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September 2018

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Following a truncated August recess, the House and the Senate returned to Washington after Labor Day with a full plate of legislative items to address prior to the end of the fiscal year on September 30. That list includes funding the federal government, reauthorizing the Federal Aviation Administration, approving the Water Infrastructure Act and wrapping up negotiations over the Farm Bill, which is currently in a conference committee (see [Farm Bill](#) section for more information).

The Senate Judiciary Committee spent the first week of September on hearings on the nomination of Judge Brett Kavanaugh to be an Associate Justice of the Supreme Court. A committee vote is expected in the next two weeks, followed by a vote on the Senate floor prior to the commencement of the Supreme Court's next term, which begins on October 1.

The Senate also is expected to pass a comprehensive opioid package with an overwhelming bipartisan margin in the next few days and then will work with the House to reconcile differing versions prior to the House adjournment at the end of September, if possible.

The Senate and the House have had an unusually productive appropriations season, with nine of the 12 annual spending bills moving through the House and the Senate and currently in the process of being reconciled through conference committees. In an attempt to avoid passing another massive, unpopular "omnibus" bill containing all 12 appropriations bills as has been typical in recent years, the House and the Senate have focused on passing the appropriations bills in the form of "minibus" appropriations bills containing multiple bills in each vehicle:

Minibus #1: Energy and Water Development, Military Construction and Veterans Affairs, and Legislative Branch

Minibus #2: Agriculture, Financial Services, Interior and Environment, and Transportation – Housing and Urban Development

Minibus #3: Defense and Labor and Health and Human Services and Education

The House and the Senate are expected to pass minibus #1 in the next few days and are working to pass minibus #3 by the end of the month. It is not clear yet whether minibus #2 will make it to the President's desk prior to September 30. At least three other appropriations bills will not be finalized prior to September 30: (1) Commerce–Justice–Science, (2) State and Foreign Operations, and (3) Homeland Security. The House and the Senate are expected to pass a Continuing Resolution by September 30 to extend funding to cover any unfinished appropriations bills until the lame duck session.

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UPDATES ON THE AGREEMENT FORMERLY KNOWN AS “NAFTA”

Updates on the Agreement Formerly Known as “NAFTA”

On Friday, August 31, President Trump notified Congress of his intent to enter into a "new" free trade agreement with Mexico—and Canada, if it is willing. In the letter, President Trump touted that this new agreement will ensure market access for U.S. farmers, create a level playing field for U.S. manufacturers as a result of amendments to the agreement's rules of origin, include the toughest and most comprehensive environmental and labor provisions, and improve protection of intellectual property (IP) rights protection. The administration submitted the notification to Congress so that it could give Mexican President Nieto an opportunity to sign the agreement before he leaves office on November 30.

In response to the President's notice to Congress, several senior members urged the administration and Canada to maintain the North American Free Trade Agreement (NAFTA) as a trilateral agreement. House Committee on Ways and Means Chairman Kevin Brady (R-TX) noted that Canada needs “to step up and demonstrate that it can take on the ambitious obligations of the agreement.” Senate Finance Committee Ranking Member Ron Wyden (D-OR) noted that “it is premature for the President to announce he intends to sign a trade agreement when so many difficult issues remain unsolved.” Earlier in the week, Senate Finance Trade Subcommittee Chairman John Cornyn (R-TX) noted that “a trilateral agreement is the best path forward.” Rep. Bill Pascrell (D-NJ), the ranking member of the Ways and Means Trade Subcommittee, also noted that the final agreement must include Canada. Sen. Pat Toomey (R-PA) also told reporters that he thinks that any final agreement must also include Canada to ensure that the implementation of the agreement receives Trade Promotion Authority (TPA) protection.

In response to U.S. lawmakers' concerns about not including Canada in a final agreement, President Trump warned U.S. lawmakers that he will “simply terminate” the current NAFTA should they interfere in the negotiations. Ranking Member Wyden refuted the President's claim that he could unilaterally withdraw from NAFTA without congressional approval, stating, “The president doesn't have a deal, he doesn't have a plan, and he doesn't even have the power to follow through on his empty threats. The president needs to take a look at the Constitution—it gives Congress authority over trade. The president cannot pull America out of NAFTA without Congress's permission.”

While negotiations with Canada resumed on Wednesday, September 5, the two countries still have a number of issues to address, including dairy market access, trade remedy dispute settlement procedures, government procurement and IP rights. Negotiations between the two countries had stalled on Friday, August 31, amidst news reports of President Trump's leaked comments indicating that he would never make concessions to

Canada. President Trump later confirmed the comments in a Tweet, where he indicated that “at least Canada knows where I stand.” Canadian Prime Minister Justin Trudeau responded before the September negotiations began, “As I’ve said, we will not sign a deal that is bad for Canadians.” He signaled that Canada will not back down on dispute settlement and added that the deal must maintain a carveout that excludes “cultural industries” from obligations under the agreement.

The administration is required under TPA rules to provide the full text of the new agreement to Congress at least 60 days before it is signed. According to that timing, the Office of the U.S. Trade Representative and negotiators from all three NAFTA countries must release the text, with or without Canada included, by September 30. (Follow our TPA timeline [here](#) as additional milestones are reached.) The Trump administration remains confident that it will be able to come to an agreement with at least Mexico in the next few weeks to provide Congress with written text.

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HHS MARKS 100 DAYS SINCE DRUG PRICING BLUEPRINT

HHS Marks 100 Days Since Drug Pricing Blueprint

On August 22, HHS released a brief report summarizing the actions that the agency has taken on drug pricing in the 100 days since the administration published its American Patients First blueprint. The report noted several manufacturers’ decisions to roll back or delay certain drug price increases, as well as the FDA’s continued efforts to streamline generic drug approvals.

The Centers for Medicare and Medicaid Services (CMS) recently took several actions to address drug prices, some of which are mentioned in the report. On August 7, the agency announced that it will permit Medicare Advantage plans to have the option of applying step therapy for physician-administered and other Part B drugs beginning on January 1, 2019. Additionally, on August 29, CMS issued guidance to allow Medicare Part D plan sponsors to use indication-based formulary design beginning in 2020. According to CMS, this change will help strengthen plans’ negotiating leverage with manufacturers.

Looking ahead, the Office of Management and Budget (OMB) is now reviewing an HHS Office of Inspector General proposed rule that would both eliminate and create new safe harbor protections related to drug rebates for pharmacy benefit managers. FDA Commissioner Scott Gottlieb and HHS Secretary Alex Azar have both discussed the possibility of re-examining the safe harbors for drug rebates.

OMB also is reviewing a proposed rule on drug pricing transparency, which is expected to propose requiring the disclosure of price information in direct-to-consumer advertising by pharmaceutical manufacturers. Additionally, the Labor–HHS appropriations bill passed by the Senate last month includes an amendment to fund implementation of such a requirement.

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FARM BILL NEGOTIATIONS CONTINUE

Farm Bill Negotiations Continue

Legislators continue to negotiate legislation to reauthorize federal agriculture programs. The House passed its “Farm Bill” in late June. The legislation contained enhanced work

requirements for recipients of the Supplemental Nutrition Assistance Program (SNAP). House passage came after a significant debate and fell largely along party lines, with some Republicans voting with Democrats against the bill. The Senate approved its version a week later by a bipartisan majority of 86-11, following committee mark-up that largely avoided partisan disagreements.

Staff from both chambers met through the recess to reach a negotiated agreement, but several issues remain unresolved. Beyond the enhanced SNAP work requirements, crop insurance and commodity prices also pose challenges to reaching a deal. The Trump administration's ongoing trade negotiations have created an additional wrinkle in completing talks over the Farm Bill. Retaliatory tariffs from other countries have, in part, been aimed at the U.S. agriculture sector.

Congress will need to pass a new Farm Bill or an extension of the current law before it expires on September 30. Some observers believe that legislators will choose to pursue the latter option, with a temporary extension giving negotiators additional time to hammer out a compromise. If Congress pursues a short-term extension, it is likely to go until after election day and into the lame duck session. Some analysts predict that the extension could go even longer, possibly into the new Congress.

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FCC SEEKS INPUT ON EXPANDING TELEHEALTH FUNDING OPPORTUNITIES

FCC Seeks Input on Expanding Telehealth Funding Opportunities

On August 2, the Federal Communications Commission (FCC) released a Notice of Inquiry in which it is seeking comment on establishing a new \$100 million "Connected Care Pilot Program" to support telehealth funding for health care providers to reach low-income Americans and veterans, with a focus on those living in rural areas. The FCC seeks comment on a number of issues related to establishing the pilot program, including its budget, design and types of telehealth pilot projects that should be funded. In addition, the FCC seeks comment on the eligibility criteria for participating health care providers, broadband service providers, and the broadband services and other communications services and equipment that should be supported. The FCC also seeks comment on whether it should require health care providers to partner with an eligible telecommunications carrier on their application. Comments were due September 10, and reply comments are due October 10.

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NEW CALIFORNIA PRIVACY LAW MAY INCREASE PRESSURE FOR FEDERAL LEGISLATION

New California Privacy Law May Increase Pressure for Federal Legislation

As part of its August session, the California State Legislature adopted modifications to the California Consumer Privacy Act of 2018 (CCPA) to tighten certain aspects concerning what would be considered a violation of the law, the standard for what is considered a violation of the law and limitation of consumer lawsuits to instances where there had been a breach. The amended language also defers the timing for enforcement, preventing the state attorney general from enforcing the law until July 2020 or six months after the regulations are final, whichever is first. The effort fell far short of changes that many had urged the legislature to make, and, as a result, the call for federal action will escalate. While there are a number of bills pending before the Congress, it is unlikely that they will move before the

end of this year, but efforts are under way to begin establishing the framework on legislation for the next Congress. The CCPA becomes effective July 1, 2020.

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RECENT LOSSES FOR TRUMP ADMINISTRATION EPA

Recent Losses for Trump Administration EPA

August was a particularly difficult month for the Trump administration Environmental Protection Agency (EPA), which suffered tough losses on some high-profile matters in which the agency sought to reverse course on Obama administration EPA actions. The losses that we highlight here were suffered on actions taken since the beginning of the Trump administration and are losses that stemmed from actions in which the various courts found that the agency failed to supply a reasoned analysis for changing its course, a prerequisite for policy change in administrative rulemaking. See *Motor Vehicles Mfgs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 57 (1983):

- On August 17, 2018, the agency's action to delay the effective date of the 2017 Risk Management Program Rule amendments issued by EPA at the end of the Obama administration was vacated by the U.S. Court of Appeals for the District of Columbia Circuit. *Air Alliance Houston v. EPA*, No. 17-1155 (D.C. Cir. 2018). In so doing, the court accused the agency of making a "mockery" of the law. *Id.* at 28. For more detail, see our alert [here](#).
- On August 16, 2018, EPA's rule attempting to suspend the implementation of the Clean Water Rule (CWR), also referred to as the Waters of the United States Rule, was enjoined following a finding that the agency suspended the rule in violation of the Administrative Procedure Act (APA) by precluding an opportunity for meaningful public comment. *S.C. Coastal Conservation League v. Pruitt*, No. 2-18-cv-330-DCN (D.S.C. 2018). In particular, the court found that EPA acted improperly by restricting comment to the narrow question of whether it was desirable and appropriate to delay implementation of the CWR and specifically precluding comment on the substance of the rule or its predecessor rule that would have purportedly been reinstated by the suspension rule. *Id.* at 7.
- On August 9, 2018, the agency was found to have erred in denying a petition to ban the use of the pesticide chlorpyrifos, finding that there was "no justification" for its March 2017 decision. *League of United Latin American Citizens v. Wheeler*, 899 F.3d 814 (9th Cir. 2018). After grappling with a jurisdictional question mired in the nuances of the APA, the 9th Circuit found that it had authority to act and summarily rejected EPA's argument that there remained "significant uncertainty" as to the health effects of the pesticide, noting that the agency "cannot refuse to act 'because of the possibility of contradiction in the future by evidence unavailable at the time of action—a possibility that will always be present.'" *Id.* at 32.

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2018 MIDTERM ELECTIONS: PRECEDENTS & OUTLOOK

2018 Midterm Elections: Precedents & Outlook

In less than two months, the public will go to the polls to select representation for the 116th Congress, which begins in January 2019. All 435 seats in the House and a third of the seats

in the Senate will be up for reelection, giving voters the opportunity to potentially reshape policy-making for the next two years.

Akin Gump Strauss Hauer & Feld LLP recently published a [report](#) that seeks to provide insight into the upcoming 2018 midterm elections by delving into the historical and political patterns that have shaped previous midterm contests. The report looks at how presidential popularity and historical precedent can shape outcomes. It explores the current state of play of the overall dynamics in the House and Senate races. Finally, the report looks at each party's strategy for success this fall. **(Note that numbers reflected in the report are accurate as of the original publication date of August 21, 2018.)**

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