SUMMARY

The Energy and Commerce Committee held a markup on twelve bills, six were proposals to lower the cost of prescription drugs, and the remaining six were ACA-related legislation. The committee voted, by voice vote, unanimously for six bills to cut drug prices after Democrats agreed to amendments introduced by Republicans to the CREATES and pay-for-delay bills.

In debate about the ACA-related legislation, Republican-introduced amendments to add Hyde language to the bill failed. There also was continued disagreements on short-term, or "junk" health care plans with Republican amendments concerning these plans failing.

Prior to consideration of the drug package, the committee considered H.R. 1644, the Save the Internet Act. Rep. Gus Bilirakis (R-FL) offered an amendment to the bill to exclude telehealth from restrictions the bill places on emerging technology. The amendment failed by voice vote.

Opening Statements:

- **Chairman Frank Pallone (D-NJ):** Urged action on all the bills before the subcommittee.

- **Ranking Member Greg Walden (R-OR):** Spoke on efforts to ensure proposed bills do not stifle competition and raise drug costs, and noted some bipartisanship with an agreement on H.R. 1503 (Orange Book Transparency Act of 2019). He reminded the committee that the six ACA-related bills do not address the underlying problem, in his opinion, that the ACA itself is failing.

- **Rep. Anna Eshoo (D-CA):** Argued that the six ACA-related bills that are not bipartisan were proposed to strengthen the ACA and strengthen the entire health insurance market. She noted that the ACA is not perfect – yet the national plan to ensure all Americans remains the goal of the Democratic Party. She spoke in opposition to the Trump Administration's recent stance that the ACA is invalid.

- **Rep. Eliot Engel (D-NY):** The proposed bills related to health care will help reverse the negative effects caused by the Trump Administration to the Affordable Care Act (ACA).

- **Rep. Diana DeGette (D-CO):** Urged action on the bills before the committee – reminded the committee of rise in insulin prices as just one example of costs for Americans.

- **Rep. G.K. Butterfield (D-NC):** Reminded the committee that Democrats are the majority and the party believes in universal health care, and urged passage of both the drug package and ACA-related bills.

- **Reps. Darren Soto (D-FL), Doris Matsui (D-CA), Scott Peters (D-CA), Tom O'Halleran (D-AZ):** Expression of support for all health care related bills

Legislation:

- H.R. 1781, the "Payment Commission Data Act of 2019"

H.R. 1781, the "Payment Commission Data Act of 2019", introduced by Reps. Carter (R-GA), O'Halleran (D-AZ), Rice (R-SC), Panetta (D-CA), Gianforte (R-MT), and Welch (D-VT), would provide the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) with access to drug pricing and rebate data under Medicare Parts B and D, as well as under Medicaid. MedPAC and MACPAC are independent, nonpartisan commissions that advise Congress on issues affecting the Medicare and Medicaid programs. Currently, MedPAC and MACPAC lack access to this drug pricing data and are limited in their ability to analyze and provide information on related topics to Congress, such as issues related to prescription drug costs. H.R. 1781 would ensure the Commissions have access to this data in order to analyze and report to Congress on these issues.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1781, without amendment, to the full Committee by a voice vote.

Carter Amendment: Voice Vote. Passed.

In full committee, Rep. Carter (R-GA) introduced an amendment that passed with voice vote.

This amendment clarifies that Medicare Advantage drug data is included in the information that would be provided to MACPAC and MedPAC.

Final Passage: Voice Vote. Favorably reported to the House, as amended (Carter Amendment).

Comments on H.R. 1781:

General bipartisan support of the transparency provided in the bill – the bipartisan agreement mirrored those during the Health Subcommittee debate.

- H.R. 938, the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019"

H.R. 938, the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019", introduced by Reps. Schrader (D-OR) and

Carter (R-GA), would discourage parking of 180-day exclusivity by a first generic applicant. It allows the Food and Drug Administration (FDA) to approve a subsequent generic application prior to the first applicant's first date of commercial marketing when the following four conditions are all met: (1) the subsequent application is ready for full approval; (2) a minimum of 30 months has passed since at least one first applicant submitted their application for the drug; (3) any related patent litigation has been fully resolved; and (4) no first applicant has received final approval.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 938, without amendment, to the full Committee by a voice vote.

Final Passage: Voice Vote. Favorably reported to the House.

Spoke In favor: Rep. Eshoo (D-CA)

Comments on H.R. 938:

The bill had bipartisan support, with Reps. Schrader (D-OR), Carter (R-GA) and Eshoo (D-CA) speaking on its behalf.

- H.R. 1520, the "Purple Book Continuity Act of 2019"

H.R. 1520, the "Purple Book Continuity Act of 2019", introduced by Rep. Eshoo (D-CA), would amend the Public Health Service Act to codify publication of approved biological products in the Purple Book in a similar format and with similar requirements to the Orange Book, specify that the Purple Book should be published electronically on FDA's website and updated routinely, and direct FDA to consider the types of patents that should be listed in the Purple Book.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1520, amended, to the full Committee by a voice vote. An amendment was adopted by voice vote that incorporates technical feedback from the FDA and clarifies that the Purple Book should be published in a searchable electronic format and that exclusivities for biological products should be listed.

Eshoo Amendment: Voice Vote. Passed.

Rep. Anna Eshoo (D-CA) introduced an amendment that passed by voice vote.

The amendment clarifies information required to be recorded in the Purple Book, and included technical assistance received from the FDA. This listed information will include approved biologics, and requires the routine update of the Purple Book on the FDA website. The amendment also asks HHS to make recommendations to Congress on what to put in the Purple Book.

Final Passage: Voice Vote. Favorably reported to the House, as amended (Eshoo Amendment).

Spoke in Favor: Reps. Anna Eshoo (D-CA) and Michael Burgess (R-TX)

Comments on H.R. 1520:

H.R. 1520 gained bipartisan support, with Rep. Burgess (R-TX) joining Rep. Eshoo (D-CA) as a co-sponsor of the bill during the Health Subcommittee markup.

- H.R. 1503, the "Orange Book Transparency Act of 2019"

H.R. 1503, the “Orange Book Transparency Act of 2019”, introduced by Rep. Kelly (D-IL), would help to ensure that the Orange Book is accurate and up-to-date, by requiring manufacturers to share complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Patents found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board would be required to be removed promptly. FDA is also directed to reconsider the types of patents that should be listed in the Orange Book within one year of enactment.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably reported H.R. 1503, amended, to the full Committee by a voice vote. An amendment was adopted by a voice vote that incorporates technical feedback from FDA and clarifies that removal of patents found to be invalid through a decision by the Patent trial and Appeal Board only occurs after no appeal has been or can be taken.

Kelly Amendment: Voice Vote. Passed.

Rep. Robin Kelly (D-IL) introduced an amendment that passed by voice vote.

The amendment eliminated language that would have removed patents for drug-delivery devices.

Final Passage: Voice Vote. Favorably reported to House, as amended. (Kelly amendment)

Comments on H.R. 1503:

Rep. Robin Kelly (D-IL) – Noted bipartisan work on H.R. 1503 with Rep. Brett Guthrie (R-KY), and argued the shared interests in the amendment she introduced.

- H.R. 1499, the "Protecting Consumer Access to Generic Drugs Act of 2019"

H.R. 1499, the “Protecting Consumer Access to Generic Drugs Act of 2019”, introduced by Rep. Rush (D-IL), would make it illegal for brand-name and generic drug

manufacturers to enter into agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep a generic equivalent off the market.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1499, amended, to the full Committee by a voice vote. An amendment was adopted by a voice vote that incorporates technical feedback from FDA, including ensuring reverse payment settlements amongst any type of manufacturer, including two generics, are unlawful, and extending the scope of unlawful agreements to include those that include a generic forgoing development of their own product in lieu of marketing or selling a brand's authorized generic.

Rush Amendment: Voice Vote. Passed.

Rep. Bobby Rush (D-IL) introduced an amendment that passed by voice vote.

The amendment eliminated the retroactive provisions of the bill while, and provided flexibility for the Federal Trade Commission to determine if an agreement was anti-competitive or not in the best interest of consumers.

Note: The original version would make pay-for-delay settlements beginning June 17, 2013 illegal, but Democrats agreed to make the bill prospective in response to Republicans' concerns about making agreements illegal 'ex post facto'.

Walden Amendment: Discussed and Withdrawn.

Ranking member, Rep. Greg Walden (R-OR) introduced and withdrew an amendment.

The amendment would provide drug manufacturers the ability to seek an advisory opinion from the FTC. Rep. Walden (R-OR) introduced the amendment with an intent to withdraw and stated that he would continue to refine the amendment in order to have it considered further in the process.

Final Passage: Voice Vote. Favorably reported to House, as amended (Rush Amendment).

Comments on H.R. 1499:

Rep. Walden (R-OR) – Introduced amendment to permit manufacturers to seek an advisory opinion from the FTC concerning settlements with other drug companies. He spoke of his hope to be able to have the amendment added to the bill at a later date.

Reps. Fred Upton (R-MI) and **Peter Welch (D-VT)** spoke in favor of the Rush Amendment and the legislation as a whole.

- H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019"

H.R. 965, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019”, introduced by Reps. Cicilline (D-RI), Sensenbrenner (R-WI), Nadler (D-NY), Collins (R-GA), Welch (D-VT), and McKinley (R-WV), would establish a process by which generic manufacturers could request that FDA authorize them to obtain sufficient quantities of samples for testing. The bill would allow a generic manufacturer facing delay tactics to bring an action in federal court to obtain the samples it needs. Courts would be authorized to award monetary damages sufficient to deter future gaming. It would also clarify FDA’s discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system instead of entering a shared safety protocol with brand manufacturers, provided that such separate protocol meets the same safety standard as the original system.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 965 to the full Committee, amended, by a voice vote. An amendment was adopted by a voice vote that incorporates technical feedback from FDA, including clarifying language regarding products that are subject to a shortage, and clarifies the ability of generic manufacturers to share separate REMS.

*Note: Before the revisions, the House and Senate versions of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) were the same. Senate Finance Committee Chair Charles Grassley (R-IA), who wrote the Senate bill, does not yet endorse the changes because Grassley has yet to review.

Flores Amendment: Withdrawn.

Rep. Bill Flores (R-TX) introduced an amendment, and withdrew the amendment when prompted by Rep. Pallone (D-NJ) for further conversations in the future. Pallone stated he could not commit to supporting such an amendment after additional conversations, but he was willing to explore the issue.

The amendment would reduce complexity of patent challenges, requiring generic manufacturing to follow the Hatch-Waxman framework to challenge brand name brands, or choose the cheaper, non-streamline IPR method, but not both.

Pallone/Walden Amendment: Voice Vote. Passed.

In full committee, Rep. Pallone (D-NJ) introduced an amendment with Rep. Walden (R-OR).

The amendment addresses a shared goal of discouraging anti-competitive behavior by providing brand drug companies with an additional affirmative defense in cases where offers are consistent with commercial market-based terms.

Final Passage: Favorably reported to the House, as amended. (51-0)

Comments on H.R. 965:

Rep. Pallone (D-NJ): Noted his strong reservations in providing relief to drug manufacturers, yet sees the amendment introduced with Rep. Walden (R-OR) as placing accountability on both sides. Rep. Walden (R-OR) argues this amendment punishes what he calls "bad actors," while avoiding frivolous litigation.

- H.R.1385, the "State Allowance for a Variety of Exchanges (SAVE) Act"

H.R. 1385, the "State Allowance for a Variety of Exchanges (SAVE) Act", introduced by Reps. Kim (D-NJ) and Fitzpatrick (R-PA), would provide states with $200 million in federal funds to establish state-based marketplaces.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1385, without amendment, to the full Committee by a voice vote.

Carter Amendment: Point of order was raised against the amendment, so it was withdrawn.

Rep. Carter (R-GA) introduced an amendment that ultimately was not considered.

The amendment would redirect allocated funds from state exchanges to a fund for states to use I combatting the opioid epidemic. When the epidemic is no longer a state emergency, funds could be reallocated to exchanges. Rep. Walden (R-OR) spoke in favor and Rep. Pallone (D-NJ) spoke opposed.

McKinley Amendment: Discussed and withdrawn.

Rep. McKinley (R-WV) introduced and withdrew an amendment after discussion.

This amendment, similar to Rep. Carter (R-GA), redirected funds so states could use the funding for the opioid epidemic. However, the amendment did not create a fund as Rep. Carter's amendment had.

Pallone Amendment: Voice Vote. Passed.

Rep. Pallone (D-NJ) introduced an amendment that passed by voice vote.

The amendment contained technical changes to permit any state that does not have an exchange to receive funding to do so.

Final Passage: Favorably reported to the House, as amended (Pallone Amendment) (29-22).

Spoke in Favor: Rep. Pallone (D-NJ)

Comments on H.R. 1385:

Rep. Frank Pallone (D-NJ) – Argued in support of the legislation, as state-based market places have displayed lower premiums and increased enrollment as health care costs rise.

- H.R.1386, the "Expand Navigators' Resources for Outreach, Learning, and Longevity (ENROLL) Act"

H.R. 1386, the "Expand Navigators' Resources for Outreach, Learning, and Longevity (ENROLL) Act of 2019", introduced by Rep. Castor (D-FL), would fund the Navigator program for the federally-facilitated marketplace (FFM) at $100 million per year. The bill would require the Department of Health and Human Services (HHS) to ensure that Navigator grants are awarded to organizations with a demonstrated capacity to carry out the duties specified in the ACA and would reinstate the requirement that there be at least two Navigator entities in each state. The legislation would further give Navigators new duties pertaining to enrolling individuals in Medicaid and the Children's Health Insurance Program, and it would allow Navigators to provide their services year-round. Lastly, the bill would prohibit HHS from taking an entity's capacity to provide information regarding association health plans or short-term, limited duration insurance (STLDI) into account in awarding grants.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1386, without amendment, to the full Committee by a voice vote.

Latta Amendment: Failed. (22-30)

Rep. Latta (R-OH) introduced an amendment that failed by roll call vote.

The amendment would require navigators to disclose if plans offered under the ACA cover abortion services, and therefore "created" a "hidden surcharge" on premiums.

Burgess Amendment: Accepted by Chair.

Rep. Burgess (R-TX) called up an amendment that was accepted by Chairman Pallone. The amendment was originally drafted by Rep. Castor (D-FL) and she was planning to offer it if the republicans would then support the overall bill. .

Addition that in consideration of grants for navigators, the entity's record concerning waste fraud and abuse must be considered in deciding whether to award the funding to that entity.

Final Passage: Favorably reported to House, as amended. (30-22)

Spoke Opposed: Rep. John Shimkus (R-IL)

Comments on H.R. 1386:

Rep. Hudson (R-NC) – Noted that the Republican members are not against reproductive rights, and that consumers should simply be given the option to make choices on their own.

Rep. Ruiz (D-NM) – Argued the committee take politics out of reproductive health and provide women the right to choose.

Rep. Castor (D-FL) – Noted that the Burgess Amendment is not needed. She also argued that CMS was now using GOP consultants to promote CMS Administrator Seema Verma's personal brand at taxpayer expense.

Rep. Walden (R-OR) – Noted that the Burgess Amendment is simple and bipartisan – originally drafted by Democrats and should be passed.

- H.R. 1425, the "State Health Care Premium Reduction Act"

H.R. 1425, the "State Health Care Premium Reduction Act", introduced by Reps. Craig (D-MN) and Peters (D-CA), would provide $10 billion annually to states, with the option for states to establish a state reinsurance program or to provide financial assistance for individuals enrolled in qualified health plans by reducing their out-of-pocket costs. The bill further requires the Centers for Medicare and Medicaid Services (CMS) to establish and implement a reinsurance program in states that do not apply for federal funding. The bill sets a state's allocation amount based on the state's share of claims of high-cost enrollees.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1425 to the full Committee by a roll call vote of 18 yeas to 13 nays. An amendment in the nature of a substitute was adopted by roll call vote of 18 yeas to 12 nays. The amendment incorporates technical feedback from CMS and streamlines the federal default reinsurance program.

Burgess Amendment: Withdrawn. Will be brought forward to the Rules Committee when the bill reaches the House floor.

Rep. Burgess (R-TX) introduced an amendment, and withdrew it for later consideration on the House floor.

The amendment would provide states with options to address rising health care costs – in nature of a substitute that includes reinsurance and structural reform of the ACA. The amendment provided more options to states concerning how to provide health insurance, and included Hyde Amendment language.

Pallone Amendment: Voice Vote. Passed.

Rep. Pallone (D-NJ) introduced an amendment that passed by voice vote.

The amendment contained technical changes to ensure CMS has the flexibility to adjust payment to states in the case that actual claims differ from CMS' projections. It also allows CMS to operate a federal reinsurance program on behalf of states that did not apply for funding.

Rodgers Amendment: Voice Vote. Failed.

Rep. McMorris Rodgers (R-WA) introduced an amendment that failed by voice vote.

Amendment would have inserted Hyde Amendment language in the bill.

Final Passage: Favorably reported to the House. (30-22)

Comments on H.R. 1425:

Rep. Schrader (D-OR): This bill is similar to bipartisan legislation debated in the 115th Congress and Rep. Schrader urged action.

Rep. Eshoo (D-CA): Noted that the bill could set lower premiums by 10%, and urged support of its passing.

Rep. DeGette (D-CO): Disagreed with the McMorris Rodgers Amendment – noted that this amendment codifies the Hyde Amendment under this bill, and wished to debate what she calls "bad public policy." Rep. Schakowsky (D-IL) supported Rep. DeGette's comments.

- H.R. 987, the "Marketing and Outreach Restoration to Empower Health Education Act of 2019" or the "MORE Health Education Act"

H.R. 987, the "Marketing and Outreach Restoration to Empower (MORE) Health Education Act of 2019", introduced by Rep. Blunt Rochester (D-DE), would require HHS to conduct consumer outreach and enrollment educational activities for the ACA marketplaces. The legislation would fund these activities at $100 million per year. The bill further prohibits HHS from expending the funds on promoting plans that do not provide comprehensive consumer protections, including STLDI plans and association health plans.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 987, without amendment, to the full Committee by a voice vote.

Blunt Rochester Amendment: Voice Vote. Passed.

Rep. Blunt Rochester (D-DE) introduced an amendment that passed by voice vote.

The amendment contained technical changes to ensure that HHS does outreach regarding ACA plans to current enrollees as well.

Carter Amendment: Voice Vote. Failed.

Rep. Carter (R-GA) introduced an amendment that failed by voice vote.

The amendment was similar to Rep. Carter's amendment offered in subcommittee which would permit advertising and education on all plans available to consumers, including short-term/limited duration plans.

Shimkus Amendment: Withdrawn.

Rep. Shimkus (R-IL) introduced an amendment that would require advertisement all options, including short-term and associated health plans. This was the same amendment as offered in subcommittee. Mr. Shimkus withdrew the amendment.

Final Passage: Favorably reported to the House, as amended (Blunt Rochester Amendment) (30-22).

Comments on H.R. 987:

Rep. Blunt Rochester (D-DE): Rep. Rochester raised recent news report on CMS Administrator Verma using taxpayer funds on public relations, and the Administration's reduction in funding and time for open enrollment activities. Urged the passage of this bill as a response to current events.

Rep. Griffin (R-VA): Asked the legal ramifications of the Blunt Rochester bill – wanted to know the reach of who HHS must advertise to, such as though who could theoretical sign up, yet are not eligible for tax credits (re: non-citizens). Rep. Blunt Rochester responded with her intent of the bill – simply to have a wide reach, and not specific targeting.

Rep. Carter (R-GA): Reintroduced his amendment from Health Subcommittee markup, reminding the committee that short-term plans are legal under the ACA and should therefore be included in advertisements and education of consumers through the bills. Rep. Carter offered to withdraw the amendment, and allow Democrats to introduce it, to ensure the best for consumers through education.

Rep. Pallone stated his appreciation of Rep. Carter's attempt to work together, yet disagrees with the existence of these short-term plans as acceptable for American consumers. Pallone stated he was not prepared to market those plans solely because they are currently available. Rep. Sarbanes agreed with Pallone, and argued that resources should promote what the ACA intended to as plans that

meant certain coverage standards. Rep. Burgess supported Rep. Carter's amendment, noting the nature of transparency by educating on all plans.

Rep. Walden (R-OR) made a call for bipartisanship and saw value in providing full disclosure of alternatives. He suggested the committee work on investigating "sham" plans in the future. Rep. Shimkus (R-IL) recommended a hearing on associated health plans and short-term plans.

Rep. Barragan (D-CA) – He stated that he did not see a point in passing Rep. Carter's amendment, when the next bill to be voted on was a bill to override the Administration's policy concerning short-term duration plans. Rep. Walden (R-OR) responded that the bill only limits these plans to 90 days, and did not eliminate them.

- H.R. 986, the "Protecting Americans with Preexisting Conditions Act of 2019"

H.R. 986, the "Protecting Americans with Preexisting Conditions Act of 2019", introduced by Reps. Kuster (D-NH), Beyer (D-VA), and Courtney (D-CT), would revoke the Section 1332 guidance issued by the Trump Administration on October 2018. The bill would also prevent the Secretaries of HHS and Treasury from promulgating any substantially similar guidance or rule.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 986, without amendment, to the full Committee by a roll call vote of 19 yeas to 13 nays.

Vote on Bill: No amendments. Voice Vote. Favorably reported to the House.

Spoke Opposed: Rep. Walden (R-OR) Rep. Walden briefly spoke and asked that they move on to the vote.

- H.R. 1010, To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect

H.R. 1010, introduced by Reps. Castor (D-FL), Barragán (D-CA), Horsford (D-NV), Moore (D-WI), Underwood (D-IL), and DeSaulnier (D-CA), would overturn the STLDI final rule, rendering it without force or effect. These plans are not required to comply with any of the ACA's consumer protections, such as guaranteed issue, community rating, and essential health benefits, and expanding them raises premiums and undermines the individual market.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1010, without amendment, to the full Committee by a roll call vote of 19 yeas to 13 nays.

Johnson Amendment: Voice Vote. Failed.

Rep. Bill Johnson (R-OH) introduced an amendment that failed by voice vote.

The amendment would allow short-term plans in counties with only one insurer on the exchange, and the plans would still be regulated as the law states today.

Rep. Pallone (D-NJ) opposed Rep. Johnson's (R-OH) amendment. Rep. Johnson responded that in counties with only one insurer that families cannot afford insurance and, short-term plans fill the gap for consumers.

Final Passage: Favorably reported to the House. **(**30-22)

Spoke in Favor: Rep. Sarbanes (D-MD)

Comments on H.R. 1010:

Rep. Pallone (D-NJ) – Rep. Pallone's comments are generally favorable for the bill.