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## Drug Pricing: What Happened in 2019 and What to Watch in 2020

Have you heard that drug prices are too high? If not, you have not been listening to President Donald Trump, Secretary of Health and Human Services (“HHS”) Alex Azar, or almost any member of Congress. In the past year, a dizzying array of drug pricing actions and proposals have come out of the White House and Congress, as well as the governor’s offices and legislative halls in most states.

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Despite the unprecedented attention, drug makers increased prices an average of 5.1% to start 2020, compared to average increases of 5.2% in January 2019 and 8.0% in January 2018.<sup>1</sup> While the Trump administration likely will claim that its policies deserve credit for this modest reduction in the rate of increase, there appear to be no signs of any price decreases. Moreover, apart from a doomed provision for direct government negotiation of prices in Speaker Nancy Pelosi’s bill, and (perhaps) a not-yet proposed rule for international reference pricing for Medicare Part B (discussed below), there are not even any current *proposals* that would limit the launch price of a new drug. Indeed, this year saw the largest list price for a new drug in American history: \$2.1 million for the gene therapy Zolgensma.<sup>2</sup> Drug makers’ arguments—that the ability to set their own prices is essential to continue the notable medical triumphs that have resulted from their research and development efforts in the past half century—largely have continued to carry the day.

That said, in the twenty months since the President unveiled his “American Patients First” strategy (the “Blueprint”) in May 2018,<sup>3</sup> there has been a great deal of governmental activity that is affecting, and will continue to affect, the ways in which Americans access prescription drugs. These include reforms of Medicare’s prescription drug benefit programs, greater transparency into drug prices and price increases, more support for generics and biosimilars, and the prospect of importing cheaper drugs from other countries. At the same time, just the continuing *conversation* about (and therefore potential for) more consequential governmental measures—direct negotiation, restructuring the supply chain to channel rebates to consumers instead of “middlemen” like pharmacy benefit managers, or international reference pricing—is likely to impact, at least at the margins, the behaviors of drug makers, insurers, providers, and others.

With this context in mind, this Alert will recap what happened on prescription drug pricing at the federal and state levels in 2019, and will speculate as to what bears watching in 2020.

### Executive Summary

In the year and a half since the Blueprint’s release, the Trump administration has released a flurry of proposed and final regulations with a mixed record of success. The administration has implemented a handful of more modest reforms that are less controversial, but do not promise to be very consequential. These include actions by the Food and Drug Administration (“FDA”) to promote competition, new transparency requirements in the Medicare program, and expanded tools for Medicare Advantage and Part D plans to steer beneficiaries towards less expensive products.

However, the administration also suffered a series of policy defeats in 2019. In the face of congressional and public pushback, HHS abandoned two of its more ambitious proposed rules to weaken the Medicare Part D protected classes and to eliminate protections under the Anti-Kickback Statute for manufacturer rebates to plans and pharmacy benefit managers (“PBMs”). The administration also had to drop language related to exclusivity for biologics from its trade agreement with Canada and Mexico, while a federal district court vacated HHS’s proposal to require drug price disclosures in television advertisements.

With little implemented thus far that appreciably lowers drug prices and with a competitive election on the horizon, President Trump is still searching for a signature drug pricing win. Accordingly, the administration has teed up two controversial proposals for potential implementation in 2020: importation of drugs from Canada and the use of

international reference pricing within Medicare Part B. If pursued, both policies could provide a strong talking point for the Trump campaign, but likely would face political, legal, and/or operational challenges.

On Capitol Hill, there appears to be a fairly bipartisan consensus that Congress ought to do something to address drug prices, but little agreement as to what such a bill should entail. On a largely party-line vote in December, Speaker Nancy Pelosi and the House Democrats passed a bill that would dramatically alter the U.S. drug market through government price negotiations and international reference pricing, but is opposed by the White House and Senate Republicans. In the Senate, Republican Finance Chairman Chuck Grassley is seeking to build support for a bipartisan drug pricing package that has the administration's blessing, but has encountered resistance from Republicans who object to the bill's provisions requiring manufacturers to pay inflationary rebates under Medicare Parts B and D. Meanwhile, a group of House and Senate Republicans have introduced legislation that packages together bipartisan bills that would make modest reforms to the drug pricing landscape, but lack the more consequential changes sought by Sen. Grassley and most congressional Democrats. The first half of 2020 likely will determine whether any comprehensive drug pricing package can pass this Congress. The 2019 year-end spending bill punted a range of must-pass legislation to May 2020 to give congressional leaders more time to arrive at a bicameral compromise on drug pricing.

Compared to their federal counterparts, states were far more successful at enacting drug pricing legislation in 2019. Last year, 37 states enacted at least one drug pricing bill.<sup>4</sup> New laws covered a range of topics from PBM licensure and wholesale importation to price reporting and transparency.

With the 2020 elections around the corner and public polls suggesting that drug prices remain a top concern of voters,<sup>5</sup> the new year is poised to bring even more activity and rhetoric focused on prescription drug prices.

## The Trump Administration

The Trump administration's drug pricing efforts began in earnest with the May 2018 announcement of the Blueprint. Without announcing any immediate policy changes, the strategy laid out four priorities for curbing prescription drug prices:

- Improve competition;
- Create a framework for better negotiations with drug makers;
- Provide incentives to lower the list prices of drugs; and
- Reduce patients' out-of-pocket costs.<sup>6</sup>

For each priority, the Blueprint provided a laundry list of potential policies. Although many of the proposals would require congressional action, which, as discussed below, has been largely lacking thus far, a significant number can be accomplished administratively. Over the past year and a half, the administration has implemented some of those ideas, while abandoning others. Notably, the administration's two most controversial proposals that are still pending—wholesale importation and international reference pricing—were not mentioned in the Blueprint.

### *Implemented Policies*

#### *Medicare Utilization Controls*

While the administration opposes direct government negotiation of drug prices—an idea that then-candidate Trump had suggested in 2016<sup>7</sup>—it has pursued policies to strengthen the negotiating power of private plans that provide coverage to Medicare beneficiaries through Part C (also known as Medicare Advantage) and Part D.

For example, starting in 2019, the Centers for Medicare & Medicaid Services (“CMS”) have granted Medicare Advantage plans the authority to use step therapy for Part B drugs (i.e., pharmaceutical products that are traditionally covered under the Part B benefit, such as physician-administered drugs).<sup>8</sup> Step therapy refers to the insurance practice of requiring that a patient try a preferred drug before covering a non-preferred and generally more expensive drug.

CMS also has taken steps to encourage Part D plans to use prior authorization and step therapy for “protected class” drugs. By statute, Part D plans must cover all available drugs in the six protected classes with few exceptions.<sup>9</sup> In its May 2019 final Part D rule, the agency codified its guidance allowing Part D plans to use prior authorization and step therapy for new starts of protected class drugs, except for drugs belonging to the anti-retroviral class.<sup>10</sup> While such utilization controls improve the ability of Part D plans to steer patients to lower-cost drugs, the impact of such policies will be limited so long as plans must cover all drugs in the protected classes. As discussed below, the Trump administration considered, but ultimately abandoned, a proposal to weaken the protected classes’ coverage mandate.

### *Transparency Initiatives*

As part of the Blueprint’s strategy to incentivize manufacturers to lower list prices, the administration frequently has sought to increase transparency of prices. Supporters of such measures hope that they will steer consumers to cheaper alternatives and shame companies into reducing prices to avoid negative publicity. Transparency initiatives generally are popular politically because they impose minimal costs on industry and government and do not restrict access to drugs for patients and providers. However, many observers are skeptical that transparency alone will have a significant influence on how manufacturers price their products.<sup>11</sup>

Transparency initiatives implemented or proposed by the Trump administration include:

- In late 2018, President Trump signed into law two bills that prohibit plans and PBMs in the commercial and Medicare markets from imposing “gag clauses” that restrict pharmacists from telling consumers when purchasing a drug out of pocket, rather than with insurance, would save them money.<sup>12</sup>
- A May 2019 final rule requires Medicare Part D plans, starting in 2021, to include drug price increases and lower-cost therapeutic alternatives in their members’ explanations of benefits.<sup>13</sup> The rule also requires Part D plans to adopt by 2021 at least one electronic “Real Time Benefit Tool” that informs prescribers at the point of service when lower-cost therapies are available under the patient’s plan.<sup>14</sup>
- In November 2019, the administration issued a proposed rule that solicits feedback on requiring commercial plans to provide estimates to members regarding prices and cost-sharing for different drugs and services.<sup>15</sup>
- As discussed below, CMS attempted to require manufacturers to include list prices in direct-to-consumer television advertisements for certain drugs reimbursable by Medicare and Medicaid, but was blocked by a federal court.<sup>16</sup>

### *Value-Based Care*

The administration has supported value-based payment models for prescription drugs, particularly in the Medicaid program. Since June 2018, CMS has approved state plan amendments authorizing Oklahoma, Michigan, and Colorado to enter into contracts with manufacturers that tie Medicaid reimbursement to certain drugs’ outcomes.<sup>17</sup> In 2019, CMS also approved proposals by Louisiana and Washington to implement subscription-based models for purchasing expensive Hepatitis C drugs.<sup>18</sup> Commonly referred to as the “Netflix model,” this arrangement allows the state to pay a flat fee to a manufacturer in exchange for unlimited access to its Hepatitis C drug over a certain period.<sup>19</sup> While value-based arrangements provide states with an innovative approach to managing Medicaid prescription drug spending, the long-term impact of such models is unclear. Thus far, states have encountered various challenges in setting up outcomes-based contracts with manufacturers,<sup>20</sup> while subscription-based models may only work for a small number of drugs with market conditions similar to those of Hepatitis C drugs.<sup>21</sup>

In October 2019, the administration released long-awaited proposed rules to amend regulations under the Anti-Kickback Statute and the Stark Law to support, among other things, value-based initiatives.<sup>22</sup> Although the proposed rules did not include any safe harbors for value-based arrangements for pharmaceutical products, the administration noted that it would consider such protections in future rule-making.<sup>23</sup>

#### *FDA Initiatives*

Although drug prices generally do not fall within FDA's jurisdiction, the agency has taken some modest administrative steps to encourage competition.<sup>24</sup> For example:

- *Promoting Generics and Biosimilars*: FDA has released a Drug Competition Action Plan, a Biosimilars Action Plan, and other guidance materials to facilitate the development and approval of lower-cost alternatives.<sup>25</sup>
- *Cracking Down on "Shenanigans"*: FDA has sought to discourage brand-name manufacturers from engaging in what many perceive to be anti-competitive behaviors. Examples include issuing new guidances regarding steps to prevent brand-name manufacturers from using FDA's citizen petition process or negotiations over shared risk evaluation and mitigation strategies ("REMS") to impede generic competition.<sup>26</sup> FDA also has resorted to publishing the names of companies that engage in certain conduct, such as blocking generic manufacturers from obtaining samples necessary to reverse engineer a brand name drug.<sup>27</sup>

#### *Policy Retreats and Defeats*

##### *Medicare Protected Classes*

In conjunction with expanding the use of prior authorization and step therapy within the Medicare protected classes, CMS also initially proposed granting Part D plans the ability to exclude certain protected drugs from their formularies altogether.<sup>28</sup> Under current law, plans have limited bargaining power to demand discounts from manufacturers for protected drugs. According to CMS, discounts for such drugs reach 20 to 30 percent in the commercial market, but average just six percent in Medicare.<sup>29</sup> To weaken the protected classes and increase Part D plans' leverage, the administration's November 2018 proposed rule would have allowed plans to exclude a protected drug from their formularies if (1) the drug was merely a new formulation of an existing single-source drug or biologic or (2) the drug's wholesale acquisition price ("WAC") rose faster than inflation.<sup>30</sup>

The proposal, however, received strong pushback from drug makers, patient and disease advocacy groups, and members of Congress concerned that scaling back the protected classes could adversely affect patients suffering from serious conditions.<sup>31</sup> The Trump administration ultimately backed off and did not include the exclusion proposal in its May 2019 final rule,<sup>32</sup> succumbing to the same political pressure that compelled the Obama administration to drop its proposal in 2014 to eliminate three of the six protected classes.<sup>33</sup> CMS's second defeat on this issue in just five years suggests that the protected classes likely are safe for the near future.

##### *Anti-Kickback Statute Safe Harbors for Drug Rebates*

Just two months after abandoning its protected class reform, the administration conceded defeat on another of its more ambitious drug pricing proposals. In July 2019, HHS withdrew its proposed rule to amend the Anti-Kickback Statute's regulatory safe harbors to encourage plans and PBMs to share rebates received from drug manufacturers directly with Medicare and Medicaid beneficiaries.<sup>34</sup> Specifically, the rule would have made three changes:

- Narrowed the existing regulatory discount safe harbor to exclude manufacturer rebates on prescription drugs offered to Medicare and Medicaid plans and the PBMs dealing on their behalf;

- Established a new safe harbor to protect discounts offered by drug manufacturers that are shared with the beneficiary at the point of sale; and
- Established a new safe harbor for service fees paid to PBMs by manufacturers that are not based on volume.<sup>35</sup>

By addressing the complex and opaque web of rebates and other price concessions between manufacturers, plans, and PBMs, the proposal threatened to fundamentally alter the current drug distribution system. However, the proposed rule would not have directly regulated the price-setting activities of manufacturers. Instead, HHS contended that the rule would reduce beneficiaries' out-of-pocket costs by redirecting rebates to the point of sale, while removing the incentive for manufacturers to keep list prices (and rebates) high to secure more favorable formulary placement for its products from PBMs and plans.<sup>36</sup>

Various policy and political considerations ultimately convinced HHS to withdraw the proposed rule. Most notably, while the proposal probably would have resulted in lower out-of-pocket costs at the pharmacy for Medicare beneficiaries, it also most likely would have caused Part D premiums to rise, as plans could no longer retain rebates to reduce premiums.<sup>37</sup> The administration may have feared the political repercussions of premium increases for seniors, especially if they coincided with the 2020 campaign.<sup>38</sup> Moreover, as a result of rising premiums, HHS estimated that the proposal could increase federal government spending by as much as \$196 billion over ten years.<sup>39</sup> Lastly, for all of the upheaval to the market, it remained unclear whether a final rule would result in any reductions to list prices.

### *Price Transparency in Television Ads*

In May 2019, CMS issued its final rule requiring manufacturers include list prices in television advertisements promoting drugs that are covered by Medicare and Medicaid and that have a WAC of greater than \$35 per month.<sup>40</sup> Three manufacturers and the Association of National Advertisers sued to block the rule on the grounds that it exceeded HHS's regulatory authority and violated the First Amendment.<sup>41</sup> In July, the federal district court for the District of Columbia sided with the plaintiffs, vacating the rule on the former grounds without opining on the First Amendment issue.<sup>42</sup> Even if HHS can convince the D.C. Circuit on appeal that it has the authority to issue such a rule, the plaintiffs likely have the upper hand with respect to the First Amendment arguments.<sup>43</sup>

Legislation to require manufacturers to make such disclosures has amassed a sizable coalition of bipartisan supporters.<sup>44</sup> If such a bill were to pass Congress, the issue of HHS's regulatory authority would be moot. Congress's blessing, however, cannot protect the proposal from a First Amendment challenge.

### *International Trade*

Most recently, the administration's drug pricing agenda appeared to suffer a setback when House Democrats succeeded at removing a provision regarding market exclusivity for biologics from the proposed United States-Mexico-Canada trade agreement (the "USMCA"). Originally announced in November 2018, the USMCA, if ratified, would have extended market exclusivity periods for biologics to 10 years in Canada and Mexico, which currently grant eight and five years, respectively.<sup>45</sup> The United States, on the other hand, provides biologic manufacturers with 12 years of exclusivity.<sup>46</sup>

House Democrats criticized the provision as a hand-out to the drug industry.<sup>47</sup> In December, the administration and House Democrats reached an agreement on a revised trade deal that dropped the exclusivity provision, among other changes.<sup>48</sup> The House passed the new agreement before Christmas, and the Senate is expected to bring it up for a vote in early 2020.<sup>49</sup>

The original trade agreement created an interesting alliance between the administration and the brand-name industry. Extending exclusivity periods abroad aligned with President Trump's criticisms of foreign countries for "free riding" by paying lower prices for drugs than American consumers. Longer exclusivity periods would allow biologic manufacturers to avoid competition and, thus, charge a higher price for a longer period in other countries. However, the delayed competition

also could dampen incentives for manufacturers to develop biosimilars, which in theory bring down prices in the long run. As a result, while the provision's demise could be seen as a capitulation by the Trump administration, its absence in the revised USMCA ultimately could be a win for the President's overall goal of lowering drug prices.<sup>50</sup>

### *Policies in the Works to Watch in 2020*

#### *Importation*

In July 2019, the Trump administration unveiled its Safe Importation Action Plan, which laid out HHS's plans to establish two new pathways for importing certain drugs originally intended for foreign markets where they are generally available at lower prices.<sup>51</sup> The administration's embrace of drug importation—an idea historically championed by Democrats<sup>52</sup>—represents a surprising reversal of both the current and past administrations' long-standing opposition to importation. In 2003, Congress authorized HHS to issue regulations permitting wholesale importation if the agency could attest to its safety and cost-effectiveness.<sup>53</sup> Since then, each administration had declined to craft such regulations, claiming that the federal government could not assure the safety of the drug supply chain.<sup>54</sup> Consistent with the position of his predecessors, Secretary Azar dismissed importation as little more than a “gimmick” just days after the release of the Blueprint, which did not even mention importation.<sup>55</sup>

The policy, however, caught the attention of President Trump, who publicly directed Mr. Azar to help the state of Florida with its efforts to gain federal approval for a wholesale importation program.<sup>56</sup> Shortly thereafter, the administration proposed the following pathways:

- *State Pilot Programs:* Pathway 1 would authorize demonstration projects developed by states to import certain drugs from Canada. To receive FDA's approval, states would need to show that the program would ensure consumer safety and achieve cost savings. States must also identify the foreign seller in Canada that will purchase drugs directly from manufacturers and the importer (*i.e.*, a wholesaler or pharmacist licensed in the United States) that will buy the drug directly from the foreign seller. Both the foreign seller and importer must comply with U.S. drug supply chain security requirements. Additionally, the manufacturer or importer must ensure the drug is tested and labeled in accordance with U.S. law. States would not be permitted to import controlled substances, biologics, or drugs subject to FDA's REMS program. The administration released the proposed rule for implementing Pathway 1 in December.<sup>57</sup>
- *Manufacturer Self-Importation:* Pathway 2 would permit manufacturers to import their own drugs that were originally manufactured and intended to be marketed in a foreign country and offer them for sale at a lower price in the United States under different National Drug Codes (“NDCs”). This pathway would be open to a broader range of drugs, including biologics. FDA released its draft guidance for Pathway 2 in December.<sup>58</sup>

By releasing the proposed rule and draft guidance in December, the administration potentially has teed up both pathways to be finalized at some point in 2020. Multiple states have expressed interest: Florida and Vermont have already submitted proposals to HHS, Colorado and Maine enacted importation bills and are currently drafting proposals, and New York's governor recently announced that he plans to convene a commission to submit a plan to HHS.<sup>59</sup>

While importation comes as a major reversal for HHS, the policy shift likely will have only a limited impact on drug prices. Canada is a relatively small prescription drug market compared to the United States, which limits the degree to which states can rely on importation.<sup>60</sup> The Canadian government likely will try to protect its citizens' access to drugs by impeding diversion to the United States, especially since manufacturers are unlikely to want to sell more drugs to Canada to make up for diverted quantities.<sup>61</sup> Likewise, established Canadian wholesalers are not eager to upset either manufacturers or the Canadian government by engaging in importation. The president of a Canadian drug distributor trade association has said, “We are not in the business of exporting. There is no merit to doing so – in fact, there is a disincentive.”<sup>62</sup>

The second pathway also seems unlikely to have much of an effect on prices. HHS claims it developed this pathway in response to complaints from manufacturers that said they would like to offer their drugs at lower list prices, but that they were restricted by contracts with supply chain entities, such as distributors and PBMs.<sup>63</sup> By allowing companies to import the same drugs under different NDCs, the administration contends that a manufacturer could avoid its contractual obligations and offer the same product at a lower price. It is unclear, though, why manufacturers would voluntarily make widespread use of this pathway. In fact, several observers have speculated that HHS created this pathway primarily to undermine manufacturers' claims that they would lower list prices, but for the commitments extracted by other entities.<sup>64</sup>

### *International Reference Pricing*

In October 2018, the administration announced what is arguably its most consequential proposal thus far: a new, mandatory Medicare Part B demonstration project that would use an international pricing index to pay for select single-source drugs and biologics.<sup>65</sup> Tying domestic prices to the prices paid in other countries that engage in more aggressive price regulation than the United States represents a remarkable reversal from the administration's Blueprint, which expressly criticized other countries' use of price controls and international reference pricing.<sup>66</sup> Specifically, the original proposal had three major parts:

- *Vendor-Based Distribution System:* Under the current "buy-and-bill" system, providers assume the financial risk of acquiring Part B drugs and are later reimbursed by Medicare for the drug's average sales price plus six percent ("ASP+6").<sup>67</sup> Under the proposal, vendors, such as PBMs, would contract with CMS to serve as "middlemen" who would take on the risk of buying drugs and then supply them to providers.
- *International Reference Pricing:* CMS would reimburse the vendors for each drug at a rate tied to the average price of the drug in select countries.<sup>68</sup> After a five-year phase-in, reimbursement would be equal to 126% of the international pricing index. According to HHS, Medicare currently pays on average 180% of what other countries pay.<sup>69</sup>
- *Eliminate ASP+6:* Since providers no longer purchase the drugs themselves, the proposal would replace the ASP+6 reimbursement with a fixed add-on fee for each drug administered, regardless of the drug's cost. Proponents argue a fixed fee would remove the financial incentive for providers to use more expensive drugs, which result in a larger six percent add-on payment for the provider than cheaper alternatives.<sup>70</sup>

The October 2018 announcement came in the form of an advance notice of proposed rulemaking. Despite rumors throughout 2019 that a proposed rule was imminent,<sup>71</sup> the proposed rule remains under review at the White House's Office of Management and Budget ("OMB") and its details are not public.<sup>72</sup> Administration officials, however, have hinted that the proposed rule may be even more aggressive than the original proposal. For example, a top White House official has suggested that the demonstration project might also apply to a subset of retail drugs reimbursed under Medicare Part D.<sup>73</sup> More recently, Secretary Azar revealed that President Trump disliked the proposal's target reimbursement of 126% of the international pricing index, as the President believes that the United States ought to be "getting the best deal among developed countries."<sup>74</sup> This comment fueled speculation that the proposed rule will take a "most favored nation" approach, setting Medicare reimbursement at the *lowest* price paid in select countries, as opposed to the *average* price.<sup>75</sup>

With a proposed rule already at OMB, an international reference pricing demonstration project likely is the most significant drug pricing action that could come out of the Trump administration this term. In fact, the administration may seek to release a proposed rule (and, if the rulemaking schedule permits, possibly a final rule) during the 2020 re-election campaign to provide Mr. Trump with an opportunity to tout his drug pricing record.

However, there are several reasons to be skeptical that such a proposal will ever be implemented by this administration. First, many commentators have long speculated that the proposal primarily was intended as a negotiating tactic to drive the drug industry, as well as congressional Republicans, to the table.<sup>76</sup> Second, the administration may be slow-walking the

proposal to give Sen. Grassley more time to build support for his White House-backed drug pricing package. Once a proposed rule is formally issued, it will reduce the Grassley bill's estimated savings, which may make it more difficult to get other Republicans on board.<sup>77</sup> Additionally, the administration may be concerned about the lack of support among congressional Republicans for the proposal. For example, during the Senate Finance Committee's markup of the Grassley bill, committee Republicans narrowly failed to add an amendment that would have blocked HHS from proceeding with the proposal.<sup>78</sup>

Political considerations aside, the proposal, if finalized, would face significant operational and legal challenges. The advance notice of proposed rulemaking deferred many important details that still need to be worked out before the demonstration project's feasibility can be fairly assessed.<sup>79</sup> Additionally, industry could sue to block any final rule on the grounds that it is inconsistent with current law, and exceeds CMS's demonstration authority.<sup>80</sup> If such arguments prevail, the Trump (or a subsequent Democratic) administration would need an act of Congress to proceed, an unlikely prospect so long as Republicans control the Senate.

### *Untested Authorities: Compulsory Licensing*

The Democratic presidential debates have put the spotlight on two workarounds under current law that empower the federal government to disregard a manufacturer's patent for a brand-name drug and grant licenses to other parties to manufacture such drug.<sup>81</sup> In theory, this would create competition that should lower prices for an otherwise high-cost drug that currently enjoys a monopoly because of intellectual property laws. The two authorities are:

- *Bayh-Dole Act*: The 1980 Bayh-Dole Act provides the federal government with "march-in" rights.<sup>82</sup> If a federal agency (e.g., the National Institutes of Health ("NIH")) has provided research funding that leads to a patented invention, the agency has the authority under certain conditions to "march in," ignore the patent owner's exclusivity rights, and grant licenses to other companies to produce the patented product. One of the conditions is if such "action is necessary to alleviate health or safety needs which are not reasonably satisfied" by the patent holder.<sup>83</sup> March-in rights have not previously been exercised by any federal agency, so the potential reach of the health or safety needs authorization is unclear.<sup>84</sup>
- *28 U.S.C. 1498*: Section 1498 is an eminent domain-like statute that authorizes the federal government to take over a patent and grant licenses to others so long as the government provides "reasonable compensation" to the patent holder.<sup>85</sup> Unlike the Bayh-Dole Act, Section 1498 applies to all patented inventions, not just those produced with federal funding.<sup>86</sup> This authority has been used in recent years by the federal government; however, such instances typically involve national security agencies and relatively small compensation amounts.<sup>87</sup> The use of Section 1498 to break brand-name manufacturers' patents on a large scale would represent an enormous change in the government's approach. The only recent example where the government purportedly considered invoking this authority with respect to prescription drugs came during the 2001 anthrax scare when, amid fears about potential shortages and price gouging, the Bush administration used the threat of Section 1498 to secure concessions from Bayer for its drug ciprofloxacin.<sup>88</sup>

Thus far, Trump administration officials, including Secretary Azar and NIH Director Francis Collins, have rejected compulsory licensing.<sup>89</sup> Industry cannot necessarily rest easy, though, considering President Trump embraced importation and international reference pricing not long after those ideas were dismissed by members of his own administration. Moreover, these two statutes likely will continue to receive increased attention as the presidential campaign unfolds, especially if a more progressive candidate captures the Democratic nomination.

### **The 116<sup>th</sup> Congress**

2019 ushered in a divided Congress for the first time in Mr. Trump's presidency. Republicans retained control of the Senate, while the Democrats, led by reinstalled Speaker Nancy Pelosi, seized a majority in the House. Along with surprise billing, drug pricing quickly emerged as one of the top health care priorities for both chambers. For example, shortly after



the 116<sup>th</sup> Congress convened in January, committees in both chambers held hearings and launched investigations into various drug pricing issues.<sup>90</sup>

While both parties appear to agree that Congress ought to do something, divisions between and within the parties have prevented Congress so far from sending a comprehensive package of drug pricing policies to the president. Nonetheless, three noteworthy, but less controversial, drug pricing reforms did become law in 2019 after being attached to other legislative vehicles:

- *The Right Rebate Act*: As part of a larger Medicaid package, Congress passed Sens. Grassley and Ron Wyden’s bipartisan Right Rebate Act in April.<sup>91</sup> Inspired by the controversy surrounding Mylan’s efforts to reduce its Medicaid rebate obligations by classifying its EpiPen product as a generic, the legislation creates new penalties for manufacturers that knowingly misclassify their drugs under the Medicaid Drug Rebate Program (“MDRP”) and gives new authorities to HHS to enforce the law.<sup>92</sup>
- *MDRP and Authorized Generics*: In September, Congress enacted another MDRP reform as part of a short-term government funding bill.<sup>93</sup> Under the MDRP, a manufacturer’s rebate obligations are based in part on the drug’s average manufacturer price (“AMP”). Previously, manufacturers could include the sales of authorized generics—drugs that the brand-name manufacturer either sells or allows a secondary manufacturer to sell as a generic drug—in the calculation of the brand-name drug’s AMP, which generally has the effect of lowering the brand-name drug’s AMP and, thus, its required rebates.<sup>94</sup> As of October 1, 2019, brand-name manufacturers no longer can take advantage of this pricing benefit.<sup>95</sup>
- *The CREATES Act*: In December’s year-end spending package, Congress finally enacted the strongly bipartisan CREATES Act, which steadily had gained momentum on Capitol Hill over the past few years.<sup>96</sup> The legislation creates new causes of action for manufacturers to bring against brand-name companies that refuse to offer samples of brand-name drugs on reasonable terms for the purposes of testing and developing generic or biosimilar alternatives. It also gives FDA more flexibility to approve alternative safety protocols when brand-name companies refuse to allow generic companies to participate in a shared REMS.<sup>97</sup> By boosting the generics industry, CREATES is projected to save the federal government \$3.7 billion over 10 years.<sup>98</sup> However, the fact that multiple brand-name manufacturers reversed their initial opposition and endorsed the bill suggests that the branded industry does not perceive CREATES to be a major threat—at least compared to other proposals that Congress might consider.<sup>99</sup>

As part of the year-end spending package that included the CREATES Act, Congress passed a short-term extension of various health care programs and provisions (commonly referred to as “extenders”) that will expire in late May.<sup>100</sup> This schedule is intended in part to give committee leaders additional time to build consensus for a drug pricing package that could be attached to an eventual must-pass extenders bill.<sup>101</sup>

There are currently three major pieces of legislation that should influence those conversations. From the most ambitious to the least, those bills are: (1) Speaker Pelosi’s sweeping government negotiation bill that passed the House in December, but has no prospects in the Republican Senate; (2) the Senate Finance Committee’s bipartisan bill crafted by Sens. Grassley and Wyden; and (3) Republican Rep. Greg Walden’s package of bipartisan, largely non-controversial, and thus relatively more modest proposals.

### ***The Pelosi Bill***

In December, the House voted 230 to 192 to pass the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3).<sup>102</sup> All Democrats and two Republicans voted in favor of Speaker Pelosi’s bill, which, if enacted, would dramatically alter the U.S. drug market.<sup>103</sup> Most notably, H.R. 3 would require HHS to negotiate prices directly with manufacturers for a minimum of 50 drugs, and up to as many as 250 drugs, per year.<sup>104</sup> The negotiated price must not exceed 120 percent of the average price paid in six reference countries (Australia, Canada, France, Germany, Japan, and the United Kingdom) and

must be offered to both federal health care programs as well as commercial plans. To drive manufacturers to the negotiation table, H.R. 3 would impose steep excise taxes on companies that refuse to negotiate or fail to agree to a price at or below the international reference price. Non-compliant manufacturers would be subject to an excise tax that starts at 65 percent of all sales of the selected drug, increasing by 10 percentage points for each 90 days of noncompliance until the penalty hits a ceiling of 95 percent.<sup>105</sup>

H.R. 3 includes variations of two of the major proposals in the Grassley bill. First, the Pelosi bill would revamp the Medicare Part D benefit design by capping beneficiaries' annual out-of-pocket drug spending at \$2,000 (currently, there is no such cap), eliminating the coverage gap (also known as the "donut hole"), and expanding brand-name manufacturers' obligations to provide discounts to beneficiaries in the initial coverage and catastrophic phases.<sup>106</sup> Second, H.R. 3 would require manufacturers to pay rebates to Medicare Parts B and D for the amount by which a drug's list price increases faster than the rate of inflation.<sup>107</sup> This effectively would cap annual price increases for drugs covered by Medicare at the rate of inflation.<sup>108</sup> Unlike the Grassley bill, H.R. 3 would extend such rebates to the commercial market as well, if the Department of Labor determines it is feasible to do so.<sup>109</sup>

According to the Congressional Budget Office ("CBO"), the bill would have far-reaching implications for the U.S. drug market. The negotiation provisions alone would cut federal spending by \$456 billion over ten years.<sup>110</sup> CBO estimates that reductions in revenue to manufacturers as a result of the bill would lead to cuts in research and development that would cause approximately 8 fewer new drugs to be introduced to the U.S. market over the next ten years and roughly 30 fewer drugs over the following decade.<sup>111</sup>

The White House ultimately opposed H.R. 3,<sup>112</sup> despite, as House Democrats like to highlight, Mr. Trump's support for government negotiations during the 2016 campaign.<sup>113</sup> While the bill as a whole has no chance of success in the Republican-held Senate, H.R. 3 will likely serve as a popular talking point for House Democrats, and certain parts, such as the Medicare Part D redesign, could be included in some form in a future drug pricing agreement.<sup>114</sup>

### *The Grassley Bill*

In the Senate, Finance Chairman Grassley's Prescription Drug Pricing Reduction Act ("PDPRA") has emerged as the leading bill.<sup>115</sup> Negotiated with Finance Ranking Member Wyden and endorsed by the White House, the bipartisan package was reported out of the Finance Committee in July by a vote of 19 to 9.<sup>116</sup> The bill, however, divided the committee's Republicans, with six voting in favor and nine voting against.<sup>117</sup>

Similar to H.R. 3, the PDPRA would require brand-name manufacturers to pay rebates to the Medicare program under Parts B and D when a product's list price rises faster than the rate of inflation.<sup>118</sup> The inflationary rebates likely are the bill's most consequential provisions—accounting for roughly \$68 billion in savings to the Medicare program over 10 years<sup>119</sup>—as well as its most controversial. The rebates are a priority for both Democrats and Sen. Grassley.<sup>120</sup> Senate Republicans, however, have largely criticized them as price controls, and an effort by Finance Committee Republicans to strip the rebates from the bill narrowly failed in July.<sup>121</sup> Several months later, Sen. Grassley has had limited success winning over his fellow Republicans and has faced resistance from Majority Leader Mitch McConnell, who reportedly believes the PDPRA is bad policy that could divide his caucus if it were to come up for a vote.<sup>122</sup> Press reports suggest Sen. McConnell has urged his colleagues not to support the bill, and some speculate that Senate Republicans may be content to wait out Sen. Grassley, who will lose his position as Finance chairman at the end of the year.<sup>123</sup>

In addition to the Medicare rebate provisions, the PDPRA contains a wide range of drug pricing reforms. Like H.R. 3, the bill would redesign the Medicare Part D benefit to cap beneficiaries' out-of-pocket drug costs and reduce their coinsurance, eliminate the donut hole, and expand manufacturers' discount obligations.<sup>124</sup> It would raise the cap on manufacturer's MDRP rebate obligations from 100 percent of a covered drug's AMP to 125 percent.<sup>125</sup> The Trump administration's Fiscal Year 2020 budget proposal called for eliminating the cap altogether.<sup>126</sup> Among other provisions, the PDPRA also would

impose new federal price reporting obligations on manufacturers, authorize new Medicaid value-based payment models, and make tweaks to various federal drug reimbursement methodologies.<sup>127</sup>

### *The Walden Bill*

Lastly, Republican Energy and Commerce Committee Ranking Member Greg Walden has introduced his own package of drug pricing policies called the Lower Costs, More Cures Act (H.R. 19).<sup>128</sup> H.R. 19 avoids more controversial policies, such as Medicare rebates and price negotiation, and instead packages together an assortment of primarily more modest, bipartisan proposals. For example, the bill contains multiple transparency measures, including requiring the disclosure of drugs' list prices in direct-to-consumer advertisements; many of the tweaks to federal health care programs included in the Grassley bill; a cap on Medicare beneficiaries' monthly cost-sharing for insulin; various FDA reforms; and measures to crack down on "pay-for-delay" agreements between manufacturers to slow generic competition.<sup>129</sup> Notably, H.R. 19 eliminates the MDRP rebate cap entirely and includes a Medicare Part D benefit redesign that caps out-of-pocket expenses for beneficiaries, eliminates the donut hole, and adjusts manufacturers' discount liability.<sup>130</sup>

Shortly before Christmas, a group of six Senate Republicans, including three Finance Committee members, introduced a similar Lower Costs, More Cures Act in the Senate (S. 3129).<sup>131</sup> The bill's introduction is further evidence of dissatisfaction with the Grassley bill among some Senate Republicans.<sup>132</sup>

### *2020 Forecast*

In the run-up to the next extenders deadline in May, each of these bills will likely play some role in the ongoing drug pricing debate. While Speaker Pelosi's government negotiation provisions are going nowhere in the Senate this year, her bill will remain a popular talking point for House Democrats and serves as an instructive marker for the Democratic Party's increasingly aggressive posture towards the drug industry.

Chairman Grassley remains committed to courting his Republican colleagues to get his bipartisan package over the finish line. However, the continued angst about Medicare inflationary rebates, Sen. McConnell's lack of support, and the introduction of a Senate version of the Walden bill all underscore the challenges Sen. Grassley faces. As Sen. Grassley has acknowledged, his bill's prospects may depend on whether President Trump and his administration are willing to pressure Sen. McConnell and other Senate Republicans to back the bill.<sup>133</sup> Thus far, there is little evidence that Mr. Trump has made advocating for Sen. Grassley's bill a priority.<sup>134</sup>

In the absence of a sustained push by the White House, the Walden bill likely is left as the most viable option. Without getting significantly more aggressive policies in return, Democrats are highly unlikely to allow the Lower Costs, More Cures Act to pass as a stand-alone bill, which would give congressional Republicans and the White House a drug pricing win ahead of the 2020 elections. That said, prognosticators can look to the Walden bill for an instructive list of more modest, less controversial, and bipartisan drug pricing measures that could catch a ride on another legislative package, such as the May extenders bill, similar to how the CREATES Act and Right Rebate Act became law last year. Two policies in particular could be attractive options. First, raising or eliminating the MDRP rebate cap was recently rumored to be a potential pay-for in the December appropriations package and could be an option in 2020.<sup>135</sup> Likewise, some form of redesigning the Medicare Part D prescription drug benefit, especially capping beneficiaries' out-of-pocket costs, could attract bipartisan interest. The drug industry also supports a cap, which may make it easier to pass; however, to pay for such a policy, manufacturers likely will need to accept changes to the Part D manufacturer discount program.<sup>136</sup>

### **The 50 States**

While Congress largely punted to 2020 on drug pricing, state legislatures last year added to their growing list of enacted drug pricing laws. According to the National Academy for State Health Policy ("NASHP"), more than 300 drug pricing

bills were introduced in state legislatures in 2019 and 37 states enacted at least one such bill.<sup>137</sup> Some of the most noteworthy measures considered by states in 2019 include:

- *Regulating PBMs*: Many of the laws enacted in 2019 targeted PBMs. For example, such laws include requiring PBMs to register with, or obtain a license from, the state; prohibiting PBMs and plans from using “gag clauses”; establishing new reporting requirements for PBMs, including reports on aggregate rebates received from manufacturers; and banning spread pricing, which refers to the practice where the PBM charges a plan more than what it had paid to the pharmacy and pockets the difference.<sup>138</sup> The volume of bills regulating PBMs and health plans suggests that state legislators have been at least somewhat receptive to the drug industry’s efforts to cast the blame for higher prices on middlemen in the distribution chain.
- *Price Reporting*: Transparency measures remain popular with state legislators. In 2019, at least six states enacted new manufacturer price reporting bills.<sup>139</sup> Such laws generally require manufacturers to report certain pricing information in connection with qualifying price increases or the launch of expensive, new drugs. As with federal transparency proposals, these laws have no direct effect on manufacturer price setting, but rather seek to shame manufacturers into lowering prices.
- *Wholesale Importation*: Legislators introduced drug importation bills in at least 19 states in 2019.<sup>140</sup> Thus far, four states (Colorado, Florida, Maine, and Vermont) have enacted laws to seek federal permission to establish wholesale importation programs.<sup>141</sup>
- *Rate-Setting Boards*: States have limited authority to regulate directly what manufacturers charge. Federal courts have struck down state laws that prohibit “excessive” or “unconscionable” prices or price increases under different constitutional doctrines, including federal preemption and the Dormant Commerce Clause.<sup>142</sup> In 2019, state legislators began toying with the idea of empowering drug affordability review boards to set an upper limit on what purchasers may *pay* for certain drugs, rather than regulating directly what manufacturers may *charge* for their products.<sup>143</sup> Similar bills were introduced in at least nine states.<sup>144</sup> Maryland and Maine passed substantially watered-down versions of their bills, which ultimately created boards with merely research and advisory functions, but no rate-setting powers (at least not for the near future).<sup>145</sup> If a state establishes a board with rate-setting powers, the drug industry almost certainly will try to block such a law through the courts.

## Conclusion

Over the past few years, the drug industry has faced unprecedented scrutiny from the media, politicians, and the public. The year 2020 should be no different. The Trump administration continues to take steps in the direction of implementing parts of its Blueprint, and may finalize in the coming year at least two groundbreaking changes to federal policy: endorsing wholesale importation and adopting international reference pricing for certain drugs paid for by Medicare. Mr. Trump’s Democratic rivals for the White House likely will make the case that they would be even more aggressive in taking on the drug industry. Congress has not given up hope on passing a comprehensive drug pricing package with more noise surely to come in the run-up to the next must-pass legislative deadline in May. And, finally, state legislatures have started to reconvene for the new year, eager to pick up where they left off.

So, if you haven’t heard lately that drug prices are too high, you’re almost certainly going to hear it in 2020.

If you have any questions, please do not hesitate to contact [Tom Bulleit](#), [Scott Falin](#), or your usual Ropes & Gray contact.

- <sup>1</sup> See Tami Luhby, Democrats and Republicans Promised to Lower Drug Prices, Instead They've Gone Up Again, CNN (Jan. 5, 2020), <https://www.cnn.com/2020/01/05/politics/2020-drug-price-increases/index.html>.
- <sup>2</sup> Denise Roland, At \$2 Million, New Novartis Drug is Priciest Ever, The Wall Street Journal (May 24, 2019), <https://www.wsj.com/articles/at-2-million-new-novartis-drug-is-priciest-ever-11558731506>.
- <sup>3</sup> U.S. Department of Health and Human Services., American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> (herein "The Blueprint").
- <sup>4</sup> National Academy for State Health Policy, State Prescription Drug Legislative Tracker 2019 (Dec. 5, 2019), <https://nashp.org/wp-content/uploads/2019/09/Rx-end-of-year-Tracker-2019-12.5.2019.pdf>.
- <sup>5</sup> See, e.g., Kaiser Family Foundation, Public Opinion on Prescription Drugs and Their Prices (Nov. 20, 2019), <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>.
- <sup>6</sup> The Blueprint, *supra* note 3.
- <sup>7</sup> See Peter Sullivan, Trump Draws Ire after Retreat on Drug Prices Pledge, The Hill (Nov. 24, 2019), <https://thehill.com/policy/healthcare/471735-trump-draws-ire-after-retreat-on-drug-prices-pledge>.
- <sup>8</sup> In August 2018, CMS announced the decision via a letter to Medicare Advantage plans. Letter from Administrator Seema Verma to Medicare Advantage Organizations, Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, CMS.gov (Aug. 7, 2018), [https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA\\_Step\\_Therapy\\_HPMS\\_Memo\\_8\\_7\\_2018.pdf](https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf). This guidance reversed the agency's prior position during the Obama administration that the Medicare statute prohibits step therapy for Part B drugs. See Letter from Director Danielle R. Moon to Medicare Advantage Organizations, Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services, CMS.gov (Sept. 17, 2012), [https://www.asrs.org/content/documents/cms\\_step\\_therapy\\_memo\\_091712-2.pdf](https://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf). CMS codified its new position for 2020 and future years in a May 2019 final rule. 84 Fed. Reg. 23832, 23835 (May 23, 2019).
- <sup>9</sup> The six protected classes are (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. 42 U.S.C. § 1395w-104(b)(3)(G).
- <sup>10</sup> 84 Fed. Reg. at 23832.
- <sup>11</sup> See, e.g., Thomas Sullivan, Transparency Push in Pharma: Will it Result in Lower Prices to Patients?, Policy & Medicine (Aug. 18, 2019), <https://www.policymed.com/2019/08/transparency-push-in-pharma-will-it-result-in-lower-prices-to-patients.html>; Kelly Davio, State-Level Drug Price Transparency Laws Miss the Mark, Say Researchers, The Center for Biosimilars (Oct. 1, 2019), <https://www.centerforbiosimilars.com/news/statelevel-drug-price-transparency-laws-miss-the-mark-say-researchers>.
- <sup>12</sup> Patient Right to Know Drug Prices Act, S. 2554, 115<sup>th</sup> Cong. (2018) (enacted); Know the Lowest Price Act, S. 2553, 115<sup>th</sup> Cong. (2018) (enacted).
- <sup>13</sup> 84 Fed. Reg. at 23833.
- <sup>14</sup> *Id.* at 23848.
- <sup>15</sup> 84 Fed. Reg. 65464 (Nov. 27, 2019).
- <sup>16</sup> See *infra* notes 40 to 44 and accompanying text.
- <sup>17</sup> Centers for Medicare & Medicaid Services, CMS Approves State Proposal to Advance Specific Value-Based Arrangements with Drug Makers (June 27, 2018), <https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicare-value-based-arrangements-drug-makers> (Oklahoma); Medicaid State Plan Amendment, Medicaid.gov (Nov. 14, 2018), <https://www.medicare.gov/State-resource-center/Medicare-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf> (Michigan); Medicaid State Plan Amendment, Medicaid.gov (Feb. 25, 2019), <https://www.medicare.gov/State-resource-center/Medicare-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf> (Colorado).
- <sup>18</sup> Centers for Medicare & Medicaid Services, CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid (June 26, 2019), <https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified>; Centers for Medicare & Medicaid Services, CMS Approves Washington State Plan Amendment Proposal to Allow Supplemental Rebates Involving a "Subscription" Model for Prescription Drug Payment in Medicaid (June 12, 2019), <https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving>.
- <sup>19</sup> See Ted Alcon, Louisiana's Deal for Hepatitis C Drugs May Serve as Model, The Wall Street Journal (Sept. 13, 2019), <https://www.wsj.com/articles/louisianas-deal-for-hepatitis-c-drugs-may-serve-as-model-11568347621>.
- <sup>20</sup> See Nicholas Fiore et al., Novel State Payment Models for Prescription Drugs: Early Implementation Successes and Challenges, Duke Margolis Center for Health Policy, 4 (Sept. 2019), [https://healthpolicy.duke.edu/sites/default/files/u31/novel\\_state\\_payment\\_models\\_final\\_revised\\_091219.pdf](https://healthpolicy.duke.edu/sites/default/files/u31/novel_state_payment_models_final_revised_091219.pdf).

- <sup>21</sup> For example, the architects of the Hepatitis C subscription model warn that certain conditions must exist for the model to work, including a proven substitutable product class and a strong need for budget predictability among both payors and manufacturers. See Mark Trusheim and Peter B. Bach, Next Steps for Netflix: Can ‘All You Can Treat’ Contracts Work Beyond Hepatitis C?, Health Affairs (Sept. 25, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190924.559225/full>.
- <sup>22</sup> 84 Fed. Reg. 55694 (Oct. 17, 2019) (Anti-Kickback Statute); 84 Fed. Reg. 55766 (Oct. 17, 2019) (Stark).
- <sup>23</sup> Michelle M. Stein, Azar: HHS Working on Protections for Value-Based Drug Contracts, InsideHealthPolicy (Oct. 9, 2019), <https://insidehealthpolicy.com/daily-news/azar-hhs-working-protections-value-based-drug-contracts>.
- <sup>24</sup> See Speech by Scott Gottlieb, Capturing the Benefits of Competition for Patients, [FDA.gov](https://www.fda.gov) (Mar. 7, 2018), <https://www.fda.gov/news-events/speeches-fda-officials/capturing-benefits-competition-patients-03072018> (“FDA, after all, doesn’t – and shouldn’t – regulate drug prices...[b]ut Congress also has charged FDA with advancing policies that maintain a balance between encouraging and rewarding medical innovation and facilitating robust and timely market competition.”).
- <sup>25</sup> See, e.g., FDA Tackles Drug Competition to Improve Patient Access, [FDA.gov](https://www.fda.gov) (June 27, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm564725.htm>; Biosimilars Action Plan: Balancing Innovation and Competition, [FDA.gov](https://www.fda.gov) (July 2018), <https://www.fda.gov/media/114574/download>; FDA In Brief: FDA issues 63 product-specific guidances to promote generic drug access and drug price competition, [FDA.gov](https://www.fda.gov) (Nov. 28, 2018), <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm626952.htm>.
- <sup>26</sup> See, e.g., Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry, [FDA.gov](https://www.fda.gov) (Oct. 2018), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622235.pdf>; Waivers of the Single, Shared System REMS Requirement: Guidance for Industry, [FDA.gov](https://www.fda.gov) (June 2018), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf>.
- <sup>27</sup> Reference Listed Drug (RLD) Access Inquiries, [FDA.gov](https://www.fda.gov) (last updated Sept. 24, 2019), <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rlld-access-inquiries>.
- <sup>28</sup> 83 Fed. Reg. 62152 (Nov. 30, 2018).
- <sup>29</sup> Alex Azar and Seema Verma, Proposed Changes to Lower Drug Prices in Medicare Advantage and Part D, [CMS.gov](https://www.cms.gov) (Nov. 26, 2018), <https://www.cms.gov/blog/proposed-changes-lower-drug-prices-medicare-advantage-and-part-d>.
- <sup>30</sup> 83 Fed. Reg. at 62152.
- <sup>31</sup> See, e.g., Mindy Yochelson, Leave Medicare Drug Coverage Alone, Patient Advocates Say, Bloomberg Law (Nov. 29, 2018), <https://news.bloomberglaw.com/health-law-and-business/leave-medicare-drug-coverage-alone-patient-advocates-say>.
- <sup>32</sup> 84 Fed. Reg. at 23832.
- <sup>33</sup> See Jeff Overley, Feds Scrap Controversial Medicare Part D Changes, Law360 (Mar. 10, 2014), <https://www.law360.com/health/articles/516919/feds-scrap-controversial-medicare-part-d-changes>.
- <sup>34</sup> 84 Fed. Reg. 2340 (Feb. 6, 2019); Dan Diamond, White House Kills Drug Rebate Rule, Politico (July 11, 2019), <https://www.politico.com/newsletters/politico-pulse/2019/07/11/white-house-kills-drug-rebate-rule-678684>.
- <sup>35</sup> 84 Fed. Reg. at 2347-50. For a more detailed summary of the proposed rule, see Tom Bulleit et al., A First Look at New HHS Prescription Drug Safe Harbors, Law360 (Feb. 15, 2019), <https://www.law360.com/articles/1128564/a-first-look-at-new-hhs-prescription-drug-safe-harbors>.
- <sup>36</sup> See U.S. Department of Health and Human Services, Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Jan. 31, 2019), <https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html>.
- <sup>37</sup> 84 Fed. Reg. at 2357-59.
- <sup>38</sup> Rachel Cohrs, White House Kills Rebate Rule Because It Would Raise Premiums, InsideHealthPolicy (July 11, 2019), <https://insidehealthpolicy.com/daily-news/white-house-kills-rebate-rule-because-it-would-raise-premiums>.
- <sup>39</sup> 84 Fed. Reg. at 2359.
- <sup>40</sup> 84 Fed. Reg. 20732 (May 10, 2019).
- <sup>41</sup> *Merck & Co. v. United States Dep’t of Health and Human Servs.*, 385 F. Supp. 3d 81 (D.D.C. 2019).
- <sup>42</sup> *Id.*
- <sup>43</sup> See Emily Field, 3 Takeaways from Nixing of Drug Pricing Rule, Law360 (July 10, 2019), <https://www.law360.com/articles/1176459/3-takeaways-from-nixing-of-drug-pricing-rule>.
- <sup>44</sup> For example, both Speaker Pelosi’s bill and the competing House Republican bill introduced by Rep. Greg Walden authorize HHS to issue regulations requiring direct-to-consumer advertisements to include drugs’ list prices. See Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116<sup>th</sup> Cong. (2019); Lower Costs, More Cures Act, H.R. 19, 116<sup>th</sup> Cong. (2019). In November, Sen. Dick Durbin attempted to pass his similar bill (S. 1437) by unanimous consent, but was blocked by Sen. Patrick Toomey. Ariel Cohen, Senators

Object to Fast-Tracking Patent Gaming, Drug Price Ad Bills (Nov. 13, 2019), <https://insidehealthpolicy.com/daily-news/senators-object-fast-tracking-patent-gaming-drug-price-ad-bills>.

<sup>45</sup> Nathaniel Weixel, Trump Targets Drug Protections to Save Trade Deal, The Hill (Dec. 3, 2019), <https://thehill.com/policy/healthcare/472913-trump-targets-drug-protections-to-save-trade-deal>.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> Nathaniel Weixel, Democrats Declare Victory for Eliminating Drug Protections in Trade Deal, The Hill (Dec. 10, 2019), <https://thehill.com/policy/healthcare/473953-democrats-declare-victory-for-eliminating-drug-protections-in-trade-deal>.

<sup>49</sup> Evie Fordham, Senate Could Approve USMCA as Early as Friday: Navarro, Fox Business (Jan. 5, 2020), <https://www.foxbusiness.com/markets/usmca-senate-fast-track-navarro>.

<sup>50</sup> In fact, press reports suggest that Mr. Trump rejected congressional Republicans' pleas to preserve the provision because he feared it would undercut his administration's messaging regarding its commitment to lowering drug prices. See Jonathan Swan and Caitlin Owens, Trump's Fine with Ditching USMCA Prescription Drug Provision, Axios (Dec. 10, 2019), <https://www.axios.com/trumps-fine-with-ditching-usmca-prescription-drug-provision-e455ba8e-fb2f-4073-aa5e-696e20bc4283.html>.

<sup>51</sup> U.S. Department of Health and Human Services, HHS Announces New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs (July 31, 2019), <https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html>.

<sup>52</sup> For example, 34 Democrats, but only 12 Republicans, in the U.S. Senate voted for a 2017 budget amendment related to importation of drugs from Canada. See Klobuchar Amdt. No. 178 (Jan. 11, 2017), [https://www.senate.gov/legislative/LIS/roll\\_call\\_lists/roll\\_call\\_vote\\_cfm.cfm?congress=115&session=1&vote=00020](https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=115&session=1&vote=00020).

<sup>53</sup> See 21 U.S.C. §§ 384(b), (1)(1).

<sup>54</sup> See, e.g., Mike Leavitt, Why Drug Importation is Flawed Policy, Morning Consult (Mar. 20, 2017),

<https://morningconsult.com/opinions/drug-importation-flawed-policy/> (“In fact, my predecessors and successors [as HHS Secretary] from both political parties, along with multiple FDA Commissioners, have consistently found that drug importation carries potential dangers that can't be ignored.”).

<sup>55</sup> Alex Azar, Remarks on Drug Pricing Blueprint, [HHS.gov](https://www.hhs.gov) (May 14, 2018),

<https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>.

<sup>56</sup> Alexandra Glorioso, Trump Directs Azar to Work on Florida Drug Import Plan, Politico (May 6, 2019),

<https://www.politico.com/states/florida/story/2019/05/06/trump-directs-azar-to-work-on-florida-drug-import-plan-1008710>.

<sup>57</sup> 84 Fed. Reg. 70796 (Dec. 23, 2019).

<sup>58</sup> Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry, [HHS.gov](https://www.hhs.gov) (Dec. 2019),:

<https://www.hhs.gov/sites/default/files/importation-of-certain-fda-approved-human-prescription-drugs-including-biological-products.pdf>.

<sup>59</sup> Ariel Cohen, New York Gov. Cuomo to Describe Canadian Drug Importation Plan, InsideHealthPolicy (Dec. 27, 2019),

<https://insidehealthpolicy.com/daily-news/new-york-gov-cuomo-describe-canadian-drug-importation-plan>.

<sup>60</sup> According to Canada's acting ambassador to the United States, Canada represents only two percent of the global pharmaceutical market, while the United States comprises 44 percent. Robert King, Canadian Ambassador Tells White House Drug Import Plan Unworkable, Not Enough Supplies, FierceHealthcare (Nov. 4, 2019), <https://www.fiercehealthcare.com/payer/canadian-ambassador-tells-white-house-drug-import-plan-unworkable-not-enough-supplies>.

<sup>61</sup> *Id.*; Megan Cerullo, Experts 'Not Optimistic' About Trump Plan to Import Drugs from Canada, CBS News (Dec. 20, 2019),

<https://www.cbsnews.com/news/prescription-drugs-imported-from-canada-wont-lower-prices-for-american-consumers-experts-say/>.

<sup>62</sup> Natalie Obiko Pearson and Simran Jagdev, Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, Bloomberg (Aug. 13, 2019), <https://www.bloomberg.com/news/articles/2019-08-13/trump-s-canada-drug-import-plan-can-t-happen-without-big-pharma>.

See also Allison Martell, Canadian Drug Distributors Say No to Trump Import Plan, Reuters (Dec. 20, 2019),

<https://www.reuters.com/article/us-usa-healthcare-canada/canadian-drug-distributors-say-no-to-trump-import-plan-idUSKBN1YO24O>.

<sup>63</sup> U.S. Department of Health and Human Services, Safe Importation Action Plan, 3 (July 31, 2019),

<https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html>.

<sup>64</sup> See, e.g., Sarah Owerhohle, Prescription Pulse: A Few Questions on Importation, Politico (Aug. 2, 2019),

<https://www.politico.com/newsletters/prescription-pulse/2019/08/02/a-few-questions-on-importation-464476>; Rachel Sachs, Trump Administration, in Shift, Announces Plan to Permit Drug Importation, Health Affairs Blog (July 31, 2019),

<https://www.healthaffairs.org/doi/10.1377/hblog20190731.727552/full/>.

<sup>65</sup> 83 Fed. Reg. 54546 (Oct. 30, 2018).

<sup>66</sup> The Blueprint, *supra* note 3 at 14-15.

- <sup>67</sup> Fact Sheet: ANPRM International Pricing Index Model for Medicare Part B Drugs, [CMS.gov](https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs) (Oct. 25, 2018), <https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs>.
- <sup>68</sup> CMS proposed using an index composed of twelve European nations, Canada, and Japan. 83 Fed. Reg. at 54557.
- <sup>69</sup> U.S. Department of Health and Human Services, What You Need to Know About President Trump Cutting Down on Foreign Freeloading (Oct. 25, 2018), <https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html>.
- <sup>70</sup> See, e.g., MedPAC, Chapter 3: Medicare Payment Strategies to Improve Price Competition and Value for Part B Drugs, 56 (June 2019), [http://www.medpac.gov/docs/default-source/reports/jun19\\_ch3\\_medpac\\_reporttocongress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun19_ch3_medpac_reporttocongress_sec.pdf?sfvrsn=0).
- <sup>71</sup> See, e.g., Robert King, Regulatory Agenda Lays Out Timetable for Major Rules on Drug Pricing, Interoperability, FierceHealthcare (Nov. 20, 2019), <https://www.fiercehealthcare.com/hospitals-health-systems/regulatory-agenda-lays-out-timetable-for-major-rules-drug-pricing>.
- <sup>72</sup> Office of Information and Regulatory Affairs, View Rule: HHS/CMS, RIN 0938-AT88, Office of Management and Budget (last visited Jan. 5, 2020), <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0938-AT88>.
- <sup>73</sup> John Wilkerson, Grogan Implies HHS Adding Part D Drugs to Int'l Pricing Index Demo, InsideHealthPolicy (Oct. 9, 2019), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/grogan-implies-hhs-adding-part-d-drugs-int%E2%80%99l-pricing-index-demo>.
- <sup>74</sup> Peter Sullivan, Trump Officials Making Changes to Signature Drug Pricing Proposal, Azar Says, The Hill (Nov. 13, 2019), <https://thehill.com/policy/healthcare/470230-trump-officials-making-changes-to-signature-drug-pricing-proposal-azar-says>.
- <sup>75</sup> *Id.*
- <sup>76</sup> See, e.g., Peter Sullivan, Key Trump Proposal to Lower Drug Prices Takes Step Forward, The Hill (June 21, 2019), <https://thehill.com/policy/healthcare/449740-key-trump-proposal-to-lower-drug-prices-takes-step-forward>.
- <sup>77</sup> John Wilkerson, Int'l Pricing Index Rule Would Take Savings From Drug Pricing Bills, InsideHealthPolicy (Sept. 17, 2019), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/int'l-pricing-index-rule-would-take-savings-drug-pricing-bills>.
- <sup>78</sup> Lev Facher, 'Don't be a Bernie Bro': Inside Conservatives' Brazen Campaign to Sabotage Trump's Signature Drug Pricing Plan, Stat (July 29, 2019), <https://www.statnews.com/2019/07/29/conservative-campaign-against-drug-prices/>.
- <sup>79</sup> See, e.g., Tom Bulleit et al., The Trump Administration's Latest Drug Pricing Initiatives, Law360 (Jan. 14, 2019), <https://www.law360.com/articles/1118068/the-trump-administration-s-latest-drug-pricing-initiatives> (noting that CMS abandoned a similar, but voluntary, competitive acquisition program in 2009 and discussing potential operational challenges, including whether there will be sufficient participation by vendors, how CMS will fulfill its promise to ensure providers are held harmless despite the shift from ASP+6% to an add-on fee, and what steps the agency will take to protect beneficiaries' access if manufacturers refuse to sell to vendors at significantly discounted prices).
- <sup>80</sup> See, e.g., Sarah Oweremohle and Sarah Karlin-Smith, Unanswered Questions on Trump's Drug-Pricing Plan, Politico Prescription Pulse (Oct. 29, 2018), <https://www.politico.com/newsletters/prescription-pulse/2018/10/29/unanswered-questions-on-trumps-drug-pricing-plan-391874>; Jeff Overley, 5 Takeaways as Trump Eyes Cut to Medicare Drug Payments, Law360 (Oct. 25, 2018), <https://www.law360.com/articles/1095721/5-takeaways-as-trump-eyes-cut-to-medicare-drug-payments>.
- <sup>81</sup> Ryan Davis, Democratic Candidates Advocate for Busting Drug Patents, Law360 (Nov. 21, 2019), <https://www.law360.com/articles/1221027/democratic-candidates-advocate-for-busting-drug-patents>.
- <sup>82</sup> 35 U.S.C. § 203.
- <sup>83</sup> Another potentially relevant condition is if the patent holder “has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention.” 35 U.S.C. § 203(a). “Practical application” is defined as the invention “is being utilized and that its benefits are...available to the public on reasonable terms.” 35 U.S.C. § 201(f).
- <sup>84</sup> John R. Thomas, March-In Rights under the Bayh-Dole Act, Congressional Research Service, 1 (Aug. 22, 2016), <https://fas.org/sgp/crs/misc/R44597.pdf>.
- <sup>85</sup> 28 U.S.C. § 1498.
- <sup>86</sup> Davis, *supra* note 81.
- <sup>87</sup> See Hannah Brennan et al., A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 Yale J.L. & Tech. 275, 302-307 (2017) (citing Judgment Fund Payment Search, U.S. Department of Treasury, <https://fiscal.treasury.gov/judgment-fund/> (last visited Jan. 7, 2020) (database listing recent § 1498 judgments)).
- <sup>88</sup> *Id.* at 303.
- <sup>89</sup> See Shefali Luthra, In the Battle to Control Drug Costs, Old Patent Laws Get New Life, Kaiser Health News (Oct. 5, 2018), <https://khn.org/news/in-the-battle-to-control-drug-costs-old-patent-laws-get-new-life/>.
- <sup>90</sup> See, e.g., U.S. Senate Finance Committee, Hearings: Drug Pricing in America: A Prescription for Change, Parts I-III, *available at* <https://www.finance.senate.gov/hearings>; U.S. Senate Finance Committee, Grassley, Wyden Launch Bipartisan Investigation into Insulin Prices (Feb. 22, 2019), <https://www.finance.senate.gov/chairmans-news/grassley-wyden-launch-bipartisan-investigation-into>



- [insulin-prices](#); U.S. House Committee on Oversight and Reform, Oversight Committee Launches Sweeping Drug Price Investigation (Jan. 14, 2019), <https://oversight.house.gov/news/press-releases/oversight-committee-launches-sweeping-drug-price-investigation>.
- <sup>91</sup> Medicaid Services Investment and Accountability Act, H.R. 1839, 116<sup>th</sup> Cong. (enacted Apr. 18, 2019) (containing the Right Rebate Act, S. 205, 116<sup>th</sup> Cong. (2019)).
- <sup>92</sup> Office of U.S. Senator Chuck Grassley, Grassley, Wyden Praise Congressional Passage of Right Rebate Act (Apr. 2, 2019), <https://www.grassley.senate.gov/news/news-releases/grassley-wyden-praise-congressional-passage-right-rebate-act>.
- <sup>93</sup> Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, H.R. 4378, 116<sup>th</sup> Cong. (enacted Sept. 27, 2019).
- <sup>94</sup> See 42 C.F.R. §§ 447.502, 447.506 (as effective prior to enactment of H.R. 4378).
- <sup>95</sup> H.R. 4378, *supra* note 93.
- <sup>96</sup> Further Consolidated Appropriations Act, H.R. 1865, 116<sup>th</sup> Cong. (enacted Dec. 20, 2019) (containing the CREATES Act, S. 340, 116<sup>th</sup> Cong. (2019)).
- <sup>97</sup> *Id.* See also Office of U.S. Senator Patrick Leahy, The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017 (last visited Jan. 6, 2020), <https://www.leahy.senate.gov/imo/media/doc/CREATES%20Press%20Background%20Materials.pdf>.
- <sup>98</sup> U.S. Senate Finance Committee, Grassley, Leahy Hail Inclusion of CREATES Act in Year-End Spending Agreement (Dec. 16, 2019), <https://www.finance.senate.gov/chairmans-news/grassley-leahy-hail-inclusion-of-creates-act-in-year-end-spending-agreement>.
- <sup>99</sup> See, e.g., Paige Winfield Cunningham, The Health 202: Congress Could Have Been Tougher on Drug Executives, The Washington Post (Feb. 27, 2019), <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/02/27/the-health-202-congress-could-have-been-tougher-on-drug-executives/5c7565351b326b71858c6c47/>.
- <sup>100</sup> H.R. 1865, *supra* note 96.
- <sup>101</sup> Paige Winfield Cunningham, The Health 202: Congress Failed to Pass a Drug Pricing Overhaul. So it Set Another Deadline., The Washington Post (Dec. 17, 2019), <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/12/17/the-health-202-congress-failed-to-pass-a-drug-pricing-overhaul-so-it-set-another-deadline/5df7c57a88e0fa32a5140777/>.
- <sup>102</sup> Elijah E. Cummings, Lower Drug Costs Now Act, H.R. 3, 116<sup>th</sup> Cong. (2019).
- <sup>103</sup> The December 12, 2019 roll call vote is available here: <http://clerk.house.gov/evs/2019/roll682.xml>.
- <sup>104</sup> HHS would negotiate prices for a minimum of 25 drugs for 2023. For 2024 and subsequent years, HHS would be subject to a 50-drug minimum. H.R. 3, *supra* note 102.
- <sup>105</sup> *Id.*
- <sup>106</sup> *Id.*
- <sup>107</sup> *Id.*
- <sup>108</sup> See Congressional Budget Office, Letter to Chairman Frank Pallone Jr. Re: Budgetary Effects of H.R. 3, 3 (Dec. 10, 2019), [https://www.cbo.gov/system/files/2019-12/hr3\\_complete.pdf](https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf).
- <sup>109</sup> H.R. 3, *supra* note 102.
- <sup>110</sup> CBO, *supra* note 108.
- <sup>111</sup> *Id.*
- <sup>112</sup> See Office of Management and Budget, Statement of Administration Policy: H.R. 3 (Dec. 10, 2019), [https://www.whitehouse.gov/wp-content/uploads/2019/12/SAP\\_HR-3.pdf](https://www.whitehouse.gov/wp-content/uploads/2019/12/SAP_HR-3.pdf); Sarah Karlin-Smith, How Trump and the Democrats Parted Ways on Lowering Drug Prices, Politico (Dec. 11, 2019), <https://www.politico.com/news/2019/12/11/donald-trump-democrats-drug-pricing-082545>.
- <sup>113</sup> See Sullivan, *supra* note 7.
- <sup>114</sup> Karlin-Smith, *supra* note 112.
- <sup>115</sup> Chairman Grassley and Ranking Member Wyden released the most recent version of the PDPRA in early December. This version is available at U.S. Senate Finance Committee, Grassley, Wyden Release Updated Prescription Drug Pricing Reduction Act, Reach Agreement on Health Extenders (December 6, 2019), <https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-updated-prescription-drug-pricing-reduction-act-reach-agreement-on-health-extenders>. The December bill updated the formal legislative text that was introduced as S. 2543 in September, which is available at U.S. Senate Finance Committee, S. 2543: The Prescription Drug Pricing Reduction Act of 2019 (Sept. 25, 2019), <https://www.finance.senate.gov/legislation/details/the-prescription-drug-pricing-reduction-act-of-2019>. The original proposal voted on by the Finance Committee in July, as well as other materials from the markup, are available at U.S. Senate Finance Committee, Open Executive Session to Consider an Original Bill Entitled The Prescription Drug Pricing Reduction Act of 2019 (July 25, 2019), <https://www.finance.senate.gov/hearings/open-executive-session-to-consider-an-original-bill-entitled-the-prescription-drug-pricing-reduction-act-of-2019>.
- <sup>116</sup> *Id.*
- <sup>117</sup> *Id.*
- <sup>118</sup> *Id.*

<sup>119</sup> Congressional Budget Office, The Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (July 24, 2019) (preliminary estimate), [https://www.cbo.gov/system/files/2019-07/PDPRA\\_preliminary\\_estimate.pdf](https://www.cbo.gov/system/files/2019-07/PDPRA_preliminary_estimate.pdf).

<sup>120</sup> John Wilkerson, Grassley Sees No Reason to Drop Inflation Rebates from Rx Pricing Bill, InsideHealthPolicy (Nov. 1, 2019), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/grassley-sees-no-reason-drop-inflation-rebates-rx-pricing-bill>.

<sup>121</sup> *Id.* For the committee markup votes, see Senate Finance Committee, Open Executive Session, *supra* note 115.

<sup>122</sup> See Marianne Levine and Sarah Karlin-Smith, Senate Quicksand Engulfs a Bipartisan Plan that Trump Backs, Politico (Dec. 1, 2019), <https://www.politico.com/news/2019/12/01/prescription-drugs-bill-trump-074077>; Peter Sullivan, McConnell, Grassley at Odds Over Trump-Backed Drug Bill, The Hill (Dec. 6, 2019), <https://thehill.com/policy/healthcare/473316-mcconnell-grassley-at-odds-over-trump-backed-drug-bill>.

<sup>123</sup> See John Wilkerson and Ariel Cohen, President Trump is the Wild Card on Drug-Pricing Action in 2020, InsideHealthPolicy (Jan. 2, 2020), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/president-trump-wild-card-drug-pricing-action-2020>; John Wilkerson et al., Grassley Says McConnell Blocking GOP Support for Drug Pricing Bill, InsideHealthPolicy (Dec. 18, 2019), <https://insidehealthpolicy.com/daily-news/grassley-says-mcconnell-blocking-gop-support-drug-pricing-bill>.

<sup>124</sup> U.S. Senate Finance Committee, Grassley, Wyden Release Updated PDPRA, *supra* note 115.

<sup>125</sup> *Id.*

<sup>126</sup> See 2020 Budget Fact Sheet: Lowering Drug Prices, [WhiteHouse.gov](https://www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet_Lowering-Drug-Pricing-and-Payment_FINAL.pdf) (last visited Jan. 6, 2020), [https://www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet\\_Lowering-Drug-Pricing-and-Payment\\_FINAL.pdf](https://www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet_Lowering-Drug-Pricing-and-Payment_FINAL.pdf).

<sup>127</sup> U.S. Senate Finance Committee, Grassley, Wyden Release Updated PDPRA, *supra* note 115.

<sup>128</sup> Lower Costs, More Cures Act, H.R. 19, 116<sup>th</sup> Cong. (2019).

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> Lower Costs, More Cures Act, S. 3129, 116<sup>th</sup> Cong. (2019).

<sup>132</sup> Ariel Cohen, Grassley Downplays Fellow GOP Senators' Drug Pricing Bill, InsideHealthPolicy (Dec. 20, 2019), <https://insidehealthpolicy.com/daily-news/grassley-downplays-fellow-gop-senators%E2%80%9999-drug-pricing-bill>.

<sup>133</sup> See Levine and Karlin-Smith, *supra* note 122.

<sup>134</sup> See, e.g., Wilkerson, Grassley Says McConnell Blocking GOP Support for Drug Pricing Bill, *supra* note 123.

<sup>135</sup> John Wilkerson, Lawmakers Consider Paying for DSH Policy with Medicaid Drug Rebates, InsideHealthPolicy (Nov. 22, 2019), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/lawmakers-consider-paying-dsh-policy-medicaid-drug-rebates>.

<sup>136</sup> John Wilkerson, PhRMA Lists Drug-Cost Lowering Policies It Supports, InsideHealthPolicy (Oct. 11, 2019), <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/phrma-lists-drug-cost-lowering-policies-it-supports>.

<sup>137</sup> See NASHP, State Prescription Drug Legislative Tracker 2019 (as of Dec. 5, 2019), *supra* note 4. NASHP regularly updates their state legislative tracker, and has posted the final trackers from 2015 through 2018, here: NASHP, State Legislative Action to Lower Pharmaceutical Costs, <https://nashp.org/rx-legislative-tracker-2019/>.

<sup>138</sup> See NASHP, State Prescription Drug Legislative Tracker 2019 (as of Dec. 5, 2019), *supra* note 4.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> See, e.g., Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664 (4th Cir. 2018) (striking down under the Dormant Commerce Clause a Maryland statute that prohibited “unconscionable increase[s]” in price for essential off-patent or generic drugs); *Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (invalidating under the Supremacy Clause a Washington, D.C. law that prohibited manufacturers from charging “an excessive price” for patented prescription drugs).

<sup>143</sup> NASHP has played a leading role in the development of drug affordability review board bills. The organization’s model legislation and other resources are available here: National Academy for State Health Policy, Model Legislation, (last visited Jan. 6, 2019), <https://nashp.org/policy/prescription-drug-pricing/model-legislation/>.

<sup>144</sup> See NASHP, State Prescription Drug Legislative Tracker 2019 (as of Dec. 5, 2019), *supra* note 4.

<sup>145</sup> See H.B. 768, 2019 Reg. Sess. (Md. 2019) (enacted May 25, 2019), <http://mgaleg.maryland.gov/webmga/frmMain.aspx?id=hb0768&stab=01&pid=billpage&tab=subject3&ys=2019RS>; L.D. 1499, 129<sup>th</sup> Leg., 2019 First Reg. Sess. (Me. 2019) (enacted June 24, 2019), <http://legislature.maine.gov/LawMakerWeb/summary.asp?ID=280073010>. Under H.B. 768, the Maryland board may acquire rate-setting powers starting in 2022. To do so, the board must receive approval from either the General Assembly’s Legislative Policy Committee or both the Governor and Attorney General. If such authority is granted, the board’s upper payment limits would apply only to drugs purchased or paid for by state or local governments.