Arnold & Porter

MID-TERM ELECTIONS 2018

Impact of the Mid-Term Elections on the Life Sciences Industry

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Following historical trends, the first mid-term Congressional election in the Trump Administration has concluded with significant losses among the House GOP, resulting in a new Democratic majority. It's too early to call it a blue wave, but Democrats flipped 29 seats as of Wednesday morning, November 7, bringing the tally to 220 Democrats, 194 Republicans, and 21 seats uncalled. Across the Capitol, Senate Republicans flipped three seats in Indiana, Missouri, and North Dakota to hold their majority with 51 seats and four still uncalled. Women had a good night overall, with over 100 tapped to serve in the new Congress. And despite losses, it seems that President Trump had a positive impact on key races in Indiana, Tennessee, and Missouri. It will take some time for the dust to settle, but we can already anticipate a challenging legislative season in the 116th Congress with a number of Democrats knocking off moderate Republicans. Moreover, a new political dynamic within the House Democratic Caucus (new members, more progressive, and many opposing Pelosi's leadership) will be cause for early soul searching to build a successful agenda to fulfill campaign promises.

Divided government often yields gridlock in Washington, but we anticipate an active agenda impacting life sciences companies both in oversight and policy. Pent-up energy among House Democrats in the minority will translate into an aggressive oversight agenda that will harken to the days of Chairman John Dingell (D-MI), with his impressive oversight infrastructure, and Henry Waxman (D-CA), who ousted Dingell to lead Energy and Commerce and struck fear in all industries with his merciless investigations. Paired with a potential Finance Committee Chairmanship of Sen. Charles Grassley (R-IA), with an impressive investigative record in his own right and top notch staff, the 116th Congress is shaping up to be a period of intense activity, with industries on high defense despite gridlock. While we do not anticipate a robust number of legislative accomplishments, we may see areas of agreement on key issues impacting the life sciences industry, particularly given the Administration's interest in fulfilling their own campaign promise of lowering drug costs.

We are mere hours past election day, but the 2020 election cycle has already begun. Democrats are under tremendous pressure to demonstrate to the electorate why they deserve the chance to keep their new House majority and take control of the White House and Senate. That means they will have to do more than throw bombs at the Republicans; they have to prove they can govern effectively, even in a divided government. Republicans claim the more vulnerable position in 2020, defending a challenging Senate map with 20 seats up (not including AZ and MS specials) and protecting an Administration with historically low approval ratings and at the center of the country's political divide.

Both parties will use the 116th Congress to set the stage for the next cycle, carefully crafting both the oversight and policy agendas to support the campaign goals of 2020. Drug pricing will be a key feature of the campaign; Democrats will certainly lead the charge, but the Administration is aggressively pursuing reforms, and we anticipate that Congressional Republicans will want to demonstrate some movement toward lowering drug prices, particularly Senate Republicans given their more vulnerable position in the 2020 election cycle. Roughly 15 companies have proactively held or reduced drug prices, but that is unlikely to satiate the Congressional appetite for more aggressive action, and more importantly, the ability to claim credit for such action in 2020.

But First, Lame Duck: Republicans will return from a disappointing cycle to a lame duck session, but how motivated will they be to legislate? There are a few must-pass items, namely funding government operations which currently expires December 7. Some Republicans have expressed interest in moving their own policies while they still maintain control of both chambers and the Administration. Stakeholders, likewise, are anxious to see some of their own priorities move before the new House Democratic majority takes over in January.

Of particular interest is a modification to a provision of the Bipartisan Budget Act of 2018 that altered manufacturers' responsibility for cost-sharing in the Part D donut hole. Beginning in 2019, beneficiary cost-sharing in the donut hole for brand drugs decreases from 35 to 25 percent, plan responsibility declines from 20 to 5 percent, while manufacturer discounts increase from 50 to 70 percent of the Part D negotiated price, saving the government nearly $12 billion in according to a revised Congressional Budget Office (CBO) estimate. The pharmaceutical industry has made headway in highlighting the problems that reducing the plans' responsibility causes for Part D, by undermining plans' incentives to contain costs, but was unsuccessful in securing a fix in the recently-passed opioids package. This remains a top priority for the industry in the lame duck, and Republican staff are attempting to negotiate, with a number of alluring trades on the table in exchange for rebalancing the relative responsibilities of plans and manufacturers, ultimately restoring incentives of plans to keep costs down and providing more relief to beneficiaries.

The proposal could include delaying the upcoming Part D cliff where beneficiaries will see an increase in their cost-sharing responsibilities in 2020, and potential inclusion of a modified version of the CREATES (Creating and Restoring Equal Access to Equivalent Samples) Act, which would make the Federal Trade Commission the arbiter of disputes between generic companies that would otherwise take action against brand name companies. Disagreements among Democratic leadership have stalled efforts, but we expect talks to continue in the lame duck, focusing on attaching a potential deal to a year-end spending package.

Other potential end of the year add-ons could include a 340B reporting package, although we anticipate the lame duck session to focus solely on must-pass and high-profile items like the Part D fix.

Oversight: The change of committee control in the House enables Democrats to pursue an ambitious oversight agenda involving the Administration (despite warnings from former Democratic lawmakers that they will lose credibility by getting bogged down in political oversight hearings). But private sector targets, particularly manufacturers, are at risk of being drawn into Congressional investigations as well, to showcase Democratic policy solutions and fulfill promises made on the campaign trail about bringing down drug prices. The Republican-led Senate could also pose risks to companies in certain instances.

Manufacturers should be prepared to navigate a dynamic environment of high-profile Congressional investigations on a range of potentially sensitive issues in the next Congress, including but not limited to domestic pricing and tax strategies. It will be important for companies not only to understand the local and national politics and policies driving particular committee leaders' focus, but also the distinct practices, procedures and authorities each committee may use to obtain information, ranging from formal or informal requests for interviews to subpoenas for documents and testimony. It is important to note that Congressional hearings and investigations involving industry can provide a vehicle for forging bipartisan alliances and fostering public support for policy solutions, which can place private sector investigative targets in difficult positions. Companies caught in the cross-hairs will need to consider all of the legal and reputational risks associated with high-profile investigations as well as the political environment and the investigators' objective in each instance.

House: While favored, we note that the return of Rep. Nancy Pelosi (D-CA) to the Speaker's post is not quite as certain as was the case in 2007. Many of the Democratic candidates running in 2018 distanced themselves from the Minority Leader, and some promised voters they would not support her bid for the Speaker's gavel. When the newly-constituted House

Democratic caucus meets later this month to vote on leadership posts, we anticipate they will ultimately recommend Leader Pelosi for Speaker. But she may need to make some behind-the-scenes concessions to quell a challenge within the caucus.

With Democrats controlling only one chamber, there will be significant pressure on House leaders to hold oversight hearings as a vehicle for Democrats to draw contrasts with the Trump White House in advance of the 2020 Presidential election. The pressure will only increase if Democrats are stymied by a Republican-led Senate in advancing their legislative policy agenda, and we expect they will use their investigative authorities to drive changes in private sector behavior. Democrats taking over key committee gavels in the House will want to use their Congressional oversight authority to position themselves as allies of patients and consumers, while drawing clear distinctions between Democrats' policy proposals on drug prices and those coming from the Administration. This could translate into wide-ranging inquiries to test the Trump Administration's claims that prices *are* lower as a platform to frame their alternative policy approach.

Reps. Frank Pallone (D-NJ) and Richard Neal (D-MA) will chair Energy and Commerce and Ways and Means, respectively, and will be working to advance a broad legislative agenda on healthcare while balancing the need for oversight at the full committee level. Rep. Pallone has indicated that his first priority is stabilizing the Affordable Care Act (ACA) next year, followed by addressing drug pricing policy. Rep. Neal has focused largely on health insurance issues while Ranking Member of Ways and Means, but could use his gavel to examine corporate beneficiaries of the Trump Administration's tax and trade policies, with manufacturers among potential targets. With respect to the Energy and Commerce Committee, Reps. Anna Eshoo (D-CA), Jan Schakowsky (D-IL), and Diana DeGette (D-CO) are top contenders for chairing two key subcommittees. If DeGette, who co-chairs the Diabetes Caucus with Tom Reed (R-NY), gains control of either the Health Subcommittee or the Oversight and Investigations Subcommittee gavel, she could well use her perch to focus on insulin prices, as well as other prescription drug issues.

We anticipate that Reps. Elijah Cummings (D-MD), Lloyd Doggett (D-TX), and Peter Welch (D-VT) largely will take the lead on a wide range of drug pricing issues. As founders of the Affordable Prescription Drug Task Force in the 2015, they have made clear they view manufacturers as the primary drivers of rising drug prices, and intend to focus on bringing transparency to manufacturers' drug pricing systems. The three leaders also may push legislation they introduced in July 2018 that would permit Medicare Part D price negotiation, and allow the Secretary of Health and Human Services (HHS) to grant additional licenses to different drug makers if government negotiations stall. We expect them to use their oversight platforms to highlight these and other policy proposals and contrast them with the Trump Administration's measures.

Rep. Cummings is likely to chair the House Oversight and Government Reform Committee and is a staunch critic of the pharmaceutical industry. Even without the benefit of subpoena power, late last year, Rep. Cummings and Rep. Welch launched a broad investigation into manufacturers' pricing strategies for drugs used to treat multiple sclerosis. Additionally, late in the 114th Congress, Cummings persuaded former Oversight Chairman Jason Chaffetz (R-UT) to summon a pharmaceutical industry CEO before the committee to testify on the company's recent product price increases.
Rep. Doggett is favored to chair the Health Subcommittee of the Ways and Means Committee, which could provide him a powerful platform for hearings to promote the Task Force's policy proposals, given the jurisdiction it shares with the Energy & Commerce Committee over the Medicare program.

Two frequent critics of pharmacy benefit managers (PBMs) and health insurance mergers could join forces on the House Judiciary Committee. Rep. Jerrold Nadler (D-NY) the likely chairman, could be joined at the top of the dais by Rep. Doug Collins (R-GA) (Rep. Steve Chabot (R-OH) has more seniority on the committee, but Collins has developed strong relationships with caucus leaders as Vice Chairman of the Republican Conference). Although pharmaceutical market oversight may take a backseat to more pressing priorities for the new chairman, such as investigating immigration and foreign interference in the elections, the two may find rare common ground by summoning PBMs and issuers before the committee to examine their role in the cost of medications. Prior committee hearings on the topic have not explored PBMs role in the supply and distribution chain, but it will be important to keep a close eye on this committee as well.

Manufacturers should also prepare for inquiries from committees without primary jurisdiction over healthcare, as well as requests from individual Members. Dozens of newly-elected Democrats, even if they do not serve on the relevant committees, may want to flex their new positions to explore drug pricing issues raised during their campaigns. And although the Committee on Science and Technology, likely to be chaired by Eddie Bernice Johnson (D-TX), is apt to prioritize oversight on Administration's approach to climate science, the committee has delved into healthcare issues involving technology in the past, such as Healthcare.gov contracts with social media companies. The committee could exercise its prerogative to advance a Democratic policy agenda by investigating, for instance, manufacturers' R&D investments.

Senate: The retirement of Sen. Orrin Hatch (R-UT) opens up the post of Senate Finance Committee chairman. Senate term limits gives Sen. Grassley, who currently chairs the Judiciary Committee, a few more years to serve as chairman (he previously served from 2003-2007), with other contenders including Sens. Mike Crapo (R-ID), Pat Roberts (R-KS), and John Cornyn (R-TX) who will cycle out of his leadership position. Sen. Grassley is known as a pharmaceutical industry watchdog and relentless investigator with populist tendencies who does not hesitate to partner with Members across the aisle on issues of concern, or to publish information he has gained through his investigative efforts. In 2015, he and Sen. Ron Wyden (D-OR) led an 18-month investigation of a company's strategy for pricing a hepatitis C drug culminating in a 144-page report published under the Finance Committee's auspices.[1] Sen. Grassley has also been a long-time advocate for importing prescription drugs from Canada as a potential solution for domestic price increases, and partnered with former Sen. John McCain (R-AZ) and Sen. Amy Klobuchar (D-MN) to urge the Administration to certify certain drugs for immediate importation. In addition, he and Sen. Patrick Leahy (D-VT) led Senate Judiciary approval this past June of the CREATES Act designed to address practices that allegedly delay market entry for generic drugs. Although he was one of the original authors of legislation establishing the Medicare Part D program, Sen. Grassley also could be open to re-examining the structure of the program in the next Congress. As Finance Committee chairman, however, while Sen. Grassley may initiate investigations into these and other topics, he may hesitate to hold hearings that could provide a public platform for Democrats eager to advance full-blown government price negotiation authority as a policy solution.

The Senate Special Committee on Aging, which Sen. Susan Collins (R-ME) is likely to chair, promises to be another potential venue for investigations into pharmaceutical market practices. In the last Congress, Sen. Collins partnered with former Ranking Member Sen. Claire McCaskill (D-MO) on a series of investigations and hearings on manufacturer pricing practices, culminating in a detailed published report.[2] Sen. Bob Casey (D-PA) is expected to continue in his post as Ranking Member of the Aging Committee in the next Congress (and to remain on Finance and the Committee on Health, Education, Labor and Pensions). He has been a reliable partner for Sen. Collins on Aging Committee drug pricing investigations, and supports prescription drug importation from Canada. We expect the Aging Committee to be active on pricing issues, and to explore Medicare beneficiaries' out-of-pocket costs in the Part D program and other issues that could require manufacturers' participation.

Policy: Prescription drug pricing is certain be a key issue in the 116th Congress, and is reflected as a cornerstone of the Democratic party's platform, *A Better Deal*. There are early signs of prescription drug pricing policy forming unlikely commonality between Democrats and President Trump, and we expect that this dynamic will continue. We expect Senate Republicans to act as the moderating force to limit which policies actually become law, which offers some but not total comfort to the industry given recent support for drug pricing proposals.

Transparency and Reporting: The Administration initially proposed requiring price disclosures in its *American Patients First* drug pricing blueprint, and recently issued a proposed rule that would require DTC television advertisements of prescription drugs and biologics to disclose the wholesale acquisition cost (WAC). Congressional efforts have been underway in parallel. The Senate passed a price disclosure amendment, led by Sens. Grassley and Dick Durbin (D-IL), as part of an appropriations measure earlier this year, which was later dropped from the conference report. The Administration expects to finalize the DTC advertising rule next summer, after which it is certain to be challenged.

We also expect Democrats to call for recent state efforts that require manufacturers to justify price increases to be adopted at the federal level. The Democrats' platform proposes requiring manufacturers to provide the Secretary with a "justification" of a "significant price increase" at least 30 days before the increase would take effect. The justification, which would be made public, would include the individual factors leading to the price increase, as well as the percentage of total expenditures on marketing and federally-supported research and development. Price justification requirements have also been reflected in Democrat-led bills, such as the FAIR Drug Pricing Act and the Stop Price Gouging Act, but have lacked broad Republican support.

Another area we are watching closely is patient assistance programs (PAPs), which have been scrutinized for their alleged ties to manufacturers and have been described as contributing to drug price increases. Following the HHS-OIG's rescission of a patient foundation's advisory opinion, Senate Finance Committee Ranking Member Ron Wyden (D-OR) questioned HHS-OIG about its plans to audit or review similar advisory opinions on PAPs and copay assistance foundations. Additionally, the most recent comprehensive Democratic prescription drug pricing proposal scrutinizes the independence of PAPs from manufacturers. The legislation distinguishes "independent charity patient assistance programs" from "manufacturer patient assistance programs," and requires manufacturers to report to Congress on financial support and usage of manufacturer patient assistance programs. This proposal is supported by several expected Democratic presidential candidates, including Sens. Cory Booker (D-NJ), Kirsten Gillibrand (D-NY), Elizabeth Warren (D-MA), and Bernie Sanders (I-VT), and we expect a new version to resurface next year.

Access and Affordability: An area where Democrats have not reached consensus is the scope of drug importation. While some proposals go much broader, others have been limited to giving the Secretary *temporary* importation authority, including during a drug shortage. Sen. Rand Paul (R-KY), who has become one of President Trump's closest allies on health policy issues, has joined Democrats in pushing for drug importation. Notably, Sen. Paul threatened to oppose HHS Secretary Alex Azar's nomination unless he would consider importation.

Other proposals, including cost-sharing caps and exercising march-in rights based on high drug prices, may be raised, but are less likely to gain traction. Similarly, the Democrats' proposal to create a Price Gouging Enforcer, a new independent agency that would identify drugs with significant price increases and impose fines relative to those increases, is likely to be a nonstarter in a divided Congress.

Medicare Part D: Should lame duck negotiations on the donut hole fix and potential inclusion of a Part D cliff delay prove unsuccessful, we expect those efforts to resume early in the 116th Congress. Reps. Pallone and Neal have introduced legislation that would avert the Part D cliff by making permanent the pre-2010 ACA growth factor used in setting the amount of out-of-pocket spending necessary to reach the catastrophic phase of the Part D benefit. Other efforts to reduce the burden of out-of-pocket drug costs on Part D beneficiaries will likely be floated, including capping prescription drug cost-sharing for Part D beneficiaries by eliminating cost-sharing in the catastrophic phase of the benefit (one component of the President's five-part reform plan for Part D).

The Administration has put forth several proposals to modify or eliminate manufacturer rebates to Part D plans and their PBMs, an area where Senate Republicans may be willing to come to the table. A proposed rule, which is expected to modify anti-kickback statute safe harbors relevant to drug rebates, is currently under review by the Office of Management and Budget (OMB). Republicans have urged the Administration to be thoughtful and deliberate when considering changes to rebates, which could have broader implications across the healthcare sector, and have urged a transparent process that includes Congressional and stakeholder input.

We expect lawmakers to take a close look at the extent to which PBM-negotiated discounts are passed along to consumers. The President's Budget would require prescription drug plans to apply at least one-third of total rebates and price concessions at the point of sale, and Senate Finance Committee Democrats have put forth a similar proposal. Under the

C-THRU Act, PBMs would be required to disclose their aggregate rebates under Part D plans, and what proportion of the rebates are passed along to beneficiaries. After two years of public reporting, the Secretary would establish a "minimum percentage" of the aggregate rebate that would be required to be passed along to beneficiaries.

Although we expect calls to repeal the non-interference clause to continue, passage is unlikely. Democrats have long pushed for repealing the Medicare Part D non-interference clause, an issue that President Trump also championed while on the campaign trail. Proposals range from striking the non-interference clause to affirmatively requiring the Secretary negotiate prices for certain drugs. Permitting government negotiation to any degree, however, will be strongly opposed by rank-and-file Republicans, who see non-interference as a critical to the structure of the Part D benefit.

Medicare Part B: The Administration has taken a lead on addressing Medicare Part B drug pricing, most recently with initial steps to establish a Center for Medicare and Medicaid Innovation (CMMI) model that would operate in half the country and (in those regions) replace ASP-based payments for most Part B drugs with an international pricing index. While Congressional Republicans have issued vaguely positive statements thus far, we expect activity will increase post-election (more below). We are also watching efforts to curb Part B drug price increases, as both House Democrats and the Administration have proposed establishing an inflation limit on reimbursement of Part B drugs. CMS also just finalized a rule limiting payments for new drugs that do not yet have an ASP-based payment to 103 percent of WAC (a three percent reduction from the current rate).

Generic Drugs: Bipartisan efforts to reduce perceived anticompetitive practices that block the market entry of generic drugs will likely continue. Sen. Grassley has been particularly vocal, leading legislation that would strengthen enforcement of pay for delay agreements, as well as the CREATES Act, as noted. We also expect proposals to encourage the use of lower-cost generics. The Administration has proposed eliminating cost-sharing for generics, biosimilar, and preferred multisource drugs for Part D low-income subsidy enrollees, which is estimated to save $210 million over 10 years.

340B Drug Pricing Program: It looked like 2018 could have been the year that Congress enacted reforms to the 340B Drug Pricing Program. The committees of jurisdiction, House Energy & Commerce and Senate Health, Education, Labor, and Pensions (HELP) Committees, held several hearings, and committee members introduced legislation calling for increased transparency and reporting on how covered entities use 340B discounts. If these bills do not move during the lame duck, then they are unlikely to move in a Democrat-led House.

Other 340B proposals could include the SERV Communities Act, introduced by Rep. Doris Matsui (D-HI), that would codify the current definition of a "patient," as set forth under a 1996 HRSA final notice, expand the list of covered entity grantees, and prohibit the Secretary from implementing reductions to Medicare hospital outpatient payments for separately payable, non-pass through drugs and biologicals purchased under the 340B program. It is also possible that Democrats could renew efforts to expand the 340B program to the inpatient setting (as was initially included as part of the ACA but then repealed by companion legislation, the Health Care Education Reconciliation Act). This will be a non-starter with budget-conscious Republicans.

Compounding: Nearly five years have passed since Congress passed the Drug Quality and Security Act (DQSA), yet lawmakers continue to question whether FDA is adequately regulating compounding. During an oversight hearing earlier this year, Energy & Commerce Committee Rep. Pallone noted that despite the DQSA, there have been over 140 recalls of compounded drugs and reports of serious health events. While DQSA follow-on legislation appears unlikely in the short-term, we expect Congressional oversight of DQSA implementation to continue in the 116th Congress. Members are looking closely at a revised draft memorandum of understanding between FDA and states, and the extent to which it clarifies their respective regulatory and enforcement jurisdictions. Federalism concerns, however, are muddling the message to the agency, with some lawmakers pressuring the FDA apply the law more forcefully and others asserting that doing so would encroach on state regulation of medicine.

Medical Device Tax: The ACA's medical device tax will once again be on the chopping block. With the backing of a diverse group of stakeholders, including industry and healthcare providers alike, Congress first imposed a moratorium on the medical device tax for sales beginning in 2016. Lawmakers have since extended the moratorium through 2019, and we expect Congress will, once again, extend the moratorium, rather than permanently repeal the tax. Though repeal carries strong bipartisan support, Congress has only managed to kick the can down the road given the high cost associated with full repeal (the current two year delay is estimated to cost the federal government $3.75 billion, while full repeal scores at $19.6 billion over a decade).

Medical Device Cybersecurity: Though increasing cybersecurity has been a priority for FDA over the past several years, a recent HHS-OIG report recommended that FDA take additional steps to address the post-market cybersecurity risk to devices. This report could spark Congressional oversight and policymaking efforts in the 116th Congress. Industry has thrown its support behind a Republican-backed proposal, Internet of Medical Things Resilience Partnership Act, that would establish a public-private working group to develop voluntary frameworks and guidelines for device cybersecurity. Democrats, on the other hand, have pushed for stronger language, including mandated testing for manufacturers.

Administration: The Trump Administration has become a non-traditional leader in the fight to bring down prescription drug costs, introducing a barrage of policies and proposals targeting the pharmaceutical industry. The President's Fiscal Year 2019 Budget for HHS included a five-part plan to "modernize" Part D including proposals to apply rebates at the point-of-sale, cap out-of-pocket spending by eliminating cost-sharing in catastrophic coverage, exclude manufacturer coverage gap discounts from beneficiary true out of pocket costs, enhance Part D formulary flexibility to allow plans to only cover one drug per class, and eliminate cost-sharing on generic drugs for low-income beneficiaries. Earlier this year, the Administration announced their much-anticipated blueprint for reducing drug prices and patient out-of-pocket costs, and subsequently released an RFI outlining proposals to address key challenges in the market through a combination of potential immediate actions, opportunities for consideration, and an open solicitation for proposals to "improve the affordability and accessibility of prescription drugs". OMB is currently reviewing a proposed rule to lower drug prices and reduce out of pocket costs in Part D and Medicare Advantage (which is expected to include proposals from the President's blueprint), as well as a proposed rule that would modify safe harbor protection for manufacturer rebates to plans or PBMs.

On October 25, the Administration announced their latest drug pricing proposal, the International Pricing Index payment model, as described in an Advance Notice of Proposed Rule Making (ANPRM), where Part B drug prices would be linked to prices in other countries. The ANPRM indicates the proposal will be included in Spring 2019 proposed rulemaking, with a five-year model beginning in 2020. The model would be mandatory for physician practices and hospital outpatient departments (HOPDs) (and potentially other Part B providers such as DME suppliers and ASCs) in selected geographic areas, and would initially be limited to single source drugs, biologicals (including biosimilars), and multisource drugs with a single manufacturer (scope to broaden in year 3). The model explicitly excludes packaged drugs furnished under the OPPS, drugs in short supply, drugs paid under miscellaneous or not otherwise classified (NOC) codes, compounded drugs, radio-pharmaceuticals, and ESRD drugs. An "add-on" payment would be made to the physicians and HOPDs that administered the drug and would be based in total on the ASP+6 for all included Part B drugs, intended to remove the perceived incentive to use high cost drugs; how this "add-on pool" would be allocated to physician practices and HOPDs administering Part B drugs is not altogether clear. The model also introduces vendors to the program, with whom CMS would contract to operate on a national basis, similar to CAP. Vendors would negotiate with manufacturers for the drug's acquisition price, and take on the risk of acquiring the drugs and billing Medicare at the prices set by CMS (which would be based on a blend of ASP and international prices until the last year of the model, at which point the CMS payments would be based entirely on international prices). Medicare would pay vendors ASP if it is lower than this internationally-based payment. Potential countries for reference pricing could include Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece,

Ireland, Italy, Japan, the Netherlands, and the UK, which have comparable economies or are included in Germany's market basket for reference pricing. For new drugs, Medicare would calculate a payment by applying a standard factor.

The Administration has made no secret of their distaste for ASP+6 and preference for moving to a competitively bid system. Secretary Azar has stated publicly that he would prefer to move some Part B drugs to Part D. The IPI model is reminiscent of the Obama Administration's Part B pricing model that failed due to intense opposition from the industry and providers, and ultimately Congressional intervention to stop the proposal from getting off the ground. The model is vulnerable to many of the key features that doomed its predecessor (mandatory, potentially exceeds the authority of CMMI), and opposition is already mounting: providers are expressing concern about patient access to therapies, and Democrats responded early saying the proposal doesn't go far enough, attempting to hold the President to his statements on direct negotiations. However, there will be some Congressional Republicans that will support the plan out of loyalty to President Trump, and new political dynamics of the 116th Congress could create the necessary environment for the IPI model to at least proceed to the next stage in the process.

Another area the Administration has expressed interest in is value-based purchasing models for drugs. The Anti-Kickback Statute and Medicaid best price policy pose significant issues for such models, and CMMI has not successfully launched demonstrations to date. In the meantime, states are exploring value based payment models. In June, Oklahoma became the first state to win approval for a Medicaid value-based arrangement with drug manufacturers, where the state will receive supplemental rebates if certain outcomes are not achieved. Michigan has also submitted a Medicaid state plan amendment to CMS to enter into outcomes-based arrangements with manufacturers. This follows similar arrangements with private payers as well as pay for performance measures with pharmacy benefit managers.

With respect to access to drugs under Medicaid (i.e., state compliance with the coverage requirements in the Medicaid rebate statute), CMS rejected a Massachusetts request for a waiver permitting a closed Medicaid formulary (because the state intended to continue collecting guaranteed rebates under the rebate statute), but continues to discuss options for states to negotiate rebates with manufacturers outside of the Medicaid rebate statute. We are closely watching for a proposed rule, expected in June 2019, which the Administration has indicated will "support value-based payment arrangements" between manufacturers and states. We anticipate that states may be incubators to test new ways to bring down drug costs, and that CMS may support those efforts. The Administration's blueprint also supports development of proposals to eliminate the cap on Medicaid rebates created by the ACA (at 100 percent of Average Manufacturer Price), which was further supported by a piece of legislation introduced by Rep. Michael Burgess (R-TX), Energy and Commerce Committee Health Subcommittee Chair. While such a proposal would require Congressional action, this could represent another area where the Administration and Congress could find common ground if they are willing to collaborate.

We expect the Administration, like Congress, to continue to advance policies aimed at drug pricing in order to fulfill campaign promises and set the stage for the 2020 Presidential election cycle.

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1 "The Price of Sovaldi and its Impact on the U.S. Health Care System," December 2015. https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf.

2 *See* e.g., December 21, 2016 Press Release, "Collins, McCaskill Release Committee Report of Bipartisan Drug Pricing Investigation." https://www.collins.senate.gov/newsroom/collins-mccaskill-release-committee-report-bipartisan-drug-pricing-investigation. *See also* S. Rept. 114-429, Special Report of the U.S. Senate Special Committee on Aging on "Sudden Price Spikes In Off-Patent Prescription Drugs: The Monopoly Business Model That Harms Patients, Taxpayers, And The U.S. Health Care System." https://www.congress.gov/congressional-report/114th-congress/senate-report/429/1.