency.*

On May 9, the House Energy and Commerce Committee's Health Subcommittee held a [hearing](#) entitled "Prescription Drug Prices: Deconstructing the Drug Supply Chain."

Topics discussed included: (1) List Prices; (2) Supply Chain Discounts; (3) Formulary Management; (4) Value-Based Contracts/Safe Harbor Rules; (5) Out-of-Pocket Cap; (6) Utilization Management; (7) Patient Adherence/Assistance Programs; (8) Advertisements; (9) Drug Waste; (10) Pay-for-Delay Settlements; (11) Drug Repurposing; (12) Transparency; (13) Sole Source Drugs/Shortages; (14) International Prices; (15) Generics/Biosimilars; (16) Industry Influence; (17) Rebate Rule; (18) 340B Drug Pricing Program; and (19) Importation.

Questions focused on negotiations between pharmaceutical manufacturers and pharmacy benefit managers (PBMs). There was bipartisan concern about the impact of high list prices on

uninsured consumers and those in high deductible plans. Members also expressed frustration about misaligned rebate incentives and the lack of transparency into list price decisions and PBM negotiations.

PBM representatives defended rebates as a necessary tool to lower costs for plans and beneficiaries. They expressed opposition to the Department of Health and Human Services' (HHS) rebate rule to require point-of-sale discounts in Medicare Part D, arguing it would impact few patients and increase beneficiary premiums.

Republicans pointed to instances of PBMs requiring manufacturers to disclose list price decreases and questioned whether negotiations are benefitting consumers. Manufacturers acknowledged the positive role of negotiations, but suggested PBMs drive higher list prices by granting preferential formulary placement to drugs with larger rebates.

Members and witnesses agreed on transitioning to value-based contracts. Witnesses were receptive to reforms of Stark Law and the Anti-Kickback Statute but suggested limiting exemptions from the rules to certain therapeutic classes. Multiple witnesses expressed support for instituting an out-of-pocket cap in Part D.

While members and witnesses agreed on the need for supply chain reforms, there was disagreement on which policies would achieve lower prices. Republicans advocated for the HHS rebate rule while Democrats favored empowering Medicare to negotiate prices. Despite disagreement, there was bipartisan and witness consensus on the need to increase generic and biosimilar products, and the need to make pricing and utilization management information more available to patients and prescribers.

House Appropriations Approves FY 2020 HHS Appropriations

Key Points:

- *The House Appropriations Committee favorably reported FY 2020 appropriations for the Department of Labor, Department of Health and Human Services, Department of Education and Related Agencies.*
- *The bill provides \$99.0 billion for the Department of Health and Human Services, an increase of \$8.5 billion above the FY 2019 enacted level.*

On May 8, the House Appropriations Committee held a [markup](#) of the Fiscal Year (FY) 2020 Labor, Health and Human Services, Education, and Related Agencies appropriations bill. The bill was favorably reported, as amended, by roll call vote, 30-23. The bill provides \$99 billion for the Department of Health and Human Services (HHS), an increase of \$8.5 billion above the FY 2019 enacted level and \$20.9 billion above the President's request.

For the National Institute of Health, the bill provides \$41.1 billion, an increase of \$2 billion and \$6.9 billion above the President's request. Included in this funding is continued support for Alzheimer's disease research, HIV/AIDS research, the All of Us precision medicine research initiative, the Cancer Moonshot, and the Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative.

For the Centers of Disease Control and Prevention, the bill provides \$8.3 billion, an increase of \$921 million. It makes significant investments into a multi-year effort to support modernization of public health data surveillance and analytics and public health

efforts like suicide prevention and the Diabetes Prevention Program.

For the Substance Abuse and Mental Health Services Administration, the bill provides \$5.9 billion, a \$115 million increase. The bill continues investments in substance use treatment, substance abuse prevention, suicide prevention, and mental health resources for children and youth.

The bill also continues investments in preparedness, providing \$.27 billion for the Public Health and Social Services Emergency Fund. This funding includes \$567 million for the Biomedical Advanced Research and Development Authority (BARDA); \$725 million for Project BioShield; \$620 million for the Strategic National Stockpile; and \$11 million for the National Ebola Training and Education Center.

Read more details including amendments, report language, and bill text [here](#).

Administration Releases Rule on Direct-to-Consumer Advertising

Key Points:

- *The Department of Health and Human Services released its final rule requiring prices to be listed in direct-to-consumer advertising.*
- *Direct-to-consumer television ads for prescription drugs covered by Medicare or Medicaid which cost more than \$35 per month for a 30-day supply or typical course of treatment must display the list price in the ad.*

On May 8, the Department of Health and Human Services announced its final rule implementing requirements for displaying prescription drug prices in direct-to-consumer (DTC) television ads. The final rule will take effect July 9, 2019.

The rule will apply to all prescription drugs and biological products for which reimbursement is available through Medicare or Medicaid. All DTC television ads must include a statement indicating the list price for a typical 30-day regimen or course of treatment as determined by the first day of the quarter in which the ad will air. The statement should read: “The list price for a [30-day supply of] [typical course of treatment] [name of prescription drug or biological product] is [insert price]. If you have health insurance that covers drugs, your cost may be different.” Products which cost less than \$35 per month for a 30-day supply or typical course of treatment would be exempt.

The Secretary will maintain a public list of the products in violation of this requirements. If a manufacturer includes price information in its DTC ads in accordance with the rule, the Food and Drug Administration’s Office of Prescription Drug Promotion will not need to review the information. FDA does not plan to review price information in advertisements unless the information explicitly or implicitly incorporates or makes claims about the safety or efficacy of the drug.

The primary enforcement mechanism will be the threat of private action under the Lanham Act for unfair competition in the form of false or misleading advertising. The rule also preempts any state-law-based claim that depends on the pricing statement required in the rule.

Read the final rule [here](#).

Senate Judiciary Examines Intellectual Policy Implications of Drug Pricing

Key Points:

- *The Senate Judiciary Committee held a hearing on “Intellectual Property and the Price*

of Prescription Drugs: Balancing Innovation and Competition.”

- *Discussion focused on patent reform, generic competition, international prices, and the drug supply chain.*

On May 7, the Senate Judiciary Committee held a [hearing](#) entitled: “Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition.”

Topics discussed in hearing included: (1) Insulin; (2) International Prices/Federal Negotiation; (3) Anti-Trust Legislation; (4) Price Transparency/DTC Advertisements; (5) Pay-for-Delay Agreements; (6) Citizen Petition Process; (7) Patent Thickets; (8) Pharmacy Benefit Managers; (9) Vial Size; (10) Opioid Epidemic; (11) Federal Role/Legislation; and (12) Sovereign Immunity.

There was bipartisan consensus on the need to address high U.S. drug prices, particularly through increased competition. Chairman Lindsey Graham (R-SC) observed that several bipartisan bills are currently moving through Congress and urged the Senate to vote on the CREATES Act of 2019 ([S. 340](#)).

Senators identified several factors inhibiting competition in prescription drug prices including the lack of transparency and anti-competitive pay-for-delay settlements. Senator Klobuchar indicated that federal legislation is necessary to codify the Supreme Court’s decision in *FTC v. Actavis*. Senator Richard Blumenthal (D-CT) announced that he and Senator John Cornyn (R-TX) will introduce legislation to combat patent thickets and product hopping.

Senators also compared drug prices in the U.S. to those in other developed countries. Republicans attributed differential prices to international “free riding,” and questioned why

U.S. consumers are subsidizing low drug prices in other nations. Democrats contended lower international prices are the result of significant leverage achieved by countries that directly negotiate on price.

Witnesses also acknowledged that drug prices are unsustainable, while offering different opinions on how to address challenges to competition. Some witnesses argued high drug prices require federal negotiation, while others cautioned that replicating international negotiation models would impact access and innovation. Perspectives also differed on the appropriate role for the federal government in defining patent thickets. Despite disagreement on other issues, all expressed support for passing the CREATES Act to facilitate better sample sharing between brand and generic manufacturers.

Upcoming Hearings and Meetings

May 13

Insulin: The Food and Drug Administration will hold a public meeting on “The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products.”

Opioids: The Bipartisan Policy Center will hold a hearing on “The Role of Litigation in Response to the Opioid Epidemic.”

May 14

Pandemics: Texas A&M University and the George H.W. Bush School of Government & Public Service’s Scowcroft Institute of International Affairs will hold its 3rd Annual Pandemic & Biosecurity Forum.

May 16

Maternal Health: The House Ways and Means Committee will hold a hearing on “Racial Disparities and Social Determinants in the Maternal Mortality Crisis.”

HIV: The House Oversight and Reform Committee will hold a hearing on “HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments.”

Patents: The Alliance for Health Policy will hold a webinar on “Prescription Drug Patents: Balancing Innovation, Access, and Affordability.”

For more information about healthcare issues you may [email](#) or call Nicole Ruzinski Bertsch or George Olsen at 202-659-8201. Thomas McGrath contributed to this section.

TRADE

Tariffs Raised on List 3 of Chinese Goods, Trade Deal Uncertain

Key Points:

- USTR released a [notice](#) raising tariffs to 25 percent on remaining List 3 imports.
- China vowed to respond to tariffs with its own countermeasures.
- The White House claimed China is backing off on a number of commitments it made.
- The Chinese trade delegation is in D.C. to continue discussions. President Trump declared it is still possible to reach a deal.
- The talks concluded this afternoon with both sides saying they had been productive, but with neither a breakthrough nor a breakdown in talks.

Original Notice Rising Tariffs and Notice of Modification of Section 301

The Office of the U.S. Trade Representative (USTR) published an [initial notice](#) on May 9 that increased tariffs for goods under List 3 of the Section 301 action on China, from 10% to 25%, effective May 10.

Subsequently, the USTR published a [notice](#), late on May 9, which indicated that the planned increase on List 3 Duties from 10 percent to 25 percent would be delayed for goods that are in transit from China, and would apply to goods that were exported from China before May 10 and arrive in the United States prior to June 1, 2019.

The late notice offers a modest practical delay in the application of increased tariffs sine most goods in transit could take a week or two or more to arrive – meaning most goods won't be subject to the higher 25% tariff for a few weeks in practical terms.

China Allegedly Backing Off Some Commitments

Early this week President Trump announced that he would impose additional tariffs on Chinese goods slated to go into effect on Friday due to China backtracking on several substantial commitments it made previously during trade talks. USTR Robert Lighthizer said Beijing had reneged on commitments it had made previously that would have changed the agreement substantially, which he characterized as “an erosion in commitments by China.” Treasury Secretary Steven Mnuchin agreed, stating that the entire U.S. economic team agrees that China's backtracking is unacceptable and supports President Trump's action to move forward with tariffs.

Discussions Continue While China Prepares to Hit Back

On Friday at 12:01 a.m., 10 percent tariffs on \$250 billion in Chinese goods rose to 25 percent. President Trump also announced Thursday that the Administration is “starting the paperwork today” to impose a 25 percent duty on all remaining imports from China. Beijing on Tuesday also announced it would respond with its own countermeasures. A spokesperson for China's Ministry of Commerce said, “[t]he Chinese side deeply regrets that if the U.S. tariff measures are implemented, China will have to take necessary countermeasures.” China has already imposed tariffs on \$110 billion worth of U.S. goods in response to the Trump Administration's Section 301 actions, which began last year with 25 percent tariffs on \$50 billion in Chinese goods. Despite these setbacks President Trump continues to be optimistic that a deal can be made. A call between President Trump and Chinese President Xi Jinping was scheduled for last night, but there is no indication that the call took place.

Talks Concluded, No Breakthrough, No Breakdown

Friday afternoon, the talks between the USTR, Treasury Secretary and Vice Premier of China concluded. Both sides commented briefly to the press that the talks had been productive; neither side suggested any breakthrough, but the fact the talks occurred suggest there was not a breakdown. Any schedule or plans for further talks remain as yet unreleased.

USMCA Developments

Key Points:

- *Speaker Pelosi continues to push for stronger enforcement.*
- *House Republicans are seeking ways to push USMCA through to a vote.*

On Thursday, USTR Lighthizer met with members of the Congressional Progressive Caucus to discuss their concerns with the U.S.-Mexico-Canada Agreement (USMCA), as he tries to chart a path toward ratification. The Congressional Progressive Caucus continues to voice their worries that the agreement's labor provisions are not enforceable and could lock in high prescription drug prices. Although USTR Lighthizer continues to work with Democrats, some Members of Congress are skeptical that he is truly open to renegotiating the deal. Speaker Nancy Pelosi (D-CA) continues to say that the Trump Administration has not addressed any of the Democrat's USMCA concerns and that House Democrats will not support the USMCA until it addresses their concerns over enforcement, labor, environment and pharmaceuticals.

Despite pushback from Speaker Pelosi and other House Democrat leaders, some coalitions are forming to support a vote on the USMCA. House Agriculture Committee Chairman Collin Peterson (D-MN) said on Friday that he would ask Speaker Pelosi to bring the USMCA up for a vote. House Minority Leader Kevin McCarthy (R-CA) has already expressed support for forcing a vote on the USMCA, and a bipartisan campaign that is co-chaired by Phil Cox and former Senator Heidi Heitkamp (D-ND) called Trade Works for America has formed to get USMCA passed. The bipartisan coalition points to concessions the Mexican government has made in terms of labor, as well as the wins it sees for the agriculture and

automobile industries, as reasons the USMCA is ready to be favorably voted on.

For more information about trade issues you may [email](#) or call Christopher Hatcher at 202-659-8201. Cullen Neely contributed to this section.

This Week in Congress was written by Alex Barcham.